

106TH CONGRESS
1ST SESSION

H. R. 2506

To amend title IX of the Public Health Service Act to revise and extend the Agency for Health Care Policy and Research.

IN THE HOUSE OF REPRESENTATIVES

JULY 14, 1999

Mr. BILIRAKIS (for himself, Mr. BROWN of Ohio, Mr. GREENWOOD, and Mrs. THURMAN) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend title IX of the Public Health Service Act to revise and extend the Agency for Health Care Policy and Research.

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.**

4 This Act may be cited as the “Health Research and
5 Quality Act of 1999”.

1 **SEC. 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
2 **ACT.**

3 (a) IN GENERAL.—Title IX of the Public Health
4 Service Act (42 U.S.C. 299 et seq.) is amended to read
5 as follows:

6 **“TITLE IX—AGENCY FOR**
7 **HEALTH RESEARCH AND**
8 **QUALITY**

9 **“PART A—ESTABLISHMENT AND GENERAL**
10 **DUTIES**

11 **“SEC. 901. MISSION AND DUTIES.**

12 “(a) IN GENERAL.—There is established within the
13 Public Health Service an agency to be known as the Agen-
14 cy for Health Research and Quality, which shall be headed
15 by a director appointed by the Secretary. The Secretary
16 shall carry out this title acting through the Director.

17 “(b) MISSION.—The purpose of the Agency is to en-
18 hance the quality, appropriateness, and effectiveness of
19 health services, and access to such services, through the
20 establishment of a broad base of scientific research and
21 through the promotion of improvements in clinical and
22 health system practices, including the prevention of dis-
23 eases and other health conditions. The Agency shall pro-
24 mote health care quality improvement by—

1 “(1) conducting and supporting research that
2 develops and presents scientific evidence regarding
3 all aspects of health, 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 health care practices, including
10 preventive measures and long-term care;

11 “(C) existing and innovative technologies;

12 “(D) the costs and utilization of, and ac-
13 cess to health care;

14 “(E) the ways in which health care services
15 are organized, delivered, and financed and the
16 interaction and impact of these factors on the
17 quality of patient care;

18 “(F) methods for measuring quality and
19 strategies for improving quality; and

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

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

5 “(3) advancing private and public efforts to im-
6 prove health care 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 health care needs, in-
19 cluding disabilities, chronic care and end-of-life
20 health care.

21 **“SEC. 902. GENERAL AUTHORITIES.**

22 “(a) IN GENERAL.—In carrying out section 901(b),
23 the Director shall support demonstration projects, conduct
24 and support research, evaluations, training, research net-
25 works, multi-disciplinary centers, technical assistance, and

1 the dissemination of information, on health care, and on
2 systems for the delivery of such care, including activities
3 with respect to—

4 “(1) the quality, effectiveness, efficiency, appro-
5 priateness and value of health care services;

6 “(2) quality measurement and improvement;

7 “(3) the outcomes, cost, cost-effectiveness, and
8 use of health care services and access to such serv-
9 ices;

10 “(4) clinical practice, including primary care
11 and practice-oriented research;

12 “(5) health care technologies, facilities, and
13 equipment;

14 “(6) health care costs, productivity, organiza-
15 tion, and market forces;

16 “(7) health promotion and disease prevention,
17 including clinical preventive services;

18 “(8) health statistics, surveys, database devel-
19 opment, and epidemiology; and

20 “(9) medical liability.

21 “(b) HEALTH SERVICES TRAINING GRANTS.—

22 “(1) IN GENERAL.—The Director may provide
23 training grants in the field of health services re-
24 search related to activities authorized under sub-
25 section (a), to include pre- and post-doctoral fellow-

1 ships and training programs, young investigator
2 awards, and other programs and activities as appro-
3 priate. In carrying out this subsection, the Director
4 shall make use of funds made available under sec-
5 tion 487.

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

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

18 “(d) RELATION TO CERTAIN AUTHORITIES REGARD-
19 ING SOCIAL SECURITY.—Activities authorized in this sec-
20 tion shall be appropriately coordinated with experiments,
21 demonstration projects, and other related activities au-
22 thorized by the Social Security Act and the Social Security
23 Amendments of 1967. Activities under subsection (a)(2)
24 of this section that affect the programs under titles XVIII,

1 XIX and XXI of the Social Security Act shall be carried
2 out consistent with section 1142 of such Act.

3 “(e) **DISCLAIMER.**—The Agency shall not mandate
4 national standards of clinical practice or quality health
5 care standards. Recommendations resulting from projects
6 funded and published by the Agency shall include a cor-
7 responding disclaimer.

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

15 **“PART B—HEALTH CARE IMPROVEMENT**

16 **RESEARCH**

17 **“SEC. 911. HEALTH CARE OUTCOME IMPROVEMENT RE-**
18 **SEARCH.**

19 “(a) **EVIDENCE RATING SYSTEMS.**—In collaboration
20 with experts from the public and private sector, the Agen-
21 cy shall identify and disseminate methods or systems that
22 it uses to assess health care research results, particularly
23 methods or systems that it uses to rate the strength of
24 the scientific evidence behind health care practice, rec-
25 ommendations in the research literature, and technology

1 assessments. The Agency shall make methods or systems
2 for evidence rating widely available. Agency publications
3 containing health care recommendations shall indicate the
4 level of substantiating evidence using such methods or sys-
5 tems.

6 “(b) HEALTH CARE IMPROVEMENT RESEARCH CEN-
7 TERS AND PROVIDER-BASED RESEARCH NETWORKS.—

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

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

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

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

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

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

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

10 “(1) SCIENTIFIC AND TECHNICAL SUPPORT.—

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

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

18 “(A) the identification and assessment of
19 methods for the evaluation of the health of—

20 “(i) enrollees in health plans by type
21 of plan, provider, and provider arrange-
22 ments; and

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

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

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

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

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

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

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

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

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

3 “(A) The conduct of state-of-the-art re-
4 search for the following purposes:

5 “(i) To increase awareness of—

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

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

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

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

17 “(I) Health care practitioners
18 and other providers of health care
19 goods or services.

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

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

1 “(IV) Health care insurers and
2 governmental agencies.

3 “(V) Patients and consumers.

4 “(iii) To improve the quality of health
5 care while reducing the cost of health care
6 through—

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

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

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

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

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

1 “(1) identify the causes of preventable health
2 care errors and patient injury in health care deliv-
3 ery;

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

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

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

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

12 “(1) conduct a survey to collect data on a
13 nationally representative sample of the population on
14 the cost, use and, for fiscal year 2001 and subse-
15 quent fiscal years, quality of health care, including
16 the types of health care services Americans use,
17 their access to health care services, frequency of use,
18 how much is paid for the services used, the source
19 of those payments, the types and costs of private
20 health insurance, access, satisfaction, and quality of
21 care for the general population and also for popu-
22 lations identified in section 901(c); and

23 “(2) develop databases and tools that provide
24 information to States on the quality, access, and use
25 of health care services provided to their residents.

1 “(b) QUALITY AND OUTCOMES INFORMATION.—

2 “(1) IN GENERAL.—Beginning in fiscal year
3 2001, the Director shall ensure that the survey con-
4 ducted under subsection (a)(1) will—

5 “(A) identify determinants of health out-
6 comes and functional status, the needs of spe-
7 cial populations in such variables as well as an
8 understanding of changes over time, relation-
9 ships to health care access and use, and mon-
10 itor the overall national impact of Federal and
11 State policy changes on health care;

12 “(B) provide information on the quality of
13 care and patient outcomes for frequently occur-
14 ring clinical conditions for a nationally rep-
15 resentative sample of the population; and

16 “(C) provide reliable national estimates for
17 children and persons with special health care
18 needs through the use of supplements or peri-
19 odic expansions of the survey.

20 In expanding the Medical Expenditure Panel Survey,
21 as in existence on the date of enactment of this title)
22 in fiscal year 2001 to collect information on the
23 quality of care, the Director shall take into account
24 any outcomes measurements generally collected by
25 private sector accreditation organizations.

1 “(2) ANNUAL REPORT.—Beginning in fiscal
2 year 2003, the Secretary, acting through the Direc-
3 tor, shall submit to Congress an annual report on
4 national trends in the quality of health care provided
5 to the American people.

6 **“SEC. 914. INFORMATION SYSTEMS FOR HEALTH CARE IM-**
7 **PROVEMENT.**

8 “(a) IN GENERAL.—In order to foster a range of in-
9 novative approaches to the management and communica-
10 tion of health information, the Agency shall support re-
11 search, evaluations and initiatives to advance—

12 “(1) the use of information systems for the
13 study of health care quality, including the generation
14 of both individual provider and plan-level compara-
15 tive performance data;

16 “(2) training for health care practitioners and
17 researchers in the use of information systems;

18 “(3) the creation of effective linkages between
19 various sources of health information, including the
20 development of information networks;

21 “(4) the delivery and coordination of evidence-
22 based health care services, including the use of real-
23 time health care decision-support programs;

24 “(5) the structure, content, definition, and cod-
25 ing of health information data and medical vocabu-

1 laries in consultation with appropriate Federal enti-
2 ties and shall seek input from appropriate private
3 entities;

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

9 “(7) the protection of individually identifiable
10 information in health services research and health
11 care quality improvement.

12 “(b) DEMONSTRATION.—The Agency shall support
13 demonstrations into the use of new information tools
14 aimed at improving shared decision-making between pa-
15 tients and their care-givers.

16 **“SEC. 915. RESEARCH SUPPORTING PRIMARY CARE AND**
17 **ACCESS IN UNDERSERVED AREAS.**

18 “(a) PREVENTIVE SERVICES TASK FORCE.—

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

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

12 “(b) PRIMARY CARE RESEARCH.—

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

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

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

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

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

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

12 **“SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVA-**
13 **TION.**

14 “(a) IN GENERAL.—The Director shall promote inno-
15 vation in evidence-based clinical practice and health care
16 technologies by—

17 “(1) conducting and supporting research on the
18 development, diffusion, and use of health care tech-
19 nology;

20 “(2) developing, evaluating, and disseminating
21 methodologies for assessments of health care prac-
22 tices and health care technologies;

23 “(3) conducting intramural and supporting ex-
24 tramural assessments of existing and new health
25 care practices and technologies;

1 “(4) promoting education, training, and pro-
2 viding technical assistance in the use of health care
3 practice and health care technology assessment
4 methodologies and results; and

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

9 “(b) SPECIFICATION OF PROCESS.—

10 “(1) IN GENERAL.—Not later than December
11 31, 2000, the Director shall develop and publish a
12 description of the methods used by the Agency and
13 its contractors for practice and technology assess-
14 ment.

15 “(2) CONSULTATIONS.—In carrying out this
16 subsection, the Director shall cooperate and consult
17 with the Assistant Secretary for Health, the Admin-
18 istrator of the Health Care Financing Administra-
19 tion, the Director of the National Institutes of
20 Health, the Commissioner of Food and Drugs, and
21 the heads of any other interested Federal depart-
22 ment or agency, and shall seek input, where appro-
23 priate, from professional societies and other private
24 and public entities.

1 “(3) METHODOLOGY.—The Director shall, in
2 developing the methods used under paragraph (1),
3 consider—

4 “(A) safety, efficacy, and effectiveness;

5 “(B) legal, social, and ethical implications;

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

7 “(D) comparisons to alternate technologies
8 and practices; and

9 “(E) requirements of Food and Drug Ad-
10 ministration approval to avoid duplication.

11 “(c) SPECIFIC ASSESSMENTS.—

12 “(1) IN GENERAL.—The Director shall conduct
13 or support specific assessments of health care tech-
14 nologies and practices.

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

22 “(3) GRANTS AND CONTRACTS.—In addition to
23 conducting assessments, the Director may make
24 grants to, or enter into cooperative agreements or
25 contracts with, entities described in paragraph (4)

1 for the purpose of conducting assessments of experi-
2 mental, emerging, existing, or potentially outmoded
3 health care technologies, and for related activities.

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

12 **“SEC. 917. COORDINATION OF FEDERAL GOVERNMENT**
13 **QUALITY IMPROVEMENT EFFORTS.**

14 “(a) REQUIREMENT.—

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

23 “(2) SPECIFIC ACTIVITIES.—The Director, in
24 collaboration with the appropriate Federal officials

1 representing all concerned executive agencies and de-
2 partments, shall develop and manage a process to—

3 “(A) improve interagency coordination, pri-
4 ority setting, and the use and sharing of re-
5 search findings and data pertaining to Federal
6 quality improvement programs, technology as-
7 sessment, and health services research;

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

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

16 “(D) strengthen the management of Fed-
17 eral health care quality improvement programs.

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

19 “(1) IN GENERAL.—To provide Congress, the
20 Department of Health and Human Services, and
21 other relevant departments with an independent, ex-
22 ternal review of their quality oversight, quality im-
23 provement and quality research programs, the Sec-
24 retary shall enter into a contract with the Institute
25 of Medicine—

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

4 “(i) an overview of pertinent health
5 services research activities and quality im-
6 provement efforts conducted by all Federal
7 programs, with particular attention paid to
8 those under titles XVIII, XIX, and XXI of
9 the Social Security Act; and

10 “(ii) a summary of the partnerships
11 that the Department of Health and
12 Human Services has pursued with private
13 accreditation, quality measurement and
14 improvement organizations; and

15 “(B) to identify options and make rec-
16 ommendations to improve the efficiency and ef-
17 fectiveness of quality improvement programs
18 through—

19 “(i) the improved coordination of ac-
20 tivities across the medicare, medicaid and
21 child health insurance programs under ti-
22 tles XVIII, XIX and XXI of the Social Se-
23 curity Act and health services research
24 programs;

1 “(ii) the strengthening of patient
2 choice and participation by incorporating
3 state-of-the-art quality monitoring tools
4 and making information on quality avail-
5 able; and

6 “(iii) the enhancement of the most ef-
7 fective programs, consolidation as appro-
8 priate, and elimination of duplicative ac-
9 tivities within various federal agencies.

10 “(2) REQUIREMENTS.—

11 “(A) IN GENERAL.—The Secretary shall
12 enter into a contract with the Institute of Medi-
13 cine for the preparation—

14 “(i) not later than 12 months after
15 the date of enactment of this title, of a re-
16 port providing an overview of the quality
17 improvement programs of the Department
18 of Health and Human Services for the
19 medicare, medicaid, and CHIP programs
20 under titles XVIII, XIX, and XXI of the
21 Social Security Act; and

22 “(ii) not later than 24 months after
23 the date of enactment of this title, of a
24 final report containing recommendations.

1 “(B) REPORTS.—The Secretary shall sub-
2 mit the reports described in subparagraph (A)
3 to the Committee on Finance and the Com-
4 mittee on Health, Education, Labor, and Pen-
5 sions of the Senate and the Committee on Ways
6 and Means and the Committee on Commerce of
7 the House of Representatives.

8 **“PART C—GENERAL PROVISIONS**

9 **“SEC. 921. ADVISORY COUNCIL FOR HEALTH CARE RE-**
10 **SEARCH AND QUALITY.**

11 “(a) ESTABLISHMENT.—There is established an advi-
12 sory council to be known as the Advisory Council for
13 Health Care Research and Quality.

14 “(b) DUTIES.—

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

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

23 “(A) priorities regarding health care re-
24 search, especially studies related to quality, out-

1 comes, cost and the utilization of, and access
2 to, health care services;

3 “(B) the field of health care research and
4 related disciplines, especially issues related to
5 training needs, and dissemination of informa-
6 tion pertaining to health care quality; and

7 “(C) the appropriate role of the Agency in
8 each of these areas in light of private sector ac-
9 tivity and identification of opportunities for
10 public-private sector partnerships.

11 “(c) MEMBERSHIP.—

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

18 “(2) APPOINTED MEMBERS.—The Secretary
19 shall appoint to the Advisory Council 18 appro-
20 priately qualified individuals. At least 14 members of
21 the Advisory Council shall be representatives of the
22 public who are not officers or employees of the
23 United States. The Secretary shall ensure that the
24 appointed members of the Council, as a group, are
25 representative of professions and entities concerned

1 with, or affected by, activities under this title and
2 under section 1142 of the Social Security Act. Of
3 such members—

4 “(A) 3 shall be individuals distinguished in
5 the conduct of research, demonstration projects,
6 and evaluations with respect to health care;

7 “(B) 3 shall be individuals distinguished in
8 the practice of medicine of which at least 1
9 shall be a primary care practitioner;

10 “(C) 3 shall be individuals distinguished in
11 the other health professions;

12 “(D) 3 shall be individuals either rep-
13 resenting the private health care sector, includ-
14 ing health plans, providers, and purchasers or
15 individuals distinguished as administrators of
16 health care delivery systems;

17 “(E) 3 shall be individuals distinguished in
18 the fields of health care quality improvement,
19 economics, information systems, law, ethics,
20 business, or public policy; and

21 “(F) 3 shall be individuals representing the
22 interests of patients and consumers of health
23 care.

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

4 “(A) the Assistant Secretary for Health,
5 the Director of the National Institutes of
6 Health, the Director of the Centers for Disease
7 Control and Prevention, the Administrator of
8 the Health Care Financing Administration, the
9 Assistant Secretary of Defense (Health Af-
10 fairs), and the Under Secretary for Health of
11 the Department of Veterans Affairs; and

12 “(B) such other Federal officials as the
13 Secretary may consider appropriate.

14 “(d) TERMS.—Members of the Advisory Council ap-
15 pointed under subsection (c)(2) shall serve for a term of
16 3 years. A member of the Council appointed under such
17 subsection may continue to serve after the expiration of
18 the term of the members until a successor is appointed.

19 “(e) VACANCIES.—If a member of the Advisory
20 Council appointed under subsection (c)(2) does not serve
21 the full term applicable under subsection (d), the indi-
22 vidual appointed to fill the resulting vacancy shall be ap-
23 pointed for the remainder of the term of the predecessor
24 of the individual.

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

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

9 “(h) COMPENSATION AND REIMBURSEMENT OF
10 EXPENSES.—

11 “(1) APPOINTED MEMBERS.—Members of the
12 Advisory Council appointed under subsection (c)(2)
13 shall receive compensation for each day (including
14 travel time) engaged in carrying out the duties of
15 the Advisory Council unless declined by the member.
16 Such compensation may not be in an amount in ex-
17 cess of the maximum rate of basic pay payable for
18 GS–18 of the General Schedule.

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

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

4 **“SEC. 922. PEER REVIEW WITH RESPECT TO GRANTS AND**
 5 **CONTRACTS.**

6 “(a) REQUIREMENT OF REVIEW.—

7 “(1) IN GENERAL.—Appropriate technical and
 8 scientific peer review shall be conducted with respect
 9 to each application for a grant, cooperative agree-
 10 ment, or contract under this title.

11 “(2) REPORTS TO DIRECTOR.—Each peer re-
 12 view group to which an application is submitted pur-
 13 suant to paragraph (1) shall report its finding and
 14 recommendations respecting the application to the
 15 Director in such form and in such manner as the
 16 Director shall require.

17 “(b) APPROVAL AS PRECONDITION OF AWARDS.—
 18 The Director may not approve an application described in
 19 subsection (a)(1) unless the application is recommended
 20 for approval by a peer review group established under sub-
 21 section (c).

22 “(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

23 “(1) IN GENERAL.—The Director shall establish
 24 such technical and scientific peer review groups as
 25 may be necessary to carry out this section. Such

1 groups shall be established without regard to the
2 provisions of title 5, United States Code, that govern
3 appointments in the competitive service, and without
4 regard to the provisions of chapter 51, and sub-
5 chapter III of chapter 53, of such title that relate
6 to classification and pay rates under the General
7 Schedule.

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

20 “(3) DURATION.—Notwithstanding section
21 14(a) of the Federal Advisory Committee Act, peer
22 review groups established under this section may
23 continue in existence until otherwise provided by
24 law.

1 “(4) QUALIFICATIONS.—Members of any peer-
2 review group shall, at a minimum, meet the fol-
3 lowing requirements:

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

9 “(B) Such members shall agree in writing
10 to recuse themselves from participation in the
11 peer-review of specific applications which
12 present a potential personal conflict of interest
13 or appearance of such conflict, including em-
14 ployment in a directly affected organization,
15 stock ownership, or any financial or other ar-
16 rangement that might introduce bias in the
17 process of peer-review.

18 “(d) AUTHORITY FOR PROCEDURAL ADJUSTMENTS
19 IN CERTAIN CASES.—In the case of applications for finan-
20 cial assistance whose direct costs will not exceed \$100,000,
21 the Director may make appropriate adjustments in the
22 procedures otherwise established by the Director for the
23 conduct of peer review under this section. Such adjust-
24 ments may be made for the purpose of encouraging the
25 entry of individuals into the field of research, for the pur-

1 pose of encouraging clinical practice-oriented or provider-
 2 based research, and for such other purposes as the Direc-
 3 tor may determine to be appropriate.

4 “(e) REGULATIONS.—The Director shall issue regula-
 5 tions for the conduct of peer review under this section.

6 **“SEC. 923. CERTAIN PROVISIONS WITH RESPECT TO DEVEL-**
 7 **OPMENT, COLLECTION, AND DISSEMINATION**
 8 **OF DATA.**

9 “(a) STANDARDS WITH RESPECT TO UTILITY OF
 10 DATA.—

11 “(1) IN GENERAL.—To ensure the utility, accu-
 12 racy, and sufficiency of data collected by or for the
 13 Agency for the purpose described in section 901(b),
 14 the Director shall establish standard methods for de-
 15 veloping and collecting such data, taking into
 16 consideration—

17 “(A) other Federal health data collection
 18 standards; and

19 “(B) the differences between types of
 20 health care plans, delivery systems, health care
 21 providers, and provider arrangements.

22 “(2) RELATIONSHIP WITH OTHER DEPARTMENT
 23 PROGRAMS.—In any case where standards under
 24 paragraph (1) may affect the administration of other
 25 programs carried out by the Department of Health

1 and Human Services, including the programs under
2 title XVIII, XIX or XXI of the Social Security Act,
3 or may affect health information that is subject to
4 a standard developed under part C of title XI of the
5 Social Security Act, they shall be in the form of rec-
6 ommendations to the Secretary for such program.

7 “(b) STATISTICS AND ANALYSES.—The Director
8 shall—

9 “(1) take appropriate action to ensure that sta-
10 tistics and analyses developed under this title are of
11 high quality, timely, and duly comprehensive, and
12 that the statistics are specific, standardized, and
13 adequately analyzed and indexed; and

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

17 “(c) AUTHORITY REGARDING CERTAIN REQUESTS.—
18 Upon request of a public or private entity, the Director
19 may conduct or support research or analyses otherwise au-
20 thorized by this title pursuant to arrangements under
21 which such entity will pay the cost of the services provided.
22 Amounts received by the Director under such arrange-
23 ments shall be available to the Director for obligation until
24 expended.

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

2 “(a) IN GENERAL.—The Director shall—

3 “(1) without regard to section 501 of title 44,
4 United States Code, promptly publish, make avail-
5 able, and otherwise disseminate, in a form under-
6 standable and on as broad a basis as practicable so
7 as to maximize its use, the results of research, dem-
8 onstration projects, and evaluations conducted or
9 supported under this title;

10 “(2) ensure that information disseminated by
11 the Agency is science-based and objective and under-
12 takes consultation as necessary to assess the appro-
13 priateness and usefulness of the presentation of in-
14 formation that is targeted to specific audiences;

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

18 “(4) provide, in collaboration with the National
19 Library of Medicine where appropriate, indexing, ab-
20 stracting, translating, publishing, and other services
21 leading to a more effective and timely dissemination
22 of information on research, demonstration projects,
23 and evaluations with respect to health care to public
24 and private entities and individuals engaged in the
25 improvement of health care delivery and the general
26 public, and undertake programs to develop new or

1 improved methods for making such information
2 available; and

3 “(5) as appropriate, provide technical assistance
4 to State and local government and health agencies
5 and conduct liaison activities to such agencies to fos-
6 ter dissemination.

7 “(b) PROHIBITION AGAINST RESTRICTIONS.—Except
8 as provided in subsection (c), the Director may not restrict
9 the publication or dissemination of data from, or the re-
10 sults of, projects conducted or supported under this title.

11 “(c) LIMITATION ON USE OF CERTAIN INFORMA-
12 TION.—No information, if an establishment or person sup-
13 plying the information or described in it is identifiable,
14 obtained in the course of activities undertaken or sup-
15 ported under this title may be used for any purpose other
16 than the purpose for which it was supplied unless such
17 establishment or person has consented (as determined
18 under regulations of the Director) to its use for such other
19 purpose. Such information may not be published or re-
20 leased in other form if the person who supplied the infor-
21 mation or who is described in it is identifiable unless such
22 person has consented (as determined under regulations of
23 the Director) to its publication or release in other form.

24 “(d) PENALTY.—Any person who violates subsection
25 (c) shall be subject to a civil monetary penalty of not more

1 than \$10,000 for each such violation involved. Such pen-
2 alty shall be imposed and collected in the same manner
3 as civil money penalties under subsection (a) of section
4 1128A of the Social Security Act are imposed and col-
5 lected.

6 **“SEC. 925. ADDITIONAL PROVISIONS WITH RESPECT TO**
7 **GRANTS AND CONTRACTS.**

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

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

17 “(2) the actions that will be taken by the Direc-
18 tor in response to any such interests identified by
19 the Director.

20 “(b) REQUIREMENT OF APPLICATION.—The Director
21 may not, with respect to any program under this title au-
22 thorizing the provision of grants, cooperative agreements,
23 or contracts, provide any such financial assistance unless
24 an application for the assistance is submitted to the Sec-
25 retary and the application is in such form, is made in such

1 manner, and contains such agreements, assurances, and
2 information as the Director determines to be necessary to
3 carry out the program involved.

4 “(c) PROVISION OF SUPPLIES AND SERVICES IN
5 LIEU OF FUNDS.—

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

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

23 “(d) APPLICABILITY OF CERTAIN PROVISIONS WITH
24 RESPECT TO CONTRACTS.—Contracts may be entered into

1 under this part without regard to sections 3648 and 3709
2 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

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

4 “(a) DEPUTY DIRECTOR AND OTHER OFFICERS AND
5 EMPLOYEES.—

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

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

16 “(b) FACILITIES.—The Secretary, in carrying out
17 this title—

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

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

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

11 “(d) UTILIZATION OF CERTAIN PERSONNEL AND RE-
12 SOURCES.—

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

21 “(2) OTHER AGENCIES.—The Director, in car-
22 rying out this title, may use, with their consent, the
23 services, equipment, personnel, information, and fa-
24 cilities of other Federal, State, or local public agen-

1 cies, or of any foreign government, with or without
2 reimbursement of such agencies.

3 “(e) CONSULTANTS.—The Secretary, in carrying out
4 this title, may secure, from time to time and for such peri-
5 ods as the Director deems advisable but in accordance
6 with section 3109 of title 5, United States Code, the as-
7 sistance and advice of consultants from the United States
8 or abroad.

9 “(f) EXPERTS.—

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

18 “(2) TRAVEL EXPENSES.—

19 “(A) IN GENERAL.—Experts and consult-
20 ants whose services are obtained under para-
21 graph (1) shall be paid or reimbursed for their
22 expenses associated with traveling to and from
23 their assignment location in accordance with
24 sections 5724, 5724a(a), 5724a(c), and
25 5726(C) of title 5, United States Code.

1 “(B) LIMITATION.—Expenses specified in
2 subparagraph (A) may not be allowed in con-
3 nection with the assignment of an expert or
4 consultant whose services are obtained under
5 paragraph (1) unless and until the expert
6 agrees in writing to complete the entire period
7 of assignment, or 1 year, whichever is shorter,
8 unless separated or reassigned for reasons that
9 are beyond the control of the expert or consult-
10 ant and that are acceptable to the Secretary. If
11 the expert or consultant violates the agreement,
12 the money spent by the United States for the
13 expenses specified in subparagraph (A) is recov-
14 erable from the expert or consultant as a statu-
15 tory obligation owed to the United States. The
16 Secretary may waive in whole or in part a right
17 of recovery under this subparagraph.

18 “(g) VOLUNTARY AND UNCOMPENSATED SERV-
19 ICES.—The Director, in carrying out this title, may accept
20 voluntary and uncompensated services.

21 **“SEC. 927. FUNDING.**

22 “(a) INTENT.—To ensure that the United States in-
23 vestment in biomedical research is rapidly translated into
24 improvements in the quality of patient care, there must
25 be a corresponding investment in research on the most ef-

1 fective clinical and organizational strategies for use of
2 these findings in daily practice. The authorization levels
3 in subsections (b) and (c) provide for a proportionate in-
4 crease in health care research as the United States invest-
5 ment in biomedical research increases.

6 “(b) AUTHORIZATION OF APPROPRIATIONS.—For the
7 purpose of carrying out this title, there are authorized to
8 be appropriated \$250,000,000 for fiscal year 2000, and
9 such sums as may be necessary for each of the fiscal years
10 2001 through 2004.

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

18 **“SEC. 928. DEFINITIONS.**

19 “In this title:

20 “(1) ADVISORY COUNCIL.—The term ‘Advisory
21 Council’ means the Advisory Council on Health Care
22 Research and Quality established under section 921.

23 “(2) AGENCY.—The term ‘Agency’ means the
24 Agency for Health Research and Quality.

1 “(3) DIRECTOR.—The term ‘Director’ means
2 the Director of the Agency for Health Research and
3 Quality.”.

4 (b) RULES OF CONSTRUCTION.—

5 (1) IN GENERAL.—Section 901(a) of the Public
6 Health Service Act (as added by subsection (a) of
7 this section) applies as a redesignation of the agency
8 that carried out title IX of such Act on the day be-
9 fore the date of enactment of this Act, and not as
10 the termination of such agency and the establish-
11 ment of a different agency. The amendment made
12 by subsection (a) of this section does not affect ap-
13 pointments of the personnel of such agency who
14 were employed at the agency on the day before such
15 date.

16 (2) REFERENCES.—Any reference in law to the
17 Agency for Health Care Policy and Research is
18 deemed to be a reference to the Agency for Health
19 Research and Quality, and any reference in law to
20 the Administrator for Health Care Policy and Re-
21 search is deemed to be a reference to the Director
22 of the Agency for Health Research and Quality.

1 **SEC. 3. GRANTS REGARDING UTILIZATION OF PREVENTIVE**
2 **HEALTH SERVICES.**

3 Subpart I of part D of title III of the Public Health
4 Service Act (42 U.S.C. 254b et seq.) is amended by adding
5 at the end the following section:

6 **“SEC. 330D. CENTERS FOR STRATEGIES ON FACILITATING**
7 **UTILIZATION OF PREVENTIVE HEALTH SERV-**
8 **ICES AMONG VARIOUS POPULATIONS.**

9 “(a) **IN GENERAL.**—The Secretary, acting through
10 the appropriate agencies of the Public Health Service,
11 shall make grants to public or nonprofit private entities
12 for the establishment and operation of regional centers
13 whose purpose is to identify particular populations of pa-
14 tients and facilitate the appropriate utilization of preven-
15 tive health services by patients in the populations through
16 developing and disseminating strategies to improve the
17 methods used by public and private health care programs
18 and providers in interacting with such patients.

19 “(b) **RESEARCH AND TRAINING.**—The activities car-
20 ried out by a center under subsection (a) may include es-
21 tablishing programs of research and training with respect
22 to the purpose described in such subsection, including the
23 development of curricula for training individuals in imple-
24 menting the strategies developed under such subsection.

25 “(c) **QUALITY MANAGEMENT.**—A condition for the
26 receipt of a grant under subsection (a) is that the appli-

1 cant involved agree that, in order to ensure that the strat-
2 egies developed under such subsection take into account
3 principles of quality management with respect to con-
4 sumer satisfaction, the applicant will make arrangements
5 with one or more private entities that have experience in
6 applying such principles.

7 “(d) PRIORITY REGARDING INFANTS AND CHIL-
8 DREN.—In carrying out the purpose described in sub-
9 section (a), the Secretary shall give priority to various
10 populations of infants, young children, and their mothers.

11 “(e) EVALUATIONS.—The Secretary, acting through
12 the appropriate agencies of the Public Health Service,
13 shall (directly or through grants or contracts) provide for
14 the evaluation of strategies under subsection (a) in order
15 to determine the extent to which the strategies have been
16 effective in facilitating the appropriate utilization of pre-
17 ventive health services in the populations with respect to
18 which the strategies were developed.

19 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
20 purpose of carrying out this section, there are authorized
21 to be appropriated such sums as may be necessary for
22 each of the fiscal years 2000 through 2004.”.

○