

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