

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