

**§ 162.910 Maintenance of standards and adoption of modifications and new standards.**

(a) *Designation of DSMOs.* (1) The Secretary may designate as a DSMO an organization that agrees to conduct, to the satisfaction of the Secretary, the following functions:

(i) Maintain standards adopted under this subchapter.

(ii) Receive and process requests for adopting a new standard or modifying an adopted standard.

(2) The Secretary designates a DSMO by notice in the FEDERAL REGISTER.

(b) *Maintenance of standards.* Maintenance of a standard by the appropriate DSMO constitutes maintenance of the standard for purposes of this part, if done in accordance with the processes the Secretary may require.

(c) *Process for modification of existing standards and adoption of new standards.* The Secretary considers a recommendation for a proposed modification to an existing standard, or a proposed new standard, only if the recommendation is developed through a process that provides for the following:

(1) Open public access.

(2) Coordination with other DSMOs.

(3) An appeals process for each of the following, if dissatisfied with the decision on the request:

(i) The requestor of the proposed modification.

(ii) A DSMO that participated in the review and analysis of the request for the proposed modification, or the proposed new standard.

(4) Expedited process to address content needs identified within the industry, if appropriate.

(5) Submission of the recommendation to the National Committee on Vital and Health Statistics (NCVHS).

**§ 162.915 Trading partner agreements.**

A covered entity must not enter into a trading partner agreement that would do any of the following:

(a) Change the definition, data condition, or use of a data element or segment in a standard.

(b) Add any data elements or segments to the maximum defined data set.

(c) Use any code or data elements that are either marked "not used" in

the standard's implementation specification or are not in the standard's implementation specification(s).

(d) Change the meaning or intent of the standard's implementation specification(s).

**§ 162.920 Availability of implementation specifications.**

(a) *Access to implementation specifications.* A person or organization may request copies (or access for inspection) of the implementation specifications for a standard described in subparts K through R of this part by identifying the standard by name, number, and version. The implementation specifications are available as follows:

(1) *ASC X12N specifications.* The implementation specifications for ASC X12N standards may be obtained from the Washington Publishing Company, PMB 161, 5284 Randolph Road, Rockville, MD, 20852-2116; telephone 301-949-9740; and FAX: 301-949-9742. They are also available through the Washington Publishing Company on the Internet at <http://www.wpc-edi.com>. The implementation specifications are as follows:

(i) The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097, as referenced in §§ 162.1102 and 162.1802.

(ii) The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098, as referenced in §§ 162.1102 and 162.1802.

(iii) The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096, as referenced in §§ 162.1102 and 162.1802.

(iv) The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092, as referenced in § 162.1202.

(v) The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094, as referenced in § 162.1302.

(vi) The ASC X12N 276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington

## § 162.923

Publishing Company, 004010X093, as referenced in § 162.1402.

(vii) The ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095, as referenced in § 162.1502.

(viii) The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, as referenced in § 162.1602.

(ix) The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061, as referenced in § 162.1702.

(2) *Retail pharmacy specifications.* The implementation specifications for all retail pharmacy standards may be obtained from the National Council for Prescription Drug Programs (NCPDP), 4201 North 24th Street, Suite 365, Phoenix, AZ, 85016; telephone 602-957-9105; and FAX 602-955-0749. It may also be obtained through the Internet at <http://www.ncdp.org>. The implementation specifications are as follows:

(i) The Telecommunication Standard Implementation Guide, Version 5 Release 1, September 1999, National Council for Prescription Drug Programs, as referenced in §§ 162.1102, 162.1202, 162.1602, and 162.1802.

(ii) The Batch Standard Batch Implementation Guide, Version 1 Release 0, February 1, 1996, National Council for Prescription Drug Programs, as referenced in §§ 162.1102, 162.1202, 162.1602, and 162.1802.

(b) *Incorporations by reference.* The Director of the Office of the Federal Register approves the implementation specifications described in paragraph (a) of this section for incorporation by reference in subparts K through R of this part in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the implementation specifications may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington, DC.

### § 162.923 Requirements for covered entities.

(a) *General rule.* Except as otherwise provided in this part, if a covered entity conducts with another covered enti-

## 45 CFR Subtitle A (10-1-00 Edition)

ty (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction.

(b) *Exception for direct data entry transactions.* A health care provider electing to use direct data entry offered by a health plan to conduct a transaction for which a standard has been adopted under this part must use the applicable data content and data condition requirements of the standard when conducting the transaction. The health care provider is not required to use the format requirements of the standard.

(c) *Use of a business associate.* A covered entity may use a business associate, including a health care clearinghouse, to conduct a transaction covered by this part. If a covered entity chooses to use a business associate to conduct all or part of a transaction on behalf of the covered entity, the covered entity must require the business associate to do the following:

(1) Comply with all applicable requirements of this part.

(2) Require any agent or subcontractor to comply with all applicable requirements of this part.

### § 162.925 Additional requirements for health plans.

(a) *General rules.* (1) If an entity requests a health plan to conduct a transaction as a standard transaction, the health plan must do so.

(2) A health plan may not delay or reject a transaction, or attempt to adversely affect the other entity or the transaction, because the transaction is a standard transaction.

(3) A health plan may not reject a standard transaction on the basis that it contains data elements not needed or used by the health plan (for example, coordination of benefits information).

(4) A health plan may not offer an incentive for a health care provider to conduct a transaction covered by this part as a transaction described under the exception provided for in § 162.923(b).

(5) A health plan that operates as a health care clearinghouse, or requires