

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).

(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.)

Editorial Notes

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. 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, 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, 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.

Statutory Notes and Related Subsidiaries

DEFINITION OF “SECRETARY”

“Secretary” means 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

Editorial Notes

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.

Statutory Notes and Related Subsidiaries**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

(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—