

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