

(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 person or an organization may directly request copies of the implementation standards described in subparts I through R of this part from the publishers listed in this section. The Director of the Office of the Federal Register approves the implementation specifications described in this section for incorporation by reference in subparts I through R of this part in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The implementation specifications described in this paragraph are also available for inspection by the public at the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Copy requests must be accompanied by the name of the standard, number, if applicable, and version number. Implementation specifications are available for the following transactions:

(a) *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 transaction implementation specifications are as follows:

(1) The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097 and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1, as referenced in § 162.1102 and § 162.1802.

(2) The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing

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Company, 004010X098A1, as referenced in § 162.1102 and § 162.1802.

(3) The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1 as referenced in § 162.1102 and § 162.1802.

(4) The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2002, Washington Publishing Company, 004010X091A1 as referenced in § 162.1602.

(5) ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 and Addenda to Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1, as referenced in § 162.1502.

(6) The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061, and Addenda to Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, October 2002, Washington Publishing Company, 004010X061A1, as referenced in § 162.1702.

(7) The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094 and Addenda to Health Care Services Review—Request for Review and Response, Version 4010, October 2002, Washington Publishing Company, 004010X094A1, as referenced in § 162.1302.

(8) The ASC X12N-276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, October 2002, Washington Publishing Company, 004010X093A1, as referenced in § 162.1402.

(9) The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company,

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004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1, as referenced in § 162.1202.

(b) *Retail pharmacy specifications.* The implementation specifications for retail pharmacy standards may be obtained for a fee from the National Council for Prescription Drug Programs (NCPDP), 9240 E. Raintree Drive, Scottsdale, AZ 85260; Telephone (480) 477-1000; and FAX (480) 767-1042. They may also be obtained through the Internet at <http://www.ncdp.org>. The transaction implementation specifications are as follows:

(1) The Telecommunication Standard Implementation Guide Version 5, Release 1 (Version 5.1), September 1999, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, § 162.1602, and § 162.1802.

(2) The Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

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

[68 FR 8396, Feb. 20, 2003, as amended at 69 FR 18803, Apr. 9, 2004]

### § 162.923 Requirements for covered entities.

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