

**§164.500 [Amended]**

6. § In 164.500(b)(1)(iv), remove the words “including the designation of health care components of a covered entity”.

**§ 165.501 [Amended]**

7. In §164.501, the definitions of the following terms are removed: *Covered functions, Disclosure, Individual, Organized health care arrangement, Plan sponsor Protected health information, Required by law, and Use.*

**§ 164.504 [Amended]**

8. In §164.504, the following changes are made:

a. The definitions of the following terms are removed: *Common control, Common ownership, Health care component, and Hybrid entity.*

b. Paragraphs (b) through (d) are removed and reserved.

**Authority:** Sections 1173 and 1175 of the Social Security Act (42 U.S.C. 1329d-2 and 1320-4).

Dated: January 13, 2003.

**Tommy G. Thompson,**  
*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### 45 CFR Part 162

[CMS-0003-F and CMS-0005-F]

RINs 0938-AK64 and 0938-AK76

#### Health Insurance Reform: Modifications to Electronic Data Transaction Standards and Code Sets

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Final rule.

**SUMMARY:** In this final rule, we respond to public comments received and finalize provisions applicable to electronic data transaction standards from two related proposed rules published in the May 31, 2002, **Federal Register**. We are also adopting proposed modifications to implementation specifications for health care entities and others. In addition, we are adopting modifications to implementation specifications for several electronic transaction standards that were omitted from the May 31, 2002, proposed rules.

**EFFECTIVE DATES:** These regulations are effective on March 24, 2003. The incorporation by reference of certain publications listed in this final rule is

approved by the Director of the Federal Register as of March 24, 2003.

**FOR FURTHER INFORMATION CONTACT:**

Gladys Wheeler, (410) 786-0273.

**SUPPLEMENTARY INFORMATION:**

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**I. Background****A. Electronic Data Interchange**

Electronic data interchange (EDI) refers to the electronic transfer of information in a standard format between trading partners. When compared with paper submissions, EDI can substantially lessen the time and costs associated with receiving, processing, and storing documents. The use of EDI can also eliminate inefficiencies and streamline processing tasks, which can in turn result in less administrative burden, lower operating costs, and improved overall data quality.

The health care industry recognizes the benefits of EDI, and many entities in the industry have developed proprietary EDI formats. However, with the increasing use of health care EDI standards, the lack of common, industry-wide standards has emerged as a major obstacle to realizing potential efficiency and savings.

**B. Statutory and Regulatory Background****1. Statutory Background**

The Congress included provisions to address the need for developing a consistent framework for electronic transactions and other administrative simplification issues in the Health

Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, which became law on August 21, 1996. Through subtitle F of title II of that statute, the Congress added to title XI of the Social Security Act (the Act) a new part C, titled “Administrative Simplification.” The purpose of this part is to improve the Medicare and Medicaid programs in particular and the efficiency and effectiveness of the health care system in general, by encouraging the development of standards and requirements to enable the electronic exchange of certain health information.

Part C of title XI consists of sections 1171 through 1179 of the Act. Section 1172 of the Act and the implementing regulations make any standard adopted under part C applicable to: (1) Health plans; (2) health care clearinghouses; and (3) health care providers who transmit any health information in electronic form in connection with a transaction covered by 45 CFR part 162.

In general, section 1172 of the Act requires any standard adopted by the Secretary of Health and Human Services (the Secretary) under this part to be a standard that has been developed, adopted, or modified by a standard setting organization (SSO). The Secretary may adopt a different standard if the standard will substantially reduce administrative costs to providers and health plans compared to the alternatives, and the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, U.S.C.

Section 1172 of the Act also sets forth consultation requirements that must be met before the Secretary may adopt standards. In the case of a standard that is developed, adopted, or modified by an SSO, the SSO must consult with the following Data Content Committees (DCCs) in the course of the development, adoption, or modification of the standard: The National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI), and the American Dental Association (ADA). In the case of any other standard, the Secretary is required to consult with each of the above-named groups before adopting the standard and must also comply with the provisions of section 1172(f) of the Act regarding consultation with the National Committee on Vital and Health Statistics (NCVHS).

Section 1173 of the Act requires the Secretary to adopt standards for transactions, and data elements for such transactions, to enable the electronic exchange of health information. Section

1173 lists the transactions and sets out requirements for the specific standards the Secretary is to adopt: Unique health identifiers, code sets, security standards, electronic signatures, and transfer of information among health plans.

Section 1174 of the Act permits the Secretary to make modifications to any established standard after the first year, but not more frequently than once every 12 months. It permits the Secretary to modify an initial standard at any time during the first year of adoption, if he determines that the modification is necessary to permit compliance with the standard.

Section 1175 of the Act requires that covered entities comply with modifications to standards or implementation specifications made after initial adoption by stating that the Secretary will designate a compliance date that may not be earlier than 180 days after the modification is adopted.

We discussed HIPAA-specific legislation in greater detail in the Transactions Rule (65 FR 50312) and the December 28, 2000, final rule, Standards for Privacy of Individually Identifiable Health Information" (65 FR 82462) (the Privacy Rule). Rather than repeating the discussion in its entirety here, we refer the reader to those documents for further information about EDI and the statutory background.

## 2. Regulatory Background

On May 7, 1998 (63 FR 25272), the Secretary proposed Standards for Electronic Transactions and Code Sets. On August 17, 2000, the final rule on Standards for Electronic Transactions and Code Sets was published in the **Federal Register** (65 FR 50312). In the August 17, 2000, final rule, (the Transactions Rule), the Secretary adopted standards for eight electronic transactions and six code sets. The transactions are:

- Health Care Claims or Equivalent Encounter Information;
- Eligibility for a Health Plan;
- Referral Certification and Authorization;
- Health Care Claim Status;
- Enrollment and Disenrollment in a Health Plan;
- Health Care Payment and Remittance Advice;
- Health Plan Premium Payments;
- and
- Coordination of Benefits.

The code sets are: International Classification of Diseases, 9th Edition, Clinical Modification, Volumes 1 and 2;

- International Classification of Diseases, 9th Edition, Clinical Modification, Volume 3 Procedures;
- National Drug Codes;

- Code on Dental Procedures and Nomenclature;

- Health Care Financing Administration Common Procedure Coding System; and

- Current Procedural Terminology, 4th Edition.

This final rule adopts modifications to the August 17, 2000 transaction and code set standards.

## 3. Statutory Requirements and Implementation Instructions for EDI Standards

Section 1172(d) of the Act requires the Secretary to establish specifications for implementing each adopted standard. However, because the implementation instructions are voluminous, they were incorporated by reference in the Transactions Rule. This approach, to incorporate by reference, is commonly used by the **Federal Register** when external organizations are tasked with developing standards that are subsequently adopted as national standards. We are using this approach in this final rule to adopt modifications to the specified standards that were proposed in the May 31, 2002 proposed rules, CMS-0003-P (67 FR 38044) and CMS-0005-P (67 FR 38050).

### *C. Designated Standard Maintenance Organization (DSMO) Process*

In our May 31, 2002, proposed rule, CMS-0005-P (67 FR 38050), we described in detail the process used by the Designated Standard Maintenance Organization (DSMO) Memorandum of Understanding (MOU) for receiving, managing and processing requested changes to the adopted standards. CMS-0005-P identified the six DSMOs and explained that we had used the process specified in the MOU to develop the proposed modifications to standards adopted in regulations. For ease of reference, we have included the DSMO names and respective websites below. Both of the SSOs (Accredited Standards Committee ASC X12N and the National Council for Prescription Drug Programs (NCPDP)) that develop standards adopted by the Secretary are DSMOs.

### *DSMO Names and Web site Addresses*

- Accredited Standards Committee X12N (ASC X12N) (<http://www.x12.org>).
- Health Level Seven, Inc. (HL 7) (<http://www.hl7.org>).
- National Council for Prescription Drug Programs (NCPDP) (<http://www.ncdp.org>).
- National Uniform Billing Committee (NUBC) (<http://www.nubc.org>).
- National Uniform Claim Committee (NUCC) (<http://www.nucc.org>).

- Dental Content Committee of the American Dental Association (<http://www.ada.org>).

For additional information regarding the DSMO change request process, see the MOU document, which is available at: [www.hipaa-dsmo.org/mou.pdf](http://www.hipaa-dsmo.org/mou.pdf).

As we stated in CMS-0005-P (67 FR 38050), a significant number of change requests were submitted through the DSMO process after the initial EDI transaction standards were adopted in the regulations. Many of those change requests were for changes that were considered by the submitters to be essential to permit initial implementation of the standards throughout the entire healthcare industry. Those change requests addressed specific details or elements within the implementation specifications.

Changes considered essential for implementation of the adopted standards were reviewed by the DSMOs and assigned "fast track" status for development within the authority of the DSMO process. (Other changes that were not considered essential are going through the general change request management process set forth in the MOU.) As specified in the MOU, the DSMOs then presented those changes deemed essential for initial implementation to the NCVHS. The NCVHS held public hearings on those proposed changes (transcripts of those hearings are available at <http://www.ncvhs.hhs.gov>). The NCVHS recommended that the Secretary adopt all of the changes proposed by the DSMOs as modifications to the national standards. Those changes are reflected in the modifications to standards that are adopted by this final rule.

## II. Provisions of the May 31, 2002, Proposed Rules

In the May 31, 2002, **Federal Register**, we published two proposed rules, CMS-0003-P (67 FR 38044) and CMS-0005-P (67 FR 38050). The two proposed rules proposed to adopt as regulations certain modifications to adopted standards.

The first proposed rule is entitled "Modifications to Standards for Electronic Transactions and Code Sets" (67 FR 38044). Hereafter, for the purposes of this final rule, we refer to this proposed rule as CMS-0003-P. CMS-0003-P contained several proposed modifications that pertained exclusively to revisions to certain electronic data interchange (EDI) standards currently in effect for retail pharmacy transactions and a repeal of the designation of National Drug Codes (NDC) as the standard medical data code

set for reporting drugs and biologics on non-retail pharmacy standard transactions.

The second proposed rule is entitled "Modifications to Transactions and Code Set Standards for Electronic Transactions" (67 FR 38050). Hereafter, for the purposes of this final rule, we refer to this proposed rule as CMS-0005-P. CMS-0005-P addressed proposals to adopt limited technical changes to implementation specifications for the transaction standards that were deemed necessary to implement industry-wide EDI standards.

Because both of these proposed rules proposed modifications or technical changes to standards that the Secretary of Health and Human Services (the Secretary) adopted in the August 17, 2000, final rule entitled "Health Insurance Reform: Standards for Electronic Transactions" (65 FR 50312), we are combining them in this final rule. Hereafter, for the purposes of this final rule, we refer to the August 17, 2000, final rule as the "Transactions Rule."

Specifically, in CMS-0003-P, we proposed to adopt the following:

- The National Council for Prescription Drug Programs (NCPDP) Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, for retail pharmacy drug claims, eligibility, and coordination of benefits transactions, to replace the earlier version (Version 1.0) that we had previously adopted in error. In this final rule, we refer to this proposed standard as the "NCPDP Batch Implementation Guide Version 1.1."

- The National Council for Prescription Drug Programs (NCPDP) Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, and the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the referral certification and authorization transaction, to replace the ASC X12N 278—Health Care Services Review standard. In this final rule, we refer to these two proposed standards as the "NCPDP Batch Implementation Guide Version 1.1" and the "NCPDP Telecommunication Guide Version 5.1," respectively.

- ASC X12N 835—Health Care Claim Payment/Advice for the retail pharmacy health care payment and remittance advice transaction, to replace the NCPDP Batch Standard Batch Implementation Guide Version 1.0 and the NCPDP Telecommunication Guide Version 5.1.

- We also proposed to repeal the adoption of the National Drug Code (NDC) as the standard for reporting drugs and biologics on all transactions except retail pharmacy transactions, also termed "non-retail pharmacy" transactions below. This repeal would result in there being no standard in place for reporting drugs and biologics on non-retail pharmacy transactions.

### III. Analysis of, and Responses to, Comments on the Proposed Rules

In response to the May 31, 2002, publication of the two proposed rules, we received over 300 timely public comments. The comments came from a variety of sources, including health care associations and societies, entities named in the HIPAA legislation, health plans, DSMOs, health care providers, Federal health plans, and private individuals.

Our process of reviewing and associating like comments identified areas of the proposed rules that required additional review in terms of their effect on policy, consistency, or clarity of the modifications to the standards, and areas that were technical and specifically related to the implementation specifications. We consulted with the DSMOs on technical comments that related specifically to the implementation specifications.

We present comments and responses generally in the order in which the proposals appeared in the May 31, 2002 proposed rules. We begin with comments and responses about the compliance dates, and continue with comments and responses on the proposals in CMS-0003-P (67 FR 38044), and those in CMS-0005-P (67 FR 38050).

#### A. Compliance Date

Under the Act, as reflected in § 160.104, the Secretary establishes the compliance date for modifications to standards. The compliance date must not be earlier than 180 days after the effective date of the adoption of the modification. We had not proposed a compliance date in the proposed rules.

The Administrative Simplification Compliance Act (ASCA) (Pub. L. 107-105) was enacted on December 27, 2001. This law provided an extension to the compliance date adopted in the Transactions Rule (65 FR 50312) for covered entities that submitted, by October 15, 2002, plans to the Secretary indicating how they will come into compliance by October 16, 2003. Small health plans were not provided with an extension opportunity, but also have a compliance date of October 16, 2003. Because this final rule is modifying

standards that are currently in effect and with which compliance is otherwise required, ASCA is relevant. ASCA did not address its effect on those covered entities otherwise required to come into compliance by October 16, 2002, or how modifications to standards were to be implemented.

*Comment:* Numerous commenters expressed support for the adoption of the modifications and stressed the urgency for implementing the modifications to meet compliance by October 16, 2003. We received some comments requesting clarification for the processing of non-compliant claims submitted before the compliance date of October 16, 2003, but processed after October 16, 2003. A few commenters recommended extensions of up to 90 days after October 16, 2003, to allow for an orderly migration to the adopted modifications. The modifications to the transactions are referred to collectively in this final rule as the "Addenda." One commenter suggested that the Department of Health and Human Services (HHS) establish a transition period as a precedent for implementation of future transaction standard versions, such as ASC X12N 4050. One commenter asked for clarification as to whether the ASCA extension was for 1 year after the 180-day adoption period for the Addenda. We received a few comments concerning the impact that publication of this rule would have on the April 2003 ASCA HIPAA testing requirements. One commenter suggested that HHS adopt the ASC X12N 4050 Version implementation specifications, instead of the ASC X12N 4010 Addenda.

*Response:* The effective date for this final rule is 30 days after the date of publication in the **Federal Register**. Standards are adopted and implementation specifications are established as of the effective date of this final rule. Trading partner agreements should determine the processing requirements for non-compliant claims submitted by covered entities that have requested a compliance extension for the period between October 16, 2002, and October 16, 2003.

To avoid confusion over the interaction between the compliance dates for the original rule, the compliance dates for these modifications, and the ASCA extension dates, we have revised the regulations text at 45 CFR 162.900. Covered entities, other than small health plans, that have timely submitted a compliance plan will be required to come into compliance with the Transactions Rule as amended

by these modifications no later than October 16, 2003. ASCA, however, complicates the compliance picture greatly.

Hundreds of thousands of entities, including numerous large health plans, have obtained 1-year extensions under ASCA. Consequently, those entities, as well as small health plans, are not required to conduct covered transactions in standard form until October 16, 2003, as clarified at section 162.900. Section 162.923 (a) provides that covered entities must conduct transactions as standard transactions, except as otherwise provided in part 162. Thus, we interpret § 162.923(a), when read with section 162.900, to mean that if both sides to a transaction are not required to conduct it in standard form (that is, if one side is required to conduct the transaction in standard form but the other side is not), neither side is required to conduct it in standard form, provided that the requirements to § 162.925 do not apply. Thus, for example, even where a covered health care provider failed to submit a compliance plan, it would not be required to comply with the Transactions Rule with respect to the covered transactions which it actually conducts during the period of October 16, 2002, through October 15, 2003, insofar as the transactions are with a health plan that is not required to comply during this period because it (1) has obtained a 1-year extension under ASCA, or (2) is a small health plan. Similarly, a health plan that is subject to the October 16, 2002, compliance date would not be required to conduct coordination of benefits in standard form with another health plan, if the latter plan was not conducting the transaction in standard form because it (1) has obtained a 1-year extension under ASCA, or (2) is a small health plan.

Further, even where compliance is required (that is, the October 16, 2002, compliance date applies to both sides to the covered transaction and neither covered entity submitted a compliance plan), we recognize that the modifications adopted as a result of CMS-0003-P and CMS-0005-P are necessary to permit the transactions covered by these proposed rules to be conducted in standard form, and that such transactions could not feasibly be required before the compliance date for the modifications in this final rule, October 16, 2003. We will not invoke our authority to penalize noncompliance with standards that our own delay in issuing this final rule has made infeasible.

With respect to the remaining universe of transactions with which compliance would otherwise be required, as between covered entities that did not submit compliance plans, we recognize that covered entities may find it difficult to determine which of their trading partners must also comply in this interim year, and may in good faith mistakenly assume that the other side to a transaction is exempted from the compliance requirement. We also note that the failure to issue the modifications below earlier has made testing of the standards between trading partners difficult, if not infeasible. Also, complying with the unmodified standards would result in implementation problems and divert resources from complying with the modified standards, which will become the industry standard in October 2003.

In light of these considerations, we have come to two decisions. First, we are affording those covered entities that have a present compliance obligation the opportunity to comply with either the unmodified transaction standards or the modified transaction standards in this interim 1-year period. This policy is reflected in § 162.900(c)(1) below. Second, we intend to take into account the numerous obstacles to compliance that exist and will work with covered entities to bring them into compliance during this interim period, through among other things, corrective action plans. We will reserve our authority to penalize noncompliance for those cases of noncompliance where such voluntary efforts fail or where covered entities fail to make reasonable efforts to come into compliance.

The modifications proposed in the two proposed rules published on May 31, 2002, and promulgated in this final rule were expressly designed and adopted to assist compliance with the standards. These modifications will, no doubt, greatly facilitate the process of becoming compliant.

We accordingly believe that publication of this final rule and the adopted revisions in the Addenda permit sufficient time to meet the ASCA testing requirements for April 2003, and the October 16, 2003, compliance date. Trading partner agreements should determine the processing requirements for non-compliant claims submitted by covered entities that have requested a compliance extension until October 16, 2003.

ASCA provided the option to obtain a 1-year extension to covered entities, excluding small health plans. We have no statutory authority to extend the compliance dates beyond this 1-year extension period. We also believe that

extending the compliance dates further, were we permitted to do so, would place additional and unacceptable burdens on covered entities that are compliant on schedule.

With regard to adopting the 4050 Version of the Implementation Guides, it is our understanding that the healthcare industry is in the midst of implementing the 4010 Version of the Implementation Guides. Adopting a new version of the guides would unfairly burden those who are completing the testing and implementation of the 4010 Version. Also, when covered entities are fully functional with the 4010 Version and its Addenda, they will have a better opportunity to assess improvements for future versions of the Implementation Guides.

#### *B. Responses to Comments on CMS-0003-P (67 FR 38044)*

##### 1. Retail Pharmacy Batch Transactions

In CMS-0003-P, we proposed that the Secretary adopt the NCPDP Batch Implementation Guide Version 1.1, supporting NCPDP Telecommunication Guide Version 5.1 for the NCPDP Data Record in the Detail Data Record. Adopting this standard would enable covered entities conducting retail pharmacy drug claims or equivalent encounter information, eligibility for a health plan, and coordination of benefits transactions to be able to submit transactions in batches.

We had intended to adopt the NCPDP Batch Implementation Guide Version 1.1 in the Transactions Rule. However, an oversight resulted in the adoption of a batch version that was not the equivalent companion to the telecommunication standard that we adopted. The oversight, if not corrected, would mean that retail pharmacy transactions could not be batched. They would instead have to be submitted individually.

*Comment:* One commenter observed that the NCPDP Telecommunication Guide Version 5.1 did not contain all the data elements required for their health plan to process the claim.

*Response:* The NCPDP, which is the SSO that developed the NCPDP Telecommunication Guide Version 5.1, has certified for us that the standard does allow the reporting of information necessary to process retail pharmacy drug claims. Because of the widespread support for this transaction standard as expressed in the public comments received and because of the assurance that essential data elements are present in the NCPDP Telecommunication Guide Version 5.1, the Secretary is

adopting that standard in this final rule. That standard and the NCPDP Batch Implementation Guide Version 1.1 are adopted for retail pharmacy drug claims or equivalent encounter information (§ 162.1102), eligibility for a health plan (§ 162.1202), and coordination of benefits (§ 162.1802).

## 2. Referral Certification and Authorization Transaction

We proposed to adopt the NCPDP Batch Implementation Guide Version 1.1, supporting the NCPDP Telecommunication Guide Version 5.1, for the NCPDP Data Record in the Detail Data Record, as the standard for the referral certification and authorization transaction. Adopting this standard would enable the reporting of all the data that are critical to retail pharmacy prior authorization transactions. This standard would replace the ASC X12N 278—Request for Review and Response Transaction, which, according to information we received from the retail pharmacy industry, does not support data that are critical to retail pharmacy prior authorization transactions. The ASC X12N standards development process for modifying standards could not be completed in time to change the standard to make it useable for retail pharmacy prior authorization transactions before the October 16, 2002, compliance date for the Transactions Rule. The NCPDP standard adequately supports this transaction for retail pharmacy, is currently in widespread industry use, and the revised 278 would not present significant advantages over it. We expect the NCPDP will continue to be the standard in the future. This modification would not affect the standard for dental, professional, and institutional referral certification and authorization transactions, which is the ASC X12N 278 standard transaction.

*Comment:* One commenter asked if the standard would apply only to retail pharmacy drug referral certifications and authorizations. The commenter believed it should apply to all retail pharmacy referral certifications and authorizations, including supplies.

*Response:* The standard would only apply to retail pharmacy drug referral certification and authorization transactions.

All of the commenters supported this proposal. We are adopting in this final rule the NCPDP Batch Implementation Guide Version 1.1 that supports the NCPDP Telecommunication Version 5.1, as the referral certification and authorization transaction standard for all retail pharmacy drug claim

certification and authorization transactions (§ 162.1302).

## 3. Health Care Claim Payment and Remittance Advice Transaction

In the May 31, 2002, proposed rule, we proposed to adopt the ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, and any adopted modifications to it, for retail pharmacy transactions. Adopting this standard would enable health plans to generate HIPAA-compliant remittance advice transactions for pharmacies. The NCPDP standard format adopted by the Transactions Rule would not have the capability of generating a per claim remittance advice transaction.

*Comment:* Several commenters pointed out that the proposed provisions in § 162.1602 list “dental, professional, and institutional health care claims and remittance advice” and recommended adding “retail pharmacy” to that list, or removing the list entirely.

*Response:* We agree with these comments and note that the ASC X12N 835 is currently the standard for health care claims payment and remittance advice for dental, professional, and institutional claims. Adopting the ASC X12N 835 for retail pharmacy health care claims payment and remittance advice would mean that it would be the standard for all types of health care claims. Therefore, there would be no need to include a list that specifies the applicable claims transactions. In this final rule, we are removing the list at § 162.1602.

*Comment:* A commenter suggested that pharmacies should not have to implement both ASC X12N and NCPDP standards at this time, and that at some point after the compliance date, future harmonization may be practical.

*Response:* Many entities today use the formats of more than one Standards Development Organization (SDO) for the electronic transactions they conduct. In addition, many entities are preparing to do so to comply with regulations. In this situation, however, the NCPDP format does not adequately support the health care payment and remittance advice transaction.

The majority of commenters who submitted comments on this proposal supported the adoption of the ASC X12N 835 for this standard, including three major pharmacy organizations. Therefore, in this final rule, we are adopting the ASC X12N 835—Health Care Claim Payment/Advice as the standard for retail pharmacy health care payment and remittance advice (§ 162.1602).

## 4. National Drug Codes (NDC) Code Set

In CMS–0003–P, we proposed to repeal the National Drug Codes (NDC) as the standard medical data code set for reporting drugs and biologics in institutional, professional, and dental claims (that is, in non-retail pharmacy drug claims). (Drugs are not reported in the adopted standard dental claim transaction.) This repeal would leave no standard in place for use in reporting drugs and biologics on those claims. A health plan could require a provider to use any one of the applicable code sets permitted by the Implementation Guides for that purpose.

The NDC code set is maintained by the Food and Drug Administration (FDA) within HHS. It is required for use on the NCPDP claim format, which is the standard for retail pharmacy drug claims. Retail pharmacies have traditionally used the NDC. However, currently in the professional and institutional health care sectors, the NDC is used much less often. The primary code set used for reporting drugs and biologics in those sectors is the Healthcare Common Procedure Coding System (HCPCS)<sup>1</sup>. In the Transactions Rule, the Secretary adopted the NDC as the standard for reporting drugs and biologics on all claims. The Secretary adopted HCPCS codes as the standard for reporting supplies and orthotic and prosthetic devices and durable medical equipment, and, in combination with the Current Procedure Terminology, Fourth Edition, for reporting physician and numerous other health care services, on all claims.

HCPCS codes are grouped in “series.” Each series begins with an alpha character, and similar items are usually grouped under the same single or multiple series. The “J series” is comprised of drugs, primarily generic drugs, and traditionally these drugs have been limited to drugs that are payable under the Medicare program. Several drug codes, however, are present in other HCPCS series for reasons that are not relevant to this discussion. The NDC, on the other hand, is currently assigned to drugs subject to listing requirements under section 510 of the Federal Food, Drug, and Cosmetic Act. The NDC is assigned to generic as well as brand name drugs. HCPCS codes are five positions in length, whereas the NDC adopted by the Transactions Rule, was originally developed as a 10-digit

<sup>1</sup> When the name of the Health Care Financing Administration was changed to the Centers for Medicare & Medicaid Services in 2001, the name of this coding system was changed from the “Health Care Financing Administration Procedure Coding System” to the “Healthcare Common Procedure Coding System.”

identifier and, when used in computer systems, may yield an 11-digit number.

With the adoption of the NDC as the standard, the HCPCS codes would not be permitted to be used in a HIPAA-compliant transaction, because the NDC would be the adopted standard for reporting drugs and biologics.

There have been many discussions about the use of the NDC in professional and institutional claims since publication of the Transactions Rule. Many members of the professional and institutional sectors did not believe that the NDC should be used on their claims. The NCVHS held hearings and heard the testimony of members of the health care industry on this issue. Information provided in that testimony led us to develop the proposal to repeal the NDC as the standard for reporting drugs and biologics on all but retail pharmacy drug claims. In CMS-0003-P (67 FR 38044), we explained why the Secretary adopted the NDC and why the Secretary was proposing the repeal.

CMS-0003-P (67 FR 38044) also solicited comments on an alternative proposal to adopt an alternative standard—in place of the NDC, to be used to report drugs and biologics on non-retail pharmacy transactions. We proposed that the HCPCS code set be the alternative standard. Below we discuss comments on the proposal to repeal the NDC and the proposal to adopt an alternative standard for non-retail pharmacy transactions.

We received approximately 200 comments on this issue. The comments fell into three major categories: (1) Repeal the NDC as the standard medical data code set for professional, institutional, and dental claims and have no standard code set; (2) repeal the NDC, but adopt HCPCS as the standard code set; and (3) retain the NDC as the sole standard code set for claims from all sectors.

*Comment:* A number of commenters supported our proposal to repeal the NDC and adopt no standard in its place. These commenters, many of which were major health care industry organizations, indicated the following: (1) The current Implementation Guide usage of the NDC should remain constant and the Implementation Guide should define when the NDC would be used; (2) if no code set was selected, the Implementation Guides should not permit payers to require providers to use local code sets for drugs and biologics; (3) the cost of converting to the NDC was very high and would not justify the benefits, if any; and (4) not naming a standard would give the industry time to fully evaluate current

practices and identify preferred alternatives.

Conversely, the proposed repeal was not favored by some Medicaid State agencies, as they are required to use the NDC to report drugs and biologics to receive drug rebates.

*Response:* We agree that repealing the NDC and having no standard would be responsive to the needs of health plans and health care providers who want to evaluate further the use of NDC. The absence of a standard would permit the use of any codes as long as that use is supported by the Implementation Guide for the transaction. Repealing the NDC and having no standard would also address the concerns of many health care providers who cited the high cost and low benefit of conversion; they could continue to use HCPCS codes. Having no standard would allow many health care entities to continue their current coding practices, reducing the implementation burden, and would accommodate State agencies' requirement to report NDCs for drug rebate programs. Additionally, if there were no standard, the selection of the code set to be used would likely be specified by health plans via trading partner agreements, as long as the Implementation Guides permitted that selection.

*Comment:* The majority of commenters supported the repeal of the NDC and the adoption of HCPCS as the sole standard for reporting drugs and biologics on non-retail pharmacy transactions. Many of these commenters were institutional providers. They indicated that drug information, which is often not reported on institutional claims, is rarely used to compute payment because claims are usually paid under prospective payment systems. Since drugs are rarely reported on institutional claims, institutional health care providers would derive no benefit from the expensive transition from HCPCS codes to the NDC.

*Response:* Repealing NDC and adopting HCPCS as the standard would allay the concerns of some health care providers that more health plans might decide to implement the NDC at some point in the future. However, adopting HCPCS as the sole standard would not respond to the needs of health plans and health care providers where the specificity of the NDC is needed to compute payment or collect drug rebates.

*Comment:* Other commenters supported retaining the NDC as the standard for reporting drugs and biologics on non-retail pharmacy drug claims. Much of the support for retaining the NDC came on behalf of

State Medicaid agencies, which must use the NDC in order to receive drug rebates.

*Response:* As we have indicated, the NDC retains certain advantages over HCPCS, such as in the area of computing payments and collecting drug rebates. Additionally, the NDC enables health care providers and health plans to track effectively the utilization of drugs and access certain manufacturer information regarding the drugs. We also acknowledge that State Medicaid agencies have strongly encouraged retaining the NDC for reporting drugs and biologics on non-retail pharmacy drug claims. Retaining the NDC, therefore, as the standard would respond to the needs of health plans and health care providers who need specificity in computing payments and collecting drug rebates. It would also foster consistent drug coding for claims and among health care providers.

Simply retaining the NDC as the sole standard, however, would not adequately respond to the express concerns of those health care providers who commented that the cost of conversion to NDC would be high while the benefits would be low or non-existent. Moreover, the majority of commenters did not support keeping the NDC as the sole standard for reporting drugs and biologics for non-retail pharmacy sectors. We concluded that adopting either the NDC or the HCPCS would fail to address many of the concerns raised.

In our considerations, we recognized that both the NDC and HCPCS remain two of the most prevalent and useful code sets for reporting drugs and biologics in non-retail pharmacy transactions. The benefits of each code set complement the other's advantages very well.

We therefore decided, as we had proposed in CMS-0003-P, to repeal the adoption of the NDC for institutional and professional claims, while allowing the NDC to remain the standard medical data code set for reporting drugs and biologics for retail pharmacy claims. We believe that this decision best addresses the majority of comments received, in that for institutional and professional claims, the choice of code set will continue to be governed by trading partner agreements. However, we wish to stress that the intent of this decision is to give covered entities the full range of choices in determining which code set to use with respect to these claims, including the HCPCS and NDC codes that have been adopted as standards for other uses. Covered entities that use HCPCS should utilize the established process for requesting new codes, rather

than supplementing the code sets with locally developed codes.

The result of this repeal will be that there is no identified standard medical data code set in place for reporting drugs and biologics on non-retail pharmacy transactions. The absence of a code set would not preclude the use of NDC for reporting drugs and biologics by covered entities on standard transactions. Covered entities could continue to report drugs and biologics as they prefer and agree upon with their trading partners.

Comments from the different parts of the industry demonstrated that no one code set is able to meet the different needs now addressed by the NDC and HCPCS. Adopting no standard at this point will allow for innovation, and permit development of new coding systems that meet the full range of business needs. Comments also indicated that the costs for a hospital or other institution to comply with the NDC for reporting drugs and biologics on institutional claims could exceed its costs for adopting all other HIPAA transaction standards. For many health care providers, entire claim systems would need to be replaced, re-engineered, or both.

We also considered the concerns expressed by the NUBC regarding the use of the NDC on institutional claims, including hospital claims. NUBC has indicated that reporting specific drugs on institutional claims introduces a systems technology requirement that is inconsistent with inpatient claims submission and institutional provider reimbursement, which are typically based on a Diagnosis-Related Group or per diem payment methodology. The NUBC has also expressed its belief that the NDC coding system is more suited for inventory control and is not appropriate for institutional provider billing, and further that the NDC pertains to retail pharmacy claims only and should not be applicable to institutional claims.

We are also aware that retaining the NDC as the sole standard for institutional claims would pose significant operational issues on institutional pharmacies because of systems incompatibility among the pharmacies, inpatient medical records, and inpatient accounting systems. Physicians generally order drugs for patients through the hospital pharmacy department by name, unit, and dosage frequency. The pharmacy department however does not reference the NDC to initiate the charge transaction. Additionally, the NDC formats do not provide information related to actual dosages administered, or provide a

methodology for multiple billing increments. Attempts by the industry to develop a complete crosswalk from the current HCPCS codes to the NDC have been unsuccessful.

Another important factor in our decision, as we mentioned in CMS-0003-P, was the information we received from the Subcommittee on Standards and Security of the NCVHS as a result of the public hearings it held on February 1, 2001, regarding HIPAA implementation issues and the NDC. In addition to the problems we identified above, concerns expressed during that meeting included the burden of training additional ancillary staff to use the NDC and the potential for increases in medical errors when new system interfaces for drug dispensing systems are created.

The NCVHS in a February 22, 2001, letter to the Secretary recommended that the Secretary repeal the adoption of the NDC as the standard medical data code set for reporting drugs and biologics in standard transactions other than retail pharmacy transactions. It also suggested that HCPCS codes as well as the NDC continue to be used in the standard institutional and professional claim transactions. Moreover, the NCVHS explained that it believes that no drug coding system in existence today meets all the needs of the health care industry. A future coding system that could be used effectively and efficiently for drug inventory, pharmacy transactions, patient care, billing arenas, and ensuring patient safety would be the best answer to this problem, according to the NCVHS.

We note therefore that another significant advantage to repealing the adoption of the NDC for reporting drugs and biologics in non-retail pharmacy standard transactions and not adopting a replacement standard code set at this time is that the industry and HHS will have time to explore the development of a new drug coding system to meet current and future needs of this sector of the health care industry. We would note that the Implementation Guides for institutional and professional claim transactions currently recognize the use of only the NDC and HCPCS codes for drugs and biologics. See the discussion at section G.2 below. The developer of a new code set could request that it be included in the guides via the DSMO maintenance process.

Thus, based on comments received and our own review of the available code sets, we believe that our decision to repeal the adoption of the NDC as the standard medical data code set for reporting drugs and biologics in all non-retail pharmacy transactions is the best

and most appropriate decision at this time. Repealing the NDC as the standard medical code set for reporting drugs and biologics in non-retail pharmacy transactions also raises opportunities for the development of a more robust drug coding system that overcomes the deficiencies inherent in the NDC and HCPCS codes for reporting drugs and biologics on standard transactions. For example, because of the inadequacy of existing codes for drug products, and the need for harmonization of medical terminology, the FDA has been working with the National Library of Medicine and the Department of Veterans Affairs to develop improved drug codes.

In preparing this final rule, we consulted with the FDA and noted that the FDA is preparing two new regulations that relate to the use of the NDC number that will be proposed for public comment soon. Both proposed rules will propose changes related to coordinating the NDC with bar coding. It is expected that the proposed changes will make the NDC number more useful to those who choose to use the NDC.

#### 5. Retail Pharmacy Drug Claims

The Transactions Rule adopted the NCPDP transaction as the standard for retail pharmacy drug claims (§ 162.1102(a)), and the ASC X12N 837—Professional Health Care Claim as the standard for professional services (§ 162.1102(c)). Neither of our May 31, 2002, proposed rules solicited comments on the formats to be used by retail pharmacies when submitting claims for drugs, supplies, durable medical equipment, prosthetics, orthotics, and professional services.

The DSMOs are currently discussing this item in their consideration of two pending change requests that were introduced into the DSMO process within the past year. (These requests were not submitted in time to be considered under the “fast track” approach described in this final rule in section I. C., “Designated Standard Maintenance Organization (DSMO) Process.”)

In submitting comments on issues presented in our two May 31, 2002, proposed rules, some commenters included comments on the formats for retail pharmacy drug claims for items and services other than drugs. Such items included syringes, which are supplies that are usually purchased with drugs such as insulin. Services included consultations with patients and the administration of vaccines (such as the influenza vaccine) to individuals. The issue of the format on which retail pharmacy supply claims should be billed is tied closely to business

practices of retail pharmacies and the administration of pharmacy and medical benefits by health plans. The Transactions Rule adopted a standard for retail pharmacy drug claims, and adopted standards for professional, institutional, and dental claims. It did not state specifically, except with respect to retail pharmacies using the NCPDP claim format, the particular types of health care providers that would use the professional and institutional ASC X12N 837 standard claim formats. The Implementation Guides themselves do not specify the types of health care providers that are expected to use those standards.

Commenters requested additional clarification of the formats (the implementation specifications) to be used by retail pharmacies in submitting claims for supplies and professional services. Below are specific comments and our responses.

*Comment:* We received comments requesting that the Secretary adopt the NCPDP format for retail pharmacy supplies and services. We also received some comments requesting that the Secretary adopt both the NCPDP format and the ASC X12N 837 format for submitting claims for supplies and services furnished by retail pharmacies, and allow the type of benefit (pharmacy or medical) to determine which format would be used. Commenters stated that splitting claims by billing drugs using the NCPDP format and supplies using the ASC X12N 837 Professional format was burdensome, and that the real-time functionality achieved with the NCPDP format could not be used for billing the supplies that are furnished in conjunction with dispensing the drug. We received conflicting comments regarding the billing of professional pharmacy services using the NCPDP format. These commenters preferred using the ASC X12N 837 Professional claim for billing professional pharmacy services.

*Response:* The commenters expressed differing business needs and concerns. Some commenters included supporting rationale and justifications, while others did not. It is apparent that much information still needs to be obtained and analyzed before we consider modifying the standards published in the Transactions Rule. We are aware that the comments do not represent a complete picture of the industry because we did not solicit comments specifically on this issue. Since formats for billing retail pharmacy supplies and professional services were not proposed in CMS-0005-P (67 FR 38050), or CMS-0003-P (67 FR 38044), many people who

may have information pertinent to this issue did not comment on it.

*Comment:* Approximately one-third of the commenters stated that the NCPDP format should not be used by retail pharmacies to submit claims for professional services; they did not provide supporting rationale.

*Response:* The NCPDP format is not used extensively by retail pharmacies to bill for professional services. Many retail pharmacies currently use the CMS-1500 "Health Insurance Claim" (the professional paper claim) in submitting claims for professional services.

*Comment:* Some commenters indicated that a more consistent and effective approach would be for retail pharmacies to use the NCPDP format for all claims, regardless of the type of service. Some commenters also elaborated on the benefits of NCPDP's real-time transaction.

*Response:* This approach would benefit retail pharmacies, which currently use the NCPDP format. However, the Transactions Rule states that claims for drugs are to use the NCPDP claims transaction. This means that retail pharmacy claims that are not for drugs are to use the ASC X12N 837 Professional claims transaction.

*Comment:* Other commenters believed that both the NCPDP and the ASC X12N formats should be used by retail pharmacies. Some of these commenters stated that drug claims and claims for supplies that are closely related should continue to be billed on the NCPDP format, and that claims for professional services and supplies that are not tied to drugs should be billed on the ASC X12N 837 Professional, which is the adopted standard for claims for supplies and professional services, and is the transaction standard that other health care providers will use for these types of claims. Several of these commenters indicated that the NCPDP format should be used for claims that fall under pharmacy benefits, and the ASC X12N 837 Professional format should be used for claims that fall under medical benefits. Some commenters expressed concern about the lack of clear industry guidelines for determining pharmacy benefits and medical benefits. Others stated that both formats should be adopted, and that health plans should determine the situations for the use of each.

*Response:* The Transactions Rule adopts in § 162.1102(a) the NCPDP format for retail pharmacy drug claims and the ASC X12N 837 Professional claim format for claims for supplies and professional services. The Transactions Rule does not specify the items or

services that would be billed on the ASC X12N 837 Professional claim. We will be providing additional guidance by other means on this issue.

#### *C. Proposal to Adopt Modifications to the Standards Adopted in the Transactions Rule*

We proposed in CMS-0005-P (67 FR 38050) to adopt modifications to certain standards adopted in the Transactions Rule (65 FR 50312). The modifications we proposed were the result of the DSMO process to maintain standards adopted by the Secretary and to process requests for adopting new standards or modifying adopted standards. (The DSMO process is described in section I. C. of this rule.)

The versions of the Addenda adopted in this final rule are referenced by the suffix "A1" and dated October 2002. It is important to note that these versions become final with publication of this final rule. Consequently, the October 2001 date is revised to October 2002 to reflect the final versions of the adopted Addenda.

#### *D. Composition of the Addenda*

Addenda are defined as modifications to items in the implementation specifications that could be considered impediments to implementation. They are first published in draft form and go through the rulemaking process before becoming final.

Two hundred thirty-one change requests were submitted to the DSMOs for consideration. Eighty-five were returned to submitters because the Implementation Guides already met the specific business need, or the need was not well substantiated; 21 were determined to be unnecessary for initial implementation and were, therefore, recommended for future changes; six were withdrawn by their submitters; and seven were referred to the Secretary as policy issues requiring resolution. The remaining 115 change requests were approved by the DSMOs and comprise the various Addenda.

Forty-eight of the 115 change requests were maintenance items to correct minor errors, or provide clarifications in the standards. Maintenance changes are technical corrections made by DSMOs to correct typographical errors or other non-substantive changes. Maintenance changes exclude activities related to the adoption of a new standard or implementation specification or modification to an adopted standard or implementation specification. Maintenance changes are typically changes that are obvious to readers of the Implementation Guides, are not controversial, and are essential to

implementation. These maintenance items are the result of DSMO change requests that were approved and recommended for adoption via the DSMO process. Therefore, we are not including a discussion of them in this final rule.

The remaining 67 of the 115 change requests were for substantive modifications to the standards, and they are detailed below.

#### *E. Proposed Modifications to the Standards*

- Changing usage of data elements from required to situational (about 20 percent of total requested changes).

Required usage of data elements means that particular data elements must be used every time the transaction is conducted. Situational usage of data elements means that, when certain specified situations or conditions exist, particular data elements must be used when the transaction is conducted.

Those who submitted DSMO change requests pointed out several data elements for which the adopted standards required usage in all cases, but that was only needed in certain situations. Usage of these data elements was made situational in the Addenda, with the situations explicitly defined. Examples follow:

1. Many health plans store Healthcare Provider Taxonomy Codes when health care providers enroll in the health plan, so there is no need to send this information on every claim. Healthcare Provider Taxonomy Codes are data elements that identify the type, classification, and specialization of providers furnishing health care. The NUCC maintains these codes. The Washington Publishing Company makes the Healthcare Provider Taxonomy Codes available on its Web site (<http://www.wpc-edi.com>). The Healthcare Provider Taxonomy Codes now will be reported only when claim adjudication is known to be impacted by the presence of the code.

2. In another case, "date last seen by physician" (used for certain physical therapy claims) is needed only by Medicare, so usage was changed from required on all claims, to required "when known to impact the payer's adjudication process."

- *Removal of certain data elements* (about 20 percent of changes).

Several data elements were removed because they do not appear to be needed by any covered entity.

- *Allowing certain information to be reported via external code sets rather than via data elements defined in the transaction* (about 20 percent of changes).

ZIP codes, maintained by the U.S. Postal Service, are an example of an external code set. Revisions and updates for transaction data elements adopted by the Transactions Rule must go through the DSMO change request process, while revisions to external code sets require requesters to submit requests to the organizations that maintain the code sets and are not subject to the DSMO review process.

There were several instances where external code sets could be used to indicate certain data elements. The replacement of data elements with external code sets will allow the maintainers of those external code sets to update the codes more easily, as opposed to having the DSMOs make changes to the standards themselves. Two external code sets adopted by the Addenda are special program indicator codes and newborn birth weights.

- *Adding additional functionality to some transactions* (about 40 percent of changes).

Requesters suggested several additional data elements, codes, or loops to enable them to perform certain business functions in the transactions.

These included cross-referencing two subscriber IDs (surviving spouse and dependents) and sending a patient's primary care physician number.

#### *F. Comments on the Modifications Included in the Addenda*

CMS-0005-P (67 FR 38050) established the scope for technical comments by limiting comments to only those items being added or changed by the Addenda.

Numerous recommendations and suggestions submitted in the comments, which were not considered critical for implementation, will be considered for improvements or clarifications to future versions of the implementation specifications.

Because the comments were technical in nature, relating to specific data elements and segments, and applied to implementation specifications that were developed and are maintained by external organizations, such as the ASC X12N and the NCPDP, the Secretary could not address all of them directly. Therefore, we analyzed the public comments received to determine which comments fell in this technical category. We consulted with representatives from each of the DSMOs on these technical comments. Some of the technical comments were referred to the external organizations that develop the standards, such as the ASC X12N transaction workgroups, for additional review and consultation.

Comments that did not pertain specifically to the proposed Addenda were considered and determined to be more appropriately addressed through the DSMO Change Request process.

The majority of comments we received generally supported adoption of the proposed Addenda. Most commenters agreed that adopting these proposed changes is necessary to permit successful initial implementation of the standards within the industry. The Workgroup for Electronic Data Interchange (WEDI), the American Hospital Association (AHA), the National Uniform Claim Committee (NUCC), a number of Medicaid State agencies, the Health Insurance Association of America (HIAA), the Blue Cross Blue Shield Association (BCBSA), and the American Medical Association (AMA) were among the numerous health care providers, health plans, and professional organizations that submitted comments expressing support for adoption of the proposed Addenda. Some commenters suggested that work on the implementation specifications continue in order to improve the clarity relating to specific situational data elements and to ensure clear, consistent interpretations and implementation by health plans.

Commenters unanimously supported many specific Addenda items, for example:

- The proposal to use existing UB-92 Condition Codes for reporting special program indicators, as well as UB-92 Value Codes to report newborn birth weights. These changes would eliminate differences in the way this information is handled for electronic and paper submission of claims. It is important wherever possible to follow the same data development paths for both paper and electronic submission in order to simplify the capturing and reporting of billing information.

- The deletion of unneeded data segments and the clarification of ambiguous usage notes.

We discuss other comments on specific modifications below. They are organized according to specific adopted transaction standards.

The Addenda are not stand-alone documents. They are supplemental implementation specifications to the initial standards adopted in the Transactions Rule. In this final rule, we therefore adopt the Addenda as part of the standards to which they apply.

#### *G. Transaction Standard for Health Care Claims or Equivalent Encounter Information*

In CMS-0005-P (67 FR 38050), we proposed to adopt the following:

- Addenda to Health Care Claim: Dental, ASC X12N 837, Version 4010, October 2002, Washington Publishing Company, 004010X097A1.

- Addenda to Health Care Claim: Professional, Volumes 1 and 2, ASC X12N 837, Version 4010, October 2002, Washington Publishing Company, 004010X098A1.

- Addenda to Health Care Claim: Institutional, Volumes 1 and 2, ASC X12N 837, Version 4010, October 2002, Washington Publishing Company, 004010X096A1 as the standard for health care claims or equivalent encounter information.

#### 1. Transaction Standard for Health Care Claims or Equivalent Encounter

Information: Institutional

*Comment:* A number of commenters objected to the usage note in the Addenda that requires reporting of HCPCS codes for all outpatient claims, because some outpatient services do not have HCPCS codes established for them. Commonly used revenue codes submitted without HCPCS codes are 250 (pharmacy drugs), 270 (medical supplies), 370 (anesthesia supplies), 710 (recovery room), and 762 (observation). HCPCS codes do not exist for many of these services. The commenters noted that the use of unlisted (miscellaneous) HCPCS codes in situations where a specific HCPCS code does not exist to describe the service or supply could result in the rejection of an entire claim because additional documentation is required for defining the unlisted code. An increase in the use of unlisted codes for these situations would cause significant claim processing delays and rework. Even though there is no additional line-item payment for these revenue codes, they must be submitted because Ambulatory Patient Classification (APC) reimbursement values are calculated by looking at all of the services submitted.

*Response:* We agree with these commenters that the Addenda proposal to require the use of HCPCS codes on all outpatient claims did not account for those services that do not have assigned HCPCS codes. The usage note was modified by the ASC X12N to indicate that HCPCS codes are only required to be reported for services when a HCPCS code exists for that particular service.

*Comment:* Several commenters objected to the Addenda's removal of the requirement for diagnosis information on "Hospital Other" bill types. "Other" is defined by the NUBC as diagnostic services, or home health services not under a plan of treatment. For example, a family physician may send blood work to a hospital-based

laboratory. The hospital never sees the patient. Some health plans use this diagnosis information to pay or reject claims based on whether a service is medically necessary, experimental, or cosmetic. The adopted Addenda modify the requirement for this diagnosis information by making its use situational, with a note explaining that a diagnosis is not needed for "Religious Non-Medical" claims and "Hospital Other" bill types.

*Response:* The original transaction standards required this diagnosis information on all inpatient and outpatient claims. The DSMO change request for not requiring the diagnosis information on certain types of claims was strongly supported by the industry because principal diagnosis information is not needed for certain hospital bill types. For example, when a physician sends a patient's blood work to a hospital-based laboratory, the hospital will bill for those services using the "Hospital Other" bill type. The hospital never sees the patient and would have no record of the patient's principal diagnosis information. We support the Addenda change to delete the requirement for principal diagnosis information in all situations, since in many cases obtaining this information creates an administrative burden when it is not readily available and not used.

*Comment:* We received numerous comments on the Addenda's institutional claim usage of Healthcare Provider Taxonomy Codes, which identify the specialty of a health care provider that provided medical services. In the implementation specification adopted in the Transactions Rule, Healthcare Provider Taxonomy Code information usage was required at the line level and the claim level for institutional claims. The Addenda modify the required use of the Healthcare Provider Taxonomy Code information at the line level and the claim level for institutional claims by making its use situational. The situation that would require its use is if the information is known to impact claim adjudication. Commenters stated that hospitals often have many caregivers involved in the delivery of a particular service, and that it is impractical or impossible in many instances to report a single Healthcare Provider Taxonomy Code or other associated provider identification at the line level. To require such reporting would impose a tremendous burden on hospitals to implement massive new system changes to track which caregivers were responsible for providing each individual service and to incur costs that would never be recouped through

payment differentials payers would assign to the service. Commenters suggested that HHS follow the NUBC recommendation to delete all references to the use of Healthcare Provider Taxonomy Codes from the institutional claim Implementation Guides. However, other commenters cited examples and reasons why Medicaid State agencies require the taxonomy information, including determining appropriate reimbursement, editing and auditing claims, routing data for State and Federal reporting, and detecting fraud and abuse. Use of taxonomy information on the institutional claim would allow Medicaid programs to use the most up-to-date information available for claim pricing and payment methodology reports. These commenters indicated that removing taxonomy codes from institutional claims could impact health care provider reimbursement and would involve complex policy changes for Medicaid State agencies.

*Response:* After extensive deliberation on this issue and evaluation of current business practices among institutional health care providers, ASC X12N has removed the required usage of Healthcare Provider Taxonomy Codes from most segments in the ASC X12N 837 Institutional Implementation Guide. We attempted to find specific situations in the industry documenting the need for this particular Healthcare Provider Taxonomy Code use. Only one health plan identified a specific need for this information at the Billing/Pay To Provider level for the institutional claim. Usage at this level will remain situational to accommodate those business situations when Healthcare Provider Taxonomy Code information is needed.

*Comment:* Numerous commenters requested that the requirement to report physician name and ID number at the line level be eliminated. The implementation specifications adopted by the Transactions Rule established this requirement. The Addenda changes recommended by the DSMOs modify the required usage to situational. The situation that would require its use is if the information is known to impact claim adjudication. According to current billing practices, an institutional claim form summarizes services and supplies provided by a hospital facility. The attending physician who has ultimate responsibility for coordinating hospital services is reported at the claim level. Line level reporting of each health care provider would be redundant since individual professional services are separately billed according to professional billing guidelines.

*Response:* After considerable discussion and evaluation of current industry practices, we determined that this information is available, but not currently required, on institutional claims. The implementation specifications adopted by the Transactions Rule established the usage of line level provider information as required when the provider information at the line level was different from that at the claim level. The Addenda for the implementation specifications modify the usage of line level provider information from required to situational. The specific situation when this information would be required is when line level provider information is known to impact claim adjudication.

*Comment:* A few commenters noted that a usage change instruction for Operating Physician Specialty Information points to an incorrect segment.

*Response:* We agree with this comment. ASC X12N has made the appropriate corrections and added this modification to the Addenda adopted by this final rule.

## 2. Transaction Standard for Health Care Claims or Equivalent Encounter Information: Professional

*Comment:* Several commenters stated that the implementation specification requirement proposed for the use of the NDC conflicted with the proposed regulation text for CMS-0003-P (67 FR 38044). In our CMS-0003-P proposed rule, we proposed repealing the NDC for reporting drugs and biologics on non-retail pharmacy transactions and that no standard for reporting drugs and biologics on non-retail pharmacy transactions be adopted at this time. CMS-0005-P (67 FR 38050) proposed adoption of the Addenda that required usage of the NDC information when necessary to add definition to a particular product. One commenter suggested that this be clarified by adding a mutually defined "ZZ" qualifier to permit usage of any code sets based on trading partner agreements.

*Response:* This final rule adopts the modified Addenda approved by ASC X12N in October 2002. The Addenda permit use of either the NDC or HCPCS to code drugs and biologics on non-retail pharmacy claims, but (with limited exceptions) do not permit other codes to be used for this purpose. However, this choice of either HCPCS or NDC codes is not consistent with our decision, reflected in § 162.1002(c) below, to repeal the standard code set for drugs and biologics for non-retail pharmacy transactions and to permit the use of all code sets in order to encourage development of a single code set that

will meet the needs of the entire health care industry. We expect that the choice of either the HCPCS or the NDC codes afforded by the Addenda will, in the usual case, result in covered entities in the non-retail pharmacy sectors of the industry continuing to code drugs and biologics as they do now, whether by NDC or by HCPCS. The Addenda will thus not create a disincentive for industry to develop, and migrate to, a single code set for use by the industry.

Although we agree that in this respect the Addenda are not consistent with our underlying policy choice regarding the code sets for drugs and biologics for non-retail pharmacy transactions, the adopted Addenda contain many important changes to the Implementation Guides that are essential if industry is to be able to test and implement the transactions in question smoothly and on time. Because we cannot, under the statute, choose among provisions in an industry-adopted standard guide without going through negotiated rule making, the critical need for the remainder of the changes in the Addenda has led us to adopt the Addenda in their present form. We intend, however, to work with industry to align the Addenda with the policy reflected at § 162.1002(c) and adopt a further modification of the standards to effect this alignment in the next update. Should we not be able to reach agreement on the inconsistency between our policy decision and the policy reflected in the Implementation Guides, we intend to pursue our options under the statute that include negotiated rule making. We recognize that the existence of what is, in effect, two standards for coding drugs and biologics within the transactions in question may cause problems between health plans and health care providers and may in some cases result in noncompliance. It is unlikely that we would pursue any such instances of noncompliance, in light of the competing demands for enforcement resources and the inconsistency between our policy decision and the policy reflected in the Implementation Guide.

With respect to the comment about ZZ codes, the adopted Addenda only permit use of ZZ qualifiers for certain situations. Thus, the problem discussed above likewise exists with respect to such codes, and we adopt the same approach thereto.

*Comment:* One commenter listed three modifications that had been approved by the DSMOs but were not included in the Addenda specifications. These modifications related to Initial Treatment Date, Spinal Manipulation Certifications for Medicare Part B, and the Test Date for Dialysis Patients.

*Response:* We verified that these modifications were adopted in the proposed Addenda but due to typographical errors were inadvertently not included in the proposed Addenda. ASC X12N has corrected these errors and added these modifications to the Addenda adopted by this final rule.

*Comment:* We received many comments from anesthesiology providers requesting that we not adopt the proposed usage instruction that allows reporting anesthesia services in minutes only. Current business practices require that reimbursement for anesthesia services be based on total anesthesia time in minutes or units. Adopting this proposed usage instruction in the Addenda would impact reimbursement methodologies and payment amounts for anesthesia providers.

A number of commenters requested HHS to adopt a standard definition for anesthesia time. A generally accepted definition for most payers, including Medicare, that is consistent with the American Society of Anesthesiologists' definition, defines anesthesia time as starting when the practitioner begins to prepare the patient for anesthesia services and ending when anesthesia services are no longer being provided and the patient is safely in postoperative care. However, a minority of payers account for anesthesia time differently, requiring multiple reporting for face-to-face start and stop times, if there are different clinical activities in a particular service. A commenter pointed out that the sporadic need to depart from a widely accepted methodology is burdensome and results in frequent reporting errors.

*Response:* We agree with the comment to delete the usage instruction requiring the reporting of minutes only for anesthesia services. Based upon various payment systems for anesthesia services that depend upon reporting unit information on claims, and the various methods for calculating one unit of time, we determined that adopting a standard requiring that only minutes be reported would impact anesthesia providers' ability to report their services adequately. Regarding the request for a standard definition for anesthesia time, we believe that the applicable comments actually seek further clarification of health plans' reimbursement policies, which are not the subject of these transaction standards.

*Comment:* Several commenters objected to a modification of the requirement for spinal and non-spinal manipulation service information. This

information was previously required on all spinal manipulation claims. The Addenda limit this requirement to Medicare Part B chiropractic claims. For some health plans, this information applies to contractual benefit exclusions and is used to adjudicate claims. Since osteopathic manipulation procedure codes can represent either spinal or non-spinal manipulations, the spinal manipulation service information segment is used by some health plans to distinguish between spinal and non-spinal services.

*Response:* We agree with this comment. ASC X12N has added a usage note to the Addenda adopted by this final rule to require the spinal manipulation service information segment when needed for claim adjudication.

*Comment:* Numerous commenters supported the Addenda modification that changed the usage for Healthcare Provider Taxonomy Codes from required to situational. However, one commenter suggested that usage of Healthcare Provider Taxonomy Codes be completely removed from the Professional claim Implementation Guide.

*Response:* Commenters generally supported the Addenda modification for usage of the Healthcare Provider Taxonomy Codes from required to situational. After extensive review and discussion of this topic, we adopt the proposed Addenda's situational usage of Healthcare Provider Taxonomy Codes on the Professional claim.

*Comment:* We received comments indicating that "Date Last Seen" information was required by a number of payers. The Addenda specified that only Medicare required this information.

*Response:* We have confirmed that other health plans do need these data. The Secretary adopts the ASC X12N modification for situational usage of this date information when it impacts the health plan's claim adjudication process.

*Comment:* One commenter requested that a description for the acronym "EPSDT" be added to the Implementation Guide.

*Response:* We believe that this information will clarify Implementation Guide requirements. Accordingly, the acronym for Early and Periodic Screening for Diagnosis and Treatment ("EPSDT") and its definition will be adopted. ASC X12N revised the Addenda to include this clarification.

*Comment:* A number of commenters referenced variations in the use of "performing provider" and "rendering

provider" information, and questioned the different terminology.

*Response:* In the Addenda performing provider (PE) and rendering provider (PR) are separate and distinct data elements. "PE" and "PR" have the same business meaning of identifying the provider who furnishes a service. However, these data are named differently because they are referenced in separate sections of the Implementation Guide. "PE" is used to denote the Performing Provider in the PRV01 section. "PR" denotes the Rendering Provider at the Loop 2310 B segment.

### 3. Transaction Standard for Health Care Claims or Equivalent Encounter Information: Dental

*Comment:* We received a number of comments requesting the use of HCPCS modifier codes for dental claims. The commenters stated that using HCPCS modifier codes improves the efficiency of processing electronic dental claims by providing necessary detail and allowing more accurate dental claim adjudication. Other commenters opposed the use of HCPCS modifier codes with the adopted Code on Dental Procedures and Nomenclature standard, stating that most dental billing systems do not support procedure code modifiers. Those commenters pointed out that the use of HCPCS modifier codes is likely to increase paper claims and would perpetuate the current lack of code standardization for payment purposes and undermine the goal of administrative simplification.

*Response:* The Code on Dental Procedures and Nomenclature (The Code), as maintained and distributed by the American Dental Association (ADA), is the adopted standard code set for reporting dental services. Using HCPCS modifier codes for dental claims reporting would require the adoption of an entire additional code set for standard dental transactions, when only 20 to 30 modifiers are needed. We recognize that no single code set in use today meets all of the business requirements related to the full range of health care services and conditions that exist, and that adopting multiple standards may be a way to address code set inadequacies. Rather than adopt the HCPCS modifier codes in addition to The Code for dental transactions, we suggest working with The Code maintainers, the ADA, to develop and add modifiers that will meet the needs of the dental industry. Dental professionals and the public may submit requests at <http://www.ada.org/prof/prac/manage/benefits/cdtform.html>.

*Comment:* We received one comment suggesting that the phrase "for services provided or proposed" be added after Dental Health Care Claims (§ 162.1102(b)). The ASC X12N 837 dental claim transaction was designed and is used to submit a request for pre-determination and pre-authorization of dental benefits. Since this function was not identified in the Transactions Rule or in the Addenda, the submission of an electronic inquiry for determining payment for proposed dental services is not an adopted transaction standard. This commenter also suggested that the word "Dental" be deleted from § 162.1302(b), Standard for Referral Certification and Authorization, dental, professional, and institutional referral certification and authorization 004010X094A1 because the adopted implementation specification for ASC X12N 278 states that it is not intended for dental pre-determination pricing, and that instead the ASC X12N 837 Dental transaction should be used for this purpose. The commenter also stated that there is no existing or anticipated need for referral certification and authorization using the ASC X12N 278 for dental services. Dental systems support the ASC X12N 837 Dental for pre-approval of dental benefits. We received conflicting comments from Medicaid-identified commenters who expressed a need for using the ASC X12N 278 for dental referral certification and authorization, and that indicated that all dental systems do not completely support the ASC X12N 837 Dental for pre-approval of dental benefits.

*Response:* We have determined that the ASC X12N 837 Dental claim is commonly used by the dental industry for pre-determination and pricing of dental services. This function does not meet the definition for the Referral Certification and Authorization Transaction in the Transactions Rule at § 162.1301, and is not a transaction standard adopted by the Transaction Rule, or proposed in CMS-0005-P.

Although not a HIPAA standard, pre-determination and pricing functionality are available for use with the ASC X12N Dental claim. However, ASC X12N has not adopted a standard response transaction for use with this function. ASC X12N will be developing and modeling the business use of the pre-determination and pricing transaction in coordination with the DSMOs for future consideration as a transaction standard and the subject of a later rule.

Based upon comments received, we also have determined that there is an expressed business need for use of the ASC X12N 278 for dental referral

certification and authorization. The word “dental” will remain in § 162.1302 so that use of ASC X12N 278 is available for referral certification and authorization of dental transactions.

In summary, adding the phrase “for Services Provided or Proposed” to § 162.1102(b) will not be adopted at this time. However, this does not preclude use of the ASC X12N 837 Dental claim pre-determination and pricing functionality. The ASC X12N 278 will remain available for dental use of the Referral Certification and Authorization Transaction. The dental industry will have available use of the ASC X12N 278 adopted transaction standard for referral certification and authorization transactions and the ASC X12N 837 Dental claim for pre-determination and pricing activities for which no standard has been adopted.

*Comment:* A number of commenters disagreed with the Addenda modification that added “Assistant Surgeon” and “Rendering Provider” information to both the line level and the claim level for dental claims. Commenters stated that tracking and reporting this information would be an enormous burden for health care providers and not conducive to administrative simplification.

*Response:* In order to reduce the administrative burden on health care providers and prevent the potential confusion that could result from sending or receiving a claim with both a “Rendering Provider” and an “Assistant Surgeon” at the same level, ASC X12N has added a note to the Addenda instructing the user not to report the “Assistant Surgeon” information when the “Rendering Provider” information is reported at the line level of the claim.

*Comment:* We received a few comments supporting the Addenda modification that changed the usage from required to situational for Healthcare Provider Taxonomy Codes.

*Response:* The Addenda modified the use of the Healthcare Provider Taxonomy Codes from required to situational on the dental claim.

*Comment:* One commenter indicated support for the Addenda and specifically supported the addition of a new code set value in the Addenda, “service provider number,” which the commenter maintained was a necessary data element for managed care programs.

*Response:* This comment supports one of the Addenda modifications adopted by this final rule that was required to permit initial implementation of the standards. Adding the “service provider number”

code set value is an example of a technical addition that better defines the implementation specifications.

#### *H. Transaction Standard for Eligibility for a Health Plan*

We proposed adoption of the Addenda to Health Care Eligibility Benefit Inquiry and Response, ASC X12N 270/271, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 as the standard for the dental, professional, and institutional health care eligibility benefit inquiry and response transaction.

*Comment:* We received two comments that expressed support for adoption of the Addenda to the ASC X12N 270/271 transaction.

*Response:* No additional comments or specific detailed requests were received for these Addenda.

#### *I. Transaction Standard for Referral Certification and Authorization*

We proposed adoption of the Addenda to the Health Care Services Review—Request for Review and Response, ASC X12N 278, Version 4010, October 2002, Washington Publishing Company, 004010X094A1 for the dental, professional, and institutional referral certification and authorization transaction.

*Comment:* We received a number of comments about use of the Logical Observation Identifier Names and Codes (LOINC™). The comments stated that use of this code set was confusing and requested that the usage requirement be deleted or a clarifying note be added. The Addenda state that this code set is not allowed for use under HIPAA at this time. It is unclear why this code set would be included in the Addenda if the code set is not an adopted standard code set.

*Response:* The LOINC™ code set was intended by the SSOs to increase functionality of the transaction. It has not been adopted as a national standard code set, but can be used in implementing this transaction. The Addenda add the use of the LOINC™ code set as an EDI option for responding to requests for additional information when conducting the standard Referral Certification and Authorization Transaction.

*Comment:* We received a number of comments suggesting that the Addenda usage notes that allow attachment of electronic documentation to this transaction were confusing because they appeared to conflict with the Claims Attachment Transaction, mandated by HIPAA but not adopted by the Secretary at this time.

*Response:* The Claims Attachment Transaction standard mandated by HIPAA, but not adopted by the Secretary, is available for voluntary EDI use from the Washington Publishing Company at the following Web site: [www.wpc-edi.com](http://www.wpc-edi.com). The functionality of this transaction allows the electronic transmission of documentation associated with a claim. It can also function as a response for the Referral Certification and Authorization Transaction, when additional information is requested. The use of the electronic attachment with the Referral Certification and Authorization Transaction is considered a two-way transaction: an EDI request and its associated EDI response. Use with the claim transaction can be either a one-way (required attachment is sent with the claim and not as a response to a request), or a two-way transaction. The Addenda do not require the provider to respond to this request for additional information by using the Claims Attachment Transaction. However, if the provider wants to respond using an EDI transaction, the preferred method is the Claims Attachment Transaction.

We agree that further clarification on the circumstances when these two transactions may be used is needed. ASC X12N has modified the standard for the referral certification and authorization implementation specification to illustrate the model use of these transactions for other applications.

*Comment:* We received one comment that referenced the absence of a needed segment regarding Dependent Detail information. The Dependent Detail loop ID 2010DA for Dependent name 270 DTP date or time period is not referenced in the Addenda. This segment is needed to convey subscriber dependent information when the dependent is the patient.

*Response:* We agree that this is an error. ASC X12N has corrected it in the adopted Addenda.

*Comment:* There were approximately 20 highly technical comments relating to requests for clarification, missing elements, misspelling, minor revisions, and improvements to the Implementation Guides.

*Response:* Because of their technical complexity, these comments that involved modifications to specific loops and data elements in the implementation specifications were referred to the ASC X12N Workgroup. The following is a summary of these comments:

- Four commenters requested minor revisions, which included creating a response code to tell the provider that

additional medical information is needed, correcting a typographical error for repeating a data element, adding a qualifier to enable the provider to link a request with an attachment, and defining two segments that only support paper attachments. These requests have been reflected in the revised Addenda.

- Fourteen of the commenters asked for additional clarification on the appropriate use of the standard for referral certification and authorization as a two-way transaction. The Implementation Guide is modified to illustrate the model use of this transaction to include a follow-up EDI or non-EDI response.

- One commenter asked a question relating to whether a transaction should be rejected if there is no patient event tracking number (TRN) segment for the patient, when the patient is not the subscriber. ASC X12N clarified in the Addenda that the transaction should not be rejected. The TRN usage instruction was made specific about when the data are required.

- One of the commenters requested that a new code be developed to replace the Assigned By Receiver (ABR) code rather than use an existing code to define an element for which it was not intended. A data maintenance request has been approved to have a code added, but it will not be in effect for the ASC X12N 4010 Version of the Implementation Guide.

#### *J. Transaction Standard for Health Care Claim Status*

We proposed the adoption of the Addenda to Health Care Claim Status Request and Response, ASC X12N 276/277, Version 4010, October 2002, Washington Publishing Company, 004010X093A1 as the standard for the health care claim status transaction.

We did not receive significant comments on this proposal.

#### *K. Transaction Standard for Enrollment and Disenrollment in a Health Plan*

We proposed the adoption of the Addenda to Benefit Enrollment and Maintenance, ASC X12N 834 Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1 as the standard for enrollment and disenrollment in a health plan transaction.

We did not receive significant comments on this proposal.

#### *L. Transaction Standard for Health Care Claim Payment/Advice*

We proposed the adoption of the Addenda to Health Care Claim Payment/Advice, ASC X12N 835,

Version 4010, October 2002, Washington Publishing Company, 004010X091A1 as the standard for dental, professional, institutional, and pharmacy health care payment and remittance advice transactions.

We did not receive significant comments on this proposal.

#### *M. Transaction Standard for Health Care Premium Payments*

*Comment:* A number of commenters pointed out that adoption of the ASC X12N 004010X061 and ASC X12N 004010X061A1 standards were not included in CMS-0005-P.

*Response:* We received comments pointing out that the transaction standard for Health Care Premium Payments, the ASC X12N 820, 004010X061 and Addenda, 004010X061A1, were omitted from CMS-0005-P. We did not specifically intend to exclude this transaction standard and its Addenda from the proposed rule. The modification for the Addenda to this Implementation Guide provides the same guidance as the Addenda for the other transaction standards; the modification provides guidance to the industry, in section A.1.3.1.2, in handling decimal points in monetary transactions. Nevertheless, we recognize that these Implementation Guide modifications were not expressly identified and separately listed in CMS-0005-P, and thus we are including them as follows in section IV below.

### **IV. Waiver of Proposed Rulemaking**

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice and public comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We find for good cause that it is unnecessary to undertake notice and comment rulemaking procedures for this final rule because the Addenda modifications for § 162.1702 “Standard for health care premium payments,” § 162.1802 “Standards for coordination of benefits,” and technical modifications approved by the DSMOs (relating to Initial Treatment Date, Spinal Manipulation Certifications for Medicare Part B, and the Test Date for

Dialysis Patients) offer no substantive changes to the standard and Addenda and merely provide explanatory guidance.

The Addenda for the Health Plan Premium Payments Transaction provides the same guidance to the industry as the Addenda for other adopted transactions that were proposed in the proposed rule at 67 FR 38050.

The Coordination of Benefits Transaction Standard is a variation of the health care claim transaction for institutional, dental, and professional providers that was proposed in CMS-0005-P.

The three modifications approved by the DSMOs but not included in the Addenda specifications are merely technical corrections relating to Initial Treatment Date, Spinal Manipulation Certifications for Medicare Part B, and the Test Date for Dialysis Patients for a single transaction standard. These corrections in essence correct a typographical error in the draft Addenda and do not require any data elements to be changed.

We received comments on the standard for the health care claim, and have responded to those in this final rule. Because each of the transaction standards adopted by the Transactions final rule has Addenda that were approved for use by the industry, we are adopting the Addenda for each of the proposed transactions so that implementation of the Addenda for each of the adopted standards will be consistent. Therefore, for good cause, we waive notice and public comment procedures under 5 U.S.C. 553(b)(B).

### **V. Collection of Information Requirements**

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The information collection requirements and associated burdens in §§ 162.1002, 162.1102, 162.1202, 162.1302, 162.1402, 162.1502, 162.1602, 162.1702, and 162.1802 are subject to the PRA. The burden of these standards is addressed under OMB approval number 0938-0866.

We are submitting a copy of these revisions to the regulation sections to OMB for its review of the information collection requirements. We will also submit the all of the revisions for review and reapproval under 0938-0866. These revisions are not effective until OMB has approved them. If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Office of Strategic Operations and Regulatory Affairs, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, MD 21244, Attn: Julie Brown, CMS-0003-F/0005-F; and  
Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, Desk Officer, CMS-0003-F/0005-F.

## VI. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258 which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules. The analysis in the Transactions Rule assumed that the adopted standards will be able to be implemented successfully by the industry. The changes adopted in this final rule are a result of industry analyses that showed certain minor modifications to the adopted standards would be necessary to permit full industry compliance with the standards.

These modifications make limited adjustments and corrections to the overall standards and would facilitate the congressional intent of implementation of national electronic standards. Thus, the impact analysis previously published, 65 FR 50350 through 50365, would reflect industry experience in implementing the changes adopted in this rule.

In relation to the prior impact analysis, this final rule imposes no additional burdens and creates no additional costs. All of the modifications adopted in this final rule and proposed in CMS-0003-P (67 FR 38044) and CMS-0005-P (67 FR 38050) are required to facilitate successful implementation of the standards. Their implementation will, in fact, avoid costs that were not anticipated in the impact analysis of the Transactions Rule.

The 115 approved modifications to the standards included 48 maintenance changes (minor error corrections or clarifications), and 67 modifications to the standards. Details of these 67 modifications include—

- Changing the usage of data elements from “required” to “situational” (about 20 percent of changes);
- Removal of certain data elements (about 20 percent of changes);
- Allowing certain data elements to be reported via external code sets rather than data elements in the transaction (about 20 percent of changes); and
- Adding additional functionality to some transactions (about 40 percent of changes).

In particular, institutional and professional providers that have submitted ASCA compliance plans will not be required to retool systems and restructure current operations to accommodate the adopted NDC for reporting drugs and biologics on non-retail pharmacy standard transactions. Estimates reported to the NCVHS indicated that the cost of transitioning to NDCs on institutional claims could easily exceed an institution’s cost for adopting all other transaction standards combined. While costs could vary depending on the size of the facility, hospitals estimate the minimum cost at \$200,000 per facility to switch from HCPCS codes to NDCs. The industry also estimates that typical physician practices may spend \$800 to as much as \$100,000 for practice management systems.<sup>2</sup> Although included for purposes of illustration, documentation to substantiate these estimates of the true costs for institutional providers of adopting the NDC as the code set

standard for transactions involving drugs and biologics was not provided. Consequently, we do not consider these to be reliable estimates of the true costs for institutional providers of adopting the NDC as the code set standard for transactions involving drugs and biologics. This final rule retracts the adoption of the NDC and does not adopt any standard medical code set for reporting drugs and biologics on nonretail pharmacy transactions. Institutional and professional providers can continue their current practices for reporting drugs and biologics on institutional and professional standard transactions.

The RFA requires agencies to determine whether a rule will have a significant economic impact on a substantial number of small entities. On November 17, 2000, the Small Business Administration (SBA) published a final rule (65 FR 69432) changing the small business size standards for the health care industry. This SBA rule became effective December 18, 2000. The size standards that the SBA now uses are those defined by the North American Industry Classification System. Before that, the SBA used size standards as defined by the Standard Industrial Codes. The size standard is no longer a uniform \$5 million in annual revenues for all components in the health care sector. Rather, the size standard now ranges from \$6 million to \$29 million. The RFA for this final rule is linked to the aggregate RFA for all the Administrative Simplification standards that appeared in the Transactions Rule, which predated the SBA change. It is appropriate, for purposes of this final rule, to continue to use the \$5 million small business size standard that was in effect at the time of publication of the Transactions Rule. Maintaining this consistent definition for small business size minimizes confusion in the industry and does not adversely impact entities that were not considered small businesses according to the Transaction Rule definition. Nonprofit organizations are considered small entities. Small government jurisdictions with a population of less than 50,000 are considered small entities. Individuals and States are not considered small entities. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less in any one year. For purposes of the RFA, all retail pharmacies are considered to be small entities. We have determined that this final rule will not have a significant economic impact on a substantial number of small entities.

<sup>2</sup> Testimony from health care providers to the NCVHS on February 1, 2001.

This final rule makes only minor modifications to the regulatory process already put in place by the Transactions Rule (65 FR 50350 through 50365), which will generally reduce compliance burden on covered entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this final rule will not have an additional significant impact on a substantial number of small rural hospitals. This final rule makes only minor modifications to the regulatory process already put in place by the Transactions Rule (65 FR 50350 through 50365), which will generally reduce compliance burden, particularly on hospitals and other institutional providers, who will no longer be required to adopt the NDC for transactions involving drugs and biologics.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This final rule will have no mandated consequential effect on State, local, or tribal governments, or on the private sector when using the Regulatory Impact Analysis for the Transactions Rule (65 FR 50350 through 50365) as a baseline.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this final rule will not significantly affect the rights, roles, and responsibilities of States. This final rule makes only minor modifications to the regulatory process already put in place by the Transactions Rule (65 FR 50350 through 50365), which will generally reduce compliance burden on covered entities.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget (OMB).

### List of Subjects in 45 CFR Part 162

Administrative practice and procedure, Electronic transactions, Health facilities, Health insurance, Hospitals, Incorporation by reference, Medicare, Medicaid, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble of this final rule, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter C, part 162 as follows:

### PART 16—ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 162 continues to read as follows:

**Authority:** Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 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)).

2. Section 162.900 is revised to read as follows:

#### § 162.900 Compliance dates for transaction standards and code sets.

(a) *Small health plans.* All small health plans must comply with applicable requirements of subparts I through R of this part no later than October 16, 2003.

(b) *Covered entities that timely submitted a compliance plan.* Any covered entity, other than a small health plan, that timely submitted a compliance plan with the Secretary under the provisions of section 2 of Pub. L. 107–105, 115 Stat. 1003 (ASCA) must comply with the applicable requirements of subparts I through R of this part no later than October 16, 2003.

(c) *Covered entities that did not timely submit a compliance plan.*

Any covered entity, other than a small health plan, that did not timely submit a compliance plan under the provisions of section 2 of Pub. L. 107–105, 115 Stat. 1003 (ASCA) must comply with the applicable requirements of subparts I through R of this part—

(1) Beginning on October 16, 2002, and ending on October 15, 2003—

(i) For the corresponding time period; or

(ii) For the time period beginning on October 16, 2003.

(2) Beginning on and after October 16, 2003, for the corresponding time period.

3. Section 162.920 is revised to read as follows:

#### § 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 Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC; and the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244. 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 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, 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.

4. Section 162.1002 is amended by—

A. Revising the introductory text to the section.

B. Redesignating paragraphs (a) through (f) as paragraphs (a)(1) through (a)(6).

C. In redesignated paragraph (a)(1), further redesignating paragraphs (1) through (5) as paragraphs (a)(1)(i) through (a)(1)(v).

D. In redesignated paragraph (a)(2), further redesignating paragraphs (1) through (4) as paragraphs (a)(2)(i) through (a)(2)(iv).

E. In redesignated paragraph (a)(3), further redesignating paragraphs (1) and (2) as paragraphs (a)(3)(i) and (a)(3)(ii).

F. In redesignated paragraph (a)(5), further redesignating paragraphs (1) through (7) as paragraphs (a)(5)(i) through (a)(5)(vii).

G. In redesignated paragraph (a)(6), further redesignating paragraphs (1) through (3) as paragraphs (a)(6)(i) through (a)(6)(iii).

H. Adding new paragraph (a) introductory text and paragraph (b).

The republication and additions read as follows:

**§ 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:

\* \* \* \* \*

(b) For the period on and after October 16, 2003:

(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.

5. Section 162.1102 is revised to read as follows:

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

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

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

(1) *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.

(Incorporated by reference in § 162.920).

(2) *Dental health care claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097. (Incorporated by reference in § 162.920).

(3) *Professional health care claims.* The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096. (Incorporated by reference in § 162.920).

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

(1) *Retail pharmacy drugs claims.* The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standards Implementation Guide, Version 5, Release 1, September 1999, and equivalent NCPDP Batch Standards Batch Implementation Guide, Version 1, Release 1, (Version 1.1), January 2000, supporting Telecommunication Version 5.1 for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, health care claims.* 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.

(Incorporated by reference in § 162.920).

(3) *Professional health care claims*. The ASC X12N 837—Health Care Claims: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claims: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010x098A1. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims*. The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096. (Incorporated by reference in § 162.920).

6. Section 162.1202 is revised to read as follows:

**§ 162.1202 Standards for eligibility for a health plan transaction.**

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

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

(1) *Retail pharmacy drugs*. The National Council for Prescription Drug Programs Telecommunications Standards Implementaiton Guide, Version 5, Release 1, September 1999, and equivalent NCPDP Batch Standards Batch Implementation Guide, Version 1, Release 0, February 1, 1996. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional health care eligibility benefit inquiry and response*. The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003:

(1) *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 1 (Version 1.1), January 2000, supporting Telecommunication Version 5.1 for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional health care eligibility benefit inquiry and response*. The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003:

(1) *Retail pharmacy drugs*. The National Council for Prescription Drug Programs Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional health care eligibility benefit inquiry and response*. The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1. (Incorporated by reference in § 162.920).

7. Section 162.1302 is revised to read as follows:

**§ 162.1302 Standards for referral certification and authorization transaction.**

The Secretary adopts the following standards for the referral certification and authorization transaction:

(a) For the period from October 16, 2002, through October 15, 2003: The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003:

(1) *Retail pharmacy drug referral certification and authorization*. The NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional referral certification and authorization*. 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.

(Incorporated by reference in § 162.920).

8. Section 162.1402 is revised to read as follows:

**§ 162.1402 Standards for health care claim status transaction.**

The Secretary adopts the following standards for the health care claim status transaction:

(a) For the period from October 16, 2002 through October 15, 2003: The ASC X12N—276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003: 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. (Incorporated by reference in § 162.920).

9. Section 162.1502 is revised to read as follows:

**§ 162.1502 Standards for enrollment and disenrollment in a health plan transaction.**

The Secretary adopts the following standards for the enrollment and disenrollment in a health plan transaction.

(a) For the period from October 16, 2002 through October 15, 2003: ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003: 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. (Incorporated by reference in § 162.920).

10. Section 162.1602 is revised to read as follows:

**§ 162.1602 Standards for health care payment and remittance advice transaction.**

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

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

(1) *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.

(Incorporated by reference in § 162.920).

(2) *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. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003: *Health care claims and remittance advice.* 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. (Incorporated by reference in § 162.920).

11. Section 162.1702 is revised to read as follows:

**§ 162.1702 Standards for health plan premium payments transaction.**

The Secretary adopts the following standards for the health care premium payments transaction.

(a) For the period from October 16, 2002 through October 15, 2003: The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003: 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. (Incorporated by reference in § 162.920).

12. Section 162.1802 is revised to read as follows:

**§ 162.1802 Standards for coordination of benefits information transaction.**

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

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

(1) *Retail pharmacy drug claims.* The National Council for Prescription Drug Programs 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. (Incorporated by reference in § 162.920).

(2) *Dental health care claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097. (Incorporated by reference in § 162.920).

(3) *Professional health care claims.* The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096. (Incorporated by reference in § 162.920).

(b) For the period on and after October 16, 2003:

(1) *Retail pharmacy drug claims.* The National Council for Prescription Drug Programs Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard

Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental health care claims.* 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. (Incorporated by reference in § 162.920).

(3) *Professional health care claims.* 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 Company, 004010X098A1. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims.* 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. (Incorporated by reference in § 162.920).

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Dated: January 31, 2003.

**Tommy G. Thompson,**  
*Secretary.*

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