

**§ 1320c-12. Medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands to be included in the quality improvement program**

For purposes of applying this part to American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands, individuals licensed to practice medicine in those places shall be considered to be physicians and doctors of medicine.

(Aug. 14, 1935, ch. 531, title XI, §1163, as added Pub. L. 97-248, title I, §143, Sept. 3, 1982, 96 Stat. 393.)

PRIOR PROVISIONS

A prior section 1320c-12, act Aug. 14, 1935, ch. 531, title XI, §1163, as added Oct. 30, 1972, Pub. L. 92-603, title II, §249F(b), 86 Stat. 1441; amended Oct. 25, 1977, Pub. L. 95-142, §5(f), (g), 91 Stat. 1189; Dec. 5, 1980, Pub. L. 96-499, title IX, §923(a)-(d), 94 Stat. 2628, related to establishment and membership of the National Professional Standards Review Council, prior to the general revision of this part by Pub. L. 97-248.

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

**§ 1320c-13. Repealed. Pub. L. 103-432, title I, § 156(a)(1), Oct. 31, 1994, 108 Stat. 4440**

Section, act Aug. 14, 1935, ch. 531, title XI, §1164, as added Apr. 7, 1986, Pub. L. 99-272, title IX, §9401(b), 100 Stat. 196; amended Oct. 22, 1986, Pub. L. 99-514, title XVIII, §1895(b)(17), 100 Stat. 2934; Dec. 19, 1989, Pub. L. 101-239, title VI, §6003(g)(3)(D)(v), 103 Stat. 2153, related to 100 percent peer review for certain surgical procedures.

EFFECTIVE DATE OF REPEAL

Repeal applicable to services provided on or after Oct. 31, 1994, see section 156(a)(3) of Pub. L. 103-432, set out as an Effective Date of 1994 Amendment note under section 1320c-3 of this title.

**§§ 1320c-14 to 1320c-19. Omitted**

CODIFICATION

Sections 1320c-14 to 1320c-19 were omitted in the general revision of this part by Pub. L. 97-248, title I, §143, Sept. 3, 1982, 96 Stat. 382.

Section 1320c-14, act Aug. 14, 1935, ch. 531, title XI, §1165, as added Oct. 30, 1972, Pub. L. 92-603, title II, §249F(b), 86 Stat. 1443, related to correlation of functions between Professional Standards Review Organizations and administrative instrumentalities.

Section 1320c-15, act Aug. 14, 1935, ch. 531, title XI, §1166, as added Oct. 30, 1972, Pub. L. 92-603, title II, §249F(b), 86 Stat. 1443; amended Oct. 25, 1977, Pub. L. 95-142, §5(h), 91 Stat. 1189, related to general prohibition against disclosure of data or information and exceptions to such prohibition. See section 1320c-9 of this title.

Section 1320c-16, act Aug. 14, 1935, ch. 531, title XI, §1167, as added Oct. 30, 1972, Pub. L. 92-603, title II, §249F(b), 86 Stat. 1443; amended Oct. 25, 1977, Pub. L. 95-142, §5(i), (n), 91 Stat. 1190, 1191, related to limitation of liability of persons providing information to Professional Standards Review Organizations and Statewide Professional Standards Review Councils. See section 1320c-6 of this title.

Section 1320c-17, act Aug. 14, 1935, ch. 531, title XI, §1168, as added Oct. 30, 1972, Pub. L. 92-603, title II, §249F(b), 86 Stat. 1444; amended Dec. 31, 1975, Pub. L.

94-182, title I, §112(c), 89 Stat. 1055; Oct. 25, 1977, Pub. L. 95-142, §5(j), 91 Stat. 1190; Aug. 13, 1981, Pub. L. 97-35, title XXI, §2113(j), 95 Stat. 795, related to authorization for use of funds for administering professional review program, transfer of moneys between funds, and payments for Professional Standards Review Organizations. See section 1320c-8 of this title.

Section 1320c-18, act Aug. 14, 1935, ch. 531, title XI, §1169, as added Oct. 30, 1972, Pub. L. 92-603, title II, §249F(b), 86 Stat. 1444, related to technical assistance given to organizations desiring to be designated as Professional Standards Review Organizations.

Section 1320c-19, act Aug. 14, 1935, ch. 531, title XI, §1170, as added Oct. 30, 1972, Pub. L. 92-603, title II, §249F(b), 86 Stat. 1445, related to exemptions of Christian Science sanatoriums. See section 1320c-11 of this title.

**§ 1320c-20. Repealed. Pub. L. 97-35, title XXI, § 2113(k), Aug. 13, 1981, 95 Stat. 795**

Section, act Aug. 14, 1935, ch. 531, title XI, §1171, as added Oct. 25, 1977, Pub. L. 95-142, §5(d)(2)(D), 91 Stat. 1186, set forth provisions respecting Federal-State relations regarding memorandum of understanding between Organization and State agency.

EFFECTIVE DATE OF REPEAL

Repeal applicable to agreements with Professional Standards Review Organizations entered into on or after Oct. 1, 1981, see section 2113(o) of Pub. L. 97-35, set out as an Effective Date of 1981 Amendment note under section 1396a of this title.

**§§ 1320c-21, 1320c-22. Omitted**

CODIFICATION

Sections 1320c-21 and 1320c-22 were omitted in the general revision of this part by Pub. L. 97-248, title I, §143, Sept. 3, 1982, 96 Stat. 382.

Section 1320c-21, act Aug. 14, 1935, ch. 531, title XI, §1172, as added Oct. 25, 1977, Pub. L. 95-142, §5(k), 91 Stat. 1190; amended Aug. 13, 1981, Pub. L. 97-35, title XXI, §§2113(l), 2193(c)(7), 95 Stat. 795, 827, related to annual reports submitted to Congress by Secretary. See section 1320c-10 of this title.

Section 1320c-22, act Aug. 14, 1935, ch. 531, title XI, §1173, as added Oct. 25, 1977, Pub. L. 95-142, §5(l)(1), 91 Stat. 1191; amended Dec. 5, 1980, Pub. L. 96-499, title IX, §923(e), 94 Stat. 2628, provided that medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands were includable in program under former Part B. See section 1320c-12 of this title.

PART C—ADMINISTRATIVE SIMPLIFICATION

**§ 1320d. Definitions**

For purposes of this part:

**(1) Code set**

The term “code set” means any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes.

**(2) Health care clearinghouse**

The term “health care clearinghouse” means a public or private entity that processes or facilitates the processing of non-standard data elements of health information into standard data elements.

**(3) Health care provider**

The term “health care provider” includes a provider of services (as defined in section 1395x(u) of this title), a provider of medical or other health services (as defined in section

1395x(s) of this title), and any other person furnishing health care services or supplies.

**(4) Health information**

The term “health information” means any information, whether oral or recorded in any form or medium, that—

(A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, 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.

**(5) Health plan**

The term “health plan” means an individual or group plan that provides, or pays the cost of, medical care (as such term is defined in section 300gg-91 of this title). Such term includes the following, and any combination thereof:

(A) A group health plan (as defined in section 300gg-91(a) of this title), but only if the plan—

(i) has 50 or more participants (as defined in section 1002(7) of title 29); or

(ii) is administered by an entity other than the employer who established and maintains the plan.

(B) A health insurance issuer (as defined in section 300gg-91(b) of this title).

(C) A health maintenance organization (as defined in section 300gg-91(b) of this title).

(D) Parts<sup>1</sup> A, B, C, or D of the Medicare program under subchapter XVIII.

(E) The medicaid program under subchapter XIX.

(F) A Medicare supplemental policy (as defined in section 1395ss(g)(1) of this title).

(G) A long-term care policy, including a nursing home fixed indemnity policy (unless the Secretary determines that such a policy does not provide sufficiently comprehensive coverage of a benefit so that the policy should be treated as a health plan).

(H) An employee welfare benefit plan or any other arrangement which is established or maintained for the purpose of offering or providing health benefits to the employees of 2 or more employers.

(I) The health care program for active military personnel under title 10.

(J) The veterans health care program under chapter 17 of title 38.

(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, includ-

ing 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.)

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”.

<sup>1</sup> So in original. Probably should be “Part”.

## 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 medicare 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.)

## PRIOR PROVISIONS

A prior section 1172 of act Aug. 14, 1935, was classified to section 1320c-21 of this title prior to the general