(K) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in section 1072(4) of title 10.

(L) The Indian health service program under the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

(M) The Federal Employees Health Benefit Plan under chapter 89 of title 5.

(6) Individually identifiable health information

The term "individually identifiable health information" means any information, including demographic information collected from an individual, that—

(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and—

(i) identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

(7) Standard

The term "standard", when used with reference to a data element of health information or a transaction referred to in section 1320d–2(a)(1) of this title, means any such data element or transaction that meets each of the standards and implementation specifications adopted or established by the Secretary with respect to the data element or transaction under sections 1320d–1 through 1320d–3 of this title.

(8) Standard setting organization

The term "standard setting organization" means a standard setting organization accredited by the American National Standards Institute, including the National Council for Prescription Drug Programs, that develops standards for information transactions, data elements, or any other standard that is necessary to, or will facilitate, the implementation of this part.

(9) Operating rules

The term "operating rules" means the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.

(Aug. 14, 1935, ch. 531, title XI, §1171, as added Pub. L. 104–191, title II, §262(a), Aug. 21, 1996, 110 Stat. 2021; amended Pub. L. 107–105, §4, Dec. 27, 2001, 115 Stat. 1007; Pub. L. 111–5, div. A, title XIII, §13102, Feb. 17, 2009, 123 Stat. 242; Pub. L. 111–148, title I, §1104(b)(1), Mar. 23, 2010, 124 Stat. 146.)

Editorial Notes

REFERENCES IN TEXT

The Indian Health Care Improvement Act, referred to in par. (5)(L), is Pub. L. 94–437, Sept. 30, 1976, 90 Stat.

1400, which is classified principally to chapter 18 (§1601 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

PRIOR PROVISIONS

A prior section 1171 of act Aug. 14, 1935, was classified to section 1320c–20 of this title prior to repeal by Pub. L. 97–35.

AMENDMENTS

2010—Par. (9). Pub. L. 111–148 added par. (9).

2009—Par. (5)(D). Pub. L. 111–5 substituted "C, or D" for "or C".

2001—Par. (5)(D). Pub. L. 107–105 substituted "Parts A, B, or C" for "Part A or part B".

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title I, §1105, Mar. 23, 2010, 124 Stat. 154, provided that: "This subtitle [subtitle B (§§1101–1105) of title I of Pub. L. 111–148, enacting subchapter I of chapter 157 of this title, amending this section and sections 1320d–2 and 1395y of this title, enacting provisions set out as a note under section 1320d–2 of this title, and amending provisions set out as a note under this section] shall take effect on the date of enactment of this Act [Mar. 23, 2010]."

PURPOSE

Pub. L. 104–191, title II, §261, Aug. 21, 1996, 110 Stat. 2021, as amended by Pub. L. 111–148, title I, §1104(a), Mar. 23, 2010, 124 Stat. 146, provided that: "It is the purpose of this subtitle [subtitle F (§§261–264) of title II of Pub. L. 104–191, enacting this part, amending sections 242k and 1395cc of this title, and enacting provisions set out as a note under section 1320d–2 of this title] to improve the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], the medicaid program under title XIX of such Act [42 U.S.C. 1396 et seq.], and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of uniform standards and requirements for the electronic transmission of certain health information and to reduce the clerical burden on patients, health care providers, and health plans."

§ 1320d–1. General requirements for adoption of standards

(a) Applicability

Any standard adopted under this part shall apply, in whole or in part, to the following persons:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction referred to in section 1320d–2(a)(1) of this title.

(b) Reduction of costs

Any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.

(c) Role of standard setting organizations

(1) In general

Except as provided in paragraph (2), any standard adopted under this part shall be a standard that has been developed, adopted, or modified by a standard setting organization.

(2) Special rules

(A) Different standards

The Secretary may adopt a standard that is different from any standard developed, adopted, or modified by a standard setting organization, if—

(i) the different standard will substantially reduce administrative costs to health care providers and health plans compared to the alternatives; and

(ii) the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5.

(B) No standard by standard setting organization

If no standard setting organization has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under this part—

(i) paragraph (1) shall not apply; and

(ii) subsection (f) shall apply.

(3) Consultation requirement

(A) In general

A standard may not be adopted under this part unless—

(i) in the case of a standard that has been developed, adopted, or modified by a standard setting organization, the organization consulted with each of the organizations described in subparagraph (B) in the course of such development, adoption, or modification; and

(ii) in the case of any other standard, the Secretary, in complying with the requirements of subsection (f), consulted with each of the organizations described in subparagraph (B) before adopting the standard.

(B) Organizations described

The organizations referred to in subparagraph (A) are the following:

(i) The National Uniform Billing Committee.

(ii) The National Uniform Claim Committee.

(iii) The Workgroup for Electronic Data Interchange.

(iv) The American Dental Association.

(d) Implementation specifications

The Secretary shall establish specifications for implementing each of the standards adopted under this part.

(e) Protection of trade secrets

Except as otherwise required by law, a standard adopted under this part shall not require disclosure of trade secrets or confidential commercial information by a person required to comply with this part.

(f) Assistance to Secretary

In complying with the requirements of this part, the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics established under section 242k(k) of this title, and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard under this part.

(g) Application to modifications of standards

This section shall apply to a modification to a standard (including an addition to a standard) adopted under section 1320d–3(b) of this title in the same manner as it applies to an initial standard adopted under section 1320d–3(a) of this title.

(Aug. 14, 1935, ch. 531, title XI, §1172, as added Pub. L. 104–191, title II, §262(a), Aug. 21, 1996, 110 Stat. 2023.)

§ 1320d–2. Standards for information transactions and data elements

(a) Standards to enable electronic exchange

(1) In general

The Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for—

(A) the financial and administrative transactions described in paragraph (2); and

(B) other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs, and subject to the requirements under paragraph (5).

(2) Transactions

The transactions referred to in paragraph (1)(A) are transactions with respect to the following:

(A) Health claims or equivalent encounter information.

(B) Health claims attachments.

(C) Enrollment and disenrollment in a health plan.

(D) Eligibility for a health plan.

(E) Health care payment and remittance advice.

(F) Health plan premium payments.

(G) First report of injury.

(H) Health claim status.

(I) Referral certification and authorization.

(J) Electronic funds transfers.

(3) Accommodation of specific providers

The standards adopted by the Secretary under paragraph (1) shall accommodate the needs of different types of health care providers.

(4) Requirements for financial and administrative transactions

(A) In general

The standards and associated operating rules adopted by the Secretary shall—