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Submitted electronically via email - NCVHSmail@cdc.gov

Jackie Monson, JD
Chair
National Committee on Vital and Health Statistics
CDC/National Center for Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

RE: Request for Public Comment on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules

Dear Ms. Monson,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors 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 business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP submits the following comments on the National Committee on Vital and Health Statistics (NCVHS) "*Request for Public Comment on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules*."

Updated X12 Transaction Standards

1. Costs. If your organization has conducted an analysis of the cost impact to implement the updated X12 version 8020 claims (e. g. the professional, institutional or dental claim) and remittance advice transactions, to what extent, relative to the potential cost of implementation, do the updated transaction implementation guides provide net positive value? Please explain.

NCPDP Response: NCPDP recognizes the significant cost involved in upgrading any industry standard; however, no cost analysis has been completed.

2. Operational impacts. If your organization has conducted an operational assessment or workflow analysis of the impact of transitioning to the updated X12 8020 claims and remittance advice transactions, what process improvements has your organization identified would result from implementation of the updated versions of any of the updated transactions? Please provide information for the Committee to reference in its considerations and feedback to HHS.

NCPDP Response: NCPDP recognizes there is an organizational impact (e.g., utilization of a new version of an 835 and an 837 transaction will require additional technical and human resources for conversion and implementation efforts) when upgrading an industry standard; however, no operational impact analysis has been completed.

3. XML Schema. X12 has indicated that each of the X12 implementation guides included in their recommendation has a corresponding XML schema definition (XSD) that supports the direct representation of the transaction using XML syntax. In its letter to NCVHS, X12 noted that it mechanically produces these representations from the same metadata used to produce the implementation guide. X12 recommends that HHS permit both the 8020 EDI Standard representation (the implementation guide) and the XML representation, and that both be named in regulation as permissible syntaxes. Please comment on the proposal to adopt the 8020 EDI standard and the XML representation as permitted syntaxes.

NCPDP Response: NCPDP supports the naming of EDI Standard and XML representation for the 8020 version of the 835 and 837s in regulation.
Also refer to the September 23, 2014 letter from NCVHS to HHS at https://ncvhs.hhs.gov/wp-content/uploads/2018/03/140923lt1.pdf

4. FHIR Crosswalks. X12 indicated that it intends to provide FHIR crosswalks for the proposed X12 version 8020 transactions (claims and electronic remittance advice) submitted for consideration in time for inclusion in the Federal rulemaking process. Please comment on how FHIR crosswalks would apply to the implementation of the HIPAA claims and remittance advice transaction standards.

NCPDP Response: No Comment

5. Unique Device Identifier (UDI). The device identifier (DI) portion of a medical device's unique device identifier (UDI) is now included as a data element on the updated claim transaction in the institutional and professional version of the 8020. The UDI is also an element in the US Core Data for Interoperability (USCDI) for Certified Health Technology required by the Office of the National Coordinator, and can be found in certified Electronic Health Records, and in standardized hospital discharge reports. Please discuss the additional value, if any, that the DI and UDI provide as data elements in the updated version of the X12 claim transaction.

NCPDP Response: NCPDP supports the inclusion of the device identifier (DI) portion of a medical device's unique device identifier (UDI). The FDA is identifying devices using the UDI and has accredited

multiple agencies to issue UDIs. The UDI is the standard for identifying devices. Other device identifiers, such as the National Drug Code (NDC) and the National Health Related Items Code (NHRIC), are being sunset.

6. Alternative Payment Models (APM) and Value Based purchasing (VBP). Does X12 version 8020 support VBP claims? In what ways does the version 8020 of the claims transactions accommodate APMs such as medical homes or accountable care organizations (ACOs)? Please discuss the implications of this topic to HIPAA administrative simplification policies and continued innovation of non-fee-for-service business models.

NCPDP Response: No Comment

7. Implementation time frame. HIPAA provides a two-year implementation window for health plans and providers after publication of a final rule (three years for small health plans). Thinking about the changes in health care, what would be the ideal time frame for the adoption and implementation of new versions of standards, and of their implementation, e. g. does the window need to be longer than two years from the publication date of a final rule? Past practice generally stipulated a January 1 implementation date; previous testimony to NCVHS indicated going live on January 1 could be problematic to some implementing organizations. What date (i.e., month/day) might be better for as the implementation date, (i.e., the close of the implementation window)?

NCPDP Response: NCPDP does not recommend a January 1 implementation date as many beneficiaries' plan benefit year begins at that time. Plans may be changing processors and/or changing plan benefit designs, so they will be focused on coding for those updates and delay programming required for a new version of the 835 and 837 transactions. The industry also experiences heavy new member enrollment/eligibility and formulary updates. Also, many employees like to enjoy time off the last quarter of the year affecting the number of resources available.

NCPDP recommends a thirty-six month implementation period to avoid disruption of patient care with multiple simultaneous standards' implementations (e.g., NCPDP Telecommunication Standard VF6). Having multiple standards being implemented at the same time may cause delayed adoption or increased requests for extensions. Additional costs may also be incurred by organizations to implement.

8. Implementation. NCVHS recently recommended the potential concurrent use of multiple versions of a standard over an extended period of time. Would industry benefit from being able to use either the version 8020 or version 5010 for some extended period of time vs. having a definitive cutover date?

NCPDP Response: NCPDP supports a transition period of at least twelve months with a definitive cutover date.

9. Simultaneity. What, if any, are the data impacts, limitations or barriers of using the version 8020 of a claims or remittance advance standard transaction while using version 5010 of any of the other mandatory transactions, e.g. claim status, eligibility, coordination of benefits, enrollment and disenrollment, authorizations and referrals and premium payment?

NCPDP Response: NCPDP membership understands resources and workflows would be impacted, and additional costs would be incurred to support a translator for multiple versions.

10. Alternatives Considered. X12 indicated that there were over 2,000 changes identified in the change logs for the four updated transactions in version 8020, categorized by operational, technical and editorial. If your organization has conducted assessments of the technical changes, what is your determination of these with respect to reducing burden on payers or providers once the updates have been implemented? What is the opportunity cost of remaining on Version 5010 and not implementing the updated version 8020 of the claims and remittance advice transaction standard? What will the healthcare industry risk by not adopting version 8020?

NCPDP Response: NCPDP reviewed previously reported concerns regarding the 7030 version of the 835 transaction, and the 8020 version has corrected several concerns previously identified including correcting references to available NCPDP resources; however, no burden or cost analysis has been conducted.

NCPDP also reviewed the 7030 version of the 837 Professional Claim (837P) and submitted fifteen comments. The comments could be categorized as nomenclature and value set changes needed in the 837P. Not all the resolutions to the comments were incorporated in the 8020 version. NCPDP has worked with X12 to submit a maintenance request (MR274) to align the SV4 Drug Service segment and element requirements with NCPDP. No burden or cost analysis has been conducted on the use of the 8020 Version of the 837P.

11. General. Does your organization support HHS adoption of the updated version of the X12 transactions for claims and remittance advice as HIPAA administrative simplification standards? Please provide a brief rationale.

NCPDP Response: NCPDP supports HHS adoption of the updated version of the X12 transactions for claim and remittance advice as HIPAA administrative simplification standards to advance reporting within the industry. It is necessary the industry use a more current version of the standard to expedite workflows to ensure pharmacies and payers utilize transparency in financial transactions.

CORE Operating Rules

NCPDP Response: NCPDP will not be submitting comments on the CORE Operating Rules.

For direct inquiries or questions related to this letter, please contact:

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Sincerely,

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