

Calendar No. 160

106TH CONGRESS
1ST Session

S. 326

[Report No. 106-82]

A BILL

To improve the access and choice of patients to
quality, affordable health care.

JUNE 17, 1999

Reported with an amendment

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106TH CONGRESS
1ST SESSION

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To improve the access and choice of patients to quality, affordable health care.

IN THE SENATE OF THE UNITED STATES

JANUARY 28, 1999

Mr. JEFFORDS (for himself, Mr. FRIST, Mr. DEWINE, Mr. ENZI, Mr. HUTCHINSON, Ms. COLLINS, Mr. BROWNBACK, Mr. HAGEL, Mr. SESSIONS, Mr. BURNS, and Mr. GREGG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JUNE 17, 1999

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To improve the access and choice of patients to quality, affordable health care.

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

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

4 (a) ~~SHORT TITLE.~~—This Act may be cited as the
5 “Patients’ Bill of Rights Act”.

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

Sec. 1. Short title; table of contents.

TITLE I—PATIENTS’ BILL OF RIGHTS

Subtitle A—Right to Advice and Care

Sec. 101. Patient right to medical advice and care.

“SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

“Sec. 721. Patient access to emergency medical care.

“Sec. 722. Offering of choice of coverage options.

“Sec. 723. Patient access to obstetric and gynecological care.

“Sec. 724. Patient access to pediatric care.

“Sec. 725. Continuity of care.

“Sec. 726. Protection of patient-provider communications.

“Sec. 727. Generally applicable provision.”

Sec. 102. Effective date and related rules.

Subtitle B—Right to Information About Plans and Providers

Sec. 111. Information about plans.

Sec. 112. Information about providers.

Subtitle C—Right to Hold Health Plans Accountable

Sec. 121. Amendment to Employee Retirement Income Security Act of 1974.

TITLE II—INDIVIDUAL RIGHTS WITH RESPECT TO PERSONAL MEDICAL INFORMATION

Sec. 201. Short title.

Subtitle A—Access to Medical Records

Sec. 211. Inspection and copying of protected health information.

Sec. 212. Amendment of protected health information.

Sec. 213. Notice of confidentiality practices.

Subtitle B—Establishment of Safeguards

Sec. 221. Establishment of safeguards.

Subtitle C—Enforcement; Definitions

Sec. 231. Civil penalty.

Sec. 232. Definitions.

Sec. 233. Effective date.

TITLE III—GENETIC INFORMATION AND SERVICES

Sec. 301. Short title.

Sec. 302. Amendments to Employee Retirement Income Security Act of 1974.

Sec. 303. Amendments to the Public Health Service Act.

TITLE IV—HEALTHCARE RESEARCH AND QUALITY

Sec. 401. Short title.

Sec. 402. Amendment to the Public Health Service Act.

“TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

“PART A—ESTABLISHMENT AND GENERAL DUTIES

“Sec. 901. Mission and duties.

“Sec. 902. General authorities.

“PART B—HEALTHCARE IMPROVEMENT RESEARCH

“Sec. 911. Healthcare outcome improvement research.

“Sec. 912. Private-public partnerships to improve organization and delivery.

“Sec. 913. Information on quality and cost of care.

“Sec. 914. Information systems for healthcare improvement.

“Sec. 915. Research supporting primary care and access in underserved areas.

“Sec. 916. Clinical practice and technology innovation.

“Sec. 917. Coordination of Federal Government quality improvement efforts.

“PART C—GENERAL PROVISIONS

“Sec. 921. Advisory Council for Healthcare Research and Quality.

“Sec. 922. Peer review with respect to grants and contracts.

“Sec. 923. Certain provisions with respect to development, collection, and dissemination of data.

“Sec. 924. Dissemination of information.

“Sec. 925. Additional provisions with respect to grants and contracts.

“Sec. 926. Certain administrative authorities.

“Sec. 927. Funding.

“Sec. 928. Definitions.”

Sec. 403. References.

Sec. 404. Study.

TITLE V—MISCELLANEOUS PROVISIONS

Sec. 501. Sense of the Committee.

1 **TITLE I—PATIENTS’ BILL OF** 2 **RIGHTS** 3 **Subtitle A—Right to Advice and** 4 **Care**

5 **SEC. 101. PATIENT RIGHT TO MEDICAL ADVICE AND CARE.**

6 (a) IN GENERAL.—Part 7 of subtitle B of title I of
7 the Employee Retirement Income Security Act of 1974
8 (29 U.S.C. 1185 et seq.) is amended—

“Subpart C—Patient Right to Medical Advice and

Care

6 "SEC. 721. PATIENT ACCESS TO EMERGENCY MEDICAL
7 CARE.

8 “(a) IN GENERAL.—To the extent that the group
9 health plan (other than a fully insured group health plan)
10 provides coverage for benefits consisting of emergency
11 medical care (as defined in subsection (c)), except for
12 items or services specifically excluded—

“(1) the plan shall provide coverage for benefits, without requiring preauthorization, for appropriate emergency medical screening examinations (within the capability of the emergency facility, including ancillary services routinely available to the emergency facility) to the extent that a prudent layperson, who possesses an average knowledge of health and medicine, would determine such examinations to be necessary to determine whether emergency medical care (as so defined) is necessary, and

23 “(2) the plan shall provide coverage for benefits
24 for additional emergency medical care to stabilize an
25 emergency medical condition following an emergency

1 medical screening examination (if determined nec-
 2 essary under paragraph (1)), pursuant to the defini-
 3 tion of stabilize under section 1867(c)(3) of the So-
 4 cial Security Act (42 U.S.C. 1395dd(c)(3)).

5 “(b) UNIFORM COST-SHARING REQUIRED.—Nothing
 6 in this section shall be construed as preventing a group
 7 health plan (other than a fully insured group health plan)
 8 from imposing any form of cost-sharing applicable to any
 9 participant or beneficiary (including coinsurance, copay-
 10 ments, deductibles, and any other charges) in relation to
 11 coverage for benefits described in subsection (a), if such
 12 form of cost-sharing is uniformly applied under such plan,
 13 with respect to similarly situated participants and bene-
 14 ficiaries, to all benefits consisting of emergency medical
 15 care (as defined in subsection (c)) provided to such simi-
 16 larly situated participants and beneficiaries under the
 17 plan.

18 “(c) DEFINITION OF EMERGENCY MEDICAL CARE.—
 19 In this section:

20 “(1) IN GENERAL.—The term “emergency med-
 21 ical care” means, with respect to a participant or
 22 beneficiary under a group health plan (other than a
 23 fully insured group health plan), covered inpatient
 24 and outpatient services that—

1 “(A) are furnished by any provider, includ-
 2 ing a nonparticipating provider, that is qualified
 3 to furnish such services; and

4 “(B) are needed to evaluate or stabilize (as
 5 such term is defined in section 1867(e)(3) of
 6 the Social Security Act (42 U.S.C. 1395dd)) an
 7 emergency medical condition (as defined in
 8 paragraph (2)).

9 “(2) EMERGENCY MEDICAL CONDITION.—The
 10 term “emergency medical condition” means a med-
 11 ical condition manifesting itself by acute symptoms
 12 of sufficient severity (including severe pain) such
 13 that a prudent layperson, who possesses an average
 14 knowledge of health and medicine, could reasonably
 15 expect the absence of immediate medical attention to
 16 result in—

17 “(A) placing the health of the participant
 18 or beneficiary (or, with respect to a pregnant
 19 woman, the health of the woman or her unborn
 20 child) in serious jeopardy;

21 “(B) serious impairment to bodily func-
 22 tions; or

23 “(C) serious dysfunction of any bodily
 24 organ or part.

1 **“SEC. 722. OFFERING OF CHOICE OF COVERAGE OPTIONS.**

2 **“(a) REQUIREMENT.—**

3 **“(1) OFFERING OF POINT-OF-SERVICE COV-**
 4 **ERAGE OPTION.—**Except as provided in paragraph
 5 **(2),** if a group health plan (other than a fully in-
 6 **sured group health plan)** provides coverage for bene-
 7 **fits only through a defined set of participating**
 8 **health care professionals,** the plan shall offer the
 9 **participant the option to purchase point-of-service**
 10 **coverage (as defined in subsection (b)) for all such**
 11 **benefits for which coverage is otherwise so limited.**
 12 **Such option shall be made available to the partici-**
 13 **pant at the time of enrollment under the plan and**
 14 **at such other times as the plan offers the participant**
 15 **a choice of coverage options.**

16 **“(2) EXCEPTION IN THE CASE OF MULTIPLE**
 17 **ISSUER OR COVERAGE OPTIONS.—**Paragraph (1)
 18 **shall not apply with respect to a participant in a**
 19 **group health plan (other than a fully insured group**
 20 **health plan) if the plan offers the participant—**

21 **“(A) a choice of health insurance coverage**
 22 **through more than one health insurance issuer;**
 23 **or**

24 **“(B) two or more coverage options that**
 25 **differ significantly with respect to the use of**

1 participating health care professionals or the
2 networks of such professionals that are used.

3 ~~“(b) POINT-OF-SERVICE COVERAGE DEFINED.—In~~
4 ~~this section, the term ‘point-of-service coverage’ means,~~
5 ~~with respect to benefits covered under a group health plan~~
6 ~~(other than a fully insured group health plan), coverage~~
7 ~~of such benefits when provided by a nonparticipating~~
8 ~~health care professional.~~

9 ~~“(c) SMALL EMPLOYER EXEMPTION.—~~

10 ~~“(1) IN GENERAL.—This section shall not apply~~
11 ~~to any group health plan (other than a fully insured~~
12 ~~group health plan) of a small employer.~~

13 ~~“(2) SMALL EMPLOYER.—For purposes of~~
14 ~~paragraph (1), the term ‘small employer’ means, in~~
15 ~~connection with a group health plan (other than a~~
16 ~~fully insured group health plan) with respect to a~~
17 ~~calendar year and a plan year, an employer who em-~~
18 ~~ployed an average of at least 2 but not more than~~
19 ~~50 employees on business days during the preceding~~
20 ~~calendar year and who employs at least 2 employees~~
21 ~~on the first day of the plan year. For purposes of~~
22 ~~this paragraph, the provisions of subparagraph (C)~~
23 ~~of section 712(c)(1) shall apply in determining em-~~
24 ~~ployer size.~~

1 “(d) **RULE OF CONSTRUCTION.**—Nothing in this sec-
2 tion shall be construed—

3 “(1) as requiring coverage for benefits for a
4 particular type of health care professional;

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

9 “(3) as preventing a group health plan (other
10 than a fully insured group health plan) from impos-
11 ing higher premiums or cost-sharing on a partici-
12 pant for the exercise of a point-of-service coverage
13 option; or

14 “(4) to require that a group health plan (other
15 than a fully insured group health plan) include cov-
16 erage of health care professionals that the plan ex-
17 cludes because of fraud, quality of care, or other
18 similar reasons with respect to such professionals.

19 **“SEC. 723. PATIENT ACCESS TO OBSTETRIC AND GYNECO-**
20 **LOGICAL CARE.**

21 “(a) **IN GENERAL.**—In any case in which a group
22 health plan (other than a fully insured group health
23 plan)—

24 “(1) provides coverage for benefits consisting
25 of—

1 “(A) gynecological care (such as preventive
2 women’s health examinations); or

3 “(B) obstetric care (such as pregnancy-re-
4 lated services);

5 provided by a participating physician who specializes
6 in such care; and

7 “(2) requires or provides for designation by a
8 participant or beneficiary of a participating primary
9 care provider;

10 if the primary care provider designated by such a partici-
11 pant or beneficiary is not such a physician as described
12 in paragraph (1); then the plan shall meet the require-
13 ments of subsection (b).

14 “(b) REQUIREMENTS.—A group health plan (other
15 than a fully insured group health plan) meets the require-
16 ments of this subsection, in connection with the coverage
17 of benefits described in subsection (a) consisting of care
18 described in subparagraph (A) or (B) of subsection (a)(1);
19 if the plan—

20 “(1) does not require authorization or a referral
21 by the primary care provider in order to obtain cov-
22 erage for such benefits; and

23 “(2) treats the ordering of other routine care
24 related to the care described in subparagraph (A) or
25 (B) of subsection (a)(1); by the participating physi-

1 eian providing the care described in either such sub-
 2 paragraph, as the authorization of the primary care
 3 provider with respect to such care.

4 “(c) **RULE OF CONSTRUCTION.**—Nothing in sub-
 5 section (b)(2) shall waive any requirements of coverage re-
 6 lating to medical necessity or appropriateness with respect
 7 to coverage of gynecological or obstetric care so ordered.
 8 Nothing in subsection (b) shall be construed to preclude
 9 the health plan from requiring that the obstetrician or
 10 gynecologist notify the primary care provider or the plan
 11 of treatment decisions.

12 **“SEC. 724. PATIENT ACCESS TO PEDIATRIC CARE.**

13 “(a) **IN GENERAL.**—In any case in which a group
 14 health plan (other than a fully insured group health
 15 plan)—

16 “(1) provides coverage for benefits consisting of
 17 pediatric care by a participating pediatrician; and

18 “(2) requires or provides for designation by a
 19 participant or beneficiary of a participating primary
 20 care provider;

21 if the primary care provider designated by such a partici-
 22 pant or beneficiary is not a physician as described in para-
 23 graph (1), then the plan shall meet the requirements of
 24 subsection (b).

1 “(b) REQUIREMENTS.—A group health plan (other
 2 than a fully insured group health plan) meets the require-
 3 ments of this subsection, in connection with the coverage
 4 of benefits described in subsection (a) consisting of care
 5 described in subsection (a)(1), if the plan—

6 “(1) does not require authorization or a referral
 7 by the primary care provider in order to obtain cov-
 8 erage for such benefits, and

9 “(2) treats the ordering of other routine care of
 10 the same type, by the participating physician pro-
 11 viding the care described in subsection (a)(1), as the
 12 authorization of the primary care provider with re-
 13 spect to such care.

14 “(c) CONSTRUCTION.—Nothing in subsection (b)(2)
 15 shall waive any requirements of coverage relating to med-
 16 ical necessity or appropriateness with respect to coverage
 17 of pediatric care so ordered.

18 **“SEC. 725. CONTINUITY OF CARE.**

19 “(a) IN GENERAL.—

20 “(1) TERMINATION OF PROVIDER.—If a con-
 21 tract between a group health plan (other than a fully
 22 insured group health plan) and a health care pro-
 23 vider is terminated (as defined in paragraph (2)), or
 24 benefits or coverage provided by a health care pro-
 25 vider are terminated because of a change in the

1 terms of provider participation in such group health
 2 plan; and an individual who is a participant or bene-
 3 ficiary in the plan is undergoing a course of treat-
 4 ment from the provider at the time of such termi-
 5 nation; the plan shall—

6 “(A) notify the individual on a timely basis
 7 of such termination;

8 “(B) provide the individual with an oppor-
 9 tunity to notify the plan of a need for transi-
 10 tional care; and

11 “(C) in the case of termination described
 12 in paragraph (2), (3), or (4) of subsection (b),
 13 and subject to subsection (c), permit the indi-
 14 vidual to continue or be covered with respect to
 15 the course of treatment with the provider’s con-
 16 sent during a transitional period (as provided
 17 under subsection (b)).

18 “(2) ~~TERMINATED.~~—In this section, the term
 19 ‘terminated’ includes, with respect to a contract, the
 20 expiration or nonrenewal of the contract by the
 21 group health plan, but does not include a termi-
 22 nation of the contract by the plan for failure to meet
 23 applicable quality standards or for fraud.

24 “(3) ~~CONTRACTS.~~—For purposes of this sec-
 25 tion, the term ‘contract between a group health plan

1 (other than a fully insured group health plan) and
2 a health care provider² shall include a contract be-
3 tween such a plan and an organized network of pro-
4 viders.

5 “(b) TRANSITIONAL PERIOD.—

6 “(1) GENERAL RULE.—Except as provided in
7 paragraph (3), the transitional period under this
8 subsection shall extend for up to 90 days from the
9 date of the notice described in subsection (a)(1)(A)
10 of the provider’s termination.

11 “(2) INSTITUTIONAL CARE.—Subject to para-
12 graph (1), the transitional period under this sub-
13 section for institutional or inpatient care from a pro-
14 vider shall extend until the discharge or termination
15 of the period of institutionalization and also shall in-
16 clude institutional care provided within a reasonable
17 time of the date of termination of the provider sta-
18 tus if the care was scheduled before the date of the
19 announcement of the termination of the provider
20 status under subsection (a)(1)(A) or if the individual
21 on such date was on an established waiting list or
22 otherwise scheduled to have such care.

23 “(3) PREGNANCY.—Notwithstanding paragraph
24 (1), if—

1 “(A) a participant or beneficiary has en-
 2 tered the second trimester of pregnancy at the
 3 time of a provider’s termination of participa-
 4 tion; and

5 “(B) the provider was treating the preg-
 6 nancy before the date of the termination;
 7 the transitional period under this subsection with re-
 8 spect to provider’s treatment of the pregnancy shall
 9 extend through the provision of post-partum care di-
 10 rectly related to the delivery.

11 “(4) **TERMINAL ILLNESS.**—Subject to para-
 12 graph (1), if—

13 “(A) a participant or beneficiary was de-
 14 termined to be terminally ill (as determined
 15 under section 1861(dd)(3)(A) of the Social Se-
 16 curity Act) prior to a provider’s termination of
 17 participation; and

18 “(B) the provider was treating the ter-
 19 minal illness before the date of termination;
 20 the transitional period under this subsection shall be
 21 for care directly related to the treatment of the ter-
 22 minal illness.

23 “(e) **PERMISSIBLE TERMS AND CONDITIONS.**—A
 24 group health plan (other than a fully insured group health
 25 plan) may condition coverage of continued treatment by

1 a provider under subsection (a)(1)(B) upon the provider
2 agreeing to the following terms and conditions:

3 ~~“(1) The provider agrees to accept reimburse-~~
4 ~~ment from the plan and individual involved (with re-~~
5 ~~spect to cost-sharing) at the rates applicable prior to~~
6 ~~the start of the transitional period as payment in~~
7 ~~full (or, in the case described in subsection (b)(2),~~
8 ~~at the rates applicable under the replacement plan~~
9 ~~after the date of the termination of the contract with~~
10 ~~the group health plan) and not to impose cost-shar-~~
11 ~~ing with respect to the individual in an amount that~~
12 ~~would exceed the cost-sharing that could have been~~
13 ~~imposed if the contract referred to in subsection~~
14 ~~(a)(1) had not been terminated.~~

15 ~~“(2) The provider agrees to adhere to the qual-~~
16 ~~ity assurance standards of the plan responsible for~~
17 ~~payment under paragraph (1) and to provide to such~~
18 ~~plan necessary medical information related to the~~
19 ~~care provided.~~

20 ~~“(3) The provider agrees otherwise to adhere to~~
21 ~~such plan’s policies and procedures, including proce-~~
22 ~~dures regarding referrals and obtaining prior au-~~
23 ~~thorization and providing services pursuant to a~~
24 ~~treatment plan (if any) approved by the plan.~~

1 “(d) **RULE OF CONSTRUCTION.**—Nothing in this sec-
 2 tion shall be construed to require the coverage of benefits
 3 which would not have been covered if the provider involved
 4 remained a participating provider.

5 “(e) **DEFINITION.**—In this section, the term ‘health
 6 care provider’ or ‘provider’ means—

7 “(1) any individual who is engaged in the deliv-
 8 ery of health care services in a State and who is re-
 9 quired by State law or regulation to be licensed or
 10 certified by the State to engage in the delivery of
 11 such services in the State; and

12 “(2) any entity that is engaged in the delivery
 13 of health care services in a State and that, if it is
 14 required by State law or regulation to be licensed or
 15 certified by the State to engage in the delivery of
 16 such services in the State, is so licensed.

17 **“SEC. 726. PROTECTION OF PATIENT-PROVIDER COMMU-**
 18 **NICATIONS.**

19 “(a) **IN GENERAL.**—Subject to subsection (b), a
 20 group health plan (other than a fully insured group health
 21 plan and in relation to a participant or beneficiary) shall
 22 not prohibit or otherwise restrict a health care professional
 23 from advising such a participant or beneficiary who is a
 24 patient of the professional about the health status of the
 25 participant or beneficiary or medical care or treatment for

1 the condition or disease of the participant or beneficiary,
 2 regardless of whether coverage for such care or treatment
 3 are provided under the contract, if the professional is act-
 4 ing within the lawful scope of practice.

5 “(b) RULE OF CONSTRUCTION.—Nothing in this sec-
 6 tion shall be construed as requiring a group health plan
 7 (other than a fully insured group health plan) to provide
 8 specific benefits under the terms of such plan.

9 **“SEC. 727. GENERALLY APPLICABLE PROVISION.**

10 “In the case of a group health plan that provides ben-
 11 efits under 2 or more coverage options, the requirements
 12 of sections 721, 723, 724, 725 and 726 shall apply sepa-
 13 rately with respect to each coverage option.”.

14 (b) DEFINITION.—Section 733(a) of the Employee
 15 Retirement Income Security Act of 1974 (42 U.S.C.
 16 1186(a)) is amended by adding at the end the following:

17 “(3) FULLY INSURED GROUP HEALTH PLAN.—
 18 The term ‘fully insured group health plan’ means a
 19 group health plan where benefits are provided pursu-
 20 ant to the terms of an arrangement between a group
 21 health plan and a health insurance issuer and are
 22 guaranteed by the health insurance issuer under a
 23 contract or policy of insurance.”.

24 (c) CONFORMING AMENDMENT.—The table of con-
 25 tents in section 1 of such Act is amended—

- 1 (1) in the item relating to subpart C, by strik-
- 2 ing “Subpart C” and inserting “Subpart D”; and
- 3 (2) by adding at the end of the items relating
- 4 to subpart B of part 7 of subtitle B of title I of such
- 5 Act the following new items:

“SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

“Sec. 721. Patient access to emergency medical care.

“Sec. 722. Offering of choice of coverage options.

“Sec. 723. Patient access to obstetric and gynecological care.

“Sec. 724. Patient access to pediatric care.

“Sec. 725. Continuity of care.

“Sec. 726. Protection of patient-provider communications.

“Sec. 727. Generally applicable provisions.”.

6 **SEC. 102. EFFECTIVE DATE AND RELATED RULES.**

7 (a) **IN GENERAL.**—The amendments made by this

8 subtitle shall apply with respect to plan years beginning

9 on or after January 1 of the second calendar year fol-

10 lowing the date of the enactment of this Act. The Sec-

11 retary shall issue all regulations necessary to carry out

12 the amendments made by this section before the effective

13 date thereof.

14 (b) **LIMITATION ON ENFORCEMENT ACTIONS.**—No

15 enforcement action shall be taken, pursuant to the amend-

16 ments made by this subtitle, against a group health plan

17 with respect to a violation of a requirement imposed by

18 such amendments before the date of issuance of regula-

19 tions issued in connection with such requirement, if the

20 plan has sought to comply in good faith with such require-

21 ment.

1 **Subtitle B—Right to Information**
 2 **About Plans and Providers**

3 **SEC. 111. INFORMATION ABOUT PLANS.**

4 ~~(a) IN GENERAL.~~—Subpart B of part 7 of subtitle
 5 B of title I of the Employee Retirement Income Security
 6 Act of 1974, as amended by the Omnibus Consolidated
 7 and Emergency Supplemental Appropriations Act, 1999
 8 (Public Law 105–277), is amended by adding at the end
 9 the following:

10 **“SEC. 714. HEALTH PLAN COMPARATIVE INFORMATION.**

11 ~~“(a) REQUIREMENT.~~—A group health plan, or health
 12 insurance issuer in connection with group health insurance
 13 coverage, shall, not later than 12 months after the date
 14 of enactment of this section, provide for the disclosure,
 15 in a clear and accurate form to each enrollee, or upon re-
 16 quest to a potential enrollee eligible to receive benefits
 17 under the plan, or plan sponsor with which the plan or
 18 issuer has contracted, of the information described in sub-
 19 section ~~(b)~~.

20 ~~“(b) REQUIRED INFORMATION.~~—The informational
 21 materials to be distributed under this section shall include
 22 for each health benefit plan the following:

23 ~~“(1) A description of the covered items and~~
 24 ~~services under each such plan and any in- and out-~~
 25 ~~of-network features of each such plan.~~

1 ~~“(2) A description of any cost-sharing, includ-~~
2 ~~ing premiums, deductibles, coinsurance, and copay-~~
3 ~~ment amounts, for which the enrollee will be respon-~~
4 ~~sible, including any annual or lifetime limits on ben-~~
5 ~~efits, for each such plan.~~

6 ~~“(3) A description of any optional supplemental~~
7 ~~benefits offered by each such plan and the terms~~
8 ~~and conditions (including premiums or cost-sharing)~~
9 ~~for such supplemental coverage.~~

10 ~~“(4) A description of any restrictions on pay-~~
11 ~~ments for services furnished to an enrollee by a~~
12 ~~health care professional that is not a participating~~
13 ~~professional and the liability of the enrollee for addi-~~
14 ~~tional payments for these services.~~

15 ~~“(5) A description of the service area of each~~
16 ~~such plan, including the provision of any out-of-area~~
17 ~~coverage.~~

18 ~~“(6) A description of the extent to which enroll-~~
19 ~~ees may select the primary care provider of their~~
20 ~~choice, including providers both within the network~~
21 ~~and outside the network of each such plan (if the~~
22 ~~plan permits out-of-network services).~~

23 ~~“(7) A description of the procedures for ad-~~
24 ~~vance directives and organ donation decisions if the~~
25 ~~plan maintains such procedures.~~

1 “(8) A description of the requirements and pro-
2 cedures to be used to obtain preauthorization for
3 health services (including telephone numbers and
4 mailing addresses), including referrals for specialty
5 care.

6 “(9) A summary of the rules and methods for
7 appealing coverage decisions and filing grievances
8 (including telephone numbers and mailing address-
9 es), as well as other available remedies.

10 “(10) A summary of the rules for access to
11 emergency room care. Also, any available edu-
12 cational material regarding proper use of emergency
13 services.

14 “(11) A description of whether or not coverage
15 is provided for experimental treatments, investiga-
16 tional treatments, or clinical trials and the cir-
17 cumstances under which access to such treatments
18 or trials is made available.

19 “(12) A description of the specific preventative
20 services covered under the plan if such services are
21 covered.

22 “(13) A statement regarding—

23 “(A) the manner in which an enrollee may
24 access an obstetrician, gynecologist, or pediatri-
25 cian in accordance with section 723 or 724;

1 ~~“(B) the manner in which an enrollee ob-~~
 2 ~~tains continuity of care as provided for in sec-~~
 3 ~~tion 725; and~~

4 ~~“(C) the manner in which an enrollee has~~
 5 ~~access to the medical records of the enrollee in~~
 6 ~~accordance with subtitle A of title II of the Pa-~~
 7 ~~tients’ Bill of Rights Act.~~

8 ~~“(14) A statement that the following informa-~~
 9 ~~tion, and instructions on obtaining such information~~
 10 ~~(including telephone numbers and, if available,~~
 11 ~~Internet websites), shall be made available upon re-~~
 12 ~~quest.~~

13 ~~“(A) The names, addresses, telephone~~
 14 ~~numbers, and State licensure status of the~~
 15 ~~plan’s participating health care professionals~~
 16 ~~and participating health care facilities; and, if~~
 17 ~~available, the education, training, speciality~~
 18 ~~qualifications or certifications of such profes-~~
 19 ~~sionals.~~

20 ~~“(B) A summary description of the meth-~~
 21 ~~ods used for compensating participating health~~
 22 ~~care professionals, such as capitation, fee-for-~~
 23 ~~service, salary, or a combination thereof. The~~
 24 ~~requirement of this subparagraph shall not be~~
 25 ~~construed as requiring plans to provide infor-~~

1 mation concerning proprietary payment meth-
2 odology.

3 “(C) A summary description of the meth-
4 ods used for compensating health care facilities,
5 including per diem, fee-for-service, capitation,
6 bundled payments, or a combination thereof.
7 The requirement of this subparagraph shall not
8 be construed as requiring plans to provide in-
9 formation concerning proprietary payment
10 methodology.

11 “(D) A summary description of the proce-
12 dures used for utilization review.

13 “(E) The list of the specific prescription
14 medications included in the formulary of the
15 plan, if the plan uses a defined formulary, and
16 any provision for obtaining off-formulary medi-
17 cations.

18 “(F) A description of the specific exclu-
19 sions from coverage under the plan.

20 “(G) Any available information related to
21 the availability of translation or interpretation
22 services for non-English speakers and people
23 with communication disabilities, including the
24 availability of audio tapes or information in
25 Braille.

1 “(H) Any information that is made public
 2 by accrediting organizations in the process of
 3 accreditation if the plan is accredited, or any
 4 additional quality indicators that the plan
 5 makes available.

6 “(c) MANNER OF DISTRIBUTION.—

7 “(1) IN GENERAL.—The information described
 8 in this section shall be distributed in an accessible
 9 format that is understandable to an average plan en-
 10 rollee.

11 “(2) RULE OF CONSTRUCTION.—For purposes
 12 of this section, a group health plan, or health insur-
 13 ance issuer in connection with group health insur-
 14 ance coverage, in reliance on records maintained by
 15 the plan or issuer, shall be deemed to have met the
 16 requirements of this section if the plan or issuer pro-
 17 vides the information requested under this section—

18 “(A) in the case of the plan, to partici-
 19 pants and beneficiaries at the address contained
 20 in such records with respect to such partici-
 21 pants and beneficiaries; or

22 “(B) in the case of the issuer, to the em-
 23 ployer of a participant if the employer provides
 24 for the coverage of such participant under the
 25 plan involved or to participants and bene-

1 ficiaries at the address contained in such
 2 records with respect to such participants and
 3 beneficiaries.

4 “(d) **RULE OF CONSTRUCTION.**—Nothing in this sec-
 5 tion may be construed to prohibit a group health plan,
 6 or health insurance issuer in connection with group health
 7 insurance coverage, from distributing any other additional
 8 information determined by the plan or issuer to be impor-
 9 tant or necessary in assisting participants and bene-
 10 ficiaries enrollees or upon request potential participants
 11 in the selection of a health plan or from providing informa-
 12 tion under subsection (b)(13) as part of the required infor-
 13 mation.

14 “(e) **HEALTH CARE PROFESSIONAL.**—In this section,
 15 the term ‘health care professional’ means a physician (as
 16 defined in section 1861(r) of the Social Security Act) or
 17 other health care professional if coverage for the profes-
 18 sional’s services is provided under the health plan involved
 19 for the services of the professional. Such term includes a
 20 podiatrist, optometrist, chiropractor, psychologist, dentist,
 21 physician assistant, physical or occupational therapist and
 22 therapy assistant, speech-language pathologist, audiol-
 23 ogist, registered or licensed practical nurse (including
 24 nurse practitioner, clinical nurse specialist, certified reg-
 25 istered nurse anesthetist, and certified nurse-midwife), li-

1 censed certified social worker, registered respiratory thera-
 2 pist, and certified respiratory therapy technician.”.

3 (b) CONFORMING AMENDMENTS.—

4 (1) Section 732(a) of the Employee Retirement
 5 Income Security Act of 1974 (29 U.S.C. 1185(a)) is
 6 amended by striking “section 711, and inserting
 7 “sections 711 and 714”.

8 (2) The table of contents in section 1 of the
 9 Employee Retirement Income Security Act of 1974
 10 (29 U.S.C. 1001) is amended by inserting after the
 11 item relating to section 713, the following:

“Sec. 714. Health plan comparative information.”.

12 **SEC. 112. INFORMATION ABOUT PROVIDERS.**

13 (a) STUDY.—The Secretary of Health and Human
 14 Services shall enter into a contract with the Institute of
 15 Medicine for the conduct of a study, and the submission
 16 to the Secretary of a report, that includes—

17 (1) an analysis of information concerning health
 18 care professionals that is currently available to pa-
 19 tients, consumers, States, and professional societies,
 20 nationally and on a State-by-State basis, including
 21 patient preferences with respect to information
 22 about such professionals and their competencies;

23 (2) an evaluation of the legal and other barriers
 24 to the sharing of information concerning health care
 25 professionals; and

1 ~~(3)~~ recommendations for the disclosure of infor-
 2 mation on health care professionals, including the
 3 competencies and professional qualifications of such
 4 practitioners, to better facilitate patient choice, qual-
 5 ity improvement, and market competition.

6 ~~(b)~~ REPORT.—Not later than 18 months after the
 7 date of enactment of this Act, the Secretary of Health and
 8 Human Services shall forward to the appropriate commit-
 9 tees of Congress a copy of the report and study conducted
 10 under subsection ~~(a)~~.

11 **Subtitle C—Right to Hold Health** 12 **Plans Accountable**

13 **SEC. 121. AMENDMENT TO EMPLOYEE RETIREMENT IN-** 14 **COME SECURITY ACT OF 1974.**

15 ~~(a)~~ IN GENERAL.—Section 503 of the Employee Re-
 16 tirement Income Security Act of 1974 (29 U.S.C. 1133)
 17 is amended to read as follows:

18 **“SEC. 503. CLAIMS PROCEDURE, COVERAGE DETERMINA-** 19 **TION, GRIEVANCES AND APPEALS.**

20 ~~“(a)~~ CLAIMS PROCEDURE.—In accordance with regu-
 21 lations of the Secretary, every employee benefit plan
 22 shall—

23 ~~“(1)~~ provide adequate notice in writing to any
 24 participant or beneficiary whose claim for benefits
 25 under the plan has been denied, setting forth the

1 specific reasons for such denial, written in a manner
 2 calculated to be understood by the participant, and
 3 ~~“(2) afford a reasonable opportunity to any~~
 4 participant whose claim for benefits has been denied
 5 for a full and fair review by the appropriate named
 6 fiduciary of the decision denying the claim.

7 ~~“(b) COVERAGE DETERMINATIONS UNDER GROUP~~
 8 HEALTH PLANS.—

9 ~~“(1) PROCEDURES.—~~

10 ~~“(A) IN GENERAL.—A group health plan~~
 11 or health insurance issuer conducting utilization
 12 review shall ensure that procedures are in place
 13 for—

14 ~~“(i) making determinations regarding~~
 15 whether an enrollee is eligible to receive a
 16 payment or coverage for health services
 17 under the plan or coverage involved and
 18 any cost-sharing amount that the enrollee
 19 is required to pay with respect to such
 20 service;

21 ~~“(ii) notifying covered enrollees (or~~
 22 the legal representative of such enrollees)
 23 and the treating health care professionals
 24 involved regarding determinations made
 25 under the plan or issuer and any addi-

1 tional payments that the enrollee may be
 2 required to make with respect to such serv-
 3 ice; and

4 “(iii) responding to requests, either
 5 written or oral, for coverage determina-
 6 tions or for internal appeals from an en-
 7 rollee (or the legal representative of such
 8 enrollee) or the treating health care profes-
 9 sional.

10 “(B) ORAL REQUESTS.—With respect to
 11 an oral request described in subparagraph
 12 (A)(iii), a group health plan or health insurance
 13 issuer may require that the requesting indi-
 14 vidual provide written evidence of such request.

15 “(2) TIMELINE FOR MAKING DETERMINA-
 16 TIONS.—

17 “(A) ROUTINE DETERMINATION.—A group
 18 health plan or a health insurance issuer shall
 19 maintain procedures to ensure that prior au-
 20 thorization determinations concerning the provi-
 21 sion of non-emergency items or services are
 22 made within 30 days from the date on which
 23 the request for a determination is submitted,
 24 except that such period may be extended where
 25 certain circumstances exist that are determined

by the Secretary to be beyond control of the plan or issuer.

~~“(B) EXPEDITED DETERMINATION.—~~

~~“(i) IN GENERAL.—A prior authorization determination under this subsection shall be made within 72 hours after a request is received by the plan or issuer under clause (ii) or (iii).~~

~~“(ii) REQUEST BY ENROLLEE.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection upon the request of an enrollee if, based on such a request, the plan or issuer determines that the normal time for making such a determination could seriously jeopardize the life or health of the enrollee.~~

~~“(iii) DOCUMENTATION BY HEALTH CARE PROFESSIONAL.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection if the request involved indicates that the treating health care professional has documented, based on the medical exigencies, that a determination under~~

1 the procedures described in subparagraph
 2 (A) could seriously jeopardize the life or
 3 health of the enrollee.

4 “(C) CONCURRENT DETERMINATIONS.—A
 5 plan or issuer shall maintain procedures to cer-
 6 tify or deny coverage of an extended stay or ad-
 7 ditional services.

8 “(D) RETROSPECTIVE DETERMINATION.—
 9 A plan or issuer shall maintain procedures to
 10 ensure that, with respect to the retrospective re-
 11 view of a determination made under paragraph
 12 (1), the determination shall be made within 30
 13 working days of the date on which the plan or
 14 issuer receives all necessary information.

15 “(3) NOTICE OF DETERMINATIONS.—

16 “(A) ROUTINE DETERMINATION.—With re-
 17 spect to a coverage determination of a plan or
 18 issuer under paragraph (2)(A), the plan or
 19 issuer shall issue notice of such determination
 20 to the enrollee (or the legal representative of
 21 the enrollee), and consistent with the medical
 22 exigencies of the case, to the treating health
 23 care professional involved not later than 2
 24 working days after the date on which the deter-
 25 mination is made.

1 “(B) ~~EXPEDITED DETERMINATION.~~—With
 2 respect to a coverage determination of a plan or
 3 issuer under paragraph (2)(B), the plan or
 4 issuer shall issue notice of such determination
 5 to the enrollee (or the legal representative of
 6 the enrollee), and consistent with the medical
 7 exigencies of the case, to the treating health
 8 care professional involved within the 72 hour
 9 period described in paragraph (2)(B).

10 “(C) ~~CONCURRENT REVIEWS.~~—With re-
 11 spect to the determination under a plan or
 12 issuer under paragraph (1) to certify or deny
 13 coverage of an extended stay or additional serv-
 14 ices, the plan or issuer shall issue notice of such
 15 determination to the treating health care pro-
 16 fessional and to the enrollee involved (or the
 17 legal representative of the enrollee) within 1
 18 working day of the date on which the initial no-
 19 tice was issued.

20 “(D) ~~RETROSPECTIVE REVIEWS.~~—With re-
 21 spect to the retrospective review under a plan
 22 or issuer of a determination made under para-
 23 graph (1), a determination shall be made within
 24 30 working days of the date on which the plan
 25 or issuer receives all necessary information. The

plan or issuer shall issue written notice of an approval or disapproval of a determination under this subparagraph to the enrollee (or the legal representative of the enrollee) and health care provider involved within 5 working days of the date on which such determination is made.

“(E) REQUIREMENTS OF NOTICE OF ADVERSE COVERAGE DETERMINATIONS.—A written or electronic notice of an adverse coverage determination under this subsection, or of an expedited adverse coverage determination under paragraph (2)(B), shall be provided to the enrollee (or the legal representative of the enrollee) and treating health care professional (if any) involved and shall include—

“(i) the reasons for the determination (including the clinical or scientific-evidence based rationale used in making the determination) written in a manner to be understandable to the average enrollee;

“(ii) the procedures for obtaining additional information concerning the determination; and

“(iii) notification of the right to appeal the determination and instructions on

1 how to initiate an appeal in accordance
2 with subsection (d).

3 ~~“(e) GRIEVANCES.—A group health plan or a health~~
4 ~~insurance issuer shall have written procedures for address-~~
5 ~~ing grievances between the plan and enrollees. Determina-~~
6 ~~tions under such procedures shall be non-appealable.~~

7 ~~“(d) INTERNAL APPEAL OF COVERAGE DETERMINA-~~
8 ~~TIONS.—~~

9 ~~“(1) IN GENERAL.—An enrollee (or the legal~~
10 ~~representative of the enrollee) and the treating~~
11 ~~health care professional with the consent of the en-~~
12 ~~rollee (or the legal representative of the enrollee),~~
13 ~~may appeal any adverse coverage determination~~
14 ~~under subsection (b) under the procedures described~~
15 ~~in this subsection.~~

16 ~~“(2) RECORDS.—A group health plan and a~~
17 ~~health insurance issuer shall maintain written~~
18 ~~records, for at least 6 years, with respect to any ap-~~
19 ~~peal under this subsection for purposes of internal~~
20 ~~quality assurance and improvement.~~

21 ~~“(3) ROUTINE DETERMINATIONS.—A group~~
22 ~~health plan or a health insurance issuer shall provide~~
23 ~~for the consideration of an appeal of an adverse rou-~~
24 ~~tine determination under this subsection not later~~

1 than 30 working days after the date on which a re-
 2 quest for such appeal is received.

3 ~~“(4) EXPEDITED DETERMINATION.—~~

4 ~~“(A) IN GENERAL.—An expedited deter-~~
 5 ~~mination with respect to an appeal under this~~
 6 ~~subsection shall be made in accordance with the~~
 7 ~~medical exigencies of the case, but in no case~~
 8 ~~more than 72 hours after the request for such~~
 9 ~~appeal is received by the plan or issuer under~~
 10 ~~subparagraph (B) or (C).~~

11 ~~“(B) REQUEST BY ENROLLEE.—A plan or~~
 12 ~~issuer shall maintain procedures for expediting~~
 13 ~~a prior authorization determination under this~~
 14 ~~subsection upon the request of an enrollee if,~~
 15 ~~based on such a request, the plan or issuer de-~~
 16 ~~termines that the normal time for making such~~
 17 ~~a determination could seriously jeopardize the~~
 18 ~~life or health of the enrollee.~~

19 ~~“(C) DOCUMENTATION BY HEALTH CARE~~
 20 ~~PROFESSIONAL.—A plan or issuer shall main-~~
 21 ~~tain procedures for expediting a prior author-~~
 22 ~~ization determination under this subsection if~~
 23 ~~the request involved indicates that the treating~~
 24 ~~health care professional has documented, based~~
 25 ~~on the medical exigencies that a determination~~

1 under the procedures described in paragraph
2 (2) could seriously jeopardize the life or health
3 of the enrollee.

4 “(5) CONDUCT OF REVIEW.—A review of an ad-
5 verse coverage determination under this subsection
6 shall be conducted by an individual with appropriate
7 expertise who was not involved in the initial deter-
8 mination.

9 “(6) LACK OF MEDICAL NECESSITY.—A review
10 of an appeal under this subsection relating to a de-
11 termination to deny coverage based on a lack of
12 medical necessity or appropriateness, or based on an
13 experimental or investigational treatment, shall be
14 made only by a physician with appropriate expertise
15 in the field of medicine involved who was not in-
16 volved in the initial determination.

17 “(7) NOTICE.—

18 “(A) IN GENERAL.—Written notice of a
19 determination made under an internal review
20 process shall be issued to the enrollee (or the
21 legal representative of the enrollee) and the
22 treating health care professional not later than
23 2 working days after the completion of the re-
24 view (or within the 72-hour period referred to
25 in paragraph (4) if applicable).

1 ~~“(B) ADVERSE COVERAGE DETERMINA-~~
 2 ~~TIONS.—~~With respect to an adverse coverage
 3 ~~determination made under this subsection,~~ the
 4 ~~notice described in subparagraph (A) shall~~
 5 ~~include—~~

6 ~~“(i) the reasons for the determination~~
 7 ~~(including the clinical or scientific-evidence~~
 8 ~~based rationale used in making the deter-~~
 9 ~~mination) written in a manner to be under-~~
 10 ~~standable to the average enrollee;~~

11 ~~“(ii) the procedures for obtaining ad-~~
 12 ~~ditional information concerning the deter-~~
 13 ~~mination; and~~

14 ~~“(iii) notification of the right to an~~
 15 ~~external review under subsection (e) and~~
 16 ~~instructions on how to initiate such a re-~~
 17 ~~view.~~

18 ~~“(e) EXTERNAL REVIEW.—~~

19 ~~“(1) IN GENERAL.—~~A group health plan or a
 20 ~~health insurance issuer shall have written procedures~~
 21 ~~to permit an enrollee (or the legal representative of~~
 22 ~~the enrollee) access to an external review with re-~~
 23 ~~spect to a coverage determination concerning a par-~~
 24 ~~ticular item or service where—~~

1 “(A) the particular item or service in-
 2 volved, when medically appropriate and nec-
 3 essary, is a covered benefit under the terms and
 4 conditions of the contract between the plan or
 5 issuer and the enrollee;

6 “(B) the coverage determination involved
 7 denied coverage for such item or service because
 8 the provision of such item or service—

9 “(i) does not meet the plan’s or
 10 issuer’s requirements for medical appro-
 11 priateness or necessity and the amount in-
 12 volved exceeds a significant financial
 13 threshold; or

14 “(ii) would constitute experimental or
 15 investigational treatment and there is a
 16 significant risk of placing the life or health
 17 of the enrollee in jeopardy; and

18 “(C) the enrollee has completed the inter-
 19 nal appeals process with respect to such deter-
 20 mination.

21 “(2) INITIATION OF THE EXTERNAL REVIEW
 22 PROCESS.—

23 “(A) FILING OF REQUEST.—An enrollee
 24 (or the legal representative of the enrollee) who
 25 desires to have an external review conducted

under this subsection shall file a written request for such a review with the plan or issuer involved not later than 30 working days after the receipt of a final denial of a claim under subsection (d). Any such request shall include the consent of the enrollee (or the legal representative of the enrollee) for the release of medical information and records to external reviewers regarding the enrollee if such information is necessary for the proper conduct of the external review.

“(B) INFORMATION AND NOTICE.—Not later than 5 working days after the receipt of a request under subparagraph (A), or earlier in accordance with the medical exigencies of the case, the plan or issuer involved shall select an external appeals entity under paragraph (3)(A) that shall be responsible for designating an external reviewer under paragraph (3)(B).

“(C) PROVISION OF INFORMATION.—The plan or issuer involved shall forward all necessary information (including medical records, any relevant review criteria, the clinical rationale consistent with the terms and conditions of the contract between the plan or issuer and the

1 enrollee for the coverage denial, and evidence of
 2 the enrollee's coverage) to the external reviewer
 3 selected under paragraph (3)(B).

4 “(D) NOTIFICATION.—The plan or issuer
 5 involved shall send a written notification to the
 6 enrollee (or the legal representative of the en-
 7 rollee) and the plan administrator, indicating
 8 that an external review has been initiated.

9 “(3) CONDUCT OF EXTERNAL REVIEW.—

10 “(A) DESIGNATION OF EXTERNAL AP-
 11 PEALS ENTITY BY PLAN OR ISSUER.—A plan or
 12 issuer that receives a request for an external re-
 13 view under paragraph (2)(A) shall designate
 14 one of the following entities to serve as the ex-
 15 ternal appeals entity:

16 “(i) An external review entity licensed
 17 or credentialed by a State.

18 “(ii) A State agency established for
 19 the purpose of conducting independent ex-
 20 ternal reviews.

21 “(iii) Any entity under contract with
 22 the Federal Government to provide exter-
 23 nal review services.

24 “(iv) Any entity accredited as an ex-
 25 ternal review entity by an accrediting body

1 recognized by the Secretary for such pur-
 2 pose.

3 “(v) Any fully accredited teaching
 4 hospital.

5 “(vi) Any other entity meeting criteria
 6 established by the Secretary for purposes
 7 of this subparagraph.

8 “(B) DESIGNATION OF EXTERNAL RE-
 9 VIEWER BY EXTERNAL APPEALS ENTITY.—The
 10 external appeals entity designated under sub-
 11 paragraph (A) shall, not later than 30 days
 12 after the date on which such entity is des-
 13 ignated under subparagraph (A), or earlier in
 14 accordance with the medical exigencies of the
 15 case, designate one or more individuals to serve
 16 as external reviewers with respect to a request
 17 received under paragraph (2)(A). Such review-
 18 ers shall be independent medical experts who
 19 shall—

20 “(i) be appropriately credentialed or
 21 licensed in any State to deliver health care
 22 services;

23 “(ii) not have any material, profes-
 24 sional, familial, or financial affiliation with
 25 the case under review, the enrollee in-

1 involved, the treating health care profes-
 2 sional, the institution where the treatment
 3 would take place, or the manufacturer of
 4 any drug, device, procedure, or other ther-
 5 apy proposed for the enrollee whose treat-
 6 ment is under review;

7 “(iii) be experts in the diagnosis or
 8 treatment under review and, when reason-
 9 ably available, be of the same speciality of
 10 the physician prescribing the treatment in
 11 question;

12 “(iv) receive only reasonable and cus-
 13 tomary compensation from the group
 14 health plan or health insurance issuer in
 15 connection with the external review that is
 16 not contingent on the decision rendered by
 17 the reviewer; and

18 “(v) not be held liable for decisions re-
 19 garding medical determinations (but may
 20 be held liable for actions that are arbitrary
 21 and capricious);

22 “(4) STANDARD OF REVIEW.—

23 “(A) IN GENERAL.—An external reviewer
 24 shall—

1 “(i) make a determination based on
2 the medical necessity, appropriateness, ex-
3 perimental or investigational nature of the
4 coverage denial;

5 “(ii) take into consideration any evi-
6 dence-based decision making or clinical
7 practice guidelines used by the group
8 health plan or health insurance issuer in
9 conducting utilization review; and

10 “(iii) submit a report on the final de-
11 terminations of the review involved to—

12 “(I) the plan or issuer involved;

13 “(II) the enrollee involved (or the
14 legal representative of the enrollee);
15 and

16 “(III) the health care profes-
17 sional involved.

18 “(B) NOTICE.—The plan or issuer involved
19 shall ensure that the enrollee receives notice,
20 within 30 days after the determination of the
21 independent medical expert, regarding the ac-
22 tions of the plan or issuer with respect to the
23 determination of such expert under the external
24 review.

25 “(5) TIMEFRAME FOR REVIEW.—

1 “(A) IN GENERAL.—An external reviewer
2 shall complete a review of an adverse coverage
3 determination in accordance with the medical
4 exigencies of the case.

5 “(B) LIMITATION.—Notwithstanding sub-
6 paragraph (A), a review described in such sub-
7 paragraph shall be completed not later than 30
8 working days after the later of—

9 “(i) the date on which such reviewer
10 is designated; or

11 “(ii) the date on which all information
12 necessary to completing such review is re-
13 ceived.

14 “(6) BINDING DETERMINATION.—The deter-
15 mination of an external reviewer under this sub-
16 section shall be binding upon the plan or issuer if
17 the provisions of this subsection or the procedures
18 implemented under such provisions were complied
19 with by the external reviewer.

20 “(7) STUDY.—Not later than 2 years after the
21 date of enactment of this section, the General Ac-
22 counting Office shall conduct a study of a statis-
23 tically appropriate sample of completed external re-
24 views. Such study shall include an assessment of the
25 process involved during an external review and the

1 basis of decisionmaking by the external reviewer.
 2 The results of such study shall be submitted to the
 3 appropriate committees of Congress.

4 “(8) EFFECT ON CERTAIN PROVISIONS.—Noth-
 5 ing in this section shall be construed as affecting or
 6 modifying section 514 of this Act with respect to a
 7 group health plan.

8 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
 9 tion shall be construed to prohibit a plan administrator
 10 or plan fiduciary or health plan medical director from re-
 11 questing an external review by an external reviewer with-
 12 out first completing the internal review process.

13 “(g) DEFINITIONS.—In this section:

14 “(1) ADVERSE COVERAGE DETERMINATION.—
 15 The term ‘adverse coverage determination’ means a
 16 coverage determination under the plan which results
 17 in a denial of coverage or reimbursement.

18 “(2) COVERAGE DETERMINATION.—The term
 19 ‘coverage determination’ means with respect to items
 20 and services for which coverage may be provided
 21 under a health plan, a determination of whether or
 22 not such items and services are covered or reimburs-
 23 able under the coverage and terms of the contract.

24 “(3) ENROLLEE.—The term enrollee means a
 25 participant or beneficiary.

1 “(4) GRIEVANCE.—The term ‘grievance’ means
2 any enrollee complaint that does not involve a cov-
3 erage determination.

4 “(5) GROUP HEALTH PLAN.—The term ‘group
5 health plan’ shall have the meaning given such term
6 in section 733(a). In applying this paragraph, ex-
7 cepted benefits described in section 733(c) shall not
8 be treated as benefits consisting of medical care.

9 “(6) HEALTH INSURANCE COVERAGE.—The
10 term ‘health insurance coverage’ has the meaning
11 given such term in section 733(b)(1). In applying
12 this paragraph, excepted benefits described in sec-
13 tion 733(c) shall not be treated as benefits con-
14 sisting of medical care.

15 “(7) HEALTH INSURER.—The term ‘health in-
16 surer’ means an insurance company, insurance serv-
17 ice, or an insurance organization that meets the re-
18 quirements of section 733(b)(2) and that offers
19 health insurance coverage in connection with a group
20 health plan.

21 “(8) PRIOR AUTHORIZATION DETERMINA-
22 TION.—The term ‘prior authorization determination’
23 means a coverage determination prior to the provi-
24 sion of the items and services as a condition of cov-
25 erage of the items and services under the coverage.

1 “(9) TREATING HEALTH CARE PROFES-
 2 SIONAL.—The term ‘treating health care profes-
 3 sional’ with respect to a group health plan, health
 4 insurance issuer or provider sponsored organization
 5 means a practitioner who is acting within the scope
 6 of their State licensure or certification for the deliv-
 7 ery of health care services and who is primarily re-
 8 sponsible for delivering those services to the enrollee.”

9 “(10) UTILIZATION REVIEW.—The term ‘utili-
 10 zation review’ with respect to a group health plan or
 11 health insurance coverage means a set of formal
 12 techniques designed to monitor the use of, or evalu-
 13 ate the clinical necessity, appropriateness, efficacy,
 14 or efficiency of, health care services, procedures, or
 15 settings. Techniques may include ambulatory review,
 16 prospective review, second opinion, certification, con-
 17 current review, case management, discharge plan-
 18 ning or retrospective review.”

19 (b) ENFORCEMENT.—Section 502(c)(1) of the Em-
 20 ployee Retirement Income Security Act of 1974 (29
 21 U.S.C. 1132(c)(1)) is amended by inserting after “or sec-
 22 tion 101(c)(1)” the following: “, or fails to comply with
 23 a coverage determination as required under section
 24 503(c)(6),”.

1 (c) CONFORMING AMENDMENT.—The table of con-
 2 tents in section 1 of the Employee Retirement Income Se-
 3 curity Act of 1974 is amended by striking the item relat-
 4 ing to section 503 and inserting the following new item:
 “Sec. 503. Claims procedures; coverage determination; grievances and appeals.”.

5 (d) EFFECTIVE DATE.—The amendments made by
 6 this section shall apply with respect to plan years begin-
 7 ning on or after 1 year after the date of enactment of
 8 this Act. The Secretary shall issue all regulations nec-
 9 essary to carry out the amendments made by this section
 10 before the effective date thereof.

11 **TITLE H—INDIVIDUAL RIGHTS** 12 **WITH RESPECT TO PERSONAL** 13 **MEDICAL INFORMATION**

14 **SEC. 201. SHORT TITLE.**

15 This title may be cited as the “Personal Medical In-
 16 formation Access Act”.

17 **Subtitle A—Access to Medical** 18 **Records**

19 **SEC. 211. INSPECTION AND COPYING OF PROTECTED** 20 **HEALTH INFORMATION.**

21 (a) IN GENERAL.—At the request of an individual
 22 and except as provided in subsection (b), a health care
 23 provider, health plan, employer, health or life insurer,
 24 school, or university shall permit an individual who is the
 25 subject of protected health information or the individual’s

1 designee, to inspect and copy protected health information
 2 concerning the individual, including records created under
 3 section 212 that such entity maintains. Such entity may
 4 set forth appropriate procedures to be followed for such
 5 inspection or copying and may require an individual to pay
 6 reasonable costs associated with such inspection or copy-
 7 ing.

8 (b) EXCEPTIONS.—Unless ordered by a court of com-
 9 petent jurisdiction, an entity described in subsection (a)
 10 is not required to permit the inspection or copying of pro-
 11 tected health information if any of the following conditions
 12 are met:

13 (1) ENDANGERMENT TO LIFE OR SAFETY.—
 14 The entity determines that the disclosure of the in-
 15 formation could reasonably be expected to endanger
 16 the life or physical safety of an individual.

17 (2) CONFIDENTIAL SOURCE.—The information
 18 identifies, or could reasonably lead to the identifica-
 19 tion of, a person who provided information under a
 20 promise of confidentiality concerning the individual
 21 who is the subject of the information.

22 (3) INFORMATION COMPILED IN ANTICIPATION
 23 OF LITIGATION.—The information is compiled
 24 principally—

1 (A) in the reasonable anticipation of a
2 civil, criminal, or administrative action or pro-
3 ceeding; or

4 (B) for use in such an action or pro-
5 ceeding.

6 (4) RESEARCH PURPOSES.—The information
7 was collected for a research project monitored by an
8 institutional review board, such project is not com-
9 plete, and the researcher involved reasonably believes
10 that access to such information would harm the con-
11 duct of the research or invalidate or undermine the
12 validity of the research.

13 (c) DENIAL OF A REQUEST FOR INSPECTION OR
14 COPYING.—If an entity described in subsection (a) denies
15 a request for inspection or copying pursuant to subsection
16 (b), the entity shall inform the individual in writing of—

17 (1) the reasons for the denial of the request for
18 inspection or copying;

19 (2) any procedures for further review of the de-
20 nial; and

21 (3) the individual's right to file with the entity
22 a concise statement setting forth the request for in-
23 spection or copying.

24 (d) STATEMENT REGARDING REQUEST.—If an indi-
25 vidual has filed a statement under subsection (c)(3), the

1 entity in any subsequent disclosure of the portion of the
 2 information requested under subsection (a) shall include—

- 3 (1) a copy of the individual's statement; and
- 4 (2) a concise statement of the reasons for deny-
 5 ing the request for inspection or copying.

6 (c) ~~INSPECTION AND COPYING OF SEGREGABLE POR-~~
 7 ~~TION.~~—An entity described in subsection (a) shall permit
 8 the inspection and copying under subsection (a) of any
 9 reasonably segregable portion of protected health informa-
 10 tion after deletion of any portion that is exempt under
 11 subsection (b).

12 (f) ~~DEADLINE.~~—An entity described in subsection (a)
 13 shall comply with or deny, in accordance with subsection
 14 (e), a request for inspection or copying of protected health
 15 information under this section not later than 45 days after
 16 the date on which the entity receives the request.

17 (g) ~~RULES GOVERNING AGENTS.~~—An agent of an en-
 18 tity described in subsection (a) shall not be required to
 19 provide for the inspection and copying of protected health
 20 information, except where—

- 21 (1) the protected health information is retained
 22 by the agent; and
- 23 (2) the agent has received in writing a request
 24 from the entity involved to fulfill the requirements of
 25 this section;

1 at which time such information shall be provided to the
 2 requesting entity. Such requesting entity shall comply with
 3 subsection (f) with respect to any such information.

4 (h) **RULE OF CONSTRUCTION.**—This section shall not
 5 be construed to require an entity described in subsection
 6 (a) to conduct a formal, informal, or other hearing or pro-
 7 ceeding concerning a request for inspection or copying of
 8 protected health information.

9 **SEC. 212. AMENDMENT OF PROTECTED HEALTH INFORMA-**
 10 **TION.**

11 (a) **REQUIREMENT.**—

12 (1) **IN GENERAL.**—Except as provided in sub-
 13 section (b) and subject to paragraph (2), a health
 14 care provider, health plan, employer, health or life
 15 insurer, school, or university that receives from an
 16 individual a request in writing to amend protected
 17 health information shall—

18 (A) amend such information as requested;

19 (B) inform the individual of the amend-
 20 ment that has been made; and

21 (C) make reasonable efforts to inform any
 22 person to whom the unamended portion of the
 23 information was previously disclosed, of any
 24 nontechnical amendment that has been made.

1 (2) COMPLIANCE.—An entity described in para-
 2 graph (1) shall comply with the requirements of
 3 such paragraph within 45 days of the date on which
 4 the request involved is received if the entity—

5 (A) created the protected health informa-
 6 tion involved; and

7 (B) determines that such information is in
 8 fact inaccurate.

9 (b) REFUSAL TO AMEND.—If an entity described in
 10 subsection (a) refuses to make the amendment requested
 11 under such subsection, the entity shall inform the indi-
 12 vidual in writing of—

13 (1) the reasons for the refusal to make the
 14 amendment;

15 (2) any procedures for further review of the re-
 16 fusal; and

17 (3) the individual's right to file with the entity
 18 a concise statement setting forth the requested
 19 amendment and the individual's reasons for dis-
 20 agreeing with the refusal.

21 (c) STATEMENT OF DISAGREEMENT.—If an indi-
 22 vidual has filed a statement of disagreement under sub-
 23 section (b)(3), the entity involved, in any subsequent dis-
 24 closure of the disputed portion of the information—

1 (1) shall include a copy of the individual's
2 statement; and

3 (2) may include a concise statement of the rea-
4 sons for not making the requested amendment.

5 (d) RULES GOVERNING AGENTS.—The agent of an
6 entity described in subsection (a) shall not be required to
7 make amendments to protected health information, except
8 where—

9 (1) the protected health information is retained
10 by the agent; and

11 (2) the agent has been asked by such entity to
12 fulfill the requirements of this section.

13 If the agent is required to comply with this section as pro-
14 vided for in paragraph (2), such agent shall be subject
15 to the 45-day deadline described in subsection (a).

16 (e) REPEATED REQUESTS FOR AMENDMENTS.—If an
17 entity described in subsection (a) receives a request for
18 an amendment of information as provided for in such sub-
19 section and a statement of disagreement has been filed
20 pursuant to subsection (c), the entity shall inform the indi-
21 vidual of such filing and shall not be required to carry
22 out the procedures required under this section.

23 (f) RULES OF CONSTRUCTION.—This section shall
24 not be construed to—

1 (1) require that an entity described in sub-
 2 section (a) conduct a formal, informal, or other
 3 hearing or proceeding concerning a request for an
 4 amendment to protected health information;

5 (2) require a provider to amend an individual's
 6 protected health information as to the type, dura-
 7 tion, or quality of treatment the individual believes
 8 he or she should have been provided; or

9 (3) permit any deletions or alterations of the
 10 original information.

11 **SEC. 213. NOTICE OF CONFIDENTIALITY PRACTICES.**

12 (a) PREPARATION OF WRITTEN NOTICE.—A health
 13 care provider, health plan, health oversight agency, public
 14 health authority, employer, health or life insurer, health
 15 researcher, school or university shall post or provide, in
 16 writing and in a clear and conspicuous manner, notice of
 17 the entity's confidentiality practices, that shall include—

18 (1) a description of an individual's rights with
 19 respect to protected health information;

20 (2) the procedures established by the entity for
 21 the exercise of the individual's rights; and

22 (3) the right to obtain a copy of the notice of
 23 the confidentiality practices required under this sub-
 24 title.

1 (b) **MODEL NOTICE.**—The Secretary, in consultation
 2 with the National Committee on Vital and Health Statis-
 3 ties and the National Association of Insurance Commis-
 4 sioners, and after notice and opportunity for public com-
 5 ment, shall develop and disseminate model notices of con-
 6 fidentiality practices. Use of the model notice shall serve
 7 as a defense against claims of receiving inappropriate no-
 8 tice.

9 **Subtitle B—Establishment of** 10 **Safeguards**

11 **SEC. 221. ESTABLISHMENT OF SAFEGUARDS.**

12 A health care provider, health plan, health oversight
 13 agency, public health authority, employer, health or life
 14 insurer, health researcher, law enforcement official, school
 15 or university shall establish and maintain appropriate ad-
 16 ministrative, technical, and physical safeguards to protect
 17 the confidentiality, security, accuracy, and integrity of
 18 protected health information created, received, obtained,
 19 maintained, used, transmitted, or disposed of by such enti-
 20 ty.

21 **Subtitle C—Enforcement;** 22 **Definitions**

23 **SEC. 231. CIVIL PENALTY.**

24 (a) **VIOLATION.**—A health care provider, health re-
 25 searcher, health plan, health oversight agency, public

1 health agency, law enforcement agency, employer, health
 2 or life insurer, school, or university, or the agent of any
 3 such individual or entity, who the Secretary, in consulta-
 4 tion with the Attorney General, determines has substan-
 5 tially and materially failed to comply with this Act shall,
 6 for a violation of this title, be subject, in addition to any
 7 other penalties that may be prescribed by law, to a civil
 8 penalty of not more than \$500 for each such violation,
 9 but not to exceed \$5,000 in the aggregate for multiple vio-
 10 lations.

11 (b) PROCEDURES FOR IMPOSITION OF PENALTIES.—
 12 Section 1128A of the Social Security Act, other than sub-
 13 sections (a) and (b) and the second sentence of subsection
 14 (f) of that section, shall apply to the imposition of a civil,
 15 monetary, or exclusionary penalty under this section in the
 16 same manner as such provisions apply with respect to the
 17 imposition of a penalty under section 1128A of such Act.

18 **SEC. 232. DEFINITIONS.**

19 In this title:

20 (1) AGENT.—The term “agent” means a person
 21 who represents and acts for another under the con-
 22 tract or relation of agency, or whose function is to
 23 bring about, modify, affect, accept performance of,
 24 or terminate contractual obligations between the
 25 principal and a third person, including a contractor.

1 (2) DISCLOSE.—The term “disclose” means to
 2 release, transfer, provide access to, or otherwise di-
 3 vulge protected health information to any person
 4 other than the individual who is the subject of such
 5 information. Such term includes the initial disclosure
 6 and any subsequent redisclosures of protected health
 7 information.

8 (3) EMPLOYER.—The term “employer” has the
 9 meaning given such term under section 3(5) of the
 10 Employee Retirement Income Security Act of 1974
 11 (29 U.S.C. 1002(5)), except that such term shall in-
 12 clude only employers of 2 or more employees.

13 (4) HEALTH CARE PROVIDER.—The term
 14 “health care provider” means a person who, with re-
 15 spect to a specific item of protected health informa-
 16 tion, receives, creates, uses, maintains, or discloses
 17 the information while acting in whole or in part in
 18 the capacity of—

19 (A) a person who is licensed, certified, reg-
 20 istered, or otherwise authorized by Federal or
 21 State law to provide an item or service that
 22 constitutes health care in the ordinary course of
 23 business, or practice of a profession;

24 (B) a Federal, State, or employer-spon-
 25 sored program that directly provides items or

1 services that constitute health care to bene-
 2 ficiaries; or

3 (C) an officer, employee, or agent of a per-
 4 son described in subparagraph (A) or (B).

5 (5) HEALTH OR LIFE INSURER.—The term
 6 “health or life insurer” means a health insurance
 7 issuer as defined in section 2791 of the Public
 8 Health Service Act (42 U.S.C. 300gg-91) or a life
 9 insurance company as defined in section 816 of the
 10 Internal Revenue Code of 1986.

11 (6) HEALTH PLAN.—The term “health plan”
 12 means any health insurance plan, including any hos-
 13 pital or medical service plan, dental or other health
 14 service plan or health maintenance organization
 15 plan, provider sponsored organization, or other pro-
 16 gram providing or arranging for the provision of
 17 health benefits, whether or not funded through the
 18 purchase of insurance.

19 (7) PERSON.—The term “person” means a gov-
 20 ernment, governmental subdivision, agency or au-
 21 thority; corporation; company; association; firm;
 22 partnership; society; estate; trust; joint venture; indi-
 23 vidual; individual representative; tribal government;
 24 and any other legal entity.

1 (8) ~~PROTECTED HEALTH INFORMATION.~~—The
 2 term “protected health information” means any in-
 3 formation (including demographic information)
 4 whether or not recorded in any form or medium—

5 (A) that relates to the past, present or
 6 future—

7 (i) physical or mental health or condi-
 8 tion of an individual (including the condi-
 9 tion or other attributes of individual cells
 10 or their components);

11 (ii) provision of health care to an indi-
 12 vidual; or

13 (iii) payment for the provision of
 14 health care to an individual;

15 (B) that is created by a health care pro-
 16 vider, health plan, health researcher, health
 17 oversight agency, public health authority, em-
 18 ployer, law enforcement official, health or life
 19 insurer, school or university; and

20 (C) that is not nonidentifiable health infor-
 21 mation.

22 (9) ~~SCHOOL OR UNIVERSITY.~~—The term
 23 “school or university” means an institution or place
 24 for instruction or education, including an elementary
 25 school, secondary school, or institution of higher

1 learning, a college, or an assemblage of colleges
 2 united under one corporate organization or govern-
 3 ment.

4 (10) SECRETARY.—The term “Secretary”
 5 means the Secretary of Health and Human Services.

6 (11) WRITING.—The term “writing” means
 7 writing in either a paper-based or computer-based
 8 form, including electronic signatures.

9 **SEC. 233. EFFECTIVE DATE.**

10 The provisions of this title shall become effective be-
 11 ginning on the date that is 1 year after the date of enact-
 12 ment of this Act. The Secretary shall issue regulations
 13 necessary to carry out this title before the effective date
 14 thereof.

15 **TITLE III—GENETIC**
 16 **INFORMATION AND SERVICES**

17 **SEC. 301. SHORT TITLE.**

18 This title may be cited as the “Genetic Information
 19 Nondiscrimination in Health Insurance Act of 1999”.

20 **SEC. 302. AMENDMENTS TO EMPLOYEE RETIREMENT IN-**
 21 **COME SECURITY ACT OF 1974.**

22 (a) PROHIBITION OF HEALTH DISCRIMINATION ON
 23 THE BASIS OF GENETIC INFORMATION OR GENETIC
 24 SERVICES.—

1 (1) NO ENROLLMENT RESTRICTION FOR GE-
 2 NETIC SERVICES.—Section 702(a)(1)(F) of the Em-
 3 ployee Retirement Income Security Act of 1974 (29
 4 U.S.C. 1182(a)(1)(F)) is amended by inserting be-
 5 fore the period the following: “(including informa-
 6 tion about a request for or receipt of genetic serv-
 7 ices)”.

8 (2) NO DISCRIMINATION IN GROUP PREMIUMS
 9 BASED ON PREDICTIVE GENETIC INFORMATION.—
 10 Subpart B of part 7 of subtitle B of title I of the
 11 Employee Retirement Income Security Act of 1974
 12 (29 U.S.C. 1185 et seq.) (as amended by section
 13 111) is further amended by adding at the end the
 14 following:

15 **“SEC. 714. PROHIBITING PREMIUM DISCRIMINATION**
 16 **AGAINST GROUPS ON THE BASIS OF PRE-**
 17 **DICTIVE GENETIC INFORMATION.**

18 “A group health plan, or a health insurance issuer
 19 offering group health insurance coverage in connection
 20 with a group health plan, shall not adjust premium or con-
 21 tribution amounts for a group on the basis of predictive
 22 genetic information concerning an individual in the group
 23 or a family member of the individual (including informa-
 24 tion about a request for or receipt of genetic services).”.

1 (3) CONFORMING AMENDMENT.—Section
 2 702(b) of the Employee Retirement Income Security
 3 Act of 1974 (29 U.S.C. 1182(b)) is amended by
 4 adding at the end the following:

5 “(3) REFERENCE TO RELATED PROVISION.—
 6 For a provision prohibiting the adjustment of pre-
 7 mium or contribution amounts for a group under a
 8 group health plan on the basis of predictive genetic
 9 information (including information about a request
 10 for or receipt of genetic services), see section 714.”.

11 (b) LIMITATION ON COLLECTION OF PREDICTIVE
 12 GENETIC INFORMATION.—Section 702 of the Employee
 13 Retirement Income Security Act of 1974 (29 U.S.C. 1182)
 14 is amended by adding at the end the following:

15 “(c) COLLECTION OF PREDICTIVE GENETIC INFOR-
 16 MATION.—

17 “(1) LIMITATION ON REQUESTING OR REQUIR-
 18 ING PREDICTIVE GENETIC INFORMATION.—Except
 19 as provided in paragraph (2), a group health plan,
 20 or a health insurance issuer offering health insur-
 21 ance coverage in connection with a group health
 22 plan, shall not request or require predictive genetic
 23 information concerning an individual or a family
 24 member of the individual (including information
 25 about a request for or receipt of genetic services).

1 ~~“(2) INFORMATION NEEDED FOR DIAGNOSIS,~~
2 ~~TREATMENT, OR PAYMENT.—~~

3 ~~“(A) IN GENERAL.—~~Notwithstanding para-
4 graph (1), a group health plan or health insur-
5 ance issuer that provides health care items and
6 services to an individual or dependent may re-
7 quest (but may not require) that such indi-
8 vidual or dependent disclose, or authorize the
9 collection or disclosure of, predictive genetic in-
10 formation for purposes of diagnosis, treatment,
11 or payment relating to the provision of health
12 care items and services to such individual or de-
13 pendent.

14 ~~“(B) NOTICE OF CONFIDENTIALITY PRAC-~~
15 ~~TICES AND DESCRIPTION OF SAFEGUARDS.—~~As
16 a part of a request under subparagraph (A),
17 the group health plan or health insurance issuer
18 shall provide to the individual or dependent a
19 description of the procedures in place to safe-
20 guard the confidentiality, as described in sec-
21 tions ~~213~~ and ~~221~~ of the Patients’ Bill of
22 Rights Act, of such individually identifiable in-
23 formation.”.

1 (e) DEFINITIONS.—Section 733(d) of the Employee
 2 Retirement Income Security Act of 1974 (29 U.S.C.
 3 1191b(d)) is amended by adding at the end the following:

4 “(5) FAMILY MEMBER.—The term ‘family
 5 member’ means with respect to an individual—

6 “(A) the spouse of the individual;

7 “(B) a dependent child of the individual,
 8 including a child who is born to or placed for
 9 adoption with the individual; and

10 “(C) all other individuals related by blood
 11 to the individual or the spouse or child de-
 12 scribed in subparagraph (A) or (B).

13 “(6) GENETIC INFORMATION.—The term ‘ge-
 14 netic information’ means information about genes,
 15 gene products, or inherited characteristics that may
 16 derive from an individual or a family member (in-
 17 cluding information about a request for or receipt of
 18 genetic services).

19 “(7) GENETIC SERVICES.—The term ‘genetic
 20 services’ means health services provided to obtain,
 21 assess, or interpret genetic information for diag-
 22 nostic and therapeutic purposes, and for genetic
 23 education and counseling.

24 “(8) PREDICTIVE GENETIC INFORMATION.—

1 “(A) IN GENERAL.—The term ‘predictive
2 genetic information’ means—

3 “(i) information about an individual’s
4 genetic tests which are associated with a
5 statistically significant increased risk of
6 developing a disease or disorder;

7 “(ii) information about genetic tests
8 of family members of the individual; or

9 “(iii) information about the occur-
10 rence of a disease or disorder in family
11 members that predicts a statistically sig-
12 nificant increased risk of a disease or dis-
13 order in the individual.

14 “(B) EXCEPTIONS.—The term ‘predictive
15 genetic information’ shall not include—

16 “(i) information about the sex or age
17 of the individual;

18 “(ii) information derived from routine
19 physical tests, such as the chemical, blood,
20 or urine analyses of the individual, unless
21 such analyses are genetic tests; and

22 “(iii) information about physical
23 exams of the individual and other informa-
24 tion relevant to determining the current
25 health status of the individual so long as

1 such information does not include informa-
 2 tion described in clauses (i), (ii), or (iii) of
 3 subparagraph (A).

4 “(9) GENETIC TEST.—The term ‘genetic test’
 5 means the analysis of human DNA, RNA, chro-
 6 mosomes, proteins, and certain metabolites, in order
 7 to detect disease-related genotypes, mutations,
 8 phenotypes, or karyotypes.”.

9 (d) EFFECTIVE DATE.—Except as provided in this
 10 section, this section and the amendments made by this
 11 section shall apply with respect to group health plans for
 12 plan years beginning 1 year after the date of the enact-
 13 ment of this Act.

14 **SEC. 303. AMENDMENTS TO THE PUBLIC HEALTH SERVICE**
 15 **ACT.**

16 (a) AMENDMENTS RELATING TO THE GROUP MAR-
 17 KET.—

18 (1) PROHIBITION OF HEALTH DISCRIMINATION
 19 ON THE BASIS OF GENETIC INFORMATION IN THE
 20 GROUP MARKET.—

21 (A) IN GENERAL.—Subpart 2 of part A of
 22 title XXVII of the Public Health Service Act,
 23 as amended by the Omnibus Consolidated and
 24 Emergency Supplemental Appropriations Act,

1 1999 (Public Law 105-277), is amended by
2 adding at the end the following new section:

3 **“SEC. 2707. PROHIBITING PREMIUM DISCRIMINATION**
4 **AGAINST GROUPS ON THE BASIS OF PRE-**
5 **DICTIVE GENETIC INFORMATION IN THE**
6 **GROUP MARKET.**

7 “A group health plan, or a health insurance issuer
8 offering group health insurance coverage in connection
9 with a group health plan shall not adjust premium or con-
10 tribution amounts for a group on the basis of predictive
11 genetic information concerning an individual in the group
12 or a family member of the individual (including informa-
13 tion about a request for or receipt of genetic services).”.

14 **(B) CONFORMING AMENDMENT.**—Section
15 2702(b) of the Public Health Service Act (42
16 U.S.C. 300gg-1(b)) is amended by adding at
17 the end the following:

18 **“(3) REFERENCE TO RELATED PROVISION.**—
19 For a provision prohibiting the adjustment of pre-
20 mium or contribution amounts for a group under a
21 group health plan on the basis of predictive genetic
22 information (including information about a request
23 for or receipt of genetic services), see section 2707.”.

24 **(C) LIMITATION ON COLLECTION AND DIS-**
25 **CLOSURE OF PREDICTIVE GENETIC INFORMA-**

1 TION.—Section 2702 of the Public Health Serv-
 2 ice Act (42 U.S.C. 300gg-1) is amended by
 3 adding at the end the following:

4 “(c) COLLECTION OF PREDICTIVE GENETIC INFOR-
 5 MATION.—

6 “(1) LIMITATION ON REQUESTING OR REQUIR-
 7 ING PREDICTIVE GENETIC INFORMATION.—Except
 8 as provided in paragraph (2), a group health plan,
 9 or a health insurance issuer offering health insur-
 10 ance coverage in connection with a group health
 11 plan, shall not request or require predictive genetic
 12 information concerning an individual or a family
 13 member of the individual (including information
 14 about a request for or receipt of genetic services):

15 “(2) INFORMATION NEEDED FOR DIAGNOSIS,
 16 TREATMENT, OR PAYMENT.—

17 “(A) IN GENERAL.—Notwithstanding para-
 18 graph (1), a group health plan or health insur-
 19 ance issuer that provides health care items and
 20 services to an individual or dependent may re-
 21 quest (but may not require) that such indi-
 22 vidual or dependent disclose, or authorize the
 23 collection or disclosure of, predictive genetic in-
 24 formation for purposes of diagnosis, treatment,
 25 or payment relating to the provision of health

1 care items and services to such individual or de-
2 pendent.

3 ~~“(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As~~
4 ~~a part of a request under subparagraph (A),~~
5 ~~the group health plan or health insurance issuer~~
6 ~~shall provide to the individual or dependent a~~
7 ~~description of the procedures in place to safe-~~
8 ~~guard the confidentiality, as described in sec-~~
9 ~~tions 213 and 221 of the Patients’ Bill of~~
10 ~~Rights Act, of such individually identifiable in-~~
11 ~~formation.”.~~

12
13 ~~(2) DEFINITIONS.—Section 2791(d) of the Pub-~~
14 ~~lie Health Service Act (42 U.S.C. 300gg-91(d)) is~~
15 ~~amended by adding at the end the following:~~

16 ~~“(15) FAMILY MEMBER.—The term ‘family~~
17 ~~member’ means, with respect to an individual—~~

18 ~~“(A) the spouse of the individual;~~

19 ~~“(B) a dependent child of the individual,~~
20 ~~including a child who is born to or placed for~~
21 ~~adoption with the individual; and~~

22 ~~“(C) all other individuals related by blood~~
23 ~~to the individual or the spouse or child de-~~
24 ~~scribed in subparagraph (A) or (B).~~

1 “(16) GENETIC INFORMATION.—The term ‘ge-
 2 netic information’ means information about genes,
 3 gene products, or inherited characteristics that may
 4 derive from an individual or a family member.

5 “(17) GENETIC SERVICES.—The term ‘genetic
 6 services’ means health services provided to obtain,
 7 assess, or interpret genetic information for diag-
 8 nostic and therapeutic purposes, and for genetic
 9 education and counseling.

10 “(18) PREDICTIVE GENETIC INFORMATION.—

11 “(A) IN GENERAL.—The term ‘predictive
 12 genetic information’ means—

13 “(i) information about an individual’s
 14 genetic tests which is associated with a
 15 statistically significant increased risk of
 16 developing a disease or disorder;

17 “(ii) information about genetic tests
 18 of family members of the individual; or

19 “(iii) information about the occur-
 20 rence of a disease or disorder in family
 21 members that predicts a statistically sig-
 22 nificant increased risk of a disease or dis-
 23 order in the individual.

24 “(B) EXCEPTIONS.—The term ‘predictive
 25 genetic information’ shall not include—

1 “(i) information about the sex or age
2 of the individual;

3 “(ii) information derived from routine
4 physical tests, such as the chemical, blood,
5 or urine analyses of the individual, unless
6 such analyses are genetic tests; and

7 “(iii) information about physical
8 exams of the individual and other informa-
9 tion relevant to determining the current
10 health status of the individual so long as
11 such information does not include informa-
12 tion described in clauses (i), (ii), or (iii) of
13 subparagraph (A).

14 “(19) GENETIC TEST.—The term ‘genetic test’
15 means the analysis of human DNA, RNA, chro-
16 mosomes, proteins, and certain metabolites, in order
17 to detect disease-related genotypes, mutations,
18 phenotypes, or karyotypes.”

19 (b) AMENDMENT RELATING TO THE INDIVIDUAL
20 MARKET.—The first subpart 3 of part B of title XXVII
21 of the Public Health Service Act (42 U.S.C. 300gg-11 et
22 seq.) (relating to other requirements), as amended by the
23 Omnibus Consolidated and Emergency Supplemental Ap-
24 propriations Act, 1999 (Public Law 105-277) is
25 amended—

1 (1) by redesignating such subpart as subpart 2;

2 and

3 (2) by adding at the end the following:

4 **“SEC. 2753. PROHIBITION OF HEALTH DISCRIMINATION ON**
 5 **THE BASIS OF PREDICTIVE GENETIC INFOR-**
 6 **MATION.**

7 “(a) PROHIBITION ON PREDICTIVE GENETIC INFOR-
 8 MATION AS A CONDITION OF ELIGIBILITY.—A health in-
 9 surance issuer offering health insurance coverage in the
 10 individual market may not use predictive genetic informa-
 11 tion as a condition of eligibility of an individual to enroll
 12 in individual health insurance coverage (including infor-
 13 mation about a request for or receipt of genetic services).

14 “(b) PROHIBITION ON PREDICTIVE GENETIC INFOR-
 15 MATION IN SETTING PREMIUM RATES.—A health insur-
 16 ance issuer offering health insurance coverage in the indi-
 17 vidual market shall not adjust premium rates for individ-
 18 uals on the basis of predictive genetic information con-
 19 cerning such an enrollee or a family member of the en-
 20 rollee (including information about a request for or receipt
 21 of genetic services).

22 “(c) COLLECTION OF PREDICTIVE GENETIC INFOR-
 23 MATION.—

24 “(1) LIMITATION ON REQUESTING OR REQUIR-
 25 ING PREDICTIVE GENETIC INFORMATION.—Except

1 as provided in paragraph (2), a health insurance
 2 issuer offering health insurance coverage in the indi-
 3 vidual market shall not request or require predictive
 4 genetic information concerning an individual or a
 5 family member of the individual (including informa-
 6 tion about a request for or receipt of genetic serv-
 7 ices).

8 “(2) INFORMATION NEEDED FOR DIAGNOSIS,
 9 TREATMENT, OR PAYMENT.—

10 “(A) IN GENERAL.—Notwithstanding para-
 11 graph (1), a health insurance issuer that pro-
 12 vides health care items and services to an indi-
 13 vidual or dependent may request (but may not
 14 require) that such individual or dependent dis-
 15 close, or authorize the collection or disclosure
 16 of, predictive genetic information for purposes
 17 of diagnosis, treatment, or payment relating to
 18 the provision of health care items and services
 19 to such individual or dependent.

20 “(B) NOTICE OF CONFIDENTIALITY PRAC-
 21 TICES AND DESCRIPTION OF SAFEGUARDS.—As
 22 a part of a request under subparagraph (A),
 23 the health insurance issuer shall provide to the
 24 individual or dependent a description of the
 25 procedures in place to safeguard the confiden-

1 tiality, as described in sections 213 and 221 of
 2 the Patients' Bill of Rights Act, of such individ-
 3 ually identifiable information.”.

4 (c) **EFFECTIVE DATE.**—The amendments made by
 5 this section shall apply with respect to—

6 (1) group health plans, and health insurance
 7 coverage offered in connection with group health
 8 plans, for plan years beginning after 1 year after the
 9 date of enactment of this Act; and

10 (2) health insurance coverage offered, sold,
 11 issued, renewed, in effect, or operated in the indi-
 12 vidual market after 1 year after the date of enact-
 13 ment of this Act.

14 **TITLE IV—HEALTHCARE** 15 **RESEARCH AND QUALITY**

16 ~~SEC. 401. SHORT TITLE.~~

17 This title may be cited as the “Healthcare Research
 18 and Quality Act of 1999”.

19 ~~SEC. 402. AMENDMENT TO THE PUBLIC HEALTH SERVICE~~ 20 ~~ACT.~~

21 Title IX of the Public Health Service Act (42 U.S.C.
 22 299 et seq.) is amended to read as follows:

1 **“TITLE IX—AGENCY FOR**
 2 **HEALTHCARE RESEARCH**
 3 **AND QUALITY**

4 **“PART A—ESTABLISHMENT AND GENERAL**
 5 **DUTIES**

6 **“SEC. 901. MISSION AND DUTIES.**

7 “(a) ~~IN GENERAL.~~—There is established within the
 8 Public Health Service an agency to be known as the Agen-
 9 cy for Healthcare Research and Quality. In carrying out
 10 this subsection, the Secretary shall redesignate the Agency
 11 for Health Care Policy and Research as the Agency for
 12 Healthcare Research and Quality.

13 “(b) ~~MISSION.~~—The purpose of the Agency is to en-
 14 hance the quality, appropriateness, and effectiveness of
 15 healthcare services, and access to such services, through
 16 the establishment of a broad base of scientific research
 17 and through the promotion of improvements in clinical
 18 and health system practice, including the prevention of
 19 diseases and other health conditions. The Agency shall
 20 promote healthcare quality improvement by—

21 “(1) conducting and supporting research that
 22 develops and presents scientific evidence regarding
 23 all aspects of healthcare, including—

24 “(A) the development and assessment of
 25 methods for enhancing patient participation in

1 their own care and for facilitating shared pa-
 2 tient-physician decision-making;

3 “(B) the outcomes, effectiveness, and cost-
 4 effectiveness of healthcare practices, including
 5 preventive measures and primary, acute and
 6 long-term care;

7 “(C) existing and innovative technologies;

8 “(D) the costs and utilization of, and ac-
 9 cess to healthcare;

10 “(E) the ways in which healthcare services
 11 are organized, delivered, and financed and the
 12 interaction and impact of these factors on the
 13 quality of patient care;

14 “(F) methods for measuring quality and
 15 strategies for improving quality; and

16 “(G) ways in which patients, consumers,
 17 purchasers, and practitioners acquire new infor-
 18 mation about best practices and health benefits,
 19 the determinants and impact of their use of this
 20 information;

21 “(2) synthesizing and disseminating available
 22 scientific evidence for use by patients, consumers,
 23 practitioners, providers, purchasers, policy makers,
 24 and educators; and

1 ~~“(3) advancing private and public efforts to im-~~
 2 ~~prove healthcare quality.~~

3 ~~“(c) REQUIREMENTS WITH RESPECT TO RURAL~~
 4 ~~AREAS AND PRIORITY POPULATIONS.—In carrying out~~
 5 ~~subsection (b), the Director shall undertake and support~~
 6 ~~research, demonstration projects, and evaluations with re-~~
 7 ~~spect to—~~

8 ~~“(1) the delivery of health services in rural~~
 9 ~~areas (including frontier areas);~~

10 ~~“(2) health services for low-income groups, and~~
 11 ~~minority groups;~~

12 ~~“(3) the health of children;~~

13 ~~“(4) the elderly; and~~

14 ~~“(5) people with special healthcare needs, in-~~
 15 ~~cluding disabilities, chronic care and end-of-life~~
 16 ~~healthcare.~~

17 ~~“(d) APPOINTMENT OF DIRECTOR.—There shall be~~
 18 ~~at the head of the Agency an official to be known as the~~
 19 ~~Director for Healthcare Research and Quality. The Direc-~~
 20 ~~tor shall be appointed by the Secretary. The Secretary,~~
 21 ~~acting through the Director, shall carry out the authorities~~
 22 ~~and duties established in this title.~~

23 ~~**“SEC. 902. GENERAL AUTHORITIES.**~~

24 ~~“(a) IN GENERAL.—In carrying out section 901(b),~~
 25 ~~the Director shall support demonstration projects, conduct~~

1 and support research, evaluations, training, research net-
 2 works, multi-disciplinary centers, technical assistance, and
 3 the dissemination of information, on healthcare, and on
 4 systems for the delivery of such care, including activities
 5 with respect to—

6 “(1) the quality, effectiveness, efficiency, appro-
 7 priateness and value of healthcare services;

8 “(2) quality measurement and improvement;

9 “(3) the outcomes, cost, cost-effectiveness, and
 10 use of healthcare services and access to such serv-
 11 ices;

12 “(4) clinical practice, including primary care
 13 and practice-oriented research;

14 “(5) healthcare technologies, facilities, and
 15 equipment;

16 “(6) healthcare costs, productivity, organiza-
 17 tion, and market forces;

18 “(7) health promotion and disease prevention,
 19 including clinical preventive services;

20 “(8) health statistics, surveys, database devel-
 21 opment, and epidemiology; and

22 “(9) medical liability.

23 “(b) HEALTH SERVICES TRAINING GRANTS.—

24 “(1) IN GENERAL.—The Director may provide
 25 training grants in the field of health services re-

1 search related to activities authorized under sub-
2 section (a), to include pre- and post-doctoral fellow-
3 ships and training programs, young investigator
4 awards, and other programs and activities as appro-
5 priate. In carrying out this subsection, the Director
6 shall make use of funds made available under sec-
7 tion 487.

8 “(2) REQUIREMENTS.—In developing priorities
9 for the allocation of training funds under this sub-
10 section, the Director shall take into consideration
11 shortages in the number of trained researchers ad-
12 dressing the priority populations.

13 “(c) MULTIDISCIPLINARY CENTERS.—The Director
14 may provide financial assistance to assist in meeting the
15 costs of planning and establishing new centers, and oper-
16 ating existing and new centers, for multidisciplinary
17 health services research, demonstration projects, evalua-
18 tions, training, and policy analysis with respect to the mat-
19 ters referred to in subsection (a).

20 “(d) RELATION TO CERTAIN AUTHORITIES REGARD-
21 ING SOCIAL SECURITY.—Activities authorized in this sec-
22 tion may include, and shall be appropriately coordinated
23 with experiments, demonstration projects, and other re-
24 lated activities authorized by the Social Security Act and
25 the Social Security Amendments of 1967. Activities under

1 subsection (a)(2) of this section that affect the programs
 2 under titles XVIII, XIX and XXI of the Social Security
 3 Act shall be carried out consistent with section 1142 of
 4 such Act.

5 “(e) **DISCLAIMER.**—The Agency shall not mandate
 6 national standards of clinical practice or quality
 7 healthcare standards. Recommendations resulting from
 8 projects funded and published by the Agency shall include
 9 a corresponding disclaimer.

10 “(f) **RULE OF CONSTRUCTION.**—Nothing in this sec-
 11 tion shall be construed to imply that the Agency’s role is
 12 to mandate a national standard or specific approach to
 13 quality measurement and reporting. In research and qual-
 14 ity improvement activities, the Agency shall consider a
 15 wide range of choices, providers, healthcare delivery sys-
 16 tems, and individual preferences.

17 **“PART B—HEALTHCARE IMPROVEMENT**
 18 **RESEARCH**

19 **“SEC. 911. HEALTHCARE OUTCOME IMPROVEMENT RE-**
 20 **SEARCH.**

21 “(a) **EVIDENCE RATING SYSTEMS.**—In collaboration
 22 with experts from the public and private sector, the Agen-
 23 cy shall identify and disseminate methods or systems used
 24 to assess healthcare research results, particularly to rate
 25 the strength of the scientific evidence behind healthcare

1 practice, recommendations in the research literature, and
 2 technology assessments. The Agency shall make methods
 3 or systems for evidence rating widely available. Agency
 4 publications containing healthcare recommendations shall
 5 indicate the level of substantiating evidence using such
 6 methods or systems.

7 “(b) ~~HEALTHCARE IMPROVEMENT RESEARCH CEN-~~
 8 ~~TERS AND PROVIDER-BASED RESEARCH NETWORKS.—~~

9 “(1) ~~IN GENERAL.—~~In order to address the full
 10 continuum of care and outcomes research, to link re-
 11 search to practice improvement, and to speed the
 12 dissemination of research findings to community
 13 practice settings, the Agency shall employ research
 14 strategies and mechanisms that will link research di-
 15 rectly with clinical practice in geographically diverse
 16 locations throughout the United States, including—

17 “(A) ~~Healthcare Improvement Research~~
 18 ~~Centers that combine demonstrated multidisci-~~
 19 ~~plinary expertise in outcomes or quality im-~~
 20 ~~provement research with linkages to relevant~~
 21 ~~sites of care;~~

22 “(B) ~~Provider-based Research Networks,~~
 23 ~~including plan, facility, or delivery system sites~~
 24 ~~of care (especially primary care), that can~~
 25 ~~evaluate and promote quality improvement; and~~

1 ~~“(C) other innovative mechanisms or strat-~~
 2 ~~egies to link research with clinical practice.~~

3 ~~“(2) REQUIREMENTS.—The Director is author-~~
 4 ~~ized to establish the requirements for entities apply-~~
 5 ~~ing for grants under this subsection.~~

6 **~~“SEC. 912. PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE~~**
 7 **~~ORGANIZATION AND DELIVERY.~~**

8 ~~“(a) SUPPORT FOR EFFORTS TO DEVELOP INFOR-~~
 9 ~~MATION ON QUALITY.—~~

10 ~~“(1) SCIENTIFIC AND TECHNICAL SUPPORT.—~~

11 ~~In its role as the principal agency for healthcare re-~~
 12 ~~search and quality, the Agency may provide sci-~~
 13 ~~entific and technical support for private and public~~
 14 ~~efforts to improve healthcare quality, including the~~
 15 ~~activities of accrediting organizations.~~

16 ~~“(2) ROLE OF THE AGENCY.—With respect to~~
 17 ~~paragraph (1), the role of the Agency shall include—~~

18 ~~“(A) the identification and assessment~~
 19 ~~of—~~

20 ~~“(i) methods for the evaluation of the~~
 21 ~~health of enrollees in health plans by type~~
 22 ~~of plan, provider, and provider arrange-~~
 23 ~~ments; and~~

24 ~~“(ii) other populations, including~~
 25 ~~those receiving long-term care services;~~

1 “(B) the ongoing development, testing, and
 2 dissemination of quality measures, including
 3 measures of health and functional outcomes;

4 “(C) the compilation and dissemination of
 5 healthcare quality measures developed in the
 6 private and public sector;

7 “(D) assistance in the development of im-
 8 proved healthcare information systems;

9 “(E) the development of survey tools for
 10 the purpose of measuring participant and bene-
 11 ficiary assessments of their healthcare; and

12 “(F) identifying and disseminating infor-
 13 mation on mechanisms for the integration of in-
 14 formation on quality into purchaser and con-
 15 sumer decision-making processes.

16 “(b) CENTERS FOR EDUCATION AND RESEARCH ON
 17 THERAPEUTICS.—

18 “(1) IN GENERAL.—The Secretary, acting
 19 through the Director and in consultation with the
 20 Commissioner of Food and Drugs, shall establish a
 21 program for the purpose of making one or more
 22 grants for the establishment and operation of one or
 23 more centers to carry out the activities specified in
 24 paragraph (2).

1 ~~“(2) REQUIRED ACTIVITIES.—~~The activities re-
 2 ferred to in this paragraph are the following:

3 ~~“(A) The conduct of state-of-the-art clin-~~
 4 ical research for the following purposes:

5 ~~“(i) To increase awareness of—~~

6 ~~“(I) new uses of drugs, biological~~
 7 products, and devices;

8 ~~“(II) ways to improve the effec-~~
 9 tive use of drugs, biological products,
 10 and devices; and

11 ~~“(III) risks of new uses and risks~~
 12 of combinations of drugs and biologi-
 13 cal products.

14 ~~“(ii) To provide objective clinical in-~~
 15 formation to the following individuals and
 16 entities:

17 ~~“(I) Healthcare practitioners and~~
 18 other providers of Healthcare goods or
 19 services.

20 ~~“(II) Pharmacists, pharmacy~~
 21 benefit managers and purchasers.

22 ~~“(III) Health maintenance orga-~~
 23 nizations and other managed
 24 healthcare organizations.

1 ~~“(IV) Healthcare insurers and~~
 2 ~~governmental agencies.~~

3 ~~“(V) Patients and consumers.~~

4 ~~“(iii) To improve the quality of~~
 5 ~~healthcare while reducing the cost of~~
 6 ~~Healthcare through—~~

7 ~~“(I) an increase in the appro-~~
 8 ~~priate use of drugs, biological prod-~~
 9 ~~ucts, or devices; and~~

10 ~~“(II) the prevention of adverse~~
 11 ~~effects of drugs, biological products,~~
 12 ~~and devices and the consequences of~~
 13 ~~such effects, such as unnecessary hos-~~
 14 ~~pitalizations.~~

15 ~~“(B) The conduct of research on the com-~~
 16 ~~parative effectiveness, cost-effectiveness, and~~
 17 ~~safety of drugs, biological products, and devices.~~

18 ~~“(C) Such other activities as the Secretary~~
 19 ~~determines to be appropriate, except that a~~
 20 ~~grant may not be expended to assist the Sec-~~
 21 ~~retary in the review of new drugs.~~

22 ~~“(e) REDUCING ERRORS IN MEDICINE.—The Direc-~~
 23 ~~tor shall conduct and support research and build private-~~
 24 ~~public partnerships to—~~

1 “(1) identify the causes of preventable
2 healthcare errors and patient injury in healthcare
3 delivery;

4 “(2) develop, demonstrate, and evaluate strate-
5 gies for reducing errors and improving patient safe-
6 ty; and

7 “(3) promote the implementation of effective
8 strategies throughout the healthcare industry.

9 **“SEC. 913. INFORMATION ON QUALITY AND COST OF CARE.**

10 “(a) IN GENERAL.—In carrying out 902(a), the Di-
11 rector shall—

12 “(1) collect data on a nationally representative
13 sample of the population on the cost, use and, for
14 fiscal year 2000 and subsequent fiscal years, quality
15 of healthcare, including the types of healthcare serv-
16 ices Americans use, their access to healthcare serv-
17 ices, frequency of use, how much is paid for the
18 services used, the source of those payments, the
19 types and costs of private health insurance, access,
20 satisfaction, and quality of care for the general pop-
21 ulation and also for children, uninsured persons,
22 poor and near-poor individuals, and persons with
23 special healthcare needs;

1 “(2) develop databases and tools that enable
2 States to track the quality, access, and use of
3 healthcare services provided to their residents; and

4 “(3) enter into agreements with public or pri-
5 vate entities to use, link, or acquire databases for re-
6 search authorized under this title.

7 “(b) QUALITY AND OUTCOMES INFORMATION.—

8 “(1) IN GENERAL.—To enhance the under-
9 standing of the quality of care, the determinants of
10 health outcomes and functional status, the needs of
11 special populations as well as an understanding of
12 these changes over time, their relationship to
13 healthcare access and use, and to monitor the overall
14 national impact of Federal and State policy changes
15 on healthcare, the Director, beginning in fiscal year
16 2000, shall ensure that the survey conducted under
17 subsection (a)(1) will—

18 “(A) provide information on the quality of
19 care and patient outcomes for frequently occur-
20 ring clinical conditions for a nationally rep-
21 resentative sample of the population; and

22 “(B) provide reliable national estimates for
23 children and persons with special healthcare
24 needs through the use of supplements or peri-
25 odic expansions of the survey.

1 In expanding the Medical Expenditure Panel Survey,
 2 as in existence on the date of enactment of this title)
 3 in fiscal year 2000 to collect information on the
 4 quality of care, the Director shall take into account
 5 any outcomes measurements generally collected by
 6 private sector accreditation organizations.

7 “(2) ANNUAL REPORT.—Beginning in fiscal
 8 year 2002, the Secretary, acting through the Direc-
 9 tor, shall submit to Congress an annual report on
 10 national trends in the quality of healthcare provided
 11 to the American people.

12 **“SEC. 914. INFORMATION SYSTEMS FOR HEALTHCARE IM-**
 13 **PROVEMENT.**

14 “‘In order to foster a range of innovative approaches
 15 to the management and communication of health informa-
 16 tion, the Agency shall support research, evaluations and
 17 initiatives to advance—

18 “(1) the use of information systems for the
 19 study of healthcare quality, including the generation
 20 of both individual provider and plan-level compara-
 21 tive performance data;

22 “(2) training for healthcare practitioners and
 23 researchers in the use of information systems;

1 “(3) the creation of effective linkages between
2 various sources of health information, including the
3 development of information networks;

4 “(4) the delivery and coordination of evidence-
5 based healthcare services, including the use of real-
6 time healthcare decision-support programs;

7 “(5) the structure, content, definition, and cod-
8 ing of health information data and medical vocabu-
9 laries in consultation with appropriate Federal and
10 private entities;

11 “(6) the use of computer-based health records
12 in outpatient and inpatient settings as a personal
13 health record for individual health assessment and
14 maintenance, and for monitoring public health and
15 outcomes of care within populations; and

16 “(7) the protection of individually identifiable
17 information in health services research and
18 healthcare quality improvement.

19 **“SEC. 915. RESEARCH SUPPORTING PRIMARY CARE AND**
20 **ACCESS IN UNDERSERVED AREAS.**

21 “(a) **PREVENTIVE SERVICES TASK FORCE.**—

22 “(1) **PURPOSE.**—The Agency shall provide on-
23 going administrative, research, and technical support
24 for the operation of the Preventive Services Task
25 Force. The Agency shall coordinate and support the

1 dissemination of the Preventive Services Task Force
2 recommendations.

3 “(2) OPERATION.—The Preventive Services
4 Task Force shall review the scientific evidence re-
5 lated to the effectiveness, appropriateness, and cost-
6 effectiveness of clinical preventive services for the
7 purpose of developing recommendations, and updat-
8 ing previous recommendations, regarding their use-
9 fulness in daily clinical practice. In carrying out its
10 responsibilities under paragraph (1), the Task Force
11 shall not be subject to the provisions of Appendix 2
12 of title 5, United States Code.

13 “(b) PRIMARY CARE RESEARCH.—

14 “(1) IN GENERAL.—There is established within
15 the Agency a Center for Primary Care Research (re-
16 ferred to in this subsection as the ‘Center’) that
17 shall serve as the principal source of funding for pri-
18 mary care research in the Department of Health and
19 Human Services. For purposes of this paragraph,
20 primary care research focuses on the first contact
21 when illness or health concerns arise, the diagnosis,
22 treatment or referral to specialty care, preventive
23 care, and the relationship between the clinician and
24 the patient in the context of the family and commu-
25 nity.

1 “(2) RESEARCH.—In carrying out this section,
2 the Center shall conduct and support research on—

3 “(A) the nature and characteristics of pri-
4 mary care practice;

5 “(B) the management of commonly occur-
6 ring clinical problems;

7 “(C) the management of undifferentiated
8 clinical problems; and

9 “(D) the continuity and coordination of
10 health services.

11 “(3) DEMONSTRATION.—The Agency shall sup-
12 port demonstrations into the use of new information
13 tools aimed at improving shared decision-making be-
14 tween patients and their care-givers.

15 **“SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVA-**
16 **TION.**

17 “(a) IN GENERAL.—The Director shall promote inno-
18 vation in evidence-based clinical practice and healthcare
19 technologies by—

20 “(1) conducting and supporting research on the
21 development, diffusion, and use of healthcare tech-
22 nology;

23 “(2) developing, evaluating, and disseminating
24 methodologies for assessments of healthcare prac-
25 tices and healthcare technologies;

1 “(3) conducting intramural and supporting ex-
2 tramural assessments of existing and new healthcare
3 practices and technologies;

4 “(4) promoting education, training, and pro-
5 viding technical assistance in the use of healthcare
6 practice and healthcare technology assessment meth-
7 odologies and results; and

8 “(5) working with the National Library of Med-
9 icine and the public and private sector to develop an
10 electronic clearinghouse of currently available assess-
11 ments and those in progress.

12 “(b) SPECIFICATION OF PROCESS.—

13 “(1) IN GENERAL.—Not later than December
14 31, 2000, the Director shall develop and publish a
15 description of the methods used by the Agency and
16 its contractors for practice and technology assess-
17 ment.

18 “(2) CONSULTATIONS.—In carrying out this
19 subsection, the Director shall cooperate and consult
20 with the Assistance Secretary for Health, the Ad-
21 ministrator of the Health Care Financing Adminis-
22 tration, the Director of the National Institutes of
23 Health, the Commissioner of Food and Drugs, and
24 the heads of any other interested Federal depart-

1 ment or agency, professional societies, and other pri-
 2 vate and public entities.

3 ~~“(3) METHODOLOGY.—The methods employed~~
 4 ~~in practice and technology assessments under para-~~
 5 ~~graph (1) shall consider—~~

6 ~~“(A) safety, efficacy, and effectiveness;~~

7 ~~“(B) legal, social, and ethical implications;~~

8 ~~“(C) costs, benefits, and cost-effectiveness;~~

9 ~~“(D) comparisons to alternative tech-~~
 10 ~~nologies and practices; and~~

11 ~~“(E) requirements of Food and Drug Ad-~~
 12 ~~ministration approval to avoid duplication.~~

13 ~~“(c) SPECIFIC ASSESSMENTS.—~~

14 ~~“(1) IN GENERAL.—The Director shall conduct~~
 15 ~~or support specific assessments of healthcare tech-~~
 16 ~~nologies and practices.~~

17 ~~“(2) REQUESTS FOR ASSESSMENTS.—The Di-~~
 18 ~~rector is authorized to conduct or support assess-~~
 19 ~~ments, on a reimbursable basis, for the Health Care~~
 20 ~~Financing Administration, the Department of De-~~
 21 ~~fense, the Department of Veterans Affairs, the Of-~~
 22 ~~fice of Personnel Management, and other public or~~
 23 ~~private entities.~~

24 ~~“(3) GRANTS AND CONTRACTS.—In addition to~~
 25 ~~conducting assessments, the Director may make~~

1 grants to, or enter into cooperative agreements or
 2 contracts with, entities described in paragraph (4)
 3 for the purpose of conducting assessments of experi-
 4 mental, emerging, existing, or potentially outmoded
 5 healthcare technologies, and for related activities.

6 “(4) ELIGIBLE ENTITIES.—An entity described
 7 in this paragraph is an entity that is determined to
 8 be appropriate by the Director, including academic
 9 medical centers, research institutions, professional
 10 organizations, third party payers, other govern-
 11 mental agencies, and consortia of appropriate re-
 12 search entities established for the purpose of con-
 13 ducting technology assessments.

14 **“SEC. 917. COORDINATION OF FEDERAL GOVERNMENT**
 15 **QUALITY IMPROVEMENT EFFORTS.**

16 “(a) REQUIREMENT.—

17 “(1) IN GENERAL.—To avoid duplication and
 18 ensure that Federal resources are used efficiently
 19 and effectively, the Secretary, acting through the Di-
 20 rector, shall coordinate all research, evaluations, and
 21 demonstrations related to health services research
 22 and quality measurement and improvement activities
 23 undertaken and supported by the Federal Govern-
 24 ment.

1 “(2) SPECIFIC ACTIVITIES.—The Director, in
2 collaboration with the appropriate Federal officials
3 representing all concerned executive agencies and de-
4 partments, shall develop and manage a process to—

5 “(A) improve interagency coordination, pri-
6 ority setting, and the use and sharing of re-
7 search findings and data pertaining to Federal
8 quality improvement programs and health serv-
9 ices research;

10 “(B) strengthen the research information
11 infrastructure, including databases, pertaining
12 to Federal health services research and
13 healthcare quality improvement initiatives;

14 “(C) set specific goals for participating
15 agencies and departments to further health
16 services research and healthcare quality im-
17 provement; and

18 “(D) strengthen the management of Fed-
19 eral healthcare quality improvement programs.

20 “(b) STUDY BY THE INSTITUTE OF MEDICINE.—

21 “(1) IN GENERAL.—To provide the Department
22 of Health and Human Services with an independent,
23 external review of its quality oversight, and quality
24 research programs, the Secretary shall enter into a
25 contract with the Institute of Medicine—

1 “(A) to describe and evaluate current qual-
2 ity improvement research and monitoring proc-
3 esses through—

4 “(i) an overview of pertinent health
5 services research activities and quality im-
6 provement efforts including those currently
7 performed by the peer review organizations
8 and the exploration of additional activities
9 that could be undertaken by the peer re-
10 view organizations to improve quality;

11 “(ii) an analysis of the various part-
12 nership activities that the Department of
13 Health and Human Services has pursued
14 with private sector accreditation and other
15 quality measurement organizations;

16 “(iii) the exploration of programmatic
17 areas where partnership activities between
18 the Federal Government and the private
19 sector or within the Federal Government
20 could be pursued to improve quality over-
21 sight of the medicare, medicaid and child
22 health insurance programs under titles
23 XVIII, XIX and XXI of the Social Secu-
24 rity Act; and

1 “(iv) an identification of opportunities
2 for enhancing health system efficiency
3 through simplification and reduction in re-
4 dundancy of Federal agency quality im-
5 provement efforts, including areas in which
6 Federal efforts unnecessarily duplicate ex-
7 isting private sector efforts; and

8 “(B) to identify options and make rec-
9 ommendations to improve the efficiency and ef-
10 fectiveness of such quality improvement pro-
11 grams through—

12 “(i) the improved coordination of ac-
13 tivities across the medicare, medicaid and
14 child health insurance programs under ti-
15 tles XVIII, XIX and XXI of the Social Se-
16 curity Act and various health services re-
17 search programs;

18 “(ii) the strengthening of patient
19 choice and participation by incorporating
20 state-of-the-art quality monitoring tools
21 and making information on quality avail-
22 able; and

23 “(iii) the enhancement of the most ef-
24 fective programs; consolidation as appro-

1 appropriate, and elimination of duplicative ac-
 2 tivities within various federal agencies.

3 ~~“(2) REQUIREMENTS.—~~

4 ~~“(A) IN GENERAL.—~~The Secretary shall
 5 enter into a contract with the Institute of Medi-
 6 cine for the preparation—

7 ~~“(i) not later than 12 months after~~
 8 the date of enactment of this title, of a re-
 9 port providing an overview of the quality
 10 improvement programs of the Department
 11 of Health and Human Services for the
 12 medicare, medicaid, and CHIP programs
 13 under titles XVIII, XIX, and XXI of the
 14 Social Security Act; and

15 ~~“(ii) not later than 24 months after~~
 16 the date of enactment of this title, of a
 17 final report containing recommendations.

18 ~~“(B) REPORTS.—~~The Secretary shall sub-
 19 mit the reports described in subparagraph (A)
 20 to the Committee on Finance and the Com-
 21 mittee on Health, Education, Labor, and Pen-
 22 sions of the Senate and the Committee on Ways
 23 and Means and the Committee on Commerce of
 24 the House of Representatives.

1 **“PART C—GENERAL PROVISIONS**

2 **“SEC. 921. ADVISORY COUNCIL FOR HEALTHCARE RE-**
 3 **SEARCH AND QUALITY.**

4 ~~“(a) ESTABLISHMENT.—~~There is established an advi-
 5 sory council to be known as the Advisory Council for
 6 Healthcare Research and Quality.

7 ~~“(b) DUTIES.—~~

8 ~~“(1) IN GENERAL.—~~The Advisory Council shall
 9 advise the Secretary and the Director with respect
 10 to activities proposed or undertaken to carry out the
 11 purpose of the Agency under section 901(b).

12 ~~“(2) CERTAIN RECOMMENDATIONS.—~~Activities
 13 of the Advisory Council under paragraph (1) shall
 14 include making recommendations to the Director
 15 regarding—

16 ~~“(A) priorities regarding healthcare re-~~
 17 search, especially studies related to quality, out-
 18 comes, cost and the utilization of, and access
 19 to, healthcare services;

20 ~~“(B) the field of healthcare research and~~
 21 related disciplines, especially issues related to
 22 training needs, and dissemination of informa-
 23 tion pertaining to healthcare quality; and

24 ~~“(C) the appropriate role of the Agency in~~
 25 each of these areas in light of private sector ac-

1 tivity and identification of opportunities for
2 public-private sector partnerships.

3 ~~“(c) MEMBERSHIP.—~~

4 ~~“(1) IN GENERAL.—~~The Advisory Council shall,
5 in accordance with this subsection, be composed of
6 appointed members and ex officio members. All
7 members of the Advisory Council shall be voting
8 members other than the individuals designated
9 under paragraph ~~(3)~~(B) as ex officio members.

10 ~~“(2) APPOINTED MEMBERS.—~~The Secretary
11 shall appoint to the Advisory Council ~~21~~ appro-
12 priately qualified individuals. At least ~~17~~ members of
13 the Advisory Council shall be representatives of the
14 public who are not officers or employees of the
15 United States. The Secretary shall ensure that the
16 appointed members of the Council, as a group, are
17 representative of professions and entities concerned
18 with, or affected by, activities under this title and
19 under section ~~1142~~ of the Social Security Act. Of
20 such members—

21 ~~“(A) 4~~ shall be individuals distinguished in
22 the conduct of research, demonstration projects,
23 and evaluations with respect to healthcare;

1 ~~“(B) 4~~ shall be individuals distinguished in
 2 the practice of medicine of which at least 1
 3 shall be a primary care practitioner;

4 ~~“(C) 3~~ shall be individuals distinguished in
 5 the other health professions;

6 ~~“(D) 4~~ shall be individuals either rep-
 7 resenting the private healthcare sector, includ-
 8 ing health plans, providers, and purchasers or
 9 individuals distinguished as administrators of
 10 healthcare delivery systems;

11 ~~“(E) 4~~ shall be individuals distinguished in
 12 the fields of healthcare quality improvement, ee-
 13 onomics, information systems, law, ethics, busi-
 14 ness, or public policy; and

15 ~~“(F) 2~~ shall be individuals representing the
 16 interests of patients and consumers of
 17 healthcare.

18 ~~“(3) EX OFFICIO MEMBERS.—~~The Secretary
 19 shall designate as ex officio members of the Advisory
 20 Council—

21 ~~“(A) the Assistant Secretary for Health,~~
 22 the Director of the National Institutes of
 23 Health, the Director of the Centers for Disease
 24 Control and Prevention, the Administrator of
 25 the Health Care Financing Administration, the

1 Assistant Secretary of Defense (Health Af-
 2 fairs), and the Chief Medical Officer of the De-
 3 partment of Veterans Affairs; and

4 “(B) such other Federal officials as the
 5 Secretary may consider appropriate.

6 ~~“(d) TERMS.—Members of the Advisory Council ap-~~
 7 ~~pointed under subsection (c)(2) shall serve for a term of~~
 8 ~~3 years. A member of the Council appointed under such~~
 9 ~~subsection may continue to serve after the expiration of~~
 10 ~~the term of the members until a successor is appointed.~~

11 ~~“(e) VACANCIES.—If a member of the Advisory~~
 12 ~~Council appointed under subsection (c)(2) does not serve~~
 13 ~~the full term applicable under subsection (d), the indi-~~
 14 ~~vidual appointed to fill the resulting vacancy shall be ap-~~
 15 ~~pointed for the remainder of the term of the predecessor~~
 16 ~~of the individual.~~

17 ~~“(f) CHAIR.—The Director shall, from among the~~
 18 ~~members of the Advisory Council appointed under sub-~~
 19 ~~section (c)(2), designate an individual to serve as the chair~~
 20 ~~of the Advisory Council.~~

21 ~~“(g) MEETINGS.—The Advisory Council shall meet~~
 22 ~~not less than once during each discrete 4-month period~~
 23 ~~and shall otherwise meet at the call of the Director or the~~
 24 ~~chair.~~

1 “(h) COMPENSATION AND REIMBURSEMENT OF EX-
2 PENSES.—

3 “(1) APPOINTED MEMBERS.—Members of the
4 Advisory Council appointed under subsection (c)(2)
5 shall receive compensation for each day (including
6 travel time) engaged in carrying out the duties of
7 the Advisory Council unless declined by the member.
8 Such compensation may not be in an amount in ex-
9 cess of the maximum rate of basic pay payable for
10 GS-18 of the General Schedule.

11 “(2) EX OFFICIO MEMBERS.—Officials des-
12 ignated under subsection (c)(3) as ex officio mem-
13 bers of the Advisory Council may not receive com-
14 pensation for service on the Advisory Council in ad-
15 dition to the compensation otherwise received for du-
16 ties carried out as officers of the United States.

17 “(i) STAFF.—The Director shall provide to the Advi-
18 sory Council such staff, information, and other assistance
19 as may be necessary to carry out the duties of the Council.

20 **“SEC. 922. PEER REVIEW WITH RESPECT TO GRANTS AND**
21 **CONTRACTS.**

22 “(a) REQUIREMENT OF REVIEW.—

23 “(1) IN GENERAL.—Appropriate technical and
24 scientific peer review shall be conducted with respect

1 to each application for a grant, cooperative agree-
 2 ment, or contract under this title.

3 ~~“(2) REPORTS TO DIRECTOR.—~~Each peer re-
 4 view group to which an application is submitted pur-
 5 suant to paragraph (1) shall report its finding and
 6 recommendations respecting the application to the
 7 Director in such form and in such manner as the
 8 Director shall require.

9 ~~“(b) APPROVAL AS PRECONDITION OF AWARDS.—~~
 10 The Director may not approve an application described in
 11 subsection (a)(1) unless the application is recommended
 12 for approval by a peer review group established under sub-
 13 section (c).

14 ~~“(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—~~

15 ~~“(1) IN GENERAL.—~~The Director shall establish
 16 such technical and scientific peer review groups as
 17 may be necessary to carry out this section. Such
 18 groups shall be established without regard to the
 19 provisions of title 5, United States Code, that govern
 20 appointments in the competitive service, and without
 21 regard to the provisions of chapter 51, and sub-
 22 chapter III of chapter 53, of such title that relate
 23 to classification and pay rates under the General
 24 Schedule.

1 ~~“(2) MEMBERSHIP.—~~The members of any peer
2 review group established under this section shall be
3 appointed from among individuals who by virtue of
4 their training or experience are eminently qualified
5 to carry out the duties of such peer review group.
6 Officers and employees of the United States may not
7 constitute more than 25 percent of the membership
8 of any such group. Such officers and employees may
9 not receive compensation for service on such groups
10 in addition to the compensation otherwise received
11 for these duties carried out as such officers and em-
12 ployees.

13 ~~“(3) DURATION.—~~Notwithstanding section
14 14(a) of the Federal Advisory Committee Act, peer
15 review groups established under this section may
16 continue in existence until otherwise provided by
17 law.

18 ~~“(4) QUALIFICATIONS.—~~Members of any peer-
19 review group shall, at a minimum, meet the fol-
20 lowing requirements:

21 ~~“(A) Such members shall agree in writing~~
22 to treat information received, pursuant to their
23 work for the group, as confidential information,
24 except that this subparagraph shall not apply to
25 public records and public information.

1 “(B) Such members shall agree in writing
 2 to recuse themselves from participation in the
 3 peer-review of specific applications which
 4 present a potential personal conflict of interest
 5 or appearance of such conflict, including em-
 6 ployment in a directly affected organization,
 7 stock ownership, or any financial or other ar-
 8 rangement that might introduce bias in the
 9 process of peer-review.

10 “(d) ~~AUTHORITY FOR PROCEDURAL ADJUSTMENTS~~
 11 ~~IN CERTAIN CASES.~~—In the case of applications for finan-
 12 cial assistance whose direct costs will not exceed \$100,000,
 13 the Director may make appropriate adjustments in the
 14 procedures otherwise established by the Director for the
 15 conduct of peer review under this section. Such adjust-
 16 ments may be made for the purpose of encouraging the
 17 entry of individuals into the field of research, for the pur-
 18 pose of encouraging clinical practice-oriented or provider-
 19 based research, and for such other purposes as the Direc-
 20 tor may determine to be appropriate.

21 “(e) ~~REGULATIONS.~~—The Director may shall issue
 22 regulations for the conduct of peer review under this sec-
 23 tion.

1 **~~“SEC. 923. CERTAIN PROVISIONS WITH RESPECT TO DEVEL-~~**
 2 **~~OPMENT, COLLECTION, AND DISSEMINATION~~**
 3 **~~OF DATA.~~**

4 ~~“(a) STANDARDS WITH RESPECT TO UTILITY OF~~
 5 ~~DATA.—~~

6 ~~“(1) IN GENERAL.—To ensure the utility, accu-~~
 7 ~~racy, and sufficiency of data collected by or for the~~
 8 ~~Agency for the purpose described in section 901(b),~~
 9 ~~the Director shall establish standards and methods~~
 10 ~~for developing and collecting such data, taking into~~
 11 ~~consideration—~~

12 ~~“(A) other Federal health data collection~~
 13 ~~standards; and~~

14 ~~“(B) the differences between types of~~
 15 ~~healthcare plans, delivery systems, healthcare~~
 16 ~~providers, and provider arrangements.~~

17 ~~“(2) RELATIONSHIP WITH OTHER DEPARTMENT~~
 18 ~~PROGRAMS.—In any case where standards under~~
 19 ~~paragraph (1) may affect the administration of other~~
 20 ~~programs carried out by the Department of Health~~
 21 ~~and Human Services, including the programs under~~
 22 ~~titles XVIII, XIX and XXI of the Social Security~~
 23 ~~Act, they shall be in the form of recommendations~~
 24 ~~to the Secretary for such program.~~

25 ~~“(b) STATISTICS AND ANALYSES.—The Director~~
 26 ~~shall—~~

1 “(1) take appropriate action to ensure that sta-
 2 tistics and analyses developed under this title are of
 3 high quality, timely, and duly comprehensive, and
 4 that the statistics are specific, standardized, and
 5 adequately analyzed and indexed; and

6 “(2) publish, make available, and disseminate
 7 such statistics and analyses on as wide a basis as is
 8 practicable.

9 “(c) **AUTHORITY REGARDING CERTAIN REQUESTS.**—
 10 Upon request of a public or private entity, the Director
 11 may conduct or support research or analyses otherwise au-
 12 thorized by this title pursuant to arrangements under
 13 which such entity will pay the cost of the services provided.
 14 Amounts received by the Director under such arrange-
 15 ments shall be available to the Director for obligation until
 16 expended.

17 **“SEC. 924. DISSEMINATION OF INFORMATION.**

18 “(a) **IN GENERAL.**—The Director shall—

19 “(1) without regard to section 501 of title 44,
 20 United States Code, promptly publish, make avail-
 21 able, and otherwise disseminate, in a form under-
 22 standable and on as broad a basis as practicable so
 23 as to maximize its use, the results of research, dem-
 24 onstration projects, and evaluations conducted or
 25 supported under this title;

1 “(2) ensure that information disseminated by
 2 the Agency is science-based and objective and under-
 3 takes consultation as necessary to assess the appro-
 4 priateness and usefulness of the presentation of in-
 5 formation that is targeted to specific audiences;

6 “(3) promptly make available to the public data
 7 developed in such research, demonstration projects,
 8 and evaluations;

9 “(4) provide, in collaboration with the National
 10 Library of Medicine where appropriate, indexing, ab-
 11 stracting, translating, publishing, and other services
 12 leading to a more effective and timely dissemination
 13 of information on research, demonstration projects,
 14 and evaluations with respect to healthcare to public
 15 and private entities and individuals engaged in the
 16 improvement of healthcare delivery and the general
 17 public, and undertake programs to develop new or
 18 improved methods for making such information
 19 available; and

20 “(5) as appropriate, provide technical assistance
 21 to State and local government and health agencies
 22 and conduct liaison activities to such agencies to fos-
 23 ter dissemination.

24 “(b) PROHIBITION AGAINST RESTRICTIONS.—Except
 25 as provided in subsection (c), the Director may not restrict

1 the publication or dissemination of data from, or the re-
 2 sults of, projects conducted or supported under this title.

3 “(e) ~~LIMITATION ON USE OF CERTAIN INFORMA-~~
 4 ~~TION.~~—No information, if an establishment or person sup-
 5 plying the information or described in it is identifiable,
 6 obtained in the course of activities undertaken or sup-
 7 ported under this title may be used for any purpose other
 8 than the purpose for which it was supplied unless such
 9 establishment or person has consented (as determined
 10 under regulations of the Secretary) to its use for such
 11 other purpose. Such information may not be published or
 12 released in other form if the person who supplied the infor-
 13 mation or who is described in it is identifiable unless such
 14 person has consented (as determined under regulations of
 15 the Secretary) to its publication or release in other form.

16 “(d) ~~PENALTY.~~—Any person who violates subsection
 17 (e) shall be subject to a civil monetary penalty of not more
 18 than \$10,000 for each such violation involved. Such pen-
 19 alty shall be imposed and collected in the same manner
 20 as civil money penalties under subsection (a) of section
 21 1128A of the Social Security Act are imposed and col-
 22 lected.

1 **“SEC. 925. ADDITIONAL PROVISIONS WITH RESPECT TO**
2 **GRANTS AND CONTRACTS.**

3 “(a) **FINANCIAL CONFLICTS OF INTEREST.**—With
4 respect to projects for which awards of grants, cooperative
5 agreements, or contracts are authorized to be made under
6 this title, the Director shall by regulation define—

7 “(1) the specific circumstances that constitute
8 financial interests in such projects that will, or may
9 be reasonably expected to, create a bias in favor of
10 obtaining results in the projects that are consistent
11 with such interests; and

12 “(2) the actions that will be taken by the Direc-
13 tor in response to any such interests identified by
14 the Director.

15 “(b) **REQUIREMENT OF APPLICATION.**—The Director
16 may not, with respect to any program under this title au-
17 thorizing the provision of grants, cooperative agreements,
18 or contracts, provide any such financial assistance unless
19 an application for the assistance is submitted to the Sec-
20 retary and the application is in such form, is made in such
21 manner, and contains such agreements, assurances, and
22 information as the Director determines to be necessary to
23 carry out the program in involved.

24 “(c) **PROVISION OF SUPPLIES AND SERVICES IN**
25 **LIEU OF FUNDS.**—

1 “(1) IN GENERAL.—Upon the request of an en-
 2 tity receiving a grant, cooperative agreement, or con-
 3 tract under this title, the Secretary may, subject to
 4 paragraph (2), provide supplies, equipment, and
 5 services for the purpose of aiding the entity in ear-
 6 rying out the project involved and, for such purpose,
 7 may detail to the entity any officer or employee of
 8 the Department of Health and Human Services.

9 “(2) CORRESPONDING REDUCTION IN FUNDS.—
 10 With respect to a request described in paragraph
 11 (1), the Secretary shall reduce the amount of the fi-
 12 nancial assistance involved by an amount equal to
 13 the costs of detailing personnel and the fair market
 14 value of any supplies, equipment, or services pro-
 15 vided by the Director. The Secretary shall, for the
 16 payment of expenses incurred in complying with
 17 such request, expend the amounts withheld.

18 “(d) APPLICABILITY OF CERTAIN PROVISIONS WITH
 19 RESPECT TO CONTRACTS.—Contracts may be entered into
 20 under this part without regard to sections 3648 and 3709
 21 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

22 **“SEC. 926. CERTAIN ADMINISTRATIVE AUTHORITIES.**

23 “(a) DEPUTY DIRECTOR AND OTHER OFFICERS AND
 24 EMPLOYEES.—

1 “(1) ~~DEPUTY DIRECTOR.~~—The Director may
2 appoint a deputy director for the Agency.

3 “(2) ~~OTHER OFFICERS AND EMPLOYEES.~~—The
4 Director may appoint and fix the compensation of
5 such officers and employees as may be necessary to
6 carry out this title. Except as otherwise provided by
7 law, such officers and employees shall be appointed
8 in accordance with the civil service laws and their
9 compensation fixed in accordance with title 5,
10 United States Code.

11 “(b) ~~FACILITIES.~~—The Secretary, in carrying out
12 this title—

13 “(1) may acquire, without regard to the Act of
14 March 3, 1877 (40 U.S.C. 34), by lease or otherwise
15 through the Director of General Services, buildings
16 or portions of buildings in the District of Columbia
17 or communities located adjacent to the District of
18 Columbia for use for a period not to exceed 10
19 years; and

20 “(2) may acquire, construct, improve, repair,
21 operate, and maintain laboratory, research, and
22 other necessary facilities and equipment, and such
23 other real or personal property (including patents)
24 as the Secretary deems necessary.

1 “(c) PROVISION OF FINANCIAL ASSISTANCE.—The
 2 Director, in carrying out this title, may make grants to
 3 public and nonprofit entities and individuals, and may
 4 enter into cooperative agreements or contracts with public
 5 and private entities and individuals.

6 “(d) UTILIZATION OF CERTAIN PERSONNEL AND RE-
 7 SOURCES.—

8 “(1) DEPARTMENT OF HEALTH AND HUMAN
 9 SERVICES.—The Director, in carrying out this title,
 10 may utilize personnel and equipment, facilities, and
 11 other physical resources of the Department of
 12 Health and Human Services, permit appropriate (as
 13 determined by the Secretary) entities and individuals
 14 to utilize the physical resources of such Department,
 15 and provide technical assistance and advice.

16 “(2) OTHER AGENCIES.—The Director, in car-
 17 rying out this title, may use, with their consent, the
 18 services, equipment, personnel, information, and fa-
 19 cilities of other Federal, State, or local public agen-
 20 cies, or of any foreign government, with or without
 21 reimbursement of such agencies.

22 “(e) CONSULTANTS.—The Secretary, in carrying out
 23 this title, may secure, from time to time and for such peri-
 24 ods as the Director deems advisable but in accordance
 25 with section 3109 of title 5, United States Code, the as-

1 sistance and advice of consultants from the United States
2 or abroad.

3 ~~“(f) EXPERTS.—~~

4 ~~“(1) IN GENERAL.—~~The Secretary may, in ear-
5 rying out this title, obtain the services of not more
6 than 50 experts or consultants who have appropriate
7 scientific or professional qualifications. Such experts
8 or consultants shall be obtained in accordance with
9 section 3109 of title 5, United States Code, except
10 that the limitation in such section on the duration
11 of service shall not apply.

12 ~~“(2) TRAVEL EXPENSES.—~~

13 ~~“(A) IN GENERAL.—~~Experts and consult-
14 ants whose services are obtained under para-
15 graph (1) shall be paid or reimbursed for their
16 expenses associated with traveling to and from
17 their assignment location in accordance with
18 sections 5724, 5724a(a), 5724a(e), and
19 5726(C) of title 5, United States Code.

20 ~~“(B) LIMITATION.—~~Expenses specified in
21 subparagraph (A) may not be allowed in con-
22 nection with the assignment of an expert or
23 consultant whose services are obtained under
24 paragraph (1) unless and until the expert
25 agrees in writing to complete the entire period

1 of assignment, or 1 year, whichever is shorter,
 2 unless separated or reassigned for reasons that
 3 are beyond the control of the expert or consult-
 4 ant and that are acceptable to the Secretary. If
 5 the expert or consultant violates the agreement,
 6 the money spent by the United States for the
 7 expenses specified in subparagraph (A) is recov-
 8 erable from the expert or consultant as a statu-
 9 tory obligation owed to the United States. The
 10 Secretary may waive in whole or in part a right
 11 of recovery under this subparagraph.

12 ~~“(g) VOLUNTARY AND UNCOMPENSATED SERV-~~
 13 ~~ICES.—The Director, in carrying out this title, may accept~~
 14 ~~voluntary and uncompensated services.~~

15 **~~“SEC. 927. FUNDING.~~**

16 ~~“(a) INTENT.—To ensure that the United States’s in-~~
 17 ~~vestment in biomedical research is rapidly translated into~~
 18 ~~improvements in the quality of patient care, there must~~
 19 ~~be a corresponding investment in research on the most ef-~~
 20 ~~fective clinical and organizational strategies for use of~~
 21 ~~these findings in daily practice. The authorization levels~~
 22 ~~in subsections (b) and (c) provide for a proportionate in-~~
 23 ~~crease in healthcare research as the United State’s invest-~~
 24 ~~ment in biomedical research increases.~~

1 “(b) **AUTHORIZATION OF APPROPRIATIONS.**—For the
 2 purpose of carrying out this title, there are authorized to
 3 be appropriated \$185,000,000 for fiscal year 2000, and
 4 such sums as may be necessary for each of the fiscal years
 5 2001 through 2006.

6 “(c) **EVALUATIONS.**—In addition to amounts avail-
 7 able pursuant to subsection (b) for carrying out this title,
 8 there shall be made available for such purpose, from the
 9 amounts made available pursuant to section 241 (relating
 10 to evaluations), an amount equal to 40 percent of the max-
 11 imum amount authorized in such section 241 to be made
 12 available for a fiscal year.

13 **“SEC. 929. DEFINITIONS.**

14 “In this title:

15 “(1) **ADVISORY COUNCIL.**—The term ‘Advisory
 16 Council’ means the Advisory Council on Healthcare
 17 Research and Quality established under section 921.

18 “(2) **AGENCY.**—The term ‘Agency’ means the
 19 Agency for Healthcare Research and Quality.

20 “(3) **DIRECTOR.**—The term ‘Director’ means
 21 the Director for the Agency for Healthcare Research
 22 and Quality.”.

23 **SEC. 403. REFERENCES.**

24 Effective upon the date of enactment of this Act, any
 25 reference in law to the “Agency for Health Care Policy

1 and Research” shall be deemed to be a reference to the
 2 “Agency for Healthcare Research and Quality”.

3 **SEC. 404. STUDY.**

4 (a) **STUDY.**—Not later than 30 days after the date
 5 of enactment of any Act providing for a qualifying health
 6 care benefit (as defined in subsection (b)), the Secretary
 7 of Health and Human Services, in consultation with the
 8 Agency for Healthcare Research and Quality, the National
 9 Institutes of Health, and the Institute of Medicine, shall
 10 conduct a study concerning such benefit that scientifically
 11 evaluates—

12 (1) the safety and efficacy of the benefit, par-
 13 ticularly the effect of the benefit on outcomes of
 14 care;

15 (2) the cost, benefits and value of such benefit;

16 (3) the benefit in comparison to alternative ap-
 17 proaches in improving care; and

18 (4) the overall impact that such benefit will
 19 have on health care as measured through research.

20 (b) **QUALIFYING HEALTH CARE BENEFIT.**—In this
 21 section, the term “qualifying health care benefit” means
 22 a health care benefit that—

23 (1) is disease- or health condition-specific;

24 (2) requires the provision of or coverage for
 25 health care items or services;

1 (3) applies to group health plan, individual
 2 health plans, or health insurance issuers under part
 3 7 of subtitle B of title I of the Employee Retirement
 4 Income Security Act of 1974 (29 U.S.C. 1181 et
 5 seq.) or under title XXVII of the Public Health
 6 Service Act (42 U.S.C. 300gg et seq.); and

7 (4) was provided under an Act (or amendment)
 8 enacted on or after January 1, 1999.

9 (c) REPORTS.—Not later than 3 years after the date
 10 of enactment of any Act described in subsection (a), the
 11 Secretary of Health and Human Services shall prepare
 12 and submit to the appropriate committees of Congress a
 13 report based on the study conducted under such sub-
 14 section with respect to the qualifying health care benefit
 15 involved.

16 **TITLE V—MISCELLANEOUS** 17 **PROVISIONS**

18 **SEC. 501. SENSE OF THE COMMITTEE.**

19 It is the sense of the Committee on Health, Edu-
 20 cation, Labor, and Pensions of the Senate that the Con-
 21 gress should take measures to further the purposes of this
 22 Act, including any necessary changes to the Internal Rev-
 23 enue Code of 1986 or to other Acts to—

1 (1) promote equity and prohibit discrimination
 2 based on genetic information with respect to the
 3 availability of health benefits;

4 (2) provide for the full deduction of health in-
 5 surance costs for self-employed individuals;

6 (3) provide for the full availability of medical
 7 savings accounts;

8 (4) provide for the carryover of unused benefits
 9 from cafeteria plans, flexible spending arrangements,
 10 and health flexible spending accounts; and

11 (5) permit contributions towards medical sav-
 12 ings account through the Federal employees health
 13 benefits program.

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

15 (a) *SHORT TITLE.*—*This Act may be cited as the “Pa-*
 16 *tients’ Bill of Rights Act”.*

17 (b) *TABLE OF CONTENTS.*—*The table of contents for*
 18 *this Act is as follows:*

Sec. 1. Short title; table of contents.

TITLE I—PATIENTS’ BILL OF RIGHTS

Subtitle A—Right to Advice and Care

Sec. 101. Patient right to medical advice and care.

“SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

“Sec. 721. Patient access to emergency medical care.

“Sec. 722. Offering of choice of coverage options.

“Sec. 723. Patient access to obstetric and gynecological care.

“Sec. 724. Patient access to pediatric care.

“Sec. 725. Access to specialists.

“Sec. 726. Continuity of care.

“Sec. 727. Protection of patient-provider communications.

“Sec. 728. Patient’s right to prescription drugs.

“Sec. 729. Self-payment for behavioral health care services.

“Sec. 730. Generally applicable provision.

Sec. 102. Comprehensive independent study of patient access to clinical trials and coverage of associated routine costs.

Sec. 103. Effective date and related rules.

Subtitle B—Right to Information About Plans and Providers

Sec. 111. Information about plans.

Sec. 112. Information about providers.

Subtitle C—Right to Hold Health Plans Accountable

Sec. 121. Amendment to Employee Retirement Income Security Act of 1974.

TITLE II—GENETIC INFORMATION AND SERVICES

Sec. 201. Short title.

Sec. 202. Amendments to Employee Retirement Income Security Act of 1974.

Sec. 203. Amendments to the Public Health Service Act.

Sec. 204. Amendments to the Internal Revenue Code of 1986.

TITLE III—HEALTHCARE RESEARCH AND QUALITY

Sec. 301. Short title.

Sec. 302. Amendment to the Public Health Service Act.

“TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

“PART A—ESTABLISHMENT AND GENERAL DUTIES

“Sec. 901. Mission and duties.

“Sec. 902. General authorities.

“PART B—HEALTHCARE IMPROVEMENT RESEARCH

“Sec. 911. Healthcare outcome improvement research.

“Sec. 912. Private-public partnerships to improve organization and delivery.

“Sec. 913. Information on quality and cost of care.

“Sec. 914. Information systems for healthcare improvement.

“Sec. 915. Research supporting primary care and access in underserved areas.

“Sec. 916. Clinical practice and technology innovation.

“Sec. 917. Coordination of Federal Government quality improvement efforts.

“PART C—GENERAL PROVISIONS

“Sec. 921. Advisory Council for Healthcare Research and Quality.

“Sec. 922. Peer review with respect to grants and contracts.

“Sec. 923. Certain provisions with respect to development, collection, and dissemination of data.

“Sec. 924. Dissemination of information.

“Sec. 925. Additional provisions with respect to grants and contracts.

“Sec. 926. Certain administrative authorities.

“Sec. 927. Funding.

“Sec. 928. Definitions.

Sec. 303. References.

TITLE IV—MISCELLANEOUS PROVISIONS

Sec. 401. Sense of the Committee.

1 ***TITLE I—PATIENTS’ BILL OF***
 2 ***RIGHTS***
 3 ***Subtitle A—Right to Advice and***
 4 ***Care***

5 ***SEC. 101. PATIENT RIGHT TO MEDICAL ADVICE AND CARE.***

6 (a) *IN GENERAL.*—Part 7 of subtitle B of title I of
 7 the Employee Retirement Income Security Act of 1974 (29
 8 U.S.C. 1181 *et seq.*) is amended—

9 (1) by redesignating subpart C as subpart D;

10 and

11 (2) by inserting after subpart B the following:

12 ***“Subpart C—Patient Right to Medical Advice and***
 13 ***Care***

14 ***“SEC. 721. PATIENT ACCESS TO EMERGENCY MEDICAL***
 15 ***CARE.***

16 “(a) *IN GENERAL.*—To the extent that the group health
 17 plan (other than a fully insured group health plan) pro-
 18 vides coverage for benefits consisting of emergency medical
 19 care (as defined in subsection (c)), except for items or serv-
 20 ices specifically excluded—

21 “(1) the plan shall provide coverage for benefits,
 22 without requiring preauthorization, for appropriate
 23 emergency medical screening examinations (within
 24 the capability of the emergency facility, including an-

1 *cillary services routinely available to the emergency*
 2 *facility) to the extent that a prudent layperson, who*
 3 *possesses an average knowledge of health and medi-*
 4 *cine, would determine such examinations to be nec-*
 5 *essary to determine whether emergency medical care*
 6 *(as so defined) is necessary; and*

7 “(2) the plan shall provide coverage for benefits,
 8 *without requiring preauthorization, for additional*
 9 *emergency medical care to stabilize an emergency*
 10 *medical condition following an emergency medical*
 11 *screening examination (if determined necessary under*
 12 *paragraph (1)), pursuant to the definition of stabilize*
 13 *under section 1867(e)(3) of the Social Security Act*
 14 *(42 U.S.C. 1395dd(e)(3)).*

15 “(b) *UNIFORM COST-SHARING REQUIRED AND OUT-*
 16 *OF-NETWORK CARE.—*

17 “(1) *UNIFORM COST-SHARING.—Nothing in this*
 18 *section shall be construed as preventing a group*
 19 *health plan (other than a fully insured group health*
 20 *plan) from imposing any form of cost-sharing appli-*
 21 *cable to any participant or beneficiary (including co-*
 22 *insurance, copayments, deductibles, and any other*
 23 *charges) in relation to coverage for benefits described*
 24 *in subsection (a), if such form of cost-sharing is uni-*
 25 *formly applied under such plan, with respect to simi-*

1 *larly situated participants and beneficiaries, to all*
 2 *benefits consisting of emergency medical care (as de-*
 3 *defined in subsection (c)) provided to such similarly sit-*
 4 *uated participants and beneficiaries under the plan.*

5 *“(2) OUT-OF-NETWORK CARE.—If a group health*
 6 *plan (other than a fully insured group health plan)*
 7 *provides any benefits with respect to emergency med-*
 8 *ical care (as defined in subsection (c)), the plan shall*
 9 *cover emergency medical care under the plan in a*
 10 *manner so that, if such care is provided to a partici-*
 11 *pant or beneficiary by a nonparticipating health care*
 12 *provider, the participant or beneficiary is not liable*
 13 *for amounts that exceed the amounts of liability that*
 14 *would be incurred if the services were provided by a*
 15 *participating provider.*

16 *“(c) DEFINITION OF EMERGENCY MEDICAL CARE.—In*
 17 *this section:*

18 *“(1) IN GENERAL.—The term ‘emergency medical*
 19 *care’ means, with respect to a participant or bene-*
 20 *ficiary under a group health plan (other than a fully*
 21 *insured group health plan), covered inpatient and*
 22 *outpatient services that—*

23 *“(A) are furnished by any provider, includ-*
 24 *ing a nonparticipating provider, that is quali-*
 25 *fied to furnish such services; and*

1 “(B) are needed to evaluate or stabilize (as
 2 such term is defined in section 1867(e)(3) of the
 3 Social Security Act (42 U.S.C. 1395dd)(e)(3))
 4 an emergency medical condition (as defined in
 5 paragraph (2)).

6 “(2) *EMERGENCY MEDICAL CONDITION.*—The
 7 term ‘emergency medical condition’ means a medical
 8 condition manifesting itself by acute symptoms of suf-
 9 ficient severity (including severe pain) such that a
 10 prudent layperson, who possesses an average knowl-
 11 edge of health and medicine, could reasonably expect
 12 the absence of immediate medical attention to result
 13 in—

14 “(A) placing the health of the participant or
 15 beneficiary (or, with respect to a pregnant
 16 woman, the health of the woman or her unborn
 17 child) in serious jeopardy,

18 “(B) serious impairment to bodily func-
 19 tions, or

20 “(C) serious dysfunction of any bodily
 21 organ or part.

22 **“SEC. 722. OFFERING OF CHOICE OF COVERAGE OPTIONS.**

23 “(a) *REQUIREMENT.*—

24 “(1) *OFFERING OF POINT-OF-SERVICE COVERAGE*
 25 *OPTION.*—Except as provided in paragraph (2), if a

1 group health plan (other than a fully insured group
 2 health plan) provides coverage for benefits only
 3 through a defined set of participating health care pro-
 4 fessionals, the plan shall offer the participant the op-
 5 tion to purchase point-of-service coverage (as defined
 6 in subsection (b)) for all such benefits for which cov-
 7 erage is otherwise so limited. Such option shall be
 8 made available to the participant at the time of en-
 9 rollment under the plan and at such other times as
 10 the plan offers the participant a choice of coverage op-
 11 tions.

12 “(2) *EXCEPTION IN THE CASE OF MULTIPLE*
 13 *ISSUER OR COVERAGE OPTIONS.*—Paragraph (1) shall
 14 not apply with respect to a participant in a group
 15 health plan (other than a fully insured group health
 16 plan) if the plan offers the participant 2 or more cov-
 17 erage options that differ significantly with respect to
 18 the use of participating health care professionals or
 19 the networks of such professionals that are used.

20 “(b) *POINT-OF-SERVICE COVERAGE DEFINED.*—In
 21 this section, the term ‘point-of-service coverage’ means, with
 22 respect to benefits covered under a group health plan (other
 23 than a fully insured group health plan), coverage of such
 24 benefits when provided by a nonparticipating health care
 25 professional.

1 “(c) *SMALL EMPLOYER EXEMPTION.*—

2 “(1) *IN GENERAL.*—*This section shall not apply*
3 *to any group health plan (other than a fully insured*
4 *group health plan) of a small employer.*

5 “(2) *SMALL EMPLOYER.*—*For purposes of para-*
6 *graph (1), the term ‘small employer’ means, in con-*
7 *nection with a group health plan (other than a fully*
8 *insured group health plan) with respect to a calendar*
9 *year and a plan year, an employer who employed an*
10 *average of at least 2 but not more than 50 employees*
11 *on business days during the preceding calendar year*
12 *and who employs at least 2 employees on the first day*
13 *of the plan year. For purposes of this paragraph, the*
14 *provisions of subparagraph (C) of section 712(c)(1)*
15 *shall apply in determining employer size.*

16 “(d) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*
17 *tion shall be construed—*

18 “(1) *as requiring coverage for benefits for a par-*
19 *ticular type of health care professional;*

20 “(2) *as requiring an employer to pay any costs*
21 *as a result of this section or to make equal contribu-*
22 *tions with respect to different health coverage options;*

23 “(3) *as preventing a group health plan (other*
24 *than a fully insured group health plan) from impos-*
25 *ing higher premiums or cost-sharing on a participant*

1 *for the exercise of a point-of-service coverage option;*
 2 *or*

3 *“(4) to require that a group health plan (other*
 4 *than a fully insured group health plan) include cov-*
 5 *erage of health care professionals that the plan ex-*
 6 *cludes because of fraud, quality of care, or other simi-*
 7 *lar reasons with respect to such professionals.*

8 **“SEC. 723. PATIENT ACCESS TO OBSTETRIC AND GYNECO-**
 9 **LOGICAL CARE.**

10 **“(a) GENERAL RIGHTS.—**

11 **“(1) WAIVER OF PLAN REFERRAL REQUIRE-**
 12 **MENT.—***If a group health plan described in subsection*
 13 *(b) requires a referral to obtain coverage for speciality*
 14 *care, the plan shall waive the referral requirement in*
 15 *the case of a female participant or beneficiary who*
 16 *seeks coverage for routine obstetrical care or routine*
 17 *gynecological care.*

18 **“(2) RELATED ROUTINE CARE.—***With respect to*
 19 *a participant or beneficiary described in paragraph*
 20 *(1), a group health plan described in subsection (b)*
 21 *shall treat the ordering of other routine care that is*
 22 *related to routine obstetric or gynecologic care, by a*
 23 *physician who specializes in obstetrics and gynecology*
 24 *as the authorization of the primary care provider for*
 25 *such other routine care.*

1 “(b) *APPLICATION OF SECTION.*—A group health plan
 2 described in this subsection is a group health plan (other
 3 than a fully insured group health plan), that—

4 “(1) provides coverage for routine obstetric care
 5 (such as pregnancy-related services) or routine
 6 gynecologic care (such as preventive women’s health
 7 examinations); and

8 “(2) requires the designation by a participant or
 9 beneficiary of a participating primary care provider
 10 who is not a physician who specializes in obstetrics
 11 or gynecology.

12 “(c) *RULES OF CONSTRUCTION.*—Nothing in this sec-
 13 tion shall be construed—

14 “(1) as waiving any coverage requirement relat-
 15 ing to medical necessity or appropriateness with re-
 16 spect to the coverage of obstetric or gynecologic care
 17 described in subsection (a);

18 “(2) to preclude the plan from requiring that the
 19 physician who specializes in obstetrics or gynecology
 20 notify the designated primary care provider or the
 21 plan of treatment decisions; or

22 “(3) to preclude a group health plan from allow-
 23 ing health care professionals other than physicians to
 24 provide routine obstetric or routine gynecologic care.

1 **“SEC. 724. PATIENT ACCESS TO PEDIATRIC CARE.**

2 “(a) *IN GENERAL.*—*In the case of a group health plan*
 3 *(other than a fully insured group health plan) that provides*
 4 *coverage for routine pediatric care and that requires the*
 5 *designation by a participant or beneficiary of a partici-*
 6 *pating primary care provider, if the designated primary*
 7 *care provider is not a physician who specializes in*
 8 *pediatrics—*

9 “(1) *the plan may not require authorization or*
 10 *referral by the primary care provider in order for a*
 11 *participant or beneficiary to obtain coverage for rou-*
 12 *tine pediatric care; and*

13 “(2) *the plan shall treat the ordering of other*
 14 *routine care related to routine pediatric care by such*
 15 *a specialist as having been authorized by the des-*
 16 *ignated primary care provider.*

17 “(b) *RULES OF CONSTRUCTION.*—*Nothing in sub-*
 18 *section (a) shall be construed—*

19 “(1) *as waiving any coverage requirement relat-*
 20 *ing to medical necessity or appropriateness with re-*
 21 *spect to the coverage of any pediatric care provided*
 22 *to, or ordered for, a participant or beneficiary;*

23 “(2) *to preclude a group health plan from re-*
 24 *quiring that a specialist described in subsection (a)*
 25 *notify the designated primary care provider or the*
 26 *plan of treatment decisions; or*

1 “(3) to preclude a group health plan from allow-
 2 ing health care professionals other than physicians to
 3 provide routine pediatric care.

4 **“SEC. 725. ACCESS TO SPECIALISTS.**

5 “(a) *IN GENERAL.*—A group health plan (other than
 6 a fully insured group health plan) shall ensure that partici-
 7 pants and beneficiaries have access to specialty care when
 8 such care is covered under the plan. Such access may be
 9 provided through contractual arrangements with specialized
 10 providers outside of the network of the plan.

11 “(b) *TREATMENT PLANS.*—

12 “(1) *IN GENERAL.*—Nothing in this section shall
 13 be construed to prohibit a group health plan (other
 14 than a fully insured group health plan) from requir-
 15 ing that speciality care be provided pursuant to a
 16 treatment plan so long as the treatment plan is—

17 “(A) developed by the specialist, in con-
 18 sultation with the primary care provider, and
 19 the participant or beneficiary;

20 “(B) approved by the plan; and

21 “(C) in accordance with the applicable
 22 quality assurance and utilization review stand-
 23 ards of the plan.

24 “(2) *NOTIFICATION.*—Nothing in paragraph (1)
 25 shall be construed as prohibiting a plan from requir-

1 *ing the specialist to provide the primary care pro-*
 2 *vider with regular updates on the specialty care pro-*
 3 *vided, as well as all other necessary medical informa-*
 4 *tion.*

5 *“(c) REFERRALS.—Nothing in this section shall be*
 6 *construed to prohibit a plan from requiring an authoriza-*
 7 *tion by the primary care provider of the participant or ben-*
 8 *eficiary in order to obtain coverage for speciality services*
 9 *so long as such authorization is for an adequate number*
 10 *of referrals under an approved treatment plan if such a*
 11 *treatment plan is required by the plan.*

12 *“(d) SPECIALITY CARE DEFINED.—For purposes of*
 13 *this subsection, the term “speciality care” means, with re-*
 14 *spect to a condition, care and treatment provided by a*
 15 *health care practitioner, facility, or center (such as a center*
 16 *of excellence) that has adequate expertise (including age-ap-*
 17 *propriate expertise) through appropriate training and ex-*
 18 *perience.*

19 **“SEC. 726. CONTINUITY OF CARE.**

20 *“(a) IN GENERAL.—*

21 *“(1) TERMINATION OF PROVIDER.—If a contract*
 22 *between a group health plan (other than a fully in-*
 23 *sured group health plan) and a health care provider*
 24 *is terminated (as defined in paragraph (2)), or bene-*
 25 *fits or coverage provided by a health care provider are*

1 *terminated because of a change in the terms of pro-*
 2 *vider participation in such group health plan, and*
 3 *an individual who is a participant or beneficiary in*
 4 *the plan is undergoing a course of treatment from the*
 5 *provider at the time of such termination, the plan*
 6 *shall—*

7 *“(A) notify the individual on a timely basis*
 8 *of such termination;*

9 *“(B) provide the individual with an oppor-*
 10 *tunity to notify the plan of a need for transi-*
 11 *tional care; and*

12 *“(C) in the case of termination described in*
 13 *paragraph (2), (3), or (4) of subsection (b), and*
 14 *subject to subsection (c), permit the individual to*
 15 *continue or be covered with respect to the course*
 16 *of treatment with the provider’s consent during*
 17 *a transitional period (as provided under sub-*
 18 *section (b)).*

19 *“(2) TERMINATED.—In this section, the term*
 20 *‘terminated’ includes, with respect to a contract, the*
 21 *expiration or nonrenewal of the contract by the group*
 22 *health plan, but does not include a termination of the*
 23 *contract by the plan for failure to meet applicable*
 24 *quality standards or for fraud.*

1 “(3) *CONTRACTS.*—*For purposes of this section,*
 2 *the term ‘contract between a group health plan (other*
 3 *than a fully insured group health plan) and a health*
 4 *care provider’ shall include a contract between such*
 5 *a plan and an organized network of providers.*

6 “(b) *TRANSITIONAL PERIOD.*—

7 “(1) *GENERAL RULE.*—*Except as provided in*
 8 *paragraph (3), the transitional period under this sub-*
 9 *section shall permit the participant or beneficiary to*
 10 *extend the coverage involved for up to 90 days from*
 11 *the date of the notice described in subsection (a)(1)(A)*
 12 *of the provider’s termination.*

13 “(2) *INSTITUTIONAL CARE.*—*Subject to para-*
 14 *graph (1), the transitional period under this sub-*
 15 *section for institutional or inpatient care from a pro-*
 16 *vider shall extend until the discharge or termination*
 17 *of the period of institutionalization and also shall in-*
 18 *clude institutional care provided within a reasonable*
 19 *time of the date of termination of the provider status*
 20 *if the care was scheduled before the date of the an-*
 21 *nouncement of the termination of the provider status*
 22 *under subsection (a)(1)(A) or if the individual on*
 23 *such date was on an established waiting list or other-*
 24 *wise scheduled to have such care.*

1 “(3) *PREGNANCY*.—Notwithstanding paragraph
2 (1), if—

3 “(A) a participant or beneficiary has en-
4 tered the second trimester of pregnancy at the
5 time of a provider’s termination of participa-
6 tion; and

7 “(B) the provider was treating the preg-
8 nancy before the date of the termination;
9 the transitional period under this subsection with re-
10 spect to provider’s treatment of the pregnancy shall
11 extend through the provision of post-partum care di-
12 rectly related to the delivery.

13 “(4) *TERMINAL ILLNESS*.—Subject to paragraph
14 (1), if—

15 “(A) a participant or beneficiary was deter-
16 mined to be terminally ill (as determined under
17 section 1861(dd)(3)(A) of the Social Security
18 Act) prior to a provider’s termination of partici-
19 pation; and

20 “(B) the provider was treating the terminal
21 illness before the date of termination;
22 the transitional period under this subsection shall be
23 for care directly related to the treatment of the ter-
24 minal illness.

1 “(c) *PERMISSIBLE TERMS AND CONDITIONS.*—A group
 2 *health plan (other than a fully insured group health plan)*
 3 *may condition coverage of continued treatment by a pro-*
 4 *vider under subsection (a)(1)(C) upon the provider agreeing*
 5 *to the following terms and conditions:*

6 “(1) *The provider agrees to accept reimburse-*
 7 *ment from the plan and individual involved (with re-*
 8 *spect to cost-sharing) at the rates applicable prior to*
 9 *the start of the transitional period as payment in full*
 10 *(or at the rates applicable under the replacement plan*
 11 *after the date of the termination of the contract with*
 12 *the group health plan) and not to impose cost-sharing*
 13 *with respect to the individual in an amount that*
 14 *would exceed the cost-sharing that could have been*
 15 *imposed if the contract referred to in subsection (a)(1)*
 16 *had not been terminated.*

17 “(2) *The provider agrees to adhere to the quality*
 18 *assurance standards of the plan responsible for pay-*
 19 *ment under paragraph (1) and to provide to such*
 20 *plan necessary medical information related to the*
 21 *care provided.*

22 “(3) *The provider agrees otherwise to adhere to*
 23 *such plan’s policies and procedures, including proce-*
 24 *dures regarding referrals and obtaining prior author-*

1 *ization and providing services pursuant to a treat-*
 2 *ment plan (if any) approved by the plan.*

3 *“(d) RULE OF CONSTRUCTION.—Nothing in this sec-*
 4 *tion shall be construed to require the coverage of benefits*
 5 *which would not have been covered if the provider involved*
 6 *remained a participating provider.*

7 *“(e) DEFINITION.—In this section, the term ‘health*
 8 *care provider’ or ‘provider’ means—*

9 *“(1) any individual who is engaged in the deliv-*
 10 *ery of health care services in a State and who is re-*
 11 *quired by State law or regulation to be licensed or*
 12 *certified by the State to engage in the delivery of such*
 13 *services in the State; and*

14 *“(2) any entity that is engaged in the delivery*
 15 *of health care services in a State and that, if it is re-*
 16 *quired by State law or regulation to be licensed or*
 17 *certified by the State to engage in the delivery of such*
 18 *services in the State, is so licensed.*

19 **“SEC. 727. PROTECTION OF PATIENT-PROVIDER COMMU-**
 20 **NICATIONS.**

21 *“(a) IN GENERAL.—Subject to subsection (b), a group*
 22 *health plan (other than a fully insured group health plan*
 23 *and in relation to a participant or beneficiary) shall not*
 24 *prohibit or otherwise restrict a health care professional from*
 25 *advising such a participant or beneficiary who is a patient*

1 *of the professional about the health status of the participant*
 2 *or beneficiary or medical care or treatment for the condition*
 3 *or disease of the participant or beneficiary, regardless of*
 4 *whether coverage for such care or treatment are provided*
 5 *under the contract, if the professional is acting within the*
 6 *lawful scope of practice.*

7 “(b) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*
 8 *tion shall be construed as requiring a group health plan*
 9 *(other than a fully insured group health plan) to provide*
 10 *specific benefits under the terms of such plan.*

11 **“SEC. 728. PATIENT’S RIGHT TO PRESCRIPTION DRUGS.**

12 *“To the extent that a group health plan (other than*
 13 *a fully insured group health plan) provides coverage for*
 14 *benefits with respect to prescription drugs, and limits such*
 15 *coverage to drugs included in a formulary, the plan shall—*

16 “(1) *ensure the participation of physicians and*
 17 *pharmacists in developing and reviewing such for-*
 18 *mulary; and*

19 “(2) *in accordance with the applicable quality*
 20 *assurance and utilization review standards of the*
 21 *plan, provide for exceptions from the formulary limi-*
 22 *tation when a non-formulary alternative is medically*
 23 *necessary and appropriate.*

1 **“SEC. 729. SELF-PAYMENT FOR BEHAVIORAL HEALTH CARE**
 2 **SERVICES.**

3 “(a) *IN GENERAL.*—A group health plan (other than
 4 a fully insured group health plan) may not—

5 “(1) prohibit or otherwise discourage a partici-
 6 pant or beneficiary from self-paying for behavioral
 7 health care services once the plan has denied coverage
 8 for such services; or

9 “(2) terminate a health care provider because
 10 such provider permits participants or beneficiaries to
 11 self-pay for behavioral health care services—

12 “(A) that are not otherwise covered under
 13 the plan; or

14 “(B) for which the group health plan pro-
 15 vides limited coverage, to the extent that the
 16 group health plan denies coverage of the services.

17 “(b) *RULE OF CONSTRUCTION.*—Nothing in subsection
 18 (a)(2)(B) shall be construed as prohibiting a group health
 19 plan from terminating a contract with a health care pro-
 20 vider for failure to meet applicable quality standards or
 21 for fraud.

22 **“SEC. 730. GENERALLY APPLICABLE PROVISION.**

23 “In the case of a group health plan that provides bene-
 24 fits under 2 or more coverage options, the requirements of
 25 this subpart, other than section 722, shall apply separately
 26 with respect to each coverage option.”.

1 (b) *DEFINITION.*—Section 733(a) of the *Employee Re-*
 2 *tirement Income Security Act of 1974 (42 U.S.C. 1191(a))*
 3 *is amended by adding at the end the following:*

4 “(3) *FULLY INSURED GROUP HEALTH PLAN.*—
 5 *The term ‘fully insured group health plan’ means a*
 6 *group health plan where benefits under the plan are*
 7 *provided pursuant to the terms of an arrangement be-*
 8 *tween a group health plan and a health insurance*
 9 *issuer and are guaranteed by the health insurance*
 10 *issuer under a contract or policy of insurance.’.”*

11 (c) *CONFORMING AMENDMENT.*—*The table of contents*
 12 *in section 1 of such Act is amended—*

13 (1) *in the item relating to subpart C, by striking*
 14 *“Subpart C” and inserting “Subpart D”; and*
 15 (2) *by adding at the end of the items relating to*
 16 *subpart B of part 7 of subtitle B of title I of such Act*
 17 *the following new items:*

“SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

“Sec. 721. *Patient access to emergency medical care.*

“Sec. 722. *Offering of choice of coverage options.*

“Sec. 723. *Patient access to obstetric and gynecological care.*

“Sec. 724. *Patient access to pediatric care.*

“Sec. 725. *Access to specialists.*

“Sec. 726. *Continuity of care.*

“Sec. 727. *Protection of patient-provider communications.*

“Sec. 728. *Patient’s right to prescription drugs.*

“Sec. 729. *Self-payment for behavioral health care services.*

“Sec. 730. *Generally applicable provisions.’.”*

1 **SEC. 102. COMPREHENSIVE INDEPENDENT STUDY OF PA-**
 2 **TIENT ACCESS TO CLINICAL TRIALS AND COV-**
 3 **ERAGE OF ASSOCIATED ROUTINE COSTS.**

4 (a) *STUDY BY THE INSTITUTE OF MEDICINE.*—Not
 5 later than 30 days after the date of enactment of this Act,
 6 the Secretary of Health and Human Services (in this sec-
 7 tion referred to as the “Secretary”) shall enter into a con-
 8 tract with the Institute of Medicine to conduct a comprehen-
 9 sive study of patient access to clinical trials and the cov-
 10 erage of routine patient care costs by private health plans
 11 and insurers.

12 (b) *MATTERS TO BE ASSESSED.*—The study shall as-
 13 sess the following:

14 (1) *The factors that hinder patient participation*
 15 *in clinical trials, including health plan and insur-*
 16 *ance policies and practices.*

17 (2) *The ability of health plans and investigators*
 18 *to distinguish between routine patient care costs and*
 19 *costs associated with clinical trials.*

20 (3) *The potential impact of health plan coverage*
 21 *of routine costs associated with clinical trials on*
 22 *health care premiums.*

23 (c) *REPORT.*—

24 (1) *IN GENERAL.*—Not later than 12 months
 25 after the date of the execution of the contract referred
 26 to in subsection (a), the Institute of Medicine shall

1 *submit a report on the study conducted pursuant to*
2 *that contract to the Committee on Health, Education,*
3 *Labor and Pensions of the Senate.*

4 (2) *MATTERS INCLUDED.*—*The report submitted*
5 *under paragraph (1) shall set forth the findings, con-*
6 *clusions, and recommendations of the Institute of*
7 *Medicine for—*

8 (A) *increasing patient participation in*
9 *clinical trials;*

10 (B) *encouraging collaboration between the*
11 *public and private sectors; and*

12 (C) *improving analysis of determining rou-*
13 *tine costs associated with the conduct of clinical*
14 *trials.*

15 (3) *COPY TO SECRETARY.*—*Concurrent with the*
16 *submission of the report under paragraph (1), the In-*
17 *stitute of Medicine shall transmit a copy of the report*
18 *to the Secretary.*

19 (d) *FUNDING.*—*Out of funds appropriated to the De-*
20 *partment of Health and Human Services for fiscal year*
21 *2000, the Secretary shall provide for such funding as the*
22 *Secretary determines is necessary in order to carry out the*
23 *study and report by the Institute of Medicine under this*
24 *section.*

1 **SEC. 103. EFFECTIVE DATE AND RELATED RULES.**

2 (a) *IN GENERAL.*—*The amendments made by this sub-*
 3 *title shall apply with respect to plan years beginning on*
 4 *or after January 1 of the second calendar year following*
 5 *the date of the enactment of this Act. The Secretary shall*
 6 *issue all regulations necessary to carry out the amendments*
 7 *made by this section before the effective date thereof.*

8 (b) *LIMITATION ON ENFORCEMENT ACTIONS.*—*No en-*
 9 *forcement action shall be taken, pursuant to the amend-*
 10 *ments made by this subtitle, against a group health plan*
 11 *with respect to a violation of a requirement imposed by such*
 12 *amendments before the date of issuance of regulations issued*
 13 *in connection with such requirement, if the plan has sought*
 14 *to comply in good faith with such requirement.*

15 ***Subtitle B—Right to Information***
 16 ***About Plans and Providers***

17 **SEC. 111. INFORMATION ABOUT PLANS.**

18 (a) *EMPLOYEE RETIREMENT INCOME SECURITY ACT*
 19 *OF 1974.*—

20 (1) *IN GENERAL.*—*Subpart B of part 7 of sub-*
 21 *title B of title I of the Employee Retirement Income*
 22 *Security Act of 1974, as amended by the Omnibus*
 23 *Consolidated and Emergency Supplemental Appro-*
 24 *propriations Act, 1999 (Public Law 105–277), is amend-*
 25 *ed by adding at the end the following:*

1 **“SEC. 714. HEALTH PLAN COMPARATIVE INFORMATION.**

2 “(a) *REQUIREMENT.*—

3 “(1) *IN GENERAL.*—A group health plan, and a
4 health insurance issuer that provides coverage in con-
5 nection with group health insurance coverage, shall,
6 not later than 12 months after the date of enactment
7 of this section, and at least annually thereafter, pro-
8 vide for the disclosure, in a clear and accurate form
9 to each participant and each beneficiary who does not
10 reside at the same address as the participant, or upon
11 request to an individual eligible for coverage under
12 the plan, of the information described in subsection
13 (b).

14 “(2) *RULE OF CONSTRUCTION.*—Nothing in this
15 section shall be construed to prevent a plan or issuer
16 from entering into any agreement under which the
17 issuer agrees to assume responsibility for compliance
18 with the requirements of this section and the plan is
19 released from liability for such compliance.

20 “(3) *PROVISION OF INFORMATION.*—Information
21 shall be provided to participants and beneficiaries
22 under this section at the address maintained by the
23 plan or issuer with respect to such participants or
24 beneficiaries.

25 “(b) *REQUIRED INFORMATION.*—The informational
26 materials to be distributed under this section shall include

1 *for each package option available under a group health plan*
2 *the following:*

3 “(1) *A description of the covered items and serv-*
4 *ices under each such plan and any in- and out-of-net-*
5 *work features of each such plan, including a sum-*
6 *mary description of the specific exclusions from cov-*
7 *erage under the plan.*

8 “(2) *A description of any cost-sharing, including*
9 *premiums, deductibles, coinsurance, and copayment*
10 *amounts, for which the participant or beneficiary will*
11 *be responsible, including any annual or lifetime lim-*
12 *its on benefits, for each such plan.*

13 “(3) *A description of any optional supplemental*
14 *benefits offered by each such plan and the terms and*
15 *conditions (including premiums or cost-sharing) for*
16 *such supplemental coverage.*

17 “(4) *A description of any restrictions on pay-*
18 *ments for services furnished to a participant or bene-*
19 *ficiary by a health care professional that is not a*
20 *participating professional and the liability of the*
21 *participant or beneficiary for additional payments*
22 *for these services.*

23 “(5) *A description of the service area of each*
24 *such plan, including the provision of any out-of-area*
25 *coverage.*

1 “(6) A description of the extent to which partici-
2 pants and beneficiaries may select the primary care
3 provider of their choice, including providers both
4 within the network and outside the network of each
5 such plan (if the plan permits out-of-network serv-
6 ices).

7 “(7) A description of the procedures for advance
8 directives and organ donation decisions if the plan
9 maintains such procedures.

10 “(8) A description of the requirements and pro-
11 cedures to be used to obtain preauthorization for
12 health services (including telephone numbers and
13 mailing addresses), including referrals for specialty
14 care.

15 “(9) A description of the definition of medical
16 necessity used in making coverage determinations by
17 each such plan.

18 “(10) A summary of the rules and methods for
19 appealing coverage decisions and filing grievances
20 (including telephone numbers and mailing addresses),
21 as well as other available remedies.

22 “(11) A summary description of any provisions
23 for obtaining off-formulary medications if the plan
24 utilizes a defined formulary for providing specific
25 prescription medications.

1 “(12) *A summary of the rules for access to emer-*
 2 *gency room care. Also, any available educational ma-*
 3 *terial regarding proper use of emergency services.*

4 “(13) *A description of whether or not coverage is*
 5 *provided for experimental treatments, investigational*
 6 *treatments, or clinical trials and the circumstances*
 7 *under which access to such treatments or trials is*
 8 *made available.*

9 “(14) *A description of the specific preventative*
 10 *services covered under the plan if such services are*
 11 *covered.*

12 “(15) *A statement regarding—*

13 “(A) *the manner in which a participant or*
 14 *beneficiary may access an obstetrician, gyne-*
 15 *cologist, or pediatrician in accordance with sec-*
 16 *tion 723 or 724; and*

17 “(B) *the manner in which a participant or*
 18 *beneficiary obtains continuity of care as pro-*
 19 *vided for in section 726.*

20 “(16) *A statement that the following informa-*
 21 *tion, and instructions on obtaining such information*
 22 *(including telephone numbers and, if available, Inter-*
 23 *net websites), shall be made available upon request:*

24 “(A) *The names, addresses, telephone num-*
 25 *bers, and State licensure status of the plan’s par-*

1 *ticipating health care professionals and partici-*
2 *pating health care facilities, and, if available,*
3 *the education, training, speciality qualifications*
4 *or certifications of such professionals.*

5 *“(B) A summary description of the methods*
6 *used for compensating participating health care*
7 *professionals, such as capitation, fee-for-service,*
8 *salary, or a combination thereof. The require-*
9 *ment of this subparagraph shall not be construed*
10 *as requiring plans to provide information con-*
11 *cerning proprietary payment methodology.*

12 *“(C) A summary description of the methods*
13 *used for compensating health care facilities, in-*
14 *cluding per diem, fee-for-service, capitation, bun-*
15 *dled payments, or a combination thereof. The re-*
16 *quirement of this subparagraph shall not be con-*
17 *strued as requiring plans to provide information*
18 *concerning proprietary payment methodology.*

19 *“(D) A summary description of the proce-*
20 *dures used for utilization review.*

21 *“(E) The list of the specific prescription*
22 *medications included in the formulary of the*
23 *plan, if the plan uses a defined formulary.*

24 *“(F) A description of the specific exclusions*
25 *from coverage under the plan.*

1 “(G) *Any available information related to*
 2 *the availability of translation or interpretation*
 3 *services for non-English speakers and people*
 4 *with communication disabilities, including the*
 5 *availability of audio tapes or information in*
 6 *Braille.*

7 “(H) *Any information that is made public*
 8 *by accrediting organizations in the process of ac-*
 9 *creditation if the plan is accredited, or any ad-*
 10 *ditional quality indicators that the plan makes*
 11 *available.*

12 “(c) *MANNER OF DISTRIBUTION.—The information de-*
 13 *scribed in this section shall be distributed in an accessible*
 14 *format that is understandable to an average plan partici-*
 15 *pant or beneficiary.*

16 “(d) *RULE OF CONSTRUCTION.—Nothing in this sec-*
 17 *tion may be construed to prohibit a group health plan, or*
 18 *health insurance issuer in connection with group health in-*
 19 *surance coverage, from distributing any other additional*
 20 *information determined by the plan or issuer to be impor-*
 21 *tant or necessary in assisting participants and beneficiaries*
 22 *or upon request potential participants and beneficiaries in*
 23 *the selection of a health plan or from providing information*
 24 *under subsection (b)(15) as part of the required informa-*
 25 *tion.*

1 “(e) *CONFORMING REGULATIONS.*—*The Secretary*
 2 *shall issue regulations to coordinate the requirements on*
 3 *group health plans and health insurance issuers under this*
 4 *section with the requirements imposed under part 1, to re-*
 5 *duce duplication with respect to any information that is*
 6 *required to be provided under any such requirements.*

7 “(f) *HEALTH CARE PROFESSIONAL.*—*In this section,*
 8 *the term ‘health care professional’ means a physician (as*
 9 *defined in section 1861(r) of the Social Security Act) or*
 10 *other health care professional if coverage for the profes-*
 11 *sional’s services is provided under the health plan involved*
 12 *for the services of the professional. Such term includes a*
 13 *podiatrist, optometrist, chiropractor, psychologist, dentist,*
 14 *physician assistant, physical or occupational therapist and*
 15 *therapy assistant, speech-language pathologist, audiologist,*
 16 *registered or licensed practical nurse (including nurse prac-*
 17 *titioner, clinical nurse specialist, certified registered nurse*
 18 *anesthetist, and certified nurse-midwife), licensed certified*
 19 *social worker, registered respiratory therapist, and certified*
 20 *respiratory therapy technician.”.*

21 (2) *CONFORMING AMENDMENTS.*—

22 (A) *Section 732(a) of the Employee Retire-*
 23 *ment Income Security Act of 1974 (29 U.S.C.*
 24 *1191a(a)) is amended by striking “section 711,*
 25 *and inserting “sections 711 and 714”.*

1 (B) *The table of contents in section 1 of the*
 2 *Employee Retirement Income Security Act of*
 3 *1974 (29 U.S.C. 1001) is amended by inserting*
 4 *after the item relating to section 713, the fol-*
 5 *lowing:*

“Sec. 714. *Health plan comparative information.*”.

6 (b) *INTERNAL REVENUE CODE OF 1986.—Subchapter*
 7 *B of chapter 100 of the Internal Revenue Code of 1986 is*
 8 *amended—*

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

“Sec. 9813. *Health plan comparative information.*”; and

11 (2) *by inserting after section 9812 the following:*

12 **“SEC. 9813. HEALTH PLAN COMPARATIVE INFORMATION.**

13 **“(a) REQUIREMENT.—**

14 **“(1) IN GENERAL.—***A group health plan shall,*
 15 *not later than 12 months after the date of enactment*
 16 *of this section, and at least annually thereafter, pro-*
 17 *vide for the disclosure, in a clear and accurate form*
 18 *to each participant and each beneficiary who does not*
 19 *reside at the same address as the participant, or upon*
 20 *request to an individual eligible for coverage under*
 21 *the plan, of the information described in subsection*
 22 **(b).**

23 **“(2) RULES OF CONSTRUCTION.—***Nothing in this*
 24 *section shall be construed to prevent a plan from en-*

1 *tering into any agreement under which a health in-*
 2 *surance issuer agrees to assume responsibility for*
 3 *compliance with the requirements of this section and*
 4 *the plan is released from liability for such compli-*
 5 *ance.*

6 “(3) *PROVISION OF INFORMATION.*—*Information*
 7 *shall be provided to participants and beneficiaries*
 8 *under this section at the address maintained by the*
 9 *plan with respect to such participants or bene-*
 10 *ficiaries.*

11 “(b) *REQUIRED INFORMATION.*—*The informational*
 12 *materials to be distributed under this section shall include*
 13 *for each package option available under a group health plan*
 14 *the following:*

15 “(1) *A description of the covered items and serv-*
 16 *ices under each such plan and any in- and out-of-net-*
 17 *work features of each such plan, including a sum-*
 18 *mary description of the specific exclusions from cov-*
 19 *erage under the plan.*

20 “(2) *A description of any cost-sharing, including*
 21 *premiums, deductibles, coinsurance, and copayment*
 22 *amounts, for which the participant or beneficiary will*
 23 *be responsible, including any annual or lifetime lim-*
 24 *its on benefits, for each such plan.*

1 “(3) *A description of any optional supplemental*
2 *benefits offered by each such plan and the terms and*
3 *conditions (including premiums or cost-sharing) for*
4 *such supplemental coverage.*

5 “(4) *A description of any restrictions on pay-*
6 *ments for services furnished to a participant or bene-*
7 *ficiary by a health care professional that is not a*
8 *participating professional and the liability of the*
9 *participant or beneficiary for additional payments*
10 *for these services.*

11 “(5) *A description of the service area of each*
12 *such plan, including the provision of any out-of-area*
13 *coverage.*

14 “(6) *A description of the extent to which partici-*
15 *pants and beneficiaries may select the primary care*
16 *provider of their choice, including providers both*
17 *within the network and outside the network of each*
18 *such plan (if the plan permits out-of-network serv-*
19 *ices).*

20 “(7) *A description of the procedures for advance*
21 *directives and organ donation decisions if the plan*
22 *maintains such procedures.*

23 “(8) *A description of the requirements and pro-*
24 *cedures to be used to obtain preauthorization for*
25 *health services (including telephone numbers and*

1 *mailing addresses), including referrals for specialty*
2 *care.*

3 “(9) *A description of the definition of medical*
4 *necessity used in making coverage determinations by*
5 *each such plan.*

6 “(10) *A summary of the rules and methods for*
7 *appealing coverage decisions and filing grievances*
8 *(including telephone numbers and mailing addresses),*
9 *as well as other available remedies.*

10 “(11) *A summary description of any provisions*
11 *for obtaining off-formulary medications if the plan*
12 *utilizes a defined formulary for providing specific*
13 *prescription medications.*

14 “(12) *A summary of the rules for access to emer-*
15 *gency room care. Also, any available educational ma-*
16 *terial regarding proper use of emergency services.*

17 “(13) *A description of whether or not coverage is*
18 *provided for experimental treatments, investigational*
19 *treatments, or clinical trials and the circumstances*
20 *under which access to such treatments or trials is*
21 *made available.*

22 “(14) *A description of the specific preventative*
23 *services covered under the plan if such services are*
24 *covered.*

25 “(15) *A statement regarding—*

1 “(A) *the manner in which a participant or*
 2 *beneficiary may access an obstetrician, gyne-*
 3 *cologist, or pediatrician in accordance with sec-*
 4 *tion 723 or 724; and*

5 “(B) *the manner in which a participant or*
 6 *beneficiary obtains continuity of care as pro-*
 7 *vided for in section 726.*

8 “(16) *A statement that the following informa-*
 9 *tion, and instructions on obtaining such information*
 10 *(including telephone numbers and, if available, Inter-*
 11 *net websites), shall be made available upon request:*

12 “(A) *The names, addresses, telephone num-*
 13 *bers, and State licensure status of the plan’s par-*
 14 *ticipating health care professionals and partici-*
 15 *pating health care facilities, and, if available,*
 16 *the education, training, speciality qualifications*
 17 *or certifications of such professionals.*

18 “(B) *A summary description of the methods*
 19 *used for compensating participating health care*
 20 *professionals, such as capitation, fee-for-service,*
 21 *salary, or a combination thereof. The require-*
 22 *ment of this subparagraph shall not be construed*
 23 *as requiring plans to provide information con-*
 24 *cerning proprietary payment methodology.*

1 “(C) *A summary description of the methods*
2 *used for compensating health care facilities, in-*
3 *cluding per diem, fee-for-service, capitation, bun-*
4 *dled payments, or a combination thereof. The re-*
5 *quirement of this subparagraph shall not be con-*
6 *strued as requiring plans to provide information*
7 *concerning proprietary payment methodology.*

8 “(D) *A summary description of the proce-*
9 *dures used for utilization review.*

10 “(E) *The list of the specific prescription*
11 *medications included in the formulary of the*
12 *plan, if the plan uses a defined formulary.*

13 “(F) *A description of the specific exclusions*
14 *from coverage under the plan.*

15 “(G) *Any available information related to*
16 *the availability of translation or interpretation*
17 *services for non-English speakers and people*
18 *with communication disabilities, including the*
19 *availability of audio tapes or information in*
20 *Braille.*

21 “(H) *Any information that is made public*
22 *by accrediting organizations in the process of ac-*
23 *creditation if the plan is accredited, or any ad-*
24 *ditional quality indicators that the plan makes*
25 *available.*

1 “(c) *MANNER OF DISTRIBUTION.*—*The information de-*
 2 *scribed in this section shall be distributed in an accessible*
 3 *format that is understandable to an average plan partici-*
 4 *pant or beneficiary.*

5 “(d) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*
 6 *tion may be construed to prohibit a group health plan from*
 7 *distributing any other additional information determined*
 8 *by the plan to be important or necessary in assisting par-*
 9 *ticipants and beneficiaries or upon request potential par-*
 10 *ticipants and beneficiaries in the selection of a health plan*
 11 *or from providing information under subsection (b)(15) as*
 12 *part of the required information.*

13 “(e) *HEALTH CARE PROFESSIONAL.*—*In this section,*
 14 *the term ‘health care professional’ means a physician (as*
 15 *defined in section 1861(r) of the Social Security Act) or*
 16 *other health care professional if coverage for the profes-*
 17 *sional’s services is provided under the health plan involved*
 18 *for the services of the professional. Such term includes a*
 19 *podiatrist, optometrist, chiropractor, psychologist, dentist,*
 20 *physician assistant, physical or occupational therapist and*
 21 *therapy assistant, speech-language pathologist, audiologist,*
 22 *registered or licensed practical nurse (including nurse prac-*
 23 *titioner, clinical nurse specialist, certified registered nurse*
 24 *anesthetist, and certified nurse-midwife), licensed certified*

1 *social worker, registered respiratory therapist, and certified*
 2 *respiratory therapy technician.”.*

3 **SEC. 112. INFORMATION ABOUT PROVIDERS.**

4 (a) *STUDY.*—*The Secretary of Health and Human*
 5 *Services shall enter into a contract with the Institute of*
 6 *Medicine for the conduct of a study, and the submission*
 7 *to the Secretary of a report, that includes—*

8 (1) *an analysis of information concerning health*
 9 *care professionals that is currently available to pa-*
 10 *tients, consumers, States, and professional societies,*
 11 *nationally and on a State-by-State basis, including*
 12 *patient preferences with respect to information about*
 13 *such professionals and their competencies;*

14 (2) *an evaluation of the legal and other barriers*
 15 *to the sharing of information concerning health care*
 16 *professionals; and*

17 (3) *recommendations for the disclosure of infor-*
 18 *mation on health care professionals, including the*
 19 *competencies and professional qualifications of such*
 20 *practitioners, to better facilitate patient choice, qual-*
 21 *ity improvement, and market competition.*

22 (b) *REPORT.*—*Not later than 18 months after the date*
 23 *of enactment of this Act, the Secretary of Health and*
 24 *Human Services shall forward to the appropriate commit-*

tees of Congress a copy of the report and study conducted under subsection (a).

Subtitle C—Right to Hold Health Plans Accountable

SEC. 121. AMENDMENT TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) *IN GENERAL.*—Section 503 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1133) is amended to read as follows:

“SEC. 503. CLAIMS PROCEDURE, COVERAGE DETERMINATION, GRIEVANCES AND APPEALS.

“(a) *CLAIMS PROCEDURE.*—In accordance with regulations of the Secretary, every employee benefit plan shall—

“(1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant; and

“(2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.

“(b) *COVERAGE DETERMINATIONS UNDER GROUP HEALTH PLANS.*—

“(1) *PROCEDURES.*—

1 “(A) *IN GENERAL.*—A group health plan or
2 health insurance issuer conducting utilization re-
3 view shall ensure that procedures are in place
4 for—

5 “(i) making determinations regarding
6 whether a participant or beneficiary is eli-
7 gible to receive a payment or coverage for
8 health services under the plan or coverage
9 involved and any cost-sharing amount that
10 the participant or beneficiary is required to
11 pay with respect to such service;

12 “(ii) notifying a covered participant or
13 beneficiary (or the authorized representative
14 of such participant or beneficiary) and the
15 treating health care professionals involved
16 regarding determinations made under the
17 plan or issuer and any additional pay-
18 ments that the participant or beneficiary
19 may be required to make with respect to
20 such service; and

21 “(iii) responding to requests, either
22 written or oral, for coverage determinations
23 or for internal appeals from a participant
24 or beneficiary (or the authorized representa-
25 tive of such participant or beneficiary) or

1 the treating health care professional with
 2 the consent of the participant or bene-
 3 ficiary.

4 “(B) *ORAL REQUESTS.*—With respect to an
 5 oral request described in subparagraph (A)(iii),
 6 a group health plan or health insurance issuer
 7 may require that the requesting individual pro-
 8 vide written evidence of such request.

9 “(2) *TIMELINE FOR MAKING DETERMINATIONS.*—

10 “(A) *ROUTINE DETERMINATION.*—A group
 11 health plan or a health insurance issuer shall
 12 maintain procedures to ensure that prior author-
 13 ization determinations concerning the provision
 14 of non-emergency items or services are made
 15 within 30 days from the date on which the re-
 16 quest for a determination is submitted, except
 17 that such period may be extended where certain
 18 circumstances exist that are determined by the
 19 Secretary to be beyond control of the plan or
 20 issuer.

21 “(B) *EXPEDITED DETERMINATION.*—

22 “(i) *IN GENERAL.*—A prior authoriza-
 23 tion determination under this subsection
 24 shall be made within 72 hours, in accord-
 25 ance with the medical exigencies of the case,

1 *after a request is received by the plan or*
 2 *issuer under clause (ii) or (iii).*

3 “(ii) *REQUEST BY PARTICIPANT OR*
 4 *BENEFICIARY.—A plan or issuer shall*
 5 *maintain procedures for expediting a prior*
 6 *authorization determination under this sub-*
 7 *section upon the request of a participant or*
 8 *beneficiary if, based on such a request, the*
 9 *plan or issuer determines that the normal*
 10 *time for making such a determination could*
 11 *seriously jeopardize the life or health of the*
 12 *participant or beneficiary.*

13 “(iii) *DOCUMENTATION BY HEALTH*
 14 *CARE PROFESSIONAL.—A plan or issuer*
 15 *shall maintain procedures for expediting a*
 16 *prior authorization determination under*
 17 *this subsection if the request involved indi-*
 18 *cates that the treating health care profes-*
 19 *sional has reasonably documented, based on*
 20 *the medical exigencies, that a determination*
 21 *under the procedures described in subpara-*
 22 *graph (A) could seriously jeopardize the life*
 23 *or health of the participant or beneficiary.*

24 “(C) *CONCURRENT DETERMINATIONS.—A*
 25 *plan or issuer shall maintain procedures to cer-*

1 *tify or deny coverage of an extended stay or ad-*
 2 *ditional services.*

3 “(D) *RETROSPECTIVE DETERMINATION.*—A
 4 *plan or issuer shall maintain procedures to en-*
 5 *sure that, with respect to the retrospective review*
 6 *of a determination made under paragraph (1),*
 7 *the determination shall be made within 30 work-*
 8 *ing days of the date on which the plan or issuer*
 9 *receives necessary information.*

10 “(3) *NOTICE OF DETERMINATIONS.*—

11 “(A) *ROUTINE DETERMINATION.*—With re-
 12 *spect to a coverage determination of a plan or*
 13 *issuer under paragraph (2)(A), the plan or*
 14 *issuer shall issue notice of such determination to*
 15 *the participant or beneficiary (or the authorized*
 16 *representative of the participant or beneficiary)*
 17 *and, consistent with the medical exigencies of the*
 18 *case, to the treating health care professional in-*
 19 *volved not later than 2 working days after the*
 20 *date on which the determination is made.*

21 “(B) *EXPEDITED DETERMINATION.*—With
 22 *respect to a coverage determination of a plan or*
 23 *issuer under paragraph (2)(B), the plan or*
 24 *issuer shall issue notice of such determination to*
 25 *the participant or beneficiary (or the authorized*

1 *representative of the participant or beneficiary),*
2 *and consistent with the medical exigencies of the*
3 *case, to the treating health care professional in-*
4 *volved within the 72 hour period described in*
5 *paragraph (2)(B).*

6 *“(C) CONCURRENT REVIEWS.—With respect*
7 *to the determination under a plan or issuer*
8 *under paragraph (2)(C) to certify or deny cov-*
9 *erage of an extended stay or additional services,*
10 *the plan or issuer shall issue notice of such deter-*
11 *mination to the treating health care professional*
12 *and to the participant or beneficiary involved*
13 *(or the authorized representative of the partici-*
14 *pant or beneficiary) within 1 working day of the*
15 *determination.*

16 *“(D) RETROSPECTIVE REVIEWS.—With re-*
17 *spect to the retrospective review under a plan or*
18 *issuer of a determination made under paragraph*
19 *(2)(D), the plan or issuer shall issue written no-*
20 *tice of an approval or disapproval of a deter-*
21 *mination under this subparagraph to the partic-*
22 *ipant or beneficiary (or the authorized represent-*
23 *ative of the participant or beneficiary) and*
24 *health care provider involved within 5 working*

1 *days of the date on which such determination is*
2 *made.*

3 “(E) *REQUIREMENTS OF NOTICE OF AD-*
4 *VERSE COVERAGE DETERMINATIONS.—A written*
5 *notice of an adverse coverage determination*
6 *under this subsection, or of an expedited adverse*
7 *coverage determination under paragraph (2)(B),*
8 *shall be provided to the participant or bene-*
9 *ficiary (or the authorized representative of the*
10 *participant or beneficiary) and treating health*
11 *care professional (if any) involved and shall*
12 *include—*

13 “(i) *the reasons for the determination*
14 *(including the clinical or scientific-evidence*
15 *based rationale used in making the deter-*
16 *mination) written in a manner to be under-*
17 *standable to the average participant or ben-*
18 *eficiary;*

19 “(ii) *the procedures for obtaining addi-*
20 *tional information concerning the deter-*
21 *mination; and*

22 “(iii) *notification of the right to ap-*
23 *peal the determination and instructions on*
24 *how to initiate an appeal in accordance*
25 *with subsection (d).*

1 “(c) *GRIEVANCES.*—A group health plan or a health
 2 insurance issuer shall have written procedures for address-
 3 ing grievances between the plan or issuer offering health
 4 insurance coverage in connection with a group health plan
 5 and a participant or beneficiary. Determinations under
 6 such procedures shall be non-appealable.

7 “(d) *INTERNAL APPEAL OF COVERAGE DETERMINA-*
 8 *TIONS.*—

9 “(1) *RIGHT TO APPEAL.*—

10 “(A) *IN GENERAL.*—A participant or bene-
 11 ficiary (or the authorized representative of the
 12 participant or beneficiary) or the treating health
 13 care professional with the consent of the partici-
 14 pant or beneficiary (or the authorized represent-
 15 ative of the participant or beneficiary), may ap-
 16 peal any adverse coverage determination under
 17 subsection (b) under the procedures described in
 18 this subsection.

19 “(B) *TIME FOR APPEAL.*—A plan or issuer
 20 shall ensure that a participant or beneficiary
 21 has a period of not less than 180 days beginning
 22 on the date of an adverse coverage determination
 23 under subsection (b) in which to appeal such de-
 24 termination under this subsection.

1 “(C) *FAILURE TO ACT.*—*The failure of a*
2 *plan or issuer to issue a determination under*
3 *subsection (b) within the applicable timeline es-*
4 *tablished for such a determination under such*
5 *subsection shall be treated as an adverse coverage*
6 *determination for purposes of proceeding to in-*
7 *ternal review under this subsection.*

8 “(2) *RECORDS.*—*A group health plan and a*
9 *health insurance issuer shall maintain written*
10 *records, for at least 6 years, with respect to any ap-*
11 *peal under this subsection for purposes of internal*
12 *quality assurance and improvement. Nothing in the*
13 *preceding sentence shall be construed as preventing a*
14 *plan and issuer from entering into an agreement*
15 *under which the issuer agrees to assume responsibility*
16 *for compliance with the requirements of this section*
17 *and the plan is released from liability for such com-*
18 *pliance.*

19 “(3) *ROUTINE DETERMINATIONS.*—*A group*
20 *health plan or a health insurance issuer shall com-*
21 *plete the consideration of an appeal of an adverse*
22 *routine determination under this subsection not later*
23 *than 30 working days after the date on which a re-*
24 *quest for such appeal is received.*

25 “(4) *EXPEDITED DETERMINATION.*—

1 “(A) *IN GENERAL.*—An expedited deter-
2 mination with respect to an appeal under this
3 subsection shall be made in accordance with the
4 medical exigencies of the case, but in no case
5 more than 72 hours after the request for such ap-
6 peal is received by the plan or issuer under sub-
7 paragraph (B) or (C).

8 “(B) *REQUEST BY PARTICIPANT OR BENE-*
9 *FICIARY.*—A plan or issuer shall maintain pro-
10 cedures for expediting a prior authorization de-
11 termination under this subsection upon the re-
12 quest of a participant or beneficiary if, based on
13 such a request, the plan or issuer determines that
14 the normal time for making such a determina-
15 tion could seriously jeopardize the life or health
16 of the participant or beneficiary.

17 “(C) *DOCUMENTATION BY HEALTH CARE*
18 *PROFESSIONAL.*—A plan or issuer shall main-
19 tain procedures for expediting a prior authoriza-
20 tion determination under this subsection if the
21 request involved indicates that the treating
22 health care professional has reasonably docu-
23 mented, based on the medical exigencies of the
24 case that a determination under the procedures
25 described in paragraph (2) could seriously jeop-

1 *ardize the life or health of the participant or*
 2 *beneficiary.*

3 “(5) *CONDUCT OF REVIEW.*—*A review of an ad-*
 4 *verse coverage determination under this subsection*
 5 *shall be conducted by an individual with appropriate*
 6 *expertise who was not directly involved in the initial*
 7 *determination.*

8 “(6) *LACK OF MEDICAL NECESSITY.*—*A review of*
 9 *an appeal under this subsection relating to a deter-*
 10 *mination to deny coverage based on a lack of medical*
 11 *necessity and appropriateness, or based on an experi-*
 12 *mental or investigational treatment, shall be made*
 13 *only by a physician with appropriate expertise, in-*
 14 *cluding age-appropriate expertise, who was not in-*
 15 *volved in the initial determination.*

16 “(7) *NOTICE.*—

17 “(A) *IN GENERAL.*—*Written notice of a de-*
 18 *termination made under an internal review*
 19 *process shall be issued to the participant or bene-*
 20 *ficiary (or the authorized representative of the*
 21 *participant or beneficiary) and the treating*
 22 *health care professional not later than 2 working*
 23 *days after the completion of the review (or with-*
 24 *in the 72-hour period referred to in paragraph*
 25 *(4) if applicable).*

1 “(B) *ADVERSE COVERAGE DETERMINA-*
 2 *TIONS.*—*With respect to an adverse coverage de-*
 3 *termination made under this subsection, the no-*
 4 *tice described in subparagraph (A) shall*
 5 *include—*

6 “(i) *the reasons for the determination*
 7 *(including the clinical or scientific-evidence*
 8 *based rationale used in making the deter-*
 9 *mination) written in a manner to be under-*
 10 *standable to the average participant or ben-*
 11 *eficiary;*

12 “(ii) *the procedures for obtaining addi-*
 13 *tional information concerning the deter-*
 14 *mination; and*

15 “(iii) *notification of the right to an*
 16 *independent external review under sub-*
 17 *section (e) and instructions on how to ini-*
 18 *tiate such a review.*

19 “(e) *INDEPENDENT EXTERNAL REVIEW.*—

20 “(1) *ACCESS TO REVIEW.*—

21 “(A) *IN GENERAL.*—*A group health plan or*
 22 *a health insurance issuer offering health insur-*
 23 *ance coverage in connection with a group health*
 24 *plan shall have written procedures to permit a*
 25 *participant or beneficiary (or the authorized rep-*

1 *representative of the participant or beneficiary) ac-*
 2 *cess to an independent external review with re-*
 3 *spect to an adverse coverage determination con-*
 4 *cerning a particular item or service (including a*
 5 *circumstance treated as an adverse coverage de-*
 6 *termination under subparagraph (B)) where—*

7 *“(i) the particular item or service*
 8 *involved—*

9 *“(I)(aa) would be a covered ben-*
 10 *efit, when medically necessary and ap-*
 11 *propriate under the terms and condi-*
 12 *tions of the plan, and the item or serv-*
 13 *ice has been determined not to be medi-*
 14 *cally necessary and appropriate under*
 15 *the internal appeals process required*
 16 *under subsection (d) or there has been*
 17 *a failure to issue a coverage determina-*
 18 *tion as described in subparagraph (B);*
 19 *and*

20 *“(bb)(AA) the amount of such*
 21 *item or service involved exceeds a sig-*
 22 *nificant financial threshold; or*

23 *“(BB) there is a significant risk*
 24 *of placing the life or health of the par-*
 25 *ticipant or beneficiary in jeopardy; or*

1 “(II) *would be a covered benefit,*
 2 *when not considered experimental or*
 3 *investigational under the terms and*
 4 *conditions of the plan, and the item or*
 5 *service has been determined to be ex-*
 6 *perimental or investigational under the*
 7 *internal appeals process required*
 8 *under subsection (d) or there has been*
 9 *a failure to issue a coverage determina-*
 10 *tion as described in subparagraph (B);*
 11 *and*

12 “(ii) *the participant or beneficiary has*
 13 *completed the internal appeals process*
 14 *under subsection (d) with respect to such de-*
 15 *termination.*

16 “(B) *FAILURE TO ACT.—The failure of a*
 17 *plan or issuer to issue a coverage determination*
 18 *under subsection (d)(6) within the applicable*
 19 *timeline established for such a determination*
 20 *under such subsection shall be treated as an ad-*
 21 *verse coverage determination for purposes of pro-*
 22 *ceeding to independent external review under*
 23 *this subsection.*

24 “(2) *INITIATION OF THE INDEPENDENT EXTER-*
 25 *NAL REVIEW PROCESS.—*

1 “(A) *FILING OF REQUEST.*—A participant
2 or beneficiary (or the authorized representative
3 of the participant or beneficiary) who desires to
4 have an independent external review conducted
5 under this subsection shall file a written request
6 for such a review with the plan or issuer in-
7 volved not later than 30 working days after the
8 receipt of a final denial of a claim under sub-
9 section (d). Any such request shall include the
10 consent of the participant or beneficiary (or the
11 authorized representative of the participant or
12 beneficiary) for the release of medical informa-
13 tion and records to independent external review-
14 ers regarding the participant or beneficiary.

15 “(B) *INFORMATION AND NOTICE.*—Not later
16 than 5 working days after the receipt of a re-
17 quest under subparagraph (A), or earlier in ac-
18 cordance with the medical exigencies of the case,
19 the plan or issuer involved shall select an exter-
20 nal appeals entity under paragraph (3)(A) that
21 shall be responsible for designating an inde-
22 pendent external reviewer under paragraph
23 (3)(B).

24 “(C) *PROVISION OF INFORMATION.*—The
25 plan or issuer involved shall forward necessary

1 *information (including medical records, any rel-*
 2 *evant review criteria, the clinical rationale con-*
 3 *sistent with the terms and conditions of the con-*
 4 *tract between the plan or issuer and the partici-*
 5 *pant or beneficiary for the coverage denial, and*
 6 *evidence of the coverage of the participant or*
 7 *beneficiary) to the independent external reviewer*
 8 *selected under paragraph (3)(B).*

9 “(D) *NOTIFICATION.*—*The plan or issuer*
 10 *involved shall send a written notification to the*
 11 *participant or beneficiary (or the authorized rep-*
 12 *resentative of the participant or beneficiary) and*
 13 *the plan administrator, indicating that an inde-*
 14 *pendent external review has been initiated.*

15 “(3) *CONDUCT OF INDEPENDENT EXTERNAL RE-*
 16 *VIEW.*—

17 “(A) *DESIGNATION OF EXTERNAL APPEALS*
 18 *ENTITY BY PLAN OR ISSUER.*—

19 “(i) *IN GENERAL.*—*A plan or issuer*
 20 *that receives a request for an independent*
 21 *external review under paragraph (2)(A)*
 22 *shall designate a qualified entity described*
 23 *in clause (ii), in a manner designed to en-*
 24 *sure that the entity so designated will make*

1 *a decision in an unbiased manner, to serve*
 2 *as the external appeals entity.*

3 “(ii) *QUALIFIED ENTITIES.—A quali-*
 4 *fied entity shall be—*

5 “(I) *an independent external re-*
 6 *view entity licensed or credentialed by*
 7 *a State;*

8 “(II) *a State agency established*
 9 *for the purpose of conducting inde-*
 10 *pendent external reviews;*

11 “(III) *any entity under contract*
 12 *with the Federal Government to pro-*
 13 *vide independent external review serv-*
 14 *ices;*

15 “(IV) *any entity accredited as an*
 16 *independent external review entity by*
 17 *an accrediting body recognized by the*
 18 *Secretary for such purpose; or*

19 “(V) *any other entity meeting cri-*
 20 *teria established by the Secretary for*
 21 *purposes of this subparagraph.*

22 “(B) *DESIGNATION OF INDEPENDENT EX-*
 23 *TERNAL REVIEWER BY EXTERNAL APPEALS ENTI-*
 24 *TY.—The external appeals entity designated*
 25 *under subparagraph (A) shall, not later than 30*

1 *days after the date on which such entity is des-*
2 *ignated under subparagraph (A), or earlier in*
3 *accordance with the medical exigencies of the*
4 *case, designate one or more individuals to serve*
5 *as independent external reviewers with respect to*
6 *a request received under paragraph (2)(A). Such*
7 *reviewers shall be independent medical experts*
8 *who shall—*

9 *“(i) be appropriately credentialed or*
10 *licensed in any State to deliver health care*
11 *services;*

12 *“(ii) not have any material, profes-*
13 *sional, familial, or financial affiliation*
14 *with the case under review, the participant*
15 *or beneficiary involved, the treating health*
16 *care professional, the institution where the*
17 *treatment would take place, or the manufac-*
18 *turer of any drug, device, procedure, or*
19 *other therapy proposed for the participant*
20 *or beneficiary whose treatment is under re-*
21 *view;*

22 *“(iii) have expertise (including age-ap-*
23 *propriate expertise) in the diagnosis or*
24 *treatment under review and, when reason-*
25 *ably available, be of the same specialty as*

1 *the physician treating the participant or*
 2 *beneficiary or recommending or prescribing*
 3 *the treatment in question;*

4 “(iv) *receive only reasonable and cus-*
 5 *tomary compensation from the group health*
 6 *plan or health insurance issuer in connec-*
 7 *tion with the independent external review*
 8 *that is not contingent on the decision ren-*
 9 *dered by the reviewer; and*

10 “(v) *not be held liable for decisions re-*
 11 *garding medical determinations (but may*
 12 *be held liable for actions that are arbitrary*
 13 *and capricious).*

14 “(4) *STANDARD OF REVIEW.—*

15 “(A) *IN GENERAL.—An independent exter-*
 16 *nal reviewer shall—*

17 “(i) *make an independent determina-*
 18 *tion based on the valid, relevant, scientific*
 19 *and clinical evidence to determine the med-*
 20 *ical necessity, appropriateness, experi-*
 21 *mental or investigational nature of the pro-*
 22 *posed treatment; and*

23 “(ii) *take into consideration appro-*
 24 *priate and available information, including*
 25 *any evidence-based decision making or clin-*

1 ical practice guidelines used by the group
 2 health plan or health insurance issuer;
 3 timely evidence or information submitted by
 4 the plan, issuer, patient or patient's physi-
 5 cian; the patient's medical record; expert
 6 consensus; and medical literature as defined
 7 in section 556(5) of the Federal Food, Drug,
 8 and Cosmetic Act.

9 “(B) NOTICE.—The plan or issuer involved
 10 shall ensure that the participant or beneficiary
 11 receives notice, within 30 days after the deter-
 12 mination of the independent medical expert, re-
 13 garding the actions of the plan or issuer with re-
 14 spect to the determination of such expert under
 15 the independent external review.

16 “(5) TIMEFRAME FOR REVIEW.—

17 “(A) IN GENERAL.—The independent exter-
 18 nal reviewer shall complete a review of an ad-
 19 verse coverage determination in accordance with
 20 the medical exigencies of the case.

21 “(B) LIMITATION.—Notwithstanding sub-
 22 paragraph (A), a review described in such sub-
 23 paragraph shall be completed not later than 30
 24 working days after the later of—

1 “(i) the date on which such reviewer is
2 designated; or

3 “(ii) the date on which all information
4 necessary to completing such review is re-
5 ceived.

6 “(6) *BINDING DETERMINATION.*—The determina-
7 tion of an independent external reviewer under this
8 subsection shall be binding upon the plan or issuer if
9 the provisions of this subsection or the procedures im-
10 plemented under such provisions were complied with
11 by the independent external reviewer.

12 “(7) *STUDY.*—Not later than 2 years after the
13 date of enactment of this section, the General Ac-
14 counting Office shall conduct a study of a statistically
15 appropriate sample of completed independent external
16 reviews. Such study shall include an assessment of the
17 process involved during an independent external re-
18 view and the basis of decisionmaking by the inde-
19 pendent external reviewer. The results of such study
20 shall be submitted to the appropriate committees of
21 Congress.

22 “(8) *EFFECT ON CERTAIN PROVISIONS.*—Nothing
23 in this section shall be construed as affecting or modi-
24 fying section 514 of this Act with respect to a group
25 health plan.

1 “(f) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*
 2 *tion shall be construed to prohibit a plan administrator or*
 3 *plan fiduciary or health plan medical director from request-*
 4 *ing an independent external review by an independent ex-*
 5 *ternal reviewer without first completing the internal review*
 6 *process.*

7 “(g) *DEFINITIONS.*—*In this section:*

8 “(1) *ADVERSE COVERAGE DETERMINATION.*—*The*
 9 *term ‘adverse coverage determination’ means a cov-*
 10 *erage determination under the plan which results in*
 11 *a denial of coverage or reimbursement.*

12 “(2) *COVERAGE DETERMINATION.*—*The term*
 13 *‘coverage determination’ means with respect to items*
 14 *and services for which coverage may be provided*
 15 *under a health plan, a determination of whether or*
 16 *not such items and services are covered or reimburs-*
 17 *able under the coverage and terms of the contract.*

18 “(3) *GRIEVANCE.*—*The term ‘grievance’ means*
 19 *any complaint made by a participant or beneficiary*
 20 *that does not involve a coverage determination.*

21 “(4) *GROUP HEALTH PLAN.*—*The term ‘group*
 22 *health plan’ shall have the meaning given such term*
 23 *in section 733(a). In applying this paragraph, ex-*
 24 *cepted benefits described in section 733(c) shall not be*
 25 *treated as benefits consisting of medical care.*

1 “(5) *HEALTH INSURANCE COVERAGE.*—*The term*
 2 *‘health insurance coverage’ has the meaning given*
 3 *such term in section 733(b)(1). In applying this*
 4 *paragraph, excepted benefits described in section*
 5 *733(c) shall not be treated as benefits consisting of*
 6 *medical care.*

7 “(6) *HEALTH INSURANCE ISSUER.*—*The term*
 8 *‘health insurance issuer’ has the meaning given such*
 9 *term in section 733(b)(2).*

10 “(7) *PRIOR AUTHORIZATION DETERMINATION.*—
 11 *The term ‘prior authorization determination’ means a*
 12 *coverage determination prior to the provision of the*
 13 *items and services as a condition of coverage of the*
 14 *items and services under the coverage.*

15 “(8) *TREATING HEALTH CARE PROFESSIONAL.*—
 16 *The term ‘treating health care professional’ with re-*
 17 *spect to a group health plan, health insurance issuer*
 18 *or provider sponsored organization means a physi-*
 19 *cian (medical doctor or doctor of osteopathy) or other*
 20 *health care practitioner who is acting within the*
 21 *scope of his or her State licensure or certification for*
 22 *the delivery of health care services and who is pri-*
 23 *marily responsible for delivering those services to the*
 24 *participant or beneficiary.*

1 “(9) *UTILIZATION REVIEW*.—The term ‘utiliza-
 2 tion review’ with respect to a group health plan or
 3 health insurance coverage means a set of formal tech-
 4 niques designed to monitor the use of, or evaluate the
 5 clinical necessity, appropriateness, efficacy, or effi-
 6 ciency of, health care services, procedures, or settings.
 7 Techniques may include ambulatory review, prospec-
 8 tive review, second opinion, certification, concurrent
 9 review, case management, discharge planning or ret-
 10 rospective review.”

11 (b) *ENFORCEMENT*.—Section 502(c)(1) of the *Em-*
 12 ployee Retirement Income Security Act of 1974 (29 U.S.C.
 13 1132(c)(1)) is amended by inserting after “or section
 14 101(e)(1)” the following: “, or fails to comply with a cov-
 15 erage determination as required under section 503(e)(6),”.

16 (c) *CONFORMING AMENDMENT*.—The table of contents
 17 in section 1 of the *Employee Retirement Income Security*
 18 Act of 1974 is amended by striking the item relating to
 19 section 503 and inserting the following new item:

“Sec. 503. Claims procedures, coverage determination, grievances and appeals.”.

20 (d) *EFFECTIVE DATE*.—The amendments made by this
 21 section shall apply with respect to plan years beginning on
 22 or after 1 year after the date of enactment of this Act. The
 23 Secretary shall issue all regulations necessary to carry out
 24 the amendments made by this section before the effective
 25 date thereof.

1 **TITLE II—GENETIC**
 2 **INFORMATION AND SERVICES**

3 **SEC. 201. SHORT TITLE.**

4 *This title may be cited as the “Genetic Information*
 5 *Nondiscrimination in Health Insurance Act of 1999”.*

6 **SEC. 202. AMENDMENTS TO EMPLOYEE RETIREMENT IN-**
 7 **COME SECURITY ACT OF 1974.**

8 *(a) PROHIBITION OF HEALTH DISCRIMINATION ON*
 9 *THE BASIS OF GENETIC INFORMATION OR GENETIC SERV-*
 10 *ICES.—*

11 *(1) NO ENROLLMENT RESTRICTION FOR GENETIC*
 12 *SERVICES.—Section 702(a)(1)(F) of the Employee Re-*
 13 *irement Income Security Act of 1974 (29 U.S.C.*
 14 *1182(a)(1)(F)) is amended by inserting before the pe-*
 15 *riod the following: “(including information about a*
 16 *request for or receipt of genetic services)”.*

17 *(2) NO DISCRIMINATION IN GROUP PREMIUMS*
 18 *BASED ON PREDICTIVE GENETIC INFORMATION.—Sub-*
 19 *part B of part 7 of subtitle B of title I of the Em-*
 20 *ployee Retirement Income Security Act of 1974, as*
 21 *amended by section 111(a), is further amended by*
 22 *adding at the end the following:*

1 **“SEC. 715. PROHIBITING PREMIUM DISCRIMINATION**
 2 **AGAINST GROUPS ON THE BASIS OF PRE-**
 3 **DICTIVE GENETIC INFORMATION.**

4 “A group health plan, or a health insurance issuer of-
 5 fering group health insurance coverage in connection with
 6 a group health plan, shall not adjust premium or contribu-
 7 tion amounts for a group on the basis of predictive genetic
 8 information concerning any individual (including a de-
 9 pendent) or family member of the individual (including in-
 10 formation about a request for or receipt of genetic serv-
 11 ices).”.

12 (3) CONFORMING AMENDMENTS.—

13 (A) IN GENERAL.—Section 702(b) of the
 14 Employee Retirement Income Security Act of
 15 1974 (29 U.S.C. 1182(b)) is amended by adding
 16 at the end the following:

17 “(3) REFERENCE TO RELATED PROVISION.—For
 18 a provision prohibiting the adjustment of premium or
 19 contribution amounts for a group under a group
 20 health plan on the basis of predictive genetic informa-
 21 tion (including information about a request for or re-
 22 ceipt of genetic services), see section 715.”.

23 (B) TABLE OF CONTENTS.—The table of
 24 contents in section 1 of the Employee Retirement
 25 Income Security Act of 1974, as amended by sec-
 26 tion 111(a), is further amended by inserting

1 *after the item relating to section 714 the fol-*
 2 *lowing new item:*

“Sec. 715. Prohibiting premium discrimination against groups on the basis of predictive genetic information.”.

3 ***(b) LIMITATION ON COLLECTION OF PREDICTIVE GE-***
 4 ***NETIC INFORMATION.***—*Section 702 of the Employee Retire-*
 5 *ment Income Security Act of 1974 (29 U.S.C. 1182) is*
 6 *amended by adding at the end the following:*

7 ***“(c) COLLECTION OF PREDICTIVE GENETIC INFORMA-***
 8 ***TION.***—

9 ***“(1) LIMITATION ON REQUESTING OR REQUIRING***
 10 ***PREDICTIVE GENETIC INFORMATION.***—*Except as pro-*
 11 *vided in paragraph (2), a group health plan, or a*
 12 *health insurance issuer offering health insurance cov-*
 13 *erage in connection with a group health plan, shall*
 14 *not request or require predictive genetic information*
 15 *concerning any individual (including a dependent) or*
 16 *family member of the individual (including informa-*
 17 *tion about a request for or receipt of genetic services).*

18 ***“(2) INFORMATION NEEDED FOR DIAGNOSIS,***
 19 ***TREATMENT, OR PAYMENT.***—

20 ***“(A) IN GENERAL.***—*Notwithstanding para-*
 21 *graph (1), a group health plan, or a health in-*
 22 *surance issuer offering health insurance coverage*
 23 *in connection with a group health plan, that*
 24 *provides health care items and services to an in-*

1 *dividual or dependent may request (but may not*
 2 *require) that such individual or dependent dis-*
 3 *close, or authorize the collection or disclosure of,*
 4 *predictive genetic information for purposes of di-*
 5 *agnosis, treatment, or payment relating to the*
 6 *provision of health care items and services to*
 7 *such individual or dependent.*

8 *“(B) NOTICE OF CONFIDENTIALITY PRAC-*
 9 *TICES AND DESCRIPTION OF SAFEGUARDS.—As a*
 10 *part of a request under subparagraph (A), the*
 11 *group health plan, or a health insurance issuer*
 12 *offering health insurance coverage in connection*
 13 *with a group health plan, shall provide to the in-*
 14 *dividual or dependent a description of the proce-*
 15 *dures in place to safeguard the confidentiality,*
 16 *as described in subsection (d), of such predictive*
 17 *genetic information.*

18 *“(d) CONFIDENTIALITY WITH RESPECT TO PRE-*
 19 *dictive Genetic Information.—*

20 *“(1) NOTICE OF CONFIDENTIALITY PRACTICES.—*

21 *“(A) PREPARATION OF WRITTEN NOTICE.—*

22 *A group health plan, or a health insurance*
 23 *issuer offering health insurance coverage in con-*
 24 *nection with a group health plan, shall post or*
 25 *provide, in writing and in a clear and con-*

1 *spicuous manner, notice of the plan or issuer's*
 2 *confidentiality practices, that shall include—*

3 *“(i) a description of an individual's*
 4 *rights with respect to predictive genetic in-*
 5 *formation;*

6 *“(ii) the procedures established by the*
 7 *plan or issuer for the exercise of the individ-*
 8 *ual's rights; and*

9 *“(iii) the right to obtain a copy of the*
 10 *notice of the confidentiality practices re-*
 11 *quired under this subsection.*

12 *“(B) MODEL NOTICE.—The Secretary, in*
 13 *consultation with the National Committee on*
 14 *Vital and Health Statistics and the National As-*
 15 *sociation of Insurance Commissioners, and after*
 16 *notice and opportunity for public comment, shall*
 17 *develop and disseminate model notices of con-*
 18 *fidentiality practices. Use of the model notice*
 19 *shall serve as a defense against claims of receiv-*
 20 *ing inappropriate notice.*

21 *“(2) ESTABLISHMENT OF SAFEGUARDS.—A*
 22 *group health plan, or a health insurance issuer offer-*
 23 *ing health insurance coverage in connection with a*
 24 *group health plan, shall establish and maintain ap-*
 25 *propriate administrative, technical, and physical*

1 *safeguards to protect the confidentiality, security, ac-*
 2 *curacy, and integrity of predictive genetic informa-*
 3 *tion created, received, obtained, maintained, used,*
 4 *transmitted, or disposed of by such plan or issuer.”.*

5 (c) *DEFINITIONS.*—*Section 733(d) of the Employee Re-*
 6 *tirement Income Security Act of 1974 (29 U.S.C. 1191b(d))*
 7 *is amended by adding at the end the following:*

8 “(5) *FAMILY MEMBER.*—*The term ‘family mem-*
 9 *ber’ means with respect to an individual—*

10 “(A) *the spouse of the individual;*

11 “(B) *a dependent child of the individual,*
 12 *including a child who is born to or placed for*
 13 *adoption with the individual; and*

14 “(C) *all other individuals related by blood*
 15 *to the individual or the spouse or child described*
 16 *in subparagraph (A) or (B).*

17 “(6) *GENETIC INFORMATION.*—*The term ‘genetic*
 18 *information’ means information about genes, gene*
 19 *products, or inherited characteristics that may derive*
 20 *from an individual or a family member (including*
 21 *information about a request for or receipt of genetic*
 22 *services).*

23 “(7) *GENETIC SERVICES.*—*The term ‘genetic*
 24 *services’ means health services provided to obtain, as-*
 25 *sess, or interpret genetic information for diagnostic*

1 *and therapeutic purposes, and for genetic education*
 2 *and counseling.*

3 “(8) *PREDICTIVE GENETIC INFORMATION.*—

4 “(A) *IN GENERAL.*—*The term ‘predictive ge-*
 5 *netic information’ means, in the absence of*
 6 *symptoms, clinical signs, or a diagnosis of the*
 7 *condition related to such information—*

8 “(i) *information about an individual’s*
 9 *genetic tests;*

10 “(ii) *information about genetic tests of*
 11 *family members of the individual; or*

12 “(iii) *information about the occurrence*
 13 *of a disease or disorder in family members.*

14 “(B) *EXCEPTIONS.*—*The term ‘predictive*
 15 *genetic information’ shall not include—*

16 “(i) *information about the sex or age of*
 17 *the individual;*

18 “(ii) *information derived from phys-*
 19 *ical tests, such as the chemical, blood, or*
 20 *urine analyses of the individual including*
 21 *cholesterol tests; and*

22 “(iii) *information about physical*
 23 *exams of the individual.*

24 “(9) *GENETIC TEST.*—*The term ‘genetic test’*
 25 *means the analysis of human DNA, RNA, chro-*

1 period the following: “(including information
2 about a request for or receipt of genetic serv-
3 ices)”.

4 (B) *NO DISCRIMINATION IN PREMIUMS*
5 *BASED ON PREDICTIVE GENETIC INFORMATION.*—
6 *Subpart 2 of part A of title XXVII of the Public*
7 *Health Service Act, as amended by the Omnibus*
8 *Consolidated and Emergency Supplemental Ap-*
9 *propriations Act, 1999 (Public Law 105–277), is*
10 *amended by adding at the end the following new*
11 *section:*

12 **“SEC. 2707. PROHIBITING PREMIUM DISCRIMINATION**
13 **AGAINST GROUPS ON THE BASIS OF PRE-**
14 **DICTIVE GENETIC INFORMATION IN THE**
15 **GROUP MARKET.**

16 “A group health plan, or a health insurance issuer of-
17 fering group health insurance coverage in connection with
18 a group health plan shall not adjust premium or contribu-
19 tion amounts for a group on the basis of predictive genetic
20 information concerning any individual (including a de-
21 pendent) or family member of the individual (including in-
22 formation about a request for or receipt of genetic serv-
23 ices).”.

24 (C) *CONFORMING AMENDMENT.*—Section
25 2702(b) of the Public Health Service Act (42

1 *U.S.C. 300gg–1(b)) is amended by adding at the*
 2 *end the following:*

3 “(3) *REFERENCE TO RELATED PROVISION.—For*
 4 *a provision prohibiting the adjustment of premium or*
 5 *contribution amounts for a group under a group*
 6 *health plan on the basis of predictive genetic informa-*
 7 *tion (including information about a request for or re-*
 8 *ceipt of genetic services), see section 2707.”.*

9 *(D) LIMITATION ON COLLECTION AND DIS-*
 10 *CLOSURE OF PREDICTIVE GENETIC INFORMA-*
 11 *TION.—Section 2702 of the Public Health Service*
 12 *Act (42 U.S.C. 300gg–1) is amended by adding*
 13 *at the end the following:*

14 “(c) *COLLECTION OF PREDICTIVE GENETIC INFORMA-*
 15 *TION.—*

16 “(1) *LIMITATION ON REQUESTING OR REQUIRING*
 17 *PREDICTIVE GENETIC INFORMATION.—Except as pro-*
 18 *vided in paragraph (2), a group health plan, or a*
 19 *health insurance issuer offering health insurance cov-*
 20 *erage in connection with a group health plan, shall*
 21 *not request or require predictive genetic information*
 22 *concerning any individual (including a dependent) or*
 23 *a family member of the individual (including infor-*
 24 *mation about a request for or receipt of genetic serv-*
 25 *ices).*

1 “(2) *INFORMATION NEEDED FOR DIAGNOSIS,*
2 *TREATMENT, OR PAYMENT.—*

3 “(A) *IN GENERAL.—*Notwithstanding para-
4 *graph (1), a group health plan, or a health in-*
5 *surance issuer offering health insurance coverage*
6 *in connection with a group health plan, that*
7 *provides health care items and services to an in-*
8 *dividual or dependent may request (but may not*
9 *require) that such individual or dependent dis-*
10 *close, or authorize the collection or disclosure of,*
11 *predictive genetic information for purposes of di-*
12 *agnosis, treatment, or payment relating to the*
13 *provision of health care items and services to*
14 *such individual or dependent.*

15 “(B) *NOTICE OF CONFIDENTIALITY PRAC-*
16 *TICES AND DESCRIPTION OF SAFEGUARDS.—*As a
17 *part of a request under subparagraph (A), the*
18 *group health plan, or a health insurance issuer*
19 *offering health insurance coverage in connection*
20 *with a group health plan, shall provide to the in-*
21 *dividual or dependent a description of the proce-*
22 *dures in place to safeguard the confidentiality,*
23 *as described in subsection (d), of such predictive*
24 *genetic information.*

1 “(d) *CONFIDENTIALITY WITH RESPECT TO PRE-*
 2 *DICTIVE GENETIC INFORMATION.*—

3 “(1) *NOTICE OF CONFIDENTIALITY PRACTICES.*—

4 “(A) *PREPARATION OF WRITTEN NOTICE.*—

5 *A group health plan, or a health insurance*
 6 *issuer offering health insurance coverage in con-*
 7 *nection with a group health plan, shall post or*
 8 *provide, in writing and in a clear and con-*
 9 *spicuous manner, notice of the plan or issuer’s*
 10 *confidentiality practices, that shall include—*

11 “(i) *a description of an individual’s*
 12 *rights with respect to predictive genetic in-*
 13 *formation;*

14 “(ii) *the procedures established by the*
 15 *plan or issuer for the exercise of the individ-*
 16 *ual’s rights; and*

17 “(iii) *the right to obtain a copy of the*
 18 *notice of the confidentiality practices re-*
 19 *quired under this subsection.*

20 “(B) *MODEL NOTICE.*—*The Secretary, in*
 21 *consultation with the National Committee on*
 22 *Vital and Health Statistics and the National As-*
 23 *sociation of Insurance Commissioners, and after*
 24 *notice and opportunity for public comment, shall*
 25 *develop and disseminate model notices of con-*

1 *fidentiality practices. Use of the model notice*
 2 *shall serve as a defense against claims of receiv-*
 3 *ing inappropriate notice.*

4 “(2) *ESTABLISHMENT OF SAFEGUARDS.—A*
 5 *group health plan, or a health insurance issuer offer-*
 6 *ing health insurance coverage in connection with a*
 7 *group health plan, shall establish and maintain ap-*
 8 *propriate administrative, technical, and physical*
 9 *safeguards to protect the confidentiality, security, ac-*
 10 *curacy, and integrity of predictive genetic informa-*
 11 *tion created, received, obtained, maintained, used,*
 12 *transmitted, or disposed of by such plan or issuer.”.*

13 (2) *DEFINITIONS.—Section 2791(d) of the Public*
 14 *Health Service Act (42 U.S.C. 300gg–91(d)) is*
 15 *amended by adding at the end the following:*

16 “(15) *FAMILY MEMBER.—The term ‘family mem-*
 17 *ber’ means, with respect to an individual—*

18 “(A) *the spouse of the individual;*

19 “(B) *a dependent child of the individual,*
 20 *including a child who is born to or placed for*
 21 *adoption with the individual; and*

22 “(C) *all other individuals related by blood*
 23 *to the individual or the spouse or child described*
 24 *in subparagraph (A) or (B).*

1 “(16) *GENETIC INFORMATION*.—The term ‘ge-
 2 netic information’ means information about genes,
 3 gene products, or inherited characteristics that may
 4 derive from an individual or a family member (in-
 5 cluding information about a request for or receipt of
 6 genetic services).

7 “(17) *GENETIC SERVICES*.—The term ‘genetic
 8 services’ means health services provided to obtain, as-
 9 sess, or interpret genetic information for diagnostic
 10 and therapeutic purposes, and for genetic education
 11 and counseling.

12 “(18) *PREDICTIVE GENETIC INFORMATION*.—

13 “(A) *IN GENERAL*.—The term ‘predictive ge-
 14 netic information’ means, in the absence of
 15 symptoms, clinical signs, or a diagnosis of the
 16 condition related to such information—

17 “(i) information about an individual’s
 18 genetic tests;

19 “(ii) information about genetic tests of
 20 family members of the individual; or

21 “(iii) information about the occurrence
 22 of a disease or disorder in family members.

23 “(B) *EXCEPTIONS*.—The term ‘predictive
 24 genetic information’ shall not include—

1 “(i) information about the sex or age of
2 the individual;

3 “(ii) information derived from phys-
4 ical tests, such as the chemical, blood, or
5 urine analyses of the individual including
6 cholesterol tests; and

7 “(iii) information about physical
8 exams of the individual.

9 “(19) *GENETIC TEST*.—The term ‘genetic test’
10 means the analysis of human DNA, RNA, chro-
11 mosomes, proteins, and certain metabolites, including
12 analysis of genotypes, mutations, phenotypes, or
13 karyotypes, for the purpose of predicting risk of dis-
14 ease in asymptomatic or undiagnosed individuals.
15 Such term does not include physical tests, such as the
16 chemical, blood, or urine analyses of the individual
17 including cholesterol tests, and physical exams of the
18 individual, in order to detect symptoms, clinical
19 signs, or a diagnosis of disease.”.

20 (b) *AMENDMENT RELATING TO THE INDIVIDUAL MAR-*
21 *KET*.—The first subpart 3 of part B of title XXVII of the
22 Public Health Service Act (42 U.S.C. 300gg–51 et seq.) (re-
23 lating to other requirements), as amended by the Omnibus
24 Consolidated and Emergency Supplemental Appropriations
25 Act, 1999 (Public Law 105-277) is amended—

1 (1) *by redesignating such subpart as subpart 2;*

2 *and*

3 (2) *by adding at the end the following:*

4 **“SEC. 2753. PROHIBITION OF HEALTH DISCRIMINATION ON**
 5 **THE BASIS OF PREDICTIVE GENETIC INFOR-**
 6 **MATION.**

7 “(a) *PROHIBITION ON PREDICTIVE GENETIC INFORMA-*
 8 *TION AS A CONDITION OF ELIGIBILITY.*—*A health insurance*
 9 *issuer offering health insurance coverage in the individual*
 10 *market may not use predictive genetic information as a*
 11 *condition of eligibility of an individual to enroll in indi-*
 12 *vidual health insurance coverage (including information*
 13 *about a request for or receipt of genetic services).*

14 “(b) *PROHIBITION ON PREDICTIVE GENETIC INFORMA-*
 15 *TION IN SETTING PREMIUM RATES.*—*A health insurance*
 16 *issuer offering health insurance coverage in the individual*
 17 *market shall not adjust premium rates for individuals on*
 18 *the basis of predictive genetic information concerning such*
 19 *an individual (including a dependent) or a family member*
 20 *of the individual (including information about a request*
 21 *for or receipt of genetic services).*

22 “(c) *COLLECTION OF PREDICTIVE GENETIC INFORMA-*
 23 *TION.*—

24 “(1) *LIMITATION ON REQUESTING OR REQUIRING*
 25 *PREDICTIVE GENETIC INFORMATION.*—*Except as pro-*

1 *vided in paragraph (2), a health insurance issuer of-*
 2 *fering health insurance coverage in the individual*
 3 *market shall not request or require predictive genetic*
 4 *information concerning any individual (including a*
 5 *dependent) or a family member of the individual (in-*
 6 *cluding information about a request for or receipt of*
 7 *genetic services).*

8 *“(2) INFORMATION NEEDED FOR DIAGNOSIS,*
 9 *TREATMENT, OR PAYMENT.—*

10 *“(A) IN GENERAL.—Notwithstanding para-*
 11 *graph (1), a health insurance issuer offering*
 12 *health insurance coverage in the individual mar-*
 13 *ket that provides health care items and services*
 14 *to an individual or dependent may request (but*
 15 *may not require) that such individual or de-*
 16 *pendent disclose, or authorize the collection or*
 17 *disclosure of, predictive genetic information for*
 18 *purposes of diagnosis, treatment, or payment re-*
 19 *lating to the provision of health care items and*
 20 *services to such individual or dependent.*

21 *“(B) NOTICE OF CONFIDENTIALITY PRAC-*
 22 *TICES AND DESCRIPTION OF SAFEGUARDS.—As a*
 23 *part of a request under subparagraph (A), the*
 24 *health insurance issuer offering health insurance*
 25 *coverage in the individual market shall provide*

1 *to the individual or dependent a description of*
 2 *the procedures in place to safeguard the con-*
 3 *fidentiality, as described in subsection (d), of*
 4 *such predictive genetic information.*

5 “(d) *CONFIDENTIALITY WITH RESPECT TO PRE-*
 6 *dictive Genetic Information.*—

7 “(1) *NOTICE OF CONFIDENTIALITY PRACTICES.*—

8 “(A) *PREPARATION OF WRITTEN NOTICE.*—

9 *A health insurance issuer offering health insur-*
 10 *ance coverage in the individual market shall post*
 11 *or provide, in writing and in a clear and con-*
 12 *spicuous manner, notice of the issuer’s confiden-*
 13 *tiality practices, that shall include—*

14 “(i) *a description of an individual’s*
 15 *rights with respect to predictive genetic in-*
 16 *formation;*

17 “(ii) *the procedures established by the*
 18 *issuer for the exercise of the individual’s*
 19 *rights; and*

20 “(iii) *the right to obtain a copy of the*
 21 *notice of the confidentiality practices re-*
 22 *quired under this subsection.*

23 “(B) *MODEL NOTICE.*—*The Secretary, in*
 24 *consultation with the National Committee on*
 25 *Vital and Health Statistics and the National As-*

1 *sociation of Insurance Commissioners, and after*
 2 *notice and opportunity for public comment, shall*
 3 *develop and disseminate model notices of con-*
 4 *fidentiality practices. Use of the model notice*
 5 *shall serve as a defense against claims of receiv-*
 6 *ing inappropriate notice.*

7 “(2) *ESTABLISHMENT OF SAFEGUARDS.—A*
 8 *health insurance issuer offering health insurance cov-*
 9 *erage in the individual market shall establish and*
 10 *maintain appropriate administrative, technical, and*
 11 *physical safeguards to protect the confidentiality, se-*
 12 *curity, accuracy, and integrity of predictive genetic*
 13 *information created, received, obtained, maintained,*
 14 *used, transmitted, or disposed of by such issuer.”.*

15 (c) *EFFECTIVE DATE.—The amendments made by this*
 16 *section shall apply with respect to—*

17 (1) *group health plans, and health insurance*
 18 *coverage offered in connection with group health*
 19 *plans, for plan years beginning after 1 year after the*
 20 *date of enactment of this Act; and*

21 (2) *health insurance coverage offered, sold,*
 22 *issued, renewed, in effect, or operated in the indi-*
 23 *vidual market after 1 year after the date of enactment*
 24 *of this Act.*

1 **SEC. 204. AMENDMENTS TO THE INTERNAL REVENUE CODE**
 2 **OF 1986.**

3 (a) *PROHIBITION OF HEALTH DISCRIMINATION ON*
 4 *THE BASIS OF GENETIC INFORMATION OR GENETIC SERV-*
 5 *ICES.—*

6 (1) *NO ENROLLMENT RESTRICTION FOR GENETIC*
 7 *SERVICES.—Section 9802(a)(1)(F) of the Internal*
 8 *Revenue Code of 1986 is amended by inserting before*
 9 *the period the following: “(including information*
 10 *about a request for or receipt of genetic services)”.*

11 (2) *NO DISCRIMINATION IN GROUP PREMIUMS*
 12 *BASED ON PREDICTIVE GENETIC INFORMATION.—*

13 (A) *IN GENERAL.—Subchapter B of chapter*
 14 *100 of the Internal Revenue Code of 1986, as*
 15 *amended by section 111(b), is further amended*
 16 *by adding at the end the following:*

17 **“SEC. 9814. PROHIBITING PREMIUM DISCRIMINATION**
 18 **AGAINST GROUPS ON THE BASIS OF PRE-**
 19 **DICTIVE GENETIC INFORMATION.**

20 “A group health plan shall not adjust premium or con-
 21 tribution amounts for a group on the basis of predictive
 22 genetic information concerning any individual (including
 23 a dependent) or a family member of the individual (includ-
 24 ing information about a request for or receipt of genetic
 25 services).”.

1 (B) *CONFORMING AMENDMENT.*—Section
 2 9802(b) of the Internal Revenue Code of 1986 is
 3 amended by adding at the end the following:

4 “(3) *REFERENCE TO RELATED PROVISION.*—For
 5 a provision prohibiting the adjustment of premium or
 6 contribution amounts for a group under a group
 7 health plan on the basis of predictive genetic informa-
 8 tion (including information about a request for or the
 9 receipt of genetic services), see section 9814.”.

10 (C) *AMENDMENT TO TABLE OF SECTIONS.*—
 11 The table of sections for subchapter B of chapter
 12 100 of the Internal Revenue Code of 1986, as
 13 amended by section 111(b), is further amended
 14 by adding at the end the following:

“Sec. 9814. Prohibiting premium discrimination against groups on the basis of
 predictive genetic information.”.

15 (b) *LIMITATION ON COLLECTION OF PREDICTIVE GE-*
 16 *NETIC INFORMATION.*—Section 9802 of the Internal Rev-
 17 enue Code of 1986 is amended by adding at the end the
 18 following:

19 “(d) *COLLECTION OF PREDICTIVE GENETIC INFORMA-*
 20 *TION.*—

21 “(1) *LIMITATION ON REQUESTING OR REQUIRING*
 22 *PREDICTIVE GENETIC INFORMATION.*—Except as pro-
 23 vided in paragraph (2), a group health plan shall not
 24 request or require predictive genetic information con-

1 *cerning any individual (including a dependent) or a*
 2 *family member of the individual (including informa-*
 3 *tion about a request for or receipt of genetic services).*

4 *“(2) INFORMATION NEEDED FOR DIAGNOSIS,*
 5 *TREATMENT, OR PAYMENT.—*

6 *“(A) IN GENERAL.—Notwithstanding para-*
 7 *graph (1), a group health plan that provides*
 8 *health care items and services to an individual*
 9 *or dependent may request (but may not require)*
 10 *that such individual or dependent disclose, or*
 11 *authorize the collection or disclosure of, pre-*
 12 *dictive genetic information for purposes of diag-*
 13 *nosis, treatment, or payment relating to the pro-*
 14 *vision of health care items and services to such*
 15 *individual or dependent.*

16 *“(B) NOTICE OF CONFIDENTIALITY PRAC-*
 17 *TICES; DESCRIPTION OF SAFEGUARDS.—As a*
 18 *part of a request under subparagraph (A), the*
 19 *group health plan shall provide to the individual*
 20 *or dependent a description of the procedures in*
 21 *place to safeguard the confidentiality, as de-*
 22 *scribed in subsection (e), of such predictive ge-*
 23 *netic information.*

24 *“(e) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE*
 25 *GENETIC INFORMATION.—*

1 “(1) *NOTICE OF CONFIDENTIALITY PRACTICES.*—

2 “(A) *PREPARATION OF WRITTEN NOTICE.*—

3 *A group health plan shall post or provide, in*
4 *writing and in a clear and conspicuous manner,*
5 *notice of the plan’s confidentiality practices, that*
6 *shall include—*

7 “(i) *a description of an individual’s*
8 *rights with respect to predictive genetic in-*
9 *formation;*

10 “(ii) *the procedures established by the*
11 *plan for the exercise of the individual’s*
12 *rights; and*

13 “(iii) *the right to obtain a copy of the*
14 *notice of the confidentiality practices re-*
15 *quired under this subsection.*

16 “(B) *MODEL NOTICE.*—*The Secretary, in*
17 *consultation with the National Committee on*
18 *Vital and Health Statistics and the National As-*
19 *sociation of Insurance Commissioners, and after*
20 *notice and opportunity for public comment, shall*
21 *develop and disseminate model notices of con-*
22 *fidentiality practices. Use of the model notice*
23 *shall serve as a defense against claims of receiv-*
24 *ing inappropriate notice.*

1 “(2) *ESTABLISHMENT OF SAFEGUARDS.*—A
 2 *group health plan shall establish and maintain ap-*
 3 *propriate administrative, technical, and physical*
 4 *safeguards to protect the confidentiality, security, ac-*
 5 *curacy, and integrity of predictive genetic informa-*
 6 *tion created, received, obtained, maintained, used,*
 7 *transmitted, or disposed of by such plan.”.*

8 (c) *DEFINITIONS.*—Section 9832(d) of the Internal
 9 Revenue Code of 1986 is amended by adding at the end
 10 the following:

11 “(6) *FAMILY MEMBER.*—The term ‘family mem-
 12 ber’ means, with respect to an individual—

13 “(A) *the spouse of the individual;*

14 “(B) *a dependent child of the individual,*
 15 *including a child who is born to or placed for*
 16 *adoption with the individual; and*

17 “(C) *all other individuals related by blood*
 18 *to the individual or the spouse or child described*
 19 *in subparagraph (A) or (B).*

20 “(7) *GENETIC INFORMATION.*—The term ‘genetic
 21 information’ means information about genes, gene
 22 products, or inherited characteristics that may derive
 23 from an individual or a family member (including
 24 information about a request for or receipt of genetic
 25 services).

1 “(8) *GENETIC SERVICES*.—The term ‘genetic
2 services’ means health services provided to obtain, as-
3 sess, or interpret genetic information for diagnostic
4 and therapeutic purposes, and for genetic education
5 and counseling.

6 “(9) *PREDICTIVE GENETIC INFORMATION*.—

7 “(A) *IN GENERAL*.—The term ‘predictive ge-
8 netic information’ means, in the absence of
9 symptoms, clinical signs, or a diagnosis of the
10 condition related to such information—

11 “(i) information about an individual’s
12 genetic tests;

13 “(ii) information about genetic tests of
14 family members of the individual; or

15 “(iii) information about the occurrence
16 of a disease or disorder in family members.

17 “(B) *EXCEPTIONS*.—The term ‘predictive
18 genetic information’ shall not include—

19 “(i) information about the sex or age of
20 the individual;

21 “(ii) information derived from phys-
22 ical tests, such as the chemical, blood, or
23 urine analyses of the individual including
24 cholesterol tests; and

1 “(iii) information about physical
2 exams of the individual.

3 “(10) *GENETIC TEST*.—The term ‘genetic test’
4 means the analysis of human DNA, RNA, chro-
5 mosomes, proteins, and certain metabolites, including
6 analysis of genotypes, mutations, phenotypes, or
7 karyotypes, for the purpose of predicting risk of dis-
8 ease in asymptomatic or undiagnosed individuals.
9 Such term does not include physical tests, such as the
10 chemical, blood, or urine analyses of the individual
11 including cholesterol tests, and physical exams of the
12 individual, in order to detect symptoms, clinical
13 signs, or a diagnosis of disease.”.

14 (d) *EFFECTIVE DATE*.—Except as provided in this sec-
15 tion, this section and the amendments made by this section
16 shall apply with respect to group health plans for plan
17 years beginning after 1 year after the date of the enactment
18 of this Act.

19 **TITLE III—HEALTHCARE** 20 **RESEARCH AND QUALITY**

21 **SEC. 301. SHORT TITLE.**

22 This title may be cited as the “Healthcare Research
23 and Quality Act of 1999”.

1 **SEC. 302. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
 2 **ACT.**

3 *Title IX of the Public Health Service Act (42 U.S.C.*
 4 *299 et seq.) is amended to read as follows:*

5 **“TITLE IX—AGENCY FOR**
 6 **HEALTHCARE RESEARCH AND**
 7 **QUALITY**

8 **“PART A—ESTABLISHMENT AND GENERAL**
 9 **DUTIES**

10 **“SEC. 901. MISSION AND DUTIES.**

11 *“(a) IN GENERAL.—There is established within the*
 12 *Public Health Service an agency to be known as the Agency*
 13 *for Healthcare Research and Quality. In carrying out this*
 14 *subsection, the Secretary shall redesignate the Agency for*
 15 *Health Care Policy and Research as the Agency for*
 16 *Healthcare Research and Quality.*

17 *“(b) MISSION.—The purpose of the Agency is to en-*
 18 *hance the quality, appropriateness, and effectiveness of*
 19 *healthcare services, and access to such services, through the*
 20 *establishment of a broad base of scientific research and*
 21 *through the promotion of improvements in clinical and*
 22 *health system practices, including the prevention of diseases*
 23 *and other health conditions. The Agency shall promote*
 24 *healthcare quality improvement by—*

1 “(1) conducting and supporting research that de-
2 velops and presents scientific evidence regarding all
3 aspects of healthcare, including—

4 “(A) the development and assessment of
5 methods for enhancing patient participation in
6 their own care and for facilitating shared pa-
7 tient-physician decision-making;

8 “(B) the outcomes, effectiveness, and cost-ef-
9 fectiveness of healthcare practices, including pre-
10 ventive measures and long-term care;

11 “(C) existing and innovative technologies;

12 “(D) the costs and utilization of, and access
13 to healthcare;

14 “(E) the ways in which healthcare services
15 are organized, delivered, and financed and the
16 interaction and impact of these factors on the
17 quality of patient care;

18 “(F) methods for measuring quality and
19 strategies for improving quality; and

20 “(G) ways in which patients, consumers,
21 purchasers, and practitioners acquire new infor-
22 mation about best practices and health benefits,
23 the determinants and impact of their use of this
24 information;

1 “(2) synthesizing and disseminating available
 2 scientific evidence for use by patients, consumers,
 3 practitioners, providers, purchasers, policy makers,
 4 and educators; and

5 “(3) advancing private and public efforts to im-
 6 prove healthcare quality.

7 “(c) *REQUIREMENTS WITH RESPECT TO RURAL*
 8 *AREAS AND PRIORITY POPULATIONS.*—*In carrying out sub-*
 9 *section (b), the Director shall undertake and support re-*
 10 *search, demonstration projects, and evaluations with respect*
 11 *to the delivery of health services—*

12 “(1) in rural areas (including frontier areas);

13 “(2) for low-income groups, and minority
 14 groups;

15 “(3) for children;

16 “(4) for elderly; and

17 “(5) for people with special healthcare needs, in-
 18 cluding disabilities, chronic care and end-of-life
 19 healthcare.

20 “(d) *APPOINTMENT OF DIRECTOR.*—*There shall be at*
 21 *the head of the Agency an official to be known as the Direc-*
 22 *tor for Healthcare Research and Quality. The Director shall*
 23 *be appointed by the Secretary. The Secretary, acting*
 24 *through the Director, shall carry out the authorities and*
 25 *duties established in this title.*

1 **“SEC. 902. GENERAL AUTHORITIES.**

2 “(a) *IN GENERAL.*—*In carrying out section 901(b), the*
 3 *Director shall support demonstration projects, conduct and*
 4 *support research, evaluations, training, research networks,*
 5 *multi-disciplinary centers, technical assistance, and the dis-*
 6 *semination of information, on healthcare, and on systems*
 7 *for the delivery of such care, including activities with re-*
 8 *spect to—*

9 “(1) *the quality, effectiveness, efficiency, appro-*
 10 *priateness and value of healthcare services;*

11 “(2) *quality measurement and improvement;*

12 “(3) *the outcomes, cost, cost-effectiveness, and use*
 13 *of healthcare services and access to such services;*

14 “(4) *clinical practice, including primary care*
 15 *and practice-oriented research;*

16 “(5) *healthcare technologies, facilities, and equip-*
 17 *ment;*

18 “(6) *healthcare costs, productivity, organization,*
 19 *and market forces;*

20 “(7) *health promotion and disease prevention,*
 21 *including clinical preventive services;*

22 “(8) *health statistics, surveys, database develop-*
 23 *ment, and epidemiology; and*

24 “(9) *medical liability.*

25 “(b) *HEALTH SERVICES TRAINING GRANTS.*—

1 “(1) *IN GENERAL.*—*The Director may provide*
 2 *training grants in the field of health services research*
 3 *related to activities authorized under subsection (a),*
 4 *to include pre- and post-doctoral fellowships and*
 5 *training programs, young investigator awards, and*
 6 *other programs and activities as appropriate. In car-*
 7 *rying out this subsection, the Director shall make use*
 8 *of funds made available under section 487 as well as*
 9 *other appropriated funds.*

10 “(2) *REQUIREMENTS.*—*In developing priorities*
 11 *for the allocation of training funds under this sub-*
 12 *section, the Director shall take into consideration*
 13 *shortages in the number of trained researchers ad-*
 14 *ressing the priority populations.*

15 “(c) *MULTIDISCIPLINARY CENTERS.*—*The Director*
 16 *may provide financial assistance to assist in meeting the*
 17 *costs of planning and establishing new centers, and oper-*
 18 *ating existing and new centers, for multidisciplinary health*
 19 *services research, demonstration projects, evaluations,*
 20 *training, and policy analysis with respect to the matters*
 21 *referred to in subsection (a).*

22 “(d) *RELATION TO CERTAIN AUTHORITIES REGARD-*
 23 *ING SOCIAL SECURITY.*—*Activities authorized in this sec-*
 24 *tion shall be appropriately coordinated with experiments,*
 25 *demonstration projects, and other related activities author-*

1 ized by the Social Security Act and the Social Security
 2 Amendments of 1967. Activities under subsection (a)(2) of
 3 this section that affect the programs under titles XVIII, XIX
 4 and XXI of the Social Security Act shall be carried out
 5 consistent with section 1142 of such Act.

6 “(e) *DISCLAIMER.*—The Agency shall not mandate na-
 7 tional standards of clinical practice or quality healthcare
 8 standards. Recommendations resulting from projects funded
 9 and published by the Agency shall include a corresponding
 10 disclaimer.

11 “(f) *RULE OF CONSTRUCTION.*—Nothing in this sec-
 12 tion shall be construed to imply that the Agency’s role is
 13 to mandate a national standard or specific approach to
 14 quality measurement and reporting. In research and qual-
 15 ity improvement activities, the Agency shall consider a wide
 16 range of choices, providers, healthcare delivery systems, and
 17 individual preferences.

18 **“PART B—HEALTHCARE IMPROVEMENT**

19 **RESEARCH**

20 **“SEC. 911. HEALTHCARE OUTCOME IMPROVEMENT RE-**
 21 **SEARCH.**

22 “(a) *EVIDENCE RATING SYSTEMS.*—In collaboration
 23 with experts from the public and private sector, the Agency
 24 shall identify and disseminate methods or systems that it
 25 uses to assess healthcare research results, particularly meth-

1 *ods or systems that it uses to rate the strength of the sci-*
 2 *entific evidence behind healthcare practice, recommenda-*
 3 *tions in the research literature, and technology assessments.*
 4 *The Agency shall make methods and systems for evidence*
 5 *rating widely available. Agency publications containing*
 6 *healthcare recommendations shall indicate the level of sub-*
 7 *stantiating evidence using such methods or systems.*

8 “(b) *HEALTHCARE IMPROVEMENT RESEARCH CEN-*
 9 *TERS AND PROVIDER-BASED RESEARCH NETWORKS.—In*
 10 *order to address the full continuum of care and outcomes*
 11 *research, to link research to practice improvement, and to*
 12 *speed the dissemination of research findings to community*
 13 *practice settings, the Agency shall employ research strate-*
 14 *gies and mechanisms that will link research directly with*
 15 *clinical practice in geographically diverse locations*
 16 *throughout the United States, including—*

17 “(1) *Healthcare Improvement Research Centers*
 18 *that combine demonstrated multidisciplinary exper-*
 19 *tise in outcomes or quality improvement research*
 20 *with linkages to relevant sites of care;*

21 “(2) *Provider-based Research Networks, includ-*
 22 *ing plan, facility, or delivery system sites of care (es-*
 23 *pecially primary care), that can evaluate and pro-*
 24 *mote quality improvement; and*

1 “(3) *other innovative mechanisms or strategies to*
 2 *link research with clinical practice.*

3 **“SEC. 912. PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE**
 4 **ORGANIZATION AND DELIVERY.**

5 “(a) *SUPPORT FOR EFFORTS TO DEVELOP INFORMA-*
 6 *TION ON QUALITY.—*

7 “(1) *SCIENTIFIC AND TECHNICAL SUPPORT.—In*
 8 *its role as the principal agency for healthcare research*
 9 *and quality, the Agency may provide scientific and*
 10 *technical support for private and public efforts to im-*
 11 *prove healthcare quality, including the activities of*
 12 *accrediting organizations.*

13 “(2) *ROLE OF THE AGENCY.—With respect to*
 14 *paragraph (1), the role of the Agency shall include—*

15 “(A) *the identification and assessment of*
 16 *methods for the evaluation of the health of—*

17 “(i) *enrollees in health plans by type of*
 18 *plan, provider, and provider arrangements;*
 19 *and*

20 “(ii) *other populations, including those*
 21 *receiving long-term care services;*

22 “(B) *the ongoing development, testing, and*
 23 *dissemination of quality measures, including*
 24 *measures of health and functional outcomes;*

1 “(C) the compilation and dissemination of
2 healthcare quality measures developed in the pri-
3 vate and public sector;

4 “(D) assistance in the development of im-
5 proved healthcare information systems;

6 “(E) the development of survey tools for the
7 purpose of measuring participant and bene-
8 ficiary assessments of their healthcare; and

9 “(F) identifying and disseminating infor-
10 mation on mechanisms for the integration of in-
11 formation on quality into purchaser and con-
12 sumer decision-making processes.

13 “(b) *CENTERS FOR EDUCATION AND RESEARCH ON*
14 *THERAPEUTICS.*—

15 “(1) *IN GENERAL.*—The Secretary, acting
16 through the Director and in consultation with the
17 Commissioner of Food and Drugs, shall establish a
18 program for the purpose of making one or more
19 grants for the establishment and operation of one or
20 more centers to carry out the activities specified in
21 paragraph (2).

22 “(2) *REQUIRED ACTIVITIES.*—The activities re-
23 ferred to in this paragraph are the following:

1 “(A) *The conduct of state-of-the-art clinical,*
2 *laboratory, or health services research for the fol-*
3 *lowing purposes:*

4 “(i) *To increase awareness of—*

5 “(I) *new uses of drugs, biological*
6 *products, and devices;*

7 “(II) *ways to improve the effective*
8 *use of drugs, biological products, and*
9 *devices; and*

10 “(III) *risks of new uses and risks*
11 *of combinations of drugs and biological*
12 *products.*

13 “(ii) *To provide objective clinical in-*
14 *formation to the following individuals and*
15 *entities:*

16 “(I) *Healthcare practitioners and*
17 *other providers of healthcare goods or*
18 *services.*

19 “(II) *Pharmacists, pharmacy ben-*
20 *efit managers and purchasers.*

21 “(III) *Health maintenance orga-*
22 *nizations and other managed*
23 *healthcare organizations.*

24 “(IV) *Healthcare insurers and*
25 *governmental agencies.*

1 “(V) *Patients and consumers.*

2 “(iii) *To improve the quality of*
3 *healthcare while reducing the cost of*
4 *Healthcare through—*

5 “(I) *an increase in the appro-*
6 *prate use of drugs, biological products,*
7 *or devices; and*

8 “(II) *the prevention of adverse ef-*
9 *fects of drugs, biological products, and*
10 *devices and the consequences of such ef-*
11 *fects, such as unnecessary hospitaliza-*
12 *tions.*

13 “(B) *The conduct of research on the com-*
14 *parative effectiveness, cost-effectiveness, and safe-*
15 *ty of drugs, biological products, and devices.*

16 “(C) *Such other activities as the Secretary*
17 *determines to be appropriate, except that grant*
18 *funds may not be used by the Secretary in con-*
19 *ducting regulatory review of new drugs.*

20 “(c) *REDUCING ERRORS IN MEDICINE.—The Director*
21 *shall conduct and support research and build private-public*
22 *partnerships to—*

23 “(1) *identify the causes of preventable healthcare*
24 *errors and patient injury in healthcare delivery;*

1 “(2) develop, demonstrate, and evaluate strate-
 2 gies for reducing errors and improving patient safety;
 3 and

4 “(3) promote the implementation of effective
 5 strategies throughout the healthcare industry.

6 **“SEC. 913. INFORMATION ON QUALITY AND COST OF CARE.**

7 “(a) *IN GENERAL.*—In carrying out 902(a), the Direc-
 8 tor shall—

9 “(1) conduct a survey to collect data on a na-
 10 tionally representative sample of the population on
 11 the cost, use and, for fiscal year 2001 and subsequent
 12 fiscal years, quality of healthcare, including the types
 13 of healthcare services Americans use, their access to
 14 healthcare services, frequency of use, how much is
 15 paid for the services used, the source of those pay-
 16 ments, the types and costs of private health insurance,
 17 access, satisfaction, and quality of care for the general
 18 population including rural residents and for the pop-
 19 ulations identified in section 901(c); and

20 “(2) develop databases and tools that provide in-
 21 formation to States on the quality, access, and use of
 22 healthcare services provided to their residents.

23 “(b) *QUALITY AND OUTCOMES INFORMATION.*—

1 “(1) *IN GENERAL.*—*Beginning in fiscal year*
2 *2001, the Director shall ensure that the survey con-*
3 *ducted under subsection (a)(1) will—*

4 “(A) *identify determinants of health out-*
5 *comes and functional status, and their relation-*
6 *ships to healthcare access and use, determine the*
7 *ways and extent to which the priority popu-*
8 *lations enumerated in section 901(c) differ from*
9 *the general population with respect to such vari-*
10 *ables, measure changes over time with respect to*
11 *such variable, and monitor the overall national*
12 *impact of changes in Federal and State policy*
13 *on healthcare;*

14 “(B) *provide information on the quality of*
15 *care and patient outcomes for frequently occur-*
16 *ring clinical conditions for a nationally rep-*
17 *resentative sample of the population including*
18 *rural residents; and*

19 “(C) *provide reliable national estimates for*
20 *children and persons with special healthcare*
21 *needs through the use of supplements or periodic*
22 *expansions of the survey.*

23 *In expanding the Medical Expenditure Panel Survey,*
24 *as in existence on the date of enactment of this title,*
25 *in fiscal year 2001 to collect information on the qual-*

1 *ity of care, the Director shall take into account any*
 2 *outcomes measurements generally collected by private*
 3 *sector accreditation organizations.*

4 “(2) *ANNUAL REPORT.*—*Beginning in fiscal year*
 5 *2003, the Secretary, acting through the Director, shall*
 6 *submit to Congress an annual report on national*
 7 *trends in the quality of healthcare provided to the*
 8 *American people.*

9 **“SEC. 914. INFORMATION SYSTEMS FOR HEALTHCARE IM-**
 10 **PROVEMENT.**

11 “(a) *IN GENERAL.*—*In order to foster a range of inno-*
 12 *vative approaches to the management and communication*
 13 *of health information, the Agency shall support research,*
 14 *evaluations and initiatives to advance—*

15 “(1) *the use of information systems for the study*
 16 *of healthcare quality, including the generation of both*
 17 *individual provider and plan-level comparative per-*
 18 *formance data;*

19 “(2) *training for healthcare practitioners and re-*
 20 *searchers in the use of information systems;*

21 “(3) *the creation of effective linkages between*
 22 *various sources of health information, including the*
 23 *development of information networks;*

“(5) the utility and comparability of health information data and medical vocabularies by addressing issues related to the content, structure, definitions and coding of such information and data in consultation with appropriate Federal, State and private entities;

“(6) the use of computer-based health records in all settings for the development of personal health records for individual health assessment and maintenance, and for monitoring public health and outcomes of care within populations; and

15 “(7) the protection of individually identifiable
16 information in health services research and healthcare
17 quality improvement.

18 “(b) *DEMONSTRATION.*—*The Agency shall support*
19 *demonstrations into the use of new information tools aimed*
20 *at improving shared decision-making between patients and*
21 *their care-givers.*

22 ***“SEC. 915. RESEARCH SUPPORTING PRIMARY CARE AND AC-***
23 ***CESS IN UNDERSERVED AREAS.***

24 “(a) *PREVENTIVE SERVICES TASK FORCE*.—

1 “(1) *ESTABLISHMENT AND PURPOSE.*—*The Di-*
 2 *rector may periodically convene a Preventive Services*
 3 *Task Force to be composed of individuals with appro-*
 4 *priate expertise. Such a task force shall review the*
 5 *scientific evidence related to the effectiveness, appro-*
 6 *priateness, and cost-effectiveness of clinical preventive*
 7 *services for the purpose of developing recommenda-*
 8 *tions for the healthcare community, and updating*
 9 *previous clinical preventive recommendations.*

10 “(2) *ROLE OF AGENCY.*—*The Agency shall pro-*
 11 *vide ongoing administrative, research, and technical*
 12 *support for the operations of the Preventive Services*
 13 *Task Force, including coordinating and supporting*
 14 *the dissemination of the recommendations of the Task*
 15 *Force.*

16 “(3) *OPERATION.*—*In carrying out its respon-*
 17 *sibilities under paragraph (1), the Task Force is not*
 18 *subject to the provisions of Appendix 2 of title 5,*
 19 *United States Code.*

20 “(b) *PRIMARY CARE RESEARCH.*—

21 “(1) *IN GENERAL.*—*There is established within*
 22 *the Agency a Center for Primary Care Research (re-*
 23 *ferred to in this subsection as the ‘Center’)* *that shall*
 24 *serve as the principal source of funding for primary*
 25 *care practice research in the Department of Health*

1 *and Human Services. For purposes of this paragraph,*
 2 *primary care research focuses on the first contact*
 3 *when illness or health concerns arise, the diagnosis,*
 4 *treatment or referral to specialty care, preventive*
 5 *care, and the relationship between the clinician and*
 6 *the patient in the context of the family and commu-*
 7 *nity.*

8 “(2) *RESEARCH.—In carrying out this section,*
 9 *the Center shall conduct and support research*
 10 *concerning—*

11 “(A) *the nature and characteristics of pri-*
 12 *mary care practice;*

13 “(B) *the management of commonly occur-*
 14 *ring clinical problems;*

15 “(C) *the management of undifferentiated*
 16 *clinical problems; and*

17 “(D) *the continuity and coordination of*
 18 *health services.*

19 **“SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVA-**
 20 **TION.**

21 “(a) *IN GENERAL.—The Director shall promote inno-*
 22 *vation in evidence-based clinical practice and healthcare*
 23 *technologies by—*

1 “(1) *conducting and supporting research on the*
 2 *development, diffusion, and use of healthcare tech-*
 3 *nology;*

4 “(2) *developing, evaluating, and disseminating*
 5 *methodologies for assessments of healthcare practices*
 6 *and healthcare technologies;*

7 “(3) *conducting intramural and supporting ex-*
 8 *tramural assessments of existing and new healthcare*
 9 *practices and technologies;*

10 “(4) *promoting education, training, and pro-*
 11 *viding technical assistance in the use of healthcare*
 12 *practice and healthcare technology assessment meth-*
 13 *odologies and results; and*

14 “(5) *working with the National Library of Medi-*
 15 *cine and the public and private sector to develop an*
 16 *electronic clearinghouse of currently available assess-*
 17 *ments and those in progress.*

18 “(b) *SPECIFICATION OF PROCESS.—*

19 “(1) *IN GENERAL.—Not later than December 31,*
 20 *2000, the Director shall develop and publish a de-*
 21 *scription of the methodology used by the Agency and*
 22 *its contractors in conducting practice and technology*
 23 *assessment.*

24 “(2) *CONSULTATIONS.—In carrying out this sub-*
 25 *section, the Director shall cooperate and consult with*

1 *the Assistant Secretary for Health, the Administrator*
 2 *of the Health Care Financing Administration, the Di-*
 3 *rector of the National Institutes of Health, the Com-*
 4 *missioner of Food and Drugs, and the heads of any*
 5 *other interested Federal department or agency, and*
 6 *shall seek input, where appropriate, from professional*
 7 *societies and other private and public entities.*

8 “(3) *METHODOLOGY.—The Director, in devel-*
 9 *oping assessment methodology, shall consider—*

10 “(A) *safety, efficacy, and effectiveness;*

11 “(B) *legal, social, and ethical implications;*

12 “(C) *costs, benefits, and cost-effectiveness;*

13 “(D) *comparisons to alternate technologies*
 14 *and practices; and*

15 “(E) *requirements of Food and Drug Ad-*
 16 *ministration approval to avoid duplication.*

17 “(c) *SPECIFIC ASSESSMENTS.—*

18 “(1) *IN GENERAL.—The Director shall conduct*
 19 *or support specific assessments of healthcare tech-*
 20 *nologies and practices.*

21 “(2) *REQUESTS FOR ASSESSMENTS.—The Direc-*
 22 *tor is authorized to conduct or support assessments,*
 23 *on a reimbursable basis, for the Health Care Financ-*
 24 *ing Administration, the Department of Defense, the*
 25 *Department of Veterans Affairs, the Office of Per-*

1 sonnel Management, and other public or private enti-
2 ties.

3 “(3) *GRANTS AND CONTRACTS.*—In addition to
4 conducting assessments, the Director may make
5 grants to, or enter into cooperative agreements or con-
6 tracts with, entities described in paragraph (4) for
7 the purpose of conducting assessments of experi-
8 mental, emerging, existing, or potentially outmoded
9 healthcare technologies, and for related activities.

10 “(4) *ELIGIBLE ENTITIES.*—An entity described
11 in this paragraph is an entity that is determined to
12 be appropriate by the Director, including academic
13 medical centers, research institutions and organiza-
14 tions, professional organizations, third party payers,
15 governmental agencies, and consortia of appropriate
16 research entities established for the purpose of con-
17 ducting technology assessments.

18 **“SEC. 917. COORDINATION OF FEDERAL GOVERNMENT**

19 **QUALITY IMPROVEMENT EFFORTS.**

20 “(a) *REQUIREMENT.*—

21 “(1) *IN GENERAL.*—To avoid duplication and
22 ensure that Federal resources are used efficiently and
23 effectively, the Secretary, acting through the Director,
24 shall coordinate all research, evaluations, and dem-
25 onstrations related to health services research, quality

1 *measurement and quality improvement activities un-*
 2 *dertaken and supported by the Federal Government.*

3 “(2) *SPECIFIC ACTIVITIES.*—*The Director, in col-*
 4 *laboration with the appropriate Federal officials rep-*
 5 *resenting all concerned executive agencies and depart-*
 6 *ments, shall develop and manage a process to—*

7 “(A) *improve interagency coordination, pri-*
 8 *ority setting, and the use and sharing of research*
 9 *findings and data pertaining to Federal quality*
 10 *improvement programs, technology assessment,*
 11 *and health services research;*

12 “(B) *strengthen the research information*
 13 *infrastructure, including databases, pertaining*
 14 *to Federal health services research and healthcare*
 15 *quality improvement initiatives;*

16 “(C) *set specific goals for participating*
 17 *agencies and departments to further health serv-*
 18 *ices research and healthcare quality improve-*
 19 *ment; and*

20 “(D) *strengthen the management of Federal*
 21 *healthcare quality improvement programs.*

22 “(b) *STUDY BY THE INSTITUTE OF MEDICINE.*—

23 “(1) *IN GENERAL.*—*To provide Congress, the De-*
 24 *partment of Health and Human Services, and other*
 25 *relevant departments with an independent, external*

1 *review of their quality oversight, quality improvement*
 2 *and quality research programs, the Secretary shall*
 3 *enter into a contract with the Institute of Medicine—*

4 *“(A) to describe and evaluate current qual-*
 5 *ity improvement, quality research and quality*
 6 *monitoring processes through—*

7 *“(i) an overview of pertinent health*
 8 *services research activities and quality im-*
 9 *provement efforts conducted by all Federal*
 10 *programs, with particular attention paid to*
 11 *those under titles XVIII, XIX, and XXI of*
 12 *the Social Security Act; and*

13 *“(ii) a summary of the partnerships*
 14 *that the Department of Health and Human*
 15 *Services has pursued with private accredi-*
 16 *tation, quality measurement and improve-*
 17 *ment organizations; and*

18 *“(B) to identify options and make rec-*
 19 *ommendations to improve the efficiency and ef-*
 20 *fectiveness of quality improvement programs*
 21 *through—*

22 *“(i) the improved coordination of ac-*
 23 *tivities across the medicare, medicaid and*
 24 *child health insurance programs under titles*

XVIII, XIX and XXI of the Social Security Act and health services research programs;

“(ii) the strengthening of patient choice and participation by incorporating state-of-the-art quality monitoring tools and making information on quality available; and

“(iii) the enhancement of the most effective programs, consolidation as appropriate, and elimination of duplicative activities within various federal agencies.

“(2) REQUIREMENTS.—

“(A) IN GENERAL.—The Secretary shall enter into a contract with the Institute of Medicine for the preparation—

“(i) not later than 12 months after the date of enactment of this title, of a report providing an overview of the quality improvement programs of the Department of Health and Human Services for the medicare, medicaid, and CHIP programs under titles XVIII, XIX, and XXI of the Social Security Act; and

“(ii) not later than 24 months after the date of enactment of this title, of a final report containing recommendations.

1 “(B) *REPORTS.*—*The Secretary shall sub-*
 2 *mit the reports described in subparagraph (A) to*
 3 *the Committee on Finance and the Committee on*
 4 *Health, Education, Labor, and Pensions of the*
 5 *Senate and the Committee on Ways and Means*
 6 *and the Committee on Commerce of the House of*
 7 *Representatives.*

8 **“PART C—GENERAL PROVISIONS**

9 **“SEC. 921. ADVISORY COUNCIL FOR HEALTHCARE RE-**
 10 **SEARCH AND QUALITY.**

11 “(a) *ESTABLISHMENT.*—*There is established an advi-*
 12 *sory council to be known as the Advisory Council for*
 13 *Healthcare Research and Quality.*

14 “(b) *DUTIES.*—

15 “(1) *IN GENERAL.*—*The Advisory Council shall*
 16 *advise the Secretary and the Director with respect to*
 17 *activities proposed or undertaken to carry out the*
 18 *purpose of the Agency under section 901(b).*

19 “(2) *CERTAIN RECOMMENDATIONS.*—*Activities of*
 20 *the Advisory Council under paragraph (1) shall in-*
 21 *clude making recommendations to the Director*
 22 *regarding—*

23 “(A) *priorities regarding healthcare re-*
 24 *search, especially studies related to quality, out-*

1 *comes, cost and the utilization of, and access to,*
 2 *healthcare services;*

3 *“(B) the field of healthcare research and re-*
 4 *lated disciplines, especially issues related to*
 5 *training needs, and dissemination of informa-*
 6 *tion pertaining to healthcare quality; and*

7 *“(C) the appropriate role of the Agency in*
 8 *each of these areas in light of private sector ac-*
 9 *tivity and identification of opportunities for*
 10 *public-private sector partnerships.*

11 *“(c) MEMBERSHIP.—*

12 *“(1) IN GENERAL.—The Advisory Council shall,*
 13 *in accordance with this subsection, be composed of ap-*
 14 *pointed members and ex officio members. All members*
 15 *of the Advisory Council shall be voting members other*
 16 *than the individuals designated under paragraph*
 17 *(3)(B) as ex officio members.*

18 *“(2) APPOINTED MEMBERS.—The Secretary shall*
 19 *appoint to the Advisory Council 21 appropriately*
 20 *qualified individuals. At least 17 members of the Ad-*
 21 *visory Council shall be representatives of the public*
 22 *who are not officers or employees of the United States.*
 23 *The Secretary shall ensure that the appointed mem-*
 24 *bers of the Council, as a group, are representative of*
 25 *professions and entities concerned with, or affected by,*

1 *activities under this title and under section 1142 of*
2 *the Social Security Act. Of such members—*

3 *“(A) 4 shall be individuals distinguished in*
4 *the conduct of research, demonstration projects,*
5 *and evaluations with respect to healthcare;*

6 *“(B) 4 shall be individuals distinguished in*
7 *the practice of medicine of which at least 1 shall*
8 *be a primary care practitioner;*

9 *“(C) 3 shall be individuals distinguished in*
10 *the other health professions;*

11 *“(D) 4 shall be individuals either rep-*
12 *resenting the private healthcare sector, including*
13 *health plans, providers, and purchasers or indi-*
14 *viduals distinguished as administrators of*
15 *healthcare delivery systems;*

16 *“(E) 4 shall be individuals distinguished in*
17 *the fields of healthcare quality improvement, eco-*
18 *nomics, information systems, law, ethics, busi-*
19 *ness, or public policy, including at least 1 indi-*
20 *vidual specializing in rural aspects in 1 or more*
21 *of these fields; and*

22 *“(F) 2 shall be individuals representing the*
23 *interests of patients and consumers of healthcare.*

1 “(3) *EX OFFICIO MEMBERS.*—*The Secretary shall*
 2 *designate as ex officio members of the Advisory*
 3 *Council—*

4 “(A) *the Assistant Secretary for Health, the*
 5 *Director of the National Institutes of Health, the*
 6 *Director of the Centers for Disease Control and*
 7 *Prevention, the Administrator of the Health Care*
 8 *Financing Administration, the Assistant Sec-*
 9 *retary of Defense (Health Affairs), and the*
 10 *Under Secretary for Health of the Department of*
 11 *Veterans Affairs; and*

12 “(B) *such other Federal officials as the Sec-*
 13 *retary may consider appropriate.*

14 “(d) *TERMS.*—*Members of the Advisory Council ap-*
 15 *pointed under subsection (c)(2) shall serve for a term of 3*
 16 *years. A member of the Council appointed under such sub-*
 17 *section may continue to serve after the expiration of the*
 18 *term of the members until a successor is appointed.*

19 “(e) *VACANCIES.*—*If a member of the Advisory Council*
 20 *appointed under subsection (c)(2) does not serve the full*
 21 *term applicable under subsection (d), the individual ap-*
 22 *pointed to fill the resulting vacancy shall be appointed for*
 23 *the remainder of the term of the predecessor of the indi-*
 24 *vidual.*

1 “(f) *CHAIR.*—*The Director shall, from among the*
 2 *members of the Advisory Council appointed under sub-*
 3 *section (c)(2), designate an individual to serve as the chair*
 4 *of the Advisory Council.*

5 “(g) *MEETINGS.*—*The Advisory Council shall meet not*
 6 *less than once during each discrete 4-month period and*
 7 *shall otherwise meet at the call of the Director or the chair.*

8 “(h) *COMPENSATION AND REIMBURSEMENT OF EX-*
 9 *PENSES.*—

10 “(1) *APPOINTED MEMBERS.*—*Members of the Ad-*
 11 *visory Council appointed under subsection (c)(2) shall*
 12 *receive compensation for each day (including travel*
 13 *time) engaged in carrying out the duties of the Advi-*
 14 *sory Council unless declined by the member. Such*
 15 *compensation may not be in an amount in excess of*
 16 *the daily equivalent of the annual rate of basic pay*
 17 *prescribed for level IV of the Executive Schedule*
 18 *under section 5315 of title 5, United States Code, for*
 19 *each day during which such member is engaged in the*
 20 *performance of the duties of the Advisory Council.*

21 “(2) *EX OFFICIO MEMBERS.*—*Officials des-*
 22 *ignated under subsection (c)(3) as ex officio members*
 23 *of the Advisory Council may not receive compensation*
 24 *for service on the Advisory Council in addition to the*

1 *compensation otherwise received for duties carried out*
 2 *as officers of the United States.*

3 “(i) *STAFF.*—*The Director shall provide to the Advi-*
 4 *sory Council such staff, information, and other assistance*
 5 *as may be necessary to carry out the duties of the Council.*

6 **“SEC. 922. PEER REVIEW WITH RESPECT TO GRANTS AND**
 7 **CONTRACTS.**

8 “(a) *REQUIREMENT OF REVIEW.*—

9 “(1) *IN GENERAL.*—*Appropriate technical and*
 10 *scientific peer review shall be conducted with respect*
 11 *to each application for a grant, cooperative agree-*
 12 *ment, or contract under this title.*

13 “(2) *REPORTS TO DIRECTOR.*—*Each peer review*
 14 *group to which an application is submitted pursuant*
 15 *to paragraph (1) shall report its finding and rec-*
 16 *ommendations respecting the application to the Direc-*
 17 *tor in such form and in such manner as the Director*
 18 *shall require.*

19 “(b) *APPROVAL AS PRECONDITION OF AWARDS.*—*The*
 20 *Director may not approve an application described in sub-*
 21 *section (a)(1) unless the application is recommended for ap-*
 22 *proval by a peer review group established under subsection*
 23 *(c).*

24 “(c) *ESTABLISHMENT OF PEER REVIEW GROUPS.*—

1 “(1) *IN GENERAL.*—*The Director shall establish*
2 *such technical and scientific peer review groups as*
3 *may be necessary to carry out this section. Such*
4 *groups shall be established without regard to the pro-*
5 *visions of title 5, United States Code, that govern ap-*
6 *pointments in the competitive service, and without re-*
7 *gard to the provisions of chapter 51, and subchapter*
8 *III of chapter 53, of such title that relate to classifica-*
9 *tion and pay rates under the General Schedule.*

10 “(2) *MEMBERSHIP.*—*The members of any peer*
11 *review group established under this section shall be*
12 *appointed from among individuals who by virtue of*
13 *their training or experience are eminently qualified*
14 *to carry out the duties of such peer review group. Of-*
15 *icers and employees of the United States may not*
16 *constitute more than 25 percent of the membership of*
17 *any such group. Such officers and employees may not*
18 *receive compensation for service on such groups in ad-*
19 *dition to the compensation otherwise received for these*
20 *duties carried out as such officers and employees.*

21 “(3) *DURATION.*—*Notwithstanding section 14(a)*
22 *of the Federal Advisory Committee Act, peer review*
23 *groups established under this section may continue in*
24 *existence until otherwise provided by law.*

1 “(4) *QUALIFICATIONS.*—*Members of any peer-re-*
2 *view group shall, at a minimum, meet the following*
3 *requirements:*

4 “(A) *Such members shall agree in writing*
5 *to treat information received, pursuant to their*
6 *work for the group, as confidential information,*
7 *except that this subparagraph shall not apply to*
8 *public records and public information.*

9 “(B) *Such members shall agree in writing*
10 *to recuse themselves from participation in the*
11 *peer-review of specific applications which present*
12 *a potential personal conflict of interest or ap-*
13 *pearance of such conflict, including employment*
14 *in a directly affected organization, stock owner-*
15 *ship, or any financial or other arrangement that*
16 *might introduce bias in the process of peer-re-*
17 *view.*

18 “(d) *AUTHORITY FOR PROCEDURAL ADJUSTMENTS IN*
19 *CERTAIN CASES.*—*In the case of applications for financial*
20 *assistance whose direct costs will not exceed \$100,000, the*
21 *Director may make appropriate adjustments in the proce-*
22 *dures otherwise established by the Director for the conduct*
23 *of peer review under this section. Such adjustments may*
24 *be made for the purpose of encouraging the entry of individ-*
25 *uals into the field of research, for the purpose of encour-*

1 *aging clinical practice-oriented or provider-based research,*
 2 *and for such other purposes as the Director may determine*
 3 *to be appropriate.*

4 “(e) *REGULATIONS.—The Director shall issue regula-*
 5 *tions for the conduct of peer review under this section.*

6 **“SEC. 923. CERTAIN PROVISIONS WITH RESPECT TO DEVEL-**
 7 **OPMENT, COLLECTION, AND DISSEMINATION**
 8 **OF DATA.**

9 “(a) *STANDARDS WITH RESPECT TO UTILITY OF*
 10 *DATA.—*

11 “(1) *IN GENERAL.—To ensure the utility, accu-*
 12 *racy, and sufficiency of data collected by or for the*
 13 *Agency for the purpose described in section 901(b),*
 14 *the Director shall establish standard methods for de-*
 15 *veloping and collecting such data, taking into*
 16 *consideration—*

17 “(A) *other Federal health data collection*
 18 *standards; and*

19 “(B) *the differences between types of*
 20 *healthcare plans, delivery systems, healthcare*
 21 *providers, and provider arrangements.*

22 “(2) *RELATIONSHIP WITH OTHER DEPARTMENT*
 23 *PROGRAMS.—In any case where standards under*
 24 *paragraph (1) may affect the administration of other*
 25 *programs carried out by the Department of Health*

1 *and Human Services, including the programs under*
 2 *title XVIII, XIX or XXI of the Social Security Act,*
 3 *or may affect health information that is subject to a*
 4 *standard developed under part C of title XI of the So-*
 5 *cial Security Act, they shall be in the form of rec-*
 6 *ommendations to the Secretary for such program.*

7 “(b) *STATISTICS AND ANALYSES.—The Director*
 8 *shall—*

9 *“(1) take appropriate action to ensure that sta-*
 10 *tistics and analyses developed under this title are of*
 11 *high quality, timely, and duly comprehensive, and*
 12 *that the statistics are specific, standardized, and ade-*
 13 *quately analyzed and indexed; and*

14 *“(2) publish, make available, and disseminate*
 15 *such statistics and analyses on as wide a basis as is*
 16 *practicable.*

17 “(c) *AUTHORITY REGARDING CERTAIN REQUESTS.—*
 18 *Upon request of a public or private entity, the Director may*
 19 *conduct or support research or analyses otherwise author-*
 20 *ized by this title pursuant to arrangements under which*
 21 *such entity will pay the cost of the services provided.*
 22 *Amounts received by the Director under such arrangements*
 23 *shall be available to the Director for obligation until ex-*
 24 *pended.*

1 **“SEC. 924. DISSEMINATION OF INFORMATION.**

2 “(a) *IN GENERAL.*—*The Director shall—*

3 “(1) *without regard to section 501 of title 44,*
4 *United States Code, promptly publish, make avail-*
5 *able, and otherwise disseminate, in a form under-*
6 *standable and on as broad a basis as practicable so*
7 *as to maximize its use, the results of research, dem-*
8 *onstration projects, and evaluations conducted or sup-*
9 *ported under this title;*

10 “(2) *ensure that information disseminated by the*
11 *Agency is science-based and objective and undertakes*
12 *consultation as necessary to assess the appropriate-*
13 *ness and usefulness of the presentation of information*
14 *that is targeted to specific audiences;*

15 “(3) *promptly make available to the public data*
16 *developed in such research, demonstration projects,*
17 *and evaluations;*

18 “(4) *provide, in collaboration with the National*
19 *Library of Medicine where appropriate, indexing, ab-*
20 *stracting, translating, publishing, and other services*
21 *leading to a more effective and timely dissemination*
22 *of information on research, demonstration projects,*
23 *and evaluations with respect to healthcare to public*
24 *and private entities and individuals engaged in the*
25 *improvement of healthcare delivery and the general*
26 *public, and undertake programs to develop new or*

1 *improved methods for making such information avail-*
2 *able; and*

3 *“(5) as appropriate, provide technical assistance*
4 *to State and local government and health agencies*
5 *and conduct liaison activities to such agencies to fos-*
6 *ter dissemination.*

7 *“(b) PROHIBITION AGAINST RESTRICTIONS.—Except*
8 *as provided in subsection (c), the Director may not restrict*
9 *the publication or dissemination of data from, or the results*
10 *of, projects conducted or supported under this title.*

11 *“(c) LIMITATION ON USE OF CERTAIN INFORMA-*
12 *TION.—No information, if an establishment or person sup-*
13 *plying the information or described in it is identifiable, ob-*
14 *tained in the course of activities undertaken or supported*
15 *under this title may be used for any purpose other than*
16 *the purpose for which it was supplied unless such establish-*
17 *ment or person has consented (as determined under regula-*
18 *tions of the Director) to its use for such other purpose. Such*
19 *information may not be published or released in other form*
20 *if the person who supplied the information or who is de-*
21 *scribed in it is identifiable unless such person has consented*
22 *(as determined under regulations of the Director) to its pub-*
23 *lication or release in other form.*

24 *“(d) PENALTY.—Any person who violates subsection*
25 *(c) shall be subject to a civil monetary penalty of not more*

1 *than \$10,000 for each such violation involved. Such penalty*
 2 *shall be imposed and collected in the same manner as civil*
 3 *money penalties under subsection (a) of section 1128A of*
 4 *the Social Security Act are imposed and collected.*

5 **“SEC. 925. ADDITIONAL PROVISIONS WITH RESPECT TO**
 6 **GRANTS AND CONTRACTS.**

7 *“(a) FINANCIAL CONFLICTS OF INTEREST.—With re-*
 8 *spect to projects for which awards of grants, cooperative*
 9 *agreements, or contracts are authorized to be made under*
 10 *this title, the Director shall by regulation define—*

11 *“(1) the specific circumstances that constitute fi-*
 12 *nancial interests in such projects that will, or may be*
 13 *reasonably expected to, create a bias in favor of ob-*
 14 *taining results in the projects that are consistent with*
 15 *such interests; and*

16 *“(2) the actions that will be taken by the Direc-*
 17 *tor in response to any such interests identified by the*
 18 *Director.*

19 *“(b) REQUIREMENT OF APPLICATION.—The Director*
 20 *may not, with respect to any program under this title au-*
 21 *thorizing the provision of grants, cooperative agreements,*
 22 *or contracts, provide any such financial assistance unless*
 23 *an application for the assistance is submitted to the Sec-*
 24 *retary and the application is in such form, is made in such*
 25 *manner, and contains such agreements, assurances, and in-*

1 *formation as the Director determines to be necessary to*
 2 *carry out the program in involved.*

3 “(c) *PROVISION OF SUPPLIES AND SERVICES IN LIEU*
 4 *OF FUNDS.*—

5 “(1) *IN GENERAL.*—*Upon the request of an enti-*
 6 *ty receiving a grant, cooperative agreement, or con-*
 7 *tract under this title, the Secretary may, subject to*
 8 *paragraph (2), provide supplies, equipment, and serv-*
 9 *ices for the purpose of aiding the entity in carrying*
 10 *out the project involved and, for such purpose, may*
 11 *detail to the entity any officer or employee of the De-*
 12 *partment of Health and Human Services.*

13 “(2) *CORRESPONDING REDUCTION IN FUNDS.*—
 14 *With respect to a request described in paragraph (1),*
 15 *the Secretary shall reduce the amount of the financial*
 16 *assistance involved by an amount equal to the costs*
 17 *of detailing personnel and the fair market value of*
 18 *any supplies, equipment, or services provided by the*
 19 *Director. The Secretary shall, for the payment of ex-*
 20 *penses incurred in complying with such request, ex-*
 21 *pend the amounts withheld.*

22 “(d) *APPLICABILITY OF CERTAIN PROVISIONS WITH*
 23 *RESPECT TO CONTRACTS.*—*Contracts may be entered into*
 24 *under this part without regard to sections 3648 and 3709*
 25 *of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).*

1 **“SEC. 926. CERTAIN ADMINISTRATIVE AUTHORITIES.**

2 “(a) *DEPUTY DIRECTOR AND OTHER OFFICERS AND*
3 *EMPLOYEES.*—

4 “(1) *DEPUTY DIRECTOR.*—*The Director may ap-*
5 *point a deputy director for the Agency.*

6 “(2) *OTHER OFFICERS AND EMPLOYEES.*—*The*
7 *Director may appoint and fix the compensation of*
8 *such officers and employees as may be necessary to*
9 *carry out this title. Except as otherwise provided by*
10 *law, such officers and employees shall be appointed in*
11 *accordance with the civil service laws and their com-*
12 *penetration fixed in accordance with title 5, United*
13 *States Code.*

14 “(b) *FACILITIES.*—*The Secretary, in carrying out this*
15 *title—*

16 “(1) *may acquire, without regard to the Act of*
17 *March 3, 1877 (40 U.S.C. 34), by lease or otherwise*
18 *through the Director of General Services, buildings or*
19 *portions of buildings in the District of Columbia or*
20 *communities located adjacent to the District of Co-*
21 *lumbia for use for a period not to exceed 10 years;*
22 *and*

23 “(2) *may acquire, construct, improve, repair, op-*
24 *erate, and maintain laboratory, research, and other*
25 *necessary facilities and equipment, and such other*

1 *real or personal property (including patents) as the*
2 *Secretary deems necessary.*

3 “(c) *PROVISION OF FINANCIAL ASSISTANCE.—The Di-*
4 *rector, in carrying out this title, may make grants to public*
5 *and nonprofit entities and individuals, and may enter into*
6 *cooperative agreements or contracts with public and private*
7 *entities and individuals.*

8 “(d) *UTILIZATION OF CERTAIN PERSONNEL AND RE-*
9 *SOURCES.—*

10 “(1) *DEPARTMENT OF HEALTH AND HUMAN*
11 *SERVICES.—The Director, in carrying out this title,*
12 *may utilize personnel and equipment, facilities, and*
13 *other physical resources of the Department of Health*
14 *and Human Services, permit appropriate (as deter-*
15 *mined by the Secretary) entities and individuals to*
16 *utilize the physical resources of such Department, and*
17 *provide technical assistance and advice.*

18 “(2) *OTHER AGENCIES.—The Director, in car-*
19 *rying out this title, may use, with their consent, the*
20 *services, equipment, personnel, information, and fa-*
21 *cilities of other Federal, State, or local public agen-*
22 *cies, or of any foreign government, with or without*
23 *reimbursement of such agencies.*

24 “(e) *CONSULTANTS.—The Secretary, in carrying out*
25 *this title, may secure, from time to time and for such peri-*

1 *ods as the Director deems advisable but in accordance with*
 2 *section 3109 of title 5, United States Code, the assistance*
 3 *and advice of consultants from the United States or abroad.*

4 “(f) *EXPERTS.*—

5 “(1) *IN GENERAL.*—*The Secretary may, in car-*
 6 *rying out this title, obtain the services of not more*
 7 *than 50 experts or consultants who have appropriate*
 8 *scientific or professional qualifications. Such experts*
 9 *or consultants shall be obtained in accordance with*
 10 *section 3109 of title 5, United States Code, except that*
 11 *the limitation in such section on the duration of serv-*
 12 *ice shall not apply.*

13 “(2) *TRAVEL EXPENSES.*—

14 “(A) *IN GENERAL.*—*Experts and consult-*
 15 *ants whose services are obtained under para-*
 16 *graph (1) shall be paid or reimbursed for their*
 17 *expenses associated with traveling to and from*
 18 *their assignment location in accordance with sec-*
 19 *tions 5724, 5724a(a), 5724a(c), and 5726(C) of*
 20 *title 5, United States Code.*

21 “(B) *LIMITATION.*—*Expenses specified in*
 22 *subparagraph (A) may not be allowed in connec-*
 23 *tion with the assignment of an expert or consult-*
 24 *ant whose services are obtained under paragraph*
 25 *(1) unless and until the expert agrees in writing*

1 to complete the entire period of assignment, or
2 1 year, whichever is shorter, unless separated or
3 reassigned for reasons that are beyond the con-
4 trol of the expert or consultant and that are ac-
5 ceptable to the Secretary. If the expert or consult-
6 ant violates the agreement, the money spent by
7 the United States for the expenses specified in
8 subparagraph (A) is recoverable from the expert
9 or consultant as a statutory obligation owed to
10 the United States. The Secretary may waive in
11 whole or in part a right of recovery under this
12 subparagraph.

13 “(g) *VOLUNTARY AND UNCOMPENSATED SERVICES.*—
14 The Director, in carrying out this title, may accept vol-
15 untary and uncompensated services.

16 **“SEC. 927. FUNDING.**

17 “(a) *INTENT.*—To ensure that the United States’s in-
18 vestment in biomedical research is rapidly translated into
19 improvements in the quality of patient care, there must be
20 a corresponding investment in research on the most effective
21 clinical and organizational strategies for use of these find-
22 ings in daily practice. The authorization levels in sub-
23 section (b) provide for a proportionate increase in
24 healthcare research as the United States investment in bio-
25 medical research increases.

1 “(b) *AUTHORIZATION OF APPROPRIATIONS.*—For the
 2 purpose of carrying out this title, there are authorized to
 3 be appropriated \$250,000,000 for fiscal year 2000, and such
 4 sums as may be necessary for each of the fiscal years 2001
 5 through 2006.

6 “(c) *EVALUATIONS.*—In addition to amounts available
 7 pursuant to subsection (b) for carrying out this title, there
 8 shall be made available for such purpose, from the amounts
 9 made available pursuant to section 241 (relating to evalua-
 10 tions), an amount equal to 40 percent of the maximum
 11 amount authorized in such section 241 to be made available
 12 for a fiscal year.

13 **“SEC. 928. DEFINITIONS.**

14 *“In this title:*

15 “(1) *ADVISORY COUNCIL.*—The term ‘Advisory
 16 Council’ means the Advisory Council on Healthcare
 17 Research and Quality established under section 921.

18 “(2) *AGENCY.*—The term ‘Agency’ means the
 19 Agency for Healthcare Research and Quality.

20 “(3) *DIRECTOR.*—The term ‘Director’ means the
 21 Director for the Agency for Healthcare Research and
 22 Quality.”.

23 **SEC. 303. REFERENCES.**

24 *Effective upon the date of enactment of this Act, any*
 25 *reference in law to the “Agency for Health Care Policy and*

1 *Research” shall be deemed to be a reference to the “Agency*
 2 *for Healthcare Research and Quality”.*

3 ***TITLE IV—MISCELLANEOUS***
 4 ***PROVISIONS***

5 ***SEC. 401. SENSE OF THE COMMITTEE.***

6 *It is the sense of the Committee on Health, Education,*
 7 *Labor, and Pensions of the Senate that the Congress should*
 8 *take measures to further the purposes of this Act, including*
 9 *any necessary changes to the Internal Revenue Code of 1986*
 10 *or to other Acts to—*

11 *(1) promote equity and prohibit discrimination*
 12 *based on genetic information with respect to the*
 13 *availability of health benefits;*

14 *(2) provide for the full deduction of health insur-*
 15 *ance costs for self-employed individuals;*

16 *(3) provide for the full availability of medical*
 17 *savings accounts;*

18 *(4) provide for the carryover of unused benefits*
 19 *from cafeteria plans, flexible spending arrangements,*
 20 *and health flexible spending accounts; and*

21 *(5) permit contributions towards medical sav-*
 22 *ings account through the Federal employees health*
 23 *benefits program.*