

methodology, and the limitations of the research, and the names of the entities, agencies, instrumentalities, and individuals who conducted any research which was published by the Institute; and

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

(b) Incorporation of research findings

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

(c) Feedback

The Office shall establish a process to receive feedback from physicians, health care providers, patients, and vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and 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 Institute from making its research findings publicly 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 Institutes of Health, shall build capacity for comparative clinical effectiveness research by establishing a grant program that provides for the training of researchers in the methods used to conduct such research, including systematic reviews of existing research and primary research such as clinical trials. At a minimum, such training shall be in methods that meet the methodological standards adopted under section 1320e(d)(9) of this title.

(f) Building data for research

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

(g) Authority to contract with the Institute

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

(July 1, 1944, ch. 373, title IX, § 937, as added Pub. L. 111-148, title VI, § 6301(b), Mar. 23, 2010, 124 Stat. 738.)

Editorial Notes

PRIOR PROVISIONS

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

PART E—GENERAL PROVISIONS

Editorial Notes

CODIFICATION

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

Pub. L. 109-41, § 2(a)(2), July 29, 2005, 119 Stat. 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 Secretary and the Director with respect to activities 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 recommendations to the Director regarding—

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

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

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

(c) Membership

(1) In general

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

(2) Appointed members

The Secretary shall appoint to the Advisory Council 21 appropriately qualified individuals. At least 17 members of the Advisory Council shall be representatives of the public who are not officers or employees of the United States and at least 1 member who shall be a specialist in the rural aspects of 1 or more of the professions or fields described in subparagraphs (A) through (G). The Secretary shall ensure that the appointed members of the Council, as a group, are representative of professions and

entities concerned with, or affected by, activities under this 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) shall serve for a term of 3 years.

(2) Staggered terms

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

(3) Service beyond term

A member of the Council appointed under subsection (c)(2) may continue to serve after the expiration of the term of the members until a successor is appointed.

(e) Vacancies

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

(f) Chair

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

(g) Meetings

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

(h) Compensation and reimbursement of expenses

(1) Appointed members

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

(2) Ex officio members

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

(i) Staff

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

(j) Duration

Notwithstanding section 1013(a) of title 5, the Advisory Council shall continue in existence until otherwise provided by law.

(July 1, 1944, ch. 373, title IX, § 941, formerly § 921, as added Pub. L. 106-129, § 2(a), Dec. 6, 1999, 113 Stat. 1663; amended Pub. L. 108-173, title IX, § 900(e)(2)(D), Dec. 8, 2003, 117 Stat. 2372; renumbered § 931, Pub. L. 109-41, § 2(a)(3), July 29, 2005, 119 Stat. 424; renumbered § 941, Pub. L. 111-148, title III, § 3013(a)(2), Mar. 23, 2010, 124 Stat. 381; Pub. L. 117-286, § 4(a)(242), Dec. 27, 2022, 136 Stat. 4332.)

Editorial Notes

PRIOR PROVISIONS

A prior section 299c, act July 1, 1944, ch. 373, title IX, § 921, as added Pub. L. 101-239, title VI, § 6103(c), Dec. 19, 1989, 103 Stat. 2199; amended Pub. L. 102-410, § 8, Oct. 13, 1992, 106 Stat. 2100, established the Advisory Council for Health Care Policy, Research, and Evaluation, prior to the general amendment of this subchapter by Pub. L. 106-129.

Another prior section 299c, act July 1, 1944, ch. 373, title IX, § 903, as added Oct. 6, 1965, Pub. L. 89-239, § 2, 79 Stat. 927; amended Oct. 15, 1968, Pub. L. 90-574, title I, § 104, 82 Stat. 1005; Oct. 30, 1970, Pub. L. 91-515, title I, §§105, 111(b), 84 Stat. 1299, 1301, authorized Secretary to make planning grants and set forth requirements for grant applications, prior to repeal by Pub. L. 99-117, § 12(d), Oct. 7, 1985, 99 Stat. 495.

AMENDMENTS

2022—Subsec. (j). Pub. L. 117-286, which directed amendment of “Section 942(j) of the Public Health Service Act” by substituting “section 1013(a) of title 5,” for “section 14(a) of the Federal Advisory Committee Act,” was executed to this section, which is section 941 of the Public Health Service Act, to reflect the probable intent of Congress.

2003—Subsec. (c)(3)(A). Pub. L. 108-173 substituted “Centers for Medicare & Medicaid Services” for “Health Care Financing Administration”.

§ 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 finding and recommendations respecting the application to the Director in such form and in such manner as the Director shall require.

(b) Approval as precondition of awards

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

(c) Establishment of peer review groups

(1) In general

The Director shall establish such technical and scientific peer review groups as may be necessary to carry out this section. Such groups shall be established without regard to the provisions of title 5 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 1013(a) of title 5, 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.

(July 1, 1944, ch. 373, title IX, § 942, formerly § 922, as added Pub. L. 106-129, § 2(a), Dec. 6, 1999, 113 Stat. 1665; renumbered § 932, Pub. L. 109-41, § 2(a)(3), July 29, 2005, 119 Stat. 424; renumbered § 942, Pub. L. 111-148, title III, § 3013(a)(2), Mar. 23, 2010, 124 Stat. 381; amended Pub. L. 117-286, § 4(a)(243), Dec. 27, 2022, 136 Stat. 4332.)

Editorial Notes

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.

PRIOR PROVISIONS

A prior section 299c-1, act July 1, 1944, ch. 373, title IX, § 922, as added Pub. L. 101-239, title VI, § 6103(c), Dec. 19, 1989, 103 Stat. 2201; amended Pub. L. 101-508, title IV, § 4118(f)(2)(F), Nov. 5, 1990, 104 Stat. 1388-70; Pub. L. 102-410, § 5(d), Oct. 13, 1992, 106 Stat. 2098, related to peer review with respect to grants and contracts, prior to the general amendment of this subchapter by Pub. L. 106-129.

AMENDMENTS

2022—Subsec. (c)(3). Pub. L. 117-286, which directed amendment of “Section 941(c)(3) of the Public Health Service Act” by substituting “section 1013(a) of title 5,” for “section 14(a) of the Federal Advisory Committee Act,” was executed to this section, which is section 942 of the Public Health Service Act, to reflect the probable intent of Congress.