NCVHS
National Committee on Vital and Health Statistics

June 14, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: NCVHS Recommendation on the Updated Version of the X12 Standard for Claims and Electronic Remittance Advice Transactions (Version 008020)

Dear Mr. Secretary:

This letter conveys recommendations from the National Committee on Vital and Health Statistics (NCVHS) regarding an updated version of the X12 standards under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[1]

NCVHS is your advisory committee on health data, statistics, privacy, and national health information policy, which includes advising the Secretary of Health and Human Services (HHS) on the adoption of standards, unique identifiers and code sets under HIPAA.

In June 2022, X12 requested a review by NCVHS of four HIPAA-adopted transactions that X12 proposed be replaced with the updated version 008020.[2] X12 further proposed that both the 008020 EDI Standard representation (the implementation guide) and the XML schema definition representation be named as permitted syntaxes for those specific transactions.

To inform development of our recommendation, NCVHS invited comments through a Request for Comment (RFC) issued in November 2022.[3] The Committee also held a hearing on January 18, 2023, to hear stakeholder testimony on the value and industry readiness of the new version.[4]

X12 Version 005010 is the currently adopted version of the HIPAA standard for the Health Care Claim (Institutional, Professional and Dental) and the Claim/Remittance Advice.[5] The standard was adopted in 2009.

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[1] HIPAA: The Health Insurance Portability and Accountability Act of 1996 – provisions of administrative simplification HIPAA, P.L. 104-191.
[2] Letter to NCVHS from X12. June 7, 2022: https://ncvhs.hhs.gov/wp-content/uploads/2022/09/X12-Request-for-review-of-8020-transactions-060822-to-NCVHS-508.pdf and in Appendix C.
[3] NCVHS Request for Comment on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules, November 1, 2022: https://ncvhs.hhs.gov/wp-content/uploads/2022/10/NCVHS-RFC-suggested-question-set-Oct-26-2022.pdf
[4] NCVHS January 18, 2023 Hearing on Requests for New and Updated Transaction Standards and Operating Rules: https://ncvhs.hhs.gov/meetings/standards-subcommittee-hearing/
[5] 008020X323 Health Care Claim: Professional (837); 008020X324 Health Care Claim: Institutional (837); 008020X325 Health Care Claim: Dental (837); 008020X322 Health Care Claim Payment/Advice (835).

We note that there are eight X12 transactions currently adopted under HIPAA. All of them are version 005010. This X12 proposal seeks to move only the three Claims transactions and the Payment/Remittance Advice transaction to version 008020; the others would remain version 005010. (See Table 1 in Appendix A.)

This raises the important question of interoperability of the proposed version of the standards with the older mandated version of the remaining standards – otherwise referred to as "backward compatibility."

Based on our assessment of industry input from both the comments received in response to the RFC and the January 2023 NCVHS public hearing, the Committee makes the following recommendation for HHS consideration.

NCVHS Recommendation:

- **NCVHS recommends that HHS not adopt the version 008020 update to the four specified transactions (i.e., Health Care Claim (Institutional, Professional and Dental) and the Claim/Remittance Advice) at this time.**

NCVHS cites three reasons not to adopt the 008020 update at this time:

- Adopting a subset of 008020 transactions versus the entire 008020 suite would result in multiple transaction versions (i.e., some 005010 and others 008020) with unknown compatibility issues, potentially causing disruption across industry trading partners. Evidence of the 008020's backward compatibility to existing 005010 transactions is needed.

- NCVHS relies on industry input to provide sufficient cost and value data, and indicated use cases along with identifying the burden, opportunity, and efficiency for proposed standards upgrades. While we appreciate X12 providing some preliminary implementation cost and value data, the depth of the information provided by X12 and the other testifiers in both written comments and oral testimony was inadequate for NCVHS to make a determination.

- Version 008020 lacks accommodation for impending updates to two critical HIPAA medical code sets:
    - First, the World Health Organization has already adopted ICD-11[6,7] to replace ICD-10. Although ICD-11 is not currently an adopted code set under HIPAA, U.S. transition to ICD-11 is under study now, and its use is expected to increase for non-payment use cases. An updated version of transaction standards is needed to accommodate ICD-11's variable-length cluster codes for current and future industry uses.
    - Second, the FDA has published a proposed rule to modify the format of the National Drug Code (NDC).[8]

[6] ICD-11: https://icd.who.int/en and https://www.paho.org/en/news/11-2-2022-whos-new-international-classification-diseases-icd-11-comes-effect

[7] Eleventh Revision of the International Classification of Diseases (ICD) Digital Version Terms of Use and License Agreement: https://icd.who.int/en/docs/ICD11-license.pdf

[8] FDA Proposed Rule, "Revising the National Drug Code Format and Drug Label Barcode Requirements," July 25, 2022: https://www.federalregister.gov/documents/2022/07/25/2022-15414/revising-the-national-drug-code-format-and-drug-label-barcode-requirements

NCVHS acknowledges the obsolescence of version 005010 and the need to move to an updated version of the X12 standard; however, concerns over accommodating multiple versions across transactions, accommodating changes in code sets and the long lead-time for regulatory processes need to be addressed. The Committee urges X12, in conjunction with industry and regulators, to speedily address the needs and submit a new version for adoption under HIPAA.

The Committee commends X12 and the participating stakeholders in its proof of concept (POC) and looks forward to the results that may shed more light on backward and cross standard compatibility. In addition, the POC could provide supplemental value data to support X12's future proposal to move the next version of these standards forward.

The Committee encourages stakeholders to submit benefit and return on investment data either to NCVHS or CMS upon request to assist in the review of all future proposals.

Additional issues for HHS considerations:

Multiple stakeholders during the NCVHS hearing and in response to the request for comments raised serious concerns regarding two issues not directly relevant to the X12 proposal addressed by this recommendation:

1. Unauthorized use of virtual credit cards.
2. Inclusion of capability to report the Device Identifier (DI) portion of UDI in claims.

To be responsive to this stakeholder input, the Committee offers these additional comments for HHS consideration. The Committee finds that both important concerns are HHS implementation guidance issues rather than issues with the 008020 implementation guides themselves.

- Similar to our September 23, 2014, letter to the Secretary on Virtual Credit Cards (VCC),[9] the Committee encourages HHS to develop and publish additional VCC guidance and education. More needs to be done so that covered entities and their business associates clearly understand permitted and non-permitted uses of the virtual credit card when used in lieu of the Electronic Funds Transfer (EFT) as currently adopted in the X12 version 005010 835 Electronic Claim Payment/Remittance Advice standard. In addition, we encourage HHS to consider increasing enforcement efforts when it investigates complaints of inappropriate (i.e., involuntary) use of virtual credit cards.
- The Committee encourages FDA review of stakeholder comment letters and testimony to identify concerns submitted to NCVHS regarding the collection of UDI codes.

Appendix A provides the rationale for the Committee's recommendation, including additional details from stakeholder testimony.

Appendix B provides additional NCVHS comments regarding the X12 proposal to adopt X12 Version 008020. Specifically, we comment in more detail on issues with the virtual credit card and EFT, as well as inclusion of the capability to report the Device Identifier (DI) portion of UDI in claims.

[9] NCVHS Letter to HHS Secretary, "Findings from the June 2014 NCVHS Hearing on Virtual Credit Cards and Credit Card Use," September 23, 2014: https://ncvhs.hhs.gov/wp-content/uploads/2018/03/140923lt2.pdf

Appendix C provides the June 2022 request letter from X12 to NCVHS.

Thank you for considering the recommendations offered in this letter. NCVHS remains available to answer questions and will continue to support HHS efforts to advance efficiencies in the health care system, and to working with the Department to shape future guidance.

Sincerely,

/s/
Jacki Monson, J.D., Chair
National Committee on Vital and Health Statistics

Enclosures

Appendix A: Rationale for NCVHS Recommendation
Appendix B: Additional NCVHS Comments Regarding the X12 Proposal to Adopt X12 Version 8020
Appendix C: June 2022 request letter from X12 to NCVHS

Appendix A

Rationale for NCVHS Recommendation

On June 7, 2022, X12 submitted a request to NCVHS and to the signatories of the Designated Standards Maintenance Organization's (DSMO) Memorandum of Understanding (MOU) requesting consideration of adoption of the updated version of a select group of the HIPAA designated X12 standard transaction suite (moving from X12 Version 005010 to X12 Version 008020). See Appendix C.

On November 1, 2022, the Subcommittee on Standards released a Request for Comment (RFC), followed by a public hearing on January 18, 2023.[3,4] The purpose of the RFC and hearing were to obtain stakeholder input to inform the Committee on its recommendations to HHS. The Committee sought additional insight from the Workgroup for Electronic Data Interchange (WEDI), which conducted an industry survey and a Member Position Advisory meeting in November 2022.

Commenters to the RFC and participants at the January hearing represented payers, providers, State Medicaid agencies, vendors, and clearinghouses.

Summary of Comments

The Committee provides the following high-level overview of the public input.

Testimony and comments received were mixed in support and concern about the X12 proposal. Some stakeholders voiced support to adopt the updated version because of the length of time between adoption of an updated version of the standard. Several expressed serious implementation concerns, while others raised concerns regarding costs, lack of documented return on investment or value of the upgraded standards versus the status quo and lack of enforcement of existing standards. A consistent concern was the unproven backward compatibility across existing X12 standards. The following are examples of testimony and comments received.

- One testifier, representing a major national health plan, noted that when NCVHS considers each HIPAA transaction individually, rather than as part of a comprehensive suite of transactions, it furthers the need for additional testing to ensure that versions are cross-compatible with one another. This commenter urged NCVHS to exercise caution in moving forward with recommending variation into the standards environment. As a result, the testifier does not support adoption of Version 008020 proposed update. Another testifier said that besides the high cost and burdens of supporting multiple versions or multiple standards, they were uncertain whether the two versions would function together, and expressed concern about the lack of testing to evaluate if the current and updated standards will work together. The same testifier cautioned against viewing a clearinghouse or other vendors as an easy solution to the versioning issues that would pose challenges to small providers and physician practices.
- Another testifier stated that as the largest integrative healthcare system in the United States, their organization had sent and received over eighty million electronic healthcare transactions in 2022. This individual stated that implementing different versions of different transactions would require extra internal development to ensure forward and backwards capability, thus potentially creating challenges across the industry.
- A large health plan expressed concern about major operational issues if the 837 updates were adopted before the 270 and 271 transactions. They stated that these operational issues around

selected implementation would not only result in a loss of revenue, but ultimately negatively impact their patients. Other commenters opposed to adoption of the updated version expressed concern about the lack of pilot testing and cost benefit analyses to support adoption. One testifier urged NCVHS to hold any recommendation about the adoption of Version 008020 837s and 835 until after results of the X12 pilot testing are made available to the industry. NCVHS looks forward to the results from that work. A vendor recommended a gap analysis be conducted to identify data content and other industry business use cases that could be impacted in using other X12 005010 transaction versions simultaneously with X12 008020 versions.

- A testifier stated that robust cross-standard testing is critical to determine the impact of multiple standards and versions and ensure cross-compatibility across standards and versions. Both are essential to evaluate return on investment (ROI).

No organizations added supplemental data to that which X12 had provided in its submission letter on costs or potential benefits; and others noted that data would not be available from their organizations until after publication of a proposed rule. Those commenters indicated that impacts would vary based on the size of the organization, and whether they implement the changes internally or rely on the services of vendors or clearinghouses.

Those who supported or were neutral on adoption indicated that HHS should avoid a January 1 compliance date. One approach would be to consider a July 1 or mid-year start date. This is consistent with prior recommendations to avoid requiring implementation on the same day as other significant business, operational, or technical implementations, e.g., open enrollment. Commenters indicated that this alternate start date may avoid conflict with other mandates, minimize undue burden, prevent cost overruns, and mitigate impact on patient care or service. Support for this suggestion came from the pharmacy industry, indicating that a June implementation date would also avoid conflicts with other pharmacy-related mandates, as well as timing of flu season when pharmacies are busiest.

One of the Designated Standard Maintenance Organizations cautioned the Committee about the limitations in adopting and implementing the 11th edition of the International Classification of Diseases (ICD-11) and lifecycle reliability as upgrades are being brought forward, noting that ICD-11 is not supported in the version being proposed.

Explanation of recommendation

- **NCVHS recommends that HHS not adopt the version 008020 update to the four specified transactions (i.e., Health Care Claim (Institutional, Professional and Dental) and the Claim/Remittance Advice) at this time.**

Three reasons not to adopt:

1) **Adopting a subset of 008020 transactions versus the entire 008020 suite would result in multiple transaction versions (i.e., some 005010 and others 008020) with unknown compatibility issues, potentially causing disruption across industry trading partners.**

   The specific group (i.e., “chunking”) of X12 transactions being proposed versus the entire suite of HIPAA transactions that was implemented for version 005010, has a high potential to impose undue burdens on regulated entities due to the cost and complexity of being on different versions, (e.g., 005010 and 008020 across the suite of transactions). In addition, version 006020

was proposed by HHS for the Referral/Certification transaction and Attachment standard under HIPAA in the Attachments Notice of Proposed Rulemaking (NPRM)[10] as shown in the table below. NCVHS suggests continuing its review of X12 proposals in bundles, but that HHS hold off rule making until the entire suite of HIPAA transactions are recommended or different versions proposed contain proof sufficient for NCVHS of backward compatibility.

Table 1: List of HIPAA X12 Standard Transactions
Note: Does not include NCPDP Pharmacy Standards

X12N Standards – Current Version 005010 8 Mandated and 2 Proposed Standards							
HIPAA Mandated Standard	Standard	Transaction	Current HIPAA Version	Subject of 1/2023 Hearing	HHS Attachments NPRM (12/22)	Proposed X12 05/2023[11]	Expected by 12/2023
1	837P 837I 837D	**Health Care Claims (Institutional, Professional, and Dental)**	005010	008020			
2	835	Health Care Claim Payment/Advice	005010	008020			
3	276/277	Health Care Claim Status Request and Response (276/277)	005010			008030	
4	834	Benefit Enrollment and Maintenance	005010			008030	
5	820	Payroll Deducted and Other Group Premium Payment for Insurance Products	005010			008030	
6	278	Referral Certification and Prior Authorization	005010		006020		
Proposed	275	Additional Information to Support a Health Care Claim or Encounter (NEW) Additional Information to Support a Health Care Services Review (NEW)	005010		006020		
Proposed	277	Health Care Claim Request for Additional Information (NEW)	005010		006020		
7	270/271	Eligibility and Benefit Verification	005010				**?**
	ACH & X12N Standard						
8	ACH CCD+Addenda ASC X12N 835	Claim Payment (or EFT, electronic funds transfer)	005010				**?**

2) **NCVHS relies on industry input to provide sufficient cost and value data, along with identifying the burden, opportunity and efficiency for proposed standards upgrades, which was inadequate to make a determination**.

[10] Federal Register: Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard (Dec 21, 2022): https://www.federalregister.gov/documents/2022/12/21/2022-27437/administrative-simplification-adoption-of-standards-for-health-care-attachments-transactions-and

[11] X12 Letter to NCVHS April 11, 2023: https://ncvhs.hhs.gov/wp-content/uploads/2023/05/Letter-to-NCVHS-X12-Standards-Request-April-11-2023.pdf

No organizations submitted additional data to that which X12 had provided in its submission letter on costs; and some noted that benefit and return on investment data would not be available from their organizations until after publication of a proposed rule. This topic needs extensive industry discussion and policy review. The Committee realizes this issue cannot be resolved in the short term. We had previously forwarded a recommendation to the Secretary to publish a guidance framework for Standards Development Organizations and other industry stakeholders that outlines how to develop and report measures for new and revised standards readiness, costs, and overall adoption value to support HIPAA standards development, testing, evaluation and adoption.[12]

Such data supports moving a proposed standard or operating rule forward into rulemaking. This information can contribute to, but it is not the extensive benefit and return on investment calculation performed during the NPRM/final rule process.

Currently, the benefit and return on investment calculation is completed during the NPRM/final rule process. Regulations require an impact analysis, and OMB has just updated those requirements to include provisions for equity. There are comprehensive instructions for how cost benefit analyses are to be conducted by any agency publishing a proposed rule. The Committee encourages stakeholders to submit such data, as available, to assist in the review of all future proposals. Any industry data will assist in expediting the regulatory process.

3) Version 008020 lacks accommodation for impending updates to two critical HIPAA medical code sets.

ICD-11 has been studied and found to have benefits compared to the use of ICD-10.[13] It can be used today on a voluntary basis for patient safety and clinical quality reporting. Specifically, ICD-11 was found to materially exceed ICD-10 capabilities in patient safety reporting of pressure ulcers, and fully represented values needed for electronic clinical quality measures (eCQMs) for ischemic stroke, hypertension, and diabetes.[14] Use of ICD-11 would impact the contents of the claim and potentially other transactions. An updated version of X12 transactions that currently carry the ICD-10 codes is required to accommodate the use of ICD-11 to meet current and future information needs. Since the recommended version cannot be updated within the proposed rule, we recommend X12 make the stated updates prior to submitting an updated version to NCVHS.

Furthermore, the Committee is working with HHS and other federal agencies on its policy analysis and research agenda for ICD-11. The Committee will monitor future updates from X12 and other standards development organizations regarding updates to standards and their ability to accommodate ICD-11 codes.

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[12] NCVHS letter to HHS, July 28, 2022, Recommendations to Modernize Adoption of HIPAA Transaction Standards, (recommendation 4): https://ncvhs.hhs.gov/wp-content/uploads/2022/08/Recommendation-Letter-Modernize-Adoption-of-HIPAA-Transaction-Standards-508.pdf

[13] Presentation on changes from ICD-10 to ICD-11 to NCVHS (August 6, 2019): https://ncvhs.hhs.gov/wp-content/uploads/2020/01/Presentation-Changes-from-ICD-10-to-ICD-11-Pickett-Anderson.pdf

[14] Susan H Fenton, Kathy L Giannangelo, Mary H Stanfill, Preliminary study of patient safety and quality use cases for ICD-11 MMS J Am Med Inform Assoc. 2021 Oct 12;28(11):2346-2353. doi: 10.1093/jamia/ocab163.

The National Drug Code (NDC) is currently a 3-segment, 10-digit code. The FDA published a Proposed Rule to expand the code to 12 digits. The Proposed Rule contemplates a 5-year delay between publication of a Final Rule and the Implementation Date. Given the long lead time and the uncertainty of medical code set adoption rules under HIPAA, it would be risky to wait until after FDA adoption of a Final Rule to begin modification of the HIPAA transactions.

Standard Review Process

X12 is implementing new approaches to reduce the time of its review and submission process by forwarding logically related transactions. However, this approach leaves uncertainty around the compatibility of existing and proposed versions and there is a lack of gap analysis between versions. A pilot or proof of concept is welcomed to assure there is no negative impact between standard versions and that Implementation Guides will work together and avoid operational conflicts.

Enforcement

Another testifier from a national medical association stated standards are only as effective as the enforcement behind them. They also indicated that their members have long been frustrated by noncompliance with these standards on the part of health plans. They have also found that the Centers for Medicare & Medicaid Services (CMS) enforcement process is often ineffective. It can take years between a complaint being filed and a health plan taking the necessary corrective action. In addition, these corrective action plans do not always result in the health plan correcting the cause of the complaint. They recognize that NCVHS does not have the responsibility to enforce standards. However, they encourage NCVHS to work with CMS to ensure these standards are strongly enforced in a timely manner.

Committee Comment

The Committee encourages HHS to review the effectiveness of the current HIPAA enforcement activities in consideration of the stakeholder concerns conveyed in the comment letters and testimony and previous NCHVS recommendations.

Appendix B

Additional NCVHS Comments Regarding the X12 Proposal to Adopt X12 Version 008020

Concerns with the virtual credit card (VCC) and Electronic Funds Transfer (EFT)

The Committee received over 500 letters specifically addressing concerns about the field in the updated transaction for use of virtual credit cards.[15] Though many letters were submitted as part of a letter writing campaign, some included substantive text about card payments, merchant processing fees, payers or their business associates using the virtual credit cards without a contractual obligation in place and other payer or business associate failures to use the adopted EFT transaction. These concerns were also shared in several testimonies.

A testifier from a professional association expressed concerns that the addition of virtual credit card payment information in the X12 835 will serve as an "enabler" of these payments. They continue to have strong concerns about the harmful impacts and coercive business tactics associated with virtual credit cards. Another professional association encouraged CMS to safeguard payment legitimacy. CMS only should proceed with further legitimization of the virtual credit card process if the agency takes proactive steps to ensure that plans are not inappropriately switching providers to costly virtual card payment methods without the mandated advanced agreement from the provider.

While the data field in the updated X12 Version 008020 835 transaction indicates use of the virtual credit card, its use may not bind the provider to that payment type. The high volume of letters citing concerns on this topic supports additional and/or ongoing guidance from HHS and X12. After reviewing the letters and testimonies, the Committee recommends that HHS provide additional guidance and education for covered entities and their business associates regarding permitted and inappropriate uses of the virtual credit card when used for payment. Additionally, increased enforcement from the anticipated inappropriate use of virtual credit cards in this standard (i.e., use of the field without a mutual agreeable contractual obligation), may be a consideration to protect providers when the standard is updated.

Committee Comment

The Committee encourages HHS to develop and publish additional published guidance and education for covered entities and their business associates about permitted uses of the virtual credit card when used in place of the currently adopted EFT standard and the use of the EFT standard. In addition, we encourage HHS to consider increasing enforcement targeting inappropriate use of virtual credit cards.

[15] Public comments received in response to the NCVHS November 1, 2022 RFC on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules: https://ncvhs.hhs.gov/wp-content/uploads/2023/05/0%20Public%20Comments-Standards%20Subcommittee%20Meeting-January%2018-19,%202023_amended.pdf and https://ncvhs.hhs.gov/wp-content/uploads/2023/05/Additional-Public-Comments-Standards-Subcommittee-Meeting-January-18-19-2023-508.pdf

Inclusion of ability to report the Device Identifier (DI) portion of UDI in claims.

Some organizations noted concerns they had submitted comments on regarding reporting of the UDI in administrative transactions, including: lack of a standard definition for "high risk" implantable devices; the fact that the USCDI already includes the UDI and supports both the device and production identifiers; and that reporting of UDI could add administrative burden on physicians and other providers because each health plan may request a different list of devices to be reported.[16] However, the FDA and a Congressperson expressed strong support for inclusion of the UDI in the claim transaction, stating that the UDI-DI in the claim enables health plans to collect device information to enhance the analysis of devices on the market, reduces medical errors by enabling health professionals to identify a device and obtain important information concerning the characteristics of the device, and enables device performance evaluation across disparate data sources such as claims, electronic health records, adverse events, recalls and registries.

A testifier expressed serious concerns about including UDI for high-risk implanted medical devices in the claim transaction. They were very active in X12's work on the request to include UDI in the claim transaction. Many organizations opposed the inclusion of UDI for several reasons. Request NCVHS include in any recommendation to adopt the Version 008020 837P and 837I that language be added to relevant sections of the guides stating that reporting of an UDI is "not a HIPAA-mandated use."

Another testifier asked that the FDA release a clear definition as to which devices are to be considered "high-risk" for the purposes of safety surveillance and reporting, based on the concerns expressed within the testimony regarding the collection of UDI codes.

The Committee notes that Version 008020 is already complete and has undergone stakeholder input and balloting. Thus, the time for these comments and input would have been during the development and balloting period. Though there is no specific recommendation from the Committee, members encourage industry stakeholders to continue engagement in the standards development process and for X12 to continue its outreach to appropriate and diverse groups of stakeholders in development of future versions of its standards to ensure input and final disposition of the transaction.

Committee Comment

The Committee encourages FDA review of stakeholder comment letters and testimony to identify concerns submitted to NCVHS regarding the collection of UDI codes.

[16] US Core Data for Interoperability (USCDI): https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi

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June 7, 2022

Jacki Monson, JD
Chair, National Committee on Vital and Health Statistics
c/o Rebecca Hines
NCVHS Executive Secretary
3311 Toledo Road
Hyattsville, MD 20782

Dear Ms. Monson,

X12 is pleased to submit the first in a series of recommendations for advancing the version of already mandated transactions and for proposing additional transactions for adoption.

Based on industry feedback, X12 is using a phased approach for the recommendations rather than presenting the entire catalog of adopted and mandated transactions at once. Each recommendation will cover a set of logically grouped transactions and will include supporting information targeted to specific healthcare stakeholders, including highlights of functionality enhancements, a high-level estimate of implementation costs, and other collateral to assist in the regulatory adoption process. More information is available on our website at X12.org/news-and-events/x12-recommendations-to-ncvhs.

Over the past few years, there have been extensive discussions related to the challenges of a lengthy Federal Rule-making process that doesn't always operate at an expected cadence and the standards development organizations' continuously evolving standards. With this dichotomy in mind, X12 is proposing that the NCVHS evaluate version 008020 of the implementation guides listed below. If the NCVHS recommends the upgraded versions for adoption, we recommend the Center for Medicare & Medicaid Services (CMS) use the 008020 versions for the initial steps of the Federal Rulemaking process. When CMS is ready to issue a Notice of Proposed Rule Making (NPRM) to gather public feedback, X12 will identify the most recently published version of the implementation guides and provide a list of any substantive revisions and additional functionality that has been added between the 008020 versions and the most recently published version of the implementation guides. CMS would include the latest versions in the NPRM. This will ensure that the versions named in the NPRM and Final Rule processes reflect the most up-to-date requirements. An example of a planned enhancement that will be a valuable tool for the industry is FHIR crosswalks, similar to those provided in other X12 implementation guides. These crosswalks

will ensure consistent and reliable transitions between the syntaxes for implementers who want to support both syntaxes. This will also allow for revisions based on lessons learned during the planned pilots and on other feedback from organizations that review the 008020 implementation guides during the NCVHS comment and hearing processes.

As each of the recommendations works its way through the federal processes, X12 will be working with its licensing partners to develop and implement pilot testing to prove the viability of the recommended transactions. Results of the pilot test use cases and results will be shared after each pilot is completed.

The implementation guides we are recommending at this time are X12's claim submission and remittance advice transaction sets including:

- 008020X323 Health Care Claim: Professional (837)
- 008020X324 Health Care Claim: Institutional (837)
- 008020X325 Health Care Claim: Dental (837)
- 008020X322 Health Care Claim Payment/Advice (835)

Each of the X12 implementation guides included in this recommendation has a corresponding XML schema definition (XSD) that supports the direct representation of the transaction using XML syntax. X12 mechanically produces these representations from the same metadata used to produce the implementation guide, ensuring there are no discrepancies between the syntaxes. X12 recommends both the 008020 EDI Standard representation (the implementation guide) and the XML representation be named as permitted syntaxes. As noted above, X12 intends to provide FHIR crosswalks in these implementation guides in time for inclusion in the Federal NRPM and Final Rule processes. These crosswalks support interoperability and allow covered entities to select the syntax that best meets their needs while ensuring the data consistency that is the bedrock of standardization.

At a high level, the 008020 versions of these implementation guides provide the following functional enhancements that improve claims and remittance processing across the health care industry.

1. Including device identifier information on claims transactions greatly improves the industry's ability to identify risks and reach patients who may be affected by device failures. This improves patient outcomes and reduces patient health risks and enhances tracking and reporting related to specific devices. It also saves taxpayer funds.

2. Explicitly supporting factoring agents' inclusion in the health care claim improves a provider's access to short-term capital which is important in today's healthcare environment.
3. The number of entities handling claims during submission, acknowledgment, and response workflows has increased over the years, allowing for longer claim identifiers improves tracking, auditing, and matching functionality throughout the claim's life cycle.
4. Reducing manual processing related to recoupment handling improves efficiency and provides cost savings for both providers and payers.
5. Including more detailed source of payment codes in remittances improves provider understanding of how their claims are adjudicated by payers, reducing the number of phone calls and other individual inquiries which reduces processing costs for all parties.
6. Clarifying ambiguities by providing additional instructions and clearer wording in the implementation guides reduces inconsistencies, friction, and misunderstandings between trading partners.

In the coming weeks, X12 will be providing several change summary options online including a complete list of revisions, a list of revisions of particular interest to business analysts, and a list of revisions of particular interest to programmers. X12 will also be hosting a series of webinars and providing on-demand computer-based training materials that will assist implementers with their assessments of the updated implementation instructions included in the 008020 versions.

As a part of the change summary preparation, X12 estimated the costs of implementing these versions based on the complexity of the enhancement, and whether business analysts, programmers, or both would need to assess the revisions. Using these calculations and estimated labor rates from reputable online hiring platforms, X12 estimates the average costs as shown below.

Implementation Guide	Estimated Cost	Number of Enhancements	Average Cost per Enhancement
008020X323 Health Care Claim: Professional (837)	$267K	1,041	$256
008020X324 Health Care Claim: Institutional (837)	$327K	1,136	$288
008020X325 Health Care Claim: Dental (837)	$222K	333	$666
008020X322 Health Care Claim Payment/Advice (835)	$318K	259	$1,227

Most organizations will be applying these incremental changes to a stable, effective, and efficient EDI infrastructure in which they have already invested substantial capital. It's important to keep in mind that these costs will not be incurred by every covered entity. In many cases, a software vendor or clearinghouse will incur implementation costs that benefit their customer base. Additionally, many health care organizations will incur the implementation costs once, making the revisions and enhancements available to any number of subsidiary organizations, internal systems, and end-users.

Per the requirement to consult with the organizations named as DSMOs in the HIPAA regulations, X12 has informed those organizations of this recommendation and requested that they review and submit feedback to the NCVHS.

X12 looks forward to discussing this recommendation in more detail with the members of the NCVHS over the coming months. In the meantime, please contact me if you need more information or have any questions about the information included in this recommendation.

Sincerely,

Cathy Sheppard

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Appendix A: Enhancements to 008020X323 Health Care Claim: Professional (837)

1. Added the ability to transmit the Device Identifier (DI) of the Unique Device Identifier (UDI) for supplies, implants, and explants.
2. Added support for Factoring Agents which are non-healthcare provider entities that purchase rights to a financial obligation or receivable from a healthcare provider and thus own the full rights to the financial obligation.
3. Replaced the Claims Adjustment (CAS) segment with the Reason Adjustment (RAS) segment to support the association of Adjustment Reason Codes and Remark Codes and better synchronization with the Healthcare Claim Payment/Advice (835).
4. Greater focus on reducing ambiguity throughout the implementation guide.
5. Added an explicit qualifier code to identify Secondary Provider IDs in the REF segment to reduce the risk of misinterpretation.
6. Expanded the Provider's Assigned Claim Identifier (CLM01) to 35 characters to accommodate longer identifiers to improve re-association and matching.
7. Revised the situational rules for Provider Accepts Assignment Code (CLM07) and Provider Agreement Code (CLM16) to provide specific data elements for both Medicare and non-Medicare payers.
8. Revisions the implementation guides to align with the National Uniform Claim Committee (NUCC) instructions.
9. Revised the Medicare Secondary Payer (MSP) codes to support the transmission of MSP data on claims to a primary non-Medicare payer.
10. Expanded the Claim Identifier for Transmission Intermediaries (REF segment with D9 qualifier) to 50 characters to accommodate longer claim identifiers.
11. Added clear instructions for real-time use of the Health Care Claim (837) transactions.
12. Added the Health Care Remark Codes (LQ) segment to the claim and service line loops to support remittance advice remark codes that are not associated with a claim or line adjustment reason code.
13. Increased the number of diagnosis code pointers from 8 to 12 per service line for Professional Claims.
14. Added support for transmitting Coordination of Benefits (COB) allowed amounts.
15. Revised to support subrogation for payers other than Medicaid.
16. Increase the maximum number of diagnosis codes supported to provide a more complete picture of the patient's condition.

17. Added the Tooth Information segment (TOO) to allow providers to send tooth and oral cavity information in a structured format.
18. Increased the number of prior authorizations and referrals that can be reported at the line level
19. Added State Care Tax (AMT) segment to allow Property and Casualty (P&C) providers to report State Care Tax separately.
20. Added Drug Service (SV4) and Drug Adjudication (SV7) segments to support the reporting of drug rebate information.

Appendix B: Enhancements to 008020X324 Health Care Claim: Institutional (837)

1. Added the ability to transmit the Device Identifier (DI) of the Unique Device Identifier (UDI) for supplies, implants, and explants.
2. Added support for Factoring Agents which are non-healthcare provider entities that purchase rights to a financial obligation or receivable from a healthcare provider and thus own the full rights to the financial obligation.
3. Replaced the Claims Adjustment (CAS) segment with the Reason Adjustment (RAS) segment to support the association of Adjustment Reason Codes and Remark Codes and better synchronization with the Healthcare Claim Payment/Advice (835).
4. Greater focus on reducing ambiguity throughout the implementation guide.
5. Added an explicit qualifier code to identify Secondary Provider IDs in the REF segment to reduce the risk of misinterpretation.
6. Expanded the Provider's Assigned Claim Identifier (CLM01) to 35 characters to accommodate longer identifiers to improve re-association and matching.
7. Revised the situational rules for Provider Accepts Assignment Code (CLM07) and Provider Agreement Code (CLM16) to provide specific data elements for both Medicare and non-Medicare payers.
8. Revisions the implementation guides to align with the National Uniform Billing Committee (NUBC).
9. Expanded the Claim Identifier for Transmission Intermediaries (REF segment with D9 qualifier) to 50 characters to accommodate longer claim identifiers.
10. Added clear instructions for real-time use of the Health Care Claim (837) transactions.
11. Added the Health Care Remark Codes (LQ) segment to the claim and service line loops to support remittance advice remark codes that are not associated with a claim or line adjustment reason code.
12. Added support for transmitting Coordination of Benefits (COB) allowed amounts.
13. Revised to support subrogation for payers other than Medicaid.
14. Increased the number of prior authorizations and referrals that can be reported at the line level
15. Added State Care Tax (AMT) segment to allow Property and Casualty (P&C) providers to report State Care Tax separately.

Appendix C: Enhancements to 008020X325 Health Care Claim: Dental (837)

1. Replaced the Claims Adjustment (CAS) segment with the Reason Adjustment (RAS) segment to support the association of Adjustment Reason Codes and Remark Codes and better synchronization with the Healthcare Claim Payment/Advice (835).
2. Added support for Factoring Agents which are non-healthcare provider entities that purchase rights to a financial obligation or receivable from a healthcare provider and thus own the full rights to the financial obligation.
3. Revised to reflect the NPI mandate and clarify the relationship to other name information.
4. Revised to support the exchange of the Medicare Assignment Code.
5. Added a data element used for Coordination of Benefits when a claim is adjusted.
6. Revised to support reporting of claim level Remark Codes not associated with an Adjustment Reason Code.
7. Revised to support up to 12 diagnosis pointers per claim line.
8. Revised to support line-level prior authorizations when no authorization is sent at the claim level. This reduces the need to split claims.
9. Revised to reflect Payer Responsibility Sequence Number Code for situations where Payer IDs are the same for multiple payers.
10. Revised to support the transmission of the allowed amount received on the primary claim.

Appendix D Enhancements to 008020X322 Health Care Claim Payment/Advice (835)

1. Added the ability to transmit the Device Identifier (DI) of the Unique Device Identifier (UDI) for supplies, implants, and explants.
2. Added instructions for real-time adjudication.
3. Added the ability to report remittance information related to card payments (p-card, debit card, and credit card) to facilitate auto-posting.
4. Added the ability to report all associated messages about an adjustment including all reasons associated with the adjustment amount.
5. Added the ability to report Remark Codes, not associated with an adjustment code.
6. Standardized and added clarity for reporting COB adjudication information.
7. Enhanced Coordination of Benefits reporting of Remark Codes associated adjustments for claims involving governmental programs.
8. Standardized the forward balance and overpayment recovery processes.
9. Added the ability to re-associate a recovery amount to a specific claim to reduce manual processes to track when the funds have been recouped.
10. Standardized the exchange of the Federal Tax Identifier to support 1099 processing.
11. Support reporting of the specific DRG type used in adjudication and the ability to report multiple DRG types.
12. Added more granular source of payment codes giving providers more transparency into the process used to adjudicate the claim. In addition, the information is needed for state and federal reporting.
13. Added the ability to report other industry remark codes that are not supported by the existing Remittance Advice Remark Code list.
14. Added information that will aid in automating the posting of remittance advice information.
15. Enhanced the functionality related to the Property & Casualty, Workers' Comp, and Auto industries.
16. Added the ability to exchange additional communication information.
17. Expanded the use of elements previously restricted to specific federal programs.
18. Added the ability to exchange more detailed patient responsibility information.
19. Enhanced the claim payment information including exchange rate and source of payment topology.
20. Added the ability to report multiple corrected names.
21. Added ability to identify atypical providers who do not have National Provider Identifiers.
22. Improved process of correct claims.
23. Added the ability to report tooth information for dental claims.