SUBCHAPTER C—ADMINISTRATIVE DATA STANDARDS AND RELATED REQUIREMENTS

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

EFFECTIVE DATE NOTE: At 65 FR 50365, Aug. 17, 2000, subchapter C was added, effective Oct. 16, 2000.

Subpart A—General Provisions

Sec.

Subpart B—[Reserved]

AUTHORITY: Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d–1320d–8), as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031, and sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)).

SOURCE: 65 FR 50365, Aug. 17, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 160.101 Statutory basis and purpose.

The requirements of this subchapter implement sections 1171 through 1179 of the Social Security Act (the Act), as added by section 262 of Public Law 104–191, and section 264 of Public Law 104–191.

§ 160.102 Applicability.

Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:

(a) A health plan.

(b) A health care clearinghouse.

(c) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

§ 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act.

ANSI stands for the American National Standards Institute.

Business associate means a person who performs a function or activity regulated by this subchapter on behalf of a covered entity, as defined in this section. A business associate may be a covered entity. Business associate excludes a person who is part of the covered entity's workforce as defined in this section.

Compliance date means the date by which a covered entity must comply with a standard, implementation specification, or modification adopted under this subchapter.

Covered entity means one of the following:

(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 covered by this subchapter.

Group health plan (also see definition of *health plan* in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 (ERISA)(29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care, as defined in section 2791(a)(2) of the Public Health Service (PHS) Act, 42 U.S.C. 300gg–91(a)(2), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that—

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HCFA stands for Health Care Financing Administration within the Department of Health and Human Services.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies furnished to an individual and related to the health of the individual. Health care includes the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or

palliative care; counseling; service; or procedure with respect to the physical or mental condition, or functional status, of an individual or affecting the structure or function of the body.

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

(3) Procurement or banking of blood, sperm, organs, or any other tissue for administration to individuals.

Health care clearinghouse means a public or private entity that does either of the following (Entities, including but not limited to, billing services, repricing companies, community health management information systems or community health information systems, and ''value-added'' networks and switches are health care clearinghouses for purposes of this subchapter if they perform these functions.):

(1) Processes or facilitates the processing of information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of information into nonstandard format or nonstandard data content for a receiving entity.

Health care provider means a provider of services as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u), a provider of medical or other health services as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information means any information, whether oral or recorded in any form or medium, that —

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health insurance issuer (as defined in section 2791(b) of the PHS Act, 42 U.S.C. 300gg-91(b)(2), and used in the definition of *health plan* in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791 of the PHS Act, 42 U.S.C. 300gg–91(b)(3), and used in the definition of health plan in this section) means a Federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)). Health plan includes, when applied to government funded programs, the components of the government agency administering the program. Health plan includes the following, singly or in combination:

(1) A group health plan, as defined in this section.

(2) A health insurance issuer, as defined in this section.

(3) An HMO, as defined in this section.

(4) Part A or Part B of the Medicare program under title XVIII of the Act.

(5) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396 et seq.

(6) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(7) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(8) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(9) The health care program for active military personnel under title 10 of the United States Code.

(10) The veterans health care program under 38 U.S.C. chapter 17.

(11) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in 10 U.S.C. 1072(4).

(12) The Indian Health Service program under the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*).

(13) The Federal Employees Health Benefit Program under 5 U.S.C. 8902 *et seq.*

(14) An approved State child health plan under title XXI of the Act, providing benefits that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397 et seq.

(15) The Medicare + Choice program under part C of title XVIII of the Act, 42 U.S.C. 1395w–21 through 1395w–28.

(16) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)).

Implementation specification means the specific instructions for implementing a standard.

Modify or modification refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

Secretary means the Secretary of Health and Human Services or any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Small health plan means a health plan with annual receipts of $5 million or less.

Standard means a prescribed set of rules, conditions, or requirements describing the following information for products, systems, services or practices:

(1) Classification of components.

(2) Specification of materials, performance, or operations.

(3) Delineation of procedures.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For health plans established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for each health plan.

(2) For all other purposes, State means the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the exchange of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information exchanges:

(1) Health care claims or equivalent encounter information.

(2) Health care payment and remittance advice.

(3) Coordination of benefits.

(4) Health care claim status.

(5) Enrollment and disenrollment in a health plan.

(6) Eligibility for a health plan.

(7) Health plan premium payments.

(8) Referral certification and authorization.

(9) First report of injury.

(10) Health claims attachments.

(11) Other transactions that the Secretary may prescribe by regulation.

Workforce means employees, volunteers, trainees, and other persons under the direct control of a covered entity, whether or not they are paid by the covered entity.

§ 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.

(b) The Secretary may adopt a modification at any time during the first

year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard.

(c) The Secretary establishes the compliance date for any standard or implementation specification modified under this section.

(1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification.

(2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.

(3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate.

Subpart B—[Reserved]

PART 162—ADMINISTRATIVE REQUIREMENTS

Subpart A—General Provisions

Subparts B–H—[Reserved]

Subpart I—General Provisions for Transactions

Subpart J—Code Sets

Subpart K—Health Care Claims or Equivalent Encounter Information

Subpart L—Eligibility for a Health Plan

Subpart M—Referral Certification and Authorization

Subpart N—Health Care Claim Status

Subpart O—Enrollment and Disenrollment in a Health Plan

Subpart P—Health Care Payment and Remittance Advice

Subpart Q—Health Plan Premium Payments

Subpart R—Coordination of Benefits

AUTHORITY: Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d—1320d–8), as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031, and sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)).

SOURCE: 65 FR 50367, Aug. 17, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 162.100 Applicability.

Covered entities (as defined in § 160.103 of this subchapter) must comply with the applicable requirements of this part.

§ 162.103 Definitions.

For purposes of this part, the following definitions apply:

Code set means any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. A code set includes the codes and the descriptors of the codes.

Code set maintaining organization means an organization that creates and maintains the code sets adopted by the Secretary for use in the transactions for which standards are adopted in this part.

Data condition means the rule that describes the circumstances under which a covered entity must use a particular data element or segment.

Data content means all the data elements and code sets inherent to a transaction, and not related to the format of the transaction. Data elements that are related to the format are not data content.

Data element means the smallest named unit of information in a transaction.

Data set means a semantically meaningful unit of information exchanged between two parties to a transaction.

Descriptor means the text defining a code.

Designated standard maintenance organization (DSMO) means an organization designated by the Secretary under § 162.910(a).

Direct data entry means the direct entry of data (for example, using dumb terminals or web browsers) that is immediately transmitted into a health plan's computer.

Electronic media means the mode of electronic transmission. It includes the Internet (wide-open), Extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and those transmissions that are physically moved from one location to another using magnetic tape, disk, or compact disk media.

Format refers to those data elements that provide or control the enveloping or hierarchical structure, or assist in identifying data content of, a transaction.

HCPCS stands for the Health [Care Financing Administration] Common Procedure Coding System.

Maintain or *maintenance* refers to activities necessary to support the use of a standard adopted by the Secretary, including technical corrections to an implementation specification, and enhancements or expansion of a code set. This term excludes the activities related to the adoption of a new standard or implementation specification, or modification to an adopted standard or implementation specification.

Maximum defined data set means all of the required data elements for a particular standard based on a specific implementation specification.

Segment means a group of related data elements in a transaction.

Standard transaction means a transaction that complies with the applicable standard adopted under this part.

Subparts B—H [Reserved]

Subpart I—General Provisions for Transactions

§ 162.900 Compliance dates of the initial implementation of the code sets and transaction standards.

(a) *Health care providers.* A covered health care provider must comply with the applicable requirements of subparts I through N of this part no later than October 16, 2002.

(b) *Health plans.* A health plan must comply with the applicable requirements of subparts I through R of this part no later than one of the following dates:

(1) *Health plans other than small health plans*—October 16, 2002.

(2) *Small health plans*—October 16, 2003.

(c) *Health care clearinghouses.* A health care clearinghouse must comply with the applicable requirements of subparts I through R of this part no later than October 16, 2002.

§ 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

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.ncpdp.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 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 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

an entity to use a health care clearinghouse to receive, process, or transmit a standard transaction may not charge fees or costs in excess of the fees or costs for normal telecommunications that the entity incurs when it directly transmits, or receives, a standard transaction to, or from, a health plan.

(b) *Coordination of benefits.* If a health plan receives a standard transaction and coordinates benefits with another health plan (or another payer), it must store the coordination of benefits data it needs to forward the standard transaction to the other health plan (or other payer).

(c) *Code sets.* A health plan must meet each of the following requirements:

(1) Accept and promptly process any standard transaction that contains codes that are valid, as provided in subpart J of this part.

(2) Keep code sets for the current billing period and appeals periods still open to processing under the terms of the health plan's coverage.

§ 162.930 Additional rules for health care clearinghouses.

When acting as a business associate for another covered entity, a health care clearinghouse may perform the following functions:

(a) Receive a standard transaction on behalf of the covered entity and translate it into a nonstandard transaction (for example, nonstandard format and/or nonstandard data content) for transmission to the covered entity.

(b) Receive a nonstandard transaction (for example, nonstandard format and/or nonstandard data content) from the covered entity and translate it into a standard transaction for transmission on behalf of the covered entity.

§ 162.940 Exceptions from standards to permit testing of proposed modifications.

(a) *Requests for an exception.* An organization may request an exception from the use of a standard from the Secretary to test a proposed modification to that standard. For each proposed modification, the organization must meet the following requirements:

(1) *Comparison to a current standard.* Provide a detailed explanation, no more than 10 pages in length, of how the proposed modification would be a significant improvement to the current standard in terms of the following principles:

(i) Improve the efficiency and effectiveness of the health care system by leading to cost reductions for, or improvements in benefits from, electronic health care transactions.

(ii) Meet the needs of the health data standards user community, particularly health care providers, health plans, and health care clearinghouses.

(iii) Be uniform and consistent with the other standards adopted under this part and, as appropriate, with other private and public sector health data standards.

(iv) Have low additional development and implementation costs relative to the benefits of using the standard.

(v) Be supported by an ANSI-accredited SSO or other private or public organization that would maintain the standard over time.

(vi) Have timely development, testing, implementation, and updating procedures to achieve administrative simplification benefits faster.

(vii) Be technologically independent of the computer platforms and transmission protocols used in electronic health transactions, unless they are explicitly part of the standard.

(viii) Be precise, unambiguous, and as simple as possible.

(ix) Result in minimum data collection and paperwork burdens on users.

(x) Incorporate flexibility to adapt more easily to changes in the health care infrastructure (such as new services, organizations, and provider types) and information technology.

(2) *Specifications for the proposed modification.* Provide specifications for the 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 paragraph (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 code set maintaining organization's code sets as the standard medical data code sets:

(a) *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:

(1) Diseases.

(2) Injuries.

(3) Impairments.

(4) Other health problems and their manifestations.

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

(b) *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:

(1) Prevention.

(2) Diagnosis.

(3) Treatment.

(4) Management.

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

(1) Drugs
(2) Biologics.

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

(e) 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:

(1) Physician services.
(2) Physical and occupational therapy services.
(3) Radiologic procedures.
(4) Clinical laboratory tests.
(5) Other medical diagnostic procedures.
(6) Hearing and vision services.
(7) Transportation services including ambulance.

(f) 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:

(1) Medical supplies.
(2) Orthotic and prosthetic devices.
(3) Durable medical equipment.

§ 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:

(a) A request to obtain payment, and the necessary accompanying information from a health care provider to a health plan, for health care.

(b) If there is no direct claim, because the reimbursement contract is based on a mechanism other than charges or reimbursement rates for specific services, the transaction is the transmission of encounter information for the purpose of reporting health care.

§ 162.1102 Standards for health care claims or equivalent encounter information.

The Secretary adopts the following standards for the health care claims or equivalent encounter information transaction:

(a) *Retail pharmacy drug claims.* The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version 5 Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1 Release 0, February 1, 1996. The implementation specifications are available at the addresses specified in § 162.920(a)(2).

(b) *Dental Health Care Claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097. The implementation specification is available at the addresses specified in § 162.920(a)(1).

(c) *Professional Health Care Claims.* The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098. The implementation specification is available at the addresses specified in § 162.920(a)(1).

(d) *Institutional Health Care Claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096. The implementation specification is available at the addresses specified in § 162.920(a)(1).

Subpart L—Eligibility for a Health Plan

§ 162.1201 Eligibility for a health plan transaction.

The eligibility for a health plan transaction is the transmission of either of the following:

(a) An inquiry from a health care provider to a health plan, or from one

health plan to another health plan, to obtain any of the following information about a benefit plan for an enrollee:

(1) Eligibility to receive health care under the health plan.

(2) Coverage of health care under the health plan.

(3) Benefits associated with the benefit plan.

(b) A response from a health plan to a health care provider's (or another health plan's) inquiry described in paragraph (a) of this section.

§ 162.1202 Standards for eligibility for a health plan.

The Secretary adopts the following standards for the eligibility for a health plan transaction:

(a) *Retail pharmacy drugs.* The NCPDP Telecommunication Standard Implementation Guide, Version 5 Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1 Release 0, February 1, 1996. The implementation specifications are available at the addresses specified in § 162.920(a)(2).

(b) *Dental, professional, and institutional.* The ASC X12N 270/271–Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092. The implementation specification is available at the addresses specified in § 162.920(a)(1).

Subpart M—Referral Certification and Authorization

§ 162.1301 Referral certification and authorization transaction.

The referral certification and authorization transaction is any of the following transmissions:

(a) A request for the review of health care to obtain an authorization for the health care.

(b) A request to obtain authorization for referring an individual to another health care provider.

(c) A response to a request described in paragraph (a) or paragraph (b) of this section.

§ 162.1302 Standard for referral certification and authorization.

The Secretary adopts the ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094 as the standard for the referral certification and authorization transaction. The implementation specification is available at the addresses specified in § 162.920(a)(1).

Subpart N—Health Care Claim Status

§ 162.1401 Health care claim status transaction.

A health care claim status transaction is the transmission of either of the following:

(a) An inquiry to determine the status of a health care claim.

(b) A response about the status of a health care claim.

§ 162.1402 Standard for health care claim status.

The Secretary adopts the ASC X12N 276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 as the standard for the health care claim status transaction. The implementation specification is available at the addresses specified in § 162.920(a)(1).

Subpart O—Enrollment and Disenrollment in a Health Plan

§ 162.1501 Enrollment and disenrollment in a health plan transaction.

The enrollment and disenrollment in a health plan transaction is the transmission of subscriber enrollment information to a health plan to establish or terminate insurance coverage.

§ 162.1502 Standard for enrollment and disenrollment in a health plan.

The Secretary adopts the ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 as the standard for the enrollment and

disenrollment in a health plan transaction. The implementation specification is available at the addresses specified in § 162.920(a)(1).

Subpart P—Health Care Payment and Remittance Advice

§ 162.1601 Health care payment and remittance advice transaction.

The health care payment and remittance advice transaction is the transmission of either of the following for health care:

(a) The transmission of any of the following from a health plan to a health care provider's financial institution:

(1) Payment.

(2) Information about the transfer of funds.

(3) Payment processing information.

(b) The transmission of either of the following from a health plan to a health care provider:

(1) Explanation of benefits.

(2) Remittance advice.

§ 162.1602 Standards for health care payment and remittance advice.

The Secretary adopts the following standards for the health care payment and remittance advice transaction:

(a) *Retail pharmacy drug claims and remittance advice.* The NCPDP Telecommunication Standard Implementation Guide, Version 5 Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1 Release 0, February 1, 1996. The implementation specifications are available at the addresses specified in § 162.920(a)(2).

(b) *Dental, professional, and institutional health care claims and remittance advice.* The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091. The implementation specification is available at the addresses specified in § 162.920(a)(1).

Subpart Q—Health Plan Premium Payments

§ 162.1701 Health plan premium payments transaction.

The health plan premium payment transaction is the transmission of any of the following from the entity that is arranging for the provision of health care or is providing health care coverage payments for an individual to a health plan:

(a) Payment.

(b) Information about the transfer of funds.

(c) Detailed remittance information about individuals for whom premiums are being paid.

(d) Payment processing information to transmit health care premium payments including any of the following:

(1) Payroll deductions.

(2) Other group premium payments.

(3) Associated group premium payment information.

§ 162.1702 Standard for health plan premium payments.

The Secretary adopts the ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061 as the standard for the health plan premium payments transaction. The implementation specification is available at the addresses specified in § 162.920(a)(1).

Subpart R—Coordination of Benefits

§ 162.1801 Coordination of benefits transaction.

The coordination of benefits transaction is the transmission from any entity to a health plan for the purpose of determining the relative payment responsibilities of the health plan, of either of the following for health care:

(a) Claims.

(b) Payment information.

§ 162.1802 Standards for coordination of benefits.

The Secretary adopts the following standards for the coordination of benefits information transaction:

(a) *Retail pharmacy drug claims.* The NCPDP Telecommunication Standard Implementation Guide, Version 5 Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1 Release 0, February 1, 1996. The implementation

specifications are available at the addresses specified in § 162.920(a)(2).

(b) *Dental claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097. The implementation specification is available at the addresses specified in § 162.920(a)(1).

(c) *Professional health care claims.* The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098. The implementation specification is available at the addresses specified in § 162.920(a)(1).

(d) *Institutional health care claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096. The implementation specification is available at the addresses specified in § 162.920(a)(1).

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