

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