A prior section 298c-7, act July 1, 1944, ch. 373, title VIII, §868, as added Nov. 3, 1966, Pub. L. 89-751, §8(b), 80 Stat. 1239; amended Nov. 18, 1971, Pub. L. 92-158, §8, 85 Stat. 478; July 29, 1975, Pub. L. 94-63, title IX, §902(g), 89 Stat. 355, authorized grants and contracts to encourage full utilization of educational talent for nursing profession and authorized appropriations from fiscal year ending June 30, 1972 through fiscal year ending June 30, 1975 for implementation, prior to repeal by Pub. L. 94-63, title IX, §\$905, 931(b), July 29, 1975, 89 Stat. 355, 362, effective July 1, 1975.

A prior section 298c-8, act July 1, 1944, ch. 373, title VIII, §869, as added Nov. 3, 1966, Pub. L. 89-751, §8(b), 80 Stat. 1240, defined "academic year", prior to repeal by Pub. L. 94-63, title IX, §§941(j)(4), 942, July 29, 1975, 89 Stat. 366, 367, effective July 1, 1975.

#### AMENDMENTS

2010—Subsec. (b)(5). Pub. L. 111–148, \$5305(c)(1), added par. (5).

Subsec. (e). Pub. L. 111-148, \$5305(c)(2), substituted "2010 through 2014" for "2003 through 2007".

#### PART I—FUNDING

#### PRIOR PROVISIONS

A prior part I, consisting of section 298, was redesignated part H of this subchapter.

#### AMENDMENTS

2010—Pub. L. 111–148, title V, \$5310(b)(7), Mar. 23, 2010, 124 Stat. 631, redesignated part F "Funding" as I.

### § 298d. Authorization of appropriations

For the purpose of carrying out parts B, C, and D (subject to section 297t(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

(July 1, 1944, ch. 373, title VIII, §871, formerly §841, as added Pub. L. 105–392, title I, §123(5), Nov. 13, 1998, 112 Stat. 3569; renumbered §871 and amended Pub. L. 111–148, title V, §§5310(b)(7), 5312, Mar. 23, 2010, 124 Stat. 631, 633.)

## CODIFICATION

Section was classified to section 297q of this title prior to renumbering by Pub. L. 111-148.

## AMENDMENTS

2010—Pub. L. 111–148, §5312, amended section generally. Prior to amendment, section related to authorization of appropriations for fiscal years 1998 through 2002, allocations of amounts, and use of methodology.

# SUBCHAPTER VII—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

## PRIOR PROVISIONS

A prior subchapter VII, related to the Agency for Health Care Policy and Research and consisted of sections 299 to 299c-6, prior to the general amendment of this subchapter by Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1653.

Another prior subchapter VII, related to education, research, training, and demonstrations in heart disease, cancer, stroke, and related diseases and consisted of sections 299 to 299j, prior to repeal by Pub. L. 99–117, § 12(d), Oct. 7, 1985, 99 Stat. 495.

PART A—ESTABLISHMENT AND GENERAL DUTIES

## § 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 costeffectiveness of health care practices, including preventive measures and long-term
    - (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 innercity 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).

(July 1, 1944, ch. 373, title IX, §901, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1653.)

#### PRIOR PROVISIONS

A prior section 299, act July 1, 1944, ch. 373, title IX, §901, as added Pub. L. 101–239, title VI, §6103(a), Dec. 19, 1989, 103 Stat. 2189; amended Pub. L. 102–410, §2(a), Oct. 13, 1992, 106 Stat. 2094, established the Agency for Health Care Policy and Research, prior to the general amendment of this subchapter by Pub. L. 106–129.

Another prior section 299, act July 1, 1944, ch. 373, title IX, \$900, as added Oct. 6, 1965, Pub. L. 89–239, \$2, 79 Stat. 926; amended Oct. 30, 1970, Pub. L. 91–515, title I, \$102, 84 Stat. 1297, set forth Congressional declaration of purpose of this subchapter to encourage and assist regional cooperative arrangements among medical schools, research institutions, and hospitals for research, training and medical data exchange, and to improve quality and capacity of health manpower and facilities available throughout the nation, prior to repeal by Pub. L. 99–117, \$12(d), Oct. 7, 1985, 99 Stat. 495.

A prior section 901 of act July 1, 1944, was classified to section 299a of this title prior to repeal by Pub. L. 99-117.

#### CONSTRUCTION

Pub. L. 106-129, §2(b), Dec. 6, 1999, 113 Stat. 1670, provided that:

"(1) IN GENERAL.—Section 901(a) of the Public Health Service Act [42 U.S.C. 299(a)] (as added by subsection (a) of this section) applies as a redesignation of the agency that carried out title IX of such Act [42 U.S.C. 299 et seq.] on the day before the date of the enactment of this Act [Dec. 6, 1999], and not as the termination of such agency and the establishment of a different agency. The amendment made by subsection (a) of this section [enacting this subchapter] does not affect appointments of the personnel of such agency who were employed at the agency on the day before such date, including the appointments of members of advisory councils or study sections of the agency who were serving on the day before such date of enactment.

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

## TRANSITIONAL AND SAVINGS PROVISIONS

Pub. L. 101–239, title VI, §6103(f), Dec. 19, 1989, 103 Stat. 2208, 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

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

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.

house.

"(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

ferences 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 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 suc-

"(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 govern-

ment 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
- "(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 multidisciplinary centers, provide technical assistance, and disseminate information on health care and on systems for the delivery of such care, including activities with respect to—

- (1) the quality, effectiveness, efficiency, appropriateness and value of health care services:
  - (2) quality measurement and improvement;
- (3) the outcomes, cost, cost-effectiveness, and use of health care services and access to such services:
- (4) clinical practice, including primary care and practice-oriented research;
- (5) health care technologies, facilities, and equipment;
- (6) health care costs, productivity, organization, and market forces;

- (7) health promotion and disease prevention, including clinical preventive services;
- (8) health statistics, surveys, database development, and epidemiology; and
  - (9) medical liability.

## (b) Health services training grants

### (1) In general

The Director may provide training grants in the field of health services research related to activities authorized under subsection (a) 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)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) 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,

<sup>&</sup>lt;sup>1</sup> See References in Text note below.