§ 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) of this section 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) of this section, 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.


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.