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HEALTH RESEARCH AND QUALITY ACT OF 1999

SEPTEMBER 8, 1999.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BLILEY, from the Committee on Commerce, submitted the following

REPORT

[To accompany H.R. 2506]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (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, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:

69–006

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Health Research and Quality Act of 1999".

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

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

"TITLE IX—AGENCY FOR HEALTH RESEARCH AND QUALITY

"PART A—ESTABLISHMENT AND GENERAL DUTIES

"SEC. 901. MISSION AND DUTIES.

"(a) IN GENERAL.—There is established within the Public Health Service an agency to be known as the Agency for Health Research and Quality, which shall be headed by a director appointed by the Secretary. The Secretary shall carry out this title acting through the Director.

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

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

"(A) the development and assessment of methods for enhancing patient participation in their own care and for facilitating shared patient-physician decision-making;

"(B) the outcomes, effectiveness, and cost-effectiveness of health care practices, including preventive measures and long-term care;

"(C) existing and innovative technologies;

"(D) the costs and utilization of, and access to health care;

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

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

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

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

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

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

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

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

"(3) the health of children;

"(4) the elderly; and

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

"SEC. 902. GENERAL AUTHORITIES.

"(a) IN GENERAL.—In carrying out section 901(b), the Director shall support demonstration projects, conduct and support research, evaluations, training, research networks, multi-disciplinary centers, technical assistance, and the dissemination of information, on health care, and on systems for the delivery of such care, including activities with respect to—

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

"(2) quality measurement and improvement;

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

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

"(5) health care technologies, facilities, and equipment;

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

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

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

"(9) medical liability.

"(b) HEALTH SERVICES TRAINING GRANTS.—

"(1) IN GENERAL.—The Director may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate. In carrying out this subsection, the Director shall make use of funds made available under section 487.

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

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

"(d) RELATION TO CERTAIN AUTHORITIES REGARDING SOCIAL SECURITY.—Activities authorized in this section shall be appropriately coordinated with experiments, demonstration projects, and other related activities authorized by the Social Security Act and the Social Security Amendments of 1967. Activities under subsection (a)(2) of this section that affect the programs under titles XVIII, XIX and XXI of the Social Security Act shall be carried out consistent with section 1142 of such Act.

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

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

"PART B—HEALTH CARE IMPROVEMENT RESEARCH

"SEC. 911. HEALTH CARE OUTCOME IMPROVEMENT RESEARCH.

"(a) EVIDENCE RATING SYSTEMS.—In collaboration with experts from the public and private sector, the Agency shall identify and disseminate methods or systems that it uses to assess health care research results, particularly methods or systems that it uses to rate the strength of the scientific evidence behind health care practice, recommendations in the research literature, and technology assessments. The Agency shall make methods or systems for evidence rating widely available. Agency publications containing health care recommendations shall indicate the level of substantiating evidence using such methods or systems.

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

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

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

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

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

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

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

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

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

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

"(A) the identification and assessment of methods for the evaluation of the health of—

"(i) enrollees in health plans by type of plan, provider, and provider arrangements; and

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

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

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

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

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

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

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

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

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

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

"(i) To increase awareness of—

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

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

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

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

"(I) Health care practitioners and other providers of health care goods or services.

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

"(III) Health maintenance organizations and other managed health care organizations.

"(IV) Health care insurers and governmental agencies.

"(V) Patients and consumers.

"(iii) To improve the quality of health care while reducing the cost of health care through—

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

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

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

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

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

"(1) identify the causes of preventable health care errors and patient injury in health care delivery;

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

"(3) promote the implementation of effective strategies throughout the health care industry.

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

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

"(1) conduct a survey to collect data on a nationally representative sample of the population on the cost, use and, for fiscal year 2001 and subsequent fiscal years, quality of health care, including the types of health care services Americans use, their access to health care services, frequency of use, how much is paid for the services used, the source of those payments, the types and costs of private health insurance, access, satisfaction, and quality of care for the general population and also for populations identified in section 901(c); and

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

"(b) QUALITY AND OUTCOMES INFORMATION.—

"(1) IN GENERAL.—Beginning in fiscal year 2001, the Director shall ensure that the survey conducted under subsection (a)(1) will—

"(A) identify determinants of health outcomes and functional status, the needs of special populations in such variables as well as an understanding of changes over time, relationships to health care access and use, and monitor the overall national impact of Federal and State policy changes on health care;

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

"(C) provide reliable national estimates for children and persons with special health care needs through the use of supplements or periodic expansions of the survey.

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

"(2) ANNUAL REPORT.—Beginning in fiscal year 2003, the Secretary, acting through the Director, shall submit to Congress an annual report on national trends in the quality of health care provided to the American people.

"SEC. 914. INFORMATION SYSTEMS FOR HEALTH CARE IMPROVEMENT.

"(a) IN GENERAL.—In order to foster a range of innovative approaches to the management and communication of health information, the Agency shall support research, evaluations and initiatives to advance—

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

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

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

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

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

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

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

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

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

"(a) PREVENTIVE SERVICES TASK FORCE.—

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

The Agency shall coordinate and support the dissemination of the Preventive Services Task Force recommendations.

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

"(b) PRIMARY CARE RESEARCH.—

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

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

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

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

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

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

"SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVATION.

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

"(1) conducting and supporting research on the development, diffusion, and use of health care technology;

"(2) developing, evaluating, and disseminating methodologies for assessments of health care practices and health care technologies;

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

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

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

"(b) SPECIFICATION OF PROCESS.—

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

"(2) CONSULTATIONS.—In carrying out this subsection, the Director shall cooperate and consult with the Assistant Secretary for Health, the Administrator of the Health Care Financing Administration, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency, and shall seek input, where appropriate, from professional societies and other private and public entities.

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

"(A) safety, efficacy, and effectiveness;

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

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

"(D) comparisons to alternate technologies and practices; and

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

"(c) SPECIFIC ASSESSMENTS.—

"(1) IN GENERAL.—The Director shall conduct or support specific assessments of health care technologies and practices.

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

"(3) GRANTS AND CONTRACTS.—In addition to conducting assessments, the Director may make grants to, or enter into cooperative agreements or contracts with, entities described in paragraph (4) for the purpose of conducting assess-

ments of experimental, emerging, existing, or potentially outmoded health care technologies, and for related activities.

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

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

"(a) REQUIREMENT.—

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

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

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

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

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

"(D) strengthen the management of Federal health care quality improvement programs.

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

"(1) IN GENERAL.—To provide Congress, the Department of Health and Human Services, and other relevant departments with an independent, external review of their quality oversight, quality improvement and quality research programs, the Secretary shall enter into a contract with the Institute of Medicine—

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

"(i) an overview of pertinent health services research activities and quality improvement efforts conducted by all Federal programs, with particular attention paid to those under titles XVIII, XIX, and XXI of the Social Security Act; and

"(ii) a summary of the partnerships that the Department of Health and Human Services has pursued with private accreditation, quality measurement and improvement organizations; and

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

"(i) the improved coordination of activities across the medicare, medicaid and child health insurance programs under titles XVIII, XIX and XXI of the Social Security Act and health services research programs;

"(ii) the strengthening of patient choice and participation by incorporating state-of-the-art quality monitoring tools and making information on quality available; and

"(iii) the enhancement of the most effective programs, consolidation as appropriate, and elimination of duplicative activities within various federal agencies.

"(2) REQUIREMENTS.—

"(A) IN GENERAL.—The Secretary shall enter into a contract with the Institute of Medicine for the preparation—

"(i) not later than 12 months after the date of enactment of this title, of a report providing an overview of the quality improvement programs of the Department of Health and Human Services for the medicare, medicaid, and CHIP programs under titles XVIII, XIX, and XXI of the Social Security Act; and

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

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

and Means and the Committee on Commerce of the House of Representatives.

"PART C—GENERAL PROVISIONS

"SEC. 921. ADVISORY COUNCIL FOR HEALTH CARE RESEARCH AND QUALITY.

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

"(b) DUTIES.—

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

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

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

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

"(C) the appropriate role of the Agency in each of these areas in light of private sector activity and identification of opportunities for public-private sector partnerships.

"(c) MEMBERSHIP.—

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

"(2) APPOINTED MEMBERS.—The Secretary shall appoint to the Advisory Council 18 appropriately qualified individuals. At least 14 members of the Advisory Council shall be representatives of the public who are not officers or employees of the United States. The Secretary shall ensure that the appointed members of the Council, as a group, are representative of professions and entities concerned with, or affected by, activities under this title and under section 1142 of the Social Security Act. Of such members—

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

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

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

"(D) 3 shall be individuals either representing the private health care sector, including health plans, providers, and purchasers or individuals distinguished as administrators of health care delivery systems;

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

"(F) 3 shall be individuals representing the interests of patients and consumers of health care.

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

"(A) the Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Care Financing Administration, the Assistant Secretary of Defense (Health Affairs), and the Under Secretary for Health of the Department of Veterans Affairs; and

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

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

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

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

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

"(h) COMPENSATION AND REIMBURSEMENT OF EXPENSES.—

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

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

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

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

"(a) REQUIREMENT OF REVIEW.—

"(1) IN GENERAL.—Appropriate technical and scientific peer review shall be conducted with respect to each application for a grant, cooperative agreement, or contract under this title.

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

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

"(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

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

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

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

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

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

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

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

vider-based research, and for such other purposes as the Director may determine to be appropriate.

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

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

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

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

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

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

"(2) RELATIONSHIP WITH OTHER DEPARTMENT PROGRAMS.—In any case where standards under paragraph (1) may affect the administration of other programs carried out by the Department of Health and Human Services, including the programs under title XVIII, XIX or XXI of the Social Security Act, or may affect health information that is subject to a standard developed under part C of title XI of the Social Security Act, they shall be in the form of recommendations to the Secretary for such program.

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

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

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

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

"SEC. 924. DISSEMINATION OF INFORMATION.

"(a) IN GENERAL.—The Director shall—

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

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

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

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

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

"(b) PROHIBITION AGAINST RESTRICTIONS.—Except as provided in subsection (c), the Director may not restrict the publication or dissemination of data from, or the results of, projects conducted or supported under this title.

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

scribed in it is identifiable unless such person has consented (as determined under regulations of the Director) to its publication or release in other form.

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

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

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

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

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

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

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

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

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

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

"SEC. 926. CERTAIN ADMINISTRATIVE AUTHORITIES.

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

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

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

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

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

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

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

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

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

"(2) OTHER AGENCIES.—The Director, in carrying out this title, may use, with their consent, the services, equipment, personnel, information, and facilities of

other Federal, State, or local public agencies, or of any foreign government, with or without reimbursement of such agencies.

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

"(f) EXPERTS.—

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

"(2) TRAVEL EXPENSES.—

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

"(B) LIMITATION.—Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless and until the expert agrees in writing to complete the entire period of assignment, or 1 year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a statutory obligation owed to the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

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

"SEC. 927. FUNDING.

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

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

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

"SEC. 928. DEFINITIONS.

"In this title:

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

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

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

(b) RULES OF CONSTRUCTION.—

(1) IN GENERAL.—Section 901(a) of the Public Health Service Act (as added by subsection (a) of this section) applies as a redesignation of the agency that carried out title IX of such Act on the day before the date of enactment of this Act, and not as the termination of such agency and the establishment of a different agency. The amendment made by subsection (a) of this section does not affect appointments of the personnel of such agency who were employed at the agency on the day before such date.

(2) REFERENCES.—Any reference in law to the Agency for Health Care Policy and Research is deemed to be a reference to the Agency for Health Research and Quality, and any reference in law to the Administrator for Health Care Policy and Research is deemed to be a reference to the Director of the Agency for Health Research and Quality.

SEC. 3. GRANTS REGARDING UTILIZATION OF PREVENTIVE HEALTH SERVICES.

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

"SEC. 330D. CENTERS FOR STRATEGIES ON FACILITATING UTILIZATION OF PREVENTIVE HEALTH SERVICES AMONG VARIOUS POPULATIONS.

"(a) IN GENERAL.—The Secretary, acting through the appropriate agencies of the Public Health Service, shall make grants to public or nonprofit private entities for the establishment and operation of regional centers whose purpose is to identify particular populations of patients and facilitate the appropriate utilization of preventive health services by patients in the populations through developing and disseminating strategies to improve the methods used by public and private health care programs and providers in interacting with such patients.

"(b) RESEARCH AND TRAINING.—The activities carried out by a center under subsection (a) may include establishing programs of research and training with respect to the purpose described in such subsection, including the development of curricula for training individuals in implementing the strategies developed under such subsection.

"(c) QUALITY MANAGEMENT.—A condition for the receipt of a grant under subsection (a) is that the applicant involved agree that, in order to ensure that the strategies developed under such subsection take into account principles of quality management with respect to consumer satisfaction, the applicant will make arrangements with one or more private entities that have experience in applying such principles.

"(d) PRIORITY REGARDING INFANTS AND CHILDREN.—In carrying out the purpose described in subsection (a), the Secretary shall give priority to various populations of infants, young children, and their mothers.

"(e) EVALUATIONS.—The Secretary, acting through the appropriate agencies of the Public Health Service, shall (directly or through grants or contracts) provide for the evaluation of strategies under subsection (a) in order to determine the extent to which the strategies have been effective in facilitating the appropriate utilization of preventive health services in the populations with respect to which the strategies were developed.

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

PURPOSE AND SUMMARY

H.R. 2506 establishes the Agency for Health Research and Quality (AHRQ) to conduct and support research on the quality, outcomes, cost, and utilization of health care services and access to those services. The Agency will promote quality by building our knowledge regarding what works best in health care, working in close partnership with the health care community to identify and address opportunities for improvement, and supporting the rapid translation of its research findings into daily practice. AHRQ will support the evidence-based practice of medicine and facilitate innovation in patient care by developing, synthesizing, and disseminating scientific knowledge regarding the outcomes, effectiveness and cost-effectiveness of health care services, health care technologies and information systems, and the ways that these services and technologies are purchased, financed, organized, and delivered. The Agency will foster the development of the science of health care quality measurement and quality improvement, build public-private partnerships to advance and share quality measures and effective strategies for quality improvement, report annually to Congress on the state of quality in the Nation, and coordinate Federal quality improvement efforts to avoid duplication. AHRQ will promote access and quality through research on the most effective ways for delivering primary care services, meeting the health care needs of under-served populations, providing services within under-

served rural and urban areas, and facilitating the utilization of effective clinical preventive health care services. Finally, the Agency will support improved health care decisionmaking at all levels of the health care system through the entire spectrum of its activities: collecting and developing data on the quality, cost, and use of health care services, conducting and supporting research and evaluations, supporting demonstrations, serving as an "honest broker" among competing interests, and acting as a "science partner" with the public and private sector.

BACKGROUND AND NEED FOR LEGISLATION

BACKGROUND

The health care system in America today is dramatically different from the system that existed a decade ago when Congress established the Agency for Health Care Policy and Research (AHCPR). This transformation is due in large part to the changing nature of our insurance system—the growing dominance of managed care plans; increased plan complexity; increasing concentration as a result of consolidations and mergers; demands of purchasers for accountability and value from health care providers; shifting financial incentives; and the growing tension between caregivers, patients, and the policies of the systems through which care is delivered. At the same time, there has been an explosion in the number of medical journals and peer-reviewed articles published each year, reflecting in part the Congressional support for basic and biomedical research over the last few years.

As a result, even the most conscientious clinicians face increasing difficulty in keeping abreast of the medical literature and putting the latest scientific findings into perspective. In fact, it has been estimated that if physicians were to read two peer-reviewed journal articles each night after a long day of practice, they would be 800 years behind in their reading at the end of the year. The exponential growth in health-related Internet web sites poses additional challenges for patients and caregivers alike in determining which information is based upon science and which information is less reliable.

While concern regarding variations in the rates at which physicians conduct medical procedures contributed to the decision to create AHCPR in 1989, public concern regarding the quality of patient care is growing and requires a more direct and coordinated response. While millions of Americans receive high-quality care every day, peer-reviewed research has documented too many instances of underuse, overuse, and misuse of services. In addition, there is growing public concern regarding the number of medical errors that take place, in which patients suffer from adverse drug events, treatment or even amputation of the wrong limb, or other oversights. The pioneering Harvard study in which Dr. Lucian Leape and his colleagues looked at the records of more than 30,000 hospital patients in New York found that nearly 4 percent suffered serious injuries that were related to the management of their illness rather than the illness itself. To their credit, health professionals have recognized the problem. To tackle these systemic issues successfully, there is a need for a sustained health services research

initiative that is undertaken in partnership with the health professions and provider community.

As demonstrated by the debate on managed care reform, issues such as the cost and appropriate use of, and access to, health services remain significant public policy concerns. Many of these concerns developed, in part, because of the lack of reliable evidence about the risks and benefits of alternative approaches for containing health care costs, organizing health care delivery systems, and structuring the policies that govern systems of care. Similarly, the debate on the long-term stability of the Medicare program only serves to reinforce the critical need for this type of scientific evidence. These developments have highlighted as never before the need for objective, science-based information at all levels of the health care system:

- at the clinical level, providing patients and those who deliver care the information they need to make informed decisions regarding treatment options;
- at the system level, getting good information to those who manage systems of care about alternative approaches to organizing and delivering care, and, for individual consumers and those who make purchasing decisions for their employees or members, information that will enable them to make more informed decisions in selecting health plans and providers and in comparing and assessing the value of the care that they are purchasing; and
- at the public policy level, providing scientific findings—about the impact on quality, cost, and access—concerning the ways we structure and deliver care, the incentives that are provided to clinicians, decisions regarding which services to offer, as well as information (not currently available) on national trends in quality.

The methods and tools of health services research are well suited for addressing these information needs. While AHCPR serves as the lead Federal Agency supporting health services research, it does not have the necessary budget or requisite coordinating authority to address these pressing information needs adequately. This legislation will transform the agency into the new Agency for Health Research and Quality (AHRQ), which will have the stature, resources, and authority to work in close collaboration with the private sector to meet the Federal responsibilities in these areas.

NEED FOR LEGISLATION

In developing this legislation, the Committee undertook a thorough review of the research and other activities of AHCPR to determine whether these activities were an appropriate Federal responsibility, whether they warranted the continued existence of a separate agency, and, if so, whether the Agency's mission needed to be refocused. The Committee reached several conclusions. First, the Agency's research and other activities provide the science-based evidence that will improve the quality of patient care. The kind of objective, reliable information developed by the Agency is essential for the successful functioning of our competitive health care marketplace. Second, the Committee found that the continued existence of a separate agency is justified because of its unique focus on the

effectiveness of care in daily practice, its demonstrated ability to bridge the worlds of research and practice, and the multiple focus of its research on the clinical aspects of care, as well as the economics, organization, and delivery of health care. Third, the Committee believes that a reformed and strengthened Agency can play a critical role as the hub and driving force for the Federal government's quality improvement efforts and in supporting private sector quality efforts by advancing the young science of health care quality measurement and improvement. Finally, the Committee found that a substantial investment in building our scientific knowledge regarding quality health care is an essential complement to the patient protections provided in the other titles of this legislation.

The rationale for a significant Federal commitment to the type of health services research supported by the AHRQ is strong. The Federal government has a compelling interest in ensuring that patients and society reap the full rewards of our growing investment in basic and biomedical research. This requires a corresponding investment in the kind of health services research that will support the effective use of these developments. Experience has shown that great opportunities for improving health, developed through biomedical research, are easily lost if physicians and patients are unable to make the best use of the knowledge in everyday care. The private sector often lacks the incentive to address these issues because the cost of the research investment is far greater than the benefits to the individual health plan, which occurs when clinical conditions are common, but not costly or when they are expensive but extremely rare. By contrast, the Federal government has both an obligation to the American people and a responsibility to see that the goal of its investment in basic and biomedical research (higher quality patient care) is realized.

The Agency has demonstrated its ability to close this gap between the promise of biomedical research and improvements in daily practice. For example, National Institutes of Health (NIH)-supported research at the University of Wisconsin demonstrated the potential of warfarin (an anticoagulant) to prevent stroke in patients with atrial fibrillation, yet this lifesaving innovation was underused in daily practice. An Agency-supported research team at Duke University conducted a meta-analysis that established warfarin as the treatment of choice, undertook research that identified the reasons that physicians were often reluctant to use this effective intervention, and conducted a trial to develop effective approaches for administering warfarin that addressed the concerns of physicians. Findings from this research project led in part to development of guidelines from the American College of Physicians, the American Hospital Association (AHA), and the Joint Council of Vascular Surgeons. Medicare Peer Review Organizations (PROs) implemented 73 projects in 42 States, to increase anticoagulation. Rates from 28 projects in 20 States showed that patients discharged on anticoagulation therapy increased from 58 percent to 71 percent. Improved anticoagulation rates through the PRO projects are projected to prevent 1285 strokes. As a result of the Agency's research, the promise of the Federal investment in the basic research that identified warfarin's potential is increasingly being re-

alized. The final demonstration project, for which the private sector contributed $2.50 for every $1.00 of Agency funds, also demonstrated for the first time the Agency's ability to collaborate with and leverage private sector funding.

In addition to supporting new research that identifies what works best in practice and how to make more effective use of existing innovations, the Federal government can support the work of busy health care professionals by assessing new scientific advances and putting them into perspective. The development of such syntheses requires methodologists to assess the research design of the studies and the scientific controls and statistics that were employed to determine the extent to which clinicians can use the studies to guide their daily practice. This is another area where there appear to be few incentives in academia or the private sector to undertake such studies, and health professionals are seldom trained to undertake such methodological assessments. Yet the development and updating of such assessments are essential for clinicians and patients to benefit from investments in basic and biomedical research. They provide essential information to clinicians which, when combined with a patient examination, medical history, and the clinicians' own clinical experience, can ensure that their patients receive care that is informed by the best science available.

As a purchaser and provider of health care services, the Federal government has a compelling need for information that will help it to manage its programs more effectively and efficiently and provide information to beneficiaries of those programs. Dr. Stuart Butler of The Heritage Foundation has argued that the Agency should play an even greater role in this area. Citing the potential conflicts of interest faced by Federal Agencies in attempting both to run programs and to provide dispassionate and objective information, he has argued for the importance of the Agency's independence "free from any interest in a particular way of providing care" (Senate Report 106–82, p. 14). The unique focus of the health services research supported by the Agency on the cost and appropriate use of and access to health care services is especially critical to the efforts of the Congress to ensure the long-term viability of the Medicare program.

Such research is an important public good in its own right. Scientific information on how to relieve suffering, maintain or restore health, and improve the effectiveness of the way health services are delivered needs to be in the public domain to the extent possible. Public funding ensures that the research methods are scrutinized, are publicly available, are peer reviewed, and are accessible.

During the Subcommittee on Health and Environment's hearing on April 29, 1999, the witnesses agreed on the need for a Federal role in advancing the science of quality, developing and validating measures and tools for evaluating and improving quality, and making that information widely available. An analogy has been suggested that the government's role in health care should be similar to the way it provides consumers with information to assess the safety of airlines or automobiles. In making those choices, consumers also have a variety of other standards or measures they can use in assessing which automobile to buy or which airline to fly. The Committee concurs with this general framework and has pro-

vided the Agency with broad authority to develop and advance the science of quality but prohibits it from mandating a single approach or national standard toward assessing quality.

The Committee concludes that, despite the Agency's past problems, a renewed and reinvigorated agency is necessary to carry out these legitimate Federal functions. As the conference report to accompany the Food and Drug Administration Modernization Act of 1997 (P.L. 105–115, H. Rpt. 105–399, p. 101) noted on the decision to assign responsibility for Centers on Education and Research on Therapeutics (CERTs) to the Agency:

> The conferees designated AHCPR as the lead agency because of its expertise in the evaluation of the effectiveness of clinical care, its non-regulatory role, and its close working relationship with the health care community in the improvement of the quality of care.

The Committee reaffirms that position in this report. The Agency has demonstrated an ability to maintain its role as an independent, objective, scientific research agency while developing close working relationships with disparate portions of the health care community. Its three-way partnership in the National Guideline Clearinghouse with the American Medical Association and the managed care trade association, the American Association of Health Plans, is an excellent example of its ability to bridge the worlds of research and practice in a way that supports private-sector efforts without Federal mandates or intrusive policy. The Agency's development of the Consumer Assessment of Health Plans Survey (CAHPS) kit, which has been voluntarily adopted by private sector and public sector plans, employers, and accreditors, is another example of the Agency's responsiveness in providing the tools that the private sector needs to improve the quality of patient care. In light of the increasing user-direction of its work and the growing number and success of these public-private sector partnerships, it is the Committee's view that shifting these activities to another agency would be shortsighted and destructive. The Committee's bill takes the opposite approach by recognizing the Agency's success in reorienting its activities, and strengthening its mandate and its resources. The Committee especially values the Agency's demonstrated ability to serve as a facilitator of groups with different philosophies, ideologies, and economic agendas. It should be noted that the Committee includes a provision in the bill that clarifies that the role of the Agency is not to mandate national standards of clinical practice or any specific approach to quality measurement and reporting. The Committee accepts the premise that definitions and measurement of quality is an evolving science.

HEARINGS

The Subcommittee on Health and the Environment held a hearing on Reauthorization of the Agency for Health Care Policy and Research on April 29, 1999. The Subcommittee received testimony from the following witnesses: Dr. John M. Eisenberg, Administrator, Agency for Health Care Policy and Research; Ms. Mary Wooley, President, Research! America; Mr. Charles N. Kahn III, President, Health Insurance Association of America; Dr. Charles S.

Mahan, Dean, College of Public Health, University of South Florida; and Mr. Brian Lindberg, Executive Director, Consumer Coalition for Quality Health Care.

COMMITTEE CONSIDERATION

On July 27, 1999, the Subcommittee on Health and the Environment met in open markup session and approved H.R. 2506, the Health Research and Quality Act of 1999, for Full Committee consideration, without amendment, by a voice vote. On August 5, 1999, the Full Committee met in open markup session and ordered H.R. 2506 reported to the House, amended, by a voice vote, a quorum being present.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 2506 reported. An amendment offered by Mr. Bilirakis, No. 1, to make two technical changes to the bill by adding the word "outcomes" which was inadvertently omitted from the bill to clarify that: (1) Provider-Based Research Networks shall evaluate outcomes as well as promote quality improvement; and (2) information systems shall be used for the study of health care quality and outcomes, was agreed to by a voice vote. A motion by Mr. Bliley to order H.R. 2506 reported to the House, amended, was agreed to by a voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a legislative hearing and made findings that are reflected in this report.

COMMITTEE ON GOVERNMENT REFORM OVERSIGHT FINDINGS

Pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2506, the Health Research and Quality Act of 1999, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 7, 1999.

Hon. TOM BLILEY,
Chairman, Committee on Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2506, the Health Research and Quality Act of 1999.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Jeanne De Sa.

Sincerely,

BARRY B. ANDERSON
(For Dan L. Crippen, Director).

Enclosure.

H.R. 2506—Health Research and Quality Act of 1999

Summary: CBO estimates that enacting H.R. 2506 would cost $28 million in fiscal year 2000 and about $900 million over the 2000–2004 period, assuming appropriation of the authorized amounts. The bill would amend title IX of the Public Health Service Act to reauthorize the Agency for Health Care Policy and Research (AHCPR), revise and extend its functions, and rename it the Agency for Health Research and Quality (AHRQ). In addition, H.R. 2506 would amend title III of the Public Health Service Act to require the Secretary of Health and Human Services to make grants to public or nonprofit entities for the establishment of regional centers that improve utilization of preventive health services for families and children.

H.R. 2506 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would not affect the budgets of state, local, or tribal governments. The bill would not affect direct spending or receipts; therefore pay-as-you-go procedures would not apply.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 2506 is shown in the following able. The costs of this legislation fall within budget function 550 (health).

	By fiscal years, in millions of dollars—					
	1999	2000	2001	2002	2003	2004
SPENDING SUBJECT TO APPROPRIATION						
With Adjustments for Inflation						
Spending Under Current Law:						
Budget Authority[1]	100	0	0	0	0	0
Estimated Outlays	88	70	40	14	3	0
Proposed Changes:						
Estimated Authorization Level	0	225	263	268	275	280
Estimated Outlays	0	28	143	222	252	266

	By fiscal years, in millions of dollars—					
	1999	2000	2001	2002	2003	2004
Spending Under H.R. 2506:						
Estimated Authorization Level [1]	100	255	263	268	275	280
Estimated Outlays	88	98	183	236	255	266
Without Adjustments for Inflations						
Spending Under Current Law:						
Budget Authority [1]	100	0	0	0	0	0
Estimated Outlays	88	70	40	14	3	0
Proposed Changes:						
Estimated Authorization Level	0	255	255	255	255	255
Estimated Outlays	0	28	142	218	243	250
Spending Under H.R. 2506:						
Estimated Authorization Level [1]	100	255	255	255	255	255
Estimated Outlays	88	98	182	232	246	250

[1] The 1999 level is the amount appropriated for that year.

Basis of estimate: H.R. 2506 has two separate authorization provisions. First, the bill would authorize $250 million in fiscal year 2000 and such sums as may be necessary for fiscal years 2001–2004 to support the activities of AHRQ. Since authorization for AHCPR has expired, CBO estimates that this provision would increase authorizations of appropriations by $250 million in 2000. Assuming appropriation of the authorized amounts and adjusting for inflation, CBO estimates that this provision would increase discretionary spending by $25 million in fiscal year 2000 and $888 million over the 2000–2004 period. Without adjustments for inflation after 2000, outlays of AHRQ over the five-year period would total $858 million. The outlay estimate is based on historical spending patterns for AHCPR.

Second, H.R. 2506 would authorize such sums as may be necessary for fiscal years 2000–2004 for the establishment of centers that would facilitate utilization of preventive health services. CBO estimated that implementing the provision would cost about $3 million in 2000 and $5 million a year from 2001 through 2004. The estimate assumes $1 million in annual grants to each of five regional centers, whose programs would be based on a model program currently operating at the University of South Florida. Although the proposed legislation does not specify which agency of the Public Health Services would administer the program, the estimate reflects historical spending patterns for health centers operated by the Health Resources Services Administration.

Intergovernmental and private-sector impact: H.R. 2506 contains no intergovernmental or private-sector mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

Estimate prepared by: Federal Costs: Jeanne De Sa. Impact on State, Local, and Tribal Governments: Leo Lex. Impact on the Private Sector: Jennifer Bullard.

Estimate approved by: Robert A. Sunshine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

Section 915 of H.R. 2506 creates the Preventative Services Task Force to review the evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventative services for the purpose of developing recommendations for the health care community regarding their usefulness in daily clinical practice. Further, section 921 establishes the Advisory Council for Health Care Research and Quality to make certain recommendations to the Director. Pursuant to the requirements of subsection 5(b) of the Federal Advisory Committee Act, the Committee finds that the functions of the proposed advisory committees are not and cannot be performed by an existing Federal agency or advisory commission or by enlarging the mandate of an existing advisory committee.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

This section provides the short title of the legislation, the "Health Research and Quality Act of 1999".

Section 2. Amendment to the Public Health Service Act

Subsection (a) amends Title IX of the Public Health Service Act (PHS; 42 U.S.C. § 299 et. seq.) in the following manner:

TITLE IX—AGENCY FOR HEALTH RESEARCH AND QUALITY

PART A—ESTABLISHMENT AND GENERAL DUTIES

Section 901. Mission and duties

This section strengthens and renames the Agency, specifically outlines its mission, and structures the Agency to serve as a "science partner" in its work with the private and public sectors. The Committee explicitly included directions for the Agency to work in collaboration and partnership with the public sector and private sector users of its research in this and subsequent sections

of the bill. The Committee deleted the word "Policy" from the Agency's name to eliminate any potential confusion regarding the Agency's role in policy making. The Committee clearly intends that the Agency's research and other activities should inform public policy, not make public policy.

Subsection (a) establishes the Agency for Health Research and Quality within the Public Health Service (hereinafter referred to as "the Agency") and authorizes the Secretary of Health and Human Services (the Secretary) to appoint a Director to serve as head of the Agency and directs the Secretary to carry out this title through the Director.

Subsection (b) states that the purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice, including the prevention of diseases and other health conditions. The bill requires the Agency to promote health care quality improvement by:

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

- methods of enhancing patient participation in their own care and for facilitating shared patient-physician decision-making;
- the outcomes, effectiveness, and cost-effectiveness of health care practices, including preventive measures and long-term care;
- existing and innovative technologies;
- the costs, utilization, and access to health care;
- the ways in which health care services are organized, delivered, and financed and the interaction and impact of these factors on the quality of patient care;
- methods for measuring and strategies for improving quality; and
- ways in which patients, consumers, and practitioners acquire and use new information about best practices and health benefits;

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

(3) advancing private and public efforts to improve health care quality.

Subsection (c) requires the Director to undertake and support research, demonstration projects, and evaluations with respect to the delivery of health services: (a) in rural areas (including frontier areas); (b) for low-income groups, and minority groups; (c) for children; (d) for the elderly; and (e) for people with special health care needs, including disabilities, chronic care, and end-of-life health care.

Section 902. General authorities

Subsection (a) requires the Director to support demonstration projects, conduct and support research, evaluations, training, research networks, multi-disciplinary centers, technical assistance,

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

- the quality, effectiveness, efficiency, appropriateness and value of health care services;
- quality measurement and improvement;
- the outcomes, cost, cost-effectiveness, and use of health care services and access to such services;
- clinical practice, including primary care and practice-oriented research;
- health care technologies, facilities, and equipment;
- health care costs, productivity, organization, and market forces;
- health promotion and disease prevention, including clinical preventive services;
- health statistics, surveys, database development, and epidemiology; and
- medical liability.

Subsection (b) authorizes the Director to provide training grants in the field of health services research to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate. Training funds for carrying out these activities are made available under section 487 of the Public Health Service Act. The bill requires the Director, in developing priorities for the allocation of such funds, to take into consideration shortages of trained researchers addressing the priority populations outlined in section 901(c).

Subsection (c) authorizes the Director to provide financial assistance toward the costs of planning, establishing, and operating centers for multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis.

Subsection (d) states the policy that activities of the Agency should be appropriately coordinated with experiments, demonstration projects, and other related activities authorized by the Social Security Act and the Social Security Amendments of 1967. The Director must carry out activities that affect Medicare, Medicaid, and the State Child Health Insurance Program consistent with provisions of the Social Security Act affecting outcomes research.

Subsection (e) prohibits the Agency from mandating national standards of clinical practice or health care quality. Published recommendations that result from the Agency's projects must include a disclaimer to that effect.

Subsection (f) clarifies that it is not the role of the Agency to mandate a national standard or specific approach to quality measurement and reporting. In determining research and quality improvement activities, the Agency must consider a wide range of choices, providers, health care delivery systems, and individual preferences. This provision reflects the Committee's response to concerns expressed during the hearing about the need for limitations in the overall Federal role in quality.

PART B—HEALTH CARE IMPROVEMENT RESEARCH

Section 911. Health care outcome improvement research

Subsection (a) requires that the Agency collaborate with experts from the public and private sector to identify and disseminate methods or systems to assess health care research results, and rate the strength of the scientific evidence behind health care practice, technology assessments, and recommendations in the research literature. It also requires the Agency to make such evidence assessment methods and systems widely available, especially those that the Agency or its contractors use. Agency publications containing clinical recommendations must indicate the level of substantiating evidence using such methods or systems.

Subsection (b) requires the Agency to use research strategies and mechanisms to link research directly with clinical practice in geographically diverse locations, including: Health Care Improvement Research Centers that provide access to multidisciplinary expertise in outcomes or quality improvement research with linkages to relevant sites of care; Provider-based Research Networks, including plan, facility, or delivery systems sites of care (especially primary care), that can evaluate outcomes and promote quality improvement; and other innovative mechanisms or strategies. It authorizes the Director to establish the requirements for entities applying for grants under this subsection.

Section 912. Private-public partnerships to improve organization and delivery

Subsection (a) designates the Agency as the principal agency for health care quality research and authorizes the Agency to provide scientific and technical support for public and private efforts to improve health care quality, including accrediting organizations. The role of the Agency is to:

- identify and assess methods for evaluating the health of health plan enrollees by type of plan, provider, and provider arrangements; and of other populations, including those receiving long-term care services;
- develop, test, and disseminate quality measures, including measures of health and functional outcomes;
- compile and disseminate health care quality measures developed in the private and public sector;
- assist in the development of improved health care information systems;
- develop survey tools to measure enrollee assessments of their health care; and
- identify and disseminate information on mechanisms to integrate quality information into purchaser and consumer decision-making.

Subsection (b) requires the Secretary, acting through the Director and in consultation with the Commissioner of Food and Drugs, to establish a program for making one or more grants to establish centers to conduct state-of-the-art research to:

- increase awareness of new uses and improvements in the use of drugs, biological products, and devices and risks of new uses and combinations of drugs and biological products;

- provide objective clinical information to health care practitioners and providers, pharmacists, pharmacy benefit managers and purchasers, health maintenance organizations and other managed health care organizations, insurers and governmental agencies, patients and consumers; and
- improve the quality of health care while reducing the cost through an increase in the appropriate use of drugs, biological products, or devices and the prevention of adverse effects.

In addition, this section requires the conduct of research on the comparative effectiveness, cost-effectiveness, and safety of drugs, biological products, and devices and such other activities as the Secretary determines to be appropriate.

Subsection (c) requires that the Director conduct and support research and build public-private partnerships to identify the causes of preventable errors and patient injury in health care delivery; develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and promote implementation of strategies for reducing errors and improving patient safety.

Section 913. Information on quality and cost of care

Subsection (a) requires that the Director:

- conduct a survey to gather data on the cost and use of health care services and, beginning in Fiscal Year 2001 and subsequent years, the quality of health care, including the types of health care services Americans use, their access to health care services, frequency of use, how much is paid for the services used, the source of those payments, the types and costs of private health insurance, access, satisfaction, and quality of care for the general population and also for children, the uninsured, poor and near-poor individuals, and persons with special health care needs; and
- develop databases and tools that enable States to track the quality, access, and use of health care services.

Subsection (b) further requires that, beginning in Fiscal Year 2001, the above survey:

- identify determinants of health outcomes and functional status, the needs of special populations with respect to such variables as well as an understanding of these changes over time, relationships to health care access and use, and monitor the overall national impact of Federal and State policy changes on health care;
- provide information on the quality of care and patient outcomes for frequently occurring clinical conditions for a nationally representative sample of the population; and
- provide reliable national estimates for children and persons with special health care needs through the use of supplements or periodic expansions of the survey if necessary.

Beginning in Fiscal Year 2003, an annual report is required to be submitted to Congress on national trends in the quality of health care.

Section 914. Information systems for health care improvement

Subsection (a) directs the Agency to support research, evaluations, and initiatives to advance:

- the use of information systems for the study of health care quality and outcomes, including the generation of both individual and plan-level comparative performance;
- training for health care practitioners and researchers in the use of information systems;
- the creation of effective linkages between various sources of health information, including information networks;
- the delivery and coordination of evidence-based health care services, including the use of real-time decision-support programs;
- the structure, content, definition, and coding of health information data and medical vocabularies in consultation with appropriate Federal entities and shall seek input from appropriate private entities;
- the use of computer-based health records in outpatient and inpatient settings as a personal health record for individual health assessment and maintenance; and
- the protection of confidential patient information.

In addition, the Agency is directed to support demonstration projects on the use of information tools for improving shared decision-making between patients and providers.

The Committee notes that this legislation places an emphasis on research and other activities related to the outcomes of medical interventions. In particular, the Agency is directed to link research and clinical practice using not only Health Care Improvement Research Centers but also Provider-Based Research Networks that can evaluate outcomes. Further, the Agency is required to support research and other initiatives to advance the use of information systems for the study of health care quality and outcomes. The Committee is aware of the importance of outcomes research and information dissemination in the continuous improvement of patient care, in virtually every area of medical practice. In the area of cancer care, for example, the ability to chart patient outcomes from a variety of interventions and use of varying clinical practices, and to communicate these outcomes effectively among practitioners, allows significant improvement in the treatment of this extremely complex set of diseases. As resources expand, the Committee anticipates that the Agency will focus greater attention on this essential area. In addition, the Agency should emphasize outcomes research activities that encompass a broad geographical dispersion of study subjects and that compile longitudinal data resulting from long-term follow-up to support efforts to improve the quality of patient care.

Section 915. Research supporting primary care and access in underserved areas

Subsection (a) clarifies the role of the Preventive Services Task Force (PSTF or the Task Force), which is to review the evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community regarding their usefulness in daily clinical practice. (Authority for the PSTF was transferred by the Secretary to the Agency several years ago.) The Agency is directed to provide ongoing administrative, research, and

technical support for the operation of the Preventive Services Task Force and to coordinate and support the dissemination of Task Force recommendations. The operation of the Task Force is exempt from the requirements of the Federal Advisory Committee Act.

Subsection (b) establishes a Center for Primary Care Delivery Research within the Agency (referred to in this subsection as the "Center") to serve as the principal source of funding for primary care delivery research in the Department of Health and Human Services. The legislation specifies the focus of primary care research as the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

The legislation also requires the Center to conduct and support research on the nature and characteristics of primary care delivery practice, producing evidence for the management of common clinical problems, the management of undifferentiated clinical problems, and the continuity and coordination of health services.

Section 916. Clinical practice and technology innovation

Subsection (a) requires that the Director promote innovation in evidence-based clinical practice and health care technologies by conducting and supporting research on the development, diffusion, and use of health care technology; developing, evaluating, and disseminating methodologies for assessments; conducting and supporting assessments of new and existing health care practices and technologies; promoting education and training and providing technical assistance in the use of assessment methodologies; and working with the National Library of Medicine and the public and private sectors to develop an electronic clearinghouse of such assessments.

Subsection (b) specifies the process for clinical practice and technology assessment. It requires that the Director, not later than December 31, 2000, develop and publish a description of the methods used by the Agency and its contractors in conducting such assessments. It also requires that the Director cooperate and consult with a specified list of Federal officials and the heads of other interested Federal departments and agencies, and other private and public entities (such as manufacturers, professional societies, or consumer advocacy organizations that have relevant, scientifically-credible knowledge and information bearing on issues integral to the assessment). It also specifies that methods used in such assessments must consider: safety, efficacy, and effectiveness; legal, social, and ethical implications; costs, benefits, and cost-effectiveness; comparisons to alternative technologies and practices; and, to avoid duplication, data previously submitted to the Food and Drug Administration.

Subsection (c) requires that the Director conduct and support specific assessments of health care technologies and practices and authorizes the Director to conduct or support assessments on a reimbursable basis for other Federal agencies and other public or private entities. In addition, the Director may make grants to, or enter into cooperative agreements or contracts for the purpose of conducting assessments of, experimental, emerging, existing, or po-

tentially outmoded health care technologies, and for related activities with entities determined to be appropriate by the Director. Such entities can include academic medical centers, research institutions, professional organizations, third party payers, other governmental agencies, and consortia of appropriate research entities established for the purpose of conducting technology assessments.

Section 917. Coordination of Federal Government quality improvement efforts

Subsection (a) requires that the Secretary, acting through the Director, coordinate all Federal research, evaluations, and demonstrations related to health services research and quality measurement and improvement activities. With respect to such activities, it requires that the Director, in collaboration with the appropriate Federal officials, develop and manage a process to improve interagency coordination, priority setting, and the use and sharing of research findings and data pertaining to Federal quality improvement programs, technology assessments, and health services research; strengthen the research information infrastructure, including databases; set specific goals; and strengthen the management of Federal health care quality improvement programs.

While this legislation instructs the Agency to have an expanded role in the coordination of Federal quality improvement efforts undertaken by the Federal government, the Committee does not intend for the Agency to have an administrative role in the operation of programs under titles XVIII, XIX, and XXI of the Social Security Act.

Subsection (b) directs the Secretary to enter into a contract with the Institute of Medicine to describe and evaluate current quality improvement, quality research, and quality monitoring processes; provide a summary of existing partnerships that the Department of Health and Human Services has pursued with private sector accreditation, quality measurement and improvement organizations; and identify options and make recommendations to improve the efficiency and effectiveness of such quality improvement programs. The requirements of the contract include the preparation of (i) a report providing an overview of the quality improvement programs of the Department of Health and Human Services for the Medicare, Medicaid, and Child Health Insurance Programs under titles XVIII, XIX, and XXI of the Social Security Act (not later than 12 months after the date of enactment), and (ii) not later than 24 months after the date of enactment of this title, of a final report containing recommendations for a comprehensive system and public-private partnerships for health care quality improvement. This subsection requires that the Secretary submit the reports to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Commerce and the Committee on Ways and Means of the House of Representatives.

The Committee recognizes that other agencies conduct and support health services research and quality measurement and improvement activities. To eliminate unnecessary duplication of effort and to streamline existing functions, the Committee has included two important provisions in this section. The first, described above in subsection (a) is to provide the Director with authority to coordi-

nate these activities across other agencies and departments. The second provision, described above in subsection (b), directs the Institute of Medicine to review existing quality activities across departments, with special emphasis on programs under Titles XVIII, XIX, and XXI of the Social Security Act that are administered by the Department of Health and Human Services, and develop recommendations for consolidation and coordination.

PART C—GENERAL PROVISIONS

Section 921. Advisory Council for Health Care Research and Quality

Subsection (a) establishes the Advisory Council for Health Care Research and Quality (the Advisory Council).

Subsection (b) directs the Advisory Council to advise the Secretary and the Director with respect to activities to carry out the purpose of the Agency under section 901(b) and to make recommendations to the Director regarding:

- health care research priorities, especially studies related to quality, outcomes, cost and the utilization of, and access to, health care services;
- the field of health care research and related disciplines, especially issues related to training needs, and dissemination of information on quality; and
- the appropriate role of the Agency in each of these areas in light of private sector activity and identification of opportunities for public-private sector partnerships.

Subsection (c) requires the Secretary to appoint 18 voting members, ensuring that they represent professions and entities concerned with, or affected by, activities under this title and under section 1142 of the Social Security Act. The appointed members must include three distinguished researchers; three individuals distinguished in the practice of medicine of which at least one is a primary care practitioner; three individuals distinguished in other health professions; three individuals either representing the private health care sector, including health plans, providers, and purchasers or individuals distinguished as health care administrators; three individuals distinguished in the fields of health care quality, economics, information systems, law, ethics, business, or public policy; and three individuals representing the interests of patients and consumers. The latter group may include consumer advocates with expertise regarding the needs and interests of patients and consumers of health care. At least 14 members are required to be representatives of the public who are not officers or employees of the United States.

The Secretary also must designate several ex officio members of the Advisory Council, including the Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Care Financing Administration, the Assistant Secretary of Defense (Health Affairs), and the Under Secretary for Health of the Department of Veterans Affairs, and such other Federal officials as the Secretary considers appropriate.

Subsection (d) requires appointed members of the Advisory Council to serve for a term of 3 years. They may continue to serve after the expiration of the term until a successor is appointed.

Subsection (e) states that if a member of the Advisory Council does not serve the full term, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the predecessor's term.

Subsection (f) states that the Director will designate a member to serve as the chair of the Advisory Council.

Subsection (g) requires that the Advisory Council meet at least once during each discrete 4–month period and may otherwise meet at the call of the Director or the chair.

Subsection (h) requires that members of the Advisory Council receive compensation for each day (including travel time) engaged in carrying out the duties of the Advisory Council unless declined by the member. Such compensation may not be in an amount in excess of the GS–18 of the General Schedule. Ex officio members may not receive compensation for service on the Advisory Council in addition to the compensation otherwise received for duties carried out as officers of the United States.

Subsection (i) requires that the Director provide the Advisory Council with such staff, information, and other assistance as may be necessary to carry out the duties of the Advisory Council.

Section 922. Peer review with respect to grants and contracts

Subsection (a) requires that appropriate technical and scientific peer review be conducted with respect to each application for a grant, cooperative agreement, or contract under this title. Each peer review group to which an application is submitted must report its finding and recommendations with respect to the application to the Director in such form and in such manner as the Director shall require.

Subsection (b) prohibits the Director from approving an application (described above) unless the application is recommended for approval by a peer review group established under subsection (c).

Subsection (c) requires the Director to establish technical and scientific peer review groups to carry out this section. Such groups must be established without regard to the provisions of title 5, United States Code, that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

Peer review group members are to be eminently qualified individuals. Not more than 25 percent of such groups' membership are to be officers and employees of the United States and such officers and employees may not receive additional compensation for service. Peer review groups established under this section may continue in existence until otherwise provided by law.

This subsection also requires that peer review group members agree in writing to treat information received, records, reports, and recommendations as confidential information and to recuse themselves from participation in the peer-review of specific applications which present a potential personal conflict of interest or appearance of a conflict.

Subsection (d) authorizes, in the case of applications for financial assistance whose direct costs will not exceed $100,000, the Director to make adjustments in the peer review procedures to encourage the entry of individuals into the field of research and to encourage clinical practice-oriented research, and for such other purposes as the Director may determine to be appropriate.

Subsection (e) grants the Director the authority to issue regulations for the conduct of peer review under this section.

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

Subsection (a) requires that the Director establish standard methods to ensure the utility, accuracy, and sufficiency of data collected by or for the Agency and requires that the Director, in doing so, take into account other Federal data collection requirements and differences among health care plans, delivery systems, providers, and provider arrangements. If the methods proposed by the Director affect the administration of other programs, including the programs under titles XVIII, XIX or XXI of the Social Security Act, they shall be issued in the form of recommendations to the Secretary.

Subsection (b) requires that the Director take appropriate action to ensure that statistics and analyses developed under this title are of high quality, timely, and comprehensive; that the statistics are specific, standardized, and adequately analyzed and indexed; and that the Director make such information available on as wide a basis as is practicable.

Subsection (c) provides the Director the authority, upon request of a public or private entity, to undertake research or analyses otherwise authorized under this title, the cost of which would be paid by the entity and such funds would remain available to the Agency until expended.

Section 924. Dissemination of information

Subsection (a) requires that the Director: promptly publish, or make broadly available, in an understandable form, the results of research, demonstration projects, and evaluations; ensure that information disseminated by the agency is science-based, objective, and useful; promptly make data available to the public; provide, in collaboration with the National Library of Medicine where appropriate, indexing, abstracting, translating, publishing, and other services leading to a more effective dissemination of research information, and undertake programs to develop new or improved methods for making such information available; and, as appropriate, provide technical assistance to State and local government and health agencies and conduct liaison activities to such agencies to foster dissemination.

Subsection (b) prohibits the Director from restricting the publication or dissemination of data or results from projects conducted or supported under this title except for those limitations described below.

Subsection (c) protects and restricts information about identifiable persons or establishments. The provision states that such information cannot be used for any purpose other than that for which

it was supplied, unless the person or establishment supplying the information or described in it consents to its use for such other purpose. The provision also prohibits the publication of such data, or release in any form, unless the person who supplied the data or described in it has consented to its publication or release.

Subsection (d) establishes a civil monetary penalty of not more than $10,000 for each violation of subsection (c).

Section 925. Additional provisions with respect to grants and contracts

Subsection (a) requires that the Director define by regulation the circumstances under which financial interests in projects may be reasonably expected to create a bias in favor of obtaining results that are consistent with such interests, and the actions the Director will take in response to such financial interests.

Subsection (b) provides that applications for grants, cooperative agreements, or contracts, may not be approved unless the application is submitted to the Secretary in the required form and contains such agreements, assurances, and information as determined by the Director to be necessary to carry out the program involved.

Subsection (c) provides that, upon request of an entity receiving a grant, cooperative agreement, or contract, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding an entity in carrying out the project involved and, for such purpose, may detail to the entity any officer or employee of the Department of Health and Human Services.

With respect to a request described for services, supplies or equipment, the Secretary is required to reduce the amount of the financial assistance by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Director. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

Subsection (d) provides that contracts may be entered into under this part without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. § 529; 41 U.S.C. § 5).

Section 926. Certain administrative authorities

Subsection (a) specifies that the Director may appoint a deputy director for the Agency, and that the Director may appoint and fix the compensation of such officers and employees as may be necessary to carry out this title. Except as otherwise provided by law, such officers and employees shall be appointed in accordance with the civil service and compensation laws.

Subsection (b) authorizes the Secretary to lease or otherwise acquire through the Director of General Services, buildings or portions of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed 10 years; and acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary.

Subsection (c) authorizes the Director to make grants to public and nonprofit entities and individuals, and enter into cooperative

agreements or contracts with public and private entities and individuals.

Subsection (d) authorizes the Director to utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, and provide technical assistance and advice. In addition, the Director may use with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, or of any foreign government, with or without reimbursement of such agencies.

Subsection (e) authorizes the Secretary to engage consultants from time to time and for such periods as the Director deems advisable in accordance with provisions of Section 3109 of title 5, United States Code, on the assistance and advice of consultants from the United States or abroad.

Subsection (f) authorizes the Secretary to obtain the services of not more than 50 experts or consultants who have appropriate scientific or professional qualifications. Such experts and consultants whose services are obtained must be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections of Government Organization and Employees (title 5, United States Code) on travel, transportation and subsistence expenses for government employees. Expenses may not be allowed in connection with an expert or consultant unless the expert agrees in writing to complete the entire period of assignment, or 1 year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a debt of the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

Subsection (g) allows the Director to accept voluntary and uncompensated services.

Section 927. Funding

Subsection (a) clarifies that the Congress intends to ensure that the United States' investment in biomedical research is rapidly translated into improvements in the quality of patient care, with a corresponding investment in research on the most effective clinical and organizational strategies for use of these findings in daily practice, and notes that funds authorized provide for a proportionate increase in health care research as the United States' investment in biomedical research increases.

Subsection (b) authorizes to be appropriated, for the purpose of carrying out this title, $250,000,000 for Fiscal Year 2000, and such sums as may be necessary for each of the Fiscal Years 2001 through 2004.

Subsection (c) provides that, in addition to appropriated amounts available above, there shall be made available for each fiscal year an amount equal to 40 percent of the maximum amount authorized in section 241 (relating to evaluations).

Section 928. Definitions

This section defines the terms "Advisory Council," "Agency," and "Director."

Section 2 (b) of the bill provides that Section 901(a) of the Public Health Service Act as amended by this bill applies as a redesignation of the Agency for Health Care Policy and Research, and not as the termination of such agency and the establishment of a different agency. Subsection (a) of this section does not affect appointments of the personnel of such agency who were employed at the agency on the day before the enactment of this bill.

This subsection also provides that, effective upon the date of enactment of this Act, any reference in law to the "Agency for Health Care Policy and Research" shall be deemed to be a reference to the "Agency for Health Research and Quality" and any reference to the "Administrator" shall be deemed a reference to the "Director."

Section 3. Grants regarding utilization of preventive health services

This section amends subpart I of part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) by adding at the end a new section, 330D, entitled "Centers for Strategies on Facilitating Utilization of Preventative Health Services Among Various Populations."

Subsection (a) directs the Secretary, acting through the appropriate agencies of the Public Health Service, to make grants to public or nonprofit private entities for the establishment and operation of regional centers whose purpose is to identify particular populations of patients and facilitate the appropriate utilization of preventive health services by patients in the identified populations through developing and disseminating strategies to improve the methods used by public and private health care programs and providers in interacting with such patients.

Subsection (b) provides that, in carrying out subsection (a), centers may establish programs of research and training, including the development of curricula for training individuals in implementing the strategies developed under such subsection.

Subsection (c) provides that, to ensure that the strategies developed under subsection (a) account for principles of quality management with respect to consumer satisfaction, applicants must agree as a condition of a grant award that they will make arrangements with one or more private entities that have experience in applying such principles.

Subsection (d) directs the Secretary to give priority to various populations of infants, young children, and their mothers.

Subsection (e) directs the Secretary, acting through the appropriate agencies of the Public Health Service, to provide for the evaluation of strategies under subsection (a) directly or through grants or contracts to determine the extent to which the strategies have been effective in facilitating the appropriate utilization of preventive health services in the populations with respect to which the strategies were developed.

Subsection (f) authorizes to be appropriated, for the purpose of carrying out this section, such sums as may be necessary for each of the Fiscal Years 2000 through 2004.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART D—PRIMARY HEALTH CARE

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Subpart I—Health Centers

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SEC. 330D. CENTERS FOR STRATEGIES ON FACILITATING UTILIZATION OF PREVENTIVE HEALTH SERVICES AMONG VARIOUS POPULATIONS.

(a) IN GENERAL.—The Secretary, acting through the appropriate agencies of the Public Health Service, shall make grants to public or nonprofit private entities for the establishment and operation of regional centers whose purpose is to identify particular populations of patients and facilitate the appropriate utilization of preventive health services by patients in the populations through developing and disseminating strategies to improve the methods used by public and private health care programs and providers in interacting with such patients.

(b) RESEARCH AND TRAINING.—The activities carried out by a center under subsection (a) may include establishing programs of research and training with respect to the purpose described in such subsection, including the development of curricula for training individuals in implementing the strategies developed under such subsection.

(c) QUALITY MANAGEMENT.—A condition for the receipt of a grant under subsection (a) is that the applicant involved agree that, in order to ensure that the strategies developed under such subsection take into account principles of quality management with respect to consumer satisfaction, the applicant will make arrangements with one or more private entities that have experience in applying such principles.

(d) PRIORITY REGARDING INFANTS AND CHILDREN.—In carrying out the purpose described in subsection (a), the Secretary shall give priority to various populations of infants, young children, and their mothers.

(e) EVALUATIONS.—The Secretary, acting through the appropriate agencies of the Public Health Service, shall (directly or through grants or contracts) provide for the evaluation of strategies under subsection (a) in order to determine the extent to which the strate-

gies have been effective in facilitating the appropriate utilization of preventive health services in the populations with respect to which the strategies were developed.

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

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[TITLE IX—AGENCY FOR HEALTH CARE POLICY AND RESEARCH

[PART A—ESTABLISHMENT AND GENERAL DUTIES

[SEC. 901. ESTABLISHMENT.

[(a) IN GENERAL.—There is established within the Service an agency to be known as the Agency for Health Care Policy and Research.

[(b) PURPOSE.—The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice (including the prevention of diseases and other health conditions) and in the organization, financing, and delivery of health care services.

[(c) APPOINTMENT OF ADMINISTRATOR.—There shall be at the head of the Agency an official to be known as the Administrator for Health Care Policy and Research. The Administrator shall be appointed by the Secretary. The Secretary, acting through the Administrator, shall carry out the authorities and duties established in this title.

[SEC. 902. GENERAL AUTHORITIES AND DUTIES.

[(a) IN GENERAL.—In carrying out section 901(b), the Administrator shall conduct and support research, demonstration projects, evaluations, training, guideline development, and the dissemination of information, on health care services and on systems for the delivery of such services, including activities with respect to—

[(1) the effectiveness, efficiency, and quality of health care services;

[(2) subject to subsection (d), the outcomes of health care services and procedures;

[(3) clinical practice, including primary care and practice-oriented research;

[(4) health care technologies, facilities, and equipment;

[(5) health care costs, productivity, and market forces;

[(6) health promotion and disease prevention;

[(7) health statistics and epidemiology; and

[(8) medical liability.

[(b) REQUIREMENTS WITH RESPECT TO RURAL AREAS AND UNDERSERVED POPULATIONS.—In carrying out subsection (a), the Administrator shall undertake and support research, demonstration projects, and evaluations with respect to—

[(1) the delivery of health care services in rural areas (including frontier areas); and

[(2) the health of low-income groups, minority groups, and the elderly.

[(c) HEALTH SERVICES TRAINING GRANTS.—The Administrator may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate.

[(d) MULTIDISCIPLINARY CENTERS.—The Administrator may provide financial assistance to public or nonprofit private entities for meeting the costs of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services research, demonstration projects, evaluations, training, policy analysis, and demonstrations respecting the matters referred to in subsection (a).

[(e) RELATION TO CERTAIN AUTHORITIES REGARDING SOCIAL SECURITY.—Activities authorized in this section may include, and shall be appropriately coordinated with, experiments, demonstration projects, and other related activities authorized by the Social Security Act and the Social Security Amendments of 1967. Activities under subsection (a)(2) of this section that affect the programs under titles XVIII and XIX of the Social Security Act shall be carried out consistent with section 1142 of such Act.

[SEC. 903. DISSEMINATION.

[(a) IN GENERAL.—The Administrator shall—

[(1) promptly publish, make available, and otherwise disseminate, in a form understandable and on as broad a basis as practicable so as to maximize its use, the results of research, demonstration projects, and evaluations conducted or supported under this title and the guidelines, standards, and review criteria developed under this title;

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

[(3) provide indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on research, demonstration projects, and evaluations with respect to health care to public and private entities and individuals engaged in the improvement of health care delivery and the general public, and undertake programs to develop new or improved methods for making such information available; and

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

[(b) PROHIBITION AGAINST RESTRICTIONS.—Except as provided in subsection (c), the Administrator may not restrict the publication or dissemination of data from, or the results of, projects conducted or supported under this title.

[(c) LIMITATION ON USE OF CERTAIN INFORMATION.—No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose. Such informa-

tion may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

[(d) CERTAIN INTERAGENCY AGREEMENT.—The Administrator and the Director of the National Library of Medicine shall enter into an agreement providing for the implementation of subsection (a)(3).

[(e) REQUIRED INTERAGENCY AGREEMENT.—The Administrator and the Director of the National Library of Medicine shall enter into an agreement providing for the implementation of section 478A.

[SEC. 904. HEALTH CARE TECHNOLOGY AND TECHNOLOGY ASSESSMENT.

[(a) IN GENERAL.—In carrying out section 901(b), the Administrator shall promote the development and application of appropriate health care technology assessments—

[(1) by identifying needs in, and establishing priorities for, the assessment of specific health care technologies;

[(2) by developing and evaluating criteria and methodologies for health care technology assessment;

[(3) by conducting and supporting research on the development and diffusion of health care technology;

[(4) by conducting and supporting research on assessment methodologies;

[(5) by promoting education, training, and technical assistance in the use of health care technology assessment methodologies and results; and

[(6) by conducting assessments and reassessments of existing and new health care technologies.

[(b) SPECIFIC ASSESSMENTS.—

[(1) IN GENERAL.—In carrying out section 901(b), the Administrator shall conduct and support specific assessments of health care technologies.

[(2) CONSIDERATION OF CERTAIN FACTORS.—In carrying out paragraph (1), the Administrator shall consider the safety, efficacy, and effectiveness, and, as appropriate, the legal, social, and ethical implications, and appropriate uses of such technologies, including consideration of geographic factors. In carrying out such paragraph, the Administrator shall also consider the cost effectiveness of such technologies where cost information is available and reliable.

[(c) AGENDA AND PRIORITIES.—

[(1) ESTABLISHMENT OF PRIORITIES.—In accordance with paragraph (2), the Administrator, in consultation with the Advisory Council established under section 921, shall establish an annual list of technology assessments under consideration by the Agency, including those assessments performed at the request of the Health Care Financing Administration and the Department of Defense and those assessments performed under subsections (d) and (f).

[(2) PUBLIC NOTICE.—The Administrator, in consultation with the Advisory Council, shall publish the list established in paragraph (1) annually in the Federal Register.

[(d) CONDUCT OF ASSESSMENTS.—

[(1) RECOMMENDATIONS WITH RESPECT TO HEALTH CARE TECHNOLOGY.—The Administrator shall make recommendations to the Secretary with respect to whether specific health care technologies should be reimbursable under federally financed health programs, including recommendations with respect to any conditions and requirements under which any such reimbursements should be made.

[(2) CONSIDERATIONS OF CERTAIN FACTORS.—In making recommendations respecting health care technologies, the Administrator shall consider the safety, efficacy, and effectiveness, and, as appropriate, the appropriate uses of such technologies. The Administrator shall also consider the cost effectiveness of such technologies where cost information is available and reliable.

[(3) ADDITIONAL ASSESSMENTS.—The Administrator may conduct technology assessments in addition to those assessments performed at the request of the Administrator of the Health Care Financing Administration or of the Secretary of Defense.

[(4) CRITERIA.—The Administrator shall develop criteria for determining the priority of assessments performed under this subsection. Such criteria shall include—

[(A) the prevalence of the health condition for which the technology aims to prevent, diagnose, treat and clinically manage;

[(B) variations in current practice;

[(C) the economic burden posed by the prevention, diagnosis, treatment, and clinical management of the health condition, including the impact on publicly-funded programs;

[(D) aggregate cost of the use of technology;

[(E) the morbidity and mortality associated with the health condition; and

[(F) the potential of an assessment to improve health outcomes or affect costs associated with the prevention, diagnosis, or treatment of the condition.

[(5) CONSULTATIONS.—In carrying out this subsection, the Administrator shall cooperate and consult with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency.

[(e) DESCRIPTION OF PROCESS.—Not later than January 1, 1994, the Administrator shall develop and publish a description of the methodology used to establish priorities for technology assessment and the process used to conduct its technology assessments under this section.

[(f) PROGRAM OF INNOVATIVE ASSESSMENTS.—

[(1) IN GENERAL.—The Administrator may make grants to, or enter cooperative agreements or contracts with, entities described in paragraph (2) for the establishment of collaborative arrangements for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded health care technologies, and for related activities. Such assessments may include controlled clinical trials, large simple trials, and other methodologies that can be conducted in partnership be-

tween the public and private sectors or among multiple government agencies.

[(2) ELIGIBLE ENTITIES.—The entities referred to in paragraph (1) are entities determined to be appropriate by the Administrator, which entities may include academic medical centers, research institutions, nonprofit professional organizations, public or private third party payers, other governmental agencies, and consortia of appropriate research entities established for the purpose of conducting technology assessments.

[(3) USE OF AWARD.—A grant, cooperative agreement, or contract under paragraph (1) may be expended for data collection, data analysis, protocol development, report development, dissemination and evaluation, and other activities determined to be appropriate by the Administrator. Such funds shall not be used for direct services.

[(4) APPLICATION FOR AWARD.—To be eligible to receive a grant, cooperative agreement, or contract under paragraph (1), an entity shall prepare and submit to the Administrator an application, at such time, in such form, and containing such information as the Administrator may require.

[(5) INTERAGENCY MEMORANDA OF UNDERSTANDING.—In carrying out paragraph (1), the Administrator may enter into memoranda of understanding with the heads of other Federal agencies.

[SEC. 905. DEMONSTRATION PROGRAM REGARDING CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.

[(a) IN GENERAL.—The Secretary, acting through the Administrator and in consultation with the Commissioner of Food and Drugs, shall establish a demonstration program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in subsection (b).

[(b) REQUIRED ACTIVITIES.—The activities referred to in subsection (a) are the following:

[(1) The conduct of state-of-the-art clinical and laboratory research for the following purposes:

[(A) To increase awareness of—

[(i) new uses of drugs, biological products, and devices;

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

[(iii) risks of new uses and risks of combinations of drugs and biological products.

[(B) To provide objective clinical information to the following individuals and entities:

[(i) Health care practitioners or other providers of health care goods or services.

[(ii) Pharmacy benefit managers.

[(iii) Health maintenance organizations or other managed health care organizations.

[(iv) Health care insurers or governmental agencies.

[(v) Consumers.

[(C) To improve the quality of health care while reducing the cost of health care through—

[(i) the appropriate use of drugs, biological products, or devices; and

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

[(2) The conduct of research on the comparative effectiveness and safety of drugs, biological products, and devices.

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

[(c) APPLICATION FOR GRANT.—A grant under subsection (a) may be made only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

[(d) PEER REVIEW.—A grant under subsection (a) may be made only if the application for the grant has undergone appropriate technical and scientific peer review.

[(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 1998, and $3,000,000 for each of fiscal years 1999 through 2002.

[PART B—FORUM FOR QUALITY AND EFFECTIVENESS IN HEALTH CARE

[SEC. 911. ESTABLISHMENT OF OFFICE.

[There is established within the Agency an office to be known as the Office of the Forum for Quality and Effectiveness in Health Care. The office shall be headed by a director, who shall be appointed by the Administrator. The Administrator shall carry out this part acting through the Director.

[SEC. 912. DUTIES.

[(a) ESTABLISHMENT OF FORUM PROGRAM.—The Administrator shall establish a program to be known as the Forum for Quality and Effectiveness in Health Care. For the purpose of promoting the quality, appropriateness, and effectiveness of health care, the Administrator, using the process set forth in section 913, shall arrange for the development and periodic review and updating of—

[(1) clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically; and

[(2) standards of quality, performance measures, and medical review criteria through which health care providers and other appropriate entities may assess or review the provision of health care and assure the quality of such care.

[(b) CERTAIN REQUIREMENTS.—Guidelines, standards, performance measures, and review criteria under subsection (a) shall—

[(1) be based on the best available research and professional judgment regarding the effectiveness and appropriateness of health care services and procedures;

[(2) be presented in formats appropriate for use by physicians, health care practitioners, providers, medical educators, and medical review organizations and in formats appropriate for use by consumers of health care;

[(3) include treatment-specific or condition-specific practice guidelines for clinical treatments and conditions in forms appropriate for use in clinical practice, for use in educational programs, and for use in reviewing quality and appropriateness of medical care; and

[(4) include information on risks and benefits of alternative strategies for prevention, diagnosis, treatment, and management of a given disease, disorder, or other health condition; and

[(5) include information on the costs of alternative strategies for the prevention, diagnosis, treatment, and management of a given disease, disorder, or other health condition, where cost information is available and reliable.

[(c) AUTHORITY FOR CONTRACTS.—In carrying out this part, the Administrator may enter into contracts with public or nonprofit private entities.

[(d) DATE CERTAIN FOR INITIAL GUIDELINES AND STANDARDS.—The Administrator, by not later than January 1, 1991, shall assure the development of an initial set of guidelines, standards, performance measures, and review criteria under subsection (a) that includes not less than 3 clinical treatments or conditions described in section 1142(a)(3) of the Social Security Act.

[(e) RELATIONSHIP WITH MEDICARE PROGRAM.—To assure an appropriate reflection of the needs and priorities of the program under title XVIII of the Social Security Act, activities under this part that affect such program shall be conducted consistent with section 1142 of such Act.

[(f) DEVELOPMENT OF CERTAIN GUIDELINES AND STANDARDS.—Not later than January 1, 1996, the Administrator shall ensure that a set of guidelines, standards, performance measures, and review criteria, are developed under subsection (a)(1) that address the prevention of not fewer than three conditions that account for significant national health expenditures. In carrying out this subsection the Administrator shall consult with the United States Preventive Services Task Force and other recognized experts in the field of disease prevention.

[SEC. 913. PROCESS FOR DEVELOPMENT OF GUIDELINES AND STANDARDS.

[(a) DEVELOPMENT THROUGH CONTRACTS AND PANELS.—The Administrator shall—

[(1) enter into contracts with public and nonprofit private entities for the purpose of developing and periodically reviewing and updating the guidelines, standards, performance measures, and review criteria described in section 912(a); and

[(2) convene panels of appropriately qualified experts (including practicing physicians with appropriate expertise) and health care consumers for the purpose of—

[(A) developing and periodically reviewing and updating the guidelines, standards, performance measures, and review criteria described in section 912(a); and

[(B) reviewing the guidelines, standards, performance measures, and review criteria developed under contracts under paragraph (1).

[(b) AUTHORITY FOR ADDITIONAL PANELS.—The Administrator may convene panels of appropriately qualified experts (including practicing physicians with appropriate expertise) and health care consumers for the purpose of—

[(1) developing the standards and criteria described in section 914(b); and

[(2) providing advice to the Administrator and the Director with respect to any other activities carried out under this part or under section 902(a)(2).

[(c) SELECTION OF PANEL MEMBERS.—The Administrator shall select the chairpersons and the members of the panels convened as well as other participants in the guideline process under this section. In selecting individuals to serve on panels convened under this section, the Administrator shall consult with a broad range of interested individuals and organizations, including organizations representing physicians in the general practice of medicine and organizations representing physicians in specialties and subspecialties pertinent to the purposes of the panel involved. The Administrator shall seek to appoint physicians reflecting a variety of practice settings. In making such selections, the Administrator shall ensure that a balance is maintained between individuals selected from academic settings and individuals selected without full-time academic appointments. At least two other members of such panels shall be individuals who do not derive their primary source of revenue directly from the performance of procedures discussed in the guideline. The Administrator shall ensure that at least one participant in the guideline process shall have expertise in epidemiology as well as familiarity with the clinical condition or treatment in question. The Administrator shall also ensure that at least one participant in the guideline process shall have expertise in health services research or health economics as well as familiarity with the clinical condition or treatment in question.

[SEC. 914. ADDITIONAL REQUIREMENTS.

[(a) PROGRAM AGENDA.—

[(1) IN GENERAL.—The Administrator shall provide for an agenda for the development of the guidelines, standards, performance measures, and review criteria described in section 912(a), including—

[(A) with respect to the guidelines, identifying specific diseases, disorders, and other health conditions for which the guidelines are to be developed and those that are to be given priority in the development of the guidelines; and

[(B) with respect to the standards, performance measures, and review criteria, identifying specific aspects of health care for which the standards, performance measures, and review criteria are to be developed and those that are to be given priority in the development of the standards, performance measures, and review criteria.

[(2) CONSIDERATION OF CERTAIN FACTORS IN ESTABLISHING PRIORITIES.—

[(A) Factors considered by the Administrator in establishing priorities for purposes of paragraph (1) shall include consideration of the extent to which the guidelines, standards, performance measures, and review criteria involved can be expected—

[(i) to improve methods for disease prevention;

[(ii) to improve methods of diagnosis, treatment, and clinical management for the benefit of a significant number of individuals;

[(iii) to reduce clinically significant variations among physicians in the particular services and procedures utilized in making diagnoses and providing treatments; and

[(iv) to reduce clinically significant variations in the outcomes of health care services and procedures.

[(B) In providing for the agenda required in paragraph (1), including the priorities, the Administrator shall consult with the Administrator of the Health Care Financing Administration and otherwise act consistent with section 1142(b)(3) of the Social Security Act.

[(C) The Administrator shall develop and publish a methodology for establishing priorities for guideline topics. Such methodology may include the considerations described in section 904(d)(2) or 914(a)(2), and other considerations determined by the Administrator to be appropriate. Using such methodology, the Administrator shall establish and publish annually in the Federal Register a list of guideline topics under consideration.

[(b) STANDARDS AND CRITERIA.—

[(1) PROCESS FOR DEVELOPMENT, REVIEW, AND UPDATING.—The Administrator shall establish standards and criteria to be utilized by the recipients of contracts under section 913, and by the expert panels convened under such section, with respect to the development and periodic review and updating of the guidelines, standards, performance measures, and review criteria described in section 912(a).

[(2) AWARD OF CONTRACTS.—The Administrator shall establish standards and criteria to be utilized for the purpose of ensuring that contracts entered into for the development or periodic review or updating of the guidelines, standards, performance measures, and review criteria described in section 912(a) will be entered into only with appropriately qualified entities.

[(3) CERTAIN REQUIREMENTS FOR STANDARDS AND CRITERIA.—The Administrator shall ensure that the standards and criteria established under paragraphs (1) and (2) specify that—

[(A) appropriate consultations with interested individuals and organizations are to be conducted in the development of the guidelines, standards, performance measures, and review criteria described in section 912(a); and

[(B) such development may be accomplished through the adoption, with or without modification, of guidelines, standards, performance measures, and review criteria that—

[(i) meet the requirements of this part; and

[(ii) are developed by entities independently of the program established in this part.

[(4) IMPROVEMENTS OF STANDARDS AND CRITERIA.—The Administrator shall conduct and support research with respect to improving the standards and criteria developed under this subsection.

[(c) DISSEMINATION.—The Administrator shall promote and support the dissemination of the guidelines, standards, performance measures, and review criteria described in section 912(a). Such dissemination shall be carried out through organizations representing health care providers, organizations representing health care consumers, peer review organizations, accrediting bodies, and other appropriate entities.

[(d) PILOT TESTING.—The Administrator may conduct or support pilot testing of the guidelines, standards, performance measures, and review criteria developed under section 912(a). Any such pilot testing may be conducted prior to, or concurrently with, their dissemination under subsection (c).

[(e) EVALUATIONS.—The Administrator shall conduct and support evaluations of the extent to which the guidelines, standards, performance standards, and review criteria developed under section 912 have had an effect on the clinical practice of medicine. Evaluations shall be developed prior to the completion and release of the guideline, so that baseline data concerning practice patterns and health care costs may be obtained as part of the evaluation.

[(f) RECOMMENDATIONS TO ADMINISTRATOR.—The Director shall make recommendations to the Administrator on activities that should be carried out under section 902(a)(2) and under section 1142 of the Social Security Act, including recommendations of particular research projects that should be carried out with respect to—

[(1) evaluating the outcomes of health care services and procedures;

[(2) developing the standards and criteria required in subsection (b); and

[(3) promoting the utilization of the guidelines, standards, performance standards, and review criteria developed under section 912(a).

[PART C—GENERAL PROVISIONS

[SEC. 921. ADVISORY COUNCIL FOR HEALTH CARE POLICY, RESEARCH, AND EVALUATION.

[(a) ESTABLISHMENT.—There is established an advisory council to be known as the National Advisory Council for Health Care Policy, Research, and Evaluation.

[(b) DUTIES.—

[(1) IN GENERAL.—The Council shall advise the Secretary and the Administrator with respect to activities to carry out the purpose of the Agency under section 901(b).

[(2) CERTAIN RECOMMENDATIONS.—Activities of the Council under paragraph [(1) shall include making recommendations to the Administrator regarding priorities for a national agenda and strategy for—

[(A) the conduct of research, demonstration projects, and evaluations with respect to health care, including clinical practice and primary care;

[(B) the development and application of appropriate health care technology assessments;

[(C) the development and periodic review and updating of guidelines for clinical practice, standards of quality, performance measures, and medical review criteria with respect to health care; and

[(D) the conduct of research on outcomes of health care services and procedures.

[(c) MEMBERSHIP.—

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

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

[(A) 8 shall be individuals distinguished in the conduct of research, demonstration projects, and evaluations with respect to health care;

[(B) 3 shall be individuals distinguished in the practice of medicine;

[(C) 2 shall be individuals distinguished in the health professions;

[(D) 2 shall be individuals distinguished in the fields of business, law, ethics, economics, and public policy; and

[(E) 2 shall be individuals representing the interests of consumers of health care.

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

[(A) the Director of the National Institutes of Health, the Director of the Centers for Disease Control, the Administrator of the Health Care Financing Administration, the Assistant Secretary of Defense (Health Affairs), the Chief Medical Officer of the Department of Veterans Affairs; and

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

[(d) TERMS.—

[(1) IN GENERAL.—Except as provided in paragraph (2), members of the Council appointed under subsection (c)(2) shall serve for a term of 3 years.

[(2) STAGGERED ROTATION.—Of the members first appointed to the Council under subsection (c)(2), the Secretary shall appoint 6 members to serve for a term of 3 years, 6 members to serve for a term of 2 years, and 5 members to serve for a term of 1 year.

[(3) SERVICE BEYOND TERM.—A member of the Council appointed under subsection (c)(2) may continue to serve after the expiration of the term of the member until a successor is appointed.

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

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

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

[(h) COMPENSATION AND REIMBURSEMENT OF EXPENSES.—

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

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

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

[(j) DURATION.—Notwithstanding section 14(a) of the Federal Advisory Committee Act, the Council shall continue in existence until otherwise provided by law.

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

[(a) REQUIREMENT OF REVIEW.—

[(1) IN GENERAL.—Appropriate technical and scientific peer review shall be conducted with respect to each application for a grant, cooperative agreement, or contract under this title.

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

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

[(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

[(1) IN GENERAL.—The Administrator shall establish such technical and scientific peer review groups as may be necessary to carry out this section. Such groups shall be established without regard to the provisions of title 5, United States Code, that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter

III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

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

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

[(d) CATEGORIES OF REVIEW.—

[(1) IN GENERAL.—With respect to technical and scientific peer review under this section, there shall be two categories of peer review groups as follows:

[(A) One category of such groups shall, subject to subparagraph (B), review applications with respect to research, demonstration projects, or evaluations.

[(B) The other category of such groups shall review applications with respect to dissemination activities or the development of research agendas (including conferences, workshops, and meetings). If the purpose of a proposal presented in an application is a matter described in the preceding sentence, the application shall be reviewed by the groups referred to in such sentence, notwithstanding that the proposal involves research, demonstration projects, or evaluations.

[(2) AUTHORITY FOR PROCEDURAL ADJUSTMENTS IN CERTAIN CASES.—In the case of applications described in subsection (a)(1) for financial assistance whose direct costs will not exceed $50,000, the Administrator may make appropriate adjustments in the procedures otherwise established by the Administrator for the conduct of peer review under this section. Such adjustments may be made for the purpose of encouraging the entry of individuals into the field of research, for the purpose of encouraging clinical practice-oriented research, and for such other purposes as the Administrator may determine to be appropriate.

[(e) REGULATIONS.—The Secretary shall issue regulations for the conduct of peer review under this section.

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

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

[(1) IN GENERAL.—With respect to data developed or collected by any entity for the purpose described in section 901(b), the Administrator shall, in order to assure the utility, accuracy, and sufficiency of such data for all interested entities, establish guidelines for uniform methods of developing and collecting such data. Such guidelines shall include specifications

for the development and collection of data on the outcomes of health care services and procedures.

[(2) RELATIONSHIP WITH MEDICARE PROGRAM.—In any case where guidelines under paragraph (1) may affect the administration of the program under title XVIII of the Social Security Act, the guidelines shall be in the form of recommendations to the Secretary for such program.

[(b) STATISTICS.—The Administrator shall—

[(1) take such action as may be necessary to assure that statistics developed under this title are of high quality, timely, and comprehensive, as well as specific, standardized, and adequately analyzed and indexed; and

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

[(c) AUTHORITY REGARDING CERTAIN REQUESTS.—Upon the request of a public or nonprofit private entity, the Administrator may tabulate and analyze statistics under arrangements under which such entity will pay the cost of the service provided. Amounts appropriated to the Administrator from payments made under such arrangements shall be available to the Administrator for obligation until expended.

[SEC. 924. ADDITIONAL PROVISIONS WITH RESPECT TO GRANTS AND CONTRACTS.

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

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

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

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

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

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

[(2) CORRESPONDING REDUCTION IN FUNDS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of the financial assistance involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided

by the Administrator. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

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

[SEC. 925. CERTAIN ADMINISTRATIVE AUTHORITIES.

[(a) DEPUTY ADMINISTRATOR AND OTHER OFFICERS AND EMPLOYEES.—

[(1) DEPUTY ADMINISTRATOR.—The Administrator may appoint a deputy administrator for the Agency.

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

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

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

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

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

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

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

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

[(e) CONSULTANTS.—The Secretary, in carrying out this title, may secure, from time to time and for such periods as the Administrator deems advisable but in accordance with section 3109 of title 5, United States Code, the assistance and advice of consultants from the United States or abroad.

[(f) EXPERTS.—

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

[(2) TRAVEL EXPENSES.—

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

[(B) Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless and until the expert agrees in writing to complete the entire period of assignment, or one year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a debt of the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

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

[SEC. 926. FUNDING.

[(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this title, there are authorized to be appropriated $115,000,000 for fiscal year 1993, $145,000,000 for fiscal year 1994, and $175,000,000 for fiscal year 1995.

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

[(c) INFORMATION CENTER.—For purposes of carrying out the activities under section 903(e), there are authorized to be appropriated $3,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 and 1995.

[(d) HEALTH CARE TECHNOLOGY ASSESSMENT.—For the purpose of carrying out technology assessment activities under section 904(d), there are authorized to be appropriated $2,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 and 1995.

[(e) PROGRAM OF INNOVATIVE ASSESSMENTS.—For purposes of establishing the program of innovative assessments under section 904(f), there are authorized to be appropriated $2,000,000 for fiscal

year 1993, and such sums as may be necessary in each of the fiscal years 1994 and 1995.

[SEC. 927. DEFINITIONS.

[For purposes of this title:

[(1) The term "Administrator" means the Administrator for Health Care Policy and Research.

[(2) The term "Agency" means the Agency for Health Care Policy and Research.

[(3) The term "Council" means the National Advisory Council on Health Care Policy, Research, and Evaluation.

[(4) The term "Director" means the Director of the Office of the Forum for Quality and Effectiveness in Health Care.]

TITLE IX—AGENCY FOR HEALTH RESEARCH AND QUALITY

PART A—ESTABLISHMENT AND GENERAL DUTIES

SEC. 901. MISSION AND DUTIES.

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

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

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

(A) the development and assessment of methods for enhancing patient participation in their own care and for facilitating shared patient-physician decision-making;

(B) the outcomes, effectiveness, and cost-effectiveness of health care practices, including preventive measures and long-term care;

(C) existing and innovative technologies;

(D) the costs and utilization of, and access to health care;

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

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

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

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

(3) advancing private and public efforts to improve health care quality.

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

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

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

(3) the health of children;

(4) the elderly; and

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

SEC. 902. GENERAL AUTHORITIES.

(a) IN GENERAL.—In carrying out section 901(b), the Director shall support demonstration projects, conduct and support research, evaluations, training, research networks, multi-disciplinary centers, technical assistance, and the dissemination of information, on health care, and on systems for the delivery of such care, including activities with respect to—

(1) the quality, effectiveness, efficiency, appropriateness and value of health care services;

(2) quality measurement and improvement;

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

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

(5) health care technologies, facilities, and equipment;

(6) health care costs, productivity, organization, and market forces;

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

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

(9) medical liability.

(b) HEALTH SERVICES TRAINING GRANTS.—

(1) IN GENERAL.—The Director may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate. In carrying out this subsection, the Director shall make use of funds made available under section 487.

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

(c) MULTIDISCIPLINARY CENTERS.—The Director may provide financial assistance to assist in meeting the costs of planning and establishing new centers, and operating existing and new centers, for

multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis with respect to the matters referred to in subsection (a).

(d) RELATION TO CERTAIN AUTHORITIES REGARDING SOCIAL SECURITY.—Activities authorized in this section shall be appropriately coordinated with experiments, demonstration projects, and other related activities authorized by the Social Security Act and the Social Security Amendments of 1967. Activities under subsection (a)(2) of this section that affect the programs under titles XVIII, XIX and XXI of the Social Security Act shall be carried out consistent with section 1142 of such Act.

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

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

PART B—HEALTH CARE IMPROVEMENT RESEARCH

SEC. 911. HEALTH CARE OUTCOME IMPROVEMENT RESEARCH.

(a) EVIDENCE RATING SYSTEMS.—In collaboration with experts from the public and private sector, the Agency shall identify and disseminate methods or systems that it uses to assess health care research results, particularly methods or systems that it uses to rate the strength of the scientific evidence behind health care practice, recommendations in the research literature, and technology assessments. The Agency shall make methods or systems for evidence rating widely available. Agency publications containing health care recommendations shall indicate the level of substantiating evidence using such methods or systems.

(b) HEALTH CARE IMPROVEMENT RESEARCH CENTERS AND PROVIDER-BASED RESEARCH NETWORKS.—

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

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

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

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

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

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

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

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

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

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

(i) enrollees in health plans by type of plan, provider, and provider arrangements; and

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

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

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

(D) assistance in the development of improved health care information systems;

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

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

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

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

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

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

(i) To increase awareness of—

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

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

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

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

(I) Health care practitioners and other providers of health care goods or services.

(II) Pharmacists, pharmacy benefit managers and purchasers.

(III) Health maintenance organizations and other managed health care organizations.

(IV) Health care insurers and governmental agencies.

(V) Patients and consumers.

(iii) To improve the quality of health care while reducing the cost of health care through—

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

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

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

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

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

(1) identify the causes of preventable health care errors and patient injury in health care delivery;

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

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

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

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

(1) conduct a survey to collect data on a nationally representative sample of the population on the cost, use and, for fiscal year 2001 and subsequent fiscal years, quality of health care, including the types of health care services Americans use, their access to health care services, frequency of use, how much is paid for the services used, the source of those payments, the types and costs of private health insurance, access, satisfaction, and quality of care for the general population and also for populations identified in section 901(c); and

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

(b) QUALITY AND OUTCOMES INFORMATION.—

(1) IN GENERAL.—Beginning in fiscal year 2001, the Director shall ensure that the survey conducted under subsection (a)(1) will—

(A) identify determinants of health outcomes and functional status, the needs of special populations in such variables as well as an understanding of changes over time, re-

lationships to health care access and use, and monitor the overall national impact of Federal and State policy changes on health care;

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

(C) provide reliable national estimates for children and persons with special health care needs through the use of supplements or periodic expansions of the survey.

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

(2) ANNUAL REPORT.—Beginning in fiscal year 2003, the Secretary, acting through the Director, shall submit to Congress an annual report on national trends in the quality of health care provided to the American people.

SEC. 914. INFORMATION SYSTEMS FOR HEALTH CARE IMPROVEMENT.

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

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

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

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

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

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

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

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

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

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

(a) PREVENTIVE SERVICES TASK FORCE.—

(1) PURPOSE.—The Agency shall provide ongoing administrative, research, and technical support for the operation of the

Preventive Services Task Force. The Agency shall coordinate and support the dissemination of the Preventive Services Task Force recommendations.

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

(b) PRIMARY CARE RESEARCH.—

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

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

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

(B) the management of commonly occurring clinical problems;

(C) the management of undifferentiated clinical problems; and

(D) the continuity and coordination of health services.

SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVATION.

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

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

(2) developing, evaluating, and disseminating methodologies for assessments of health care practices and health care technologies;

(3) conducting intramural and supporting extramural assessments of existing and new health care practices and technologies;

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

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

(b) SPECIFICATION OF PROCESS.—

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

(2) CONSULTATIONS.—In carrying out this subsection, the Director shall cooperate and consult with the Assistant Secretary for Health, the Administrator of the Health Care Financing Administration, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency, and shall seek input, where appropriate, from professional societies and other private and public entities.

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

(A) safety, efficacy, and effectiveness;

(B) legal, social, and ethical implications;

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

(D) comparisons to alternate technologies and practices; and

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

(c) SPECIFIC ASSESSMENTS.—

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

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

(3) GRANTS AND CONTRACTS.—In addition to conducting assessments, the Director may make grants to, or enter into cooperative agreements or contracts with, entities described in paragraph (4) for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded health care technologies, and for related activities.

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

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

(a) REQUIREMENT.—

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

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

(A) improve interagency coordination, priority setting, and the use and sharing of research findings and data per-

taining to Federal quality improvement programs, technology assessment, and health services research;

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

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

(D) strengthen the management of Federal health care quality improvement programs.

(b) STUDY BY THE INSTITUTE OF MEDICINE.—

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

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

(i) an overview of pertinent health services research activities and quality improvement efforts conducted by all Federal programs, with particular attention paid to those under titles XVIII, XIX, and XXI of the Social Security Act; and

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

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

(i) the improved coordination of activities across the medicare, medicaid and child health insurance programs under titles XVIII, XIX and XXI of the Social Security Act and health services research programs;

(ii) the strengthening of patient choice and participation by incorporating state-of-the-art quality monitoring tools and making information on quality available; and

(iii) the enhancement of the most effective programs, consolidation as appropriate, and elimination of duplicative activities within various federal agencies.

(2) REQUIREMENTS.—

(A) IN GENERAL.—The Secretary shall enter into a contract with the Institute of Medicine for the preparation—

(i) not later than 12 months after the date of enactment of this title, of a report providing an overview of the quality improvement programs of the Department of Health and Human Services for the medicare, medicaid, and CHIP programs under titles XVIII, XIX, and XXI of the Social Security Act; and

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

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

PART C—GENERAL PROVISIONS

SEC. 921. ADVISORY COUNCIL FOR HEALTH CARE RESEARCH AND QUALITY.

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

(b) DUTIES.—

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

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

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

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

(C) the appropriate role of the Agency in each of these areas in light of private sector activity and identification of opportunities for public-private sector partnerships.

(c) MEMBERSHIP.—

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

(2) APPOINTED MEMBERS.—The Secretary shall appoint to the Advisory Council 18 appropriately qualified individuals. At least 14 members of the Advisory Council shall be representatives of the public who are not officers or employees of the United States. The Secretary shall ensure that the appointed members of the Council, as a group, are representative of professions and entities concerned with, or affected by, activities under this title and under section 1142 of the Social Security Act. Of such members—

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

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

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

(D) 3 shall be individuals either representing the private health care sector, including health plans, providers, and purchasers or individuals distinguished as administrators of health care delivery systems;

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

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

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

(A) the Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Care Financing Administration, the Assistant Secretary of Defense (Health Affairs), and the Under Secretary for Health of the Department of Veterans Affairs; and

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

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

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

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

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

(h) COMPENSATION AND REIMBURSEMENT OF EXPENSES.—

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

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

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

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

(a) REQUIREMENT OF REVIEW.—

(1) IN GENERAL.—Appropriate technical and scientific peer review shall be conducted with respect to each application for a grant, cooperative agreement, or contract under this title.

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

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

(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

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

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

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

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

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

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

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

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

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

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

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

(A) other Federal health data collection standards; and

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

(2) RELATIONSHIP WITH OTHER DEPARTMENT PROGRAMS.—In any case where standards under paragraph (1) may affect the administration of other programs carried out by the Department of Health and Human Services, including the programs under title XVIII, XIX or XXI of the Social Security Act, or may affect health information that is subject to a standard developed under part C of title XI of the Social Security Act, they shall be in the form of recommendations to the Secretary for such program.

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

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

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

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

SEC. 924. DISSEMINATION OF INFORMATION.

(a) IN GENERAL.—The Director shall—

(1) without regard to section 501 of title 44, United States Code, promptly publish, make available, and otherwise disseminate, in a form understandable and on as broad a basis as practicable so as to maximize its use, the results of research,

demonstration projects, and evaluations conducted or supported under this title;

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

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

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

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

(b) PROHIBITION AGAINST RESTRICTIONS.—Except as provided in subsection (c), the Director may not restrict the publication or dissemination of data from, or the results of, projects conducted or supported under this title.

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

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

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

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

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

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

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

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

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

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

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

SEC. 926. CERTAIN ADMINISTRATIVE AUTHORITIES.

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

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

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

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

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

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

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

(d) UTILIZATION OF CERTAIN PERSONNEL AND RESOURCES.—

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

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

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

(f) EXPERTS.—

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

(2) TRAVEL EXPENSES.—

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

(B) LIMITATION.—Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless and until the expert agrees in writing to complete the entire period of assignment, or 1 year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a statutory obligation owed to the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

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

SEC. 927. FUNDING.

(a) INTENT.—To ensure that the United States investment in biomedical research is rapidly translated into improvements in the quality of patient care, there must be a corresponding investment in research on the most effective clinical and organizational strategies

for use of these findings in daily practice. The authorization levels in subsections (b) and (c) provide for a proportionate increase in health care research as the United States investment in biomedical research increases.

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

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

SEC. 928. DEFINITIONS.

In this title:

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

(2) AGENCY.—The term "Agency" means the Agency for Health Research and Quality.

(3) DIRECTOR.—The term "Director" means the Director of the Agency for Health Research and Quality.

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