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
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[Report No. 106–82]

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

~~SECTION 1. SHORT TITLE; TABLE OF CONTENTS.~~

~~(a) SHORT TITLE.—This Act may be cited as the "Patients' Bill of Rights Act".~~

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

TITLE I—PATIENTS' BILL OF RIGHTS

Subtitle A—Right to Advice and Care

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

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

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

(2) by inserting after subpart B the following:

"Subpart C—Patient Right to Medical Advice and Care

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

''(a) IN GENERAL.—To the extent that the group health plan (other than a fully insured group health plan) provides coverage for benefits consisting of emergency medical care (as defined in subsection (c)), except for 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

''(2) the plan shall provide coverage for benefits for additional emergency medical care to stabilize an emergency medical condition following an emergency

medical screening examination (if determined necessary under paragraph (1)), pursuant to the definition of stabilize under section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

''(b) UNIFORM COST-SHARING REQUIRED.—Nothing in this section shall be construed as preventing a group health plan (other than a fully insured group health plan) from imposing any form of cost-sharing applicable to any participant or beneficiary (including coinsurance, copayments, deductibles, and any other charges) in relation to coverage for benefits described in subsection (a), if such form of cost-sharing is uniformly applied under such plan, with respect to similarly situated participants and beneficiaries, to all benefits consisting of emergency medical care (as defined in subsection (c)) provided to such similarly situated participants and beneficiaries under the plan.

''(c) DEFINITION OF EMERGENCY MEDICAL CARE.—In this section:

''(1) IN GENERAL.—The term ''emergency medical care'' means, with respect to a participant or beneficiary under a group health plan (other than a fully insured group health plan), covered inpatient and outpatient services that—

''(A) are furnished by any provider, including a nonparticipating provider, that is qualified to furnish such services; and

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

''(2) EMERGENCY MEDICAL CONDITION.—The term ''emergency medical condition'' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

''(A) placing the health of the participant or beneficiary (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

''(B) serious impairment to bodily functions, or

''(C) serious dysfunction of any bodily organ or part.

"SEC. 722. OFFERING OF CHOICE OF COVERAGE OPTIONS.

"(a) REQUIREMENT.—

"(1) OFFERING OF POINT-OF-SERVICE COVERAGE OPTION.—Except as provided in paragraph (2), if a group health plan (other than a fully insured group health plan) provides coverage for benefits only through a defined set of participating health care professionals, the plan shall offer the participant the option to purchase point-of-service coverage (as defined in subsection (b)) for all such benefits for which coverage is otherwise so limited. Such option shall be made available to the participant at the time of enrollment under the plan and at such other times as the plan offers the participant a choice of coverage options.

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

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

"(B) two or more coverage options that differ significantly with respect to the use of

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

''(b) POINT-OF-SERVICE COVERAGE DEFINED.—In this section, the term 'point-of-service coverage' means, with respect to benefits covered under a group health plan (other than a fully insured group health plan), coverage of such benefits when provided by a nonparticipating health care professional.

''(c) SMALL EMPLOYER EXEMPTION.—

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

''(2) SMALL EMPLOYER.—For purposes of paragraph (1), the term 'small employer' means, in connection with a group health plan (other than a fully insured group health plan) with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of this paragraph, the provisions of subparagraph (C) of section 712(c)(1) shall apply in determining employer size.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

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

''(2) as requiring an employer to pay any costs as a result of this section or to make equal contributions with respect to different health coverage options;

''(3) as preventing a group health plan (other than a fully insured group health plan) from imposing higher premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option; or

''(4) to require that a group health plan (other than a fully insured group health plan) include coverage of health care professionals that the plan excludes because of fraud, quality of care, or other similar reasons with respect to such professionals.

''SEC. 723. PATIENT ACCESS TO OBSTETRIC AND GYNECOLOGICAL CARE.

''(a) IN GENERAL.—In any case in which a group health plan (other than a fully insured group health plan)—

''(1) provides coverage for benefits consisting of—

‘‘(A) gynecological care (such as preventive women’s health examinations); or

‘‘(B) obstetric care (such as pregnancy-related services);

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

‘‘(2) requires or provides for designation by a participant or beneficiary of a participating primary care provider;

if the primary care provider designated by such a participant or beneficiary is not such a physician as described in paragraph (1), then the plan shall meet the requirements of subsection (b).

‘‘(b) REQUIREMENTS.—A group health plan (other than a fully insured group health plan) meets the requirements of this subsection, in connection with the coverage of benefits described in subsection (a) consisting of care described in subparagraph (A) or (B) of subsection (a)(1), if the plan—

‘‘(1) does not require authorization or a referral by the primary care provider in order to obtain coverage for such benefits, and

‘‘(2) treats the ordering of other routine care related to the care described in subparagraph (A) or (B) of subsection (a)(1), by the participating physi-

cian providing the care described in either such subparagraph, as the authorization of the primary care provider with respect to such care.

''(c) RULE OF CONSTRUCTION.—Nothing in subsection (b)(2) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of gynecological or obstetric care so ordered. Nothing in subsection (b) shall be construed to preclude the health plan from requiring that the obstetrician or gynecologist notify the primary care provider or the plan of treatment decisions.

''SEC. 724. PATIENT ACCESS TO PEDIATRIC CARE.

''(a) IN GENERAL.—In any case in which a group health plan (other than a fully insured group health plan)—

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

''(2) requires or provides for designation by a participant or beneficiary of a participating primary care provider;

if the primary care provider designated by such a participant or beneficiary is not a physician as described in paragraph (1), then the plan shall meet the requirements of subsection (b).

''(b) REQUIREMENTS.—A group health plan (other than a fully insured group health plan) meets the requirements of this subsection, in connection with the coverage of benefits described in subsection (a) consisting of care described in subsection (a)(1), if the plan—

''(1) does not require authorization or a referral by the primary care provider in order to obtain coverage for such benefits, and

''(2) treats the ordering of other routine care of the same type, by the participating physician providing the care described in subsection (a)(1), as the authorization of the primary care provider with respect to such care.

''(c) CONSTRUCTION.—Nothing in subsection (b)(2) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of pediatric care so ordered.

''SEC. 725. CONTINUITY OF CARE.

''(a) IN GENERAL.—

''(1) TERMINATION OF PROVIDER.—If a contract between a group health plan (other than a fully insured group health plan) and a health care provider is terminated (as defined in paragraph (2)), or benefits or coverage provided by a health care provider are terminated because of a change in the

terms of provider participation in such group health plan, and an individual who is a participant or beneficiary in the plan is undergoing a course of treatment from the provider at the time of such termination, the plan shall—

"(A) notify the individual on a timely basis of such termination;

"(B) provide the individual with an opportunity to notify the plan of a need for transitional care; and

"(C) in the case of termination described in paragraph (2), (3), or (4) of subsection (b), and subject to subsection (c), permit the individual to continue or be covered with respect to the course of treatment with the provider's consent during a transitional period (as provided under subsection (b)).

"(2) TERMINATED.—In this section, the term 'terminated' includes, with respect to a contract, the expiration or nonrenewal of the contract by the group health plan, but does not include a termination of the contract by the plan for failure to meet applicable quality standards or for fraud.

"(3) CONTRACTS.—For purposes of this section, the term 'contract between a group health plan

(other than a fully insured group health plan) and a health care provider' shall include a contract between such a plan and an organized network of providers.

''(b) TRANSITIONAL PERIOD.—

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

''(2) INSTITUTIONAL CARE.—Subject to paragraph (1), the transitional period under this subsection for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutionalization and also shall include institutional care provided within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

''(3) PREGNANCY.—Notwithstanding paragraph (1), if—

"(A) a participant or beneficiary has entered the second trimester of pregnancy at the time of a provider's termination of participation; and

"(B) the provider was treating the pregnancy before the date of the termination;

the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

"(4) TERMINAL ILLNESS.—Subject to paragraph (1), if—

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

"(B) the provider was treating the terminal illness before the date of termination;

the transitional period under this subsection shall be for care directly related to the treatment of the terminal illness.

"(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan (other than a fully insured group health plan) may condition coverage of continued treatment by

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

''(1) The provider agrees to accept reimbursement from the plan and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in subsection (b)(2), at the rates applicable under the replacement plan after the date of the termination of the contract with the group health plan) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

''(2) The provider agrees to adhere to the quality assurance standards of the plan responsible for payment under paragraph (1) and to provide to such plan necessary medical information related to the care provided.

''(3) The provider agrees otherwise to adhere to such plan's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan.

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

''(e) DEFINITION.—In this section, the term 'health care provider' or 'provider' means—

''(1) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State; and

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

''SEC. 726. PROTECTION OF PATIENT-PROVIDER COMMUNICATIONS.

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

the condition or disease of the participant or beneficiary, regardless of whether coverage for such care or treatment are provided under the contract, if the professional is acting within the lawful scope of practice.

''(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as requiring a group health plan (other than a fully insured group health plan) to provide specific benefits under the terms of such plan.

''SEC. 727. GENERALLY APPLICABLE PROVISION.

''In the case of a group health plan that provides benefits under 2 or more coverage options, the requirements of sections 721, 723, 724, 725 and 726 shall apply separately with respect to each coverage option.''.

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

''(3) FULLY INSURED GROUP HEALTH PLAN.—The term 'fully insured group health plan' means a group health plan where benefits are provided pursuant to the terms of an arrangement between a group health plan and a health insurance issuer and are guaranteed by the health insurance issuer under a contract or policy of insurance.''.

(c) CONFORMING AMENDMENT.—The table of contents in section 1 of such Act is amended—

(1) in the item relating to subpart C, by striking ''Subpart C'' and inserting ''Subpart D''; and

(2) by adding at the end of the items relating to subpart B of part 7 of subtitle B of title I of such 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.''.

SEC. 102. EFFECTIVE DATE AND RELATED RULES.

(a) IN GENERAL.—The amendments made by this subtitle shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act. The Secretary shall issue all regulations necessary to carry out the amendments made by this section before the effective date thereof.

(b) LIMITATION ON ENFORCEMENT ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this subtitle, against a group health plan with respect to a violation of a requirement imposed by such amendments before the date of issuance of regulations issued in connection with such requirement, if the plan has sought to comply in good faith with such requirement.

Subtitle B—Right to Information About Plans and Providers

SEC. 111. INFORMATION ABOUT PLANS.

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

"SEC. 714. HEALTH PLAN COMPARATIVE INFORMATION.

"(a) REQUIREMENT.—A group health plan, or health insurance issuer in connection with group health insurance coverage, shall, not later than 12 months after the date of enactment of this section, provide for the disclosure, in a clear and accurate form to each enrollee, or upon request to a potential enrollee eligible to receive benefits under the plan, or plan sponsor with which the plan or issuer has contracted, of the information described in subsection (b).

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

"(1) A description of the covered items and services under each such plan and any in- and out-of-network features of each such plan.

~~"(2) A description of any cost-sharing, including premiums, deductibles, coinsurance, and copayment amounts, for which the enrollee will be responsible, including any annual or lifetime limits on benefits, for each such plan.~~

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

~~"(4) A description of any restrictions on payments for services furnished to an enrollee by a health care professional that is not a participating professional and the liability of the enrollee for additional payments for these services.~~

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

~~"(6) A description of the extent to which enrollees may select the primary care provider of their choice, including providers both within the network and outside the network of each such plan (if the plan permits out-of-network services).~~

~~"(7) A description of the procedures for advance directives and organ donation decisions if the plan maintains such procedures.~~

"(8) A description of the requirements and procedures to be used to obtain preauthorization for health services (including telephone numbers and mailing addresses), including referrals for specialty care.

"(9) A summary of the rules and methods for appealing coverage decisions and filing grievances (including telephone numbers and mailing addresses), as well as other available remedies.

"(10) A summary of the rules for access to emergency room care. Also, any available educational material regarding proper use of emergency services.

"(11) A description of whether or not coverage is provided for experimental treatments, investigational treatments, or clinical trials and the circumstances under which access to such treatments or trials is made available.

"(12) A description of the specific preventative services covered under the plan if such services are covered.

"(13) A statement regarding—

"(A) the manner in which an enrollee may access an obstetrician, gynecologist, or pediatrician in accordance with section 723 or 724;

"(B) the manner in which an enrollee obtains continuity of care as provided for in section 725; and

"(C) the manner in which an enrollee has access to the medical records of the enrollee in accordance with subtitle A of title H of the Patients' Bill of Rights Act.

"(14) A statement that the following information, and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request.

"(A) The names, addresses, telephone numbers, and State licensure status of the plan's participating health care professionals and participating health care facilities, and, if available, the education, training, speciality qualifications or certifications of such professionals.

"(B) A summary description of the methods used for compensating participating health care professionals, such as capitation, fee-for-service, salary, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide infor-

mation concerning proprietary payment methodology.

''(C) A summary description of the methods used for compensating health care facilities, including per diem, fee-for-service, capitation, bundled payments, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

''(D) A summary description of the procedures used for utilization review.

''(E) The list of the specific prescription medications included in the formulary of the plan, if the plan uses a defined formulary, and any provision for obtaining off-formulary medications.

''(F) A description of the specific exclusions from coverage under the plan.

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

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

"(c) MANNER OF DISTRIBUTION.—

"(1) IN GENERAL.—The information described in this section shall be distributed in an accessible format that is understandable to an average plan enrollee.

"(2) RULE OF CONSTRUCTION.—For purposes of this section, a group health plan, or health insurance issuer in connection with group health insurance coverage, in reliance on records maintained by the plan or issuer, shall be deemed to have met the requirements of this section if the plan or issuer provides the information requested under this section—

"(A) in the case of the plan, to participants and beneficiaries at the address contained in such records with respect to such participants and beneficiaries; or

"(B) in the case of the issuer, to the employer of a participant if the employer provides for the coverage of such participant under the plan involved or to participants and bene-

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

''(d) RULE OF CONSTRUCTION.—Nothing in this section may be construed to prohibit a group health plan, or health insurance issuer in connection with group health insurance coverage, from distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants and beneficiaries enrollees or upon request potential participants in the selection of a health plan or from providing information under subsection (b)(13) as part of the required information.

''(e) HEALTH CARE PROFESSIONAL.—In this section, the term 'health care professional' means a physician (as defined in section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional's services is provided under the health plan involved for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), li-

censed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.''.

(b) CONFORMING AMENDMENTS.—

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

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

''Sec. 714. Health plan comparative information.''.

SEC. 112. INFORMATION ABOUT PROVIDERS.

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

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

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

(3) recommendations for the disclosure of information on health care professionals, including the competencies and professional qualifications of such practitioners, to better facilitate patient choice, quality improvement, and market competition.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall forward to the appropriate committees 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.—

''(A) IN GENERAL.—A group health plan or health insurance issuer conducting utilization review shall ensure that procedures are in place for—

''(i) making determinations regarding whether an enrollee is eligible to receive a payment or coverage for health services under the plan or coverage involved and any cost-sharing amount that the enrollee is required to pay with respect to such service;

''(ii) notifying covered enrollees (or the legal representative of such enrollees) and the treating health care professionals involved regarding determinations made under the plan or issuer and any addi-

tional payments that the enrollee may be required to make with respect to such service; and

"(iii) responding to requests, either written or oral, for coverage determinations or for internal appeals from an enrollee (or the legal representative of such enrollee) or the treating health care professional.

"(B) ORAL REQUESTS.—With respect to an oral request described in subparagraph (A)(iii), a group health plan or health insurance issuer may require that the requesting individual provide written evidence of such request.

"(2) TIMELINE FOR MAKING DETERMINATIONS.—

"(A) ROUTINE DETERMINATION.—A group health plan or a health insurance issuer shall maintain procedures to ensure that prior authorization determinations concerning the provision of non-emergency items or services are made within 30 days from the date on which the request for a determination is submitted, except that such period may be extended where 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

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

"(C) CONCURRENT DETERMINATIONS.—A plan or issuer shall maintain procedures to certify or deny coverage of an extended stay or additional services.

"(D) RETROSPECTIVE DETERMINATION.—A plan or issuer shall maintain procedures to ensure that, with respect to the retrospective review of a determination made under paragraph (1), the determination shall be made within 30 working days of the date on which the plan or issuer receives all necessary information.

"(3) NOTICE OF DETERMINATIONS.—

"(A) ROUTINE DETERMINATION.—With respect to a coverage determination of a plan or issuer under paragraph (2)(A), the plan or issuer shall issue notice of such determination to the enrollee (or the legal representative of the enrollee), and consistent with the medical exigencies of the case, to the treating health care professional involved not later than 2 working days after the date on which the determination is made.

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

"(C) CONCURRENT REVIEWS.—With respect to the determination under a plan or issuer under paragraph (1) to certify or deny coverage of an extended stay or additional services, the plan or issuer shall issue notice of such determination to the treating health care professional and to the enrollee involved (or the legal representative of the enrollee) within 1 working day of the date on which the initial notice was issued.

"(D) RETROSPECTIVE REVIEWS.—With respect to the retrospective review under a plan or issuer of a determination made under paragraph (1), a determination shall be made within 30 working days of the date on which the plan 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

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

''(c) GRIEVANCES.—A group health plan or a health insurance issuer shall have written procedures for addressing grievances between the plan and enrollees. Determinations under such procedures shall be non-appealable.

''(d) INTERNAL APPEAL OF COVERAGE DETERMINATIONS.—

''(1) IN GENERAL.—An enrollee (or the legal representative of the enrollee) and the treating health care professional with the consent of the enrollee (or the legal representative of the enrollee), may appeal any adverse coverage determination under subsection (b) under the procedures described in this subsection.

''(2) RECORDS.—A group health plan and a health insurance issuer shall maintain written records, for at least 6 years, with respect to any appeal under this subsection for purposes of internal quality assurance and improvement.

''(3) ROUTINE DETERMINATIONS.—A group health plan or a health insurance issuer shall provide for the consideration of an appeal of an adverse routine determination under this subsection not later

than 30 working days after the date on which a request for such appeal is received.

"(4) EXPEDITED DETERMINATION.—

"(A) IN GENERAL.—An expedited determination with respect to an appeal under this subsection shall be made in accordance with the medical exigencies of the case, but in no case more than 72 hours after the request for such appeal is received by the plan or issuer under subparagraph (B) or (C).

"(B) 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.

"(C) 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 the procedures described in paragraph (2) could seriously jeopardize the life or health of the enrollee.

"(5) CONDUCT OF REVIEW.—A review of an adverse coverage determination under this subsection shall be conducted by an individual with appropriate expertise who was not involved in the initial determination.

"(6) LACK OF MEDICAL NECESSITY.—A review of an appeal under this subsection relating to a determination to deny coverage based on a lack of medical necessity or appropriateness, or based on an experimental or investigational treatment, shall be made only by a physician with appropriate expertise in the field of medicine involved who was not involved in the initial determination.

"(7) NOTICE.—

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

"(B) ADVERSE COVERAGE DETERMINATIONS.—With respect to an adverse coverage determination made under this subsection, the notice described in subparagraph (A) 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 an external review under subsection (c) and instructions on how to initiate such a review.

"(c) EXTERNAL REVIEW.—

"(1) IN GENERAL.—A group health plan or a health insurance issuer shall have written procedures to permit an enrollee (or the legal representative of the enrollee) access to an external review with respect to a coverage determination concerning a particular item or service where—

"(A) the particular item or service involved, when medically appropriate and necessary, is a covered benefit under the terms and conditions of the contract between the plan or issuer and the enrollee;

"(B) the coverage determination involved denied coverage for such item or service because the provision of such item or service—

"(i) does not meet the plan's or issuer's requirements for medical appropriateness or necessity and the amount involved exceeds a significant financial threshold; or

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

"(C) the enrollee has completed the internal appeals process with respect to such determination.

"(2) INITIATION OF THE EXTERNAL REVIEW PROCESS.—

"(A) FILING OF REQUEST.—An enrollee (or the legal representative of the enrollee) who 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

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

''(D) NOTIFICATION.—The plan or issuer involved shall send a written notification to the enrollee (or the legal representative of the enrollee) and the plan administrator, indicating that an external review has been initiated.

''(3) CONDUCT OF EXTERNAL REVIEW.—

''(A) DESIGNATION OF EXTERNAL APPEALS ENTITY BY PLAN OR ISSUER.—A plan or issuer that receives a request for an external review under paragraph (2)(A) shall designate one of the following entities to serve as the external appeals entity:

''(i) An external review entity licensed or credentialed by a State.

''(ii) A State agency established for the purpose of conducting independent external reviews.

''(iii) Any entity under contract with the Federal Government to provide external review services.

''(iv) Any entity accredited as an external review entity by an accrediting body

recognized by the Secretary for such purpose.

''(v) Any fully accredited teaching hospital.

''(vi) Any other entity meeting criteria established by the Secretary for purposes of this subparagraph.

''(B) DESIGNATION OF EXTERNAL REVIEWER BY EXTERNAL APPEALS ENTITY.—The external appeals entity designated under subparagraph (A) shall, not later than 30 days after the date on which such entity is designated under subparagraph (A), or earlier in accordance with the medical exigencies of the case, designate one or more individuals to serve as external reviewers with respect to a request received under paragraph (2)(A). Such reviewers shall be independent medical experts who shall—

''(i) be appropriately credentialed or licensed in any State to deliver health care services;

''(ii) not have any material, professional, familial, or financial affiliation with the case under review, the enrollee in-

volved, the treating health care professional, the institution where the treatment would take place, or the manufacturer of any drug, device, procedure, or other therapy proposed for the enrollee whose treatment is under review;

''(iii) be experts in the diagnosis or treatment under review and, when reasonably available, be of the same speciality of the physician prescribing the treatment in question;

''(iv) receive only reasonable and customary compensation from the group health plan or health insurance issuer in connection with the external review that is not contingent on the decision rendered by the reviewer; and

''(v) not be held liable for decisions regarding medical determinations (but may be held liable for actions that are arbitrary and capricious).

''(4) STANDARD OF REVIEW.—

''(A) IN GENERAL.—An external reviewer shall—

"(i) make a determination based on the medical necessity, appropriateness, experimental or investigational nature of the coverage denial;

"(ii) take into consideration any evidence-based decision making or clinical practice guidelines used by the group health plan or health insurance issuer in conducting utilization review; and

"(iii) submit a report on the final determinations of the review involved to—

"(I) the plan or issuer involved;

"(II) the enrollee involved (or the legal representative of the enrollee); and

"(III) the health care professional involved.

"(B) NOTICE.—The plan or issuer involved shall ensure that the enrollee receives notice, within 30 days after the determination of the independent medical expert, regarding the actions of the plan or issuer with respect to the determination of such expert under the external review.

"(5) TIMEFRAME FOR REVIEW.—

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

"(B) LIMITATION.—Notwithstanding subparagraph (A), a review described in such subparagraph shall be completed not later than 30 working days after the later of—

"(i) the date on which such reviewer is designated; or

"(ii) the date on which all information necessary to completing such review is received.

"(6) BINDING DETERMINATION.—The determination of an external reviewer under this subsection shall be binding upon the plan or issuer if the provisions of this subsection or the procedures implemented under such provisions were complied with by the external reviewer.

"(7) STUDY.—Not later than 2 years after the date of enactment of this section, the General Accounting Office shall conduct a study of a statistically appropriate sample of completed external reviews. Such study shall include an assessment of the process involved during an external review and the

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

''(8) EFFECT ON CERTAIN PROVISIONS.—Nothing in this section shall be construed as affecting or modifying section 514 of this Act with respect to a group health plan.

''(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a plan administrator or plan fiduciary or health plan medical director from requesting an external review by an external reviewer without first completing the internal review process.

''(g) DEFINITIONS.—In this section:

''(1) ADVERSE COVERAGE DETERMINATION.—The term 'adverse coverage determination' means a coverage determination under the plan which results in a denial of coverage or reimbursement.

''(2) COVERAGE DETERMINATION.—The term 'coverage determination' means with respect to items and services for which coverage may be provided under a health plan, a determination of whether or not such items and services are covered or reimbursable under the coverage and terms of the contract.

''(3) ENROLLEE.—The term enrollee means a participant or beneficiary.

''(4) GRIEVANCE.—The term 'grievance' means any enrollee complaint that does not involve a coverage determination.

''(5) GROUP HEALTH PLAN.—The term 'group health plan' shall have the meaning given such term in section 733(a). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

''(6) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning given such term in section 733(b)(1). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

''(7) HEALTH INSURER.—The term 'health insurer' means an insurance company, insurance service, or an insurance organization that meets the requirements of section 733(b)(2) and that offers health insurance coverage in connection with a group health plan.

''(8) PRIOR AUTHORIZATION DETERMINATION.—The term 'prior authorization determination' means a coverage determination prior to the provision of the items and services as a condition of coverage of the items and services under the coverage.

''(9) TREATING HEALTH CARE PROFESSIONAL.—The term 'treating health care professional' with respect to a group health plan, health insurance issuer or provider sponsored organization means a practitioner who is acting within the scope of their State licensure or certification for the delivery of health care services and who is primarily responsible for delivering those services to the enrollee.

''(10) UTILIZATION REVIEW.—The term 'utilization review' with respect to a group health plan or health insurance coverage means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning or retrospective review.''

(b) ENFORCEMENT.—Section 502(c)(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(c)(1)) is amended by inserting after ''or section 101(c)(1)'' the following: '', or fails to comply with a coverage determination as required under section 503(c)(6),''.

(c) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by striking the item relating to section 503 and inserting the following new item:

"Sec. 503. Claims procedures, coverage determination, grievances and appeals.".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after 1 year after the date of enactment of this Act. The Secretary shall issue all regulations necessary to carry out the amendments made by this section before the effective date thereof.

TITLE II—INDIVIDUAL RIGHTS WITH RESPECT TO PERSONAL MEDICAL INFORMATION

SEC. 201. SHORT TITLE.

This title may be cited as the "Personal Medical Information Access Act".

Subtitle A—Access to Medical Records

SEC. 211. INSPECTION AND COPYING OF PROTECTED HEALTH INFORMATION.

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

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

~~(b) EXCEPTIONS.—Unless ordered by a court of competent jurisdiction, an entity described in subsection (a) is not required to permit the inspection or copying of protected health information if any of the following conditions are met:~~

~~(1) ENDANGERMENT TO LIFE OR SAFETY.—The entity determines that the disclosure of the information could reasonably be expected to endanger the life or physical safety of an individual.~~

~~(2) CONFIDENTIAL SOURCE.—The information identifies, or could reasonably lead to the identification of, a person who provided information under a promise of confidentiality concerning the individual who is the subject of the information.~~

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

(A) in the reasonable anticipation of a civil, criminal, or administrative action or proceeding; or

(B) for use in such an action or proceeding.

(4) RESEARCH PURPOSES.—The information was collected for a research project monitored by an institutional review board, such project is not complete, and the researcher involved reasonably believes that access to such information would harm the conduct of the research or invalidate or undermine the validity of the research.

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

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

(2) any procedures for further review of the denial; and

(3) the individual's right to file with the entity a concise statement setting forth the request for inspection or copying.

(d) STATEMENT REGARDING REQUEST.—If an individual has filed a statement under subsection (c)(3), the

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

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

(2) a concise statement of the reasons for denying the request for inspection or copying.

(e) INSPECTION AND COPYING OF SEGREGABLE PORTION.—An entity described in subsection (a) shall permit the inspection and copying under subsection (a) of any reasonably segregable portion of protected health information after deletion of any portion that is exempt under subsection (b).

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

(g) RULES GOVERNING AGENTS.—An agent of an entity described in subsection (a) shall not be required to provide for the inspection and copying of protected health information, except where—

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

(2) the agent has received in writing a request from the entity involved to fulfill the requirements of this section;

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

(h) RULE OF CONSTRUCTION.—This section shall not be construed to require an entity described in subsection (a) to conduct a formal, informal, or other hearing or proceeding concerning a request for inspection or copying of protected health information.

SEC. 212. AMENDMENT OF PROTECTED HEALTH INFORMATION.

(a) REQUIREMENT.—

(1) IN GENERAL.—Except as provided in subsection (b) and subject to paragraph (2), a health care provider, health plan, employer, health or life insurer, school, or university that receives from an individual a request in writing to amend protected health information shall—

(A) amend such information as requested;

(B) inform the individual of the amendment that has been made; and

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

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

(A) created the protected health information involved; and

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

(b) REFUSAL TO AMEND.—If an entity described in subsection (a) refuses to make the amendment requested under such subsection, the entity shall inform the individual in writing of—

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

(2) any procedures for further review of the refusal; and

(3) the individual's right to file with the entity a concise statement setting forth the requested amendment and the individual's reasons for disagreeing with the refusal.

(c) STATEMENT OF DISAGREEMENT.—If an individual has filed a statement of disagreement under subsection (b)(3), the entity involved, in any subsequent disclosure of the disputed portion of the information—

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

(2) may include a concise statement of the reasons for not making the requested amendment.

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

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

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

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

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

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

(1) require that an entity described in subsection (a) conduct a formal, informal, or other hearing or proceeding concerning a request for an amendment to protected health information;

(2) require a provider to amend an individual's protected health information as to the type, duration, or quality of treatment the individual believes he or she should have been provided; or

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

SEC. 213. NOTICE OF CONFIDENTIALITY PRACTICES.

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

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

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

(3) the right to obtain a copy of the notice of the confidentiality practices required under this subtitle.

(b) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

Subtitle B—Establishment of Safeguards

SEC. 221. ESTABLISHMENT OF SAFEGUARDS.

A health care provider, health plan, health oversight agency, public health authority, employer, health or life insurer, health researcher, law enforcement official, school or university shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of protected health information created, received, obtained, maintained, used, transmitted, or disposed of by such entity.

Subtitle C—Enforcement; Definitions

SEC. 231. CIVIL PENALTY.

(a) VIOLATION.—A health care provider, health researcher, health plan, health oversight agency, public

health agency, law enforcement agency, employer, health or life insurer, school, or university, or the agent of any such individual or entity, who the Secretary, in consultation with the Attorney General, determines has substantially and materially failed to comply with this Act shall, for a violation of this title, be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not more than $500 for each such violation, but not to exceed $5,000 in the aggregate for multiple violations.

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

SEC. 232. DEFINITIONS.

In this title:

(1) AGENT.—The term ''agent'' means a person who represents and acts for another under the contract or relation of agency, or whose function is to bring about, modify, affect, accept performance of, or terminate contractual obligations between the principal and a third person, including a contractor.

(2) DISCLOSE.—The term ''disclose'' means to release, transfer, provide access to, or otherwise divulge protected health information to any person other than the individual who is the subject of such information. Such term includes the initial disclosure and any subsequent rediscloures of protected health information.

(3) EMPLOYER.—The term ''employer'' has the meaning given such term under section 3(5) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(5)), except that such term shall include only employers of 2 or more employees.

(4) HEALTH CARE PROVIDER.—The term ''health care provider'' means a person who, with respect to a specific item of protected health information, receives, creates, uses, maintains, or discloses the information while acting in whole or in part in the capacity of—

(A) a person who is licensed, certified, registered, or otherwise authorized by Federal or State law to provide an item or service that constitutes health care in the ordinary course of business, or practice of a profession;

(B) a Federal, State, or employer-sponsored program that directly provides items or

services that constitute health care to beneficiaries; or

(C) an officer, employee, or agent of a person described in subparagraph (A) or (B).

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

(6) HEALTH PLAN.—The term ''health plan'' means any health insurance plan, including any hospital or medical service plan, dental or other health service plan or health maintenance organization plan, provider sponsored organization, or other program providing or arranging for the provision of health benefits, whether or not funded through the purchase of insurance.

(7) PERSON.—The term ''person'' means a government, governmental subdivision, agency or authority; corporation; company; association; firm; partnership; society; estate; trust; joint venture; individual; individual representative; tribal government; and any other legal entity.

(8) PROTECTED HEALTH INFORMATION.—The term ''protected health information'' means any information (including demographic information) whether or not recorded in any form or medium—

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

(i) physical or mental health or condition of an individual (including the condition or other attributes of individual cells or their components);

(ii) provision of health care to an individual; or

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

(B) that is created by a health care provider, health plan, health researcher, health oversight agency, public health authority, employer, law enforcement official, health or life insurer, school or university; and

(C) that is not nonidentifiable health information.

(9) SCHOOL OR UNIVERSITY.—The term ''school or university'' means an institution or place for instruction or education, including an elementary school, secondary school, or institution of higher

learning, a college, or an assemblage of colleges united under one corporate organization or government.

(10) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(11) WRITING.—The term ''writing'' means writing in either a paper-based or computer-based form, including electronic signatures.

SEC. 233. EFFECTIVE DATE.

The provisions of this title shall become effective beginning on the date that is 1 year after the date of enactment of this Act. The Secretary shall issue regulations necessary to carry out this title before the effective date thereof.

TITLE III—GENETIC INFORMATION AND SERVICES

SEC. 301. SHORT TITLE.

This title may be cited as the ''Genetic Information Nondiscrimination in Health Insurance Act of 1999''.

SEC. 302. AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

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

(1) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 702(a)(1)(F) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(a)(1)(F)) is amended by inserting before the period the following: ''(including information about a request for or receipt of genetic services)''.

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

''SEC. 714. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

''A group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning an individual in the group or a family member of the individual (including information about a request for or receipt of genetic services).''.

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

"(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 714.".

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

"(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require predictive genetic information concerning an individual or a family member of the individual (including information about a request for or receipt of genetic services).

''(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

''(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan or health insurance issuer that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

''(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan or health insurance issuer shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in sections 213 and 221 of the Patients' Bill of Rights Act, of such individually identifiable information.''.

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

"(5) FAMILY MEMBER.—The term 'family member' means with respect to an individual—

"(A) the spouse of the individual;

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

"(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

"(6) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

"(7) GENETIC SERVICES.—The term 'genetic services' means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

"(8) PREDICTIVE GENETIC INFORMATION.—

''(A) IN GENERAL.—The term 'predictive genetic information' means—

''(i) information about an individual's genetic tests which are associated with a statistically significant increased risk of developing a disease or disorder;

''(ii) information about genetic tests of family members of the individual; or

''(iii) information about the occurrence of a disease or disorder in family members that predicts a statistically significant increased risk of a disease or disorder in the individual.

''(B) EXCEPTIONS.—The term 'predictive genetic information' shall not include—

''(i) information about the sex or age of the individual;

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

''(iii) information about physical exams of the individual and other information relevant to determining the current health status of the individual so long as

such information does not include information described in clauses (i), (ii), or (iii) of subparagraph (A).

''(9) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, in order to detect disease-related genotypes, mutations, phenotypes, or karyotypes.''.

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

SEC. 303. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.

(a) AMENDMENTS RELATING TO THE GROUP MARKET.—

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

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

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

"SEC. 2707. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION IN THE GROUP MARKET.

"A group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning an individual in the group or a family member of the individual (including information about a request for or receipt of genetic services).".

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

"(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 2707.".

(C) LIMITATION ON COLLECTION AND DISCLOSURE OF PREDICTIVE GENETIC INFORMA-

TION.—Section 2702 of the Public Health Service Act (42 U.S.C. 300gg–1) is amended by adding at the end the following:

"(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require predictive genetic information concerning an individual or a family member of the individual (including information about a request for or receipt of genetic services).

"(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan or health insurance issuer that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health

care items and services to such individual or dependent.

''(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan or health insurance issuer shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in sections 213 and 221 of the Patients' Bill of Rights Act, of such individually identifiable information.''.

(2) DEFINITIONS.—Section 2791(d) of the Public Health Service Act (42 U.S.C. 300gg–91(d)) is amended by adding at the end the following:

''(15) FAMILY MEMBER.—The term 'family member' means, with respect to an individual—

''(A) the spouse of the individual;

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

''(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

''(16) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member.

''(17) GENETIC SERVICES.—The term 'genetic services' means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

''(18) PREDICTIVE GENETIC INFORMATION.—

''(A) IN GENERAL.—The term 'predictive genetic information' means—

''(i) information about an individual's genetic tests which is associated with a statistically significant increased risk of developing a disease or disorder;

''(ii) information about genetic tests of family members of the individual; or

''(iii) information about the occurrence of a disease or disorder in family members that predicts a statistically significant increased risk of a disease or disorder in the individual.

''(B) EXCEPTIONS.—The term 'predictive genetic information' shall not include—

''(i) information about the sex or age of the individual;

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

''(iii) information about physical exams of the individual and other information relevant to determining the current health status of the individual so long as such information does not include information described in clauses (i), (ii), or (iii) of subparagraph (A).

''(19) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, in order to detect disease-related genotypes, mutations, phenotypes, or karyotypes.''.

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

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

(2) by adding at the end the following:

"SEC. 2753. PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

"(a) PROHIBITION ON PREDICTIVE GENETIC INFORMATION AS A CONDITION OF ELIGIBILITY.—A health insurance issuer offering health insurance coverage in the individual market may not use predictive genetic information as a condition of eligibility of an individual to enroll in individual health insurance coverage (including information about a request for or receipt of genetic services).

"(b) PROHIBITION ON PREDICTIVE GENETIC INFORMATION IN SETTING PREMIUM RATES.—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium rates for individuals on the basis of predictive genetic information concerning such an enrollee or a family member of the enrollee (including information about a request for or receipt of genetic services).

"(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except

as provided in paragraph (2), a health insurance issuer offering health insurance coverage in the individual market shall not request or require predictive genetic information concerning an individual or a family member of the individual (including information about a request for or receipt of genetic services).

"(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a health insurance issuer that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

"(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the health insurance issuer shall provide to the individual or dependent a description of the procedures in place to safeguard the confiden-

tiality, as described in sections 213 and 221 of the Patients' Bill of Rights Act, of such individually identifiable information.''.

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

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

(2) health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after 1 year after the date of enactment of this Act.

TITLE IV—HEALTHCARE RESEARCH AND QUALITY

SEC. 401. SHORT TITLE.

This title may be cited as the ''Healthcare Research and Quality Act of 1999''.

SEC. 402. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

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

‘‘TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

‘‘PART A—ESTABLISHMENT AND GENERAL DUTIES

‘‘SEC. 901. MISSION AND DUTIES.

‘‘(a) IN GENERAL.—There is established within the Public Health Service an agency to be known as the Agency for Healthcare Research and Quality. In carrying out this subsection, the Secretary shall redesignate the Agency for Health Care Policy and Research as the Agency for Healthcare Research and Quality.

‘‘(b) MISSION.—The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of healthcare services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practice, including the prevention of diseases and other health conditions. The Agency shall promote healthcare quality improvement by—

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

‘‘(A) the development and assessment of methods for enhancing patient participation in

their own care and for facilitating shared patient-physician decision-making;

''(B) the outcomes, effectiveness, and cost-effectiveness of healthcare practices, including preventive measures and primary, acute and long-term care;

''(C) existing and innovative technologies;

''(D) the costs and utilization of, and access to healthcare;

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

''(F) methods for measuring quality and strategies for improving quality; and

''(G) ways in which patients, consumers, purchasers, and practitioners acquire new information about best practices and health benefits, the determinants and impact of their use of this information;

''(2) synthesizing and disseminating available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

"(3) advancing private and public efforts to improve healthcare quality.

"(c) REQUIREMENTS WITH RESPECT TO RURAL AREAS AND PRIORITY POPULATIONS.—In carrying out subsection (b), the Director shall undertake and support research, demonstration projects, and evaluations with respect to—

"(1) the delivery of health services in rural areas (including frontier areas);

"(2) health services for low-income groups, and minority groups;

"(3) the health of children;

"(4) the elderly; and

"(5) people with special healthcare needs, including disabilities, chronic care and end-of-life healthcare.

"(d) APPOINTMENT OF DIRECTOR.—There shall be at the head of the Agency an official to be known as the Director for Healthcare Research and Quality. The Director shall be appointed by the Secretary. The Secretary, acting through the Director, shall carry out the authorities and duties established in this title.

"SEC. 902. GENERAL AUTHORITIES.

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

and support research, evaluations, training, research networks, multi-disciplinary centers, technical assistance, and the dissemination of information, on healthcare, and on systems for the delivery of such care, including activities with respect to—

"(1) the quality, effectiveness, efficiency, appropriateness and value of healthcare services;

"(2) quality measurement and improvement;

"(3) the outcomes, cost, cost-effectiveness, and use of healthcare services and access to such services;

"(4) clinical practice, including primary care and practice-oriented research;

"(5) healthcare technologies, facilities, and equipment;

"(6) healthcare costs, productivity, organization, and market forces;

"(7) health promotion and disease prevention, including clinical preventive services;

"(8) health statistics, surveys, database development, and epidemiology; and

"(9) medical liability.

"(b) HEALTH SERVICES TRAINING GRANTS.—

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

search related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate. In carrying out this subsection, the Director shall make use of funds made available under section 487.

''(2) REQUIREMENTS.—In developing priorities for the allocation of training funds under this subsection, the Director shall take into consideration shortages in the number of trained researchers addressing the priority populations.

''(c) MULTIDISCIPLINARY CENTERS.—The Director may provide financial assistance to assist in meeting the costs of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis with respect to the matters referred to in subsection (a).

''(d) RELATION TO CERTAIN AUTHORITIES REGARDING SOCIAL SECURITY.—Activities authorized in this section may include, and shall be appropriately coordinated with experiments, demonstration projects, and other related activities authorized by the Social Security Act and the Social Security Amendments of 1967. Activities under

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

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

''(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to imply that the Agency's role is to mandate a national standard or specific approach to quality measurement and reporting. In research and quality improvement activities, the Agency shall consider a wide range of choices, providers, healthcare delivery systems, and individual preferences.

''PART B—HEALTHCARE IMPROVEMENT RESEARCH

''SEC. 911. HEALTHCARE OUTCOME IMPROVEMENT RESEARCH.

''(a) EVIDENCE RATING SYSTEMS.—In collaboration with experts from the public and private sector, the Agency shall identify and disseminate methods or systems used to assess healthcare research results, particularly to rate the strength of the scientific evidence behind healthcare

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

"(b) HEALTHCARE IMPROVEMENT RESEARCH CENTERS AND PROVIDER-BASED RESEARCH NETWORKS.—

"(1) IN GENERAL.—In order to address the full continuum of care and outcomes research, to link research to practice improvement, and to speed the dissemination of research findings to community practice settings, the Agency shall employ research strategies and mechanisms that will link research directly with clinical practice in geographically diverse locations throughout the United States, including—

"(A) Healthcare Improvement Research Centers that combine demonstrated multidisciplinary expertise in outcomes or quality improvement research with linkages to relevant sites of care;

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

''(C) other innovative mechanisms or strategies to link research with clinical practice.

''(2) REQUIREMENTS.—The Director is authorized to establish the requirements for entities applying for grants under this subsection.

"SEC. 912. PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE ORGANIZATION AND DELIVERY.

''(a) SUPPORT FOR EFFORTS TO DEVELOP INFORMATION ON QUALITY.—

''(1) SCIENTIFIC AND TECHNICAL SUPPORT.—In its role as the principal agency for healthcare research and quality, the Agency may provide scientific and technical support for private and public efforts to improve healthcare quality, including the activities of accrediting organizations.

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

''(A) the identification and assessment of—

''(i) methods for the evaluation of the health of enrollees in health plans by type of plan, provider, and provider arrangements; and

''(ii) other populations, including those receiving long-term care services;

"(B) the ongoing development, testing, and dissemination of quality measures, including measures of health and functional outcomes;

"(C) the compilation and dissemination of healthcare quality measures developed in the private and public sector;

"(D) assistance in the development of improved healthcare information systems;

"(E) the development of survey tools for the purpose of measuring participant and beneficiary assessments of their healthcare; and

"(F) identifying and disseminating information on mechanisms for the integration of information on quality into purchaser and consumer decision-making processes.

"(b) CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.—

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

‘‘(2) REQUIRED ACTIVITIES.—The activities referred to in this paragraph are the following:

‘‘(A) The conduct of state-of-the-art clinical research for the following purposes:

‘‘(i) To increase awareness of—

‘‘(I) new uses of drugs, biological products, and devices;

‘‘(II) ways to improve the effective use of drugs, biological products, and devices; and

‘‘(III) risks of new uses and risks of combinations of drugs and biological products.

‘‘(ii) To provide objective clinical information to the following individuals and entities:

‘‘(I) Healthcare practitioners and other providers of Healthcare goods or services.

‘‘(II) Pharmacists, pharmacy benefit managers and purchasers.

‘‘(III) Health maintenance organizations and other managed healthcare organizations.

“(IV) Healthcare insurers and governmental agencies.

“(V) Patients and consumers.

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

“(I) an increase in the appropriate use of drugs, biological products, or devices; and

“(II) the prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.

“(B) The conduct of research on the comparative effectiveness, cost-effectiveness, and safety of drugs, biological products, and devices.

“(C) Such other activities as the Secretary determines to be appropriate, except that a grant may not be expended to assist the Secretary in the review of new drugs.

“(c) REDUCING ERRORS IN MEDICINE.—The Director shall conduct and support research and build private-public partnerships to—

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

''(2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and

''(3) promote the implementation of effective strategies throughout the healthcare industry.

''SEC. 913. INFORMATION ON QUALITY AND COST OF CARE.

''(a) IN GENERAL.—In carrying out 902(a), the Director shall—

''(1) collect data on a nationally representative sample of the population on the cost, use and, for fiscal year 2000 and subsequent fiscal years, quality of healthcare, including the types of healthcare services Americans use, their access to healthcare services, frequency of use, how much is paid for the services used, the source of those payments, the types and costs of private health insurance, access, satisfaction, and quality of care for the general population and also for children, uninsured persons, poor and near-poor individuals, and persons with special healthcare needs;

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

‘‘(3) enter into agreements with public or private entities to use, link, or acquire databases for research authorized under this title.

‘‘(b) QUALITY AND OUTCOMES INFORMATION.—

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

‘‘(A) provide information on the quality of care and patient outcomes for frequently occurring clinical conditions for a nationally representative sample of the population; and

‘‘(B) provide reliable national estimates for children and persons with special healthcare needs through the use of supplements or periodic expansions of the survey.

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

''(2) ANNUAL REPORT.—Beginning in fiscal year 2002, the Secretary, acting through the Director, shall submit to Congress an annual report on national trends in the quality of healthcare provided to the American people.

''SEC. 914. INFORMATION SYSTEMS FOR HEALTHCARE IMPROVEMENT.

''In order to foster a range of innovative approaches to the management and communication of health information, the Agency shall support research, evaluations and initiatives to advance—

''(1) the use of information systems for the study of healthcare quality, including the generation of both individual provider and plan-level comparative performance data;

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

~~"(3) the creation of effective linkages between various sources of health information, including the development of information networks;~~

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

~~"(5) the structure, content, definition, and coding of health information data and medical vocabularies in consultation with appropriate Federal and private entities;~~

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

~~"(7) the protection of individually identifiable information in health services research and healthcare quality improvement.~~

~~"SEC. 915. RESEARCH SUPPORTING PRIMARY CARE AND ACCESS IN UNDERSERVED AREAS.~~

~~"(a) PREVENTIVE SERVICES TASK FORCE.—~~

~~"(1) PURPOSE.—The Agency shall provide ongoing administrative, research, and technical support for the operation of the Preventive Services Task Force. The Agency shall coordinate and support the~~

dissemination of the Preventive Services Task Force recommendations.

''(2) OPERATION.—The Preventive Services Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations, and updating previous recommendations, regarding their usefulness in daily clinical practice. In carrying out its responsibilities under paragraph (1), the Task Force shall not be subject to the provisions of Appendix 2 of title 5, United States Code.

''(b) PRIMARY CARE RESEARCH.—

''(1) IN GENERAL.—There is established within the Agency a Center for Primary Care Research (referred to in this subsection as the 'Center') that shall serve as the principal source of funding for primary care research in the Department of Health and Human Services. For purposes of this paragraph, primary care research focuses on the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

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

‘‘(A) the nature and characteristics of primary care practice;

‘‘(B) the management of commonly occurring clinical problems;

‘‘(C) the management of undifferentiated clinical problems; and

‘‘(D) the continuity and coordination of health services.

‘‘(3) DEMONSTRATION.—The Agency shall support demonstrations into the use of new information tools aimed at improving shared decision-making between patients and their care-givers.

‘‘SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVATION.

‘‘(a) IN GENERAL.—The Director shall promote innovation in evidence-based clinical practice and healthcare technologies by—

‘‘(1) conducting and supporting research on the development, diffusion, and use of healthcare technology;

‘‘(2) developing, evaluating, and disseminating methodologies for assessments of healthcare practices and healthcare technologies;

"(3) conducting intramural and supporting extramural assessments of existing and new healthcare practices and technologies;

"(4) promoting education, training, and providing technical assistance in the use of healthcare practice and healthcare technology assessment methodologies and results; and

"(5) working with the National Library of Medicine and the public and private sector to develop an electronic clearinghouse of currently available assessments and those in progress.

"(b) SPECIFICATION OF PROCESS.—

"(1) IN GENERAL.—Not later than December 31, 2000, the Director shall develop and publish a description of the methods used by the Agency and its contractors for practice and technology assessment.

"(2) CONSULTATIONS.—In carrying out this subsection, the Director shall cooperate and consult with the Assistance Secretary for Health, the Administrator of the Health Care Financing Administration, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal depart-

ment or agency, professional societies, and other private and public entities.

''(3) METHODOLOGY.—The methods employed in practice and technology assessments under paragraph (1) shall consider—

''(A) safety, efficacy, and effectiveness;

''(B) legal, social, and ethical implications;

''(C) costs, benefits, and cost-effectiveness;

''(D) comparisons to alternative technologies and practices; and

''(E) requirements of Food and Drug Administration approval to avoid duplication.

''(c) SPECIFIC ASSESSMENTS.—

''(1) IN GENERAL.—The Director shall conduct or support specific assessments of healthcare technologies and practices.

''(2) REQUESTS FOR ASSESSMENTS.—The Director is authorized to conduct or support assessments, on a reimbursable basis, for the Health Care Financing Administration, the Department of Defense, the Department of Veterans Affairs, the Office of Personnel Management, and other public or private entities.

''(3) GRANTS AND CONTRACTS.—In addition to conducting assessments, the Director may make

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

''(4) ELIGIBLE ENTITIES.—An entity described in this paragraph is an entity that is determined to be appropriate by the Director, including academic medical centers, research institutions, professional organizations, third party payers, other governmental agencies, and consortia of appropriate research entities established for the purpose of conducting technology assessments.

''SEC. 917. COORDINATION OF FEDERAL GOVERNMENT QUALITY IMPROVEMENT EFFORTS.

''(a) REQUIREMENT.—

''(1) IN GENERAL.—To avoid duplication and ensure that Federal resources are used efficiently and effectively, the Secretary, acting through the Director, shall coordinate all research, evaluations, and demonstrations related to health services research and quality measurement and improvement activities undertaken and supported by the Federal Government.

‘‘(2) SPECIFIC ACTIVITIES.—The Director, in collaboration with the appropriate Federal officials representing all concerned executive agencies and departments, shall develop and manage a process to—

‘‘(A) improve interagency coordination, priority setting, and the use and sharing of research findings and data pertaining to Federal quality improvement programs and health services research;

‘‘(B) strengthen the research information infrastructure, including databases, pertaining to Federal health services research and healthcare quality improvement initiatives;

‘‘(C) set specific goals for participating agencies and departments to further health services research and healthcare quality improvement; and

‘‘(D) strengthen the management of Federal healthcare quality improvement programs.

‘‘(b) STUDY BY THE INSTITUTE OF MEDICINE.—

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

“(A) to describe and evaluate current quality improvement research and monitoring processes through—

“(i) an overview of pertinent health services research activities and quality improvement efforts including those currently performed by the peer review organizations and the exploration of additional activities that could be undertaken by the peer review organizations to improve quality;

“(ii) an analysis of the various partnership activities that the Department of Health and Human Services has pursued with private sector accreditation and other quality measurement organizations;

“(iii) the exploration of programmatic areas where partnership activities between the Federal Government and the private sector or within the Federal Government could be pursued to improve quality oversight of the medicare, medicaid and child health insurance programs under titles XVIII, XIX and XXI of the Social Security Act; and

‘‘(iv) an identification of opportunities for enhancing health system efficiency through simplification and reduction in redundancy of Federal agency quality improvement efforts, including areas in which Federal efforts unnecessarily duplicate existing private sector efforts; and

‘‘(B) to identify options and make recommendations to improve the efficiency and effectiveness of such quality improvement programs through—

‘‘(i) the improved coordination of activities across the medicare, medicaid and child health insurance programs under titles XVIII, XIX and XXI of the Social Security Act and various 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 appro-

priate, 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.

"(B) REPORTS.—The Secretary shall submit the reports described in subparagraph (A) to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Commerce of the House of Representatives.

“PART C—GENERAL PROVISIONS

“SEC. 921. ADVISORY COUNCIL FOR HEALTHCARE RESEARCH AND QUALITY.

“(a) ESTABLISHMENT.—There is established an advisory council to be known as the Advisory Council for Healthcare Research and Quality.

“(b) DUTIES.—

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

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

“(A) priorities regarding healthcare research, especially studies related to quality, outcomes, cost and the utilization of, and access to, healthcare services;

“(B) the field of healthcare research and related disciplines, especially issues related to training needs, and dissemination of information pertaining to healthcare quality; and

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

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

''(c) MEMBERSHIP.—

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

''(2) APPOINTED MEMBERS.—The Secretary shall appoint to the Advisory Council 21 appropriately qualified individuals. At least 17 members of the Advisory Council shall be representatives of the public who are not officers or employees of the United States. The Secretary shall ensure that the appointed members of the Council, as a group, are representative of professions and entities concerned with, or affected by, activities under this title and under section 1142 of the Social Security Act. Of such members—

''(A) 4 shall be individuals distinguished in the conduct of research, demonstration projects, and evaluations with respect to healthcare;

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

"(C) 3 shall be individuals distinguished in the other health professions;

"(D) 4 shall be individuals either representing the private healthcare sector, including health plans, providers, and purchasers or individuals distinguished as administrators of healthcare delivery systems;

"(E) 4 shall be individuals distinguished in the fields of healthcare quality improvement, economics, information systems, law, ethics, business, or public policy; and

"(F) 2 shall be individuals representing the interests of patients and consumers of healthcare.

"(3) EX OFFICIO MEMBERS.—The Secretary shall designate as ex officio members of the Advisory Council—

"(A) the Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Care Financing Administration, the

Assistant Secretary of Defense (Health Affairs), and the Chief Medical Officer of the Department of Veterans Affairs; and

''(B) such other Federal officials as the Secretary may consider appropriate.

''(d) TERMS.—Members of the Advisory Council appointed under subsection (c)(2) shall serve for a term of 3 years. A member of the Council appointed under such subsection may continue to serve after the expiration of the term of the members until a successor is appointed.

''(e) VACANCIES.—If a member of the Advisory Council appointed under subsection (c)(2) does not serve the full term applicable under subsection (d), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(f) CHAIR.—The Director shall, from among the members of the Advisory Council appointed under subsection (c)(2), designate an individual to serve as the chair of the Advisory Council.

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

~~"(h) COMPENSATION AND REIMBURSEMENT OF EXPENSES.—~~

~~"(1) APPOINTED MEMBERS.—Members of the Advisory Council appointed under subsection (c)(2) shall receive compensation for each day (including travel time) engaged in carrying out the duties of the Advisory Council unless declined by the member. Such compensation may not be in an amount in excess of the maximum rate of basic pay payable for GS–18 of the General Schedule.~~

~~"(2) EX OFFICIO MEMBERS.—Officials designated under subsection (c)(3) as ex officio members of the Advisory Council may not receive compensation for service on the Advisory Council in addition to the compensation otherwise received for duties carried out as officers of the United States.~~

~~"(i) STAFF.—The Director shall provide to the Advisory Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.~~

"SEC. 922. PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS.

~~"(a) REQUIREMENT OF REVIEW.—~~

~~"(1) IN GENERAL.—Appropriate technical and scientific peer review shall be conducted with respect~~

to each application for a grant, cooperative agreement, or contract under this title.

''(2) REPORTS TO DIRECTOR.—Each peer review group to which an application is submitted pursuant to paragraph (1) shall report its finding and recommendations respecting the application to the Director in such form and in such manner as the Director shall require.

''(b) APPROVAL AS PRECONDITION OF AWARDS.—The Director may not approve an application described in subsection (a)(1) unless the application is recommended for approval by a peer review group established under subsection (c).

''(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

''(1) IN GENERAL.—The Director shall establish such technical and scientific peer review groups as may be necessary to carry out this section. Such groups shall be established without regard to the provisions of title 5, United States Code, that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

"(2) MEMBERSHIP.—The members of any peer review group established under this section shall be appointed from among individuals who by virtue of their training or experience are eminently qualified to carry out the duties of such peer review group. Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group. Such officers and employees may not receive compensation for service on such groups in addition to the compensation otherwise received for these duties carried out as such officers and employees.

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

"(4) QUALIFICATIONS.—Members of any peer-review group shall, at a minimum, meet the following requirements:

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

''(B) Such members shall agree in writing to recuse themselves from participation in the peer-review of specific applications which present a potential personal conflict of interest or appearance of such conflict, including employment in a directly affected organization, stock ownership, or any financial or other arrangement that might introduce bias in the process of peer-review.

''(d) AUTHORITY FOR PROCEDURAL ADJUSTMENTS IN CERTAIN CASES.—In the case of applications for financial assistance whose direct costs will not exceed $100,000, the Director may make appropriate adjustments in the procedures otherwise established by the Director for the conduct of peer review under this section. Such adjustments may be made for the purpose of encouraging the entry of individuals into the field of research, for the purpose of encouraging clinical practice-oriented or provider-based research, and for such other purposes as the Director may determine to be appropriate.

''(e) REGULATIONS.—The Director may shall issue regulations for the conduct of peer review under this section.

"SEC. 923. CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA.

"(a) STANDARDS WITH RESPECT TO UTILITY OF DATA.—

"(1) IN GENERAL.—To ensure the utility, accuracy, and sufficiency of data collected by or for the Agency for the purpose described in section 901(b), the Director shall establish standards and methods for developing and collecting such data, taking into consideration—

"(A) other Federal health data collection standards; and

"(B) the differences between types of healthcare plans, delivery systems, healthcare providers, and provider arrangements.

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

"(b) STATISTICS AND ANALYSES.—The Director shall—

‘‘(1) take appropriate action to ensure that statistics and analyses developed under this title are of high quality, timely, and duly comprehensive, and that the statistics are specific, standardized, and adequately analyzed and indexed; and

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

‘‘(c) AUTHORITY REGARDING CERTAIN REQUESTS.—Upon request of a public or private entity, the Director may conduct or support research or analyses otherwise authorized by this title pursuant to arrangements under which such entity will pay the cost of the services provided. Amounts received by the Director under such arrangements shall be available to the Director for obligation until expended.

‘‘SEC. 924. DISSEMINATION OF INFORMATION.

‘‘(a) IN GENERAL.—The Director shall—

‘‘(1) without regard to section 501 of title 44, United States Code, promptly publish, make available, and otherwise disseminate, in a form understandable and on as broad a basis as practicable so as to maximize its use, the results of research, demonstration projects, and evaluations conducted or supported under this title;

''(2) ensure that information disseminated by the Agency is science-based and objective and undertakes consultation as necessary to assess the appropriateness and usefulness of the presentation of information that is targeted to specific audiences;

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

''(4) provide, in collaboration with the National Library of Medicine where appropriate, indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on research, demonstration projects, and evaluations with respect to healthcare to public and private entities and individuals engaged in the improvement of healthcare delivery and the general public, and undertake programs to develop new or improved methods for making such information available; and

''(5) as appropriate, provide technical assistance to State and local government and health agencies and conduct liaison activities to such agencies to foster dissemination.

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

the publication or dissemination of data from, or the results of, projects conducted or supported under this title.

''(c) LIMITATION ON USE OF CERTAIN INFORMATION.—No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

''(d) PENALTY.—Any person who violates subsection (c) shall be subject to a civil monetary penalty of not more than $10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected.

"SEC. 925. ADDITIONAL PROVISIONS WITH RESPECT TO GRANTS AND CONTRACTS.

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

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

"(2) the actions that will be taken by the Director in response to any such interests identified by the Director.

"(b) REQUIREMENT OF APPLICATION.—The Director may not, with respect to any program under this title authorizing the provision of grants, cooperative agreements, or contracts, provide any such financial assistance unless an application for the assistance is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out the program in involved.

"(c) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF FUNDS.—

‘‘(1) IN GENERAL.—Upon the request of an entity receiving a grant, cooperative agreement, or contract under this title, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the entity in carrying out the project involved and, for such purpose, may detail to the entity any officer or employee of the Department of Health and Human Services.

‘‘(2) CORRESPONDING REDUCTION IN FUNDS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of the financial assistance involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Director. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

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

‘‘SEC. 926. CERTAIN ADMINISTRATIVE AUTHORITIES.

‘‘(a) DEPUTY DIRECTOR AND OTHER OFFICERS AND EMPLOYEES.—

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

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

~~"(b) FACILITIES.—The Secretary, in carrying out this title—~~

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

~~"(2) may acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary.~~

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

"(d) UTILIZATION OF CERTAIN PERSONNEL AND RESOURCES.—

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

"(2) OTHER AGENCIES.—The Director, in carrying out this title, may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, or of any foreign government, with or without reimbursement of such agencies.

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

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

''(f) EXPERTS.—

''(1) IN GENERAL.—The Secretary may, in carrying out this title, obtain the services of not more than 50 experts or consultants who have appropriate scientific or professional qualifications. Such experts or consultants shall be obtained in accordance with section 3109 of title 5, United States Code, except that the limitation in such section on the duration of service shall not apply.

''(2) TRAVEL EXPENSES.—

''(A) IN GENERAL.—Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a), 5724a(c), and 5726(C) of title 5, United States Code.

''(B) LIMITATION.—Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless and until the expert agrees in writing to complete the entire period

of assignment, or 1 year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a statutory obligation owed to the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

''(g) VOLUNTARY AND UNCOMPENSATED SERVICES.—The Director, in carrying out this title, may accept voluntary and uncompensated services.

''SEC. 927. FUNDING.

''(a) INTENT.—To ensure that the United States's investment in biomedical research is rapidly translated into improvements in the quality of patient care, there must be a corresponding investment in research on the most effective clinical and organizational strategies for use of these findings in daily practice. The authorization levels in subsections (b) and (c) provide for a proportionate increase in healthcare research as the United State's investment in biomedical research increases.

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

''(c) EVALUATIONS.—In addition to amounts available pursuant to subsection (b) for carrying out this title, there shall be made available for such purpose, from the amounts made available pursuant to section 241 (relating to evaluations), an amount equal to 40 percent of the maximum amount authorized in such section 241 to be made available for a fiscal year.

''SEC. 929. DEFINITIONS.

''In this title:

''(1) ADVISORY COUNCIL.—The term 'Advisory Council' means the Advisory Council on Healthcare Research and Quality established under section 921.

''(2) AGENCY.—The term 'Agency' means the Agency for Healthcare Research and Quality.

''(3) DIRECTOR.—The term 'Director' means the Director for the Agency for Healthcare Research and Quality.''.

SEC. 403. REFERENCES.

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

and Research'' shall be deemed to be a reference to the ''Agency for Healthcare Research and Quality''.

SEC. 404. STUDY.

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

(1) the safety and efficacy of the benefit, particularly the effect of the benefit on outcomes of care;

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

(3) the benefit in comparison to alternative approaches in improving care; and

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

(b) QUALIFYING HEALTH CARE BENEFIT.—In this section, the term ''qualifying health care benefit'' means a health care benefit that—

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

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

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

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

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

TITLE V—MISCELLANEOUS PROVISIONS

SEC. 501. SENSE OF THE COMMITTEE.

It is the sense of the Committee on Health, Education, Labor, and Pensions of the Senate that the Congress should take measures to further the purposes of this Act, including any necessary changes to the Internal Revenue Code of 1986 or to other Acts to—

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

~~(2) provide for the full deduction of health insurance costs for self-employed individuals;~~

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

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

~~(5) permit contributions towards medical savings account through the Federal employees health benefits program.~~

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Patients' Bill of Rights Act".

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

TITLE I—PATIENTS' BILL OF RIGHTS

Subtitle A—Right to Advice and Care

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

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

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

(2) by inserting after subpart B the following:

"Subpart C—Patient Right to Medical Advice and Care

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

"(a) IN GENERAL.—To the extent that the group health plan (other than a fully insured group health plan) provides coverage for benefits consisting of emergency medical care (as defined in subsection (c)), except for 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 an-

cillary 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

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

"(b) UNIFORM COST-SHARING REQUIRED AND OUT-OF-NETWORK CARE.—

"(1) UNIFORM COST-SHARING.—Nothing in this section shall be construed as preventing a group health plan (other than a fully insured group health plan) from imposing any form of cost-sharing applicable to any participant or beneficiary (including coinsurance, copayments, deductibles, and any other charges) in relation to coverage for benefits described in subsection (a), if such form of cost-sharing is uniformly applied under such plan, with respect to simi-

larly situated participants and beneficiaries, to all benefits consisting of emergency medical care (as defined in subsection (c)) provided to such similarly situated participants and beneficiaries under the plan.

"(2) OUT-OF-NETWORK CARE.—If a group health plan (other than a fully insured group health plan) provides any benefits with respect to emergency medical care (as defined in subsection (c)), the plan shall cover emergency medical care under the plan in a manner so that, if such care is provided to a participant or beneficiary by a nonparticipating health care provider, the participant or beneficiary is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating provider.

"(c) DEFINITION OF EMERGENCY MEDICAL CARE.—In this section:

"(1) IN GENERAL.—The term 'emergency medical care' means, with respect to a participant or beneficiary under a group health plan (other than a fully insured group health plan), covered inpatient and outpatient services that—

"(A) are furnished by any provider, including a nonparticipating provider, that is qualified to furnish such services; and

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

"(2) EMERGENCY MEDICAL CONDITION.—The term 'emergency medical condition' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

"(A) placing the health of the participant or beneficiary (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

"(B) serious impairment to bodily functions, or

"(C) serious dysfunction of any bodily organ or part.

"SEC. 722. OFFERING OF CHOICE OF COVERAGE OPTIONS.

"(a) REQUIREMENT.—

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

group health plan (other than a fully insured group health plan) provides coverage for benefits only through a defined set of participating health care professionals, the plan shall offer the participant the option to purchase point-of-service coverage (as defined in subsection (b)) for all such benefits for which coverage is otherwise so limited. Such option shall be made available to the participant at the time of enrollment under the plan and at such other times as the plan offers the participant a choice of coverage options.

"(2) EXCEPTION IN THE CASE OF MULTIPLE ISSUER OR COVERAGE OPTIONS.—Paragraph (1) shall not apply with respect to a participant in a group health plan (other than a fully insured group health plan) if the plan offers the participant 2 or more coverage options that differ significantly with respect to the use of participating health care professionals or the networks of such professionals that are used.

"(b) POINT-OF-SERVICE COVERAGE DEFINED.—In this section, the term 'point-of-service coverage' means, with respect to benefits covered under a group health plan (other than a fully insured group health plan), coverage of such benefits when provided by a nonparticipating health care professional.

"(c) SMALL EMPLOYER EXEMPTION.—

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

"(2) SMALL EMPLOYER.—For purposes of paragraph (1), the term 'small employer' means, in connection with a group health plan (other than a fully insured group health plan) with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of this paragraph, the provisions of subparagraph (C) of section 712(c)(1) shall apply in determining employer size.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

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

"(2) as requiring an employer to pay any costs as a result of this section or to make equal contributions with respect to different health coverage options;

"(3) as preventing a group health plan (other than a fully insured group health plan) from imposing higher premiums or cost-sharing on a participant

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

"(4) to require that a group health plan (other than a fully insured group health plan) include coverage of health care professionals that the plan excludes because of fraud, quality of care, or other similar reasons with respect to such professionals.

"SEC. 723. PATIENT ACCESS TO OBSTETRIC AND GYNECOLOGICAL CARE.

"(a) GENERAL RIGHTS.—

"(1) WAIVER OF PLAN REFERRAL REQUIREMENT.—If a group health plan described in subsection (b) requires a referral to obtain coverage for speciality care, the plan shall waive the referral requirement in the case of a female participant or beneficiary who seeks coverage for routine obstetrical care or routine gynecological care.

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

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

"(1) provides coverage for routine obstetric care (such as pregnancy-related services) or routine gynecologic care (such as preventive women's health examinations); and

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

"(c) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

"(1) as waiving any coverage requirement relating to medical necessity or appropriateness with respect to the coverage of obstetric or gynecologic care described in subsection (a);

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

"(3) to preclude a group health plan from allowing health care professionals other than physicians to provide routine obstetric or routine gynecologic care.

"SEC. 724. PATIENT ACCESS TO PEDIATRIC CARE.

"(a) IN GENERAL.—In the case of a group health plan (other than a fully insured group health plan) that provides coverage for routine pediatric care and that requires the designation by a participant or beneficiary of a participating primary care provider, if the designated primary care provider is not a physician who specializes in pediatrics—

"(1) the plan may not require authorization or referral by the primary care provider in order for a participant or beneficiary to obtain coverage for routine pediatric care; and

"(2) the plan shall treat the ordering of other routine care related to routine pediatric care by such a specialist as having been authorized by the designated primary care provider.

"(b) RULES OF CONSTRUCTION.—Nothing in subsection (a) shall be construed—

"(1) as waiving any coverage requirement relating to medical necessity or appropriateness with respect to the coverage of any pediatric care provided to, or ordered for, a participant or beneficiary;

"(2) to preclude a group health plan from requiring that a specialist described in subsection (a) notify the designated primary care provider or the plan of treatment decisions; or

"(3) to preclude a group health plan from allowing health care professionals other than physicians to provide routine pediatric care.

"SEC. 725. ACCESS TO SPECIALISTS.

"(a) IN GENERAL.—A group health plan (other than a fully insured group health plan) shall ensure that participants and beneficiaries have access to specialty care when such care is covered under the plan. Such access may be provided through contractual arrangements with specialized providers outside of the network of the plan.

"(b) TREATMENT PLANS.—

"(1) IN GENERAL.—Nothing in this section shall be construed to prohibit a group health plan (other than a fully insured group health plan) from requiring that speciality care be provided pursuant to a treatment plan so long as the treatment plan is—

"(A) developed by the specialist, in consultation with the primary care provider, and the participant or beneficiary;

"(B) approved by the plan; and

"(C) in accordance with the applicable quality assurance and utilization review standards of the plan.

"(2) NOTIFICATION.—Nothing in paragraph (1) shall be construed as prohibiting a plan from requir-

ing the specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all other necessary medical information.

"(c) REFERRALS.—Nothing in this section shall be construed to prohibit a plan from requiring an authorization by the primary care provider of the participant or beneficiary in order to obtain coverage for speciality services so long as such authorization is for an adequate number of referrals under an approved treatment plan if such a treatment plan is required by the plan.

"(d) SPECIALITY CARE DEFINED.—For purposes of this subsection, the term "speciality care" means, with respect to a condition, care and treatment provided by a health care practitioner, facility, or center (such as a center of excellence) that has adequate expertise (including age-appropriate expertise) through appropriate training and experience.

"SEC. 726. CONTINUITY OF CARE.

"(a) IN GENERAL.—

"(1) TERMINATION OF PROVIDER.—If a contract between a group health plan (other than a fully insured group health plan) and a health care provider is terminated (as defined in paragraph (2)), or benefits or coverage provided by a health care provider are

terminated because of a change in the terms of provider participation in such group health plan, and an individual who is a participant or beneficiary in the plan is undergoing a course of treatment from the provider at the time of such termination, the plan shall—

"(A) notify the individual on a timely basis of such termination;

"(B) provide the individual with an opportunity to notify the plan of a need for transitional care; and

"(C) in the case of termination described in paragraph (2), (3), or (4) of subsection (b), and subject to subsection (c), permit the individual to continue or be covered with respect to the course of treatment with the provider's consent during a transitional period (as provided under subsection (b)).

"(2) TERMINATED.—In this section, the term 'terminated' includes, with respect to a contract, the expiration or nonrenewal of the contract by the group health plan, but does not include a termination of the contract by the plan for failure to meet applicable quality standards or for fraud.

"(3) CONTRACTS.—For purposes of this section, the term 'contract between a group health plan (other than a fully insured group health plan) and a health care provider' shall include a contract between such a plan and an organized network of providers.

"(b) TRANSITIONAL PERIOD.—

"(1) GENERAL RULE.—Except as provided in paragraph (3), the transitional period under this subsection shall permit the participant or beneficiary to extend the coverage involved for up to 90 days from the date of the notice described in subsection (a)(1)(A) of the provider's termination.

"(2) INSTITUTIONAL CARE.—Subject to paragraph (1), the transitional period under this subsection for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutionalization and also shall include institutional care provided within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

"(3) PREGNANCY.—Notwithstanding paragraph (1), if—

"(A) a participant or beneficiary has entered the second trimester of pregnancy at the time of a provider's termination of participation; and

"(B) the provider was treating the pregnancy before the date of the termination;

the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

"(4) TERMINAL ILLNESS.—Subject to paragraph (1), if—

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

"(B) the provider was treating the terminal illness before the date of termination;

the transitional period under this subsection shall be for care directly related to the treatment of the terminal illness.

"(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan (other than a fully insured group health plan) may condition coverage of continued treatment by a provider under subsection (a)(1)(C) upon the provider agreeing to the following terms and conditions:

"(1) The provider agrees to accept reimbursement from the plan and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or at the rates applicable under the replacement plan after the date of the termination of the contract with the group health plan) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

"(2) The provider agrees to adhere to the quality assurance standards of the plan responsible for payment under paragraph (1) and to provide to such plan necessary medical information related to the care provided.

"(3) The provider agrees otherwise to adhere to such plan's policies and procedures, including procedures regarding referrals and obtaining prior author-

ization and providing services pursuant to a treatment plan (if any) approved by the plan.

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

"(e) DEFINITION.—In this section, the term 'health care provider' or 'provider' means—

"(1) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State; and

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

"SEC. 727. PROTECTION OF PATIENT-PROVIDER COMMUNICATIONS.

"(a) IN GENERAL.—Subject to subsection (b), a group health plan (other than a fully insured group health plan and in relation to a participant or beneficiary) shall not prohibit or otherwise restrict a health care professional from advising such a participant or beneficiary who is a patient

of the professional about the health status of the participant or beneficiary or medical care or treatment for the condition or disease of the participant or beneficiary, regardless of whether coverage for such care or treatment are provided under the contract, if the professional is acting within the lawful scope of practice.

"(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as requiring a group health plan (other than a fully insured group health plan) to provide specific benefits under the terms of such plan.

"SEC. 728. PATIENT'S RIGHT TO PRESCRIPTION DRUGS.

"To the extent that a group health plan (other than a fully insured group health plan) provides coverage for benefits with respect to prescription drugs, and limits such coverage to drugs included in a formulary, the plan shall—

"(1) ensure the participation of physicians and pharmacists in developing and reviewing such formulary; and

"(2) in accordance with the applicable quality assurance and utilization review standards of the plan, provide for exceptions from the formulary limitation when a non-formulary alternative is medically necessary and appropriate.

"SEC. 729. SELF-PAYMENT FOR BEHAVIORAL HEALTH CARE SERVICES.

"(a) IN GENERAL.—A group health plan (other than a fully insured group health plan) may not—

"(1) prohibit or otherwise discourage a participant or beneficiary from self-paying for behavioral health care services once the plan has denied coverage for such services; or

"(2) terminate a health care provider because such provider permits participants or beneficiaries to self-pay for behavioral health care services—

"(A) that are not otherwise covered under the plan; or

"(B) for which the group health plan provides limited coverage, to the extent that the group health plan denies coverage of the services.

"(b) RULE OF CONSTRUCTION.—Nothing in subsection (a)(2)(B) shall be construed as prohibiting a group health plan from terminating a contract with a health care provider for failure to meet applicable quality standards or for fraud.

"SEC. 730. GENERALLY APPLICABLE PROVISION.

"In the case of a group health plan that provides benefits under 2 or more coverage options, the requirements of this subpart, other than section 722, shall apply separately with respect to each coverage option.".

(b) DEFINITION.—Section 733(a) of the Employee Retirement Income Security Act of 1974 (42 U.S.C. 1191(a)) is amended by adding at the end the following:

"(3) FULLY INSURED GROUP HEALTH PLAN.—The term 'fully insured group health plan' means a group health plan where benefits under the plan are provided pursuant to the terms of an arrangement between a group health plan and a health insurance issuer and are guaranteed by the health insurance issuer under a contract or policy of insurance.".

(c) CONFORMING AMENDMENT.—The table of contents in section 1 of such Act is amended—

(1) in the item relating to subpart C, by striking "Subpart C" and inserting "Subpart D"; and

(2) by adding at the end of the items relating to subpart B of part 7 of subtitle B of title I of such Act the following new items:

"SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

SEC. 102. COMPREHENSIVE INDEPENDENT STUDY OF PATIENT ACCESS TO CLINICAL TRIALS AND COVERAGE OF ASSOCIATED ROUTINE COSTS.

(a) STUDY BY THE INSTITUTE OF MEDICINE.—Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the "Secretary") shall enter into a contract with the Institute of Medicine to conduct a comprehensive study of patient access to clinical trials and the coverage of routine patient care costs by private health plans and insurers.

(b) MATTERS TO BE ASSESSED.—The study shall assess the following:

(1) The factors that hinder patient participation in clinical trials, including health plan and insurance policies and practices.

(2) The ability of health plans and investigators to distinguish between routine patient care costs and costs associated with clinical trials.

(3) The potential impact of health plan coverage of routine costs associated with clinical trials on health care premiums.

(c) REPORT.—

(1) IN GENERAL.—Not later than 12 months after the date of the execution of the contract referred to in subsection (a), the Institute of Medicine shall

submit a report on the study conducted pursuant to that contract to the Committee on Health, Education, Labor and Pensions of the Senate.

(2) MATTERS INCLUDED.—The report submitted under paragraph (1) shall set forth the findings, conclusions, and recommendations of the Institute of Medicine for—

(A) increasing patient participation in clinical trials;

(B) encouraging collaboration between the public and private sectors; and

(C) improving analysis of determining routine costs associated with the conduct of clinical trials.

(3) COPY TO SECRETARY.—Concurrent with the submission of the report under paragraph (1), the Institute of Medicine shall transmit a copy of the report to the Secretary.

(d) FUNDING.—Out of funds appropriated to the Department of Health and Human Services for fiscal year 2000, the Secretary shall provide for such funding as the Secretary determines is necessary in order to carry out the study and report by the Institute of Medicine under this section.

SEC. 103. EFFECTIVE DATE AND RELATED RULES.

(a) IN GENERAL.—The amendments made by this subtitle shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act. The Secretary shall issue all regulations necessary to carry out the amendments made by this section before the effective date thereof.

(b) LIMITATION ON ENFORCEMENT ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this subtitle, against a group health plan with respect to a violation of a requirement imposed by such amendments before the date of issuance of regulations issued in connection with such requirement, if the plan has sought to comply in good faith with such requirement.

Subtitle B—Right to Information About Plans and Providers

SEC. 111. INFORMATION ABOUT PLANS.

(a) EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

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

"SEC. 714. HEALTH PLAN COMPARATIVE INFORMATION.

"(a) REQUIREMENT.—

"(1) IN GENERAL.—A group health plan, and a health insurance issuer that provides coverage in connection with group health insurance coverage, shall, not later than 12 months after the date of enactment of this section, and at least annually thereafter, provide for the disclosure, in a clear and accurate form to each participant and each beneficiary who does not reside at the same address as the participant, or upon request to an individual eligible for coverage under the plan, of the information described in subsection (b).

"(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent a plan or issuer from entering into any agreement under which the issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

"(3) PROVISION OF INFORMATION.—Information shall be provided to participants and beneficiaries under this section at the address maintained by the plan or issuer with respect to such participants or beneficiaries.

"(b) REQUIRED INFORMATION.—The informational materials to be distributed under this section shall include

for each package option available under a group health plan the following:

"(1) A description of the covered items and services under each such plan and any in- and out-of-network features of each such plan, including a summary description of the specific exclusions from coverage under the plan.

"(2) A description of any cost-sharing, including premiums, deductibles, coinsurance, and copayment amounts, for which the participant or beneficiary will be responsible, including any annual or lifetime limits on benefits, for each such plan.

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

"(4) A description of any restrictions on payments for services furnished to a participant or beneficiary by a health care professional that is not a participating professional and the liability of the participant or beneficiary for additional payments for these services.

"(5) A description of the service area of each such plan, including the provision of any out-of-area coverage.

"(6) A description of the extent to which participants and beneficiaries may select the primary care provider of their choice, including providers both within the network and outside the network of each such plan (if the plan permits out-of-network services).

"(7) A description of the procedures for advance directives and organ donation decisions if the plan maintains such procedures.

"(8) A description of the requirements and procedures to be used to obtain preauthorization for health services (including telephone numbers and mailing addresses), including referrals for specialty care.

"(9) A description of the definition of medical necessity used in making coverage determinations by each such plan.

"(10) A summary of the rules and methods for appealing coverage decisions and filing grievances (including telephone numbers and mailing addresses), as well as other available remedies.

"(11) A summary description of any provisions for obtaining off-formulary medications if the plan utilizes a defined formulary for providing specific prescription medications.

"(12) A summary of the rules for access to emergency room care. Also, any available educational material regarding proper use of emergency services.

"(13) A description of whether or not coverage is provided for experimental treatments, investigational treatments, or clinical trials and the circumstances under which access to such treatments or trials is made available.

"(14) A description of the specific preventative services covered under the plan if such services are covered.

"(15) A statement regarding—

"(A) the manner in which a participant or beneficiary may access an obstetrician, gynecologist, or pediatrician in accordance with section 723 or 724; and

"(B) the manner in which a participant or beneficiary obtains continuity of care as provided for in section 726.

"(16) A statement that the following information, and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request:

"(A) The names, addresses, telephone numbers, and State licensure status of the plan's par-

ticipating health care professionals and participating health care facilities, and, if available, the education, training, speciality qualifications or certifications of such professionals.

"(B) A summary description of the methods used for compensating participating health care professionals, such as capitation, fee-for-service, salary, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

"(C) A summary description of the methods used for compensating health care facilities, including per diem, fee-for-service, capitation, bundled payments, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

"(D) A summary description of the procedures used for utilization review.

"(E) The list of the specific prescription medications included in the formulary of the plan, if the plan uses a defined formulary.

"(F) A description of the specific exclusions from coverage under the plan.

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

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

"(c) MANNER OF DISTRIBUTION.—The information described in this section shall be distributed in an accessible format that is understandable to an average plan participant or beneficiary.

"(d) RULE OF CONSTRUCTION.—Nothing in this section may be construed to prohibit a group health plan, or health insurance issuer in connection with group health insurance coverage, from distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants and beneficiaries or upon request potential participants and beneficiaries in the selection of a health plan or from providing information under subsection (b)(15) as part of the required information.

"(e) CONFORMING REGULATIONS.—The Secretary shall issue regulations to coordinate the requirements on group health plans and health insurance issuers under this section with the requirements imposed under part 1, to reduce duplication with respect to any information that is required to be provided under any such requirements.

"(f) HEALTH CARE PROFESSIONAL.—In this section, the term 'health care professional' means a physician (as defined in section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional's services is provided under the health plan involved for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.".

(2) CONFORMING AMENDMENTS.—

(A) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking "section 711, and inserting "sections 711 and 714".

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

"Sec. 714. Health plan comparative information.".

(b) INTERNAL REVENUE CODE OF 1986.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

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

"Sec. 9813. Health plan comparative information."; and

(2) by inserting after section 9812 the following:

"SEC. 9813. HEALTH PLAN COMPARATIVE INFORMATION.

"(a) REQUIREMENT.—

"(1) IN GENERAL.—A group health plan shall, not later than 12 months after the date of enactment of this section, and at least annually thereafter, provide for the disclosure, in a clear and accurate form to each participant and each beneficiary who does not reside at the same address as the participant, or upon request to an individual eligible for coverage under the plan, of the information described in subsection (b).

"(2) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to prevent a plan from en-

tering into any agreement under which a health insurance issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

"(3) PROVISION OF INFORMATION.—Information shall be provided to participants and beneficiaries under this section at the address maintained by the plan with respect to such participants or beneficiaries.

"(b) REQUIRED INFORMATION.—The informational materials to be distributed under this section shall include for each package option available under a group health plan the following:

"(1) A description of the covered items and services under each such plan and any in- and out-of-network features of each such plan, including a summary description of the specific exclusions from coverage under the plan.

"(2) A description of any cost-sharing, including premiums, deductibles, coinsurance, and copayment amounts, for which the participant or beneficiary will be responsible, including any annual or lifetime limits on benefits, for each such plan.

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

"(4) A description of any restrictions on payments for services furnished to a participant or beneficiary by a health care professional that is not a participating professional and the liability of the participant or beneficiary for additional payments for these services.

"(5) A description of the service area of each such plan, including the provision of any out-of-area coverage.

"(6) A description of the extent to which participants and beneficiaries may select the primary care provider of their choice, including providers both within the network and outside the network of each such plan (if the plan permits out-of-network services).

"(7) A description of the procedures for advance directives and organ donation decisions if the plan maintains such procedures.

"(8) A description of the requirements and procedures to be used to obtain preauthorization for health services (including telephone numbers and

mailing addresses), including referrals for specialty care.

"(9) A description of the definition of medical necessity used in making coverage determinations by each such plan.

"(10) A summary of the rules and methods for appealing coverage decisions and filing grievances (including telephone numbers and mailing addresses), as well as other available remedies.

"(11) A summary description of any provisions for obtaining off-formulary medications if the plan utilizes a defined formulary for providing specific prescription medications.

"(12) A summary of the rules for access to emergency room care. Also, any available educational material regarding proper use of emergency services.

"(13) A description of whether or not coverage is provided for experimental treatments, investigational treatments, or clinical trials and the circumstances under which access to such treatments or trials is made available.

"(14) A description of the specific preventative services covered under the plan if such services are covered.

"(15) A statement regarding—

"(A) the manner in which a participant or beneficiary may access an obstetrician, gynecologist, or pediatrician in accordance with section 723 or 724; and

"(B) the manner in which a participant or beneficiary obtains continuity of care as provided for in section 726.

"(16) A statement that the following information, and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request:

"(A) The names, addresses, telephone numbers, and State licensure status of the plan's participating health care professionals and participating health care facilities, and, if available, the education, training, speciality qualifications or certifications of such professionals.

"(B) A summary description of the methods used for compensating participating health care professionals, such as capitation, fee-for-service, salary, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

"(C) A summary description of the methods used for compensating health care facilities, including per diem, fee-for-service, capitation, bundled payments, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

"(D) A summary description of the procedures used for utilization review.

"(E) The list of the specific prescription medications included in the formulary of the plan, if the plan uses a defined formulary.

"(F) A description of the specific exclusions from coverage under the plan.

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

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

"(c) MANNER OF DISTRIBUTION.—The information described in this section shall be distributed in an accessible format that is understandable to an average plan participant or beneficiary.

"(d) RULE OF CONSTRUCTION.—Nothing in this section may be construed to prohibit a group health plan from distributing any other additional information determined by the plan to be important or necessary in assisting participants and beneficiaries or upon request potential participants and beneficiaries in the selection of a health plan or from providing information under subsection (b)(15) as part of the required information.

"(e) HEALTH CARE PROFESSIONAL.—In this section, the term 'health care professional' means a physician (as defined in section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional's services is provided under the health plan involved for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified

social worker, registered respiratory therapist, and certified respiratory therapy technician.".

SEC. 112. INFORMATION ABOUT PROVIDERS.

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

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

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

(3) recommendations for the disclosure of information on health care professionals, including the competencies and professional qualifications of such practitioners, to better facilitate patient choice, quality improvement, and market competition.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and 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.—

"(A) IN GENERAL.—A group health plan or health insurance issuer conducting utilization review shall ensure that procedures are in place for—

"(i) making determinations regarding whether a participant or beneficiary is eligible to receive a payment or coverage for health services under the plan or coverage involved and any cost-sharing amount that the participant or beneficiary is required to pay with respect to such service;

"(ii) notifying a covered participant or beneficiary (or the authorized representative of such participant or beneficiary) and the treating health care professionals involved regarding determinations made under the plan or issuer and any additional payments that the participant or beneficiary may be required to make with respect to such service; and

"(iii) responding to requests, either written or oral, for coverage determinations or for internal appeals from a participant or beneficiary (or the authorized representative of such participant or beneficiary) or

the treating health care professional with the consent of the participant or beneficiary.

"(B) ORAL REQUESTS.—With respect to an oral request described in subparagraph (A)(iii), a group health plan or health insurance issuer may require that the requesting individual provide written evidence of such request.

"(2) TIMELINE FOR MAKING DETERMINATIONS.—

"(A) ROUTINE DETERMINATION.—A group health plan or a health insurance issuer shall maintain procedures to ensure that prior authorization determinations concerning the provision of non-emergency items or services are made within 30 days from the date on which the request for a determination is submitted, except that such period may be extended where 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, in accordance with the medical exigencies of the case,

after a request is received by the plan or issuer under clause (ii) or (iii).

"(ii) REQUEST BY PARTICIPANT OR BENEFICIARY.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection upon the request of a participant or beneficiary 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 participant or beneficiary.

"(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 reasonably documented, based on the medical exigencies, that a determination under the procedures described in subparagraph (A) could seriously jeopardize the life or health of the participant or beneficiary.

"(C) CONCURRENT DETERMINATIONS.—A plan or issuer shall maintain procedures to cer-

tify or deny coverage of an extended stay or additional services.

"(D) RETROSPECTIVE DETERMINATION.—A plan or issuer shall maintain procedures to ensure that, with respect to the retrospective review of a determination made under paragraph (1), the determination shall be made within 30 working days of the date on which the plan or issuer receives necessary information.

"(3) NOTICE OF DETERMINATIONS.—

"(A) ROUTINE DETERMINATION.—With respect to a coverage determination of a plan or issuer under paragraph (2)(A), the plan or issuer shall issue notice of such determination to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and, consistent with the medical exigencies of the case, to the treating health care professional involved not later than 2 working days after the date on which the determination is made.

"(B) EXPEDITED DETERMINATION.—With respect to a coverage determination of a plan or issuer under paragraph (2)(B), the plan or issuer shall issue notice of such determination to the participant or beneficiary (or the authorized

representative of the participant or beneficiary), and consistent with the medical exigencies of the case, to the treating health care professional involved within the 72 hour period described in paragraph (2)(B).

"(C) CONCURRENT REVIEWS.—With respect to the determination under a plan or issuer under paragraph (2)(C) to certify or deny coverage of an extended stay or additional services, the plan or issuer shall issue notice of such determination to the treating health care professional and to the participant or beneficiary involved (or the authorized representative of the participant or beneficiary) within 1 working day of the determination.

"(D) RETROSPECTIVE REVIEWS.—With respect to the retrospective review under a plan or issuer of a determination made under paragraph (2)(D), the plan or issuer shall issue written notice of an approval or disapproval of a determination under this subparagraph to the participant or beneficiary (or the authorized representative of the participant or beneficiary) 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 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 participant or beneficiary (or the authorized representative of the participant or beneficiary) 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 participant or beneficiary;

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

"(iii) notification of the right to appeal the determination and instructions on how to initiate an appeal in accordance with subsection (d).

"(c) GRIEVANCES.—A group health plan or a health insurance issuer shall have written procedures for addressing grievances between the plan or issuer offering health insurance coverage in connection with a group health plan and a participant or beneficiary. Determinations under such procedures shall be non-appealable.

"(d) INTERNAL APPEAL OF COVERAGE DETERMINATIONS.—

"(1) RIGHT TO APPEAL.—

"(A) IN GENERAL.—A participant or beneficiary (or the authorized representative of the participant or beneficiary) or the treating health care professional with the consent of the participant or beneficiary (or the authorized representative of the participant or beneficiary), may appeal any adverse coverage determination under subsection (b) under the procedures described in this subsection.

"(B) TIME FOR APPEAL.—A plan or issuer shall ensure that a participant or beneficiary has a period of not less than 180 days beginning on the date of an adverse coverage determination under subsection (b) in which to appeal such determination under this subsection.

"(C) FAILURE TO ACT.—The failure of a plan or issuer to issue a determination under subsection (b) within the applicable timeline established for such a determination under such subsection shall be treated as an adverse coverage determination for purposes of proceeding to internal review under this subsection.

"(2) RECORDS.—A group health plan and a health insurance issuer shall maintain written records, for at least 6 years, with respect to any appeal under this subsection for purposes of internal quality assurance and improvement. Nothing in the preceding sentence shall be construed as preventing a plan and issuer from entering into an agreement under which the issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

"(3) ROUTINE DETERMINATIONS.—A group health plan or a health insurance issuer shall complete the consideration of an appeal of an adverse routine determination under this subsection not later than 30 working days after the date on which a request for such appeal is received.

"(4) EXPEDITED DETERMINATION.—

"(A) IN GENERAL.—An expedited determination with respect to an appeal under this subsection shall be made in accordance with the medical exigencies of the case, but in no case more than 72 hours after the request for such appeal is received by the plan or issuer under subparagraph (B) or (C).

"(B) REQUEST BY PARTICIPANT OR BENEFICIARY.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection upon the request of a participant or beneficiary 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 participant or beneficiary.

"(C) 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 reasonably documented, based on the medical exigencies of the case that a determination under the procedures described in paragraph (2) could seriously jeop-

ardize the life or health of the participant or beneficiary.

"(5) CONDUCT OF REVIEW.—A review of an adverse coverage determination under this subsection shall be conducted by an individual with appropriate expertise who was not directly involved in the initial determination.

"(6) LACK OF MEDICAL NECESSITY.—A review of an appeal under this subsection relating to a determination to deny coverage based on a lack of medical necessity and appropriateness, or based on an experimental or investigational treatment, shall be made only by a physician with appropriate expertise, including age-appropriate expertise, who was not involved in the initial determination.

"(7) NOTICE.—

"(A) IN GENERAL.—Written notice of a determination made under an internal review process shall be issued to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and the treating health care professional not later than 2 working days after the completion of the review (or within the 72-hour period referred to in paragraph (4) if applicable).

"(B) ADVERSE COVERAGE DETERMINATIONS.—With respect to an adverse coverage determination made under this subsection, the notice described in subparagraph (A) 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 participant or beneficiary;

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

"(iii) notification of the right to an independent external review under subsection (e) and instructions on how to initiate such a review.

"(e) INDEPENDENT EXTERNAL REVIEW.—

"(1) ACCESS TO REVIEW.—

"(A) IN GENERAL.—A group health plan or a health insurance issuer offering health insurance coverage in connection with a group health plan shall have written procedures to permit a participant or beneficiary (or the authorized rep-

resentative of the participant or beneficiary) access to an independent external review with respect to an adverse coverage determination concerning a particular item or service (including a circumstance treated as an adverse coverage determination under subparagraph (B)) where—

"(i) the particular item or service involved—

"(I)(aa) would be a covered benefit, when medically necessary and appropriate under the terms and conditions of the plan, and the item or service has been determined not to be medically necessary and appropriate under the internal appeals process required under subsection (d) or there has been a failure to issue a coverage determination as described in subparagraph (B); and

"(bb)(AA) the amount of such item or service involved exceeds a significant financial threshold; or

"(BB) there is a significant risk of placing the life or health of the participant or beneficiary in jeopardy; or

"(II) would be a covered benefit, when not considered experimental or investigational under the terms and conditions of the plan, and the item or service has been determined to be experimental or investigational under the internal appeals process required under subsection (d) or there has been a failure to issue a coverage determination as described in subparagraph (B); and

"(ii) the participant or beneficiary has completed the internal appeals process under subsection (d) with respect to such determination.

"(B) FAILURE TO ACT.—The failure of a plan or issuer to issue a coverage determination under subsection (d)(6) within the applicable timeline established for such a determination under such subsection shall be treated as an adverse coverage determination for purposes of proceeding to independent external review under this subsection.

"(2) INITIATION OF THE INDEPENDENT EXTERNAL REVIEW PROCESS.—

"(A) FILING OF REQUEST.—A participant or beneficiary (or the authorized representative of the participant or beneficiary) who desires to have an independent 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 participant or beneficiary (or the authorized representative of the participant or beneficiary) for the release of medical information and records to independent external reviewers regarding the participant or beneficiary.

"(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 independent external reviewer under paragraph (3)(B).

"(C) PROVISION OF INFORMATION.—The plan or issuer involved shall forward 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 participant or beneficiary for the coverage denial, and evidence of the coverage of the participant or beneficiary) to the independent external reviewer selected under paragraph (3)(B).

"(D) NOTIFICATION.—The plan or issuer involved shall send a written notification to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and the plan administrator, indicating that an independent external review has been initiated.

"(3) CONDUCT OF INDEPENDENT EXTERNAL REVIEW.—

"(A) DESIGNATION OF EXTERNAL APPEALS ENTITY BY PLAN OR ISSUER.—

"(i) IN GENERAL.—A plan or issuer that receives a request for an independent external review under paragraph (2)(A) shall designate a qualified entity described in clause (ii), in a manner designed to ensure that the entity so designated will make

a decision in an unbiased manner, to serve as the external appeals entity.

"(ii) QUALIFIED ENTITIES.—A qualified entity shall be—

"(I) an independent external review entity licensed or credentialed by a State;

"(II) a State agency established for the purpose of conducting independent external reviews;

"(III) any entity under contract with the Federal Government to provide independent external review services;

"(IV) any entity accredited as an independent external review entity by an accrediting body recognized by the Secretary for such purpose; or

"(V) any other entity meeting criteria established by the Secretary for purposes of this subparagraph.

"(B) DESIGNATION OF INDEPENDENT EXTERNAL REVIEWER BY EXTERNAL APPEALS ENTITY.—The external appeals entity designated under subparagraph (A) shall, not later than 30

days after the date on which such entity is designated under subparagraph (A), or earlier in accordance with the medical exigencies of the case, designate one or more individuals to serve as independent external reviewers with respect to a request received under paragraph (2)(A). Such reviewers shall be independent medical experts who shall—

"(i) be appropriately credentialed or licensed in any State to deliver health care services;

"(ii) not have any material, professional, familial, or financial affiliation with the case under review, the participant or beneficiary involved, the treating health care professional, the institution where the treatment would take place, or the manufacturer of any drug, device, procedure, or other therapy proposed for the participant or beneficiary whose treatment is under review;

"(iii) have expertise (including age-appropriate expertise) in the diagnosis or treatment under review and, when reasonably available, be of the same specialty as

the physician treating the participant or beneficiary or recommending or prescribing the treatment in question;

"(iv) receive only reasonable and customary compensation from the group health plan or health insurance issuer in connection with the independent external review that is not contingent on the decision rendered by the reviewer; and

"(v) not be held liable for decisions regarding medical determinations (but may be held liable for actions that are arbitrary and capricious).

"(4) STANDARD OF REVIEW.—

"(A) IN GENERAL.—An independent external reviewer shall—

"(i) make an independent determination based on the valid, relevant, scientific and clinical evidence to determine the medical necessity, appropriateness, experimental or investigational nature of the proposed treatment; and

"(ii) take into consideration appropriate and available information, including any evidence-based decision making or clin-

ical practice guidelines used by the group health plan or health insurance issuer; timely evidence or information submitted by the plan, issuer, patient or patient's physician; the patient's medical record; expert consensus; and medical literature as defined in section 556(5) of the Federal Food, Drug, and Cosmetic Act.

"(B) NOTICE.—The plan or issuer involved shall ensure that the participant or beneficiary receives notice, within 30 days after the determination of the independent medical expert, regarding the actions of the plan or issuer with respect to the determination of such expert under the independent external review.

"(5) TIMEFRAME FOR REVIEW.—

"(A) IN GENERAL.—The independent external reviewer shall complete a review of an adverse coverage determination in accordance with the medical exigencies of the case.

"(B) LIMITATION.—Notwithstanding subparagraph (A), a review described in such subparagraph shall be completed not later than 30 working days after the later of—

"(i) the date on which such reviewer is designated; or

"(ii) the date on which all information necessary to completing such review is received.

"(6) BINDING DETERMINATION.—The determination of an independent external reviewer under this subsection shall be binding upon the plan or issuer if the provisions of this subsection or the procedures implemented under such provisions were complied with by the independent external reviewer.

"(7) STUDY.—Not later than 2 years after the date of enactment of this section, the General Accounting Office shall conduct a study of a statistically appropriate sample of completed independent external reviews. Such study shall include an assessment of the process involved during an independent external review and the basis of decisionmaking by the independent external reviewer. The results of such study shall be submitted to the appropriate committees of Congress.

"(8) EFFECT ON CERTAIN PROVISIONS.—Nothing in this section shall be construed as affecting or modifying section 514 of this Act with respect to a group health plan.

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a plan administrator or plan fiduciary or health plan medical director from requesting an independent external review by an independent external reviewer without first completing the internal review process.

"(g) DEFINITIONS.—In this section:

"(1) ADVERSE COVERAGE DETERMINATION.—The term 'adverse coverage determination' means a coverage determination under the plan which results in a denial of coverage or reimbursement.

"(2) COVERAGE DETERMINATION.—The term 'coverage determination' means with respect to items and services for which coverage may be provided under a health plan, a determination of whether or not such items and services are covered or reimbursable under the coverage and terms of the contract.

"(3) GRIEVANCE.—The term 'grievance' means any complaint made by a participant or beneficiary that does not involve a coverage determination.

"(4) GROUP HEALTH PLAN.—The term 'group health plan' shall have the meaning given such term in section 733(a). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

"(5) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning given such term in section 733(b)(1). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

"(6) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning given such term in section 733(b)(2).

"(7) PRIOR AUTHORIZATION DETERMINATION.—The term 'prior authorization determination' means a coverage determination prior to the provision of the items and services as a condition of coverage of the items and services under the coverage.

"(8) TREATING HEALTH CARE PROFESSIONAL.—The term 'treating health care professional' with respect to a group health plan, health insurance issuer or provider sponsored organization means a physician (medical doctor or doctor of osteopathy) or other health care practitioner who is acting within the scope of his or her State licensure or certification for the delivery of health care services and who is primarily responsible for delivering those services to the participant or beneficiary.

"(9) UTILIZATION REVIEW.—The term 'utilization review' with respect to a group health plan or health insurance coverage means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning or retrospective review."

(b) ENFORCEMENT.—Section 502(c)(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(c)(1)) is amended by inserting after "or section 101(e)(1)" the following: ", or fails to comply with a coverage determination as required under section 503(e)(6),".

(c) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by striking the item relating to section 503 and inserting the following new item:

"Sec. 503. Claims procedures, coverage determination, grievances and appeals.".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after 1 year after the date of enactment of this Act. The Secretary shall issue all regulations necessary to carry out the amendments made by this section before the effective date thereof.

TITLE II—GENETIC INFORMATION AND SERVICES

SEC. 201. SHORT TITLE.

This title may be cited as the "Genetic Information Nondiscrimination in Health Insurance Act of 1999".

SEC. 202. AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

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

(1) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 702(a)(1)(F) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(a)(1)(F)) is amended by inserting before the period the following: "(including information about a request for or receipt of genetic services)".

(2) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as amended by section 111(a), is further amended by adding at the end the following:

"SEC. 715. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

"A group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).".

(3) CONFORMING AMENDMENTS.—

(A) IN GENERAL.—Section 702(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(b)) is amended by adding at the end the following:

"(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 715.".

(B) TABLE OF CONTENTS.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974, as amended by section 111(a), is further amended by inserting

after the item relating to section 714 the following new item:

"Sec. 715. Prohibiting premium discrimination against groups on the basis of predictive genetic information.".

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

"(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).

"(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, that provides health care items and services to an in-

dividual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

"(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

"(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

"(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

"(A) PREPARATION OF WRITTEN NOTICE.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall post or provide, in writing and in a clear and con-

spicuous manner, notice of the plan or issuer's confidentiality practices, that shall include—

"(i) a description of an individual's rights with respect to predictive genetic information;

"(ii) the procedures established by the plan or issuer for the exercise of the individual's rights; and

"(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

"(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

"(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall establish and maintain appropriate administrative, technical, and physical

safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer.".

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

"(5) FAMILY MEMBER.—The term 'family member' means with respect to an individual—

"(A) the spouse of the individual;

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

"(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

"(6) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

"(7) GENETIC SERVICES.—The term 'genetic services' means health services provided to obtain, assess, or interpret genetic information for diagnostic

and therapeutic purposes, and for genetic education and counseling.

"(8) PREDICTIVE GENETIC INFORMATION.—

"(A) IN GENERAL.—The term 'predictive genetic information' means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

"(i) information about an individual's genetic tests;

"(ii) information about genetic tests of family members of the individual; or

"(iii) information about the occurrence of a disease or disorder in family members.

"(B) EXCEPTIONS.—The term 'predictive genetic information' shall not include—

"(i) information about the sex or age of the individual;

"(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

"(iii) information about physical exams of the individual.

"(9) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chro-

mosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.''.

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

SEC. 203. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.

(a) AMENDMENTS RELATING TO THE GROUP MARKET.—

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

(A) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 2702(a)(1)(F) of the Public Health Service Act (42 U.S.C. 300gg–1(a)(1)(F)) is amended by inserting before the

period the following: "(including information about a request for or receipt of genetic services)".

(B) NO DISCRIMINATION IN PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—Subpart 2 of part A of title XXVII of the Public Health Service Act, as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105–277), is amended by adding at the end the following new section:

"SEC. 2707. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION IN THE GROUP MARKET.

"A group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).".

(C) CONFORMING AMENDMENT.—Section 2702(b) of the Public Health Service Act (42

U.S.C. 300gg–1(b)) is amended by adding at the end the following:

"(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 2707.".

(D) LIMITATION ON COLLECTION AND DISCLOSURE OF PREDICTIVE GENETIC INFORMATION.—Section 2702 of the Public Health Service Act (42 U.S.C. 300gg–1) is amended by adding at the end the following:

"(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

"(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

"(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

"(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

"(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

"(A) PREPARATION OF WRITTEN NOTICE.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer's confidentiality practices, that shall include—

"(i) a description of an individual's rights with respect to predictive genetic information;

"(ii) the procedures established by the plan or issuer for the exercise of the individual's rights; and

"(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

"(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of con-

fidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

"(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer.".

(2) DEFINITIONS.—Section 2791(d) of the Public Health Service Act (42 U.S.C. 300gg–91(d)) is amended by adding at the end the following:

"(15) FAMILY MEMBER.—The term 'family member' means, with respect to an individual—

"(A) the spouse of the individual;

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

"(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

"(16) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

"(17) GENETIC SERVICES.—The term 'genetic services' means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

"(18) PREDICTIVE GENETIC INFORMATION.—

"(A) IN GENERAL.—The term 'predictive genetic information' means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

"(i) information about an individual's genetic tests;

"(ii) information about genetic tests of family members of the individual; or

"(iii) information about the occurrence of a disease or disorder in family members.

"(B) EXCEPTIONS.—The term 'predictive genetic information' shall not include—

"(i) information about the sex or age of the individual;

"(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

"(iii) information about physical exams of the individual.

"(19) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.".

(b) AMENDMENT RELATING TO THE INDIVIDUAL MARKET.—The first subpart 3 of part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–51 et seq.) (relating to other requirements), as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105-277) is amended—

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

(2) by adding at the end the following:

"SEC. 2753. PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

"(a) PROHIBITION ON PREDICTIVE GENETIC INFORMATION AS A CONDITION OF ELIGIBILITY.—A health insurance issuer offering health insurance coverage in the individual market may not use predictive genetic information as a condition of eligibility of an individual to enroll in individual health insurance coverage (including information about a request for or receipt of genetic services).

"(b) PROHIBITION ON PREDICTIVE GENETIC INFORMATION IN SETTING PREMIUM RATES.—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium rates for individuals on the basis of predictive genetic information concerning such an individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

"(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as pro-

vided in paragraph (2), a health insurance issuer offering health insurance coverage in the individual market shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

"(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a health insurance issuer offering health insurance coverage in the individual market that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

"(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the health insurance issuer offering health insurance coverage in the individual market shall provide

to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

"(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

"(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

"(A) PREPARATION OF WRITTEN NOTICE.—A health insurance issuer offering health insurance coverage in the individual market shall post or provide, in writing and in a clear and conspicuous manner, notice of the issuer's confidentiality practices, that shall include—

"(i) a description of an individual's rights with respect to predictive genetic information;

"(ii) the procedures established by the issuer for the exercise of the individual's rights; and

"(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

"(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National As-

sociation of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

"(2) ESTABLISHMENT OF SAFEGUARDS.—A health insurance issuer offering health insurance coverage in the individual market shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such issuer.".

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

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

(2) health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after 1 year after the date of enactment of this Act.

SEC. 204. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.

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

(1) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 9802(a)(1)(F) of the Internal Revenue Code of 1986 is amended by inserting before the period the following: "(including information about a request for or receipt of genetic services)".

(2) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—

(A) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 111(b), is further amended by adding at the end the following:

"SEC. 9814. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

"A group health plan shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).".

(B) CONFORMING AMENDMENT.—Section 9802(b) of the Internal Revenue Code of 1986 is amended by adding at the end the following:

"(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or the receipt of genetic services), see section 9814.".

(C) AMENDMENT TO TABLE OF SECTIONS.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 111(b), is further amended by adding at the end the following:

"Sec. 9814. Prohibiting premium discrimination against groups on the basis of predictive genetic information.".

(b) LIMITATION ON COLLECTION OF PREDICTIVE GENETIC INFORMATION.—Section 9802 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

"(d) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan shall not request or require predictive genetic information con-

cerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

"(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

"(B) NOTICE OF CONFIDENTIALITY PRACTICES; DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (e), of such predictive genetic information.

"(e) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

"(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

"(A) PREPARATION OF WRITTEN NOTICE.—A group health plan shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan's confidentiality practices, that shall include—

"(i) a description of an individual's rights with respect to predictive genetic information;

"(ii) the procedures established by the plan for the exercise of the individual's rights; and

"(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

"(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

"(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan.".

(c) DEFINITIONS.—Section 9832(d) of the Internal Revenue Code of 1986 is amended by adding at the end the following:

"(6) FAMILY MEMBER.—The term 'family member' means, with respect to an individual—

"(A) the spouse of the individual;

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

"(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

"(7) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

"(8) GENETIC SERVICES.—The term 'genetic services' means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

"(9) PREDICTIVE GENETIC INFORMATION.—

"(A) IN GENERAL.—The term 'predictive genetic information' means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

"(i) information about an individual's genetic tests;

"(ii) information about genetic tests of family members of the individual; or

"(iii) information about the occurrence of a disease or disorder in family members.

"(B) EXCEPTIONS.—The term 'predictive genetic information' shall not include—

"(i) information about the sex or age of the individual;

"(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

"(iii) information about physical exams of the individual.

"(10) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.".

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

TITLE III—HEALTHCARE RESEARCH AND QUALITY

SEC. 301. SHORT TITLE.

This title may be cited as the "Healthcare Research and Quality Act of 1999".

SEC. 302. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

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

"TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

"PART A—ESTABLISHMENT AND GENERAL DUTIES

"SEC. 901. MISSION AND DUTIES.

"(a) IN GENERAL.—There is established within the Public Health Service an agency to be known as the Agency for Healthcare Research and Quality. In carrying out this subsection, the Secretary shall redesignate the Agency for Health Care Policy and Research as the Agency for Healthcare Research and Quality.

"(b) MISSION.—The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of healthcare services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions. The Agency shall promote healthcare quality improvement by—

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

"(A) the development and assessment of methods for enhancing patient participation in their own care and for facilitating shared patient-physician decision-making;

"(B) the outcomes, effectiveness, and cost-effectiveness of healthcare practices, including preventive measures and long-term care;

"(C) existing and innovative technologies;

"(D) the costs and utilization of, and access to healthcare;

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

"(F) methods for measuring quality and strategies for improving quality; and

"(G) ways in which patients, consumers, purchasers, and practitioners acquire new information about best practices and health benefits, the determinants and impact of their use of this information;

"(2) synthesizing and disseminating available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

"(3) advancing private and public efforts to improve healthcare quality.

"(c) REQUIREMENTS WITH RESPECT TO RURAL AREAS AND PRIORITY POPULATIONS.—In carrying out subsection (b), the Director shall undertake and support research, demonstration projects, and evaluations with respect to the delivery of health services—

"(1) in rural areas (including frontier areas);

"(2) for low-income groups, and minority groups;

"(3) for children;

"(4) for elderly; and

"(5) for people with special healthcare needs, including disabilities, chronic care and end-of-life healthcare.

"(d) APPOINTMENT OF DIRECTOR.—There shall be at the head of the Agency an official to be known as the Director for Healthcare Research and Quality. The Director shall be appointed by the Secretary. The Secretary, acting through the Director, shall carry out the authorities and duties established in this title.

"SEC. 902. GENERAL AUTHORITIES.

"(a) IN GENERAL.—In carrying out section 901(b), the Director shall support demonstration projects, conduct and support research, evaluations, training, research networks, multi-disciplinary centers, technical assistance, and the dissemination of information, on healthcare, and on systems for the delivery of such care, including activities with respect to—

"(1) the quality, effectiveness, efficiency, appropriateness and value of healthcare services;

"(2) quality measurement and improvement;

"(3) the outcomes, cost, cost-effectiveness, and use of healthcare services and access to such services;

"(4) clinical practice, including primary care and practice-oriented research;

"(5) healthcare technologies, facilities, and equipment;

"(6) healthcare costs, productivity, organization, and market forces;

"(7) health promotion and disease prevention, including clinical preventive services;

"(8) health statistics, surveys, database development, and epidemiology; and

"(9) medical liability.

"(b) HEALTH SERVICES TRAINING GRANTS.—

"(1) IN GENERAL.—The Director may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate. In carrying out this subsection, the Director shall make use of funds made available under section 487 as well as other appropriated funds.

"(2) REQUIREMENTS.—In developing priorities for the allocation of training funds under this subsection, the Director shall take into consideration shortages in the number of trained researchers addressing the priority populations.

"(c) MULTIDISCIPLINARY CENTERS.—The Director may provide financial assistance to assist in meeting the costs of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis with respect to the matters referred to in subsection (a).

"(d) RELATION TO CERTAIN AUTHORITIES REGARDING SOCIAL SECURITY.—Activities authorized in this section shall be appropriately coordinated with experiments, demonstration projects, and other related activities author-

ized by the Social Security Act and the Social Security Amendments of 1967. Activities under subsection (a)(2) of this section that affect the programs under titles XVIII, XIX and XXI of the Social Security Act shall be carried out consistent with section 1142 of such Act.

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

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to imply that the Agency's role is to mandate a national standard or specific approach to quality measurement and reporting. In research and quality improvement activities, the Agency shall consider a wide range of choices, providers, healthcare delivery systems, and individual preferences.

"PART B—HEALTHCARE IMPROVEMENT RESEARCH

"SEC. 911. HEALTHCARE OUTCOME IMPROVEMENT RESEARCH.

"(a) EVIDENCE RATING SYSTEMS.—In collaboration with experts from the public and private sector, the Agency shall identify and disseminate methods or systems that it uses to assess healthcare research results, particularly meth-

ods or systems that it uses to rate the strength of the scientific evidence behind healthcare practice, recommendations in the research literature, and technology assessments. The Agency shall make methods and systems for evidence rating widely available. Agency publications containing healthcare recommendations shall indicate the level of substantiating evidence using such methods or systems.

"(b) HEALTHCARE IMPROVEMENT RESEARCH CENTERS AND PROVIDER-BASED RESEARCH NETWORKS.—In order to address the full continuum of care and outcomes research, to link research to practice improvement, and to speed the dissemination of research findings to community practice settings, the Agency shall employ research strategies and mechanisms that will link research directly with clinical practice in geographically diverse locations throughout the United States, including—

"(1) Healthcare Improvement Research Centers that combine demonstrated multidisciplinary expertise in outcomes or quality improvement research with linkages to relevant sites of care;

"(2) Provider-based Research Networks, including plan, facility, or delivery system sites of care (especially primary care), that can evaluate and promote quality improvement; and

"(3) other innovative mechanisms or strategies to link research with clinical practice.

"SEC. 912. PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE ORGANIZATION AND DELIVERY.

"(a) SUPPORT FOR EFFORTS TO DEVELOP INFORMATION ON QUALITY.—

"(1) SCIENTIFIC AND TECHNICAL SUPPORT.—In its role as the principal agency for healthcare research and quality, the Agency may provide scientific and technical support for private and public efforts to improve healthcare quality, including the activities of accrediting organizations.

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

"(A) the identification and assessment of methods for the evaluation of the health of—

"(i) enrollees in health plans by type of plan, provider, and provider arrangements; and

"(ii) other populations, including those receiving long-term care services;

"(B) the ongoing development, testing, and dissemination of quality measures, including measures of health and functional outcomes;

"(C) the compilation and dissemination of healthcare quality measures developed in the private and public sector;

"(D) assistance in the development of improved healthcare information systems;

"(E) the development of survey tools for the purpose of measuring participant and beneficiary assessments of their healthcare; and

"(F) identifying and disseminating information on mechanisms for the integration of information on quality into purchaser and consumer decision-making processes.

"(b) CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.—

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

"(2) REQUIRED ACTIVITIES.—The activities referred to in this paragraph are the following:

"(A) The conduct of state-of-the-art clinical, laboratory, or health services research for the following purposes:

"(i) To increase awareness of—

"(I) new uses of drugs, biological products, and devices;

"(II) ways to improve the effective use of drugs, biological products, and devices; and

"(III) risks of new uses and risks of combinations of drugs and biological products.

"(ii) To provide objective clinical information to the following individuals and entities:

"(I) Healthcare practitioners and other providers of healthcare goods or services.

"(II) Pharmacists, pharmacy benefit managers and purchasers.

"(III) Health maintenance organizations and other managed healthcare organizations.

"(IV) Healthcare insurers and governmental agencies.

"(V) Patients and consumers.

"(iii) To improve the quality of healthcare while reducing the cost of Healthcare through—

"(I) an increase in the appropriate use of drugs, biological products, or devices; and

"(II) the prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.

"(B) The conduct of research on the comparative effectiveness, cost-effectiveness, and safety of drugs, biological products, and devices.

"(C) Such other activities as the Secretary determines to be appropriate, except that grant funds may not be used by the Secretary in conducting regulatory review of new drugs.

"(c) REDUCING ERRORS IN MEDICINE.—The Director shall conduct and support research and build private-public partnerships to—

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

"(2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and

"(3) promote the implementation of effective strategies throughout the healthcare industry.

"SEC. 913. INFORMATION ON QUALITY AND COST OF CARE.

"(a) IN GENERAL.—In carrying out 902(a), the Director shall—

"(1) conduct a survey to collect data on a nationally representative sample of the population on the cost, use and, for fiscal year 2001 and subsequent fiscal years, quality of healthcare, including the types of healthcare services Americans use, their access to healthcare services, frequency of use, how much is paid for the services used, the source of those payments, the types and costs of private health insurance, access, satisfaction, and quality of care for the general population including rural residents and for the populations identified in section 901(c); and

"(2) develop databases and tools that provide information to States on the quality, access, and use of healthcare services provided to their residents.

"(b) QUALITY AND OUTCOMES INFORMATION.—

"(1) IN GENERAL.—Beginning in fiscal year 2001, the Director shall ensure that the survey conducted under subsection (a)(1) will—

"(A) identify determinants of health outcomes and functional status, and their relationships to healthcare access and use, determine the ways and extent to which the priority populations enumerated in section 901(c) differ from the general population with respect to such variables, measure changes over time with respect to such variable, and monitor the overall national impact of changes in Federal and State policy on healthcare;

"(B) provide information on the quality of care and patient outcomes for frequently occurring clinical conditions for a nationally representative sample of the population including rural residents; and

"(C) provide reliable national estimates for children and persons with special healthcare needs through the use of supplements or periodic expansions of the survey.

In expanding the Medical Expenditure Panel Survey, as in existence on the date of enactment of this title, in fiscal year 2001 to collect information on the qual-

ity of care, the Director shall take into account any outcomes measurements generally collected by private sector accreditation organizations.

"(2) ANNUAL REPORT.—Beginning in fiscal year 2003, the Secretary, acting through the Director, shall submit to Congress an annual report on national trends in the quality of healthcare provided to the American people.

"SEC. 914. INFORMATION SYSTEMS FOR HEALTHCARE IMPROVEMENT.

"(a) IN GENERAL.—In order to foster a range of innovative approaches to the management and communication of health information, the Agency shall support research, evaluations and initiatives to advance—

"(1) the use of information systems for the study of healthcare quality, including the generation of both individual provider and plan-level comparative performance data;

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

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

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

"(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

"(7) the protection of individually identifiable information in health services research and healthcare quality improvement.

"(b) DEMONSTRATION.—The Agency shall support demonstrations into the use of new information tools aimed at improving shared decision-making between patients and their care-givers.

"SEC. 915. RESEARCH SUPPORTING PRIMARY CARE AND ACCESS IN UNDERSERVED AREAS.

"(a) PREVENTIVE SERVICES TASK FORCE.—

"(1) ESTABLISHMENT AND PURPOSE.—The Director may periodically convene a Preventive Services Task Force to be composed of individuals with appropriate expertise. Such a task force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the healthcare community, and updating previous clinical preventive recommendations.

"(2) ROLE OF AGENCY.—The Agency shall provide ongoing administrative, research, and technical support for the operations of the Preventive Services Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force.

"(3) OPERATION.—In carrying out its responsibilities under paragraph (1), the Task Force is not subject to the provisions of Appendix 2 of title 5, United States Code.

"(b) PRIMARY CARE RESEARCH.—

"(1) IN GENERAL.—There is established within the Agency a Center for Primary Care Research (referred to in this subsection as the 'Center') that shall serve as the principal source of funding for primary care practice research in the Department of Health

and Human Services. For purposes of this paragraph, primary care research focuses on the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

"(2) RESEARCH.—In carrying out this section, the Center shall conduct and support research concerning—

"(A) the nature and characteristics of primary care practice;

"(B) the management of commonly occurring clinical problems;

"(C) the management of undifferentiated clinical problems; and

"(D) the continuity and coordination of health services.

"SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVATION.

"(a) IN GENERAL.—The Director shall promote innovation in evidence-based clinical practice and healthcare technologies by—

"(1) conducting and supporting research on the development, diffusion, and use of healthcare technology;

"(2) developing, evaluating, and disseminating methodologies for assessments of healthcare practices and healthcare technologies;

"(3) conducting intramural and supporting extramural assessments of existing and new healthcare practices and technologies;

"(4) promoting education, training, and providing technical assistance in the use of healthcare practice and healthcare technology assessment methodologies and results; and

"(5) working with the National Library of Medicine and the public and private sector to develop an electronic clearinghouse of currently available assessments and those in progress.

"(b) SPECIFICATION OF PROCESS.—

"(1) IN GENERAL.—Not later than December 31, 2000, the Director shall develop and publish a description of the methodology used by the Agency and its contractors in conducting practice and technology assessment.

"(2) CONSULTATIONS.—In carrying out this subsection, the Director shall cooperate and consult with

the Assistant Secretary for Health, the Administrator of the Health Care Financing Administration, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency, and shall seek input, where appropriate, from professional societies and other private and public entities.

"(3) METHODOLOGY.—The Director, in developing assessment methodology, shall consider—

"(A) safety, efficacy, and effectiveness;

"(B) legal, social, and ethical implications;

"(C) costs, benefits, and cost-effectiveness;

"(D) comparisons to alternate technologies and practices; and

"(E) requirements of Food and Drug Administration approval to avoid duplication.

"(c) SPECIFIC ASSESSMENTS.—

"(1) IN GENERAL.—The Director shall conduct or support specific assessments of healthcare technologies and practices.

"(2) REQUESTS FOR ASSESSMENTS.—The Director is authorized to conduct or support assessments, on a reimbursable basis, for the Health Care Financing Administration, the Department of Defense, the Department of Veterans Affairs, the Office of Per-

sonnel Management, and other public or private entities.

"(3) GRANTS AND CONTRACTS.—In addition to conducting assessments, the Director may make grants to, or enter into cooperative agreements or contracts with, entities described in paragraph (4) for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded healthcare technologies, and for related activities.

"(4) ELIGIBLE ENTITIES.—An entity described in this paragraph is an entity that is determined to be appropriate by the Director, including academic medical centers, research institutions and organizations, professional organizations, third party payers, governmental agencies, and consortia of appropriate research entities established for the purpose of conducting technology assessments.

"SEC. 917. COORDINATION OF FEDERAL GOVERNMENT QUALITY IMPROVEMENT EFFORTS.

"(a) REQUIREMENT.—

"(1) IN GENERAL.—To avoid duplication and ensure that Federal resources are used efficiently and effectively, the Secretary, acting through the Director, shall coordinate all research, evaluations, and demonstrations related to health services research, quality

measurement and quality improvement activities undertaken and supported by the Federal Government.

"(2) SPECIFIC ACTIVITIES.—The Director, in collaboration with the appropriate Federal officials representing all concerned executive agencies and departments, shall develop and manage a process to—

"(A) improve interagency coordination, priority setting, and the use and sharing of research findings and data pertaining to Federal quality improvement programs, technology assessment, and health services research;

"(B) strengthen the research information infrastructure, including databases, pertaining to Federal health services research and healthcare quality improvement initiatives;

"(C) set specific goals for participating agencies and departments to further health services research and healthcare quality improvement; and

"(D) strengthen the management of Federal healthcare quality improvement programs.

"(b) STUDY BY THE INSTITUTE OF MEDICINE.—

"(1) IN GENERAL.—To provide Congress, the Department of Health and Human Services, and other relevant departments with an independent, external

review of their quality oversight, quality improvement and quality research programs, the Secretary shall enter into a contract with the Institute of Medicine—

"(A) to describe and evaluate current quality improvement, quality research and quality monitoring processes through—

"(i) an overview of pertinent health services research activities and quality improvement efforts conducted by all Federal programs, with particular attention paid to those under titles XVIII, XIX, and XXI of the Social Security Act; and

"(ii) a summary of the partnerships that the Department of Health and Human Services has pursued with private accreditation, quality measurement and improvement organizations; and

"(B) to identify options and make recommendations to improve the efficiency and effectiveness of quality improvement programs through—

"(i) the improved coordination of activities across the medicare, medicaid and 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.

"(B) REPORTS.—The Secretary shall submit the reports described in subparagraph (A) to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Commerce of the House of Representatives.

"PART C—GENERAL PROVISIONS

"SEC. 921. ADVISORY COUNCIL FOR HEALTHCARE RESEARCH AND QUALITY.

"(a) ESTABLISHMENT.—There is established an advisory council to be known as the Advisory Council for Healthcare Research and Quality.

"(b) DUTIES.—

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

"(2) CERTAIN RECOMMENDATIONS.—Activities of the Advisory Council under paragraph (1) shall include making recommendations to the Director regarding—

"(A) priorities regarding healthcare research, especially studies related to quality, out-

comes, cost and the utilization of, and access to, healthcare services;

"(B) the field of healthcare research and related disciplines, especially issues related to training needs, and dissemination of information pertaining to healthcare quality; and

"(C) the appropriate role of the Agency in each of these areas in light of private sector activity and identification of opportunities for public-private sector partnerships.

"(c) MEMBERSHIP.—

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

"(2) APPOINTED MEMBERS.—The Secretary shall appoint to the Advisory Council 21 appropriately qualified individuals. At least 17 members of the Advisory Council shall be representatives of the public who are not officers or employees of the United States. The Secretary shall ensure that the appointed members of the Council, as a group, are representative of professions and entities concerned with, or affected by,

activities under this title and under section 1142 of the Social Security Act. Of such members—

"(A) 4 shall be individuals distinguished in the conduct of research, demonstration projects, and evaluations with respect to healthcare;

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

"(C) 3 shall be individuals distinguished in the other health professions;

"(D) 4 shall be individuals either representing the private healthcare sector, including health plans, providers, and purchasers or individuals distinguished as administrators of healthcare delivery systems;

"(E) 4 shall be individuals distinguished in the fields of healthcare quality improvement, economics, information systems, law, ethics, business, or public policy, including at least 1 individual specializing in rural aspects in 1 or more of these fields; and

"(F) 2 shall be individuals representing the interests of patients and consumers of healthcare.

"(3) EX OFFICIO MEMBERS.—The Secretary shall designate as ex officio members of the Advisory Council—

"(A) the Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Care Financing Administration, the Assistant Secretary of Defense (Health Affairs), and the Under Secretary for Health of the Department of Veterans Affairs; and

"(B) such other Federal officials as the Secretary may consider appropriate.

"(d) TERMS.—Members of the Advisory Council appointed under subsection (c)(2) shall serve for a term of 3 years. A member of the Council appointed under such subsection may continue to serve after the expiration of the term of the members until a successor is appointed.

"(e) VACANCIES.—If a member of the Advisory Council appointed under subsection (c)(2) does not serve the full term applicable under subsection (d), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

"(f) CHAIR.—The Director shall, from among the members of the Advisory Council appointed under subsection (c)(2), designate an individual to serve as the chair of the Advisory Council.

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

"(h) COMPENSATION AND REIMBURSEMENT OF EXPENSES.—

"(1) APPOINTED MEMBERS.—Members of the Advisory Council appointed under subsection (c)(2) shall receive compensation for each day (including travel time) engaged in carrying out the duties of the Advisory Council unless declined by the member. Such compensation may not be in an amount in excess of the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day during which such member is engaged in the performance of the duties of the Advisory Council.

"(2) EX OFFICIO MEMBERS.—Officials designated under subsection (c)(3) as ex officio members of the Advisory Council may not receive compensation for service on the Advisory Council in addition to the

compensation otherwise received for duties carried out as officers of the United States.

"(i) STAFF.—The Director shall provide to the Advisory Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

"SEC. 922. PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS.

"(a) REQUIREMENT OF REVIEW.—

"(1) IN GENERAL.—Appropriate technical and scientific peer review shall be conducted with respect to each application for a grant, cooperative agreement, or contract under this title.

"(2) REPORTS TO DIRECTOR.—Each peer review group to which an application is submitted pursuant to paragraph (1) shall report its finding and recommendations respecting the application to the Director in such form and in such manner as the Director shall require.

"(b) APPROVAL AS PRECONDITION OF AWARDS.—The Director may not approve an application described in subsection (a)(1) unless the application is recommended for approval by a peer review group established under subsection (c).

"(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

"(1) IN GENERAL.—The Director shall establish such technical and scientific peer review groups as may be necessary to carry out this section. Such groups shall be established without regard to the provisions of title 5, United States Code, that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

"(2) MEMBERSHIP.—The members of any peer review group established under this section shall be appointed from among individuals who by virtue of their training or experience are eminently qualified to carry out the duties of such peer review group. Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group. Such officers and employees may not receive compensation for service on such groups in addition to the compensation otherwise received for these duties carried out as such officers and employees.

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

"(4) QUALIFICATIONS.—Members of any peer-review group shall, at a minimum, meet the following requirements:

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

"(B) Such members shall agree in writing to recuse themselves from participation in the peer-review of specific applications which present a potential personal conflict of interest or appearance of such conflict, including employment in a directly affected organization, stock ownership, or any financial or other arrangement that might introduce bias in the process of peer-review.

"(d) AUTHORITY FOR PROCEDURAL ADJUSTMENTS IN CERTAIN CASES.—In the case of applications for financial assistance whose direct costs will not exceed $100,000, the Director may make appropriate adjustments in the procedures otherwise established by the Director for the conduct of peer review under this section. Such adjustments may be made for the purpose of encouraging the entry of individuals into the field of research, for the purpose of encour-

aging clinical practice-oriented or provider-based research, and for such other purposes as the Director may determine to be appropriate.

"(e) REGULATIONS.—The Director shall issue regulations for the conduct of peer review under this section.

"SEC. 923. CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA.

"(a) STANDARDS WITH RESPECT TO UTILITY OF DATA.—

"(1) IN GENERAL.—To ensure the utility, accuracy, and sufficiency of data collected by or for the Agency for the purpose described in section 901(b), the Director shall establish standard methods for developing and collecting such data, taking into consideration—

"(A) other Federal health data collection standards; and

"(B) the differences between types of healthcare plans, delivery systems, healthcare providers, and provider arrangements.

"(2) RELATIONSHIP WITH OTHER DEPARTMENT PROGRAMS.—In any case where standards under paragraph (1) may affect the administration of other programs carried out by the Department of Health

and Human Services, including the programs under title XVIII, XIX or XXI of the Social Security Act, or may affect health information that is subject to a standard developed under part C of title XI of the Social Security Act, they shall be in the form of recommendations to the Secretary for such program.

"(b) STATISTICS AND ANALYSES.—The Director shall—

"(1) take appropriate action to ensure that statistics and analyses developed under this title are of high quality, timely, and duly comprehensive, and that the statistics are specific, standardized, and adequately analyzed and indexed; and

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

"(c) AUTHORITY REGARDING CERTAIN REQUESTS.—Upon request of a public or private entity, the Director may conduct or support research or analyses otherwise authorized by this title pursuant to arrangements under which such entity will pay the cost of the services provided. Amounts received by the Director under such arrangements shall be available to the Director for obligation until expended.

"SEC. 924. DISSEMINATION OF INFORMATION.

"(a) IN GENERAL.—The Director shall—

"(1) without regard to section 501 of title 44, United States Code, promptly publish, make available, and otherwise disseminate, in a form understandable and on as broad a basis as practicable so as to maximize its use, the results of research, demonstration projects, and evaluations conducted or supported under this title;

"(2) ensure that information disseminated by the Agency is science-based and objective and undertakes consultation as necessary to assess the appropriateness and usefulness of the presentation of information that is targeted to specific audiences;

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

"(4) provide, in collaboration with the National Library of Medicine where appropriate, indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on research, demonstration projects, and evaluations with respect to healthcare to public and private entities and individuals engaged in the improvement of healthcare delivery and the general public, and undertake programs to develop new or

improved methods for making such information available; and

"(5) as appropriate, provide technical assistance to State and local government and health agencies and conduct liaison activities to such agencies to foster dissemination.

"(b) PROHIBITION AGAINST RESTRICTIONS.—Except as provided in subsection (c), the Director may not restrict the publication or dissemination of data from, or the results of, projects conducted or supported under this title.

"(c) LIMITATION ON USE OF CERTAIN INFORMATION.—No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Director) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Director) to its publication or release in other form.

"(d) PENALTY.—Any person who violates subsection (c) shall be subject to a civil monetary penalty of not more

than $10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected.

"SEC. 925. ADDITIONAL PROVISIONS WITH RESPECT TO GRANTS AND CONTRACTS.

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

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

"(2) the actions that will be taken by the Director in response to any such interests identified by the Director.

"(b) REQUIREMENT OF APPLICATION.—The Director may not, with respect to any program under this title authorizing the provision of grants, cooperative agreements, or contracts, provide any such financial assistance unless an application for the assistance is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and in-

formation as the Director determines to be necessary to carry out the program in involved.

"(c) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF FUNDS.—

"(1) IN GENERAL.—Upon the request of an entity receiving a grant, cooperative agreement, or contract under this title, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the entity in carrying out the project involved and, for such purpose, may detail to the entity any officer or employee of the Department of Health and Human Services.

"(2) CORRESPONDING REDUCTION IN FUNDS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of the financial assistance involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Director. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

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

"SEC. 926. CERTAIN ADMINISTRATIVE AUTHORITIES.

"(a) DEPUTY DIRECTOR AND OTHER OFFICERS AND EMPLOYEES.—

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

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

"(b) FACILITIES.—The Secretary, in carrying out this title—

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

"(2) may acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other

real or personal property (including patents) as the Secretary deems necessary.

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

"(d) UTILIZATION OF CERTAIN PERSONNEL AND RESOURCES.—

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

"(2) OTHER AGENCIES.—The Director, in carrying out this title, may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, or of any foreign government, with or without reimbursement of such agencies.

"(e) CONSULTANTS.—The Secretary, in carrying out this title, may secure, from time to time and for such peri-

ods as the Director deems advisable but in accordance with section 3109 of title 5, United States Code, the assistance and advice of consultants from the United States or abroad.

"(f) EXPERTS.—

"(1) IN GENERAL.—The Secretary may, in carrying out this title, obtain the services of not more than 50 experts or consultants who have appropriate scientific or professional qualifications. Such experts or consultants shall be obtained in accordance with section 3109 of title 5, United States Code, except that the limitation in such section on the duration of service shall not apply.

"(2) TRAVEL EXPENSES.—

"(A) IN GENERAL.—Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a), 5724a(c), and 5726(C) of title 5, United States Code.

"(B) LIMITATION.—Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless and until the expert agrees in writing

to complete the entire period of assignment, or 1 year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a statutory obligation owed to the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

"(g) VOLUNTARY AND UNCOMPENSATED SERVICES.—The Director, in carrying out this title, may accept voluntary and uncompensated services.

"SEC. 927. FUNDING.

"(a) INTENT.—To ensure that the United States's investment in biomedical research is rapidly translated into improvements in the quality of patient care, there must be a corresponding investment in research on the most effective clinical and organizational strategies for use of these findings in daily practice. The authorization levels in subsection (b) provide for a proportionate increase in healthcare research as the United States investment in biomedical research increases.

"(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this title, there are authorized to be appropriated $250,000,000 for fiscal year 2000, and such sums as may be necessary for each of the fiscal years 2001 through 2006.

"(c) EVALUATIONS.—In addition to amounts available pursuant to subsection (b) for carrying out this title, there shall be made available for such purpose, from the amounts made available pursuant to section 241 (relating to evaluations), an amount equal to 40 percent of the maximum amount authorized in such section 241 to be made available for a fiscal year.

"SEC. 928. DEFINITIONS.

"In this title:

"(1) ADVISORY COUNCIL.—The term 'Advisory Council' means the Advisory Council on Healthcare Research and Quality established under section 921.

"(2) AGENCY.—The term 'Agency' means the Agency for Healthcare Research and Quality.

"(3) DIRECTOR.—The term 'Director' means the Director for the Agency for Healthcare Research and Quality.".

SEC. 303. REFERENCES.

Effective upon the date of enactment of this Act, any reference in law to the "Agency for Health Care Policy and

Research" shall be deemed to be a reference to the "Agency for Healthcare Research and Quality".

TITLE IV—MISCELLANEOUS PROVISIONS

SEC. 401. SENSE OF THE COMMITTEE.

It is the sense of the Committee on Health, Education, Labor, and Pensions of the Senate that the Congress should take measures to further the purposes of this Act, including any necessary changes to the Internal Revenue Code of 1986 or to other Acts to—

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

(2) provide for the full deduction of health insurance costs for self-employed individuals;

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

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

(5) permit contributions towards medical savings account through the Federal employees health benefits program.