§ 298d. Authorization of appropriations

For the purpose of carrying out parts B, C, and D (subject to section 297(g) of this title), there are authorized to be appropriated $338,000,000 for fiscal year 2010, and such sums as may be necessary for each of the fiscal years 2011 through 2016.


AMENDMENTS

SUBCHAPTER VII—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

PRIOR PROVISIONS
A prior subchapter VII, related to the Agency for Health Care Policy and Research, was designated subchapter VII of chapter 298 of this title.
§ 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 subchapter 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;

(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 subchapter, 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).

Prior Provisions


Part A—Establishment and General Duties

§ 299. Mission and duties

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(C) existing and innovative technologies;

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(3) Office of Priority Populations

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Prior Provisions


Art. 103A...

Establishment and Duties...

(a) In general...

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(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—

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

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(C) existing and innovative technologies;

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

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

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

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

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(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).

Prior Provisions


Constitutional and Savings Provisions

Section 6103(f) of Pub. L. 101–239 provided that personnel of the Department of Health and Human Services...
employed, and Department assets used in connection with Department functions, on Dec. 19, 1989, be transferred to the Administrator for Health Care Policy and Research for appropriate allocation, and provided that orders, rules, regulations, grants, contracts, certificates, licenses, privileges, and other determinations, actions, or official documents would continue in effect according to their terms unless changed pursuant to law.

IOM REPORTS ON BEST PRACTICES FOR DEVELOPING CLINICAL PROTOCOLS


"(1) Warning. Not later than 90 days after the date of the enactment of this Act [July 15, 2008], the Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine of the National Academies (in this section [this note] referred to as the 'Institute') under which the Institute shall conduct a study on the best methods used in developing clinical practice guidelines in order to ensure that organizations developing such guidelines have information on approaches that are objective, scientifically valid, and consistent.

"(2) Report. Not later than 18 months after the effective date of the contract under paragraph (1), the Institute, as part of such contract, shall submit to the Secretary of Health and Human Services and the appropriate committees of jurisdiction of Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Institute determines appropriate.

"(3) Participation. The contract under paragraph (1) shall require that stakeholders with expertise in making clinical recommendations participate on the panel responsible for conducting the study under paragraph (1) and preparing the report under paragraph (2).

"(4) Identification.

"(A) In general. Following receipt of the report submitted under paragraph (2), and not less than every 3 years thereafter, the Secretary shall contract with the Institute to employ the results of the study performed under paragraph (1) and the best methods identified by the Institute for the purpose of identifying existing and new clinical practice guidelines that were developed using such best methods, including guidelines listed in the National Guideline Clearinghouse.

"(B) Consultation. In carrying out the identification process under subparagraph (A), the Secretary shall allow for consultation with professional societies, voluntary health care organizations, and expert panels.

IOM STUDY ON DRUG SAFETY AND QUALITY


"(1) In general. The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine of the National Academies of Science (such Institutes referred to in this subsection as the 'IOM') to carry out a comprehensive study (in this subsection referred to as the 'study') of drug safety and quality issues in order to provide a blueprint for system-wide change.

"(2) Objectives.

"(A) The study shall develop a full understanding of drug safety and quality issues through an evidence-based review of literature, case studies, and analysis. This review will consider the nature and causes of medication errors, their impact on patients, the differences in causation, impact, and prevention across multiple dimensions of health care delivery-including patient populations, care settings, clinicians, and institutional cultures.

"(B) The study shall attempt to develop credible estimates of the incidence, severity, costs of medication errors that can be useful in prioritizing resources for national quality improvement efforts and influencing national health care policy.

"(C) The study shall evaluate alternative approaches to reducing medication errors in terms of their efficacy, cost-effectiveness, appropriateness in different settings and circumstances, feasibility, institutional barriers to implementation, associated risks, and the quality of evidence supporting the approach.

"(D) The study shall provide guidance to consumers, providers, payers, and other key stakeholders to help set priorities for high-priority strategies to achieve both short-term and long-term drug safety goals, to elucidate the goals and expected results of such initiatives and support the business case for them, and to identify critical success factors and key levers for achieving success.

"(E) The study shall assess the opportunities and key impediments to broad nationwide implementation of medication error reductions, and to provide guidance to policy-makers and government agencies (including the Food and Drug Administration, the Centers for Medicare & Medicaid Services, and the National Institutes of Health) in promoting a national agenda for medication error reduction.

"(F) The study shall develop an applied research agenda to evaluate the health and cost impact of alternative interventions, and to assess collaborative public and private strategies for implementing the research agenda through AHRQ and other government agencies.

"(3) Conduct of study.

"(A) Expert committee. In conducting the study, the IOM shall convene a committee of leading experts and key stakeholders in pharmaceutical management and drug safety, including clinicians, health services researchers, pharmacists, system administrators, payer representatives, and others.

"(B) Completion. The study shall be completed within an 18-month period.

"(4) Report. A report on the study shall be submitted to Congress upon the completion of the study.

"(5) Authorization of Appropriations. There are authorized to be appropriated to carry out this section such sums as may be necessary.

HEALTH CARE THAT WORKS FOR ALL AMERICANS: CITIZENS HEALTH CARE WORKING GROUP

Pub. L. 108–173, title X, §1014, Dec. 8, 2003, 117 Stat. 2441, directed the Secretary of Health and Human Services to establish the Citizens’ Health Care Working Group, composed of the Secretary and 14 other members, which was to hold hearings to examine various public and private health care coverage issues, make final recommendations to the President and Congress, and terminate 2 years after the members were chosen (Feb. 28, 2005) and appropriations were first made available.

EXECUTIVE ORDER NO. 13017


§299a. General authorities

(a) In general

In carrying out section 299(b) of this title, the Director shall conduct and support research, evaluations, and training, support demonstration projects, research networks, and multidisciplinary reviews, and support public health care improvement and health promotion activities.
pital 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) of this section, 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 288(d)(3) of this title 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 299(c)(1)(B) of this title 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) of this section.

(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 [42 U.S.C. 301 et seq.] 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 [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.] shall be carried out consistent with section 1142 of such Act [42 U.S.C. 1320b–12].

(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.


REFERENCES IN TEXT


PRIORITY PROVISIONS


A prior section 902 of act July 1, 1944, was classified to section 299b of this title prior to repeal by Pub. L. 99–117.

AMENDMENTS

1999—Subsec. (g). Pub. L. 106–525 struck out heading and text of subsec. (g). Text read as follows: “Beginning with fiscal year 2003, the Director shall 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.”

REDUCING ADMINISTRATIVE HEALTH CARE COSTS

As part of my Administration’s ongoing effort to reform our health care system, we have reached out to members of both political parties and listened to the concerns many have raised about the need to improve patient safety and to reform our medical liability system. Between 44,000 and 98,000 patients die each year from medical errors. Many physicians continue to struggle to pay their medical malpractice premiums, which vary tremendously by specialty and by State. The cost of insurance continues to be one of the highest practice expenses for some specialties. And although malpractice premiums do not account for a large percentage of total medical costs, many physicians report that fear of lawsuits leads them to practice defensive medicine. But what are the reasons for these premiums and for the growing fears of doctors about liability? And we must work to reduce liability premiums.

We should explore medical liability reform as one way to improve the quality of care and patient-safety practices and to reduce defensive medicine. But whatever steps we pursue, medical liability reform must be just one part of broader health insurance reform—reform that offers more security and stability to Americans who lack coverage, and slows the growth of health care costs for families, businesses, and government.

In recent years, there have been calls from organizations like The Joint Commission and the Institute of Medicine to begin funding demonstration projects that can test a variety of medical liability models and determine which reforms work. These groups and others have identified several important goals and core commitments of malpractice reform that should serve as a starting point for such projects. We must put patient safety first and work to reduce preventable injuries. We must foster better communication between doctors and their patients. We must ensure that patients are compensated in a fair and timely manner for medical injuries, while also reducing the incidence of frivolous lawsuits. And we must work to reduce liability premiums.

In 1999, the Congress authorized the Agency for Healthcare Research and Quality, which is located within the Department of Health and Human Services, to support demonstration projects and to evaluate the effectiveness of projects regarding all aspects of health care, including medical liability. I hereby request that you announce, within 30 days of this memorandum, that the Department will make available demonstration grants to States, localities, and health systems for the development, implementation, and evaluation of alternatives to our current medical liability system, consistent with the goals and core commitments outlined above.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entitities, its officers, employees, or agents, or any other person.

You are authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

§ 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 299a(c) of this title, 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) of this section, 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 multi-disciplinary 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 254b of this title 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 chapter, the Director shall consult with the heads of the relevant agencies of the Public Health Service.

(3) Report

Not later than 36 months after November 22, 2000, 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 quality 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 285t of this title, 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 300a–6 of this title.


Prior Provisions


A prior section 903 of act July 1, 1944, was classified to section 299c of this title prior to repeal by Pub. L. 99–117.

Prior sections 299a–2 and 299a–3 were omitted in the general amendment of this subchapter by Pub. L. 106–129.


Section 299a–3, act July 1, 1944, ch. 373, title IX, §905, as added Pub. L. 105–115, title IV, §409, Nov. 21, 1997, 111 Stat. 2371, established demonstration program regarding centers for education and research on therapeutics. See section 299b–1(b) of this title.

Amendments


PART B—HEALTH CARE IMPROVEMENT RESEARCH

§ 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.

(July 1, 1944, ch. 373, title IX, §911, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1656.)

PRIOR PROVISIONS


§ 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 of this subchapter, 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.


Prior Provisions


Amendments


§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 299(c) of this title; 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) of this section will—

(A) identify determinants of health outcomes and functional status, including the health care needs of populations identified in section 299(c) of this title, 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 December 6, 1999, 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.

(701, 1944, ch. 373, title IX, §913, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1658.)

Codification

December 6, 1999, referred to in subsec. (b)(1), was in the original “the date of the enactment of this title”, which was translated as meaning the date of enactment of Pub. L. 106–129, which amended this subchapter generally, to reflect the probable intent of Congress.

Prior Provisions

A prior section 299b–2, act July 1, 1944, ch. 373, title IX, §913, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1658.)

§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.

(July 1, 1944, ch. 373, title IX, § 914, as added Pub. L. 106-129, § 2(a), Dec. 6, 1999, 113 Stat. 1658.)

Prior Provisions

§ 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’s 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 supporting 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.
§ 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
§ 299b–6

(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).


Amendments

§ 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 health services research and health care quality improvement initiatives;
(B) strengthen the research information infrastructure, including databases, pertaining to Federal health services research and health care quality improvement 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 [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.]; 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 December 6, 1999, 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 December 6, 1999, 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 Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Commerce of the House of Representatives.

(REFERENCE IN TEXT)

(CODIFICATION)
December 6, 1999, referred to in subsec. (b)(2)(A), was in the original “the date of the enactment of this title”, which was translated as meaning the date of enactment of Pub. L. 106–129, which amended this subchapter generally, to reflect the probable intent of Congress.

CHANGE OF NAME
Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

§ 299b–7. Research on outcomes of health care items and services
(a) Research, demonstrations, and evaluations
(1) Improvement of effectiveness and efficiency
(A) In general
To improve the quality, effectiveness, and efficiency of health care delivered pursuant to the programs established under titles XVIII, XIX, and XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.], the Secretary acting through the Director of the Agency for Healthcare Research and Quality (in this section referred to as the “Director”), shall conduct and support research to meet the priorities and requests for scientific evidence and information identified by such programs with respect to—
(i) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs); and
(ii) strategies for improving the efficiency and effectiveness of such programs, including the ways in which such items and services are organized, managed, and delivered under such programs.
(B) Specification
To respond to priorities and information requests in subparagraph (A), the Secretary may conduct or support, by grant, contract, or interagency agreement, research, demonstrations, evaluations, technology assessments, or other activities, including the provision of technical assistance, scientific expertise, or methodological assistance.
(2) Priorities
(A) In general
The Secretary shall establish a process to develop priorities that will guide the research, demonstrations, and evaluation activities undertaken pursuant to this section.
(B) Initial list
Not later than 6 months after December 8, 2003, the Secretary shall establish an initial list of priorities for research related to health care items and services (including prescription drugs).
(C) Process
In carrying out subparagraph (A), the Secretary—
(i) shall ensure that there is broad and ongoing consultation with relevant stakeholders in identifying the highest priorities for research, demonstrations, and evaluations to support and improve the programs established under titles XVIII, XIX, and XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.];

1 So in original. Probably should be followed by a comma.
(ii) may include health care items and services which impose a high cost on such programs, as well as those which may be underutilized or overutilized and which may significantly improve the prevention, treatment, or cure of diseases and conditions (including chronic conditions) which impose high direct or indirect costs on patients or society; and

(iii) shall ensure that the research and activities undertaken pursuant to this section are responsive to the specified priorities and are conducted in a timely manner.

(3) Evaluation and synthesis of scientific evidence

(A) In general

The Secretary shall—

(i) evaluate and synthesize available scientific evidence related to health care items and services (including prescription drugs) identified as priorities in accordance with paragraph (2) with respect to the comparative clinical effectiveness, outcomes, appropriateness, and provision of such items and services (including prescription drugs);

(ii) identify issues for which existing scientific evidence is insufficient with respect to such health care items and services (including prescription drugs);

(iii) disseminate to prescription drug plans and MA–PD plans under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.], other health plans, and the public the findings made under clauses (i) and (ii); and

(iv) work in voluntary collaboration with public and private sector entities to facilitate the development of new scientific knowledge regarding health care items and services (including prescription drugs).

(B) Initial research

The Secretary shall complete the evaluation and synthesis of the initial research required by the priority list developed under paragraph (2) not later than 18 months after the development of such list.

(C) Dissemination

(i) In general

To enhance patient safety and the quality of health care, the Secretary shall make available and disseminate in appropriate formats to prescription drugs plans under part D, and MA–PD plans under part C, of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq., 1395w–21 et seq.], other health plans, and the public the evaluations and syntheses prepared pursuant to subparagraph (A) and the findings of research conducted pursuant to paragraph (1). In carrying out this clause the Secretary, in order to facilitate the availability of such evaluations and syntheses or findings at every decision point in the health care system, shall—

(I) present such evaluations and syntheses or findings in a form that is easily understood by the individuals receiving health care items and services (including prescription drugs) under such plans and periodically assess that the requirements of this subclause have been met; and

(II) provide such evaluations and syntheses or findings and other relevant information through easily accessible and searchable electronic mechanisms, and in hard copy formats as appropriate.

(ii) Rule of construction

Nothing in this section shall be construed as—

(I) affecting the authority of the Secretary or the Commissioner of Food and Drugs under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the Public Health Service Act [42 U.S.C. 201 et seq.]; or

(II) conferring any authority referred to in subclause (I) to the Director.

(D) Accountability

In carrying out this paragraph, the Secretary shall implement activities in a manner that—

(i) makes publicly available all scientific evidence relied upon and the methodologies employed, provided such evidence and method are not protected from public disclosure by section 1905 of title 18 or other applicable law so that the results of the research, analyses, or syntheses can be evaluated or replicated; and

(ii) ensures that any information needs and unresolved issues identified in subparagraph (A)(ii) are taken into account in priority-setting for future research conducted by the Secretary.

(4) Confidentiality

(A) In general

In making use of administrative, clinical, and program data and information developed or collected with respect to the programs established under titles XVIII, XIX, and XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.], for purposes of carrying out the requirements of this section or the activities authorized under title IX of the Public Health Service Act [42 U.S.C. 299 et seq.], such data and information shall be protected in accordance with the confidentiality requirements of title IX of the Public Health Service Act.

(B) Rule of construction

Nothing in this section shall be construed to require or permit the disclosure of data provided to the Secretary that is otherwise protected from disclosure under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], section 1905 of title 18, or other applicable law.

(5) Evaluations

The Secretary shall conduct and support evaluations of the activities carried out under this section to determine the extent to which such activities have had an effect on outcomes.
and utilization of health care items and services.

(6) Improving information available to health care providers, patients, and policymakers

Not later than 18 months after December 8, 2003, the Secretary shall identify options that could be undertaken in voluntary collaboration with private and public entities (as appropriate) for the—

(A) provision of more timely information through the programs established under titles XVIII, XIX, and XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.], regarding the outcomes and quality of patient care, including clinical and patient-reported outcomes, especially with respect to interventions and conditions for which clinical trials would not be feasible or raise ethical concerns that are difficult to address;

(B) acceleration of the adoption of innovation and quality improvement under such programs; and

(C) development of management tools for the programs established under titles XIX and XXI of the Social Security Act [42 U.S.C. 1396 et seq., 1397aa et seq.], and with respect to the programs established under such titles, assess the feasibility of using administrative or claims data, to—

(i) improve oversight by State officials;

(ii) support Federal and State initiatives to improve the quality, safety, and efficiency of services provided under such programs; and

(iii) provide a basis for estimating the fiscal and coverage impact of Federal or State program and policy changes.

(b) Recommendations

(1) Disclaimer

In carrying out this section, the Director shall—

(A) not mandate national standards of clinical practice or quality health care standards; and

(B) include in any recommendations resulting from projects funded and published by the Director, a corresponding reference to the prohibition described in subparagraph (A).

(2) Requirement for implementation

Research, evaluation, and communication activities performed pursuant to this section shall reflect the principle that clinicians and patients should have the best available evidence upon which to make choices in health care items and services, in providers, and in health care delivery systems, recognizing that patient subpopulations and patient and physician preferences may vary.

(3) Rule of construction

Nothing in this section shall be construed to provide the Director with authority to mandate a national standard or require a specific approach to quality measurement and reporting.

(c) Research with respect to dissemination

The Secretary, acting through the Director, may conduct or support research with respect to improving methods of disseminating information in accordance with subsection (a)(3)(C) of this section.

(d) Limitation on CMS

The Administrator of the Centers for Medicare & Medicaid Services may not use data obtained in accordance with this section to withhold coverage of a prescription drug.

(e) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2004, and such sums as may be necessary for each fiscal year thereafter.


References in Text

The Social Security Act, referred to in this section, is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. Parts C and D of title XVIII of the Act are classified generally to parts C (§1395w–21 et seq.) and D (§1395w–101 et seq.), respectively, of subchapter XVIII of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a)(3)(C), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Public Health Service Act, referred to in subsec. (a)(3)(C)(ii), is act June 25, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 1305 of this title and Tables.


(a) Establishment

There is hereby established a Federal Coordinating Council for Comparative Effectiveness Research (in this section referred to as the “Council”).

(b) Purpose

The Council shall foster optimum coordination of comparative effectiveness and related health services research conducted or supported by relevant Federal departments and agencies, with the goal of reducing duplicative efforts and encouraging coordinated and complementary use of resources.

(c) Duties

The Council shall—
(1) assist the offices and agencies of the Federal Government, including the Departments of Health and Human Services, Veterans Affairs, and Defense, and other Federal departments or agencies, to coordinate the conduct or support of comparative effectiveness and related health services research; and
(2) advise the President and Congress on—
(A) strategies with respect to the infrastructure needs of comparative effectiveness research within the Federal Government; and
(B) organizational expenditures for comparative effectiveness research by relevant Federal departments and agencies.

(d) Membership

(1) Number and appointment
The Council shall be composed of not more than 15 members, all of whom are senior Federal officers or employees with responsibility for health-related programs, appointed by the President, acting through the Secretary of Health and Human Services (in this section referred to as the “Secretary”). Members shall first be appointed to the Council not later than 30 days after February 17, 2009.

(2) Members

(A) In general
The members of the Council shall include one senior officer or employee from each of the following agencies:
(i) The Agency for Healthcare Research and Quality.
(ii) The Centers for Medicare and Medicaid Services.
(iii) The National Institutes of Health.
(iv) The Office of the National Coordinator for Health Information Technology.
(v) The Food and Drug Administration.
(vi) The Veterans Health Administration within the Department of Veterans Affairs.
(vii) The office within the Department of Defense responsible for management of the Department of Defense Military Health Care System.

(B) Qualifications
At least half of the members of the Council shall be physicians or other experts with clinical expertise.

(3) Chairman; Vice Chairman
The Secretary shall serve as Chairman of the Council and shall designate a member to serve as Vice Chairman.

(e) Reports

(1) Initial report
Not later than June 30, 2009, the Council shall submit to the President and the Congress a report containing information describing current Federal activities on comparative effectiveness research and recommendations for such research conducted or supported from funds made available for allotment by the Secretary for comparative effectiveness research in this Act.

(2) Annual report
The Council shall submit to the President and Congress an annual report regarding its activities and recommendations concerning the infrastructure needs, organizational expenditures and opportunities for better coordination of comparative effectiveness research by relevant Federal departments and agencies.

(f) Staffing; support
From funds made available for allotment by the Secretary for comparative effectiveness research in this Act, the Secretary shall make available not more than 1 percent to the Council for staff and administrative support.

(g) Rules of construction

(1) Coverage
Nothing in this section shall be construed to permit the Council to mandate coverage, reimbursement, or other policies for any public or private payer.

(2) Reports and recommendations
None of the reports submitted under this section or recommendations made by the Council shall be construed as mandates or clinical guidelines for payment, coverage, or treatment.


REFERENCES IN TEXT
This Act, referred to in subsecs. (e)(1) and (f), is div. A of Pub. L. 111–5, Feb. 17, 2009, 123 Stat. 116. For complete classification of this Act to the Code, see Tables.

CODIFICATION
Section was enacted as part of the American Recovery and Reinvestment Act of 2009, and not as part of the Public Health Service Act which comprises this chapter.

TERMINATION OF FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH

PART C—PATIENT SAFETY IMPROVEMENT

§ 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 299b–22(e) of this title.

(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 299b–24(d) of this title.

(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.


REFERENCES IN TEXT
Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in par. (1), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

PRIOR PROVISIONS
A prior section 921 of act July 1, 1944, was renumbered section 941 and is classified to section 299c of this title.
§ 299b-22. Privilege and confidentiality protections

(a) Privilege

Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, 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 discovery pursuant to section 552 of title 5 (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 rule-making 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) of this section, patient safety work product shall be confidential and shall not be disclosed.

(c) Exceptions

Except as provided in subsection (g)(3) of this section—

(1) Exceptions from privilege and confidentiality

Subsections (a) and (b) of this section 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) of this section.

(2) Exceptions from confidentiality

Subsection (b) of this section 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) of this section 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) of this section shall continue to be privileged and confidential as provided for in subsections (a) and (b) of this section, 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) of this section shall no longer apply to the work product so disclosed; and
(B) if patient safety work product is disclosed as provided for in subsections (a) and (b) of this section, the privilege and confidentiality protections provided for in subsections (a) and (b) of this section 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 subsections (a) and (b) of this section with respect to patient safety work product other than the specific patient safety work product disclosed as provided for in subsection (c) of this section.

(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) of this section.

(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) of this section 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 1320a–7a of this title, 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 1320a–7a of this title.

(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) of this section 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) of this section 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) of this section, to alter or affect the implementation of any provision of the HIPAA confidentiality regulations or section 1320d–5 of this title (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;
bases 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 this section 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 [42 U.S.C. 1320d et seq.].

(c) Use of information

Information reported to and among the network of patient safety databases under subsection (a) of this section 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 299b–2(b)(2) of this title.

(July 1, 1944, ch. 373, title IX, § 923, as added Pub. L. 109–41, §2(a)(5), July 29, 2005, 119 Stat. 431.)

REFERENCES IN TEXT


PRIOR PROVISIONS

A prior section 923 of act July 1, 1944, was renumbered section 943 and is classified to section 299c–2 of this title.

Another prior section 923 of act July 1, 1944, was classified to section 299c–2 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§ 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 299b–21(5) of this title; and

(B) upon being listed under subsection (d) of this section, will comply with the criteria described in subsection (b) of this section.
§ 299b–24

(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) of this section a subsequent certification to the Secretary that the entity:
(A) is performing each of the patient safety activities described in section 299b–21(b) of this title; and
(B) is complying with the criteria described in subsection (b) of this section.

(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) of this section, 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 300gg–91(b)(2) of this title).
(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) of this section, 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) of this section, 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 therefore.

(3) Disclosures regarding relationship to providers
The Secretary shall consider any disclosures under subsection (b)(1)(E) of this section 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) of this section 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) of this section that has not been revoked under subsection (e) of this section 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) of this section, 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 ac-
tions 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) of this section; 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 299b–22 of this title, data submitted to an entity within 30 days after the entity is removed from the listing under subsection (e)(3)(A) of this section 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 299b–22 of this title 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) of this section.

(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) of this section, with respect to the patient safety work product or data described in subsection (f)(1) of this section 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.

(3) Prior provisions
A prior section 925 of act July 1, 1944, was renumbered section 926 and is classified to section 299b–3 of this title.

Another prior section 925 of act July 1, 1944, was renumbered section 946 and is classified to section 299c–4 of this title.

§ 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, non-governmental 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 237a(b)(4) of this title).

(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.

(3) Prior provisions
A prior section 925 of act July 1, 1944, was renumbered section 926 and is classified to section 299b–25 of this title.

Another prior section 925 of act July 1, 1944, was renumbered section 945 and is classified to section 299c–4 of this title.

Another prior section 925 of act July 1, 1944, was classified to section 299c–4 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§ 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.

(3) Prior provisions
A prior section 926 of act July 1, 1944, was renumbered section 927 and is classified to section 299b–26 of this title.

Another prior section 926 of act July 1, 1944, was renumbered section 945 and is classified to section 299c–5 of this title.
§ 299b–26. Severability

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


§ 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 280j of this title, 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 [42 U.S.C. 1395aaa(a)] and other stakeholders;

(B) quality measures identified by the pediatric quality measures program under section 1139A of the Social Security Act [42 U.S.C. 1320b–9a]; and

(C) quality measures identified through the Medicaid Quality Measurement Program under section 1139B of the Social Security Act [42 U.S.C. 1320b–9b].

(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 decision-making tools and preference sensitive care (as defined in section 299b–36 of this title) and geographic areas;

(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 285t of this title) and geographic areas;

(H) patient experience and satisfaction;

(I) the use of innovative strategies and methodologies identified under section 299b–33 of this title; 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 [42 U.S.C. 1395aaa(a)] 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

See References in Text note below.
the entity with a contract under such section 11390(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 [42 U.S.C. 1320b–9a] and the Medicare Quality Measurement Program under section 1139B of the Social Security Act [42 U.S.C. 1320b–9b], where applicable.

(B) Such measures support measures developed under section 1139A of the Social Security Act [42 U.S.C. 1320b–9a] and the Medicaid Quality Measurement Program under section 1139B of such Act [42 U.S.C. 1320b–9b], 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 11390(a) of the Social Security Act [42 U.S.C. 1395aaa(a)] 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 March 23, 2010, 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 March 23, 2010, the Secretary shall develop not less than 10 measures described in paragraph (2)(B).


REFERENCES IN TEXT
Section 285t of this title, referred to in subsec. (c)(2)(G), was in the original “section 485E”, meaning section 485E of act July 1, 1944, which was renumbered section 464E–3 by Pub. L. 111–148, title X, §10334(c)(1)(D)(i), Mar. 23, 2010, 124 Stat. 973, and is classified to section 285t of this title. The act of July 1, 1944, no longer contains a section 485E.


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.

The purposes of this section are to—

(a) Purpose

(b) General functions of the Center

The Center for Quality Improvement and Patient Safety of the Agency for Healthcare Re-
search 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 efficiency 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 280j of this title;

(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 1395aaa(a) of this title in the report required under section 280j–2 of this title;

(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 Enterococcus 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 1320b–9a of this title 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 efficiency 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 300jj–32 of this title, 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 300ij of this title. (f) Coordination The Center shall coordinate its activities with activities conducted by the Center for Medicare and Medicaid Innovation established under section 1315a of this title. (g) Funding There is authorized to be appropriated to carry out this section $20,000,000 for fiscal years 2010 through 2014. (July 1, 1944, ch. 373, title IX, § 933, as added Pub. L. 111–148, title III, § 3501, Mar. 23, 2010, 124 Stat. 508.) Prior Provisions A prior section 933 of act July 1, 1944, was renumbered section 943 and is classified to section 299c–2 of this title. § 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 280g–12 of this title, a Federal Indian Health Service pro-
gram or a health program operated by an Indian tribe (as defined in section 1603 of title 25), 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 of 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 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 299b–3 of this title;

(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 300jj–32(c) of this title and the primary care extension program established under section 280g–12 of this title regarding the dissemination of quality improvement, system delivery reform, and best practices information.

(july 1, 1944, ch. 373, title ix, §934, as added and amended pub. l. 111–148, title iii, §3501, title x, §10501(f)(3), mar. 23, 2010, 124 stat. 511, 996.)

Prior provisions

A prior section 934 of act July 1, 1944, was renumbered section 944 and is classified to section 299c–3 of this title.

Amendments


§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 299b–33 of this title (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, multi-disciplinary, 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 256a–1 of this title or in collaboration with primary care extension programs established in section 280g–12 of this title;
(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 1395aaa of this title, 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.

(b) Grants or contracts to fund development of performance measures

The Secretary may, through the quality measure development program under section 299b–31 of this title, 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.


PRIOR PROVISIONS

A prior section 935 of act July 1, 1944, was renumbered section 945 and is classified to section 299c–4 of this title.

AMENDMENTS


§ 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 1395aaa of this title. Such contract shall provide that the entity perform the duties described in paragraph (2).

(B) Timing for first contract

As soon as practicable after March 23, 2010, 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 produce 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, rel-

1 So in original. Probably should be “engage”.
2 So in original. Probably should be “provide”.
3 So in original. Probably should be “facilitate”.
4 So in original. Probably should be “option. The”.
5 So in original.
§ 299b–37

TITLE 42—THE PUBLIC HEALTH AND WELFARE

Page 892

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 decision 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.


PRIOR PROVISIONS

A prior section 936 of act July 1, 1944, was renumbered section 946 and is classified to section 299c–5 of this title.

§ 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
clinical decision support to promote the timely
dissemination of health information technology focused on
clinical and clinical associations, shall assist users
in the incorporation of research findings disseminated
under subsection (a) into clinical practices and
to promote the ease of use of such incorpo-
ration.

(2) Requirements

The Office shall provide for the dissemina-
tion of the Institute’s research findings and
government-funded research relevant to com-
parative clinical effectiveness research to phy-
sicians, health care providers, patients, vend-
ers of health information technology focused on
clinical decision support, appropriate profes-
sional 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 re-
search, and the names of the entities, agen-
cies, instrumentalities, and individuals who
directed any research which was published
by the Institute; and
(B) not be construed as mandates, guide-
lines, or recommendations for payment, cov-
erage, or treatment.

(b) Incorporation of research findings

The Office, in consultation with relevant med-
ical 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 incorpora-
tion.

(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 Fed-
eral and private 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 In-
istitute from making its research findings pub-
lcally available as required under section
1320e(d)(8) of this title.

(e) Training of researchers

The Agency for Health Care Research and
Quality, in consultation with the National Insti-
tutes of Health, shall build capacity for com-
parative clinical effectiveness research by estab-
lishing a grant program that provides for the
training of researchers in the methods used to
conduct such research, including systematic re-
views 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
1320e(d)(9) of this title.

(f) Building data for research

The Secretary shall provide for the coordina-
tion of relevant Federal health programs to
build data capacity for comparative clinical ef-
fectiveness research, including the development
and use of clinical registries and health out-
comes research data networks, in order to de-
velop and maintain a comprehensive, interop-
erable data network to collect, link, and analyze
data on outcomes and effectiveness from mul-
tiple 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 con-
ducted or supported under such agreements is
authorized under the governing statutes of such
agencies and instrumentalities.

(July 1, 1944, ch. 73, title IX, § 937, as added Pub.
L. 111–148, title VI, § 6301(b), Mar. 23, 2010, 124
Stat. 738.)

Prior Provisions

A prior section 937 of act July 1, 1944, was renumbered
section 947 and is classified to section 299e–6 of this
title.

PART E—GENERAL PROVISIONS

Amendments

2010—Pub. L. 111–148, title III, § 3013(a)(1), Mar. 23,
2010, 124 Stat. 381, redesignated part D “General Provi-
sions” as E.

424, redesignated part C “General Provisions” as D.

§ 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 Sec-
retary and the Director with respect to activi-
ties proposed or undertaken to carry out the
mission of the Agency under section 299(b) of
this title.

(2) Certain recommendations

Activities of the Advisory Council under
paragraph (1) shall include making recom-
mendations to the Director regarding—
(A) priorities regarding health care re-
search, 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 re-
lated disciplines, especially issues related to
training needs, and dissemination of infor-
mation 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 subchapter and under section 1320b–12 of this title. 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) of this section 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) of this section 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) of this section does not serve the full term applicable under subsection (d) of this section, 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) of this section, 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) of this section 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 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) of this section 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, the Advisory Council
shall continue in existence until otherwise provided by law.


REFERENCES IN TEXT
Section 14(a) of the Federal Advisory Committee Act, referred to in subsec. (j), is section 14(a) of Pub. L. 92–463, which is set out in the Appendix to Title 5.

PRIOR PROVISIONS

$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 subchapter.

(2) Reports to Director

Each peer review group to which an application is submitted pursuant to paragraph (1) shall report its findings 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) of this section unless the application is recommended for approval by a peer review group established under subsection (c) of this section.

(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 that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

(2) Membership

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

(3) Duration

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

(4) Qualifications

Members of any peer review group shall, at a minimum, meet the following requirements:

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

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

(d) Authority for procedural adjustments in certain cases

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

(e) Regulations

The Director shall issue regulations for the conduct of peer review under this section.

(References in Text)

The provisions of title 5 that govern appointments in the competitive service, referred to in subsec. (c)(1), are classified generally to section 3301 et seq. of Title 5, Government Organization and Employees. Section 14(a) of the Federal Advisory Committee Act, referred to in subsec. (c)(3), is section 14(a) of Pub. L. 92–463, which is set out in the Appendix to Title 5.
§ 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 299(b) of this title, the Director shall establish standards 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 [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.], or may affect health information that is subject to a standard developed under part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.,], 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 subchapter are of high quality, timely, and clearly 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 subchapter 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.


References in Text

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) of this section 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 1320a–7a of this title are imposed and collected.


PRIOR PROVISIONS


§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 subchapter, 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 subchapter 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 subchapter, 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 section 3324(a) and (b) of title 31 and section 6101 of title 41.


CODIFICATION


PRIOR PROVISIONS


§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 subchapter. 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.

(b) Facilities

The Secretary, in carrying out this subchapter—

(1) may acquire, without regard to section 8141 of title 40, 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 subchapter, may make grants to public and nonprofit enti-
ties 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 subchapter, 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 subchapter, 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 subchapter, may secure, from time to time and for such periods as the Director deems advisable but in accordance with section 3109 of title 5, the assistance and advice of consultants from the United States or abroad.

(f) Experts

(1) In general

The Secretary may, in carrying out this subchapter, 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, 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 3724, 5724a(a), 5724a(c), and 5726(c) of title 5.

(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 subchapter, may accept voluntary and uncompensated services.


CODIFICATION


PRIOR PROVISIONS


§ 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) of this section 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 subchapter, 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) of this section for carrying out this subchapter, there shall be made available for such purpose, from the amounts made available pursuant to section 238 of this title (relating to evaluations), an amount equal to 40 percent of the maximum amount authorized in such section 238 of this title to be made available for a fiscal year.

(d) Health disparities research

For the purpose of carrying out the activities under section 299a–1 of this title, 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 of this subchapter, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2006 through 2010.
§ 299c–7. Definitions

In this subchapter:

(1) **Advisory Council**

The term "Advisory Council" means the National Advisory Council on Healthcare Research and Quality established under section 299c of this title.

(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.

(300) **Project grants and contracts for family planning services**

(a) **Authority of Secretary**

The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practical, entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection.

(b) **Factors determining awards; establishment and preservation of rights of local and regional entities**

In making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c) **Reduction of grant amount**

The Secretary, at the request of a recipient of a grant under subsection (a) of this section, may reduce the amount of such grant by the fair

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1 So in original. Probably should be "family".