National Committee on Vital and Health Statistics (NCVHS)
Subcommittee on Standards
Hearing on Attachments

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,500 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

Conference calls were held with NCPDP members to obtain input to the questions posed regarding Attachments. NCPDP assumed the attachment standards and code sets referred to in the questions are the ASC X12N 275 and 277RFAI, LOINC, and the HL7 Attachment Specification Consolidated CDA Templated Guide.

In 2009, NCPDP standards were adopted for the following retail pharmacy drug transactions: healthcare claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization, coordination of benefits; and Medicaid pharmacy subrogation. In the Modifications final rule, HHS adopted the NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (hereinafter referred to as Version D.0) and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2) in place of the NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1) and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 1 (Version 1.1), for the HIPAA retail pharmacy drug transactions.

NCPDP members use the Version D.0 claim and service transactions (B1, B2, B3/S1, S2, S3) and the *ASC X12 Standards for Electronic Data Interchange Technical Report 3 (TR3) - Health Care Claim: Profession (837)*, May 2006, ASC X12N/005010X222A1 (hereinafter referred to as X12N 837).

The Version D.0 claim transaction (B1/B2/B3) is sent from the pharmacy provider to the processor to request payment from the processor for a specific patient for claims billed according to appropriate plan parameters. Billings may be for products dispensed, DUR conflict resolution, or professional services rendered. Services may be correlated with a dispensing event or may be separate and unrelated to any particular prescription. Professional pharmacy services may include but are not limited to blood pressure monitoring, taking a patient history for a new disease or diagnosis, referring patients to other

health care providers, and counseling and education beyond the act of describing a medication's use and side effects. Service billings use the Version D.0 S1/S2/S3 transactions. The Version D.0 B1/B2/B3 transaction is also used to report health care product/services from the provider to the payer (encounters).

Processors/payers do not require a claim attachment to adjudicate a Version D.0 claim. Therefore the NCPDP Version D.0 claim must be exempted from using the proposed standards and code sets that are required for other healthcare claim transactions.

The X12N 837 is used to bill medications and supplies covered under the Medicare Part B program and for professional pharmacy services covered under a medical plan. The type of claims submitted by pharmacy providers using the X12N 837 rarely requires an attachment.

The pharmacy sector has little to no experience in implementing the proposed standards for claim attachments. For the pharmacy sector to implement them for the very small volume of X12N 837 claims requiring an attachment would be cost prohibitive, require major system changes, and would provide little to no value to this sector of the healthcare industry.

The proposed attachment standards and code sets can support other business functions such as prior authorizations.

In November 2004, NCPDP formed a Prior Authorization Workflow to Transactions Task Group (ePA Task Group) as a multi-standards development organization collaborative. The initial intent was to leverage existing standards, notably the ASC X12N 278 transaction standard.

The ePA Task Group's first effort was to map workflow for medication prior authorizations, collect and analyze paper forms and review the X12N 278 to determine if it could accommodate the pharmacy need for standardized automation of paper, fax and phone-based processes.

The ePA Task Group determined the X12N 278 could not accommodate the information payers viewed as necessary to make a prior authorization determination and began to research alternatives to accommodate this business need. The HL7 claim attachments were identified as a potential solution. As the X12N 278 transaction could not support an attachment within the transaction, an ASC X12N 275 would need to be used as a "wrapper" around the actual attachment.

The group of industry collaborators began to analyze the different claims attachments, comparing them to the analysis that it had done on the forms the payers were using in the marketplace at that time. It was determined the industry would have to use more than one of the claims attachments, which was viewed as technically awkward. At this point, the multi-SDO task group decided to create its own prior authorization attachments, with subsets around the different therapeutic classes which contained drugs which commonly required a prior authorization. The HL7 participants of the task group provided the templates and guidance.

Most of 2005 was spent working to create prior authorization attachments for six of the most common therapeutic classes requiring a prior authorization: ED, Antifungals, NSAIDS/Cox2, Growth Hormones, PPIs and Opioid Agonists.

Since the Medicare Modernization Act (MMA) of 2003 called for ePrescribing pilots, task group participants wanted to initiate the electronic prior authorization (ePA) request during the ePrescribing process and wanted to test the process and standards during the pilot. In 2006, four of the five MMA pilots tested the process and standards. The ASC X12N 270/271 transaction for eligibility and the NCPDP Formulary and Benefit Standard were used to determine which drugs required a prior authorization. The X12N 278, the X12N 275, and the HL7 prior authorization attachment were used for the prior authorization request and response. The NCPDP SCRIPT transaction was used to send the prescription with a prior authorization number to the pharmacy.

In April 2007, the pilot companies recommended creating a new standard instead of using the X12N 278. In 2008, the Agency for Healthcare Research and Quality (AHRQ) convened an expert panel to review the pilot findings and create a recommendation. The expert panel laid out a vision for the future and a five year roadmap. The roadmap called for the creation of a new standard for drug prior authorizations. The expert panel recommended the standard be created in NCPDP. The ePA Task Group was repurposed to develop the standard.

The ePA Task Group created new transactions for medication prior authorization using the SCRIPT standard as the foundation. The ePA transactions were built for the exchange of data between prescribers and payers for medications and supplies covered under the pharmacy benefit. The transactions support the process of determining if a prior authorization is required, requesting a prior authorization and communicated the status of the prior authorization. The standard supports a way to convey a set of prior authorization questions so that it can be presented logically in any system and the answers returned reliably. The standard also supports features to minimize what the prescriber is asked, based on earlier answers or data in their EHR system, thus reducing the amount of time a prescriber or staff have to review the prior authorization questions.

In July 2013, the ePA transactions as part of the NCPDP SCRIPT standard were approved and are being used in the industry today.

In May 2014, NCVHS recommended to HHS:

> "Recommendation 1: HHS should name the NCPDP SCRIPT Standard Version 2013101 Prior Authorization transactions as the adopted standard for the exchange of prior authorization information between prescribers and processors for the pharmacy benefit.
> Recommendation 2: HHS should adopt Recommendation 1 under the most appropriate regulatory sections and processes that would enable prompt industry implementation and at the earliest possible implementation time."

The ePA transactions do accommodate attachments; however, we are not aware of any organization using a HL7 C-CDA attachment for pharmacy prior authorizations.

NCPDP respectfully requests the exchange of prior authorization information between prescribers and processors for the pharmacy benefit be exempted from any mandate to use the proposed standards and code sets in healthcare claims transactions or attachments.