

## § 162.1000

proposed modification, including any additional system requirements.

(3) *Testing of the proposed modification.* Provide an explanation, no more than 5 pages in length, of how the organization intends to test the standard, including the number and types of health plans and health care providers expected to be involved in the test, geographical areas, and beginning and ending dates of the test.

(4) *Trading partner concurrences.* Provide written concurrences from trading partners who would agree to participate in the test.

(b) *Basis for granting an exception.* The Secretary may grant an initial exception, for a period not to exceed 3 years, based on, but not limited to, the following criteria:

(1) An assessment of whether the proposed modification demonstrates a significant improvement to the current standard.

(2) The extent and length of time of the exception.

(3) Consultations with DSMOs.

(c) *Secretary's decision on exception.* The Secretary makes a decision and notifies the organization requesting the exception whether the request is granted or denied.

(1) *Exception granted.* If the Secretary grants an exception, the notification includes the following information:

(i) The length of time for which the exception applies.

(ii) The trading partners and geographical areas the Secretary approves for testing.

(iii) Any other conditions for approving the exception.

(2) *Exception denied.* If the Secretary does not grant an exception, the notification explains the reasons the Secretary considers the proposed modification would not be a significant improvement to the current standard and any other rationale for the denial.

(d) *Organization's report on test results.* Within 90 days after the test is completed, an organization that receives an exception must submit a report on the results of the test, including a cost-benefit analysis, to a location specified by the Secretary by notice in the FEDERAL REGISTER.

(e) *Extension allowed.* If the report submitted in accordance with para-

## 45 CFR Subtitle A (10-1-10 Edition)

graph (d) of this section recommends a modification to the standard, the Secretary, on request, may grant an extension to the period granted for the exception.

### Subpart J—Code Sets

#### § 162.1000 General requirements.

When conducting a transaction covered by this part, a covered entity must meet the following requirements:

(a) *Medical data code sets.* Use the applicable medical data code sets described in §162.1002 as specified in the implementation specification adopted under this part that are valid at the time the health care is furnished.

(b) *Nonmedical data code sets.* Use the nonmedical data code sets as described in the implementation specifications adopted under this part that are valid at the time the transaction is initiated.

#### § 162.1002 Medical data code sets.

The Secretary adopts the following maintaining organization's code sets as the standard medical data code sets:

(a) For the period from October 16, 2002 through October 15, 2003:

(1) *International Classification of Diseases, 9th Edition, Clinical Modification, (ICD-9-CM), Volumes 1 and 2* (including The Official ICD-9-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:

(i) Diseases.

(ii) Injuries.

(iii) Impairments.

(iv) Other health problems and their manifestations.

(v) Causes of injury, disease, impairment, or other health problems.

(2) *International Classification of Diseases, 9th Edition, Clinical Modification, Volume 3 Procedures* (including The Official ICD-9-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals:

(i) Prevention.

(ii) Diagnosis.

(iii) Treatment.

(iv) Management.

(3) *National Drug Codes* (NDC), as maintained and distributed by HHS, in collaboration with drug manufacturers, for the following:

- (i) Drugs
- (ii) Biologics.

(4) *Code on Dental Procedures and Nomenclature*, as maintained and distributed by the American Dental Association, for dental services.

(5) The combination of *Health Care Financing Administration Common Procedure Coding System (HCPCS)*, as maintained and distributed by HHS, and *Current Procedural Terminology, Fourth Edition (CPT-4)*, as maintained and distributed by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following:

- (i) Physician services.
- (ii) Physical and occupational therapy services.
- (iii) Radiologic procedures.
- (iv) Clinical laboratory tests.
- (v) Other medical diagnostic procedures.
- (vi) Hearing and vision services.
- (vii) Transportation services including ambulance.

(6) The *Health Care Financing Administration Common Procedure Coding System (HCPCS)*, as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services. These items include, but are not limited to, the following:

- (i) Medical supplies.
- (ii) Orthotic and prosthetic devices.
- (iii) Durable medical equipment.

(b) For the period on and after October 16, 2003 through September 30, 2013:

(1) The code sets specified in paragraphs (a)(1), (a)(2),(a)(4), and (a)(5) of this section.

(2) *National Drug Codes* (NDC), as maintained and distributed by HHS, for reporting the following by retail pharmacies:

- (i) Drugs.
- (ii) Biologics.

(3) *The Healthcare Common Procedure Coding System (HCPCS)*, as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services, with the exception of drugs and

biologics. These items include, but are not limited to, the following:

- (i) Medical supplies.
- (ii) Orthotic and prosthetic devices.
- (iii) Durable medical equipment.

(c) For the period on and after October 1, 2013:

(1) The code sets specified in paragraphs (a)(4), (a)(5), (b)(2), and (b)(3) of this section.

(2) International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) (including The Official ICD-10-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:

- (i) Diseases.
- (ii) Injuries.
- (iii) Impairments.
- (iv) Other health problems and their manifestations.

(v) Causes of injury, disease, impairment, or other health problems.

(3) International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) (including The Official ICD-10-PCS Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals:

- (i) Prevention.
- (ii) Diagnosis.
- (iii) Treatment.
- (iv) Management.

[65 FR 50367, Aug. 17, 2000, as amended at 68 FR 8397, Feb. 20, 2003; 74 FR 3362, Jan. 16, 2009]

#### § 162.1011 Valid code sets.

Each code set is valid within the dates specified by the organization responsible for maintaining that code set.

### Subpart K—Health Care Claims or Equivalent Encounter Information

#### § 162.1101 Health care claims or equivalent encounter information transaction.

The health care claims or equivalent encounter information transaction is the transmission of either of the following: