

106TH CONGRESS  
1ST SESSION

# S. 580

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

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## IN THE SENATE OF THE UNITED STATES

MARCH 10, 1999

Mr. FRIST (for himself, Mr. JEFFORDS, Mr. KENNEDY, Mr. NICKLES, Ms. COLLINS, Mr. BREAUX, Mr. INOUE, Mr. MACK, Mr. HAGEL, Mr. SANTORUM, Ms. MIKULSKI, and Mr. BINGAMAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend title IX of the Public Health Service Act to revise and extend the Agency for Healthcare 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 “Healthcare Research  
5       and Quality Act of 1999”.

1 **SEC. 2. 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 practices, 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 long-term care;

11                  “(C) existing and innovative technologies;

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

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

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

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

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

5           “(3) advancing private and public efforts to im-  
6           prove healthcare quality.

7           “(c) REQUIREMENTS WITH RESPECT TO RURAL  
8           AREAS AND PRIORITY POPULATIONS.—In carrying out  
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;

1           “(8) health statistics, surveys, database devel-  
2           opment, and epidemiology; and

3           “(9) medical liability.

4           “(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-  
18          dressing the priority populations.

19          “(c) MULTIDISCIPLINARY CENTERS.—The Director  
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).

1       “(d) RELATION TO CERTAIN AUTHORITIES REGARD-  
2   ING SOCIAL SECURITY.—Activities authorized in this sec-  
3   tion shall be appropriately coordinated with experiments,  
4   demonstration projects, and other related activities au-  
5   thorized by the Social Security Act and the Social Security  
6   Amendments of 1967. Activities under subsection (a)(2)  
7   of this section that affect the programs under titles XVIII,  
8   XIX and XXI of the Social Security Act shall be carried  
9   out consistent with section 1142 of such Act.

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

15       “(f) RULE OF CONSTRUCTION.—Nothing in this sec-  
16   tion shall be construed to imply that the Agency’s role is  
17   to mandate a national standard or specific approach to  
18   quality measurement and reporting. In research and qual-  
19   ity improvement activities, the Agency shall consider a  
20   wide range of choices, providers, healthcare delivery sys-  
21   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 that  
8 it uses to assess healthcare research results, particularly  
9 methods or systems that it uses to rate the strength of  
10 the scientific evidence behind healthcare practice, rec-  
11 ommendations in the research literature, and technology  
12 assessments. The Agency shall make methods or systems  
13 for evidence rating widely available. Agency publications  
14 containing healthcare recommendations shall indicate the  
15 level of substantiating evidence using such methods or sys-  
16 tems.

17           “(b) HEALTHCARE IMPROVEMENT RESEARCH CEN-  
18 TERS AND PROVIDER-BASED RESEARCH NETWORKS.—

19                   “(1) IN GENERAL.—In order to address the full  
20 continuum of care and outcomes research, to link re-  
21 search to practice improvement, and to speed the  
22 dissemination of research findings to community  
23 practice settings, the Agency shall employ research  
24 strategies and mechanisms that will link research di-  
25 rectly with clinical practice in geographically diverse  
26 locations throughout the United States, including—

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-  
18           MATION ON QUALITY.—

19           “(1) SCIENTIFIC AND TECHNICAL SUPPORT.—  
20           In its role as the principal agency for healthcare re-  
21           search and quality, the Agency may provide sci-  
22           entific and technical support for private and public  
23           efforts to improve healthcare quality, including the  
24           activities of accrediting organizations.

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 of  
4 methods for the evaluation of the health of—

5           “(i) enrollees in health plans by type  
6 of plan, provider, and provider arrange-  
7 ments; and

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

10          “(B) the ongoing development, testing, and  
11 dissemination of quality measures, including  
12 measures of health and functional outcomes;

13          “(C) the compilation and dissemination of  
14 healthcare quality measures developed in the  
15 private and public sector;

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

18          “(E) the development of survey tools for  
19 the purpose of measuring participant and bene-  
20 ficiary assessments of their healthcare; and

21          “(F) identifying and disseminating infor-  
22 mation on mechanisms for the integration of in-  
23 formation on quality into purchaser and con-  
24 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  
18          Director shall—

19          “(1) conduct a survey to collect data on a  
20          nationally representative sample of the population on  
21          the cost, use and, for fiscal year 2001 and subse-  
22          quent fiscal years, quality of healthcare, including  
23          the types of healthcare services Americans use, their  
24          access to healthcare services, frequency of use, how  
25          much is paid for the services used, the source of

1 those payments, the types and costs of private  
2 health insurance, access, satisfaction, and quality of  
3 care for the general population and also for popu-  
4 lations identified in section 901(c); and

5 “(2) develop databases and tools that provide  
6 information to States on the quality, access, and use  
7 of healthcare services provided to their residents.

8 “(b) QUALITY AND OUTCOMES INFORMATION.—

9 “(1) IN GENERAL.—Beginning in fiscal year  
10 2001, the Director shall ensure that the survey con-  
11 ducted under subsection (a)(1) will—

12 “(A) identify determinants of health out-  
13 comes and functional status, the needs of spe-  
14 cial populations in such variables as well as an  
15 understanding of changes over time, relation-  
16 ships to healthcare access and use, and monitor  
17 the overall national impact of Federal and State  
18 policy changes on healthcare;

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

23 “(C) provide reliable national estimates for  
24 children and persons with special healthcare

1 needs through the use of supplements or peri-  
2 odic expansions of the survey.

3 In expanding the Medical Expenditure Panel Survey,  
4 as in existence on the date of enactment of this title)  
5 in fiscal year 2001 to collect information on the  
6 quality of care, the Director shall take into account  
7 any outcomes measurements generally collected by  
8 private sector accreditation organizations.

9 “(2) ANNUAL REPORT.—Beginning in fiscal  
10 year 2003, the Secretary, acting through the Direc-  
11 tor, shall submit to Congress an annual report on  
12 national trends in the quality of healthcare provided  
13 to the American people.

14 **“SEC. 914. INFORMATION SYSTEMS FOR HEALTHCARE IM-  
15 PROVEMENT.**

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

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

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

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

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

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

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

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

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

1 **“SEC. 915. RESEARCH SUPPORTING PRIMARY CARE AND**  
2 **ACCESS IN UNDERSERVED AREAS.**

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

4 **“(1) PURPOSE.—**The Agency shall provide on-  
5 going administrative, research, and technical support  
6 for the operation of the Preventive Services Task  
7 Force. The Agency shall coordinate and support the  
8 dissemination of the Preventive Services Task Force  
9 recommendations.

10 **“(2) OPERATION.—**The Preventive Services  
11 Task Force shall review the scientific evidence relat-  
12 ed to the effectiveness, appropriateness, and cost-ef-  
13 fectiveness of clinical preventive services for the pur-  
14 pose of developing recommendations for the  
15 healthcare community, and updating previous rec-  
16 ommendations, regarding their usefulness in daily  
17 clinical practice. In carrying out its responsibilities  
18 under paragraph (1), the Task Force shall not be  
19 subject to the provisions of Appendix 2 of title 5,  
20 United States Code.

21 **“(b) PRIMARY CARE RESEARCH.—**

22 **“(1) IN GENERAL.—**There is established within  
23 the Agency a Center for Primary Care Research (re-  
24 ferred to in this subsection as the ‘Center’) that  
25 shall serve as the principal source of funding for pri-  
26 mary care practice research in the Department of

1 Health and Human Services. For purposes of this  
2 paragraph, primary care research focuses on the  
3 first contact when illness or health concerns arise,  
4 the diagnosis, treatment or referral to specialty care,  
5 preventive care, and the relationship between the cli-  
6 nician and the patient in the context of the family  
7 and community.

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

11 “(A) the nature and characteristics of pri-  
12 mary care practice;

13 “(B) the management of commonly occur-  
14 ring clinical problems;

15 “(C) the management of undifferentiated  
16 clinical problems; and

17 “(D) the continuity and coordination of  
18 health services.

19 **“SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVA-**  
20 **TION.**

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

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

4           “(2) developing, evaluating, and disseminating  
5           methodologies for assessments of healthcare 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 Assistant Secretary for Health, the Admin-  
2 istrator of the Health Care Financing Administra-  
3 tion, 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, and shall seek input, where appro-  
7 priate, from professional societies and other private  
8 and public entities.

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

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

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

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

15 “(D) comparisons to alternate technologies  
16 and practices; and

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

19 “(c) SPECIFIC ASSESSMENTS.—

20 “(1) IN GENERAL.—The Director shall conduct  
21 or support specific assessments of healthcare tech-  
22 nologies and practices.

23 “(2) REQUESTS FOR ASSESSMENTS.—The Di-  
24 rector is authorized to conduct or support assess-  
25 ments, on a reimbursable basis, for the Health Care

1 Financing Administration, the Department of De-  
2 fense, the Department of Veterans Affairs, the Of-  
3 fice of Personnel Management, and other public or  
4 private entities.

5 “(3) GRANTS AND CONTRACTS.—In addition to  
6 conducting assessments, the Director may make  
7 grants to, or enter into cooperative agreements or  
8 contracts with, entities described in paragraph (4)  
9 for the purpose of conducting assessments of experi-  
10 mental, emerging, existing, or potentially outmoded  
11 healthcare technologies, and for related activities.

12 “(4) ELIGIBLE ENTITIES.—An entity described  
13 in this paragraph is an entity that is determined to  
14 be appropriate by the Director, including academic  
15 medical centers, research institutions and organiza-  
16 tions, professional organizations, third party payers,  
17 governmental agencies, and consortia of appropriate  
18 research entities established for the purpose of con-  
19 ducting technology assessments.

20 **“SEC. 917. COORDINATION OF FEDERAL GOVERNMENT**  
21 **QUALITY IMPROVEMENT EFFORTS.**

22 “(a) REQUIREMENT.—

23 “(1) IN GENERAL.—To avoid duplication and  
24 ensure that Federal resources are used efficiently  
25 and effectively, the Secretary, acting through the Di-

1 rector, shall coordinate all research, evaluations, and  
2 demonstrations related to health services research,  
3 quality measurement and quality improvement ac-  
4 tivities undertaken and supported by the Federal  
5 Government.

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

10 “(A) improve interagency coordination, pri-  
11 ority setting, and the use and sharing of re-  
12 search findings and data pertaining to Federal  
13 quality improvement programs, technology as-  
14 sessment, and health services research;

15 “(B) strengthen the research information  
16 infrastructure, including databases, pertaining  
17 to Federal health services research and  
18 healthcare quality improvement initiatives;

19 “(C) set specific goals for participating  
20 agencies and departments to further health  
21 services research and healthcare quality im-  
22 provement; and

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

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

1           “(1) IN GENERAL.—To provide Congress, the  
2           Department of Health and Human Services, and  
3           other relevant departments with an independent, ex-  
4           ternal review of their quality oversight, quality im-  
5           provement and quality research programs, the Sec-  
6           retary shall enter into a contract with the Institute  
7           of Medicine—

8                   “(A) to describe and evaluate current qual-  
9                   ity improvement, quality research and quality  
10                  monitoring processes through—

11                           “(i) an overview of pertinent health  
12                           services research activities and quality im-  
13                           provement efforts conducted by all Federal  
14                           programs, with particular attention paid to  
15                           those under titles XVIII, XIX, and XXI of  
16                           the Social Security Act; and

17                           “(ii) a summary of the partnerships  
18                           that the Department of Health and  
19                           Human Services has pursued with private  
20                           accreditation, quality measurement and  
21                           improvement organizations; and

22                   “(B) to identify options and make rec-  
23                   ommendations to improve the efficiency and ef-  
24                   fectiveness of quality improvement programs  
25                   through—

1           “(i) the improved coordination of ac-  
2           tivities across the medicare, medicaid and  
3           child health insurance programs under ti-  
4           tles XVIII, XIX and XXI of the Social Se-  
5           curity Act and health services research  
6           programs;

7           “(ii) the strengthening of patient  
8           choice and participation by incorporating  
9           state-of-the-art quality monitoring tools  
10          and making information on quality avail-  
11          able; and

12          “(iii) the enhancement of the most ef-  
13          fective programs, consolidation as appro-  
14          priate, and elimination of duplicative ac-  
15          tivities within various federal agencies.

16          “(2) REQUIREMENTS.—

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

20                         “(i) not later than 12 months after  
21                         the date of enactment of this title, of a re-  
22                         port providing an overview of the quality  
23                         improvement programs of the Department  
24                         of Health and Human Services for the  
25                         medicare, medicaid, and CHIP programs

1 under titles XVIII, XIX, and XXI of the  
2 Social Security Act; and

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

6 “(B) REPORTS.—The Secretary shall sub-  
7 mit the reports described in subparagraph (A)  
8 to the Committee on Finance and the Commit-  
9 tee on Health, Education, Labor, and Pensions  
10 of the Senate and the Committee on Ways and  
11 Means and the Committee on Commerce of the  
12 House of Representatives.

13 **“PART C—GENERAL PROVISIONS**

14 **“SEC. 921. ADVISORY COUNCIL FOR HEALTHCARE RE-**  
15 **SEARCH AND QUALITY.**

16 “(a) ESTABLISHMENT.—There is established an advi-  
17 sory council to be known as the Advisory Council for  
18 Healthcare Research and Quality.

19 “(b) DUTIES.—

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

24 “(2) CERTAIN RECOMMENDATIONS.—Activities  
25 of the Advisory Council under paragraph (1) shall

1 include making recommendations to the Director  
2 regarding—

3 “(A) priorities regarding healthcare re-  
4 search, especially studies related to quality, out-  
5 comes, cost and the utilization of, and access  
6 to, healthcare services;

7 “(B) the field of healthcare research and  
8 related disciplines, especially issues related to  
9 training needs, and dissemination of informa-  
10 tion pertaining to healthcare quality; and

11 “(C) the appropriate role of the Agency in  
12 each of these areas in light of private sector ac-  
13 tivity and identification of opportunities for  
14 public-private sector partnerships.

15 “(c) MEMBERSHIP.—

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

22 “(2) APPOINTED MEMBERS.—The Secretary  
23 shall appoint to the Advisory Council 21 appro-  
24 priately qualified individuals. At least 17 members of  
25 the Advisory Council shall be representatives of the

1 public who are not officers or employees of the  
2 United States. The Secretary shall ensure that the  
3 appointed members of the Council, as a group, are  
4 representative of professions and entities concerned  
5 with, or affected by, activities under this title and  
6 under section 1142 of the Social Security Act. Of  
7 such members—

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

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

14 “(C) 3 shall be individuals distinguished in  
15 the other health professions;

16 “(D) 4 shall be individuals either rep-  
17 resenting the private healthcare sector, includ-  
18 ing health plans, providers, and purchasers or  
19 individuals distinguished as administrators of  
20 healthcare delivery systems;

21 “(E) 4 shall be individuals distinguished in  
22 the fields of healthcare quality improvement, ec-  
23 nomics, information systems, law, ethics, busi-  
24 ness, or public policy; and

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

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

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

15          “(B) such other Federal officials as the  
16          Secretary may consider appropriate.

17          “(d) TERMS.—Members of the Advisory Council ap-  
18          pointed under subsection (c)(2) shall serve for a term of  
19          3 years. A member of the Council appointed under such  
20          subsection may continue to serve after the expiration of  
21          the term of the members until a successor is appointed.

22          “(e) VACANCIES.—If a member of the Advisory  
23          Council appointed under subsection (c)(2) does not serve  
24          the full term applicable under subsection (d), the individ-  
25          ual appointed to fill the resulting vacancy shall be ap-

1 pointed for the remainder of the term of the predecessor  
2 of the individual.

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

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

11 “(h) COMPENSATION AND REIMBURSEMENT OF  
12 EXPENSES.—

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

21 “(2) EX OFFICIO MEMBERS.—Officials des-  
22 ignated under subsection (c)(3) as ex officio mem-  
23 bers of the Advisory Council may not receive com-  
24 pensation for service on the Advisory Council in ad-



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

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

23          “(3) DURATION.—Notwithstanding section  
24          14(a) of the Federal Advisory Committee Act, peer  
25          review groups established under this section may

1 continue in existence until otherwise provided by  
2 law.

3 “(4) QUALIFICATIONS.—Members of any peer-  
4 review group shall, at a minimum, meet the follow-  
5 ing requirements:

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

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

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

1 ments may be made for the purpose of encouraging the  
 2 entry of individuals into the field of research, for the pur-  
 3 pose of encouraging clinical practice-oriented or provider-  
 4 based research, and for such other purposes as the Direc-  
 5 tor may determine to be appropriate.

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

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

11 “(a) STANDARDS WITH RESPECT TO UTILITY OF  
 12 DATA.—

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

19 “(A) other Federal health data collection  
 20 standards; and

21 “(B) the differences between types of  
 22 healthcare plans, delivery systems, healthcare  
 23 providers, and provider arrangements.

24 “(2) RELATIONSHIP WITH OTHER DEPARTMENT  
 25 PROGRAMS.—In any case where standards under

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

9 “(b) STATISTICS AND ANALYSES.—The Director  
10 shall—

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

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

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

1 ments shall be available to the Director for obligation until  
2 expended.

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

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

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

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

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

20 “(4) provide, in collaboration with the National  
21 Library of Medicine where appropriate, indexing, ab-  
22 stracting, translating, publishing, and other services  
23 leading to a more effective and timely dissemination  
24 of information on research, demonstration projects,  
25 and evaluations with respect to healthcare to public

1 and private entities and individuals engaged in the  
2 improvement of healthcare delivery and the general  
3 public, and undertake programs to develop new or  
4 improved methods for making such information  
5 available; and

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

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

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

1 person has consented (as determined under regulations of  
2 the Director) to its publication or release in other form.

3 “(d) PENALTY.—Any person who violates subsection  
4 (c) shall be subject to a civil monetary penalty of not more  
5 than \$10,000 for each such violation involved. Such pen-  
6 alty shall be imposed and collected in the same manner  
7 as civil money penalties under subsection (a) of section  
8 1128A of the Social Security Act are imposed and col-  
9 lected.

10 **“SEC. 925. ADDITIONAL PROVISIONS WITH RESPECT TO**  
11 **GRANTS AND CONTRACTS.**

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

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

21 “(2) the actions that will be taken by the Direc-  
22 tor in response to any such interests identified by  
23 the Director.

24 “(b) REQUIREMENT OF APPLICATION.—The Director  
25 may not, with respect to any program under this title au-

1 thoring the provision of grants, cooperative agreements,  
2 or contracts, provide any such financial assistance unless  
3 an application for the assistance is submitted to the Sec-  
4 retary and the application is in such form, is made in such  
5 manner, and contains such agreements, assurances, and  
6 information as the Director determines to be necessary to  
7 carry out the program involved.

8 “(c) PROVISION OF SUPPLIES AND SERVICES IN  
9 LIEU OF FUNDS.—

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

18 “(2) CORRESPONDING REDUCTION IN FUNDS.—  
19 With respect to a request described in paragraph  
20 (1), the Secretary shall reduce the amount of the fi-  
21 nancial assistance involved by an amount equal to  
22 the costs of detailing personnel and the fair market  
23 value of any supplies, equipment, or services pro-  
24 vided by the Director. The Secretary shall, for the

1 payment of expenses incurred in complying with  
2 such request, expend the amounts withheld.

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

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

8 “(a) **DEPUTY DIRECTOR AND OTHER OFFICERS AND**  
9 **EMPLOYEES.**—

10 “(1) **DEPUTY DIRECTOR.**—The Director may  
11 appoint a deputy director for the Agency.

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

20 “(b) **FACILITIES.**—The Secretary, in carrying out  
21 this title—

22 “(1) may acquire, without regard to the Act of  
23 March 3, 1877 (40 U.S.C. 34), by lease or otherwise  
24 through the Director of General Services, buildings  
25 or portions of buildings in the District of Columbia

1 or communities located adjacent to the District of  
2 Columbia for use for a period not to exceed 10  
3 years; and

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

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

14 “(d) UTILIZATION OF CERTAIN PERSONNEL AND RE-  
15 SOURCES.—

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

24 “(2) OTHER AGENCIES.—The Director, in car-  
25 rying out this title, may use, with their consent, the

1 services, equipment, personnel, information, and fa-  
2 cilities of other Federal, State, or local public agen-  
3 cies, or of any foreign government, with or without  
4 reimbursement of such agencies.

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

11 “(f) EXPERTS.—

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

20 “(2) TRAVEL EXPENSES.—

21 “(A) IN GENERAL.—Experts and consult-  
22 ants whose services are obtained under para-  
23 graph (1) shall be paid or reimbursed for their  
24 expenses associated with traveling to and from  
25 their assignment location in accordance with

1 sections 5724, 5724a(a), 5724a(c), and  
2 5726(C) of title 5, United States Code.

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

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

23 **“SEC. 927. FUNDING.**

24 “(a) INTENT.—To ensure that the United States’s in-  
25 vestment in biomedical research is rapidly translated into

1 improvements in the quality of patient care, there must  
 2 be a corresponding investment in research on the most ef-  
 3 fective clinical and organizational strategies for use of  
 4 these findings in daily practice. The authorization levels  
 5 in subsections (b) and (c) provide for a proportionate in-  
 6 crease in healthcare research as the United State’s invest-  
 7 ment in biomedical research increases.

8       “(b) AUTHORIZATION OF APPROPRIATIONS.—For the  
 9 purpose of carrying out this title, there are authorized to  
 10 be appropriated \$250,000,000 for fiscal year 2000, and  
 11 such sums as may be necessary for each of the fiscal years  
 12 2001 through 2006.

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

20 **“SEC. 928. DEFINITIONS.**

21       “In this title:

22               “(1) ADVISORY COUNCIL.—The term ‘Advisory  
 23 Council’ means the Advisory Council on Healthcare  
 24 Research and Quality established under section 921.

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

3           “(3) DIRECTOR.—The term ‘Director’ means  
4           the Director for the Agency for Healthcare Research  
5           and Quality.”.

6 **SEC. 3. REFERENCES.**

7           Effective upon the date of enactment of this Act, any  
8           reference in law to the “Agency for Health Care Policy  
9           and Research” shall be deemed to be a reference to the  
10          “Agency for Healthcare Research and Quality”.

○