

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

Pub. L. 110-275, title III, §304(b), July 15, 2008, 122 Stat. 2595, as amended by Pub. L. 111-148, title X, §10303(c), Mar. 23, 2010, 124 Stat. 938, provided that:

“(1) **STUDY.**—Not later than 60 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

Pub. L. 108-173, title I, §107(c), Dec. 8, 2003, 117 Stat. 2170, provided that:

“(1) **IN GENERAL.**—The Secretary [of Health and Human Services] shall enter into a contract with the Institutes 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 medica-

tion 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 on 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 impacts 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

Ex. Ord. No. 13017, Sept. 5, 1996, 61 F.R. 47659, as amended by Ex. Ord. No. 13040, Mar. 25, 1997, 62 F.R. 14773; Ex. Ord. No. 13056, July 21, 1997, 62 F.R. 39415, which established the Advisory Commission on Consumer Protection and Quality in the Health Care Industry, was revoked by Ex. Ord. No. 13138, §3(a), Sept. 30, 1999, 64 F.R. 53880, formerly set out as a note under section 14 of the Federal Advisory Committee Act in the Appendix to Title 5, Government Organization and Employees.

§ 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 multidisci-

plinary centers, provide technical assistance, and disseminate information on health care and on systems for the delivery of such care, including activities with respect to—

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

(b) Health services training grants

(1) In general

The Director may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate. In carrying out this subsection, the Director shall make use of funds made available under section 288(d)(3)¹ 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).

(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.

(July 1, 1944, ch. 373, title IX, §902, as added Pub. L. 106-129, §2(a), Dec. 6, 1999, 113 Stat. 1654; amended Pub. L. 106-525, title II, §201(a)(1), Nov. 22, 2000, 114 Stat. 2505.)

REFERENCES IN TEXT

Section 288(d)(3) of this title, referred to in subsec. (b)(1), was repealed by Pub. L. 109-482, title I, §103(b)(47), Jan. 15, 2007, 120 Stat. 3688.

The Social Security Act, referred to in subsec. (d), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, which is classified generally to chapter 7 (§301 et seq.) of this title. 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. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Social Security Amendments of 1967, referred to in subsec. (d), is Pub. L. 90-248, Jan. 2, 1968, 81 Stat. 821, as amended. For complete classification of this Act to the Code, see Short Title of 1968 Amendment note set out under section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 299a, act July 1, 1944, ch. 373, title IX, §902, as added Pub. L. 101-239, title VI, §6103(a), Dec. 19, 1989, 103 Stat. 2189; amended Pub. L. 101-639, §3(d), Nov. 28, 1990, 104 Stat. 4603; Pub. L. 102-410, §2(b), Oct. 13, 1992, 106 Stat. 2094, required Administrator to conduct and support research, demonstration projects, evaluations, training, guideline development, and dissemination of information on health care services and on systems for delivery of such services, prior to the general amendment of this subchapter by Pub. L. 106-129.

Another prior section 299a, act July 1, 1944, ch. 373, title IX, §901, as added Oct. 6, 1965, Pub. L. 89-239, §2, 79 Stat. 926; amended Oct. 15, 1968, Pub. L. 90-574, title I, §§101, 102, 107, 82 Stat. 1005, 1006; June 30, 1970, Pub. L. 91-296, title IV, §401(b)(1)(F), 84 Stat. 352; Oct. 30, 1970, Pub. L. 91-515, title I, §103, 84 Stat. 1298; June 18, 1973, Pub. L. 93-45, title I, §110, 87 Stat. 93, authorized appropriations for grants and contracts to carry out purposes of this subchapter and set forth extent of and limitations on grants, prior to repeal by Pub. L. 99-117, §12(d), Oct. 7, 1985, 99 Stat. 495.

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

2000—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."

¹ See References in Text note below.

REDUCING ADMINISTRATIVE HEALTH CARE COSTS

Pub. L. 103-43, title XIX, § 1909, June 10, 1993, 107 Stat. 205, as amended by Pub. L. 106-129, § 2(b)(2), Dec. 6, 1999, 113 Stat. 1670; Pub. L. 108-173, title IX, § 900(e)(6)(F), Dec. 8, 2003, 117 Stat. 2374, provided that: “The Secretary of Health and Human Services, acting through the Agency for Healthcare Research and Quality and, to the extent possible, in consultation with the Centers for Medicare & Medicaid Services, may fund research to develop a text-based standardized billing process, through the utilization of text-based information retrieval and natural language processing techniques applied to automatic coding and analysis of textual patient discharge summaries and other text-based electronic medical records, within a parallel general purpose (shared memory) high performance computing environment. The Secretary shall determine whether such a standardized approach to medical billing, through the utilization of the text-based hospital discharge summary as well as electronic patient records can reduce the administrative billing costs of health care delivery.”

DEMONSTRATION GRANTS FOR THE DEVELOPMENT, IMPLEMENTATION, AND EVALUATION OF ALTERNATIVES TO THE CURRENT MEDICAL LIABILITY SYSTEM

Memorandum of President of the United States, Sept. 17, 2009, 74 F.R. 48133, provided:

Memorandum for the Secretary of Health And Human Services

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, which may contribute to higher costs.

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 have insurance, offers insurance 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, con-

sistent 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 entities, 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), 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 dis-