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

(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.