§ 299b–6. Coordination of Federal Government quality improvement efforts

(a) Requirement

(1) In general

To avoid duplication and ensure that Federal resources are used efficiently and effectively, the Secretary, acting through the Director, shall coordinate all research, evaluations, and demonstrations related to health services research, quality measurement and quality improvement activities undertaken and supported by the Federal Government.

(2) Specific activities

The Director, in collaboration with the appropriate Federal officials representing all concerned executive agencies and departments, shall develop and manage a process to—

(A) improve interagency coordination, priority setting, and the use and sharing of research findings and data pertaining to Federal quality improvement programs, technology assessment, and health services research;

(B) strengthen the research information infrastructure, including databases, pertaining to Federal health services research and health care quality improvement initiatives;

(C) set specific goals for participating agencies and departments to further health services research and health care quality improvement; and

(D) strengthen the management of Federal health care quality improvement programs.

(b) Study by the Institute of Medicine

(1) In general

To provide Congress, the Department of Health and Human Services, and other relevant departments with an independent, external review of their quality oversight, quality improvement and quality research programs, the Secretary shall enter into a contract with the Institute of Medicine—

(A) to describe and evaluate current quality improvement, quality research and quality monitoring processes through—

(i) an overview of pertinent health services research activities and quality improvement efforts conducted by all Federal programs, with particular attention paid to those under titles XVIII, XIX, and XXI of the Social Security Act [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 Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Commerce of the House of Representatives.

(July 1, 1944, ch. 373, title IX, § 917, as added Pub. L. 106–129, § 2(a), Dec. 6, 1999, 113 Stat. 1661.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. 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.

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[1] 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.];

(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)(B) 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—

[1] So in original. Probably should be followed by a comma.

(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.

(Pub. L. 108–173, title X, § 1013, Dec. 8, 2003, 117 Stat. 2438.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(1)(A), (2)(C)(i), (3)(A)(iii), (C)(i), (4)(A), (6)(A), (C), 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)(ii)(I), (4)(B), is act June 25, 1938, ch. 675, 52 Stat. 1040, 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 301 of Title 21 and Tables.

The Public Health Service Act, referred to in subsec. (a)(3)(C)(ii)(I), (4)(A), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to this chapter. Title IX of the Act is classified generally to this subchapter. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and not as part of the Public Health Service Act which comprises this chapter.

DEFINITION OF ''SECRETARY''

''Secretary'' as meaning the Secretary of Health and Human Services, see section 1(c)(2) of Pub. L. 108–173, set out as a note under section 1301 of this title.

§ 299b–8. Omitted

CODIFICATION

Section, Pub. L. 111–5, div. A, title VIII, § 804, Feb. 17, 2009, 123 Stat. 187, established the Federal Coordinating Council for Comparative Effectiveness Research.

TERMINATION OF FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH

Pub. L. 111–148, title VI, § 6302, Mar. 23, 2010, 124 Stat. 747, provided that the Federal Coordinating Council for Comparative Effectiveness Research established under this section terminated on Mar. 23, 2010.

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