

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)¹. 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

¹ 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.”