S. 300

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

IN THE SENATE OF THE UNITED STATES

January 22, 1999

Mr. Lott (for himself, Mr. Nickles, Ms. Collins, Mr. Frist, Mr. Gramm, Mr. Hagel, Mr. Jeffords, Mr. Roth, Mr. Santorum, Mr. Mack, Mr. Craig, Mr. Coverdell, Mr. McConnell, Mr. Abraham, Mr. Allard, Mr. Ashcroft, Mr. Bennett, Mr. Bond, Mr. Brownback, Mr. Bunning, Mr. Burns, Mr. Campbell, Mr. Cochran, Mr. DeWine, Mr. Domenici, Mr. Enzi, Mr. Gorton, Mr. Grams, Mr. Grassley, Mr. Gregg, Mr. Hatch, Mr. Helms, Mr. Hutchinson, Mrs. Hutchison, Mr. Inhofe, Mr. Lugar, Mr. McCain, Mr. Murkowski, Mr. Roberts, Mr. Sessions, Mr. Shelby, Mr. Smith of New Hampshire, Mr. Smith of Oregon, Ms. Snowe, Mr. Stevens, Mr. Thomas, Mr. Thompson, Mr. Thurmond, Mr. Voinovich, and Mr. Warner) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

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

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
- 4 (a) Short Title.—This Act may be cited as the
- 5 "Patients' Bill of Rights Plus Act".

1 (b) Table of Contents for

2 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—PATIENTS' BILL OF RIGHTS

Subtitle A—Right to Advice and Care

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

"SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

- "Sec. 721. Patient access to emergency medical care.
- "Sec. 722. Offering of choice of coverage options.
- "Sec. 723. Patient access to obstetric and gynecological care.
- "Sec. 724. Patient access to pediatric care.
- "Sec. 725. Continuity of care.
- "Sec. 726. Protection of patient-provider communications.
- "Sec. 727. Generally applicable provision.

Sec. 102. Effective date and related rules.

Subtitle B—Right to Information About Plans and Providers

- Sec. 111. Information about plans.
- Sec. 112. Information about providers.

Subtitle C—Right to Hold Health Plans Accountable

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

Subtitle D—Miscellaneous Provisions

Sec. 131. Amendments to the Internal Revenue Code of 1986.

TITLE II—INDIVIDUAL RIGHTS WITH RESPECT TO PERSONAL MEDICAL INFORMATION

Sec. 201. Short title.

Subtitle A—Access to Medical Records

- Sec. 211. Inspection and copying of protected health information.
- Sec. 212. Amendment of protected health information.
- Sec. 213. Notice of confidentiality practices.

Subtitle B—Establishment of Safeguards

Sec. 221. Establishment of safeguards.

Subtitle C—Enforcement; Definitions

- Sec. 231. Civil penalty.
- Sec. 232. Definitions.
- Sec. 233. Effective date.

TITLE III—GENETIC INFORMATION AND SERVICES

Sec. 301. Short title.

- Sec. 302. Amendments to Employee Retirement Income Security Act of 1974.
- Sec. 303. Amendments to the Public Health Service Act.
- Sec. 304. Amendments to the Internal Revenue Code of 1986.

TITLE IV—HEALTHCARE RESEARCH AND QUALITY

- Sec. 401. Short title.
- Sec. 402. Amendment to the Public Health Service Act.

"TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

"PART A—ESTABLISHMENT AND GENERAL DUTIES

- "Sec. 901. Mission and duties.
- "Sec. 902. General authorities.

"PART B—HEALTHCARE IMPROVEMENT RESEARCH

- "Sec. 911. Healthcare outcome improvement research.
- "Sec. 912. Private-public partnerships to improve organization and delivery.
- "Sec. 913. Information on quality and cost of care.
- "Sec. 914. Information systems for healthcare improvement.
- "Sec. 915. Research supporting primary care and access in underserved areas.
- "Sec. 916. Clinical practice and technology innovation.
- "Sec. 917. Coordination of Federal Government quality improvement efforts

"PART C—GENERAL PROVISIONS

- "Sec. 921. Advisory Council for Healthcare Research and Quality.
- "Sec. 922. Peer review with respect to grants and contracts.
- "Sec. 923. Certain provisions with respect to development, collection, and dissemination of data.
- "Sec. 924. Dissemination of information.
- "Sec. 925. Additional provisions with respect to grants and contracts.
- "Sec. 926. Certain administrative authorities.
- "Sec. 927. Funding.
- "Sec. 928. Definitions.
- Sec. 403. References.
- Sec. 404. Study.

TITLE V—ENHANCED ACCESS TO HEALTH INSURANCE COVERAGE

- Sec. 501. Full deduction of health insurance costs for self-employed individuals.
- Sec. 502. Full availability of medical savings accounts.
- Sec. 503. Carryover of unused benefits from cafeteria plans, flexible spending arrangements, and health flexible spending accounts.
- Sec. 504. Permitting contribution towards medical savings account through Federal employees health benefits program (FEHBP).

1	TITLE I—PATIENTS' BILL OF
2	RIGHTS
3	Subtitle A—Right to Advice and
4	Care
5	SEC. 101. PATIENT RIGHT TO MEDICAL ADVICE AND CARE.
6	(a) In General.—Part 7 of subtitle B of title I of
7	the Employee Retirement Income Security Act of 1974
8	(29 U.S.C. 1185 et seq.) is amended—
9	(1) by redesignating subpart C as subpart D;
10	and
11	(2) by inserting after subpart B the following:
12	"Subpart C—Patient Right to Medical Advice and
13	Care
14	"SEC. 721. PATIENT ACCESS TO EMERGENCY MEDICAL
15	CARE.
16	"(a) In General.—To the extent that the group
17	health plan (other than a fully insured group health plan)
18	provides coverage for benefits consisting of emergency
19	medical care (as defined in subsection (c)), except for
20	items or services specifically excluded—
21	"(1) the plan shall provide coverage for bene-
22	fits, without requiring preauthorization, for appro-
23	priate emergency medical screening examinations
24	(within the capability of the emergency facility, in-
25	cluding ancillary services routinely available to the

1 emergency facility) to the extent that a prudent 2 layperson, who possesses an average knowledge of health and medicine, would determine such examina-3 tions to be necessary to determine whether emer-5 gency medical care (as so defined) is necessary, and 6 "(2) the plan shall provide coverage for benefits 7 for additional emergency medical care to stabilize an 8 emergency medical condition following an emergency 9 medical screening examination (if determined nec-10 essary under paragraph (1)), pursuant to the defini-11 tion of stabilize under section 1867(e)(3) of the So-12 cial Security Act (42 U.S.C. 1395dd(e)(3)). 13 "(b) Uniform Cost-Sharing Required.—Nothing in this section shall be construed as preventing a group 14 health plan (other than a fully insured group health plan) from imposing any form of cost-sharing applicable to any 16 17 participant or beneficiary (including coinsurance, copay-18 ments, deductibles, and any other charges) in relation to 19 coverage for benefits described in subsection (a), if such form of cost-sharing is uniformly applied under such plan, 20 21 with respect to similarly situated participants and beneficiaries, to all benefits consisting of emergency medical

care (as defined in subsection (c)) provided to such simi-

larly situated participants and beneficiaries under the

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25 plan.

1	"(c) Definition of Emergency Medical Care.—
2	In this section:
3	"(1) IN GENERAL.—The term "emergency med-
4	ical care" means, with respect to a participant or
5	beneficiary under a group health plan (other than a
6	fully insured group health plan), covered inpatient
7	and outpatient services that—
8	"(A) are furnished by any provider, includ-
9	ing a nonparticipating provider, that is qualified
10	to furnish such services; and
11	"(B) are needed to evaluate or stabilize (as
12	such term is defined in section 1867(e)(3) of
13	the Social Security Act (42 U.S.C. 1395dd)) an
14	emergency medical condition (as defined in
15	paragraph (2)).
16	"(2) Emergency medical condition.—The
17	term "emergency medical condition" means a medi-
18	cal condition manifesting itself by acute symptoms
19	of sufficient severity (including severe pain) such
20	that a prudent layperson, who possesses an average
21	knowledge of health and medicine, could reasonably
22	expect the absence of immediate medical attention to
23	result in—
24	"(A) placing the health of the participant
25	or beneficiary (or, with respect to a pregnant

1	woman, the health of the woman or her unborn
2	child) in serious jeopardy,
3	"(B) serious impairment to bodily func-
4	tions, or
5	"(C) serious dysfunction of any bodily
6	organ or part.
7	"SEC. 722. OFFERING OF CHOICE OF COVERAGE OPTIONS.
8	"(a) Requirement.—
9	"(1) Offering of Point-of-Service Cov-
10	ERAGE OPTION.—Except as provided in paragraph
11	(2), if a group health plan (other than a fully in-
12	sured group health plan) provides coverage for bene-
13	fits only through a defined set of participating
14	health care professionals, the plan shall offer the
15	participant the option to purchase point-of-service
16	coverage (as defined in subsection (b)) for all such
17	benefits for which coverage is otherwise so limited.
18	Such option shall be made available to the partici-
19	pant at the time of enrollment under the plan and
20	at such other times as the plan offers the participant
21	a choice of coverage options.
22	"(2) Exception in the case of multiple
23	ISSUER OR COVERAGE OPTIONS.—Paragraph (1)
24	shall not apply with respect to a participant in a

1	group health plan (other than a fully insured group
2	health plan) if the plan offers the participant—
3	"(A) a choice of health insurance coverage
4	through more than one health insurance issuer;
5	or
6	"(B) two or more coverage options that
7	differ significantly with respect to the use of
8	participating health care professionals or the
9	networks of such professionals that are used.
10	"(b) Point-of-Service Coverage Defined.—In
11	this section, the term 'point-of-service coverage' means,
12	with respect to benefits covered under a group health plan
13	(other than a fully insured group health plan), coverage
14	of such benefits when provided by a nonparticipating
15	health care professional.
16	"(c) Small Employer Exemption.—
17	"(1) In general.—This section shall not apply
18	to any group health plan (other than a fully insured
19	group health plan) of a small employer.
20	"(2) Small employer.—For purposes of
21	paragraph (1), the term 'small employer' means, in
22	connection with a group health plan (other than a
23	fully insured group health plan) with respect to a
24	calendar year and a plan year, an employer who em-
25	ployed an average of at least 2 but not more than

1	50 employees on business days during the preceding
2	calendar year and who employs at least 2 employees
3	on the first day of the plan year. For purposes of
4	this paragraph, the provisions of subparagraph (C)
5	of section 712(c)(1) shall apply in determining em-
6	ployer size.
7	"(d) Rule of Construction.—Nothing in this sec-
8	tion shall be construed—
9	"(1) as requiring coverage for benefits for a
10	particular type of health care professional;
11	"(2) as requiring an employer to pay any costs
12	as a result of this section or to make equal contribu-
13	tions with respect to different health coverage op-
14	tions;
15	"(3) as preventing a group health plan (other
16	than a fully insured group health plan) from impos-
17	ing higher premiums or cost-sharing on a partici-
18	pant for the exercise of a point-of-service coverage
19	option; or
20	"(4) to require that a group health plan (other
21	than a fully insured group health plan) include cov-
22	erage of health care professionals that the plan ex-
23	cludes because of fraud quality of care or other

similar reasons with respect to such professionals.

1	"SEC. 723. PATIENT ACCESS TO OBSTETRIC AND GYNECO-
2	LOGICAL CARE.
3	"(a) In General.—In any case in which a group
4	health plan (other than a fully insured group health
5	plan)—
6	"(1) provides coverage for benefits consisting
7	of—
8	"(A) gynecological care (such as preventive
9	women's health examinations); or
10	"(B) obstetric care (such as pregnancy-re-
11	lated services);
12	provided by a participating physician who specializes
13	in such care; and
14	"(2) requires or provides for designation by a
15	participant or beneficiary of a participating primary
16	care provider;
17	if the primary care provider designated by such a partici-
18	pant or beneficiary is not such a physician as described
19	in paragraph (1), then the plan shall meet the require-
20	ments of subsection (b).
21	"(b) Requirements.—A group health plan (other
22	than a fully insured group health plan) meets the require-
23	ments of this subsection, in connection with the coverage
24	of benefits described in subsection (a) consisting of care
25	described in subparagraph (A) or (B) of subsection (a)(1),
26	if the plan—

1	"(1) does not require authorization or a referral
2	by the primary care provider in order to obtain cov-
3	erage for such benefits, and
4	"(2) treats the ordering of other routine care
5	related to the care described in subparagraph (A) or
6	(B) of subsection (a)(1), by the participating physi-
7	cian providing the care described in either such sub-
8	paragraph, as the authorization of the primary care
9	provider with respect to such care.
10	"(c) Rule of Construction.—Nothing in sub-
11	section (b)(2) shall waive any requirements of coverage re-
12	lating to medical necessity or appropriateness with respect
13	to coverage of gynecological or obstetric care so ordered.
14	Nothing in subsection (b) shall be construed to preclude
15	the health plan from requiring that the obstetrician or
16	gynecologist notify the primary care provider or the plan
17	of treatment decisions.
18	"SEC. 724. PATIENT ACCESS TO PEDIATRIC CARE.
19	"(a) In General.—In any case in which a group
20	health plan (other than a fully insured group health
21	plan)—
22	"(1) provides coverage for benefits consisting of
23	pediatric care by a participating pediatrician; and

1	"(2) requires or provides for designation by a
2	participant or beneficiary of a participating primary
3	care provider;
4	if the primary care provider designated by such a partici-
5	pant or beneficiary is not a physician as described in para
6	graph (1), then the plan shall meet the requirements of
7	subsection (b).
8	"(b) REQUIREMENTS.—A group health plan (other
9	than a fully insured group health plan) meets the require
10	ments of this subsection, in connection with the coverage
11	of benefits described in subsection (a) consisting of care
12	described in subsection (a)(1), if the plan—
13	"(1) does not require authorization or a referra
14	by the primary care provider in order to obtain cov-
15	erage for such benefits, and
16	"(2) treats the ordering of other routine care or
17	the same type, by the participating physician provid-
18	ing the care described in subsection (a)(1), as the
19	authorization of the primary care provider with re-
20	spect to such care.
21	"(c) Construction.—Nothing in subsection (b)(2)
22	shall waive any requirements of coverage relating to medi-

23 cal necessity or appropriateness with respect to coverage

24 of pediatric care so ordered.

1 "SEC. 725. CONTINUITY OF CARE.

2	"(a) In General.—
3	"(1) Termination of Provider.—If a con-
4	tract between a group health plan (other than a fully
5	insured group health plan) and a health care pro-
6	vider is terminated (as defined in paragraph (2)), or
7	benefits or coverage provided by a health care pro-
8	vider are terminated because of a change in the
9	terms of provider participation in such group health
10	plan, and an individual who is a participant or bene-
11	ficiary in the plan is undergoing a course of treat-
12	ment from the provider at the time of such termi-
13	nation, the plan shall—
14	"(A) notify the individual on a timely basis
15	of such termination;
16	"(B) provide the individual with an oppor-
17	tunity to notify the plan of a need for transi-
18	tional care; and
19	"(C) in the case of termination described
20	in paragraph (2), (3), or (4) of subsection (b),
21	and subject to subsection (c), permit the indi-
22	vidual to continue or be covered with respect to
23	the course of treatment with the provider's con-
24	sent during a transitional period (as provided
25	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 sta-

1	tus if the care was scheduled before the date of the
2	announcement of the termination of the provider
3	status under subsection (a)(1)(A) or if the individual
4	on such date was on an established waiting list or
5	otherwise scheduled to have such care.
6	"(3) Pregnancy.—Notwithstanding paragraph
7	(1), if—
8	"(A) a participant or beneficiary has en-
9	tered the second trimester of pregnancy at the
10	time of a provider's termination of participa-
11	tion; and
12	"(B) the provider was treating the preg-
13	nancy before the date of the termination;
14	the transitional period under this subsection with re-
15	spect to provider's treatment of the pregnancy shall
16	extend through the provision of post-partum care di-
17	rectly related to the delivery.
18	"(4) Terminal illness.—Subject to para-
19	graph (1), if—
20	"(A) a participant or beneficiary was de-
21	termined to be terminally ill (as determined
22	under section 1861(dd)(3)(A) of the Social Se-
23	curity Act) prior to a provider's termination of
24	participation; and

1	"(B) the provider was treating the termi-
2	nal illness before the date of termination;
3	the transitional period under this subsection shall be
4	for care directly related to the treatment of the ter-
5	minal illness.
6	"(c) Permissible Terms and Conditions.—A
7	group health plan (other than a fully insured group health
8	plan) may condition coverage of continued treatment by
9	a provider under subsection (a)(1)(B) upon the provider
10	agreeing to the following terms and conditions:
11	"(1) The provider agrees to accept reimburse-
12	ment from the plan and individual involved (with re-
13	spect to cost-sharing) at the rates applicable prior to
14	the start of the transitional period as payment in
15	full (or, in the case described in subsection (b)(2),
16	at the rates applicable under the replacement plan
17	after the date of the termination of the contract with
18	the group health plan) and not to impose cost-shar-
19	ing with respect to the individual in an amount that
20	would exceed the cost-sharing that could have been
21	imposed if the contract referred to in subsection
22	(a)(1) had not been terminated.
23	"(2) The provider agrees to adhere to the qual-
24	ity 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.
- 8 "(d) RULE OF CONSTRUCTION.—Nothing in this sec-9 tion shall be construed to require the coverage of benefits 10 which would not have been covered if the provider involved 11 remained a participating provider.
- 12 "(e) Definition.—In this section, the term 'health 13 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.

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1	"SEC. 726. PROTECTION OF PATIENT-PROVIDER COMMU-
2	NICATIONS.
3	"(a) In General.—Subject to subsection (b), a
4	group health plan (other than a fully insured group health
5	plan and in relation to a participant or beneficiary) shall
6	not prohibit or otherwise restrict a health care professional
7	from advising such a participant or beneficiary who is a
8	patient of the professional about the health status of the
9	participant or beneficiary or medical care or treatment for
10	the condition or disease of the participant or beneficiary,
11	regardless of whether coverage for such care or treatment
12	are provided under the contract, if the professional is act-
13	ing within the lawful scope of practice.
14	"(b) Rule of Construction.—Nothing in this sec-
15	tion shall be construed as requiring a group health plan
16	(other than a fully insured group health plan) to provide
17	specific benefits under the terms of such plan.
18	"SEC. 727. GENERALLY APPLICABLE PROVISION.
19	"In the case of a group health plan that provides ben-
20	efits under 2 or more coverage options, the requirements
21	of sections 721, 723, 724, 725 and 726 shall apply sepa-
22	rately with respect to each coverage option.".
23	(b) Rule With Respect to Certain Plans.—
24	(1) In general.—Notwithstanding any other
25	provision of law, health insurance issuers may offer,
26	and eligible individuals may purchase, high deduct-

- ible health plans described in section 220(c)(2)(A) of the Internal Revenue Code of 1986. Effective for the 4-year period beginning on the date of the enactment of this Act, such health plans shall not be required to provide payment for any health care items or services that are exempt from the plan's deductible.
 - (2) Existing state laws.—A State law relating to payment for health care items and services in effect on the date of enactment of this Act that is preempted under paragraph (1), shall not apply to high deductible health plans after the expiration of the 4-year period described in such paragraph unless the State reenacts such law after such period.
- 15 (c) Definition.—Section 733(a) of the Employee Retirement Income Security Act of 1974 (42 U.S.C. 16 17 1186(a)) is amended by adding at the end the following: 18 "(3) Fully insured group health plan.— 19 The term 'fully insured group health plan' means a 20 group health plan where benefits are provided pursu-21 ant to the terms of an arrangement between a group 22 health plan and a health insurance issuer and are 23 guaranteed by the health insurance issuer under a 24 contract or policy of insurance.".

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- 1 (d) Conforming Amendment.—The table of con-
- 2 tents in section 1 of such Act is amended—
- 3 (1) in the item relating to subpart C, by strik-
- 4 ing "Subpart C" and inserting "Subpart D"; and
- 5 (2) by adding at the end of the items relating
- 6 to subpart B of part 7 of subtitle B of title I of such
- 7 Act the following new items:

"SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

8 SEC. 102. EFFECTIVE DATE AND RELATED RULES.

- 9 (a) In General.—The amendments made by this
- 10 subtitle shall apply with respect to plan years beginning
- 11 on or after January 1 of the second calendar year follow-
- 12 ing the date of the enactment of this Act. The Secretary
- 13 shall issue all regulations necessary to carry out the
- 14 amendments made by this section before the effective date
- 15 thereof.
- 16 (b) Limitation on Enforcement Actions.—No
- 17 enforcement action shall be taken, pursuant to the amend-
- 18 ments made by this subtitle, against a group health plan
- 19 with respect to a violation of a requirement imposed by
- 20 such amendments before the date of issuance of regula-
- 21 tions issued in connection with such requirement, if the

[&]quot;Sec. 721. Patient access to emergency medical care.

[&]quot;Sec. 722. Offering of choice of coverage options.

[&]quot;Sec. 723. Patient access to obstetric and gynecological care.

[&]quot;Sec. 724. Patient access to pediatric care.

[&]quot;Sec. 725. Continuity of care.

[&]quot;Sec. 726. Protection of patient-provider communications.

[&]quot;Sec. 727. Generally applicable provisions.".

- 1 plan has sought to comply in good faith with such require-
- 2 ment.

3 Subtitle B—Right to Information

4 About Plans and Providers

- 5 SEC. 111. INFORMATION ABOUT PLANS.
- 6 (a) In General.—Subpart B of part 7 of subtitle
- 7 B of title I of the Employee Retirement Income Security
- 8 Act of 1974, as amended by the Omnibus Consolidated
- 9 and Emergency Supplemental Appropriations Act, 1999
- 10 (Public Law 105-277), is amended by adding at the end
- 11 the following:
- 12 "SEC. 714. HEALTH PLAN COMPARATIVE INFORMATION.
- 13 "(a) REQUIREMENT.—A group health plan, or health
- 14 insurance issuer in connection with group health insurance
- 15 coverage, shall, not later than 12 months after the date
- 16 of enactment of this section, provide for the disclosure,
- 17 in a clear and accurate form to each enrollee, or upon re-
- 18 quest to a potential enrollee eligible to receive benefits
- 19 under the plan, or plan sponsor with which the plan or
- 20 issuer has contracted, of the information described in sub-
- 21 section (b).
- 22 "(b) Required Information.—The informational
- 23 materials to be distributed under this section shall include
- 24 for each health benefit plan the following:

- 1 "(1) A description of the covered items and 2 services under each such plan and any in- and out-3 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).

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- 1 "(7) A description of the procedures for ad-2 vance directives and organ donation decisions if the 3 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.
- 25 "(13) A statement regarding—

1	"(A) the manner in which an enrollee may
2	access an obstetrician, gynecologist, or pediatri-
3	cian in accordance with section 723 or 724;
4	"(B) the manner in which an enrollee ob-
5	tains continuity of care as provided for in sec-
6	tion 725; and
7	"(C) the manner in which an enrollee has
8	access to the medical records of the enrollee in
9	accordance with subtitle A of title II of the Pa-
10	tients' Bill of Rights Plus Act.
11	"(14) A statement that the following informa-
12	tion, and instructions on obtaining such information
13	(including telephone numbers and, if available,
14	Internet websites), shall be made available upon re-
15	quest:
16	"(A) The names, addresses, telephone
17	numbers, and State licensure status of the
18	plan's participating health care professionals
19	and participating health care facilities, and, if
20	available, the education, training, speciality
21	qualifications or certifications of such profes-
22	sionals.
23	"(B) A summary description of the meth-
24	ods used for compensating participating health
25	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, 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

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1 "(B) in the case of the issuer, to the em2 ployer of a participant if the employer provides
3 for the coverage of such participant under the
4 plan involved or to participants and bene5 ficiaries at the address contained in such
6 records with respect to such participants and
7 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

- 1 therapy assistant, speech-language pathologist, audiol-
- 2 ogist, registered or licensed practical nurse (including
- 3 nurse practitioner, clinical nurse specialist, certified reg-
- 4 istered nurse anesthetist, and certified nurse-midwife), li-
- 5 censed certified social worker, registered respiratory thera-
- 6 pist, and certified respiratory therapy technician.".
- 7 (b) Conforming Amendments.—
- 8 (1) Section 732(a) of the Employee Retirement
- 9 Income Security Act of 1974 (29 U.S.C. 1185(a)) is
- amended by striking "section 711, and inserting
- "sections 711 and 714".
- 12 (2) The table of contents in section 1 of the
- 13 Employee Retirement Income Security Act of 1974
- 14 (29 U.S.C. 1001) is amended by inserting after the
- item relating to section 713, the following: "Sec. 714. Health plan comparative information.".

16 SEC. 112. INFORMATION ABOUT PROVIDERS.

- 17 (a) STUDY.—The Secretary of Health and Human
- 18 Services shall enter into a contract with the Institute of
- 19 Medicine for the conduct of a study, and the submission
- 20 to the Secretary of a report, that includes—
- 21 (1) an analysis of information concerning health
- care professionals that is currently available to pa-
- 23 tients, consumers, States, and professional societies,
- 24 nationally and on a State-by-State basis, including

1	patient preferences with respect to information
2	about such professionals and their competencies;
3	(2) an evaluation of the legal and other barriers
4	to the sharing of information concerning health care
5	professionals; and
6	(3) recommendations for the disclosure of infor-
7	mation on health care professionals, including the
8	competencies and professional qualifications of such
9	practitioners, to better facilitate patient choice, qual-
10	ity improvement, and market competition.
11	(b) Report.—Not later than 18 months after the
12	date of enactment of this Act, the Secretary of Health and
13	Human Services shall forward to the appropriate commit-
14	tees of Congress a copy of the report and study conducted
15	under subsection (a).
16	Subtitle C—Right to Hold Health
17	Plans Accountable
18	SEC. 121. AMENDMENT TO EMPLOYEE RETIREMENT IN-
19	COME SECURITY ACT OF 1974.
20	(a) In General.—Section 503 of the Employee Re-
21	tirement Income Security Act of 1974 (29 U.S.C. 1133)
22	is amended to read as follows:

1	"SEC. 503. CLAIMS PROCEDURE, COVERAGE DETERMINA-
2	TION, GRIEVANCES AND APPEALS.
3	"(a) Claims Procedure.—In accordance with regu-
4	lations of the Secretary, every employee benefit plan
5	shall—
6	"(1) provide adequate notice in writing to any
7	participant or beneficiary whose claim for benefits
8	under the plan has been denied, setting forth the
9	specific reasons for such denial, written in a manner
10	calculated to be understood by the participant, and
11	"(2) afford a reasonable opportunity to any
12	participant whose claim for benefits has been denied
13	for a full and fair review by the appropriate named
14	fiduciary of the decision denying the claim.
15	"(b) Coverage Determinations Under Group
16	HEALTH PLANS.—
17	"(1) Procedures.—
18	"(A) In general.—A group health plan
19	or health insurance issuer conducting utilization
20	review shall ensure that procedures are in place
21	for—
22	"(i) making determinations regarding
23	whether an enrollee is eligible to receive a
24	payment or coverage for health services
25	under the plan or coverage involved and
26	any cost-sharing amount that the enrollee

1	is required to pay with respect to such
2	service;
3	"(ii) notifying covered enrollees (or
4	the legal representative of such enrollees)
5	and the treating health care professionals
6	involved regarding determinations made
7	under the plan or issuer and any addi-
8	tional payments that the enrollee may be
9	required to make with respect to such serv-
10	ice; and
11	"(iii) responding to requests, either
12	written or oral, for coverage determina-
13	tions or for internal appeals from an en-
14	rollee (or the legal representative of such
15	enrollee) or the treating health care profes-
16	sional.
17	"(B) Oral requests.—With respect to
18	an oral request described in subparagraph
19	(A)(iii), a group health plan or health insurance
20	issuer may require that the requesting individ-
21	ual provide written evidence of such request.
22	"(2) Timeline for making determina-
23	TIONS.—
24	"(A) ROUTINE DETERMINATION.—A group
25	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 enrolles.—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.

1	"(iii) Documentation by health
2	CARE PROFESSIONAL.—A plan or issuer
3	shall maintain procedures for expediting a
4	prior authorization determination under
5	this subsection if the request involved indi-
6	cates that the treating health care profes-
7	sional has documented, based on the medi-
8	cal exigencies, that a determination under
9	the procedures described in subparagraph
10	(A) could seriously jeopardize the life or
11	health of the enrollee.
12	"(C) Concurrent determinations.—A
13	plan or issuer shall maintain procedures to cer-
14	tify or deny coverage of an extended stay or ad-
15	ditional services.
16	"(D) Retrospective determination.—
17	A plan or issuer shall maintain procedures to
18	ensure that, with respect to the retrospective re-
19	view of a determination made under paragraph
20	(1), the determination shall be made within 30
21	working days of the date on which the plan or
22	issuer receives all necessary information.
23	"(3) Notice of Determinations.—
24	"(A) ROUTINE DETERMINATION.—With re-
25	spect 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 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 AD-VERSE 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

1	based rationale used in making the deter-
2	mination) written in a manner to be under-
3	standable to the average enrollee;
4	"(ii) the procedures for obtaining ad-
5	ditional information concerning the deter-
6	mination; and
7	"(iii) notification of the right to ap-
8	peal the determination and instructions on
9	how to initiate an appeal in accordance
10	with subsection (d).
11	"(c) Grievances.—A group health plan or a health
12	insurance issuer shall have written procedures for address-
13	ing grievances between the plan and enrollees. Determina-
14	tions under such procedures shall be non-appealable.
15	"(d) Internal Appeal of Coverage Determina-
16	TIONS.—
17	"(1) In general.—An enrollee (or the legal
18	representative of the enrollee) and the treating
19	health care professional with the consent of the en-
20	rollee (or the legal representative of the enrollee),
21	may appeal any adverse coverage determination
22	under subsection (b) under the procedures described
23	in this subsection.
24	"(2) Records.—A group health plan and a
25	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 enrolles.—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.—

1	"(A) In general.—Written notice of a
2	determination made under an internal review
3	process shall be issued to the enrollee (or the
4	legal representative of the enrollee) and the
5	treating health care professional not later than
6	2 working days after the completion of the re-
7	view (or within the 72-hour period referred to
8	in paragraph (4) if applicable).
9	"(B) Adverse coverage determina-
10	TIONS.—With respect to an adverse coverage
11	determination made under this subsection, the
12	notice described in subparagraph (A) shall
13	include—
14	"(i) the reasons for the determination
15	(including the clinical or scientific-evidence
16	based rationale used in making the deter-
17	mination) written in a manner to be under-
18	standable to the average enrollee;
19	"(ii) the procedures for obtaining ad-
20	ditional information concerning the deter-
21	mination; and
22	"(iii) notification of the right to an
23	external review under subsection (e) and
24	instructions on how to initiate such a re-
25	view.

1	"(e) External Review.—
2	"(1) In general.—A group health plan or a
3	health insurance issuer shall have written procedures
4	to permit an enrollee (or the legal representative of
5	the enrollee) access to an external review with re-
6	spect to a coverage determination concerning a par-
7	ticular item or service where—
8	"(A) the particular item or service in-
9	volved, when medically appropriate and nec-
10	essary, is a covered benefit under the terms and
11	conditions of the contract between the plan or
12	issuer and the enrollee;
13	"(B) the coverage determination involved
14	denied coverage for such item or service because
15	the provision of such item or service—
16	"(i) does not meet the plan's or
17	issuer's requirements for medical appro-
18	priateness or necessity and the amount in-
19	volved exceeds a significant financial
20	threshold; or
21	"(ii) would constitute experimental or
22	investigational treatment and there is a
23	significant risk of placing the life or health
24	of the enrollee in jeopardy; and

1	"(C) the enrollee has completed the inter-
2	nal appeals process with respect to such deter-
3	mination.

"(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)

1	that shall be responsible for designating an ex-
2	ternal reviewer under paragraph (3)(B).
3	"(C) Provision of Information.—The
4	plan or issuer involved shall forward all nec-
5	essary information (including medical records,
6	any relevant review criteria, the clinical ration-
7	ale consistent with the terms and conditions of
8	the contract between the plan or issuer and the
9	enrollee for the coverage denial, and evidence of
10	the enrollee's coverage) to the external reviewer
11	selected under paragraph (3)(B).
12	"(D) Notification.—The plan or issuer
13	involved shall send a written notification to the
14	enrollee (or the legal representative of the en-
15	rollee) and the plan administrator, indicating
16	that an external review has been initiated.
17	"(3) Conduct of external review.—
18	"(A) Designation of External Ap-
19	PEALS ENTITY BY PLAN OR ISSUER.—A plan or
20	issuer that receives a request for an external re-
21	view under paragraph (2)(A) shall designate
22	one of the following entities to serve as the ex-
23	ternal appeals entity:
24	"(i) An external review entity licensed
25	or credentialed by a State.

1	"(ii) A State agency established for
2	the purpose of conducting independent ex-
3	ternal reviews.
4	"(iii) Any entity under contract with
5	the Federal Government to provide exter-
6	nal review services.
7	"(iv) Any entity accredited as an ex-
8	ternal review entity by an accrediting body
9	recognized by the Secretary for such pur-
10	pose.
11	"(v) Any fully accredited teaching
12	hospital.
13	"(vi) Any other entity meeting criteria
14	established by the Secretary for purposes
15	of this subparagraph.
16	"(B) Designation of External Re-
17	VIEWER BY EXTERNAL APPEALS ENTITY.—The
18	external appeals entity designated under sub-
19	paragraph (A) shall, not later than 30 days
20	after the date on which such entity is des-
21	ignated under subparagraph (A), or earlier in
22	accordance with the medical exigencies of the
23	case, designate one or more individuals to serve
24	as external reviewers with respect to a request
25	receives under paragraph (2)(A). Such review-

1	ers shall be independent medical experts who
2	shall—
3	"(i) be appropriately credentialed or
4	licensed in any State to deliver health care
5	services;
6	"(ii) not have any material, profes-
7	sional, familial, or financial affiliation with
8	the case under review, the enrollee in-
9	volved, the treating health care profes-
10	sional, the institution where the treatment
11	would take place, or the manufacturer of
12	any drug, device, procedure, or other ther-
13	apy proposed for the enrollee whose treat-
14	ment is under review;
15	"(iii) be experts in the diagnosis or
16	treatment under review and, when reason-
17	ably available, be of the same speciality of
18	the physician prescribing the treatment in
19	question;
20	"(iv) receive only reasonable and cus-
21	tomary compensation from the group
22	health plan or health insurance issuer in
23	connection with the external review that is
24	not contingent on the decision rendered by
25	the reviewer: and

1	"(v) not be held liable for decisions re-
2	garding medical determinations (but may
3	be held liable for actions that are arbitrary
4	and capricious).
5	"(4) Standard of Review.—
6	"(A) In general.—An external reviewer
7	shall—
8	"(i) make a determination based on
9	the medical necessity, appropriateness, ex-
10	perimental or investigational nature of the
11	coverage denial;
12	"(ii) take into consideration any evi-
13	dence-based decision making or clinical
14	practice guidelines used by the group
15	health plan or health insurance issuer in
16	conducting utilization review; and
17	"(iii) submit a report on the final de-
18	terminations of the review involved to—
19	"(I) the plan or issuer involved;
20	"(II) the enrollee involved (or the
21	legal representative of the enrollee);
22	and
23	"(III) the health care profes-
24	sional involved.

1 "(B) Notice.—The plan or issuer involved 2 shall ensure that the enrollee receives notice, 3 within 30 days after the determination of the 4 independent medical expert, regarding the ac-5 tions of the plan or issuer with respect to the 6 determination of such expert under the external 7 review. "(5) Timeframe for review.— 8 "(A) IN GENERAL.—An external reviewer 9 10 shall complete a review of an adverse coverage 11 determination in accordance with the medical 12 exigencies of the case. 13 "(B) LIMITATION.—Notwithstanding sub-14 paragraph (A), a review described in such sub-15 paragraph shall be completed not later than 30 16 working days after the later of— "(i) the date on which such reviewer 17 18 is designated; or 19 "(ii) the date on which all information 20 necessary to completing such review is re-21 ceived. 22 "(6) BINDING DETERMINATION.—The deter-23 mination of an external reviewer under this sub-24 section shall be binding upon the plan or issuer if 25 the provisions of this subsection or the procedures

- implemented under such provisions were compliedwith by the external reviewer.
- "(7) STUDY.—Not later than 2 years after the 3 date of enactment of this section, the General Ac-5 counting Office shall conduct a study of a statis-6 tically appropriate sample of completed external re-7 views. Such study shall include an assessment of the 8 process involved during an external review and the 9 basis of decisionmaking by the external reviewer. 10 The results of such study shall be submitted to the 11 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.
- 21 "(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 re-

- quirements of section 733(b)(2) and that offers health insurance coverage in connection with a group health plan.
 - "(8) 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, con-

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1	current review, case management, discharge plan-
2	ning or retrospective review."
3	(b) Enforcement.—Section 502(c)(1) of the Em-
4	ployee Retirement Income Security Act of 1974 (29
5	U.S.C. 1132(c)(1)) is amended by inserting after "or sec-
6	tion 101(e)(1)" the following: ", or fails to comply with
7	a coverage determination as required under section
8	503(e)(6),".
9	(c) Conforming Amendment.—The table of con-
10	tents in section 1 of the Employee Retirement Income Se-
11	curity Act of 1974 is amended by striking the item relat-
12	ing to section 503 and inserting the following new item:
	"Sec. 503. Claims procedures, coverage determination, grievances and appeals.".
13	(d) Effective Date.—The amendments made by
14	this section shall apply with respect to plan years begin-
15	ning on or after 1 year after the date of enactment of
16	this Act. The Secretary shall issue all regulations nec-
17	essary to carry out the amendments made by this section
18	before the effective date thereof.
19	Subtitle D—Miscellaneous
20	Provisions
21	SEC. 131. AMENDMENTS TO THE INTERNAL REVENUE CODE
22	OF 1986.
23	Subchapter B of chapter 100 of the Internal Revenue

24 Code of 1986 (as amended by section 1531(a) of the Tax-25 payer Relief Act of 1997) is amended—

1	(1) in the table of sections, by inserting after
2	the item relating to section 9812 the following new
3	item:
	"Sec. 9813. Standard relating to Patients' bill of rights."; and
4	(2) by inserting after section 9812 the follow-
5	ing:
6	"SEC. 9813. STANDARD RELATING TO PATIENTS' BILL OF
7	RIGHTS.
8	"A group health plan shall comply with the require
9	ments of section 714 and subpart C of part 7 of subtitle
10	B of title I of the Employee Retirement Income Security
11	Act of 1974 (as in effect as of the date of the enactment
12	of the Patients' Bill of Rights Plus Act), and such require
13	ments shall be deemed to be incorporated into this sec
14	tion.".
15	TITLE II—INDIVIDUAL RIGHTS
16	WITH RESPECT TO PERSONAL
17	MEDICAL INFORMATION
18	SEC. 201. SHORT TITLE.
19	This title may be cited as the "Personal Medical In-
20	formation Aggess Act'

52 **Subtitle A—Access to Medical** 1 Records 2 SEC. 211. INSPECTION AND COPYING OF PROTECTED 4 HEALTH INFORMATION. 5 (a) IN GENERAL.—At the request of an individual and except as provided in subsection (b), a health care 6 provider, health plan, employer, health or life insurer, 7 8 school, or university shall permit an individual who is the subject of protected health information or the individual's 9 10 designee, to inspect and copy protected health information 11 concerning the individual, including records created under 12 section 212 that such entity maintains. Such entity may 13 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 copy-16 ing. 17 (b) Exceptions.—Unless ordered by a court of com-18 petent jurisdiction, an entity described in subsection (a) is not required to permit the inspection or copying of pro-20 tected health information if any of the following conditions 21 are met: 22 (1) Endangerment to life or safety.— 23 The entity determines that the disclosure of the in-

formation could reasonably be expected to endanger

the life or physical safety of an individual.

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- 1 (2) CONFIDENTIAL SOURCE.—The information 2 identifies, or could reasonably lead to the identifica-3 tion of, a person who provided information under a 4 promise of confidentiality concerning the individual 5 who is the subject of the information.
 - (3) Information compiled in anticipation of Litigation.—The information is compiled principally—
- 9 (A) in the reasonable anticipation of a 10 civil, criminal, or administrative action or pro-11 ceeding; or
- 12 (B) for use in such an action or proceed-13 ing.
 - (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.
- 21 (c) Denial of a Request for Inspection or 22 Copying.—If an entity described in subsection (a) denies 23 a request for inspection or copying pursuant to subsection 24 (b), the entity shall inform the individual in writing of—

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1	(1) the reasons for the denial of the request for
2	inspection or copying;
3	(2) any procedures for further review of the de-
4	nial; and
5	(3) the individual's right to file with the entity
6	a concise statement setting forth the request for in-
7	spection or copying.
8	(d) Statement Regarding Request.—If an indi-
9	vidual has filed a statement under subsection (c)(3), the
10	entity in any subsequent disclosure of the portion of the
11	information requested under subsection (a) shall include—
12	(1) a copy of the individual's statement; and
13	(2) a concise statement of the reasons for deny-
14	ing the request for inspection or copying.
15	(e) Inspection and Copying of Segregable Por-
16	TION.—An entity described in subsection (a) shall permit
17	the inspection and copying under subsection (a) of any
18	reasonably segregable portion of protected health informa-
19	tion after deletion of any portion that is exempt under
20	subsection (b).
21	(f) Deadline.—An entity described in subsection (a)
22	shall comply with or deny, in accordance with subsection
23	(c), a request for inspection or copying of protected health
24	information under this section not later than 45 days after
25	the date on which the entity receives the request.

1	(g) Rules Governing Agents.—An agent of an en-
2	tity described in subsection (a) shall not be required to
3	provide for the inspection and copying of protected health
4	information, except where—
5	(1) the protected health information is retained
6	by the agent; and
7	(2) the agent has received in writing a request
8	from the entity involved to fulfill the requirements of
9	this section;
10	at which time such information shall be provided to the
11	requesting entity. Such requesting entity shall comply with
12	subsection (f) with respect to any such information.
13	(h) Rule of Construction.—This section shall not
14	be construed to require an entity described in subsection
15	(a) to conduct a formal, informal, or other hearing or pro-
16	ceeding concerning a request for inspection or copying of
17	protected health information.
18	SEC. 212. AMENDMENT OF PROTECTED HEALTH INFORMA
19	TION.
20	(a) Requirement.—
21	(1) In general.—Except as provided in sub-
22	section (b) and subject to paragraph (2), a health
23	care provider, health plan, employer, health or life
24	insurer, school, or university that receives from an

1	individual a request in writing to amend protected
2	health information shall—
3	(A) amend such information as requested;
4	(B) inform the individual of the amend-
5	ment that has been made; and
6	(C) make reasonable efforts to inform any
7	person to whom the unamended portion of the
8	information was previously disclosed, of any
9	nontechnical amendment that has been made.
10	(2) Compliance.—An entity described in para-
11	graph (1) shall comply with the requirements of
12	such paragraph within 45 days of the date on which
13	the request involved is received if the entity—
14	(A) created the protected health informa-
15	tion involved; and
16	(B) determines that such information is in
17	fact inaccurate.
18	(b) Refusal To Amend.—If an entity described in
19	subsection (a) refuses to make the amendment requested
20	under such subsection, the entity shall inform the individ-
21	ual in writing of—
22	(1) the reasons for the refusal to make the
23	amendment;
24	(2) any procedures for further review of the re-
25	fusal: and

1	(3) the individual's right to file with the entity
2	a concise statement setting forth the requested
3	amendment and the individual's reasons for dis-
4	agreeing with the refusal.
5	(c) Statement of Disagreement.—If an individ-
6	ual has filed a statement of disagreement under subsection
7	(b)(3), the entity involved, in any subsequent disclosure
8	of the disputed portion of the information—
9	(1) shall include a copy of the individual's
10	statement; and
11	(2) may include a concise statement of the rea-
12	sons for not making the requested amendment.
13	(d) Rules Governing Agents.—The agent of an
14	entity described in subsection (a) shall not be required to
15	make amendments to protected health information, except
16	where—
17	(1) the protected health information is retained
18	by the agent; and
19	(2) the agent has been asked by such entity to
20	fulfill the requirements of this section.
21	If the agent is required to comply with this section as pro-

- 21 If the agent is required to comply with this section as pro-
- 22 vided for in paragraph (2), such agent shall be subject
- 23 to the 45-day deadline described in subsection (a).
- 24 (e) Repeated Requests for Amendments.—If an
- 25 entity described in subsection (a) receives a request for

- 1 an amendment of information as provided for in such sub-
- 2 section and a statement of disagreement has been filed
- 3 pursuant to subsection (c), the entity shall inform the indi-
- 4 vidual of such filing and shall not be required to carry
- 5 out the procedures required under this section.
- 6 (f) Rules of Construction.—This section shall
- 7 not be construed to—
- 8 (1) require that an entity described in sub-
- 9 section (a) conduct a formal, informal, or other
- 10 hearing or proceeding concerning a request for an
- amendment to protected health information;
- 12 (2) require a provider to amend an individual's
- protected health information as to the type, dura-
- tion, or quality of treatment the individual believes
- 15 he or she should have been provided; or
- 16 (3) permit any deletions or alterations of the
- original information.

18 SEC. 213. NOTICE OF CONFIDENTIALITY PRACTICES.

- 19 (a) Preparation of Written Notice.—A health
- 20 care provider, health plan, health oversight agency, public
- 21 health authority, employer, health or life insurer, health
- 22 researcher, school or university shall post or provide, in
- 23 writing and in a clear and conspicuous manner, notice of
- 24 the entity's confidentiality practices, that shall include—

1	(1) a description of an individual's rights with
2	respect to protected health information;
3	(2) the procedures established by the entity for
4	the exercise of the individual's rights; and
5	(3) the right to obtain a copy of the notice of
6	the confidentiality practices required under this sub-
7	title.
8	(b) Model Notice.—The Secretary, in consultation
9	with the National Committee on Vital and Health Statis-
10	tics and the National Association of Insurance Commis-
11	sioners, and after notice and opportunity for public com-
12	ment, shall develop and disseminate model notices of con-
13	fidentiality practices. Use of the model notice shall serve
14	as a defense against claims of receiving inappropriate no-
15	tice.
16	Subtitle B—Establishment of
17	Safeguards
18	SEC. 221. ESTABLISHMENT OF SAFEGUARDS.
19	A health care provider, health plan, health oversight
20	agency, public health authority, employer, health or life
21	insurer, health researcher, law enforcement official, school
22	or university shall establish and maintain appropriate ad-
23	ministrative, technical, and physical safeguards to protect
24	the confidentiality, security, accuracy, and integrity of
25	protected health information created, received, obtained,

- 1 maintained, used, transmitted, or disposed of by such en-
- 2 tity.

3 Subtitle C—Enforcement;

4 **Definitions**

- 5 SEC. 231. CIVIL PENALTY.
- 6 (a) Violation.—A health care provider, health re-
- 7 searcher, health plan, health oversight agency, public
- 8 health agency, law enforcement agency, employer, health
- 9 or life insurer, school, or university, or the agent of any
- 10 such individual or entity, who the Secretary, in consulta-
- 11 tion with the Attorney General, determines has substan-
- 12 tially and materially failed to comply with this Act shall,
- 13 for a violation of this title, be subject, in addition to any
- 14 other penalties that may be prescribed by law, to a civil
- 15 penalty of not more than \$500 for each such violation,
- 16 but not to exceed \$5,000 in the aggregate for multiple vio-
- 17 lations.
- 18 (b) Procedures for Imposition of Penalties.—
- 19 Section 1128A of the Social Security Act, other than sub-
- 20 sections (a) and (b) and the second sentence of subsection
- 21 (f) of that section, shall apply to the imposition of a civil,
- 22 monetary, or exclusionary penalty under this section in the
- 23 same manner as such provisions apply with respect to the
- 24 imposition of a penalty under section 1128A of such Act.

1 SEC. 232. DEFINITIONS.

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- (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 redisclosures 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 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—

- 1 (A) a person who is licensed, certified, reg2 istered, or otherwise authorized by Federal or
 3 State law to provide an item or service that
 4 constitutes health care in the ordinary course of
 5 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.

1	(7) Person.—The term "person" means a gov-
2	ernment, governmental subdivision, agency or au-
3	thority; corporation; company; association; firm;
4	partnership; society; estate; trust; joint venture; indi-
5	vidual; individual representative; tribal government;
6	and any other legal entity.
7	(8) PROTECTED HEALTH INFORMATION.—The
8	term "protected health information" means any in-
9	formation (including demographic information)
10	whether or not recorded in any form or medium—
11	(A) that relates to the past, present or
12	future—
13	(i) physical or mental health or condi-
14	tion of an individual (including the condi-
15	tion or other attributes of individual cells
16	or their components);
17	(ii) provision of health care to an indi-
18	vidual; or
19	(iii) payment for the provision of
20	health care to an individual;
21	(B) that is created by a health care pro-
22	vider, health plan, health researcher, health
23	oversight agency, public health authority, em-
24	ployer, law enforcement official, health or life
25	insurer, school or university; and

1	(C) that is not nonidentifiable health infor-
2	mation.
3	(9) School or university.—The term
4	"school or university" means an institution or place
5	for instruction or education, including an elementary
6	school, secondary school, or institution of higher
7	learning, a college, or an assemblage of colleges
8	united under one corporate organization or govern-
9	ment.
10	(10) Secretary.—The term "Secretary"
11	means the Secretary of Health and Human Services.
12	(11) Writing.—The term "writing" means
13	writing in either a paper-based or computer-based
14	form, including electronic signatures.
15	SEC. 233. EFFECTIVE DATE.
16	The provisions of this title shall become effective be-
17	ginning on the date that is 1 year after the date of enact-
18	ment of this Act. The Secretary shall issue regulations
19	necessary to carry out this title before the effective date
20	thereof.
21	TITLE III—GENETIC
22	INFORMATION AND SERVICES
23	SEC. 301. SHORT TITLE.
24	This title may be cited as the "Genetic Information
25	Nondiscrimination in Health Insurance Act of 1999".

1	SEC. 302. AMENDMENTS TO EMPLOYEE RETIREMENT IN-
2	COME SECURITY ACT OF 1974.
3	(a) Prohibition of Health Discrimination on
4	THE BASIS OF GENETIC INFORMATION OR GENETIC
5	Services.—
6	(1) No enrollment restriction for ge-
7	NETIC SERVICES.—Section 702(a)(1)(F) of the Em-
8	ployee Retirement Income Security Act of 1974 (29
9	U.S.C. 1182(a)(1)(F)) is amended by inserting be-
10	fore the period the following: "(including informa-
11	tion about a request for or receipt of genetic serv-
12	ices)".
13	(2) No discrimination in group premiums
14	BASED ON PREDICTIVE GENETIC INFORMATION.—
15	Subpart B of part 7 of subtitle B of title I of the
16	Employee Retirement Income Security Act of 1974
17	(29 U.S.C. 1185 et seq.) (as amended by section
18	111) is further amended by adding at the end the
19	following:
20	"SEC. 714. PROHIBITING PREMIUM DISCRIMINATION
21	AGAINST GROUPS ON THE BASIS OF PRE-
22	DICTIVE GENETIC INFORMATION.
23	"A group health plan, or a health insurance issuer
24	offering group health insurance coverage in connection
25	with a group health plan, shall not adjust premium or con-
26	tribution amounts for a group on the basis of predictive

- 1 genetic information concerning an individual in the group
- 2 or a family member of the individual (including informa-
- 3 tion about a request for or receipt of genetic services).".
- 4 (3) Conforming amendment.—Section
- 5 702(b) of the Employee Retirement Income Security
- 6 Act of 1974 (29 U.S.C. 1182(b)) is amended by
- 7 adding at the end the following:
- 8 "(3) Reference to related provision.—
- 9 For a provision prohibiting the adjustment of pre-
- mium 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.".
- 14 (b) Limitation on Collection of Predictive
- 15 GENETIC INFORMATION.—Section 702 of the Employee
- 16 Retirement Income Security Act of 1974 (29 U.S.C. 1182)
- 17 is amended by adding at the end the following:
- 18 "(c) Collection of Predictive Genetic Infor-
- 19 MATION.—
- 20 "(1) Limitation on requesting or requir-
- 21 ING PREDICTIVE GENETIC INFORMATION.—Except
- as provided in paragraph (2), a group health plan,
- or a health insurance issuer offering health insur-
- ance coverage in connection with a group health
- 25 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 the procedures in place to safeguard the confidentiality, as described in sections 213 and 221 of the Patients' Bill of

1	Rights Plus Act, of such individually identifi-
2	able information.".
3	(c) Definitions.—Section 733(d) of the Employee
4	Retirement Income Security Act of 1974 (29 U.S.C.
5	1191b(d)) is amended by adding at the end the following:
6	"(5) Family Member.—The term 'family
7	member' means with respect to an individual—
8	"(A) the spouse of the individual;
9	"(B) a dependent child of the individual,
10	including a child who is born to or placed for
11	adoption with the individual; and
12	"(C) all other individuals related by blood
13	to the individual or the spouse or child de-
14	scribed in subparagraph (A) or (B).
15	"(6) Genetic information.—The term 'ge-
16	netic information' means information about genes,
17	gene products, or inherited characteristics that may
18	derive from an individual or a family member (in-
19	cluding information about a request for or receipt of
20	genetic services).
21	"(7) Genetic services.—The term 'genetic
22	services' means health services provided to obtain,
23	assess, or interpret genetic information for diag-
24	nostic and therapeutic purposes, and for genetic
25	education and counseling.

1	"(8) Predictive genetic information.—
2	"(A) In General.—The term 'predictive
3	genetic information' means—
4	"(i) information about an individual's
5	genetic tests which are associated with a
6	statistically significant increased risk of
7	developing a disease or disorder;
8	"(ii) information about genetic tests
9	of family members of the individual; or
10	"(iii) information about the occur-
11	rence of a disease or disorder in family
12	members that predicts a statistically sig-
13	nificant increased risk of a disease or dis-
14	order in the individual.
15	"(B) Exceptions.—The term 'predictive
16	genetic information' shall not include—
17	"(i) information about the sex or age
18	of the individual;
19	"(ii) information derived from routine
20	physical tests, such as the chemical, blood,
21	or urine analyses of the individual, unless
22	such analyses are genetic tests; and
23	"(iii) information about physical
24	exams of the individual and other informa-
25	tion relevant to determining the current

1	health status of the individual so long as
2	such information does not include informa-
3	tion described in clauses (i), (ii), or (iii) of
4	subparagraph (A).
5	"(9) Genetic test.—The term 'genetic test'
6	means the analysis of human DNA, RNA, chro-
7	mosomes, proteins, and certain metabolites, in order
8	to detect disease-related genotypes, mutations,
9	phenotypes, or karyotypes.".
10	(d) Effective Date.—Except as provided in this
11	section, this section and the amendments made by this
12	section shall apply with respect to group health plans for
13	plan years beginning 1 year after the date of the enact-
14	ment of this Act.
15	SEC. 303. AMENDMENTS TO THE PUBLIC HEALTH SERVICE
16	ACT.
17	(a) Amendments Relating to the Group Mar-
18	KET.—
19	(1) Prohibition of Health discrimination
20	ON THE BASIS OF GENETIC INFORMATION IN THE
21	GROUP MARKET.—
22	(A) In general.—Subpart 2 of part A of
23	title XXVII of the Public Health Service Act,
24	
	as amended by the Omnibus Consolidated and

1	1999 (Public Law 105-277), is amended by
2	adding at the end the following new section:
3	"SEC. 2707. PROHIBITING PREMIUM DISCRIMINATION
4	AGAINST GROUPS ON THE BASIS OF PRE-
5	DICTIVE GENETIC INFORMATION IN THE
6	GROUP MARKET.
7	"A group health plan, or a health insurance issuer
8	offering group health insurance coverage in connection
9	with a group health plan shall not adjust premium or con-
10	tribution amounts for a group on the basis of predictive
11	genetic information concerning an individual in the group
12	or a family member of the individual (including informa-
13	tion about a request for or receipt of genetic services).".
14	(B) Conforming amendment.—Section
15	2702(b) of the Public Health Service Act (42
16	U.S.C. 300gg-1(b)) is amended by adding at
17	the end the following:
18	"(3) Reference to related provision.—
19	For a provision prohibiting the adjustment of pre-
20	mium or contribution amounts for a group under a
21	group health plan on the basis of predictive genetic
22	information (including information about a request
23	for or receipt of genetic services), see section 2707.".
24	(C) Limitation on collection and dis-
25	CLOSURE OF PREDICTIVE GENETIC INFORMA-

1	TION.—Section 2702 of the Public Health Serv-
2	ice Act (42 U.S.C. 300gg-1) is amended by
3	adding at the end the following:
4	"(c) Collection of Predictive Genetic Infor-
5	MATION.—
6	"(1) Limitation on requesting or requir-
7	ING PREDICTIVE GENETIC INFORMATION.—Except
8	as provided in paragraph (2), a group health plan,
9	or a health insurance issuer offering health insur-
10	ance coverage in connection with a group health
11	plan, shall not request or require predictive genetic
12	information concerning an individual or a family
13	member of the individual (including information
14	about a request for or receipt of genetic services).
15	"(2) Information needed for diagnosis,
16	TREATMENT, OR PAYMENT.—
17	"(A) In general.—Notwithstanding para-
18	graph (1), a group health plan or health insur-
19	ance issuer that provides health care items and
20	services to an individual or dependent may re-
21	quest (but may not require) that such individ-
22	ual or dependent disclose, or authorize the col-
23	lection or disclosure of, predictive genetic infor-
24	mation for purposes of diagnosis, treatment, or
25	payment relating to the provision of health care

1	items and services to such individual or depend-
2	ent.
3	"(B) Notice of confidentiality prac-
4	TICES AND DESCRIPTION OF SAFEGUARDS.—As
5	a part of a request under subparagraph (A),
6	the group health plan or health insurance issuer
7	shall provide to the individual or dependent a
8	description of the procedures in place to safe-
9	guard the confidentiality, as described in sec-
10	tions 213 and 221 of the Patients' Bill of
11	Rights Plus Act, of such individually identifi-
12	able information.".
13	(2) Definitions.—Section 2791(d) of the Pub-
14	lic Health Service Act (42 U.S.C. 300gg-91(d)) is
15	amended by adding at the end the following:
16	"(15) Family member.—The term 'family
17	member' means, with respect to an individual—
18	"(A) the spouse of the individual;
19	"(B) a dependent child of the individual,
20	including a child who is born to or placed for
21	adoption with the individual; and
22	"(C) all other individuals related by blood
23	to the individual or the spouse or child de-
24	scribed in subparagraph (A) or (B).

1	"(16) Genetic information.—The term 'ge-
2	netic information' means information about genes,
3	gene products, or inherited characteristics that may
4	derive from an individual or a family member.
5	"(17) Genetic services.—The term 'genetic
6	services' means health services provided to obtain,
7	assess, or interpret genetic information for diag-
8	nostic and therapeutic purposes, and for genetic
9	education and counseling.
10	"(18) Predictive genetic information.—
11	"(A) In general.—The term 'predictive
12	genetic information' means—
13	"(i) information about an individual's
14	genetic tests which is associated with a
15	statistically significant increased risk of
16	developing a disease or disorder;
17	"(ii) information about genetic tests
18	of family members of the individual; or
19	"(iii) information about the occur-
20	rence of a disease or disorder in family
21	members that predicts a statistically sig-
22	nificant increased risk of a disease or dis-
23	order in the individual.
24	"(B) Exceptions.—The term 'predictive
25	genetic information' shall not include—

1	"(i) information about the sex or age
2	of the individual;
3	"(ii) information derived from routine
4	physical tests, such as the chemical, blood,
5	or urine analyses of the individual, unless
6	such analyses are genetic tests; and
7	"(iii) information about physical
8	exams of the individual and other informa-
9	tion relevant to determining the current
10	health status of the individual so long as
11	such information does not include informa-
12	tion described in clauses (i), (ii), or (iii) of
13	subparagraph (A).
14	"(19) Genetic test.—The term 'genetic test'
15	means the analysis of human DNA, RNA, chro-
16	mosomes, proteins, and certain metabolites, in order
17	to detect disease-related genotypes, mutations,
18	phenotypes, or karyotypes.".
19	(b) Amendment Relating to the Individual
20	Market.—The first subpart 3 of part B of title XXVII
21	of the Public Health Service Act (42 U.S.C. 300gg-11 et
22	seq.) (relating to other requirements), as amended by the
23	Omnibus Consolidated and Emergency Supplemental
24	Appropriations Act, 1999 (Public Law 105-277) is
25	amended—

1	(1) by redesignating such subpart as subpart 2;
2	and
3	(2) by adding at the end the following:
4	"SEC. 2753. PROHIBITION OF HEALTH DISCRIMINATION ON
5	THE BASIS OF PREDICTIVE GENETIC INFOR-
6	MATION.
7	"(a) Prohibition on Predictive Genetic Infor-
8	MATION AS A CONDITION OF ELIGIBILITY.—A health in-
9	surance issuer offering health insurance coverage in the
10	individual market may not use predictive genetic informa-
11	tion as a condition of eligibility of an individual to enroll
12	in individual health insurance coverage (including infor-
13	mation about a request for or receipt of genetic services).
14	"(b) Prohibition on Predictive Genetic Infor-
15	MATION IN SETTING PREMIUM RATES.—A health insur-
16	ance issuer offering health insurance coverage in the indi-
17	vidual market shall not adjust premium rates for individ-
18	uals on the basis of predictive genetic information concern-
19	ing such an enrollee or a family member of the enrollee
20	(including information about a request for or receipt of
21	genetic services).
22	"(c) Collection of Predictive Genetic Infor-
23	MATION.—
24	"(1) Limitation on requesting or requir-
25	INC 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 PRAC-TICES 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-

1	tiality, as described in sections 213 and 221 of
2	the Patients' Bill of Rights Plus Act, of such
3	individually identifiable information.".
4	(c) Effective Date.—The amendments made by
5	this section shall apply with respect to—
6	(1) group health plans, and health insurance
7	coverage offered in connection with group health
8	plans, for plan years beginning after 1 year after the
9	date of enactment of this Act; and
10	(2) health insurance coverage offered, sold,
11	issued, renewed, in effect, or operated in the individ-
12	ual market after 1 year after the date of enactment
13	of this Act.
14	SEC. 304. AMENDMENTS TO THE INTERNAL REVENUE CODE
15	OF 1986.
16	(a) Prohibition of Health Discrimination on
17	THE BASIS OF PREDICTIVE GENETIC INFORMATION.—
18	(1) In General.—Subchapter B of chapter
19	100 of the Internal Revenue Code of 1986 (as
20	amended by section 131) is further amended by add-
21	ing at the end the following:

1	"SEC. 9814. PROHIBITING HEALTH DISCRIMINATION
2	AGAINST GROUPS ON THE BASIS OF PRE-
3	DICTIVE GENETIC INFORMATION.
4	"A group health plan shall not adjust premium or
5	contribution amounts for a group on the basis of predictive
6	genetic information concerning an individual in the group
7	or a family member of the individual (including informa-
8	tion about a request for or receipt of genetic services).".
9	(2) Conforming Amendment.—Section
10	9802(b) of the Internal Revenue Code of 1986 is
11	amended by adding at the end the following:
12	"(3) Reference to related provision.—
13	For a provision prohibiting the adjustment of pre-
14	mium or contribution amounts for a group under a
15	group health plan on the basis of predictive genetic
16	information (including information about a request
17	for or the receipt of genetic services), see section
18	9814.".
19	(3) Amendment to table of sections.—
20	The table of sections for subchapter B of chapter
21	100 of the Internal Revenue Code of 1986 (as
22	amended by section 131) is further amended by add-
23	ing at the end the following:

"Sec. 9814. Prohibiting premium discrimination against groups on the basis of predictive genetic information.".

1	(b) Limitation on Collection of Predictive
2	GENETIC INFORMATION.—Section 9802 of the Internal
3	Revenue Code of 1986 is amended by adding at the end
4	the following:
5	"(c) Collection of Predictive Genetic Infor-
6	MATION.—
7	"(1) Limitation on requesting or requir-
8	ING PREDICTIVE GENETIC INFORMATION.—Except
9	as provided in paragraph (2), a group health plan
10	shall not request or require predictive genetic infor-
11	mation concerning an individual or a family member
12	of the individual (including information about a re-
13	quest for or receipt of genetic services).
14	"(2) Information needed for diagnosis.
15	TREATMENT, OR PAYMENT.—
16	"(A) In general.—Notwithstanding para-
17	graph (1), a group health plan that provides
18	health care items and services to an individual
19	or dependent may request (but may not re-
20	quire) that such individual or dependent dis-
21	close, or authorize the collection or disclosure
22	of, predictive genetic information for purposes
23	of diagnosis, treatment, or payment relating to
24	the provision of health care items and services
25	to such individual or dependent.

1	"(B) Notice of confidentiality prac-
2	TICES; DESCRIPTION OF SAFEGUARDS.—As a
3	part of a request under subparagraph (A), the
4	group health plan shall provide to the individual
5	or dependent a description of the procedures in
6	place to safeguard the confidentiality, as de-
7	scribed in sections 213 and 221 of the Patients'
8	Bill of Rights Plus Act, of such individually
9	identifiable information.".
10	(c) Definitions.—Section 9832(d) of the Internal
11	Revenue Code of 1986 is amended by adding at the end
12	the following:
13	"(6) Family member.—The term 'family
14	member' means, with respect to an individual—
15	"(A) the spouse of the individual;
16	"(B) a dependent child of the individual,
17	including a child who is born to or placed for
18	adoption with the individual; and
19	"(C) all other individuals related by blood
20	to the individual or the spouse or child de-
21	scribed in subparagraph (A) or (B).
22	"(7) Genetic information.—The term 'ge-
23	netic information' means information about genes,
24	gene products, or inherited characteristics that may
25	derive from an individual or a family member.

1	"(8) Genetic services.—The term 'genetic
2	services' means health services provided to obtain
3	assess, or interpret genetic information for diag-
4	nostic and therapeutic purposes, and for genetic
5	education and counseling.
6	"(9) Predictive genetic information.—
7	"(A) IN GENERAL.—The term 'predictive
8	genetic information' means—
9	"(i) information about an individual's
10	genetic tests which is associated with a
11	statistically significant increased risk of
12	developing a disease or disorder;
13	"(ii) information about genetic tests
14	of family members of the individual; or
15	"(iii) information about the occur-
16	rence of a disease or disorder in family
17	members that predicts a statistically sig-
18	nificant increased risk of a disease or dis-
19	order in the individual.
20	"(B) Exceptions.—The term 'predictive
21	genetic information' shall not include—
22	"(i) information about the sex or age
23	of the individual;
24	"(ii) information derived from routine
25	physical tests, such as the chemical, blood

1	or urine analyses of the individual, unless
2	such analyses are genetic tests; and
3	"(iii) information about physical
4	exams of the individual and other informa-
5	tion relevant to determining the current
6	health status of the individual so long as
7	such information does not include informa-
8	tion described in clauses (i), (ii), or (iii) of
9	subparagraph (A).
10	"(10) Genetic test.—The term 'genetic test'
11	means the analysis of human DNA, RNA, chro-
12	mosomes, proteins, and certain metabolites, in order
13	to detect disease-related genotypes, mutations,
14	phenotypes, or karyotypes.".
15	(d) Effective Date.—Except as provided in this
16	section, this section and the amendments made by this
17	section shall apply with respect to group health plans for
18	plan years beginning after 1 year after the date of the
19	enactment of this Act.
20	TITLE IV—HEALTHCARE
21	RESEARCH AND QUALITY
22	SEC. 401. SHORT TITLE.
23	This title may be cited as the "Healthcare Research
24	and Quality Act of 1999".

1	SEC. 402. AMENDMENT TO THE PUBLIC HEALTH SERVICE
2	ACT.
3	Title IX of the Public Health Service Act (42 U.S.C.
4	299 et seq.) is amended to read as follows:
5	"TITLE IX—AGENCY FOR
6	HEALTHCARE RESEARCH
7	AND QUALITY
8	"PART A—ESTABLISHMENT AND GENERAL
9	DUTIES
10	"SEC. 901. MISSION AND DUTIES.
11	"(a) In General.—There is established within the
12	Public Health Service an agency to be known as the Agen-
13	cy for Healthcare Research and Quality. In carrying out
14	this subsection, the Secretary shall redesignate the Agency
15	for Health Care Policy and Research as the Agency for
16	Healthcare Research and Quality.
17	"(b) Mission.—The purpose of the Agency is to en-
18	hance the quality, appropriateness, and effectiveness of
19	healthcare services, and access to such services, through
20	the establishment of a broad base of scientific research
21	and through the promotion of improvements in clinical
22	and health system practice, including the prevention of
23	diseases and other health conditions. The Agency shall
24	promote healthcare quality improvement by—

1	"(1) conducting and supporting research that
2	develops and presents scientific evidence regarding
3	all aspects of healthcare, including—
4	"(A) the development and assessment of
5	methods for enhancing patient participation in
6	their own care and for facilitating shared pa-
7	tient-physician decision-making;
8	"(B) the outcomes, effectiveness, and cost-
9	effectiveness of healthcare practices, including
10	preventive measures and primary, acute and
11	long-term care;
12	"(C) existing and innovative technologies;
13	"(D) the costs and utilization of, and ac-
14	cess to healthcare;
15	"(E) the ways in which healthcare services
16	are organized, delivered, and financed and the
17	interaction and impact of these factors on the
18	quality of patient care;
19	"(F) methods for measuring quality and
20	strategies for improving quality; and
21	"(G) ways in which patients, consumers
22	purchasers, and practitioners acquire new infor-
23	mation about best practices and health benefits
24	the determinants and impact of their use of this
25	information;

1	"(2) synthesizing and disseminating available
2	scientific evidence for use by patients, consumers,
3	practitioners, providers, purchasers, policy makers,
4	and educators; and
5	"(3) advancing private and public efforts to im-
6	prove healthcare quality.
7	"(c) Requirements With Respect to Rural
8	Areas and Priority Populations.—In carrying out
9	subsection (b), the Director shall undertake and support
10	research, demonstration projects, and evaluations with re-
11	spect to—
12	"(1) the delivery of health services in rural
13	areas (including frontier areas);
14	"(2) health services for low-income groups, and
15	minority groups;
16	"(3) the health of children;
17	"(4) the elderly; and
18	"(5) people with special healthcare needs, in-
19	cluding disabilities, chronic care and end-of-life
20	healthcare.
21	"(d) Appointment of Director.—There shall be
22	at the head of the Agency an official to be known as the
23	Director for Healthcare Research and Quality. The Direc-
24	tor shall be appointed by the Secretary. The Secretary,

1	acting through the Director, shall carry out the authorities
2	and duties established in this title.
3	"SEC. 902. GENERAL AUTHORITIES.
4	"(a) In General.—In carrying out section 901(b),
5	the Director shall support demonstration projects, conduct
6	and support research, evaluations, training, research net-
7	works, multi-disciplinary centers, technical assistance, and
8	the dissemination of information, on healthcare, and on
9	systems for the delivery of such care, including activities
10	with respect to—
11	"(1) the quality, effectiveness, efficiency, appro-
12	priateness and value of healthcare services;
13	"(2) quality measurement and improvement;
14	"(3) the outcomes, cost, cost-effectiveness, and
15	use of healthcare services and access to such serv-
16	ices;
17	"(4) clinical practice, including primary care
18	and practice-oriented research;
19	"(5) healthcare technologies, facilities, and
20	equipment;
21	"(6) healthcare costs, productivity, organiza-
22	tion, and market forces;
23	"(7) health promotion and disease prevention,
24	including clinical preventive services:

"(8) health statistics, surveys, database devel-1 2 opment, and epidemiology; and 3 "(9) medical liability. "(b) Health Services Training Grants.— 5 "(1) IN GENERAL.—The Director may provide 6 training grants in the field of health services re-7 search related to activities authorized under sub-8 section (a), to include pre- and post-doctoral fellow-9 ships and training programs, young investigator 10 awards, and other programs and activities as appro-11 priate. In carrying out this subsection, the Director 12 shall make use of funds made available under sec-13 tion 487. 14 "(2) REQUIREMENTS.—In developing priorities 15 for the allocation of training funds under this sub-16 section, the Director shall take into consideration 17 shortages in the number of trained researchers ad-

19 "(c) Multidisciplinary Centers.—The Director

dressing the priority populations.

20 may provide financial assistance to assist in meeting the

21 costs of planning and establishing new centers, and oper-

22 ating existing and new centers, for multidisciplinary

23 health services research, demonstration projects, evalua-

24 tions, training, and policy analysis with respect to the mat-

25 ters referred to in subsection (a).

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- 1 "(d) Relation to Certain Authorities Regard-
- 2 ING SOCIAL SECURITY.—Activities authorized in this sec-
- 3 tion may include, and shall be appropriately coordinated
- 4 with experiments, demonstration projects, and other relat-
- 5 ed activities authorized by the Social Security Act and the
- 6 Social Security Amendments of 1967. Activities under
- 7 subsection (a)(2) of this section that affect the programs
- 8 under titles XVIII, XIX and XXI of the Social Security
- 9 Act shall be carried out consistent with section 1142 of
- 10 such Act.
- 11 "(e) DISCLAIMER.—The Agency shall not mandate
- 12 national standards of clinical practice or quality
- 13 healthcare standards. Recommendations resulting from
- 14 projects funded and published by the Agency shall include
- 15 a corresponding disclaimer.
- 16 "(f) Rule of Construction.—Nothing in this sec-
- 17 tion shall be construed to imply that the Agency's role is
- 18 to mandate a national standard or specific approach to
- 19 quality measurement and reporting. In research and qual-
- 20 ity improvement activities, the Agency shall consider a
- 21 wide range of choices, providers, healthcare delivery sys-
- 22 tems, and individual preferences.

1	"PART B—HEALTHCARE IMPROVEMENT
2	RESEARCH
3	"SEC. 911. HEALTHCARE OUTCOME IMPROVEMENT RE-
4	SEARCH.
5	"(a) Evidence Rating Systems.—In collaboration
6	with experts from the public and private sector, the Agen-
7	cy shall identify and disseminate methods or systems used
8	to assess healthcare research results, particularly to rate
9	the strength of the scientific evidence behind healthcare
10	practice, recommendations in the research literature, and
11	technology assessments. The Agency shall make methods
12	or systems for evidence rating widely available. Agency
13	publications containing healthcare recommendations shall
14	indicate the level of substantiating evidence using such
15	methods or systems.
16	"(b) Healthcare Improvement Research Cen-
17	TERS AND PROVIDER-BASED RESEARCH NETWORKS.—
18	"(1) IN GENERAL.—In order to address the full
19	continuum of care and outcomes research, to link re-
20	search to practice improvement, and to speed the
21	dissemination of research findings to community
22	practice settings, the Agency shall employ research
23	strategies and mechanisms that will link research di-
24	rectly with clinical practice in geographically diverse

locations throughout the United States, including—

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1	"(A) Healthcare Improvement Research
2	Centers that combine demonstrated multidisci-
3	plinary expertise in outcomes or quality im-
4	provement research with linkages to relevant
5	sites of care;
6	"(B) Provider-based Research Networks,
7	including plan, facility, or delivery system sites
8	of care (especially primary care), that can
9	evaluate and promote quality improvement; and
10	"(C) other innovative mechanisms or strat-
11	egies to link research with clinical practice.
12	"(2) Requirements.—The Director is author-
13	ized to establish the requirements for entities apply-
14	ing for grants under this subsection.
15	"SEC. 912. PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE
16	ORGANIZATION AND DELIVERY.
17	"(a) Support for Efforts To Develop Infor-
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10	MATION ON QUALITY.—
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	MATION ON QUALITY.—
19	MATION ON QUALITY.— "(1) SCIENTIFIC AND TECHNICAL SUPPORT.—
19 20	MATION ON QUALITY.— "(1) Scientific and technical support.— In its role as the principal agency for healthcare re-
19 20 21	MATION ON QUALITY.— "(1) Scientific and technical support.— In its role as the principal agency for healthcare research and quality, the Agency may provide sci-

1	"(2) Role of the agency.—With respect to
2	paragraph (1), the role of the Agency shall include—
3	"(A) the identification and assessment
4	of—
5	"(i) methods for the evaluation of the
6	health of enrollees in health plans by type
7	of plan, provider, and provider arrange-
8	ments; and
9	"(ii) other populations, including
10	those receiving long-term care services;
11	"(B) the ongoing development, testing, and
12	dissemination of quality measures, including
13	measures of health and functional outcomes;
14	"(C) the compilation and dissemination of
15	healthcare quality measures developed in the
16	private and public sector;
17	"(D) assistance in the development of im-
18	proved healthcare information systems;
19	"(E) the development of survey tools for
20	the purpose of measuring participant and bene-
21	ficiary assessments of their healthcare; and
22	"(F) identifying and disseminating infor-
23	mation on mechanisms for the integration of in-
24	formation on quality into purchaser and con-
25	sumer decision-making processes.

1	"(b) Centers for Education and Research on
2	THERAPEUTICS.—
3	"(1) In General.—The Secretary, acting
4	through the Director and in consultation with the
5	Commissioner of Food and Drugs, shall establish a
6	program for the purpose of making one or more
7	grants for the establishment and operation of one or
8	more centers to carry out the activities specified in
9	paragraph (2).
10	"(2) REQUIRED ACTIVITIES.—The activities re-
11	ferred to in this paragraph are the following:
12	"(A) The conduct of state-of-the-art clini-
13	cal research for the following purposes:
14	"(i) To increase awareness of—
15	"(I) new uses of drugs, biological
16	products, and devices;
17	"(II) ways to improve the effec-
18	tive use of drugs, biological products,
19	and devices; and
20	"(III) risks of new uses and risks
21	of combinations of drugs and biologi-
22	cal products.
23	"(ii) To provide objective clinical in-
24	formation to the following individuals and
25	entities:

1	"(I) Healthcare practitioners and
2	other providers of Healthcare goods or
3	services.
4	"(II) Pharmacists, pharmacy
5	benefit managers and purchasers.
6	"(III) Health maintenance orga-
7	nizations and other managed
8	healthcare organizations.
9	"(IV) Healthcare insurers and
10	governmental agencies.
11	"(V) Patients and consumers.
12	"(iii) To improve the quality of
13	healthcare while reducing the cost of
14	Healthcare through—
15	"(I) an increase in the appro-
16	priate use of drugs, biological prod-
17	ucts, or devices; and
18	"(II) the prevention of adverse
19	effects of drugs, biological products,
20	and devices and the consequences of
21	such effects, such as unnecessary hos-
22	pitalizations.
23	"(B) The conduct of research on the com-
24	parative effectiveness, cost-effectiveness, and
25	safety of drugs, biological products, and devices.

1	"(C) Such other activities as the Secretary
2	determines to be appropriate, except that a
3	grant may not be expended to assist the Sec-
4	retary in the review of new drugs.
5	"(c) Reducing Errors in Medicine.—The Direc-
6	tor shall conduct and support research and build private-
7	public partnerships to—
8	"(1) identify the causes of preventable
9	healthcare errors and patient injury in healthcare
10	delivery;
11	"(2) develop, demonstrate, and evaluate strate-
12	gies for reducing errors and improving patient safe-
13	ty; and
14	"(3) promote the implementation of effective
15	strategies throughout the healthcare industry.
16	"SEC. 913. INFORMATION ON QUALITY AND COST OF CARE.
17	"(a) In General.—In carrying out 902(a), the Di-
18	rector shall—
19	"(1) collect data on a nationally representative
20	sample of the population on the cost, use and, for
21	fiscal year 2000 and subsequent fiscal years, quality
22	of healthcare, including the types of healthcare serv-
23	ices Americans use, their access to healthcare serv-
24	ices, frequency of use, how much is paid for the
25	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—
- 23 "(A) provide information on the quality of 24 care and patient outcomes for frequently occur-

1	ring clinical conditions for a nationally rep-
2	resentative sample of the population; and
3	"(B) provide reliable national estimates for
4	children and persons with special healthcare
5	needs through the use of supplements or peri-
6	odic expansions of the survey.
7	In expanding the Medical Expenditure Panel Survey,
8	as in existence on the date of enactment of this title)
9	in fiscal year 2000 to collect information on the
10	quality of care, the Director shall take into account
11	any outcomes measurements generally collected by
12	private sector accreditation organizations.
13	"(2) Annual Report.—Beginning in fiscal
14	year 2002, the Secretary, acting through the Direc-
15	tor, shall submit to Congress an annual report on
16	national trends in the quality of healthcare provided
17	to the American people.
18	"SEC. 914. INFORMATION SYSTEMS FOR HEALTHCARE IM-
19	PROVEMENT.
20	"In order to foster a range of innovative approaches
21	to the management and communication of health informa-
22	tion, the Agency shall support research, evaluations and
23	initiatives to advance—
24	"(1) the use of information systems for the
25	study of healthcare quality, including the generation

1	of both individual provider and plan-level compara-
2	tive performance data;
3	"(2) training for healthcare practitioners and
4	researchers in the use of information systems;
5	"(3) the creation of effective linkages between
6	various sources of health information, including the
7	development of information networks;
8	"(4) the delivery and coordination of evidence-
9	based healthcare services, including the use of real-
10	time healthcare decision-support programs;
11	"(5) the structure, content, definition, and cod-
12	ing of health information data and medical vocabu-
13	laries in consultation with appropriate Federal and
14	private entities;
15	"(6) the use of computer-based health records
16	in outpatient and inpatient settings as a personal
17	health record for individual health assessment and
18	maintenance, and for monitoring public health and
19	outcomes of care within populations; and
20	"(7) the protection of individually identifiable
21	information in health services research and
22	healthcare quality improvement.
23	"SEC. 915. RESEARCH SUPPORTING PRIMARY CARE AND
24	ACCESS IN UNDERSERVED AREAS.
25	"(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,

1	treatment or referral to specialty care, preventive
2	care, and the relationship between the clinician and
3	the patient in the context of the family and commu-
4	nity.
5	"(2) Research.—In carrying out this section,
6	the Center shall conduct and support research on—
7	"(A) the nature and characteristics of pri-
8	mary care practice;
9	"(B) the management of commonly occur-
10	ring clinical problems;
11	"(C) the management of undifferentiated
12	clinical problems; and
13	"(D) the continuity and coordination of
14	health services.
15	"(3) Demonstration.—The Agency shall sup-
16	port demonstrations into the use of new information
17	tools aimed at improving shared decision-making be-
18	tween patients and their care-givers.
19	"SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVA-
20	TION.
21	"(a) In General.—The Director shall promote inno-
22	vation in evidence-based clinical practice and healthcare
23	technologies by—

1	"(1) conducting and supporting research on the
2	development, diffusion, and use of healthcare tech-
3	nology;
4	"(2) developing, evaluating, and disseminating
5	methodologies for assessments of healthcare prac-
6	tices and healthcare technologies;
7	"(3) conducting intramural and supporting ex-
8	tramural assessments of existing and new healthcare
9	practices and technologies;
10	"(4) promoting education, training, and provid-
11	ing technical assistance in the use of healthcare
12	practice and healthcare technology assessment meth-
13	odologies and results; and
14	"(5) working with the National Library of Med-
15	icine and the public and private sector to develop an
16	electronic clearinghouse of currently available assess-
17	ments and those in progress.
18	"(b) Specification of Process.—
19	"(1) In General.—Not later than December
20	31, 2000, the Director shall develop and publish a
21	description of the methods used by the Agency and
22	its contractors for practice and technology assess-
23	ment.
24	"(2) Consultations.—In carrying out this
25	subsection, the Director shall cooperate and consult

1	with the Assistance Secretary for Health, the Ad-
2	ministrator of the Health Care Financing Adminis-
3	tration, the Director of the National Institutes of
4	Health, the Commissioner of Food and Drugs, and
5	the heads of any other interested Federal depart-
6	ment or agency, professional societies, and other pri-
7	vate and public entities.
8	"(3) Methodology.—The methods employed
9	in practice and technology assessments under para-
10	graph (1) shall consider—
11	"(A) safety, efficacy, and effectiveness;
12	"(B) legal, social, and ethical implications;
13	"(C) costs, benefits, and cost-effectiveness;
14	"(D) comparisons to alternative tech-
15	nologies and practices; and
16	"(E) requirements of Food and Drug Ad-
17	ministration approval to avoid duplication.
18	"(c) Specific Assessments.—
19	"(1) In general.—The Director shall conduct
20	or support specific assessments of healthcare tech-
21	nologies and practices.
22	"(2) Requests for assessments.—The Di-
23	rector is authorized to conduct or support assess-
24	ments, on a reimbursable basis, for the Health Care
25	Financing Administration, the Department of De-

- fense, 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.

19 "SEC. 917. COORDINATION OF FEDERAL GOVERNMENT 20 QUALITY IMPROVEMENT EFFORTS.

21 "(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

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1	demonstrations related to health services research
2	and quality measurement and improvement activities
3	undertaken and supported by the Federal Govern-
4	ment.
5	"(2) Specific activities.—The Director, in
6	collaboration with the appropriate Federal officials
7	representing all concerned executive agencies and de-
8	partments, shall develop and manage a process to—
9	"(A) improve interagency coordination, pri-
10	ority setting, and the use and sharing of re-
11	search findings and data pertaining to Federal
12	quality improvement programs and health serv-
13	ices research;
14	"(B) strengthen the research information
15	infrastructure, including databases, pertaining
16	to Federal health services research and
17	healthcare quality improvement initiatives;
18	"(C) set specific goals for participating
19	agencies and departments to further health
20	services research and healthcare quality im-
21	provement; and
22	"(D) strengthen the management of Fed-
23	eral healthcare quality improvement programs.
24	"(b) Study by the Institute of Medicine.—

1	"(1) In general.—To provide the Department
2	of Health and Human Services with an independent,
3	external review of its quality oversight, and quality
4	research programs, the Secretary shall enter into a
5	contract with the Institute of Medicine—
6	"(A) to describe and evaluate current qual-
7	ity improvement research and monitoring proc-
8	esses through—
9	"(i) an overview of pertinent health
10	services research activities and quality im-
11	provement efforts including those currently
12	performed by the peer review organizations
13	and the exploration of additional activities
14	that could be undertaken by the peer re-
15	view organizations to improve quality;
16	"(ii) an analysis of the various part-
17	nership activities that the Department of
18	Health and Human Services has pursued
19	with private sector accreditation and other
20	quality measurement organizations;
21	"(iii) the exploration of programmatic
22	areas where partnership activities between
23	the Federal Government and the private
24	sector or within the Federal Government
25	could be pursued to improve quality over-

1	sight of the medicare, medicaid and child
2	health insurance programs under titles
3	XVIII, XIX and XXI of the Social Secu-
4	rity Act; and
5	"(iv) an identification of opportunities
6	for enhancing health system efficiency
7	through simplification and reduction in re-
8	dundancy of Federal agency quality im-
9	provement efforts, including areas in which
10	Federal efforts unnecessarily duplicate ex-
11	isting private sector efforts; and
12	"(B) to identify options and make rec-
13	ommendations to improve the efficiency and ef-
14	fectiveness of such quality improvement pro-
15	grams through—
16	"(i) the improved coordination of ac-
17	tivities across the medicare, medicaid and
18	child health insurance programs under ti-
19	tles XVIII, XIX and XXI of the Social Se-
20	curity Act and various health services re-
21	search programs;
22	"(ii) the strengthening of patient
23	choice and participation by incorporating
24	state-of-the-art quality monitoring tools

1	and making information on quality avail-
2	able; and
3	"(iii) the enhancement of the most ef-
4	fective programs, consolidation as appro-
5	priate, and elimination of duplicative ac-
6	tivities within various federal agencies.
7	"(2) Requirements.—
8	"(A) IN GENERAL.—The Secretary shall
9	enter into a contract with the Institute of Medi-
10	cine for the preparation—
11	"(i) not later than 12 months after
12	the date of enactment of this title, of a re-
13	port providing an overview of the quality
14	improvement programs of the Department
15	of Health and Human Services for the
16	medicare, medicaid, and CHIP programs
17	under titles XVIII, XIX, and XXI of the
18	Social Security Act; and
19	"(ii) not later than 24 months after
20	the date of enactment of this title, of a
21	final report containing recommendations.
22	"(B) Reports.—The Secretary shall sub-
23	mit the reports described in subparagraph (A)
24	to the Committee on Finance and the Commit-
25	tee on Health, Education, Labor, and Pensions

1	of the Senate and the Committee on Ways and
2	Means and the Committee on Commerce of the
3	House of Representatives.
4	"PART C—GENERAL PROVISIONS
5	"SEC. 921. ADVISORY COUNCIL FOR HEALTHCARE RE-
6	SEARCH AND QUALITY.
7	"(a) Establishment.—There is established an advi-
8	sory council to be known as the Advisory Council for
9	Healthcare Research and Quality.
10	"(b) Duties.—
11	"(1) In General.—The Advisory Council shall
12	advise the Secretary and the Director with respect
13	to activities proposed or undertaken to carry out the
14	purpose of the Agency under section 901(b).
15	"(2) Certain recommendations.—Activities
16	of the Advisory Council under paragraph (1) shall
17	include making recommendations to the Director
18	regarding—
19	"(A) priorities regarding healthcare re-
20	search, especially studies related to quality, out-
21	comes, cost and the utilization of, and access
22	to, healthcare services;
23	"(B) the field of healthcare research and
24	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—

1	"(A) 4 shall be individuals distinguished in
2	the conduct of research, demonstration projects,
3	and evaluations with respect to healthcare;
4	"(B) 4 shall be individuals distinguished in
5	the practice of medicine of which at least 1
6	shall be a primary care practitioner;
7	"(C) 3 shall be individuals distinguished in
8	the other health professions;
9	"(D) 4 shall be individuals either rep-
10	resenting the private healthcare sector, includ-
11	ing health plans, providers, and purchasers or
12	individuals distinguished as administrators of
13	healthcare delivery systems;
14	"(E) 4 shall be individuals distinguished in
15	the fields of healthcare quality improvement, ec-
16	onomics, information systems, law, ethics, busi-
17	ness, or public policy; and
18	"(F) 2 shall be individuals representing the
19	interests of patients and consumers of
20	healthcare.
21	"(3) Ex officio members.—The Secretary
22	shall designate as ex officio members of the Advisory
23	Council—
24	"(A) the Assistant Secretary for Health,
25	the Director of the National Institutes of

- 1 Health, the Director of the Centers for Disease
- 2 Control and Prevention, the Administrator of
- 3 the Health Care Financing Administration, the
- 4 Assistant Secretary of Defense (Health Af-
- 5 fairs), and the Chief Medical Officer of the De-
- 6 partment of Veterans Affairs; and
- 7 "(B) such other Federal officials as the
- 8 Secretary may consider appropriate.
- 9 "(d) Terms.—Members of the Advisory Council ap-
- 10 pointed under subsection (c)(2) shall serve for a term of
- 11 3 years. A member of the Council appointed under such
- 12 subsection may continue to serve after the expiration of
- 13 the term of the members until a successor is appointed.
- 14 "(e) Vacancies.—If a member of the Advisory
- 15 Council appointed under subsection (c)(2) does not serve
- 16 the full term applicable under subsection (d), the individ-
- 17 ual appointed to fill the resulting vacancy shall be ap-
- 18 pointed for the remainder of the term of the predecessor
- 19 of the individual.
- 20 "(f) Chair.—The Director shall, from among the
- 21 members of the Advisory Council appointed under sub-
- 22 section (c)(2), designate an individual to serve as the chair
- 23 of the Advisory Council.
- 24 "(g) Meetings.—The Advisory Council shall meet
- 25 not less than once during each discrete 4-month period

1	and shall otherwise meet at the call of the Director or the
2	chair.
3	"(h) Compensation and Reimbursement of Ex-
4	PENSES.—
5	"(1) Appointed members.—Members of the
6	Advisory Council appointed under subsection (c)(2)
7	shall receive compensation for each day (including
8	travel time) engaged in carrying out the duties of
9	the Advisory Council unless declined by the member.
10	Such compensation may not be in an amount in ex-
11	cess of the maximum rate of basic pay payable for
12	GS-18 of the General Schedule.
13	"(2) Ex officio members.—Officials des-
14	ignated under subsection $(c)(3)$ as ex officio mem-
15	bers of the Advisory Council may not receive com-
16	pensation for service on the Advisory Council in ad-
17	dition to the compensation otherwise received for du-
18	ties carried out as officers of the United States.
19	"(i) STAFF.—The Director shall provide to the Advi-
20	sory Council such staff, information, and other assistance
21	as may be necessary to carry out the duties of the Council.
22	"SEC. 922. PEER REVIEW WITH RESPECT TO GRANTS AND
23	CONTRACTS.
24	"(a) Requirement of Review.—

- 1 "(1) IN GENERAL.—Appropriate technical and 2 scientific peer review shall be conducted with respect 3 to each application for a grant, cooperative agree-4 ment, or contract under this title.
- 5 "(2) Reports to director.—Each peer re-6 view group to which an application is submitted pur-7 suant to paragraph (1) shall report its finding and 8 recommendations respecting the application to the 9 Director in such form and in such manner as the 10 Director shall require.
- "(b) APPROVAL AS PRECONDITION OF AWARDS.—

 12 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.— 16 17 "(1) IN GENERAL.—The Director shall establish 18 such technical and scientific peer review groups as 19 may be necessary to carry out this section. Such 20 groups shall be established without regard to the 21 provisions of title 5, United States Code, that govern 22 appointments in the competitive service, and without 23 regard to the provisions of chapter 51, and sub-24 chapter III of chapter 53, of such title that relate

1	to classification and pay rates under the General
2	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 peerreview group shall, at a minimum, meet the following requirements:
- 23 "(A) Such members shall agree in writing 24 to treat information received, pursuant to their 25 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.

12 "(d) Authority for Procedural Adjustments IN CERTAIN CASES.—In the case of applications for financial assistance whose direct costs will not exceed \$100,000, 14 15 the Director may make appropriate adjustments in the procedures otherwise established by the Director for the 16 17 conduct of peer review under this section. Such adjustments may be made for the purpose of encouraging the 18 19 entry of individuals into the field of research, for the purpose of encouraging clinical practice-oriented or provider-21 based research, and for such other purposes as the Direc-22 tor may determine to be appropriate.

23 "(e) Regulations.—The Director shall issue regula-24 tions for the conduct of peer review under this section.

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1	"SEC. 923. CERTAIN PROVISIONS WITH RESPECT TO DEVEL-
2	OPMENT, COLLECTION, AND DISSEMINATION
3	OF DATA.
4	"(a) Standards With Respect to Utility of
5	Data.—
6	"(1) In general.—To ensure the utility, accu-
7	racy, and sufficiency of data collected by or for the
8	Agency for the purpose described in section 901(b),
9	the Director shall establish standards and methods
10	for developing and collecting such data, taking into
11	consideration—
12	"(A) other Federal health data collection
13	standards; and
14	"(B) the differences between types of
15	healthcare plans, delivery systems, healthcare
16	providers, and provider arrangements.
17	"(2) Relationship with other department
18	PROGRAMS.—In any case where standards under
19	paragraph (1) may affect the administration of other
20	programs carried out by the Department of Health
21	and Human Services, including the programs under
22	titles XVIII, XIX and XXI of the Social Security
23	Act, they shall be in the form of recommendations
24	to the Secretary for such program.
25	"(b) STATISTICS AND ANALYSES.—The Director
26	shall—

1	"(1) take appropriate action to ensure that sta-
2	tistics and analyses developed under this title are of
3	high quality, timely, and duly comprehensive, and
4	that the statistics are specific, standardized, and
5	adequately analyzed and indexed; and
6	"(2) publish, make available, and disseminate
7	such statistics and analyses on as wide a basis as is
8	practicable.
9	"(c) Authority Regarding Certain Requests.—
10	Upon request of a public or private entity, the Director
11	may conduct or support research or analyses otherwise au-
12	thorized by this title pursuant to arrangements under
13	which such entity will pay the cost of the services provided.
14	Amounts received by the Director under such arrange-
15	ments shall be available to the Director for obligation until
16	expended.
17	"SEC. 924. DISSEMINATION OF INFORMATION.
18	"(a) In General.—The Director shall—
19	"(1) without regard to section 501 of title 44,
20	United States Code, promptly publish, make avail-
21	able, and otherwise disseminate, in a form under-
22	standable and on as broad a basis as practicable so
23	as to maximize its use, the results of research, dem-
24	onstration projects, and evaluations conducted or

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.
- 24 "(b) Prohibition Against Restrictions.—Except 25 as provided in subsection (c), the Director may not restrict

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- 1 the publication or dissemination of data from, or the re-
- 2 sults of, projects conducted or supported under this title.
- 3 "(c) Limitation on Use of Certain Informa-
- 4 TION.—No information, if an establishment or person sup-
- 5 plying the information or described in it is identifiable,
- 6 obtained in the course of activities undertaken or sup-
- 7 ported under this title may be used for any purpose other
- 8 than the purpose for which it was supplied unless such
- 9 establishment or person has consented (as determined
- 10 under regulations of the Secretary) to its use for such
- 11 other purpose. Such information may not be published or
- 12 released in other form if the person who supplied the infor-
- 13 mation or who is described in it is identifiable unless such
- 14 person has consented (as determined under regulations of
- 15 the Secretary) to its publication or release in other form.
- 16 "(d) Penalty.—Any person who violates subsection
- 17 (c) shall be subject to a civil monetary penalty of not more
- 18 than \$10,000 for each such violation involved. Such pen-
- 19 alty shall be imposed and collected in the same manner
- 20 as civil money penalties under subsection (a) of section
- 21 1128A of the Social Security Act are imposed and col-
- 22 lected.

1	"SEC. 925. ADDITIONAL PROVISIONS WITH RESPECT TO
2	GRANTS AND CONTRACTS.
3	"(a) Financial Conflicts of Interest.—With
4	respect to projects for which awards of grants, cooperative
5	agreements, or contracts are authorized to be made under
6	this title, the Director shall by regulation define—
7	"(1) the specific circumstances that constitute
8	financial interests in such projects that will, or may
9	be reasonably expected to, create a bias in favor of
10	obtaining results in the projects that are consistent
11	with such interests; and
12	"(2) the actions that will be taken by the Direc-
13	tor in response to any such interests identified by
14	the Director.
15	"(b) Requirement of Application.—The Director
16	may not, with respect to any program under this title au-
17	thorizing the provision of grants, cooperative agreements,
18	or contracts, provide any such financial assistance unless
19	an application for the assistance is submitted to the Sec-
20	retary and the application is in such form, is made in such
21	manner, and contains such agreements, assurances, and
22	information as the Director determines to be necessary to
23	carry out the program involved.
24	"(c) Provision of Supplies and Services in
25	Lieu of Funds.—

- 1 "(1) IN GENERAL.—Upon the request of an en-2 tity receiving a grant, cooperative agreement, or con-3 tract under this title, the Secretary may, subject to 4 paragraph (2), provide supplies, equipment, and 5 services for the purpose of aiding the entity in carry-6 ing out the project involved and, for such purpose, 7 may detail to the entity any officer or employee of 8 the Department of Health and Human Services.
- 9 "(2) Corresponding reduction in funds.— 10 With respect to a request described in paragraph 11 (1), the Secretary shall reduce the amount of the fi-12 nancial assistance involved by an amount equal to 13 the costs of detailing personnel and the fair market 14 value of any supplies, equipment, or services pro-15 vided by the Director. The Secretary shall, for the 16 payment of expenses incurred in complying with 17 such request, expend the amounts withheld.
- 19 RESPECT TO CONTRACTS.—Contracts may be entered into 20 under this part without regard to sections 3648 and 3709 21 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

"(d) Applicability of Certain Provisions With

- 22 "SEC. 926. CERTAIN ADMINISTRATIVE AUTHORITIES.
- 23 "(a) Deputy Director and Other Officers and
- 24 Employees.—

1	"(1) Deputy director.—The Director may
2	appoint a deputy director for the Agency.
3	"(2) Other officers and employees.—The
4	Director may appoint and fix the compensation of
5	such officers and employees as may be necessary to
6	carry out this title. Except as otherwise provided by
7	law, such officers and employees shall be appointed
8	in accordance with the civil service laws and their
9	compensation fixed in accordance with title 5,
10	United States Code.
11	"(b) Facilities.—The Secretary, in carrying out
12	this title—
13	"(1) may acquire, without regard to the Act of
14	March 3, 1877 (40 U.S.C. 34), by lease or otherwise
15	through the Director of General Services, buildings
16	or portions of buildings in the District of Columbia
17	or communities located adjacent to the District of
18	Columbia for use for a period not to exceed 10
19	years; and
20	"(2) may acquire, construct, improve, repair,
21	operate, and maintain laboratory, research, and
22	other necessary facilities and equipment, and such
23	other real or personal property (including patents)
24	as the Secretary deems necessary.

1	"(c)	PI	ROVISION	OF	FINA	ANCIA	L As	SISTAN	ICE.—T	'he
2	Director,	in	carrying	out	this	title,	may	make	grants	to

- 3 public and nonprofit entities and individuals, and may
- 4 enter into cooperative agreements or contracts with public
- 5 and private entities and individuals.
- 6 "(d) Utilization of Certain Personnel and Re-
- 7 sources.—
- 8 "(1) DEPARTMENT OF HEALTH AND HUMAN
 9 SERVICES.—The Director, in carrying out this title,
 10 may utilize personnel and equipment, facilities, and
 11 other physical resources of the Department of
 12 Health and Human Services, permit appropriate (as
- determined by the Secretary) entities and individuals
- to utilize the physical resources of such Department,
- and provide technical assistance and advice.
- 16 "(2) Other agencies.—The Director, in car-
- 17 rying out this title, may use, with their consent, the
- services, equipment, personnel, information, and fa-
- cilities of other Federal, State, or local public agen-
- cies, or of any foreign government, with or without
- reimbursement of such agencies.
- 22 "(e) Consultants.—The Secretary, in carrying out
- 23 this title, may secure, from time to time and for such peri-
- 24 ods as the Director deems advisable but in accordance
- 25 with section 3109 of title 5, United States Code, the as-

1 sistance and advice of consultants from the United States2 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, 1 2 unless separated or reassigned for reasons that 3 are beyond the control of the expert or consult-4 ant and that are acceptable to the Secretary. If 5 the expert or consultant violates the agreement, 6 the money spent by the United States for the 7 expenses specified in subparagraph (A) is recov-8 erable from the expert or consultant as a statu-9 tory obligation owed to the United States. The 10 Secretary may waive in whole or in part a right 11 of recovery under this subparagraph.

12 "(g) Voluntary and Uncompensated Serv-13 ICES.—The Director, in carrying out this title, may accept 14 voluntary and uncompensated services.

15 "SEC. 927. FUNDING.

"(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 1 purpose of carrying out this title, there are authorized to 3 be appropriated \$185,000,000 for fiscal year 2000, and 4 such sums as may be necessary for each of the fiscal years 5 2001 through 2006. 6 "(c) Evaluations.—In addition to amounts available pursuant to subsection (b) for carrying out this title, 8 there shall be made available for such purpose, from the amounts made available pursuant to section 241 (relating
- 10 to evaluations), an amount equal to 40 percent of the max-
- imum amount authorized in such section 241 to be made
- 12 available for a fiscal year.
- 13 "SEC. 929. DEFINITIONS.
- "In this title: 14
- 15 "(1) Advisory Council.—The term 'Advisory
- 16 Council' means the Advisory Council on Healthcare
- 17 Research and Quality established under section 921.
- 18 "(2) AGENCY.—The term 'Agency' means the
- 19 Agency for Healthcare Research and Quality.
- "(3) DIRECTOR.—The term 'Director' means 20
- 21 the Director for the Agency for Healthcare Research
- 22 and Quality.".
- 23 SEC. 403. REFERENCES.
- 24 Effective upon the date of enactment of this Act, any
- reference in law to the "Agency for Health Care Policy

1	and Research" shall be deemed to be a reference to the
2	"Agency for Healthcare Research and Quality".
3	SEC. 404. STUDY.
4	(a) STUDY.—Not later than 30 days after the date
5	of enactment of any Act providing for a qualifying health
6	care benefit (as defined in subsection (b), the Secretary
7	of Health and Human Services, in consultation with the
8	Agency for Healthcare Research and Quality, the National
9	Institutes of Health, and the Institute of Medicine, shall
10	conduct a study concerning such benefit that scientifically
11	evaluates—
12	(1) the safety and efficacy of the benefit, par-
13	ticularly the effect of the benefit on outcomes of
14	$\operatorname{care};$
15	(2) the cost, benefits and value of such benefit
16	(3) the benefit in comparison to alternative ap-
17	proaches in improving care; and
18	(4) the overall impact that such benefit will
19	have on health care as measured through research
20	(b) QUALIFYING HEALTH CARE BENEFIT.—In this
21	section, the term "qualifying health care benefit" means
22	a health care benefit that—
23	(1) is disease- or health condition-specific;
24	(2) requires the provision of or coverage for
25	health care items or services.

1	(3) applies to group health plan, individual
2	health plans, or health insurance issuers under part
3	7 of subtitle B of title I of the Employee Retirement
4	Income Security Act of 1974 (29 U.S.C. 1181 et
5	seq.) or under title XXVII of the Public Health
6	Service Act (42 U.S.C. 300gg et seq.); and
7	(4) was provided under an Act (or amendment)
8	enacted on or after January 1, 1999.
9	(c) Reports.—Not later than 3 years after the date
10	of enactment of any Act described in subsection (a), the
11	Secretary of Health and Human Services shall prepare
12	and submit to the appropriate committees of Congress a
13	report based on the study conducted under such sub-
14	section with respect to the qualifying health care benefit
15	involved.
16	TITLE V—ENHANCED ACCESS TO
17	HEALTH INSURANCE COVERAGE
18	SEC. 501. FULL DEDUCTION OF HEALTH INSURANCE COSTS
19	FOR SELF-EMPLOYED INDIVIDUALS.
20	(a) In General.—Section 162(l)(1) of the Internal
21	Revenue Code of 1986 (relating to allowance of deduc-
22	tions) is amended to read as follows:
23	"(1) ALLOWANCE OF DEDUCTION.—In the case
24	of an individual who is an employee within the
25	meaning of section 401(c)(1), there shall be allowed

1	as a deduction under this section an amount equal
2	to the amount paid during the taxable year for in-
3	surance which constitutes medical care for the tax-
4	payer, his spouse, and his dependents."
5	(b) Effective Date.—The amendments made by
6	this section shall apply to taxable years beginning after
7	December 31, 1999.
8	SEC. 502. FULL AVAILABILITY OF MEDICAL SAVINGS AC
9	COUNTS.
10	(a) Availability Not Limited To Accounts for
11	EMPLOYEES OF SMALL EMPLOYERS AND SELF-EM-
12	PLOYED INDIVIDUALS.—
13	(1) In general.—Section 220(c)(1)(A) of the
14	Internal Revenue Code of 1986 (relating to eligible
15	individual) is amended to read as follows:
16	"(A) IN GENERAL.—The term 'eligible in-
17	dividual' means, with respect to any month, any
18	individual if—
19	"(i) such individual is covered under a
20	high deductible health plan as of the 1st
21	day of such month, and
22	"(ii) such individual is not, while cov-
23	ered under a high deductible health plan
24	covered under any health plan—

1	"(I) which is not a high deduct-
2	ible health plan, and
3	"(II) which provides coverage for
4	any benefit which is covered under the
5	high deductible health plan.".
6	(2) Conforming amendments.—
7	(A) Section 220(c)(1) of such Code is
8	amended by striking subparagraphs (C) and
9	(D).
10	(B) Section 220(c) of such Code is amend-
11	ed by striking paragraph (4) (defining small
12	employer) and by redesignating paragraph (5)
13	as paragraph (4).
14	(C) Section 220(b) of such Code is amend-
15	ed by striking paragraph (4) (relating to deduc-
16	tion limited by compensation) and by redesig-
17	nating paragraphs (5), (6), and (7) as para-
18	graphs (4), (5), and (6), respectively.
19	(b) Removal of Limitation on Number of Tax-
20	PAYERS HAVING MEDICAL SAVINGS ACCOUNTS.—
21	(1) In general.—Section 220 of the Internal
22	Revenue Code of 1986 (relating to medical savings
23	accounts) is amended by striking subsections (i) and
24	(i).

1	(2) Medicare+choice.—Section 138 of such
2	Code (relating to Medicare+Choice MSA) is amend-
3	ed by striking subsection (f).
4	(c) REDUCTION IN HIGH DEDUCTIBLE PLAN MINI-
5	MUM ANNUAL DEDUCTIBLE.—Section 220(c)(2)(A) of the
6	Internal Revenue Code of 1986 (relating to high deduct-
7	ible health plan) is amended—
8	(1) by striking "\$1,500" in clause (i) and in-
9	serting "\$1,000", and
10	(2) by striking "\$3,000" in clause (ii) and in-
11	serting "\$2,000".
12	(d) Increase in Contribution Limit to 100 Per-
13	CENT OF ANNUAL DEDUCTIBLE.—
14	(1) In general.—Section 220(b)(2) of the In-
15	ternal Revenue Code of 1986 (relating to monthly
16	limitation) is amended to read as follows:
17	"(2) Monthly Limitation.—The monthly lim-
18	itation for any month is the amount equal to $\frac{1}{12}$ of
19	the annual deductible of the high deductible health
20	plan of the individual."
21	(2) Conforming Amendment.—Section
22	220(d)(1)(A) of such Code is amended by striking
23	"75 percent of".
24	(e) Limitation on Additional Tax on Distribu-
25	TIONS NOT USED FOR QUALIFIED MEDICAL EX-

- 1 PENSES.—Section 220(f)(4) of the Internal Revenue Code
- 2 of 1986 (relating to additional tax on distributions not
- 3 used for qualified medical expenses) is amended by adding
- 4 at the end the following:
- 5 "(D) Exception in case of sufficient
- 6 ACCOUNT BALANCE.—Subparagraph (A) shall
- 7 not apply to any payment or distribution in any
- 8 taxable year, but only to the extent such pay-
- 9 ment or distribution does not reduce the fair
- market value of the assets of the medical sav-
- ings account to an amount less than the annual
- deductible for the high deductible health plan of
- the account holder (determined as of January 1
- of the calendar year in which the taxable year
- begins).".
- 16 (f) Effective Date.—The amendments made by
- 17 this section shall apply to taxable years beginning after
- 18 December 31, 1999.
- 19 SEC. 503. CARRYOVER OF UNUSED BENEFITS FROM CAFE-
- TERIA PLANS, FLEXIBLE SPENDING AR-
- 21 RANGEMENTS, AND HEALTH FLEXIBLE
- 22 SPENDING ACCOUNTS.
- 23 (a) IN GENERAL.—Section 125 of the Internal Reve-
- 24 nue Code of 1986 (relating to cafeteria plans) is amended
- 25 by redesignating subsections (h) and (i) as subsections (i)

1	and (j) and by inserting after subsection (g) the following
2	new subsection:
3	"(h) Allowance of Carryovers of Unused Ben-
4	EFITS TO LATER TAXABLE YEARS.—
5	"(1) In general.—For purposes of this title—
6	"(A) notwithstanding subsection $(d)(2)$, a
7	plan or other arrangement shall not fail to be
8	treated as a cafeteria plan or flexible spending
9	or similar arrangement, and
10	"(B) no amount shall be required to be in-
11	cluded in gross income by reason of this section
12	or any other provision of this chapter,
13	solely because under such plan or other arrangement
14	any nontaxable benefit which is unused as of the
15	close of a taxable year may be carried forward to 1
16	or more succeeding taxable years.
17	"(2) Limitation.—Paragraph (1) shall not
18	apply to amounts carried from a plan to the extent
19	such amounts exceed \$500 (applied on an annual
20	basis). For purposes of this paragraph, all plans and
21	arrangements maintained by an employer or any re-
22	lated person shall be treated as 1 plan.
23	"(3) Allowance of Rollover.—
24	"(A) IN GENERAL.—In the case of any un-
25	used benefit described in paragraph (1) which

1	consists of amounts in a health flexible spend-
2	ing account or dependent care flexible spending
3	account, the plan or arrangement shall provide
4	that a participant may elect, in lieu of such car-
5	ryover, to have such amounts distributed to the
6	participant.
7	"(B) Amounts not included in in-
8	come.—Any distribution under subparagraph
9	(A) shall not be included in gross income to the
10	extent that such amount is transferred in a
11	trustee-to-trustee transfer, or is contributed
12	within 60 days of the date of the distribution,
13	to—
14	"(i) a qualified cash or deferred ar-
15	rangement described in section 401(k),
16	"(ii) a plan under which amounts are
17	contributed by an individual's employer for
18	an annuity contract described in section
19	403(b),
20	"(iii) an eligible deferred compensa-
21	tion plan described in section 457, or
22	"(iv) a medical savings account (with-
23	in the meaning of section 220).
24	Any amount rolled over under this subpara-
25	graph shall be treated as a rollover contribution

for the taxable year from which the unused amount would otherwise be carried.

"(C) Treatment of Rollover.—Any amount rolled over under subparagraph (B) shall be treated as an eligible rollover under section 220, 401(k), 403(b), or 457, whichever is applicable, and shall be taken into account in applying any limitation (or participation requirement) on employer or employee contributions under such section or any other provision of this chapter for the taxable year of the rollover.

- "(4) Cost-of-living adjustment.—In the case of any taxable year beginning in a calendar year after 1999, the \$500 amount under paragraph (2) shall be adjusted at the same time and in the same manner as under section 415(d)(2), except that the base period taken into account shall be the calendar quarter beginning October 1, 1998, and any increase which is not a multiple of \$50 shall be rounded to the next lowest multiple of \$50."
- "(5) APPLICABILITY.—This subsection shall apply to taxable years beginning after December 31, 1999."

1	(b) Effective Date.—The amendments made by
2	this section shall apply to taxable years beginning after
3	December 31, 1999.
4	SEC. 504. PERMITTING CONTRIBUTION TOWARDS MEDICAL
5	SAVINGS ACCOUNT THROUGH FEDERAL EM-
6	PLOYEES HEALTH BENEFITS PROGRAM
7	(FEHBP).
8	(a) Government Contribution to Medical Sav-
9	INGS ACCOUNT.—
10	(1) In General.—Section 8906 of title 5,
11	United States Code, is amended by adding at the
12	end the following:
13	"(j)(1) In the case of an employee or annuitant who
14	is enrolled in a catastrophic plan described by section
15	8903(5), there shall be a Government contribution under
16	this subsection to a medical savings account established
17	or maintained for the benefit of the individual. The con-
18	tribution under this subsection shall be in addition to the
19	Government contribution under subsection (b).
20	"(2) The amount of the Government contribution
21	under this subsection with respect to an individual is equal
22	to the amount by which—
23	"(A) the maximum contribution allowed under
24	subsection $(b)(1)$ with respect to any employee or
25	annuitant exceeds

1	"(B) the amount of the Government contribu-
2	tion actually made with respect to the individual
3	under subsection (b) for coverage under the cata-
4	strophic plan.
5	"(3) The Government contributions under this sub-
6	section shall be paid into a medical savings account (des-
7	ignated by the individual involved) in a manner that is
8	specified by the Office and consistent with the timing of
9	contributions under subsection (b).
10	"(4) Subsections (f) and (g) shall apply to contribu-
11	tions under this section in the same manner as they apply
12	to contributions under subsection (b).
13	"(5) For the purpose of this subsection, the term
14	'medical savings account' has the meaning given such term
15	by section 220(d) of the Internal Revenue Code of 1986.".
16	(2) Allowing payment of full amount of
17	CHARGE FOR CATASTROPHIC PLAN.—Section
18	8906(b)(2) of such title is amended by inserting "(or
19	100 percent of the subscription charge in the case
20	of a catastrophic plan)" after "75 percent of the
21	subscription charge".
22	(b) Offering of Catastrophic Plans.—
23	(1) In general.—Section 8903 of title 5,
24	United States Code, is amended by adding at the
25	end the following:

1	"(5) Catastrophic plans.—One or more
2	plans described in paragraph (1), (2), or (3), but
3	which provide benefits of the types referred to by
4	paragraph (5) of section 8904(a), instead of the
5	types referred to in paragraphs (1), (2), and (3) of
5	such section.".

- (2) Types of Benefits.—Section 8904(a) of such title is amended by inserting after paragraph (4) the following new paragraph:
- "(5) Catastrophic plans.—Benefits of the types named under paragraph (1) or (2) of this subsection or both, to the extent expenses covered by the plan exceed \$500.".
- (3) Determining Level of Government Contributions.—Section 8906(b) of such title is amended by adding at the end the following: "Subscription charges for medical savings accounts shall be deemed to be the amount of Government contributions made under subsection (j)(2).".
- 20 (c) Effective Date.—The amendments made by 21 this section shall apply to contract terms beginning on or 22 after January 1, 2000.