PUBLIC HEALTH SERVICE ACT

[As Amended Through P.L. 117–286, Enacted December 27, 2022]

[Currency: This publication is a compilation of the text of title IX of Chapter 373 of the 78th Congress. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at https://www.govinfo.gov/app/collection/comps/]

[Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).]

[References in brackets [] are to title 42, United States Code]

TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY [1]

PART A—ESTABLISHMENT AND GENERAL DUTIES

SEC. 901. [299] MISSION AND DUTIES.

(a) IN GENERAL.—There is established within the Public Health Service an agency to be known as the Agency for Healthcare Research and Quality, 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 conducting and supporting—

(1) research that develops and presents scientific evidence regarding all aspects of health care, 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;

[1] Section 2 of Public Law 106–129 (113 Stat. 1653) designated the Agency as the Agency for Healthcare Research and Quality. Formerly it was designated as the Agency for Health Care Policy and Research. See section 6103 of Public Law 101–239 (103 Stat. 2189).

(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) the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

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

(c) REQUIREMENTS WITH RESPECT TO RURAL AND INNER-CITY AREAS AND PRIORITY POPULATIONS.—

(1) RESEARCH, EVALUATIONS AND DEMONSTRATION PROJECTS.—In carrying out this title, the Director shall conduct and support research and evaluations, and support demonstration projects, with respect to—

(A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and

(B) health care for priority populations, which shall include—

(i) low-income groups;

(ii) minority groups;

(iii) women;

(iv) children;

(v) the elderly; and

(vi) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

(2) PROCESS TO ENSURE APPROPRIATE RESEARCH.—The Director shall establish a process to ensure that the requirements of paragraph (1) are reflected in the overall portfolio of research conducted and supported by the Agency.

(3) OFFICE OF PRIORITY POPULATIONS.—The Director shall establish an Office of Priority Populations to assist in carrying out the requirements of paragraph (1).

SEC. 902. [299a] GENERAL AUTHORITIES.

(a) IN GENERAL.—In carrying out section 901(b), the Director shall conduct and support research, evaluations, and training, support demonstration projects, research networks, and multidisciplinary centers, provide technical assistance, and disseminate 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(d)(3) as well as other appropriated funds.

(2) REQUIREMENTS.—In developing priorities for the allocation of training funds under this subsection, the Director shall take into consideration shortages in the number of trained researchers who are addressing health care issues for the priority populations identified in section 901(c)(1)(B) and in addition, shall take into consideration indications of long-term commitment, amongst applicants for training funds, to addressing health care needs of 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.

SEC. 903. [299a–1] RESEARCH ON HEALTH DISPARITIES.

(a) IN GENERAL.—The Director shall—

(1) conduct and support research to identify populations for which there is a significant disparity in the quality, outcomes, cost, or use of health care services or access to and satisfaction with such services, as compared to the general population;

(2) conduct and support research on the causes of and barriers to reducing the health disparities identified in paragraph (1), taking into account such factors as socioeconomic status, attitudes toward health, the language spoken, the extent of formal education, the area or community in which the population resides, and other factors the Director determines to be appropriate;

(3) conduct and support research and support demonstration projects to identify, test, and evaluate strategies for reducing or eliminating health disparities, including development or identification of effective service delivery models, and disseminate effective strategies and models;

(4) develop measures and tools for the assessment and improvement of the outcomes, quality, and appropriateness of health care services provided to health disparity populations;

(5) in carrying out section 902(c), provide support to increase the number of researchers who are members of health disparity populations, and the health services research capacity of institutions that train such researchers; and

(6) beginning with fiscal year 2003, annually submit to the Congress a report regarding prevailing disparities in health care delivery as it relates to racial factors and socioeconomic factors in priority populations.

(b) RESEARCH AND DEMONSTRATION PROJECTS.—

(1) IN GENERAL.—In carrying out subsection (a), the Director shall conduct and support research and support demonstrations to—

(A) identify the clinical, cultural, socioeconomic, geographic, and organizational factors that contribute to health disparities, including minority health disparity populations, which research shall include behavioral research, such as examination of patterns of clinical decisionmaking, and research on access, outreach, and the availability of related support services (such as cultural and linguistic services);

(B) identify and evaluate clinical and organizational strategies to improve the quality, outcomes, and access to care for health disparity populations, including minority health disparity populations;

(C) test such strategies and widely disseminate those strategies for which there is scientific evidence of effectiveness; and

(D) determine the most effective approaches for disseminating research findings to health disparity populations, including minority populations.

(2) USE OF CERTAIN STRATEGIES.—In carrying out this section, the Director shall implement research strategies and mechanisms that will enhance the involvement of individuals who are members of minority health disparity populations or

other health disparity populations, health services researchers who are such individuals, institutions that train such individuals as researchers, members of minority health disparity populations or other health disparity populations for whom the Agency is attempting to improve the quality and outcomes of care, and representatives of appropriate tribal or other community-based organizations with respect to health disparity populations. Such research strategies and mechanisms may include the use of—

(A) centers of excellence that can demonstrate, either individually or through consortia, a combination of multidisciplinary expertise in outcomes or quality improvement research, linkages to relevant sites of care, and a demonstrated capacity to involve members and communities of health disparity populations, including minority health disparity populations, in the planning, conduct, dissemination, and translation of research;

(B) provider-based research networks, including health plans, facilities, or delivery system sites of care (especially primary care), that make extensive use of health care providers who are members of health disparity populations or who serve patients in such populations and have the capacity to evaluate and promote quality improvement;

(C) service delivery models (such as health centers under section 330 and the Indian Health Service) to reduce health disparities; and

(D) innovative mechanisms or strategies that will facilitate the translation of past research investments into clinical practices that can reasonably be expected to benefit these populations.

(c) QUALITY MEASUREMENT DEVELOPMENT.—

(1) IN GENERAL.—To ensure that health disparity populations, including minority health disparity populations, benefit from the progress made in the ability of individuals to measure the quality of health care delivery, the Director shall support the development of quality of health care measures that assess the experience of such populations with health care systems, such as measures that assess the access of such populations to health care, the cultural competence of the care provided, the quality of the care provided, the outcomes of care, or other aspects of health care practice that the Director determines to be important.

(2) EXAMINATION OF CERTAIN PRACTICES.—The Director shall examine the practices of providers that have a record of reducing health disparities or have experience in providing culturally competent health services to minority health disparity populations or other health disparity populations. In examining such practices of providers funded under the authorities of this Act, the Director shall consult with the heads of the relevant agencies of the Public Health Service.

(3) REPORT.—Not later than 36 months after the date of the enactment of this section, the Secretary, acting through the Director, shall prepare and submit to the appropriate committees of Congress a report describing the state-of-the-art of qual-

ity measurement for minority and other health disparity populations that will identify critical unmet needs, the current activities of the Department to address those needs, and a description of related activities in the private sector.

(d) DEFINITION.—For purposes of this section:

(1) The term "health disparity population" has the meaning given such term in section 464z–3, except that in addition to the meaning so given, the Director may determine that such term includes populations for which there is a significant disparity in the quality, outcomes, cost, or use of health care services or access to or satisfaction with such services as compared to the general population.

(2) The term "minority", with respect to populations, refers to racial and ethnic minority groups as defined in section 1707.

PART B—HEALTH CARE IMPROVEMENT RESEARCH

SEC. 911. [299b] 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 to assess health care research results, particularly methods or systems to rate the strength of the scientific evidence underlying 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 evaluate and promote quality improvement; and

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

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

SEC. 912. [299b–1] 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 care 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, biological products, and devices.

(c) REDUCING ERRORS IN MEDICINE.—The Director shall, in accordance with part C, 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) disseminate such effective strategies throughout the health care industry.

SEC. 913. [299b–2] INFORMATION ON QUALITY AND COST OF CARE.

(a) IN GENERAL.—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 including rural residents 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, including the health care needs of populations identified in section 901(c), provide data to study

the relationships between health care quality, outcomes, access, use, and cost, measure changes over time, 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 including rural residents; 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 the 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. [299b–3] 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 conduct and 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 utility and comparability of health information data and medical vocabularies by addressing issues related to the content, structure, definitions and coding of such information and data in consultation with appropriate Federal, State and private entities;

(6) the use of computer-based health records in all settings for the development of personal health records for individual health assessment and maintenance, and for monitoring public health and outcomes of care within populations; and

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

(c) FACILITATING PUBLIC ACCESS TO INFORMATION.—The Director shall work with appropriate public and private sector entities

to facilitate public access to information regarding the quality of and consumer satisfaction with health care.

SEC. 915. [299b–4] RESEARCH SUPPORTING PRIMARY CARE AND ACCESS IN UNDERSERVED AREAS.

(a) PREVENTIVE SERVICES TASK FORCE.—

(1) ESTABLISHMENT AND PURPOSE.—The Director shall convene an independent Preventive Services Task Force (referred to in this subsection as the "Task Force") to be composed of individuals with appropriate expertise. Such 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 clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services (referred to in this section as the "Guide"), for individuals and organizations delivering clinical services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, Congress and other policy-makers, governmental public health agencies, health care quality organizations, and organizations developing national health objectives. Such recommendations shall consider clinical preventive best practice recommendations from the Agency for Healthcare Research and Quality, the National Institutes of Health, the Centers for Disease Control and Prevention, the Institute of Medicine, specialty medical associations, patient groups, and scientific societies.

(2) DUTIES.—The duties of the Task Force shall include—

(A) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific sub-populations and age groups;

(B) at least once during every 5-year period, review interventions and update recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions;

(C) improved integration with Federal Government health objectives and related target setting for health improvement;

(D) the enhanced dissemination of recommendations;

(E) the provision of technical assistance to those health care professionals, agencies and organizations that request help in implementing the Guide recommendations; and

(F) the submission of yearly reports to Congress and related agencies identifying gaps in research, such as preventive services that receive an insufficient evidence statement, and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

(3) ROLE OF AGENCY.—The Agency shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and sup-

porting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of the Guide's recommendations.

(4) COORDINATION WITH COMMUNITY PREVENTIVE SERVICES TASK FORCE.—The Task Force shall take appropriate steps to coordinate its work with the Community Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community.

(5) OPERATION.—Operation. In carrying out the duties under paragraph (2), the Task Force is not subject to the provisions of chapter 10 of title 5, United States Code.

(6) INDEPENDENCE.—All members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure.

(7) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.

(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. [299b–5] HEALTH CARE PRACTICE AND TECHNOLOGY INNOVATION.

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

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

(4) promoting education and training and providing technical assistance in the use of health care practice and 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 health care 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 Centers for Medicare & Medicaid Services, 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 health care practices and technologies; 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 Centers for Medicare & Medicaid Services, 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, minority institutions of higher education (such as Historically Black Colleges and Universities, and Hispanic institutions), and consortia of appropriate research entities established for the purpose of conducting technology assessments.

(d) MEDICAL EXAMINATION OF CERTAIN VICTIMS.—

(1) IN GENERAL.—The Director shall develop and disseminate a report on evidence-based clinical practices for—

(A) the examination and treatment by health professionals of individuals who are victims of sexual assault (including child molestation) or attempted sexual assault; and

(B) the training of health professionals, in consultation with the Health Resources and Services Administration, on performing medical evidentiary examinations of individuals who are victims of child abuse or neglect, sexual assault, elder abuse, or domestic violence.

(2) CERTAIN CONSIDERATIONS.—In identifying the issues to be addressed by the report, the Director shall, to the extent practicable, take into consideration the expertise and experience of Federal and State law enforcement officials regarding the victims referred to in paragraph (1), and of other appropriate public and private entities (including medical societies, victim services organizations, sexual assault prevention organizations, and social services organizations).

SEC. 917. [299b–6] 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 the 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 the 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—PATIENT SAFETY IMPROVEMENT

SEC. 921. [299b–21] DEFINITIONS.

In this part:

(1) HIPAA CONFIDENTIALITY REGULATIONS.—The term "HIPAA confidentiality regulations" means regulations promulgated under section 264(c) of the Health Insurance Portability

and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).

(2) IDENTIFIABLE PATIENT SAFETY WORK PRODUCT.—The term "identifiable patient safety work product" means patient safety work product that—

(A) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

(B) constitutes individually identifiable health information as that term is defined in the HIPAA confidentiality regulations; or

(C) is presented in a form and manner that allows the identification of an individual who reported information in the manner specified in section 922(e).

(3) NONIDENTIFIABLE PATIENT SAFETY WORK PRODUCT.—The term "nonidentifiable patient safety work product" means patient safety work product that is not identifiable patient safety work product (as defined in paragraph (2)).

(4) PATIENT SAFETY ORGANIZATION.—The term "patient safety organization" means a private or public entity or component thereof that is listed by the Secretary pursuant to section 924(d).

(5) PATIENT SAFETY ACTIVITIES.—The term "patient safety activities" means the following activities:

(A) Efforts to improve patient safety and the quality of health care delivery.

(B) The collection and analysis of patient safety work product.

(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

(D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

(F) The provision of appropriate security measures with respect to patient safety work product.

(G) The utilization of qualified staff.

(H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

(6) PATIENT SAFETY EVALUATION SYSTEM.—The term "patient safety evaluation system" means the collection, management, or analysis of information for reporting to or by a patient safety organization.

(7) PATIENT SAFETY WORK PRODUCT.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—

(i) which—

(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

(B) CLARIFICATION.—

(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

(iii) Nothing in this part shall be construed to limit—

(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

(8) PROVIDER.—The term "provider" means—

(A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—

(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

(B) any other individual or entity specified in regulations promulgated by the Secretary.

SEC. 922. [299b–22] PRIVILEGE AND CONFIDENTIALITY PROTECTIONS.

(a) PRIVILEGE.—Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be privileged and shall not be—

(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(3) subject to disclosure pursuant to section 552 of title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;

(4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or

(5) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

(b) CONFIDENTIALITY OF PATIENT SAFETY WORK PRODUCT.—Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be confidential and shall not be disclosed.

(c) EXCEPTIONS.—Except as provided in subsection (g)(3)—

(1) EXCEPTIONS FROM PRIVILEGE AND CONFIDENTIALITY.—Subsections (a) and (b) shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in camera determination that such patient safety work product contains evidence of a criminal act and that such patient safety work product is material to the proceeding and not reasonably available from any other source.

(B) Disclosure of patient safety work product to the extent required to carry out subsection (f)(4)(A).

(C) Disclosure of identifiable patient safety work product if authorized by each provider identified in such work product.

(2) EXCEPTIONS FROM CONFIDENTIALITY.—Subsection (b) shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of patient safety work product to carry out patient safety activities.

(B) Disclosure of nonidentifiable patient safety work product.

(C) Disclosure of patient safety work product to grantees, contractors, or other entities carrying out research, evaluation, or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research to the extent that disclosure of protected health information would be allowed for such purpose under the HIPAA confidentiality regulations.

(D) Disclosure by a provider to the Food and Drug Administration with respect to a product or activity regulated by the Food and Drug Administration.

(E) Voluntary disclosure of patient safety work product by a provider to an accrediting body that accredits that provider.

(F) Disclosures that the Secretary may determine, by rule or other means, are necessary for business operations and are consistent with the goals of this part.

(G) Disclosure of patient safety work product to law enforcement authorities relating to the commission of a crime (or to an event reasonably believed to be a crime) if the person making the disclosure believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

(H) With respect to a person other than a patient safety organization, the disclosure of patient safety work product that does not include materials that—

(i) assess the quality of care of an identifiable provider; or

(ii) describe or pertain to one or more actions or failures to act by an identifiable provider.

(3) EXCEPTION FROM PRIVILEGE.—Subsection (a) shall not apply to (and shall not be construed to prohibit) voluntary disclosure of nonidentifiable patient safety work product.

(d) CONTINUED PROTECTION OF INFORMATION AFTER DISCLOSURE.—

(1) IN GENERAL.—Patient safety work product that is disclosed under subsection (c) shall continue to be privileged and confidential as provided for in subsections (a) and (b), and such disclosure shall not be treated as a waiver of privilege or confidentiality, and the privileged and confidential nature of such work product shall also apply to such work product in the possession or control of a person to whom such work product was disclosed.

(2) EXCEPTION.—Notwithstanding paragraph (1), and subject to paragraph (3)—

(A) if patient safety work product is disclosed in a criminal proceeding, the confidentiality protections provided for in subsection (b) shall no longer apply to the work product so disclosed; and

(B) if patient safety work product is disclosed as provided for in subsection (c)(2)(B) (relating to disclosure of nonidentifiable patient safety work product), the privilege

and confidentiality protections provided for in subsections (a) and (b) shall no longer apply to such work product.

(3) CONSTRUCTION.—Paragraph (2) shall not be construed as terminating or limiting the privilege or confidentiality protections provided for in subsection (a) or (b) with respect to patient safety work product other than the specific patient safety work product disclosed as provided for in subsection (c).

(4) LIMITATIONS ON ACTIONS.—

(A) PATIENT SAFETY ORGANIZATIONS.—

(i) IN GENERAL.—A patient safety organization shall not be compelled to disclose information collected or developed under this part whether or not such information is patient safety work product unless such information is identified, is not patient safety work product, and is not reasonably available from another source.

(ii) NONAPPLICATION.—The limitation contained in clause (i) shall not apply in an action against a patient safety organization or with respect to disclosures pursuant to subsection (c)(1).

(B) PROVIDERS.—An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this part. An accrediting body may not require a provider to reveal its communications with any patient safety organization established in accordance with this part.

(e) REPORTER PROTECTION.—

(1) IN GENERAL.—A provider may not take an adverse employment action, as described in paragraph (2), against an individual based upon the fact that the individual in good faith reported information—

(A) to the provider with the intention of having the information reported to a patient safety organization; or

(B) directly to a patient safety organization.

(2) ADVERSE EMPLOYMENT ACTION.—For purposes of this subsection, an "adverse employment action" includes—

(A) loss of employment, the failure to promote an individual, or the failure to provide any other employment-related benefit for which the individual would otherwise be eligible; or

(B) an adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

(f) ENFORCEMENT.—

(1) CIVIL MONETARY PENALTY.—Subject to paragraphs (2) and (3), a person who discloses identifiable patient safety work product in knowing or reckless violation of subsection (b) shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

(2) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1), shall apply to civil money penalties under this subsection in the same manner as such

provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

(3) RELATION TO HIPAA.—Penalties shall not be imposed both under this subsection and under the regulations issued pursuant to section 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note) for a single act or omission.

(4) EQUITABLE RELIEF.—

(A) IN GENERAL.—Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (e) and to obtain other appropriate equitable relief (including reinstatement, back pay, and restoration of benefits) to redress such violation.

(B) AGAINST STATE EMPLOYEES.—An entity that is a State or an agency of a State government may not assert the privilege described in subsection (a) unless before the time of the assertion, the entity or, in the case of and with respect to an agency, the State has consented to be subject to an action described in subparagraph (A), and that consent has remained in effect.

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

(1) to limit the application of other Federal, State, or local laws that provide greater privilege or confidentiality protections than the privilege and confidentiality protections provided for in this section;

(2) to limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under this section;

(3) except as provided in subsection (i), to alter or affect the implementation of any provision of the HIPAA confidentiality regulations or section 1176 of the Social Security Act (or regulations promulgated under such section);

(4) to limit the authority of any provider, patient safety organization, or other entity to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this section;

(5) as preempting or otherwise affecting any State law requiring a provider to report information that is not patient safety work product; or

(6) to limit, alter, or affect any requirement for reporting to the Food and Drug Administration information regarding the safety of a product or activity regulated by the Food and Drug Administration.

(h) CLARIFICATION.—Nothing in this part prohibits any person from conducting additional analysis for any purpose regardless of whether such additional analysis involves issues identical to or similar to those for which information was reported to or assessed by a patient safety organization or a patient safety evaluation system.

(i) CLARIFICATION OF APPLICATION OF HIPAA CONFIDENTIALITY REGULATIONS TO PATIENT SAFETY ORGANIZATIONS.—For purposes of applying the HIPAA confidentiality regulations—

(1) patient safety organizations shall be treated as business associates; and

(2) patient safety activities of such organizations in relation to a provider are deemed to be health care operations (as defined in such regulations) of the provider.

(j) REPORTS ON STRATEGIES TO IMPROVE PATIENT SAFETY.—

(1) DRAFT REPORT.—Not later than the date that is 18 months after any network of patient safety databases is operational, the Secretary, in consultation with the Director, shall prepare a draft report on effective strategies for reducing medical errors and increasing patient safety. The draft report shall include any measure determined appropriate by the Secretary to encourage the appropriate use of such strategies, including use in any federally funded programs. The Secretary shall make the draft report available for public comment and submit the draft report to the Institute of Medicine for review.

(2) FINAL REPORT.—Not later than 1 year after the date described in paragraph (1), the Secretary shall submit a final report to the Congress.

SEC. 923. [299b–23] NETWORK OF PATIENT SAFETY DATABASES.

(a) IN GENERAL.—The Secretary shall facilitate the creation of, and maintain, a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other entities. The network of databases shall have the capacity to accept, aggregate across the network, and analyze nonidentifiable patient safety work product voluntarily reported by patient safety organizations, providers, or other entities. The Secretary shall assess the feasibility of providing for a single point of access to the network for qualified researchers for information aggregated across the network and, if feasible, provide for implementation.

(b) DATA STANDARDS.—The Secretary may determine common formats for the reporting to and among the network of patient safety databases maintained under subsection (a) of nonidentifiable patient safety work product, including necessary work product elements, common and consistent definitions, and a standardized computer interface for the processing of such work product. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act.

(c) USE OF INFORMATION.—Information reported to and among the network of patient safety databases under subsection (a) shall be used to analyze national and regional statistics, including trends and patterns of health care errors. The information resulting from such analyses shall be made available to the public and included in the annual quality reports prepared under section 913(b)(2).

SEC. 924. [299b–24] PATIENT SAFETY ORGANIZATION CERTIFICATION AND LISTING.

(a) CERTIFICATION.—

(1) INITIAL CERTIFICATION.—An entity that seeks to be a patient safety organization shall submit an initial certification to the Secretary that the entity—

(A) has policies and procedures in place to perform each of the patient safety activities described in section 921(5); and

(B) upon being listed under subsection (d), will comply with the criteria described in subsection (b).

(2) SUBSEQUENT CERTIFICATIONS.—An entity that is a patient safety organization shall submit every 3 years after the date of its initial listing under subsection (d) a subsequent certification to the Secretary that the entity—

(A) is performing each of the patient safety activities described in section 921(5); and

(B) is complying with the criteria described in subsection (b).

(b) CRITERIA.—

(1) IN GENERAL.—The following are criteria for the initial and subsequent certification of an entity as a patient safety organization:

(A) The mission and primary activity of the entity are to conduct activities that are to improve patient safety and the quality of health care delivery.

(B) The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals.

(C) The entity, within each 24-month period that begins after the date of the initial listing under subsection (d), has bona fide contracts, each of a reasonable period of time, with more than 1 provider for the purpose of receiving and reviewing patient safety work product.

(D) The entity is not, and is not a component of, a health insurance issuer (as defined in section 2791(b)(2)).

(E) The entity shall fully disclose—

(i) any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity; and

(ii) if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity.

(F) To the extent practical and appropriate, the entity collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.

(G) The utilization of patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

(2) ADDITIONAL CRITERIA FOR COMPONENT ORGANIZATIONS.—If an entity that seeks to be a patient safety organization is a component of another organization, the following are additional criteria for the initial and subsequent certification of the entity as a patient safety organization:

(A) The entity maintains patient safety work product separately from the rest of the organization, and establishes appropriate security measures to maintain the confidentiality of the patient safety work product.

(B) The entity does not make an unauthorized disclosure under this part of patient safety work product to the rest of the organization in breach of confidentiality.

(C) The mission of the entity does not create a conflict of interest with the rest of the organization.

(c) REVIEW OF CERTIFICATION.—

(1) IN GENERAL.—

(A) INITIAL CERTIFICATION.—Upon the submission by an entity of an initial certification under subsection (a)(1), the Secretary shall determine if the certification meets the requirements of subparagraphs (A) and (B) of such subsection.

(B) SUBSEQUENT CERTIFICATION.—Upon the submission by an entity of a subsequent certification under subsection (a)(2), the Secretary shall review the certification with respect to requirements of subparagraphs (A) and (B) of such subsection.

(2) NOTICE OF ACCEPTANCE OR NON-ACCEPTANCE.—If the Secretary determines that—

(A) an entity's initial certification meets requirements referred to in paragraph (1)(A), the Secretary shall notify the entity of the acceptance of such certification; or

(B) an entity's initial certification does not meet such requirements, the Secretary shall notify the entity that such certification is not accepted and the reasons therefor.

(3) DISCLOSURES REGARDING RELATIONSHIP TO PROVIDERS.—The Secretary shall consider any disclosures under subsection (b)(1)(E) by an entity and shall make public findings on whether the entity can fairly and accurately perform the patient safety activities of a patient safety organization. The Secretary shall take those findings into consideration in determining whether to accept the entity's initial certification and any subsequent certification submitted under subsection (a) and, based on those findings, may deny, condition, or revoke acceptance of the entity's certification.

(d) LISTING.—The Secretary shall compile and maintain a listing of entities with respect to which there is an acceptance of a certification pursuant to subsection (c)(2)(A) that has not been revoked under subsection (e) or voluntarily relinquished.

(e) REVOCATION OF ACCEPTANCE OF CERTIFICATION.—

(1) IN GENERAL.—If, after notice of deficiency, an opportunity for a hearing, and a reasonable opportunity for correction, the Secretary determines that a patient safety organization does not meet the certification requirements under subsection (a)(2), including subparagraphs (A) and (B) of such subsection, the Secretary shall revoke the Secretary's acceptance of the certification of such organization.

(2) SUPPLYING CONFIRMATION OF NOTIFICATION TO PROVIDERS.—Within 15 days of a revocation under paragraph (1), a patient safety organization shall submit to the Secretary a confirmation that the organization has taken all reasonable actions to notify each provider whose patient safety work product is collected or analyzed by the organization of such revocation.

(3) PUBLICATION OF DECISION.—If the Secretary revokes the certification of an organization under paragraph (1), the Secretary shall—

(A) remove the organization from the listing maintained under subsection (d); and

(B) publish notice of the revocation in the Federal Register.

(f) STATUS OF DATA AFTER REMOVAL FROM LISTING.—

(1) NEW DATA.—With respect to the privilege and confidentiality protections described in section 922, data submitted to an entity within 30 days after the entity is removed from the listing under subsection (e)(3)(A) shall have the same status as data submitted while the entity was still listed.

(2) PROTECTION TO CONTINUE TO APPLY.—If the privilege and confidentiality protections described in section 922 applied to patient safety work product while an entity was listed, or to data described in paragraph (1), such protections shall continue to apply to such work product or data after the entity is removed from the listing under subsection (e)(3)(A).

(g) DISPOSITION OF WORK PRODUCT AND DATA.—If the Secretary removes a patient safety organization from the listing as provided for in subsection (e)(3)(A), with respect to the patient safety work product or data described in subsection (f)(1) that the patient safety organization received from another entity, such former patient safety organization shall—

(1) with the approval of the other entity and a patient safety organization, transfer such work product or data to such patient safety organization;

(2) return such work product or data to the entity that submitted the work product or data; or

(3) if returning such work product or data to such entity is not practicable, destroy such work product or data.

SEC. 925. [299b–24a] ACTIVITIES REGARDING WOMEN'S HEALTH.

(a) ESTABLISHMENT.—There is established within the Office of the Director, an Office of Women's Health and Gender-Based Research (referred to in this section as the "Office"). The Office shall be headed by a director who shall be appointed by the Director of Healthcare and Research Quality.

(b) PURPOSE.—The official designated under subsection (a) shall—

(1) report to the Director on the current Agency level of activity regarding women's health, across, where appropriate, age, biological, and sociocultural contexts, in all aspects of Agency work, including the development of evidence reports and clinical practice protocols and the conduct of research into patient outcomes, delivery of health care services, quality of care, and access to health care;

(2) establish short-range and long-range goals and objectives within the Agency for research important to women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Agency that relate to health services and medical effectiveness research, for issues of particular concern to women;

(3) identify projects in women's health that should be conducted or supported by the Agency;

(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on Agency policy with regard to women; and

(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).

(c) 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 2010 through 2014.

SEC. 926. [299b–25] TECHNICAL ASSISTANCE.

The Secretary, acting through the Director, may provide technical assistance to patient safety organizations, including convening annual meetings for patient safety organizations to discuss methodology, communication, data collection, or privacy concerns.

SEC. 927. [299b–26] SEVERABILITY.

If any provision of this part is held to be unconstitutional, the remainder of this part shall not be affected.

PART D—HEALTH CARE QUALITY IMPROVEMENT

Subpart I—Quality Measure Development

SEC. 931. [299b–31] QUALITY MEASURE DEVELOPMENT.

(a) QUALITY MEASURE.—In this subpart, the term "quality measure" means a standard for measuring the performance and improvement of population health or of health plans, providers of services, and other clinicians in the delivery of health care services.

(b) IDENTIFICATION OF QUALITY MEASURES.—

(1) IDENTIFICATION.—The Secretary, in consultation with the Director of the Agency for Healthcare Research and Quality and the Administrator of the Centers for Medicare & Medicaid Services, shall identify, not less often than triennially, gaps where no quality measures exist and existing quality measures that need improvement, updating, or expansion, consistent with the national strategy under section 399HH, to the extent available, for use in Federal health programs. In identifying such gaps and existing quality measures that need improvement, the Secretary shall take into consideration—

(A) the gaps identified by the entity with a contract under section 1890(a) of the Social Security Act and other stakeholders;

(B) quality measures identified by the pediatric quality measures program under section 1139A of the Social Security Act; and

(C) quality measures identified through the Medicaid Quality Measurement Program under section 1139B of the Social Security Act.

(2) PUBLICATION.—The Secretary shall make available to the public on an Internet website a report on any gaps identified under paragraph (1) and the process used to make such identification.

(c) GRANTS OR CONTRACTS FOR QUALITY MEASURE DEVELOPMENT.—

(1) IN GENERAL.—The Secretary shall award grants, contracts, or intergovernmental agreements to eligible entities for purposes of developing, improving, updating, or expanding quality measures identified under subsection (b).

(2) PRIORITIZATION IN THE DEVELOPMENT OF QUALITY MEASURES.—In awarding grants, contracts, or agreements under this subsection, the Secretary shall give priority to the development of quality measures that allow the assessment of—

(A) health outcomes and functional status of patients;

(B) the management and coordination of health care across episodes of care and care transitions for patients across the continuum of providers, health care settings, and health plans;

(C) the experience, quality, and use of information provided to and used by patients, caregivers, and authorized representatives to inform decisionmaking about treatment options, including the use of shared decisionmaking tools and preference sensitive care (as defined in section 936);

(D) the meaningful use of health information technology;

(E) the safety, effectiveness, patient-centeredness, appropriateness, and timeliness of care;

(F) the efficiency of care;

(G) the equity of health services and health disparities across health disparity populations (as defined in section 485E) and geographic areas;

(H) patient experience and satisfaction;

(I) the use of innovative strategies and methodologies identified under section 933; and

(J) other areas determined appropriate by the Secretary.

(3) ELIGIBLE ENTITIES.—To be eligible for a grant or contract under this subsection, an entity shall—

(A) have demonstrated expertise and capacity in the development and evaluation of quality measures;

(B) have adopted procedures to include in the quality measure development process—

(i) the views of those providers or payers whose performance will be assessed by the measure; and

(ii) the views of other parties who also will use the quality measures (such as patients, consumers, and health care purchasers);

(C) collaborate with the entity with a contract under section 1890(a) of the Social Security Act and other stakeholders, as practicable, and the Secretary so that quality measures developed by the eligible entity will meet the requirements to be considered for endorsement by the entity with a contract under such section 1890(a);

(D) have transparent policies regarding governance and conflicts of interest; and

(E) submit an application to the Secretary at such time and in such manner, as the Secretary may require.

(4) USE OF FUNDS.—An entity that receives a grant, contract, or agreement under this subsection shall use such award to develop quality measures that meet the following requirements:

(A) Such measures support measures required to be reported under the Social Security Act, where applicable, and in support of gaps and existing quality measures that need improvement, as described in subsection (b)(1)(A).

(B) Such measures support measures developed under section 1139A of the Social Security Act and the Medicaid Quality Measurement Program under section 1139B of such Act, where applicable.

(C) To the extent practicable, data on such quality measures is able to be collected using health information technologies.

(D) Each quality measure is free of charge to users of such measure.

(E) Each quality measure is publicly available on an Internet website.

(d) OTHER ACTIVITIES BY THE SECRETARY.—The Secretary may use amounts available under this section to update and test, where applicable, quality measures endorsed by the entity with a contract under section 1890(a) of the Social Security Act or adopted by the Secretary.

(e) COORDINATION OF GRANTS.—The Secretary shall ensure that grants or contracts awarded under this section are coordinated with grants and contracts awarded under sections 1139A(5) and 1139B(4)(A) of the Social Security Act.

(f) DEVELOPMENT OF OUTCOME MEASURES.—

(1) IN GENERAL.—The Secretary shall develop, and periodically update (not less than every 3 years), provider-level outcome measures for hospitals and physicians, as well as other providers as determined appropriate by the Secretary.

(2) CATEGORIES OF MEASURES.—The measures developed under this subsection shall include, to the extent determined appropriate by the Secretary—

(A) outcome measurement for acute and chronic diseases, including, to the extent feasible, the 5 most prevalent and resource-intensive acute and chronic medical conditions; and

(B) outcome measurement for primary and preventative care, including, to the extent feasible, measurements that cover provision of such care for distinct patient populations (such as healthy children, chronically ill adults, or infirm elderly individuals).

(3) GOALS.—In developing such measures, the Secretary shall seek to—

(A) address issues regarding risk adjustment, accountability, and sample size;

(B) include the full scope of services that comprise a cycle of care; and

(C) include multiple dimensions.

(4) TIMEFRAME.—

(A) ACUTE AND CHRONIC DISEASES.—Not later than 24 months after the date of enactment of this Act, the Secretary shall develop not less than 10 measures described in paragraph (2)(A).

(B) PRIMARY AND PREVENTIVE CARE.—Not later than 36 months after the date of enactment of this Act, the Secretary shall develop not less than 10 measures described in paragraph (2)(B).

Subpart II—Health Care Quality Improvement Programs

SEC. 933. [299b–33] HEALTH CARE DELIVERY SYSTEM RESEARCH.

(a) PURPOSE.—The purposes of this section are to—

(1) enable the Director to identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices (referred to as "best practices") in health care quality, safety, and value; and

(2) ensure that the Director is accountable for implementing a model to pursue such research in a collaborative manner with other related Federal agencies.

(b) GENERAL FUNCTIONS OF THE CENTER.—The Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (referred to in this section as the "Center"), or any other relevant agency or department designated by the Director, shall—

(1) carry out its functions using research from a variety of disciplines, which may include epidemiology, health services, sociology, psychology, human factors engineering, biostatistics, health economics, clinical research, and health informatics;

(2) conduct or support activities consistent with the purposes described in subsection (a), and for—

(A) best practices for quality improvement practices in the delivery of health care services; and

(B) that include changes in processes of care and the redesign of systems used by providers that will reliably result in intended health outcomes, improve patient safety, and reduce medical errors (such as skill development for health care providers in team-based health care delivery and rapid cycle process improvement) and facilitate adoption of improved workflow;

(3) identify health care providers, including health care systems, single institutions, and individual providers, that—

(A) deliver consistently high-quality, efficient health care services (as determined by the Secretary); and

(B) employ best practices that are adaptable and scalable to diverse health care settings or effective in improving care across diverse settings;

(4) assess research, evidence, and knowledge about what strategies and methodologies are most effective in improving health care delivery;

(5) find ways to translate such information rapidly and effectively into practice, and document the sustainability of those improvements;

(6) create strategies for quality improvement through the development of tools, methodologies, and interventions that can successfully reduce variations in the delivery of health care;

(7) identify, measure, and improve organizational, human, or other causative factors, including those related to the culture and system design of a health care organization, that contribute to the success and sustainability of specific quality improvement and patient safety strategies;

(8) provide for the development of best practices in the delivery of health care services that—

(A) have a high likelihood of success, based on structured review of empirical evidence;

(B) are specified with sufficient detail of the individual processes, steps, training, skills, and knowledge required for implementation and incorporation into workflow of health care practitioners in a variety of settings;

(C) are designed to be readily adapted by health care providers in a variety of settings; and

(D) where applicable, assist health care providers in working with other health care providers across the continuum of care and in engaging patients and their families in improving the care and patient health outcomes;

(9) provide for the funding of the activities of organizations with recognized expertise and excellence in improving the delivery of health care services, including children's health care, by involving multiple disciplines, managers of health care entities, broad development and training, patients, caregivers and families, and frontline health care workers, including activities for the examination of strategies to share best quality improvement practices and to promote excellence in the delivery of health care services; and

(10) build capacity at the State and community level to lead quality and safety efforts through education, training, and mentoring programs to carry out the activities under paragraphs (1) through (9).

(c) RESEARCH FUNCTIONS OF CENTER.—

(1) IN GENERAL.—The Center shall support, such as through a contract or other mechanism, research on health care delivery system improvement and the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services. Such support may include establishing a Quality Improvement Network Research Program for the purpose of testing, scaling, and disseminating of interventions to improve quality and effi-

ciency in health care. Recipients of funding under the Program may include national, State, multi-State, or multi-site quality improvement networks.

(2) RESEARCH REQUIREMENTS.—The research conducted pursuant to paragraph (1) shall—

(A) address the priorities identified by the Secretary in the national strategic plan established under section 399HH;

(B) identify areas in which evidence is insufficient to identify strategies and methodologies, taking into consideration areas of insufficient evidence identified by the entity with a contract under section 1890(a) of the Social Security Act in the report required under section 399JJ;

(C) address concerns identified by health care institutions and providers and communicated through the Center pursuant to subsection (d);

(D) reduce preventable morbidity, mortality, and associated costs of morbidity and mortality by building capacity for patient safety research;

(E) support the discovery of processes for the reliable, safe, efficient, and responsive delivery of health care, taking into account discoveries from clinical research and comparative effectiveness research;

(F) allow communication of research findings and translate evidence into practice recommendations that are adaptable to a variety of settings, and which, as soon as practicable after the establishment of the Center, shall include—

(i) the implementation of a national application of Intensive Care Unit improvement projects relating to the adult (including geriatric), pediatric, and neonatal patient populations;

(ii) practical methods for addressing health care associated infections, including Methicillin-Resistant Staphylococcus Aureus and Vancomycin-Resistant Entercoccus infections and other emerging infections; and

(iii) practical methods for reducing preventable hospital admissions and readmissions;

(G) expand demonstration projects for improving the quality of children's health care and the use of health information technology, such as through Pediatric Quality Improvement Collaboratives and Learning Networks, consistent with provisions of section 1139A of the Social Security Act for assessing and improving quality, where applicable;

(H) identify and mitigate hazards by—

(i) analyzing events reported to patient safety reporting systems and patient safety organizations; and

(ii) using the results of such analyses to develop scientific methods of response to such events;

(I) include the conduct of systematic reviews of existing practices that improve the quality, safety, and effi-

ciency of health care delivery, as well as new research on improving such practices; and

(J) include the examination of how to measure and evaluate the progress of quality and patient safety activities.

(d) DISSEMINATION OF RESEARCH FINDINGS.—

(1) PUBLIC AVAILABILITY.—The Director shall make the research findings of the Center available to the public through multiple media and appropriate formats to reflect the varying needs of health care providers and consumers and diverse levels of health literacy.

(2) LINKAGE TO HEALTH INFORMATION TECHNOLOGY.—The Secretary shall ensure that research findings and results generated by the Center are shared with the Office of the National Coordinator of Health Information Technology and used to inform the activities of the health information technology extension program under section 3012, as well as any relevant standards, certification criteria, or implementation specifications.

(e) PRIORITIZATION.—The Director shall identify and regularly update a list of processes or systems on which to focus research and dissemination activities of the Center, taking into account—

(1) the cost to Federal health programs;

(2) consumer assessment of health care experience;

(3) provider assessment of such processes or systems and opportunities to minimize distress and injury to the health care workforce;

(4) the potential impact of such processes or systems on health status and function of patients, including vulnerable populations including children;

(5) the areas of insufficient evidence identified under subsection (c)(2)(B); and

(6) the evolution of meaningful use of health information technology, as defined in section 3000.

(f) COORDINATION.—The Center shall coordinate its activities with activities conducted by the Center for Medicare and Medicaid Innovation established under section 1115A of the Social Security Act.

(g) FUNDING.—There is authorized to be appropriated to carry out this section $20,000,000 for fiscal years 2010 through 2014.

SEC. 934. [299b–34] QUALITY IMPROVEMENT TECHNICAL ASSISTANCE AND IMPLEMENTATION.

(a) IN GENERAL.—The Director, through the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (referred to in this section as the "Center"), shall award—

(1) technical assistance grants or contracts to eligible entities to provide technical support to institutions that deliver health care and health care providers (including rural and urban providers of services and suppliers with limited infrastructure and financial resources to implement and support quality improvement activities, providers of services and suppliers with poor performance scores, and providers of services and suppliers for which there are disparities in care among

subgroups of patients) so that such institutions and providers understand, adapt, and implement the models and practices identified in the research conducted by the Center, including the Quality Improvement Networks Research Program; and

(2) implementation grants or contracts to eligible entities to implement the models and practices described under paragraph (1).

(b) ELIGIBLE ENTITIES.—

(1) TECHNICAL ASSISTANCE AWARD.—To be eligible to receive a technical assistance grant or contract under subsection (a)(1), an entity—

(A) may be a health care provider, health care provider association, professional society, health care worker organization, Indian health organization, quality improvement organization, patient safety organization, local quality improvement collaborative, the Joint Commission, academic health center, university, physician-based research network, primary care extension program established under section 399V–1, a Federal Indian Health Service program or a health program operated by an Indian tribe (as defined in section 4 of the Indian Health Care Improvement Act), or any other entity identified by the Secretary; and

(B) shall have demonstrated expertise in providing information and technical support and assistance to health care providers regarding quality improvement.

(2) IMPLEMENTATION AWARD.—To be eligible to receive an implementation grant or contract under subsection (a)(2), an entity—

(A) may be a hospital or other health care provider or consortium or providers, as determined by the Secretary; and

(B) shall have demonstrated expertise in providing information and technical support and assistance to health care providers regarding quality improvement.

(c) APPLICATION.—

(1) TECHNICAL ASSISTANCE AWARD.—To receive a technical assistance grant or contract under subsection (a)(1), an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing—

(A) a plan for a sustainable business model that may include a system of—

(i) charging fees to institutions and providers that receive technical support from the entity; and

(ii) reducing or eliminating such fees for such institutions and providers that serve low-income populations; and

(B) such other information as the Director may require.

(2) IMPLEMENTATION AWARD.—To receive a grant or contract under subsection (a)(2), an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing—

(A) a plan for implementation of a model or practice identified in the research conducted by the Center including—

(i) financial cost, staffing requirements, and timeline for implementation; and

(ii) pre- and projected post-implementation quality measure performance data in targeted improvement areas identified by the Secretary; and

(B) such other information as the Director may require.

(d) MATCHING FUNDS.—The Director may not award a grant or contract under this section to an entity unless the entity agrees that it will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant or contract in an amount equal to $1 for each $5 of Federal funds provided under the grant or contract. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) EVALUATION.—

(1) IN GENERAL.—The Director shall evaluate the performance of each entity that receives a grant or contract under this section. The evaluation of an entity shall include a study of—

(A) the success of such entity in achieving the implementation, by the health care institutions and providers assisted by such entity, of the models and practices identified in the research conducted by the Center under section 933;

(B) the perception of the health care institutions and providers assisted by such entity regarding the value of the entity; and

(C) where practicable, better patient health outcomes and lower cost resulting from the assistance provided by such entity.

(2) EFFECT OF EVALUATION.—Based on the outcome of the evaluation of the entity under paragraph (1), the Director shall determine whether to renew a grant or contract with such entity under this section.

(f) COORDINATION.—The entities that receive a grant or contract under this section shall coordinate with health information technology regional extension centers under section 3012(c) and the primary care extension program established under section 399V–1 regarding the dissemination of quality improvement, system delivery reform, and best practices information.

SEC. 935. [299b–35] GRANTS OR CONTRACTS TO IMPLEMENT MEDICATION MANAGEMENT SERVICES IN TREATMENT OF CHRONIC DISEASES.

(a) IN GENERAL.—The Secretary, acting through the Patient Safety Research Center established in section 933 (referred to in this section as the "Center"), shall establish a program to provide grants or contracts to eligible entities to implement medication management (referred to in this section as "MTM") services provided by licensed pharmacists, as a collaborative, multidisciplinary,

inter-professional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such diseases. The Secretary shall commence the program under this section not later than May 1, 2010.

(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant or contract under subsection (a), an entity shall—

(1) provide a setting appropriate for MTM services, as recommended by the experts described in subsection (e);

(2) submit to the Secretary a plan for achieving long-term financial sustainability;

(3) where applicable, submit a plan for coordinating MTM services through local community health teams established in section 3502 of the Patient Protection and Affordable Care Act or in collaboration with primary care extension programs established in section 399V–1;

(4) submit a plan for meeting the requirements under subsection (c); and

(5) submit to the Secretary such other information as the Secretary may require.

(c) MTM SERVICES TO TARGETED INDIVIDUALS.—The MTM services provided with the assistance of a grant or contract awarded under subsection (a) shall, as allowed by State law including applicable collaborative pharmacy practice agreements, include—

(1) performing or obtaining necessary assessments of the health and functional status of each patient receiving such MTM services;

(2) formulating a medication treatment plan according to therapeutic goals agreed upon by the prescriber and the patient or caregiver or authorized representative of the patient;

(3) selecting, initiating, modifying, recommending changes to, or administering medication therapy;

(4) monitoring, which may include access to, ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, including safety and effectiveness;

(5) performing an initial comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events, quarterly targeted medication reviews for ongoing monitoring, and additional followup interventions on a schedule developed collaboratively with the prescriber;

(6) documenting the care delivered and communicating essential information about such care, including a summary of the medication review, and the recommendations of the pharmacist to other appropriate health care providers of the patient in a timely fashion;

(7) providing education and training designed to enhance the understanding and appropriate use of the medications by the patient, caregiver, and other authorized representative;

(8) providing information, support services, and resources and strategies designed to enhance patient adherence with therapeutic regimens;

(9) coordinating and integrating MTM services within the broader health care management services provided to the patient; and

(10) such other patient care services allowed under pharmacist scopes of practice in use in other Federal programs that have implemented MTM services.

(d) TARGETED INDIVIDUALS.—MTM services provided by licensed pharmacists under a grant or contract awarded under subsection (a) shall be offered to targeted individuals who—

(1) take 4 or more prescribed medications (including over-the-counter medications and dietary supplements);

(2) take any "high risk" medications;

(3) have 2 or more chronic diseases, as identified by the Secretary; or

(4) have undergone a transition of care, or other factors, as determined by the Secretary, that are likely to create a high risk of medication-related problems.

(e) CONSULTATION WITH EXPERTS.—In designing and implementing MTM services provided under grants or contracts awarded under subsection (a), the Secretary shall consult with Federal, State, private, public-private, and academic entities, pharmacy and pharmacist organizations, health care organizations, consumer advocates, chronic disease groups, and other stakeholders involved with the research, dissemination, and implementation of pharmacist-delivered MTM services, as the Secretary determines appropriate. The Secretary, in collaboration with this group, shall determine whether it is possible to incorporate rapid cycle process improvement concepts in use in other Federal programs that have implemented MTM services.

(f) REPORTING TO THE SECRETARY.—An entity that receives a grant or contract under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out under subsection (c), including quality measures endorsed by the entity with a contract under section 1890 of the Social Security Act, as determined by the Secretary.

(g) EVALUATION AND REPORT.—The Secretary shall submit to the relevant committees of Congress a report which shall—

(1) assess the clinical effectiveness of pharmacist-provided services under the MTM services program, as compared to usual care, including an evaluation of whether enrollees maintained better health with fewer hospitalizations and emergency room visits than similar patients not enrolled in the program;

(2) assess changes in overall health care resource use by targeted individuals;

(3) assess patient and prescriber satisfaction with MTM services;

(4) assess the impact of patient-cost sharing requirements on medication adherence and recommendations for modifications;

(5) identify and evaluate other factors that may impact clinical and economic outcomes, including demographic characteristics, clinical characteristics, and health services use of the

patient, as well as characteristics of the regimen, pharmacy benefit, and MTM services provided; and

(6) evaluate the extent to which participating pharmacists who maintain a dispensing role have a conflict of interest in the provision of MTM services, and if such conflict is found, provide recommendations on how such a conflict might be appropriately addressed.

(h) GRANTS OR CONTRACTS TO FUND DEVELOPMENT OF PERFORMANCE MEASURES.—The Secretary may, through the quality measure development program under section 931 of the Public Health Service Act, award grants or contracts to eligible entities for the purpose of funding the development of performance measures that assess the use and effectiveness of medication therapy management services.

SEC. 936. [299b–36] PROGRAM TO FACILITATE SHARED DECISION-MAKING.

(a) PURPOSE.—The purpose of this section is to facilitate collaborative processes between patients, caregivers or authorized representatives, and clinicians that engages the patient, caregiver or authorized representative in decisionmaking, provides patients, caregivers or authorized representatives with information about trade-offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan.

(b) DEFINITIONS.—In this section:

(1) PATIENT DECISION AID.—The term "patient decision aid" means an educational tool that helps patients, caregivers or authorized representatives understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.

(2) PREFERENCE SENSITIVE CARE.—The term "preference sensitive care" means medical care for which the clinical evidence does not clearly support one treatment option such that the appropriate course of treatment depends on the values of the patient or the preferences of the patient, caregivers or authorized representatives regarding the benefits, harms and scientific evidence for each treatment option, the use of such care should depend on the informed patient choice among clinically appropriate treatment options.

(c) ESTABLISHMENT OF INDEPENDENT STANDARDS FOR PATIENT DECISION AIDS FOR PREFERENCE SENSITIVE CARE.—

(1) CONTRACT WITH ENTITY TO ESTABLISH STANDARDS AND CERTIFY PATIENT DECISION AIDS.—

(A) IN GENERAL.—For purposes of supporting consensus-based standards for patient decision aids for preference sensitive care and a certification process for patient decision aids for use in the Federal health programs and by other interested parties, the Secretary shall have in effect a contract with the entity with a contract under section 1890 of the Social Security Act. Such contract shall provide that the entity perform the duties described in paragraph (2).

(B) TIMING FOR FIRST CONTRACT.—As soon as practicable after the date of the enactment of this section, the Secretary shall enter into the first contract under subparagraph (A).

(C) PERIOD OF CONTRACT.—A contract under subparagraph (A) shall be for a period of 18 months (except such contract may be renewed after a subsequent bidding process).

(2) DUTIES.—The following duties are described in this paragraph:

(A) DEVELOP AND IDENTIFY STANDARDS FOR PATIENT DECISION AIDS.—The entity shall synthesize evidence and convene a broad range of experts and key stakeholders to develop and identify consensus-based standards to evaluate patient decision aids for preference sensitive care.

(B) ENDORSE PATIENT DECISION AIDS.—The entity shall review patient decision aids and develop a certification process whether patient decision aids meet the standards developed and identified under subparagraph (A). The entity shall give priority to the review and certification of patient decision aids for preference sensitive care.

(d) PROGRAM TO DEVELOP, UPDATE AND PATIENT DECISION AIDS TO ASSIST HEALTH CARE PROVIDERS AND PATIENTS.—

(1) IN GENERAL.—The Secretary, acting through the Director, and in coordination with heads of other relevant agencies, such as the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish a program to award grants or contracts—

(A) to develop, update, and produce patient decision aids for preference sensitive care to assist health care providers in educating patients, caregivers, and authorized representatives concerning the relative safety, relative effectiveness (including possible health outcomes and impact on functional status), and relative cost of treatment or, where appropriate, palliative care options;

(B) to test such materials to ensure such materials are balanced and evidence based in aiding health care providers and patients, caregivers, and authorized representatives to make informed decisions about patient care and can be easily incorporated into a broad array of practice settings; and

(C) to educate providers on the use of such materials, including through academic curricula.

(2) REQUIREMENTS FOR PATIENT DECISION AIDS.—Patient decision aids developed and produced pursuant to a grant or contract under paragraph (1)—

(A) shall be designed to engage patients, caregivers, and authorized representatives in informed decision-making with health care providers;

(B) shall present up-to-date clinical evidence about the risks and benefits of treatment options in a form and manner that is age-appropriate and can be adapted for patients, caregivers, and authorized representatives from a

variety of cultural and educational backgrounds to reflect the varying needs of consumers and diverse levels of health literacy;

(C) shall, where appropriate, explain why there is a lack of evidence to support one treatment option over another; and

(D) shall address health care decisions across the age span, including those affecting vulnerable populations including children.

(3) DISTRIBUTION.—The Director shall ensure that patient decision aids produced with grants or contracts under this section are available to the public.

(4) NONDUPLICATION OF EFFORTS.—The Director shall ensure that the activities under this section of the Agency and other agencies, including the Centers for Disease Control and Prevention and the National Institutes of Health, are free of unnecessary duplication of effort.

(e) GRANTS TO SUPPORT SHARED DECISIONMAKING IMPLEMENTATION.—

(1) IN GENERAL.—The Secretary shall establish a program to provide for the phased-in development, implementation, and evaluation of shared decisionmaking using patient decision aids to meet the objective of improving the understanding of patients of their medical treatment options.

(2) SHARED DECISIONMAKING RESOURCE CENTERS.—

(A) IN GENERAL.—The Secretary shall provide grants for the establishment and support of Shared Decisionmaking Resource Centers (referred to in this subsection as "Centers") to provide technical assistance to providers and to develop and disseminate best practices and other information to support and accelerate adoption, implementation, and effective use of patient decision aids and shared decisionmaking by providers.

(B) OBJECTIVES.—The objective of a Center is to enhance and promote the adoption of patient decision aids and shared decisionmaking through—

(i) providing assistance to eligible providers with the implementation and effective use of, and training on, patient decision aids; and

(ii) the dissemination of best practices and research on the implementation and effective use of patient decision aids.

(3) SHARED DECISIONMAKING PARTICIPATION GRANTS.—

(A) IN GENERAL.—The Secretary shall provide grants to health care providers for the development and implementation of shared decisionmaking techniques and to assess the use of such techniques.

(B) PREFERENCE.—In order to facilitate the use of best practices, the Secretary shall provide a preference in making grants under this subsection to health care providers who participate in training by Shared Decisionmaking Resource Centers or comparable training.

(C) LIMITATION.—Funds under this paragraph shall not be used to purchase or implement use of patient deci-

sion aids other than those certified under the process identified in subsection (c).

(4) GUIDANCE.—The Secretary may issue guidance to eligible grantees under this subsection on the use of patient decision aids.

(f) FUNDING.—For purposes of carrying out this section there are authorized to be appropriated such sums as may be necessary for fiscal year 2010 and each subsequent fiscal year.

SEC. 937. [299b–37] DISSEMINATION AND BUILDING CAPACITY FOR RESEARCH.

(a) IN GENERAL.—

(1) DISSEMINATION.—The Office of Communication and Knowledge Transfer (referred to in this section as the "Office") at the Agency for Healthcare Research and Quality (or any other relevant office designated by Agency for Healthcare Research and Quality), in consultation with the National Institutes of Health, shall broadly disseminate the research findings that are published by the Patient Centered Outcomes Research Institute established under section 1181(b) of the Social Security Act (referred to in this section as the "Institute") and other government-funded research relevant to comparative clinical effectiveness research. The Office shall create informational tools that organize and disseminate research findings for physicians, health care providers, patients, payers, and policy makers. The Office shall also develop a publicly available resource database that collects and contains government-funded evidence and research from public, private, not-for profit, and academic sources.

(2) REQUIREMENTS.—The Office shall provide for the dissemination of the Institute's research findings and government-funded research relevant to comparative clinical effectiveness research to physicians, health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans. Materials, forums, and media used to disseminate the findings, informational tools, and resource databases shall—

(A) include a description of considerations for specific subpopulations, the research methodology, and the limitations of the research, and the names of the entities, agencies, instrumentalities, and individuals who conducted any research which was published by the Institute; and

(B) not be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.

(b) INCORPORATION OF RESEARCH FINDINGS.—The Office, in consultation with relevant medical and clinical associations, shall assist users of health information technology focused on clinical decision support to promote the timely incorporation of research findings disseminated under subsection (a) into clinical practices and to promote the ease of use of such incorporation.

(c) FEEDBACK.—The Office shall establish a process to receive feedback from physicians, health care providers, patients, and vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and pri-

vate health plans about the value of the information disseminated and the assistance provided under this section.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall preclude the Institute from making its research findings publicly available as required under section 1181(d)(8) of the Social Security Act.

(e) TRAINING OF RESEARCHERS.—The Agency for Health Care Research and Quality, in consultation with the National Institutes of Health, shall build capacity for comparative clinical effectiveness research by establishing a grant program that provides for the training of researchers in the methods used to conduct such research, including systematic reviews of existing research and primary research such as clinical trials. At a minimum, such training shall be in methods that meet the methodological standards adopted under section 1181(d)(9) of the Social Security Act.

(f) BUILDING DATA FOR RESEARCH.—The Secretary shall provide for the coordination of relevant Federal health programs to build data capacity for comparative clinical effectiveness research, including the development and use of clinical registries and health outcomes research data networks, in order to develop and maintain a comprehensive, interoperable data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records.

(g) AUTHORITY TO CONTRACT WITH THE INSTITUTE.—Agencies and instrumentalities of the Federal Government may enter into agreements with the Institute, and accept and retain funds, for the conduct and support of research described in this part, provided that the research to be conducted or supported under such agreements is authorized under the governing statutes of such agencies and instrumentalities.

PART E—GENERAL PROVISIONS

SEC. 941. [299c] ADVISORY COUNCIL FOR HEALTHCARE RESEARCH AND QUALITY.

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

(b) DUTIES.—

(1) IN GENERAL.—The Advisory Council shall advise the Secretary and the Director with respect to activities proposed or undertaken to carry out the mission 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 21 appropriately qualified individuals. At least 17 members of the Advisory Council shall be representatives of the public who are not officers or employees of the United States and at least 1 member who shall be a specialist in the rural aspects of 1 or more of the professions or fields described in subparagraphs (A) through (G). 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) three shall be individuals distinguished in the conduct of research, demonstration projects, and evaluations with respect to health care;

(B) three shall be individuals distinguished in the fields of health care quality research or health care improvement;

(C) three shall be individuals distinguished in the practice of medicine of which at least one shall be a primary care practitioner;

(D) three shall be individuals distinguished in the other health professions;

(E) three 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;

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

(G) three 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 Centers for Medicare & Medicaid Services, the Commissioner of the Food and Drug Administration, the Director of the Office of Personnel Management, 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.—

(1) IN GENERAL.—Members of the Advisory Council appointed under subsection (c)(2) shall serve for a term of 3 years.

(2) STAGGERED TERMS.—To ensure the staggered rotation of one-third of the members of the Advisory Council each year, the Secretary is authorized to appoint the initial members of the Advisory Council for terms of 1, 2, or 3 years.

(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 members until a successor is appointed.

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

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

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

(h) COMPENSATION AND REIMBURSEMENT OF EXPENSES.—

(1) APPOINTED MEMBERS.—Members of the Advisory Council appointed under subsection (c)(2) shall receive compensation for each day (including travel time) engaged in carrying out the duties of the Advisory Council unless declined by the member. Such compensation may not be in an amount in excess of the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day during which such member is engaged in the performance of the duties of the Advisory Council.

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

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

(j) DURATION.—Notwithstanding section 14(a) of the Federal Advisory Committee Act,[2] the Advisory Council shall continue in existence until otherwise provided by law.

SEC. 942. [299c–1] 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] Section 4(a)(242) of Public Law 117–286 provides for an amendment to "[s]ection 942(j) of the Public Health Service Act (42 U.S.C. 299c(j))" by striking "section 14(a) of the Federal Advisory Committee Act," and inserting "section 1013(a) of title 5, United States Code,". The stricken matter does not appear in section 942(j), however, it does appear in section 941(j).

(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[3], 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

[3] Section 4(a)(243) of Public Law 117–286 provides for an amendment to "[s]ection 941(c)(3) of the Public Health Service Act (42 U.S.C. 299c–1(c)(3))" by striking "section 14(a) of the Federal Advisory Committee Act," and inserting "section 1013(a) of title 5, United States Code,". The stricken matter does not appear in section 941(c)(3), however, it does appear in section 942(c)(3).

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. 943. [299c–2] 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. 944. [299c–3] 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. 945. [299c–4] 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 and 41 U.S.C. 5).

SEC. 946. [299c–5] 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 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 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. 947. [299c–6] 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 2005.

(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.

(d) HEALTH DISPARITIES RESEARCH.—For the purpose of carrying out the activities under section 903, there are authorized to be appropriated $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005.

(e) PATIENT SAFETY AND QUALITY IMPROVEMENT.—For the purpose of carrying out part C, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2006 through 2010.

SEC. 948. [299c–7] DEFINITIONS.

In this title:

(1) ADVISORY COUNCIL.—The term "Advisory Council" means the National Advisory Council on Healthcare Research and Quality established under section 941.

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

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