#### 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  $242 \, \mathrm{k}$  and  $1395 \, \mathrm{cc}$  of this title, and enacting provisions set out as a note under section 1320d-2 of this titlel 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.)

## PRIOR PROVISIONS

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

amendment of part B of this subchapter by Pub. L. 97-248

#### § 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—

- (i) to the extent feasible and appropriate, enable determination of an individual's eligibility and financial responsibility for specific services prior to or at the point of care:
- (ii) be comprehensive, requiring minimal augmentation by paper or other communications:
- (iii) provide for timely acknowledgment, response, and status reporting that supports a transparent claims and denial management process (including adjudication and appeals); and
- (iv) describe all data elements (including reason and remark codes) in unambiguous terms, require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where necessary to imple-

ment State or Federal law, or to protect against fraud and abuse).

#### (B) Reduction of clerical burden

In adopting standards and operating rules for the transactions referred to under paragraph (1), the Secretary shall seek to reduce the number and complexity of forms (including paper and electronic forms) and data entry required by patients and providers.

# (5) Consideration of standardization of activities and items

#### (A) In general

For purposes of carrying out paragraph (1)(B), the Secretary shall solicit, not later than January 1, 2012, and not less than every 3 years thereafter, input from entities described in subparagraph (B) on—

- (i) whether there could be greater uniformity in financial and administrative activities and items, as determined appropriate by the Secretary; and
- (ii) whether such activities should be considered financial and administrative transactions (as described in paragraph (1)(B)) for which the adoption of standards and operating rules would improve the operation of the health care system and reduce administrative costs.

## (B) Solicitation of input

For purposes of subparagraph (A), the Secretary shall seek input from—

- (i) the National Committee on Vital and Health Statistics, the Health Information Technology Policy Committee, and the Health Information Technology Standards Committee; and
- (ii) standard setting organizations and stakeholders, as determined appropriate by the Secretary.

## (b) Unique health identifiers

## (1) In general

The Secretary shall adopt standards providing for a standard unique health identifier for each individual, employer, health plan, and health care provider for use in the health care system. In carrying out the preceding sentence for each health plan and health care provider, the Secretary shall take into account multiple uses for identifiers and multiple locations and specialty classifications for health care providers.

## (2) Use of identifiers

The standards adopted under paragraph (1) shall specify the purposes for which a unique health identifier may be used.

#### (c) Code sets

## (1) In general

The Secretary shall adopt standards that—

- (A) select code sets for appropriate data elements for the transactions referred to in subsection (a)(1) from among the code sets that have been developed by private and public entities; or
- (B) establish code sets for such data elements if no code sets for the data elements have been developed.