Subcommittee on Standards Hearing on Requests for New and Updated Transaction Standards and Operating Rules

Meeting Summary

January 18-19, 2023

National Committee on Vital and Health Statistics (NCVHS)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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NCVHS Members and Staff in Attendance

Tammy Banks, MBA, Subcommittee Co-chair*

Richard W. Landen, MPH, MBA, Subcommittee Co-chair*

Denise Love, BSN, MBA, Subcommittee Co-chair*

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John Halter, JD, NCHS, CDC, HHS
Grace Singson, PharmD, MS, ASPE, HHS
Marietta Squire, NCHS, CDC, HHS

See Appendix A for complete lists of meeting participants.

National Committee on Vital and Health Statistics – NCVHS

The National Committee on Vital and Health Statistics (NCVHS) serves as the statutory [42 U.S.C.242(k)] public advisory body to the Secretary of the Department of Health and Human Services (HHS) in the areas of health data, standards, statistics, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA). In that capacity, the Committee provides advice and assistance to HHS and serves as a forum for interaction with relevant private sector groups on a range of health data issues. The Committee is composed of eighteen individuals from the private sector who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Sixteen of the members are appointed by the Secretary of HHS for terms of four years each. Two additional members are selected by Congress. Additional information, including membership roster is available at: https://ncvhs.hhs.gov/

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Day 1: January 18, 2023

Welcome, Call to Order, Roll Call, and Review of Proceedings

To open the meeting on Wednesday, January 18, 2023, Executive Secretary and Designated Federal Officer Ms. Rebecca Hines welcomed Standards Subcommittee members, invited speakers, and public viewers and called roll. The Subcommittee members introduced themselves. Ms. Banks reviewed the hearing's agenda.

NCVHS Presentation Regarding the Proposal from X12 and Next Steps

The purpose of Day 1's hearing conducted by the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards is to gather input from industry stakeholders regarding the proposal from X12 for an updated version of Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards Claims and Payment/Remittance Advice and use of Extensible Markup Language (XML). This input, along with previously gathered input and public comments received, will be used to inform the Subcommittee's recommendations to the Secretary of the Department of Health and Human Services (HHS) regarding adoption of the proposal.

X12 has requested that NCVHS recommend to the HHS Secretary to adopt version 008020 for the following transaction implementation guides (IGs): Claims (837 Professional, Institutional, and Dental) and Payment/Remittance Advice (835). All other adopted transaction IGs will remain on version 005010. X12's proposal recommends 1,041 enhancements to the Professional Health Care Claim guide, 1,136 enhancements to the Institutional Health Care Claim guide, 333 enhancements to the Dental Health Care Claim guide, and 259 enhancements to the Payment/Remittance Advice Health Care Claim guide. In addition, X12 has also requested that the 8020 Electronic Data Interchange (EDI) Standard representation (i.e., IG) and XML representation be named as permitted syntaxes.

The roles and responsibilities for NCVHS regarding updated standards include (1) receiving requests from Standards Development Organizations (SDOs); (2) obtaining input from industry, including Designated Standards Maintenance Organizations (DSMOs), regarding requested modifications; and (3) making recommendations to the HHS Secretary. HIPAA requires NCVHS to render advice, but the Secretary is not bound by the proposed recommendations that it makes. The role of health care stakeholders in the advancement of the standards process is to provide input and comments; these comments can be in support of the proposal with or without modifications, as well as against the proposal with rationale.

To address X12's proposal, as well as the proposal from the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE), NCVHS invited X12 and CAQH CORE to present to the Standards Subcommittee in July 2022. NCVHS also initiated a collaboration with the Workgroup for Electronic Data Interchange (WEDI), which was named an advisor to HHS in the HIPAA statute, to conduct informational sessions, the WEDI Industry Survey, and a Member Position Advisory (MPA) event. NCVHS published a Request for Comment (RFC) related to X12's proposal and received more than 600 comments in response. Subsequently, the Standards Subcommittee held consultative conversations with the Centers for Medicare & Medicaid Services (CMS) Office of Burden Reduction and Health Informatics (OBRHI) and the National Standards Group (NSG), as well as the Office of the National Coordinator for Health Information Technology (ONC).

This meeting will focus on gathering industry input and consensus regarding the need for the proposed changes from X12, the available cost-benefit or value for one or more of the changes proposed by X12

to assess the impact on implementation, and how the requests from X12 support the objectives of HIPAA and the Affordable Care Act (ACA). Activities that are out of scope for today's hearing include disagreements about contractual relationships among stakeholders (e.g., providers and payers) and non-HIPAA requirements for the use of a specific field or standard transaction. Following this hearing, the Standards Subcommittee will consolidate and analyze input received from stakeholders, discuss and deliberate, develop and present recommendations for NCVHS review, and finalize and share the recommendations with the HHS Secretary.

Presentation from CMS Regarding Process to Adopt Updated and Modified Standards under HIPAA

The CMS OBRHI and NSG, on behalf of the HHS Secretary, adopts national standards and operating rules under the Administrative Simplification provisions of HIPAA and responds to standard requests with relevant rulemaking activities. Implementation specifications are necessary for each HIPAA transaction and contain, at minimum, the data and format conformance requirements for a transaction. If specifications are not provided for a transaction, OBRHI and NSG will not adopt a standard. Implementation specifications are required for the following transactions as defined in 42 U.S. Code (USC) §1320d–2: health claims or equivalent encounter information, health claims attachments, enrollment and disenrollment in a health plan, eligibility for a health plan, health care payment and remittance advice, health plan premium payments, first report of injury, health claim status, referral certification and authorization, and electronic funds transfers (EFTs). Operating rules are defined within 42 USC §1320d–2 as "the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part." Operating rules add additional business requirements to standard transactions to facilitate easier implementation and standardization of administrative transactions across covered entities (CEs). Operating rules explain how to use an implementation specification when the specification itself does not.

Adopted standards must support the HHS Secretary's objective to reduce the administrative costs of providing and paying for health care and improve overall operations of health care systems. In order to adopt a new or updated standard and operating rules, NSG must assess all costs and benefits (including economic, environmental, public health and safety, distributive impacts, and equity) of the proposed standards and available regulatory alternatives in order to select approaches that maximize net benefits. The Secretary relies on the recommendations of NCVHS related to updated standards, and NCVHS relies on industry to provide sufficient data in order to ensure that any recommended standard will ultimately reduce administrative costs.

Under HIPAA, a modification to a standard relates to a change of an already adopted implementation specification. If a CE believes that an adopted standard must be modified, it may request an exemption from the Secretary to test a proposed modification to determine whether it improves the efficiency and effectiveness of the health care system by leading to cost reductions or improvements in benefits from electronic transactions. More information on the regulatory requirements for testing can be found within 45 Code of Federal Regulations (CFR) §162.940 and the Go-To-Guidance Letters on CMS' website.

Historically, implementation specifications have been adopted in batches. HIPAA requires that one transaction has only one standard. Multiple standards pose difficulties that would preclude them from achieving the overall goal to reduce costs and improve efficiencies. However, adoption and implementation cadences and approaches, as well as the need for multiple standards, can be considered if industry provides a persuasive argument. Mr. Kalwa invited participants to share any questions or

comments with CMS (AdministrativeSimplification@cms.hhs.gov or CMSAdministrativeSimplificationException@cms.hhs.gov for exemption requests).

Discussion

Ms. Banks asked for additional information regarding why multiple standards for a transaction cannot be supported. Mr. Kalwa noted that HIPAA and industry structure standards differently and therefore multiple standards could cause confusion; however, multiple standards are possible.

Ms. Love asked about the level of flexibility given to NSG during standard implementation timelines. Mr. Kalwa noted that, during the adoption and implementation of version 005010, previous and new standards were allowed for a certain period of time but the new standard was required to be implemented by a specific date. He emphasized that the timeline can be flexible to enable the best approach to implementation.

Presentation from X12 Regarding the Updated Transactions

In 2021, X12 conducted a survey related to HIPAA mandates. Approximately 74 percent of responders were X12 members. Of all responders, many were implementers, trading partners, vendors, clearinghouses, value-added networks, and consultants. Ms. Sheppard highlighted several findings from survey respondents:

- 85 percent reported that health care claims related to 837 transactions are an important component of their current EDI system.
- 87 percent reported that health care payments/remittance advice claims related to 835 transactions are an important component of their current EDI system.
- 75 percent indicated support for moving newer versions forward for mandated adoption; 16 percent indicated no opinion, and 9 percent were opposed.
- 66 percent indicated their organization would benefit from new or enhanced functionality available in X12's latest versions; 27 percent were unaware of the enhancements.
- 40 percent were supportive of alternative syntaxes (e.g., Fast Healthcare Interoperability Resources [FHIR], XML, JavaScript Object Notation [JSON]) if X12 verifies that the alternative syntax supports the same data content, whereas 27 percent were supportive if an American National Standards Institute (ANSI) National Standards Developer (NSD) verifies the alternative syntaxes; 16 percent were opposed to allowing alternative syntaxes.

The federal rulemaking process (1) is the critical path of recommendation, (2) is a very lengthy process based on the number of requirements for accepting and reviewing public comments, and providing implementers with a development timeline before transitioning to the new version, and (3) does not operate at an expected cadence. X12 publishes enhanced standards annually, including functional enhancements, housekeeping revisions, and supplemental information that assists implementers.

The gap between the federal rulemaking timeline and X12's publication of enhancements that support the evolving business needs of health care implementers presents a significant challenge for X12 and industry stakeholders whose needs are not being met in a timely manner. Given the challenges with timing, X12 proposed a new approach for recommendations that allows the lengthy federal process to begin as quickly as possible and enables health care implementers and X12 time to verify functionality and include helpful supporting information. X12 has also proposed the adoption of version 008020 of specific IGs. If NCVHS supports these recommendations, X12 proposes that HHS then base the initiate steps of the federal rulemaking process on the 008020 versions. As the recommendations advance through the federal processes, X12 and select licensing partners will continue executing the proof-of-

concept (POC) pilot study and review feedback from stakeholders; both the results of the pilot and stakeholder feedback will inform improvements in X12's annual releases. Once HHS is preparing to issue a Notice of Propose Rulemaking (NPRM), X12 recommends that the most recently published version of the IGs be named in place of the 008020 versions. This process ensures that the versions named in the NPRM and Final Rule reflect the most current requirements, including solutions for items identified during X12's pilot and stakeholder reviews, rewording to clarify instructions or correct grammatical issues, revisions to ensure consistency across instructions, and addition of supporting information. X12 will provide a list of the revisions applied to versions past 008020 to clarify the differences between that version that the version named in the NPRM.

X12 has developed a phased approach to reduce the impact of these recommendations on CEs. Each phase of this approach involves a group of logically related transactions and will provide supporting information. The timing of each phase is based on the approval of necessary maintenance, functionality of enhancements, and supporting information. X12's position is that implementers should be able to exchange consistently defined data using the syntax that best meets their needs. In support of that position, each of X12's recommendations include the naming of both the EDI standard representation and the associated XML representation as permitted syntaxes.

X12 submitted the first set of recommendations in June 2022, and these recommendations involve updates to the following currently mandated transactions: (1) 008020X323 Health Care Claim—Professional, (2) 008020X324 Health Care Claim—Institutional, (3) 008020X325 Health Care Claim—Dental, and (4) 008020X322 Health Care Claim Payment/Advice. Each of the X12 IGs 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 IG, ensuring that no discrepancies are found between the syntaxes. Per HIPAA regulations, X12 informed DSMOs of these recommendations in June 2022 and asked those DSMOs to review the recommended IGs, consult with X12, and provide feedback on the enhancements. X12 did not receive any questions, suggestions, or feedback from DSMOs in advance of this hearing.

The recommended IGs include enhancements that improve claims and remittance processing through several processes:

- Supporting Device Identifier (DI) information, which improves the industry's ability to identify risks, reach patients affected by device failures, improve patient outcomes, enhance tracking and reporting abilities, reduce patient health risks, and save taxpayer funds
- Supporting factoring agent information that improves provider access to short-term capital, which is a critical tool in today's health care environment
- Supporting longer claim identifiers, which improves tracking, auditing, and matching functionality throughout the claim's life cycle
- Reducing manual processing related to recoupment, improving efficiency and providing cost saving for both providers and payers
- Supporting more detailed source of payment codes in remittances to improve provider understanding of how claims are adjudicated by payers and thus reduce the processing costs
- Clarifying ambiguities with additional instructions and clearer wording to reduce inconsistencies, friction, and misunderstandings between trading partners

A list of each individual enhancement included in the recommendations can be found on X12's website.

Ms. Sheppard highlighted two errors within the list of enhancements. One error is related the 008020X324 Heath Care Claim: Institutional guide's Item 14, which increased the number of prior authorizations (PAs) and referrals that can be reported at the line level. This enhancement was not

implemented in the 008020 version, but is expected to be included in the following version. The second error resides in the enhancements to the 008020X322 Health Care Claim Payment/Remittance Advice's Item 3, which adds the ability to report remittance information related to card payments in order to facilitate auto-posting. Concerns emerged regarding the addition of this functionality and its impact on providers; thus, X12 wants to provide further clarification on this item. X12 conducted discussions to debate the merits of this item and determined that the inclusion of card payment options is based on approval via X12's ANSI-accredited, consensus-based process. X12 does not mandate the exchange of virtual credit card payments. The inclusion of virtual credit card payments ensures consistency for organizations currently using inconsistent solutions to transmit information. Discussions related to fees and other impacts are important but are outside the scope of X12's responsibility.

Although cost estimates in an NPRM are the responsibility of NSG, X12 has provided high-level cost estimates in its set of recommendations as a starting point for NSG. X12's licensing partners are also tracking costs as part of the pilot study, and information captured during this exercise will be available to NSG in the future.

Industry stakeholders can submit questions and suggestions related to X12's recommendations using an online feedback form. In addition, questions regarding the IG instructions can be directly submitted to X12 via the online Request for Interpretation (RFI) form.

Discussion

Ms. Banks asked about the impact of updating only a select number of standards at a time. Ms. Sheppard confirmed that the impact of adopting standards individually will be tested during X12's pilot study, noting that one benefit may be accelerating the ability to transition to a new standard without sacrificing accuracy.

Ms. Banks asked whether version 008020 supports post-coding related to International Classification of Diseases 11 (ICD-11). Ms. Sheppard confirmed that X12 is working on a solution for ICD-11 post-coding, but that this work will not be included in the transition to version 008020. She also agreed to share with NCVHS and the Standards Subcommittee additional information on this topic.

Ms. Love asked for preliminary information on version 008040. Ms. Sheppard agreed to develop and publish a high-level summary on versions 008030 and 008040 on X12's website.

X12 Proof-of-Concept Pilot Update on Use of Version 008020

X12's POC Program was created to verify that the expected business benefits of these new versions and transactions are achievable, identify unforeseen obstacles and adjust accordingly, and establish a baseline of expected implementation costs. Participants in this program include clearinghouses, software vendors, payers, and providers. Ms. Rose presented several benefits of participating in the current POC pilot study, summarized below:

- Verify the impact, benefits, opportunities, challenges, and potential costs to upgrade from the current to proposed future versions.
- Understand the intentions and implementations of changes between the current HIPAA-mandated transactions and the proposed new versions.
- Create opportunities to collaborate with trading partners and service and software vendors.
- Provide early access to new versions of X12 standards, derivatives, and related exclusive content.

The pilot follows an end-to-end approach that focuses on using de-identified real scenarios and synthetically generated test data to perform X12 standard validation, IG validation, balancing and inter-segment validation, code set validation, and cross-version computability assessments. The process will also involve X12 artifacts, resources, and insights, including online IG, differences summaries, table data and XSDs, and test data and files.

Optum will conduct the POC pilot and conduct the following steps in order: (1) gap analysis, (2) edit review, (3) import table data/creation of databases, (4) development, (5) quality assurance testing, (6) review output with X12, and (7) implement the transactions into the Optum Transaction Validation Management and Optum Transaction Integrity systems. Optum will implement the proposed updated transactions in the following order: 837 Professional, 837 Institutional, 837 Dental, and 835 Remittance Advice. Optum has begun the gap analysis and edit review. X12 has elected to participate in this study because the pilot will allow the teams involved to report on time spent on development, testing, and implementation, which will provide insight into potential costs. In addition, testers will review an inside view of the IG and access to X12 resources without additional cost.

Discussion

Ms. Rose confirmed that Optum has conducted approximately 40 hours of development efforts related to the pilot, as well as 80 hours for the gap and edit analyses.

Panel 1: Designated Standards Maintenance Organizations and Code Content Committees

Moderator: Tammy Banks, Standards Subcommittee Co-Chair

Terry Cunningham, DSMO

On August 17, 2000, the HHS Secretary of named six entities as DSMOs under HIPAA. The organizations include three standards setting organizations (i.e., X12, Health Level 7 International [HL7], and the National Council for Prescription Drug Programs [NCPDP]) and three data content committees (i.e., the Dental Content Committee of the American Dental Association, the National Uniform Billing Committee, and the National Uniform Claim Committee [NUCC]). HIPAA regulations have established that the HHS Secretary considers a recommendation for a proposed modification of an existing standard or a proposed new standard only if the recommendation is developed through a process that provides open public access and coordination among DSMOs. In order to ensure adequate coordination, DSMO members have historically submitted new or updated standards to a DSMO, which will formally review the material and then issue a recommendation to NCVHS. Inconsistent with these established processes, DSMOs were notified of the X12 recommendations on June 8, 2022, which is the day after the recommendations were sent to NCVHS. X12's DSMO submission failed to include a copy of the actual standard, as well as a usable changelog displaying the updates proposed. As a result, these submissions were not subject to a coordinated review analysis in advance of their submission to NCVHS. Mr. Cunningham, on behalf of DSMOs, encouraged NCVHS to support DSMO efforts to reinforce the consultation requirement found in Public Law 104-192 and the related subsequent relations.

Over the past few months, DSMOs have engaged in a review and analysis of the X12 recommendations and associated claims guides. Three major themes emerged during this review. First, the standards need additional pilot testing to ensure that the transactions will function properly and meet industry needs. Second, industry should not begin to adopt new versions of the remittance claims transactions without more cost/benefit analysis. Third, industry requires additional clarity regarding whether the recommendations allow multiples of versions or standards to be permitted simultaneously. Regarding the first theme, no real-time pilot testing of the proposed transactions has occurred to date. Such

testing is an essential step in evaluating the effectiveness of a new standard, because it will also aid efforts to identify accurate impact analysis and reveal the benefits of adopting the proposed upgrades. In addition, pilot testing also ensures that the affected transactions can work across versions throughout the piece-meal implementation process. Such an implementation process necessitates substantial cross-version piloting before stakeholders can adequately engage in a cost/benefit analysis. Testing also helps to avoid claim and remittance disruptions, particularly when the industry is experiencing financial strain resulting from the multi-year effects of the COVID-19 pandemic.

In relation to the second theme—the need for a cost/benefit analysis—X12 provided estimated implementation costs for each of the impacted standards in its recommendations letter. The DSMO strongly agrees that clear implementation cost and benefit estimates are essential parts of an actionable recommendation. However, the DSMOs do not believe that the offered estimates provide sufficient clarity to support a recommendation. Specifically, the X12 estimates generalize across all stakeholders and treat all enhancements as equal to one another, and lack detail about their creation. As a result, the DSMOs do not believe that these estimates are reliable or usable for the stakeholders at this time. A cost/benefit analysis must review information gathered from pilot testing so that industry stakeholders can accurately understand the costs to support the updated transactions, the savings in time and resources, and the return on investment (ROI) for each stakeholder.

Finally, in a July 2022 letter titled, "Recommendations to Modernize Adoption of HIPAA Transaction Standards," NCVHS recognized that new drivers of transformation in health care data exchange are within HHS' purview. NCVHS recommended that HHS update relevant HIPAA policies to allow the adoption and use of more than one standard per business function. The letter calls for HHS to enable HIPAA CEs to support one or more versions of adopted standards for business functions. HHS has yet to respond to these recommendations. DSMOs believe that the most critical item related to the prospective cost/benefit analysis is whether more than one version of a standard's implementation specification or more than one standard per business function will be allowable. Should stakeholders be required to support multiple IG versions or standards simultaneously, the tools and framework needed to support the adopted standards may increase costs for stakeholders. In addition, CEs and their vendors may need to hire full-time teams to review and implement new versions of IG, which would necessitate a sustained capital investment.

In conclusion, as a result of these aforementioned concerns, the DSMO finds that the X12 transactions have not undergone adequate testing and piloting to ensure that the proposed updates to the currently mandated standards will produce legitimate benefits and will not have unintended consequences for the industry. The DSMO does not recommend that NCVHS pursue adoption of the proposed standards until (1) completion of real-world pilot testing demonstrates their functionality, (2) completion of a more detailed cost/benefit analysis occurs, and (3) greater clarity is provided regarding whether multiple standards or versions for the same business function will be allowed.

Discussion

Ms. Banks asked for additional information regarding the DSMOs' process for reviewing standards. Mr. Cunningham noted that the process begins when recommendations have been shared with the DSMOs, leading to a discussion of these recommendations among stakeholders. The DSMOs also perform a cost/benefit analysis and share overall findings and recommendations with NCVHS.

Ms. Spector, Chair of NUCC, provided an overview of the recommendation review process that led to the adoption of version 005010. These recommendations were received in 2008, and each DSMO reviewed the recommendations before convening for discussion. DSMO leadership then adjudicated issues that emerged from that discussion, and the resultant findings and recommendations were shared

with NCVHS. This process did not occur for version 008020 because X12 did not share these recommendations with the DSMOs in a timely manner before sharing them with NCVHS.

WEDI Member Survey and Advisory Event Outcomes

WEDI was formed in 1991 by then HHS Secretary Dr. Louis Sullivan and named in HIPAA legislation as an advisor to the HHS Secretary. WEDI now has 18 work groups, each focused on a specific topic (e.g., claims or remittance/advice payment). WEDI's stakeholders include health care plan organizations, providers, vendors, SDOs, and government agencies. In addition, WEDI has productive working relationships with CMS and ONC.

The WEDI MPA process is designed to solicit WEDI member input on a specific issue, public or private proposals, or government regulations and to result in advisements to the WEDI Board of Directors. In response to the NCVHS RFC, WEDI collected member perspectives through workgroup discussions on claims, remittance and payments, industry surveys, and virtual events. WEDI conducted the survey from September 28, 2022, to October 27, 2022, with a 77 percent response rate; approximately 15.6 percent of the respondents were providers, 46.6 percent were payers, 14.3 percent were clearinghouses, and 23.4 percent were vendors. Dr. Tennant summarized findings from the survey respondents:

Familiarity with the X12 Initiative to Create Updated and New Operating Rules in Support of Electronic Transactions

- 45.6 percent are X12 members and participated in the development of the updated standards.
- 8.8 percent are X12 members but did not participate in the development of the updated standards.
- 19.1 percent have reviewed these X12 proposals.
- 22.1 percent are aware that X12 has developed updated transaction versions but do not know the details.
- 4.4 percent had no familiarity with these proposals.

837 Institutional Transaction Updates

- 51 percent responded that adding the ability to transmit the DI of the Unique Device Identifier (UDI) for supplies, implants, and explants would have positive or strong positive impact.
- 59 percent responded that increasing the number of PAs and referrals that can be reported at the line level would have positive or strong positive impact.
- 71 percent responded that replacing the Claim Adjustment Segment (CAS) with the Reason Adjustment Segment (RAS) to support the association of Adjustment Reason Codes and Remark Codes and better synchronization with the 835 would have positive or strong positive impact.
- 72 percent responded that adding support for transmitting coordination of benefits (COB) allowed amounts would have a positive or strong positive impact.

837 Professional Transaction Updates

- 63 percent responded that increasing the maximum number of diagnosis codes from 12 to 24 to provide a more complete picture of the patient's condition would have positive or strong positive impact.
- 65 percent responded that increasing the number of diagnosis code pointers from 8 to 12 per service line for professional claims would have positive or strong positive impact.
- 72 percent responded that adding support for transmitting COB allowed amounts would have positive or strong positive impact.

- 74 percent responded that greater focus on reducing ambiguity throughout the IG would have positive or strong positive impact.

837 Dental Transaction Updates

- 66 percent responded that adding a data element used for COB when a claim is adjusted would have positive or strong positive impact.
- 69 percent responded that revising to support reporting claim-level Remark Codes not associated with an Adjustment Reason Code would have positive or strong positive impact.
- 72 percent responded that revising to support line-level PAs when no authorization is sent at the claim level reducing the need to split claims would have positive or strong positive impact.
- 72 percent responded that revising to support the transmission of allowed amount received on the primary claim would have positive or strong positive impact.

835 Payment/Remittance Advice Transaction Updates

- 71 percent responded that adding information that will aid in automating the positing of remittance advice information would have positive or strong positive impact.
- 72 percent responded that standardizing and adding clarity for reporting COB adjudication information would have positive or strong positive impact.
- 73 percent responded that standardizing the forward balance and overpayment recovery processes would have positive or strong positive impact.
- 73 percent responded that adding the ability to reassociate a recovery amount to a specific claim to reduce manual processes to track when funds have been recouped would have positive or strong positive impact.

Should the government permit industry use of multiple versions of one standard?

- 20 percent responded “Yes.”
- 70 percent responded “No.”
- 10 percent responded “Unsure.”

WEDI members noted that if multiple standards are allowed, they should be semantically equivalent and interoperable. WEDI does not support moving forward individual transactions (i.e., transaction by transaction).

In addition, WEDI hosted a 4-hour virtual event on November 9, 2022, that convened 75 participants to share perspectives on the RFC and discuss how best to implement new standards and operating rules. During this event, WEDI conducted several polls of the participants; the poll questions and associated answers are provided below:

When will you conduct an analysis of the impact on your organization related to the new X12 transactions?

- 4 percent have already conducted an analysis.
- 29 percent will conduct an analysis within the next year.
- 38 percent will conduct an analysis only when CMS issues a Proposed Rule.
- 8 percent will conduct an analysis only when CMS issues a Final Rule.
- 21 percent have no plans to conduct an analysis.

Do you support the proposal to adopt 008020 EDI standards and the XML representation as permitted synaxes?

- 58 percent responded "Yes."
- 8 percent responded "No."
- 33 percent responded "Don't Know."

Rate the level of potential additional value that the DI and UDI provide as data elements in the updated version of the X12 claim transactions.

- 36 percent responded "Significantly" or "Somewhat Improved Value."
- 12 percent responded "No Change in Value."
- 0 percent responded "Somewhat Decreased Value."
- 8 percent responded "Significant Decrease in Value."
- 44 percent responded "Don't Know."

Overall, should WEDI recommend adoption of the proposed 008020 837 (Dental, Institutional, and Professional) transactions?

- 62 percent responded "Yes."
- 17 percent responded "No."
- 21 percent responded "Don't Know."

Overall, should WEDI recommend adoption of the proposed 008020 835 transactions?

- 46 percent responded "Yes."
- 21 percent responded "No."
- 33 percent responded "Don't Know."

Should the implementation window for standards be longer than 2 years from the publication date of the Finale Rule?

- 6 percent responded "Yes."
- 44 percent responded "No."
- 50 percent responded "Don't Know."

WEDI members noted that the January 1 date overlaps with many compliance and contractual obligations and recommended exploring an alternative date for implementation of new standards.

How important is it that new and updated administrative transactions be implemented on a regular schedule?

- 42 percent responded "Very Important" or "Important."
- 21 percent responded "Somewhat Important."
- 22 percent responded "Somewhat Unimportant."
- 16 percent responded "Very Unimportant."
- 11 percent responded "Don't Know."

Would industry benefit from being able to use either the version 008020 or version 005010 for some extended period of time versus having a definitive transition date?

- 25 percent responded "Yes."
- 54 percent responded "No."
- 17 percent responded "Unsure."
- 4 percent responded "Don't Know."

If standards are adopted in batches and not as a full suite of transactions, effective dates for transitioning to new versions will likely be different. WEDI members expressed a preference for moving forward a full suite of standards, or at least moving forward similar transactions as a batch. WEDI MPA event participants expressed concern that out-of-sync adoption and implementation cycles may be confusing for the industry.

Rate your level of support for the following statement: No administrative transaction standard should be nationally mandated until a pilot test is conducted and the results indicate a clear ROI for the industry.

- 59.2 percent support or strongly support the statement.
- 20.4 percent neither supported nor opposed the statement.
- 20.4 percent opposed the statement.
- No respondents strongly opposed the statement.

Dr. Tennant noted that transitioning to the latest version of HIPAA administrative transactions took approximately 15 years, and thus WEDI encourages the development of a known and predictable standards upgrade cycle. In addition, the current health information technology (HIT) landscape is complex, challenging, and rapidly changing. Requirements for new and updated HIPAA administrative standards and operating rules must compete with 21st Century Cures Act interoperability requirements, No Surprises Act data exchange provisions, and mother federal mandates for scarce human and financial resources. WEDI encourages the development of a comprehensive and achievable roadmap that prioritizes these HIT requirements and recognizes the many implementation challenges faced by the industry. WEDI's full response to the NCVHS RFC can be accessed on WEDI's website.

Discussion

Ms. Banks asked Dr. Tennant to summarize WEDI's recommendation related to the X12 proposed updates. Dr. Tennant noted that WEDI supports moving forward with the new transactions but recognizes the need to establish the ROI and conduct pilot testing and a cost/benefit analysis.

Despite X12's proposed updates relating to more than 1,000 enhancements, WEDI's survey only focused on a small portion of these enhancements. Dr. Tennant noted that many of the enhancements are wordsmithing and grammatical errors being corrected, and the WEDI survey focused on the most substantive and key changes.

Ms. Love asked about industry's interest in performing real-world testing related to X12's proposal. Dr. Tennant confirmed that buy-in from industry is critical and that industry could be incentivized to increase the number of organizations participating in real-world testing.

Panel 2: Provider Perspective on Proposed Updates to X12 Transaction Standards

Moderator: Jamie Ferguson, Member of Standards Subcommittee

Andrea Preisler, American Hospital Association

From the provider perspective, the American Hospital Association (AHA) is evaluating two major considerations related to the proposed adoption of version 008020: (1) cost and operational considerations and (2) functional considerations. These considerations focus on whether the adoption of version 008020 will help or hinder the provider workflow. A major concern from AHA's perspective is that, to date, very little pilot testing has been completed. Without pilot testing, AHA finds it difficult to quantify operational effectiveness and challenges, identify advantages and disadvantages of the new version, estimate costs, and assess compatibility of transactions on different versions. AHA's cost and operational considerations focus on the current state of hospital finances, implementation timeframes, and implementation and simultaneity. The current state of hospital finances is impacted by intense financial and staffing pressures as expenses have increased significantly. For example, 2022 expenses are projected to be nearly $135 million more than 2021 expenses. AHA recognizes a need to avoid claim and remittance transaction disruptions as well as increased costs. AHA is generally in favor of maintaining a 2-year implementation window for health plans and providers after the Final Rule publication.

The 005010 transition revealed that testing delays coupled with limited staff and finite budgets strained hospital resources. During this transition, hospitals expressed concern that testing delays encroached on their ability to implement necessary system changes. AHA emphasized the importance of creating and maintaining the least disruptive pathway to implementation possible and of balancing these HIT initiatives with the need to acquire sufficient resources, educate industry, provide adequate testing time. Staggered implementation timeframes may require hospital systems to hire full-time staff dedicated to implementation, which poses a financial burden.

Regarding NCVHS's RFC question related to concurrent use of multiple versions of a standard, AHA is uncertain of the intended benefits and expresses significant concern related to providing the necessary support for multiple versions, which likely will pose a substantial administrative burden and cost to providers. Standards are adopted to provide a singular approach to communication between parties while increasing efficiency and reducing cost. Thus, AHA questions whether allowing multiple versions promotes the goal of uniformity and predictability across the industry. Further, robust cross-standard testing is critical; such testing must determine the impact of multiple standards and evaluate ROI. **Overall, AHA urges NCVHS to exercise caution in moving forward with recommending variation in the health care standards environment.**

AHA's functional considerations focus on UDIs, virtual credit cards, good faith estimates, and advanced explanation of benefits (AEOB). AHA is supportive of device safety and improved safety surveillance. However, AHA is unsure of the value in inserting UDI information into claims. Before adopting these policies, AHA wants to better understand how UDI information fits into the surveillance system within today's health care environment, particularly because the U.S. Food and Drug Administration (FDA) has not yet clearly defined which devices are considered high-risk for the purposes of safety surveillance and reporting.

AHA also has major concerns related to virtual credit cards. Health plans often switch to virtual credit card payments without provider authorization. This shift results in substantial processing fees and reduced payment receipts for providers, as well as considerable administrative hassles. To safeguard payment legitimacy, AHA recommends that NCVHS only proceed with further legitimization of the virtual credit card process if it can proactively ensure that plans do not inappropriately switch providers to costly virtual card payment methods without the mandated advanced agreement from the provider.

AHA is also interested in how adoption of the updated version 008020 could support implementation of the AEOB price transparency provisions under the No Surprises Act. For example, AHA strongly supports leveraging existing provider and health plan workflows, standards, and technology for claims submission and adjudication to support the creation of AEOBs for patients. However, AHA is uncertain that utilization of version 008020 transactions would be necessary in this situation, because version 005010 can complete the predetermination of benefits. As a result, AHA welcomes insight from X12 about whether 005010 in fact has the claims pre-adjudication capability that could be leveraged for transmitting good faith estimates to health plans.

In conclusion, AHA is concerned that the X12 transactions have not undergone adequate testing and piloting to ensure that the proposed standard updates will produce legitimate benefits and not have unintended consequences for the industry. At this time, AHA recommends that X12 conduct pilots and tests to demonstrate that unforeseen technical issues will not occur, provide details about the envisioned implementation process, and sufficiently articulate how the updated transaction's proposed benefits will improve the industry. In addition, AHA recommends that NCVHS pursue additional clarification surrounding its recommendations that would allow multiple standards and versions to exist simultaneously, because adherence to such recommendation would significantly alter the impact of adopting new standards. Ms. Preisler highlighted that these changes would occur at a time when the nation's hospitals and hospital systems are experiencing significant financial strains and the current transactions are functioning well. As a result, AHA does not support NCVHS recommending adoption of the proposed transactions at this time.

Nancy Spector, American Medical Association

As the only medical association that convenes more than 190 state and specialty medical societies and other critical stakeholders, the American Medical Association (AMA) represents physicians with a unified voice to all key players in health care. AMA leverages its strength by removing the obstacles that interfere with patient care, leading the charge to prevent chronic disease and confront public health crises, and driving the future of medicine to tackle the biggest challenges in health care. AMA's mission is to promote the art and science of medicine and the betterment of public health. AMA is a long-time champion of administrative simplification and its important role in improving patient experience of care, health of populations, and work life of physicians, and in reducing health care costs. AMA is also a long-time advocate for the adoption of electronic transaction and code set standards to reduce administrative burdens for physicians, particularly those working in small or rural practices or serving minoritized or marginalized communities with limited resources. AMA is a long-time active participant in cross-industry, multi-stakeholder efforts to advance HIT to meet unmet business needs and build consensus on the best path forward for adopting these innovations in real-world settings.

AMA's core principles for adopting new or updated standards involves (1) recognize, preserve, and enforce successful transaction and code set standards; (2) prioritize identifying and addressing unmet business needs; (3) rigorously evaluate and test any new transaction standards being considered for adoption prior to a federal mandate to ensure their maturity, viability in real-world settings; and (4) adopt only one new standard for a particular business function (i.e., new or revised standards should replace previously adopted ones). Using these principles, AMA believes that implementing version 008020 of the 837 and 835 claims transactions standards at the current time is premature. X12's proposal does not include sufficient information on the costs, benefits, and operational impact of version 008020 of 837 and 835 transactions. Costs to physicians will vary widely and will depend on size of practice, current IT systems, current software systems, current software needs, vendor readiness, impact on their services, and training needs. To estimate the costs, physicians require more real-world data related to the changes and work needed to implement these transaction updates. AMA urges

NCVHS to hold any recommendation until the results of the X12 pilot testing are made available to the industry.

AMA does not support NCVHS' recommendation to allow multiple versions of a standard or multiple standards for the same business function. This approach abandons the basic tenets of HIPAA administrative simplification, lacks uniformity, increases costs, and exhibits major inefficiencies. Testing has not been completed to reveal whether multiple versions or standards can function together. AMA strongly cautions against viewing clearinghouses or other vendors as an easy solution for physician practices. Further, X12's proposal outlines several possible benefits of version 008020, including the change from CAS to RAS, new functionalities for predetermination, revisions for reporting property and casualty data, increased number of diagnosis codes, additional clarifications, and updated data field lengths. However, AMA highlights that real-world testing of version 008020 of 837 and 835 transactions is necessary to quantify these benefits.

AMA has serious concerns regarding the inclusion of the UDI for high-risk implanted medical devices in the claim transaction. AMA requests that NCVHS include in any recommendation to adopt version 008020 of 837P and 835I transactions language in relevant sections that highlights stating that reporting of a UDI is not a HIPAA-mandated use. This language will prevent a payer from circumventing the need to enter into a trading partner agreement by instructing physicians to report all HIPAA-mandated data, which would include UDIs. AMA is also concerned that the addition of virtual credit card payment information in 835 transactions will serve as an "enabler" of these payments, which have been associated with harmful impacts and coercive business tactics. A full understanding of the financial and administrative burden that will impact physicians is needed before recommending adoption of version 008020.

In conclusion, AMA believes that supporting implementation of version 008020 of 837s and 835 transactions is premature because the overall cost or benefit is unclear. More industry-wide data are needed related to costs, benefits, and values before a decision can be made. AMA continues to question whether version 008020 is the best use of physician practice's limited resources.

Katie Knapp, Department of Veterans Affairs

As the largest integrative health care system in the United States, Veterans Affairs (VA) sent and received more than 80 million electronic health care transactions in 2022. VA is committed to implementing and continued monitoring of the HIPAA-mandated electronic transactions to ensure that the benefits of administrative simplification are realized across the health care industry and passed on to the nation's veterans.

This testimony addresses the questions posed by NCVHS about the proposed updates to the adopted X12 standards, specifically for the 837 and 835 transactions. Responses are organized into two categories: (1) VA's comments on specific 837 and 835 updates and (2) VA's view on moving forward with the full suite of proposed updates for the X12 standards. VA's experience implementing electronic transactions under HIPAA demonstrates its commitment to proactive development of internal software solutions to meet electronic standards. VA has participated in reviews of updates to the 005010 standard over the past 10 years. When reviewing these two transactions in detail, VA has no specific reservations about the changes proposed. VA strongly believes that the industry should move forward and implement the next version of transactions. Thus, VA stands ready to make the necessary system changes to comply with the new standards.

Further delay in implementing these updates would complicate operational use and would add scope to the development of the software solutions necessary to maintain the standards. The main concern for VA involves the distinction between the software development and the implementation of the new

transactions. VA's position is to approve the transactions, thus enabling providers, payers, and health care clearinghouses to complete the software development while delaying implementation until the full suite of transactions is ready and approved. This approach enables VA to incrementally develop and focus on each transaction, as well as organizations to better justify the IT investment required to implement these updates. In this scenario, organizations are able to develop software solutions to meet industry changes, but then place these software upgrades in a dormant state until all transactions are ready to be enacted by the Secretary.

When the 837 and 835 transaction updates were proposed to NCVHS, VA appreciated the opportunity to focus on a smaller subset of transactions. In previous NCVHS hearings, testifying on the entire suite of X12 updates was overwhelming. Thus, VA supports the structured incremental approach proposed. Implementing a few transactions at a time as currently proposed could create major operational challenges. VA experienced challenges with trading partner exchanges that impacted operations during the transition from version 004010 to version 005010. The challenges from the last conversion were experienced across payer and clearinghouse operations, which created downstream impacts on veterans.

Implementing different versions of transactions will require extra internal development, thus the potential for challenges across the industry each time a transaction set is released. If NCVHS were to recommend implementation of transactions separately, it should solicit industry feedback on the best order to move the transactions forward. For example, VA foresees major operational issues if the 837 updates were adopted before the 270 and 271 updates, as well as loss of revenue and harm to veterans.

As the largest health care organization in the United States, VA interacts with thousands of payers nationwide in multiple clearinghouses. VA is concerned about the potential adoption of multiple versions of each individual standard. VA believes that this recommendation will be successful only if the decision about which version is sent and received is provider-driven, with if clear implementation and compliance dates are assigned. VA remains committed to the benefits of HIPAA's electronic transactions. The updates to these transactions are supported in the hopes that they will continue to benefit the veteran community.

Discussion

Mr. Ferguson asked about the advantages and disadvantages of updating only selected transactions to version 008020 and leaving the majority of transactions in version 005010. Ms. Spector noted that this question requires testing to answer because previous version transitions did not allow multiple versions to exist at a time. In addition, cost/benefit analyses are needed to understand the advantages and disadvantages, as well as the effect of these changes on physician workflows.

Mr. Ferguson noted that HIPAA provides a 2-year timeline for implementation of standards updates after publication of a Final Rule, which corresponds to approximately 4 years after NCVHS makes the recommendation to the HHS Secretary. He asked panelists for their opinions on implementation timing. Ms. Knapp noted that the 2-year implementation timeline is appropriate. Ms. Spector noted that implementation requires nearly eight phases, which could easily extend implementation to 3 years. Ms. Preisler noted that the timeline must allow for adequate testing with industry and trading partners to determine whether the updates are truly ready for implementation.

Dr. Ferguson asked panelists to highlight any must-have updates in this version that industry needs to improve provider workflow. Ms. Spector underscored the importance of incorporating more diagnosis codes, which will benefit the collection of social determinants of health (SDOH) data. Ms. Preisler added that AHA is interested in understanding how version 008020 can support implementation of the No Surprises Act.

Panel 3: Health Plan Perspective on Proposed Updates to X12 Transaction Standards

Moderator: Denise Love, Standards Subcommittee Co-Chair

Natalie Chalmers, CMS Medicare Dental Program

Every day, CMS ensures that 158.5 million people in the United States have effective health coverage, including those receiving coverage through Medicaid, Medicare, state-based and federal marketplaces, and Children's Health Insurance Program. CMS' vision is to serve the public as a trusted partner and steward, dedicated to advancing health equity, expanding access to affordable coverage and care, and improving health outcomes.

In 2018, the majority of individuals (37.1 percent; 121.1 million) engaged the health care system through dental and medical visits, but some engaged the health care system through only dental (8.6 percent; 28.2 million) or medical (34.4 percent; 112.3 million) visits. Other individual had no access to either dental or medical visits (19.8 percent; 64.7 million). Regardless of private, public, or no insurance, approximately 9 percent of the population's only point of access to the health care system was through a dental appointment in 2019.

Medicaid provides dental coverage to all children who are beneficiaries; however, the uptake of this dental coverage vastly differs across regions of the United States. For example, in 2020, 12.4 to 35.4 percent of Medicaid beneficiaries aged 1-20 years in midwestern states, such as Illinois and Ohio, received preventative dental services, compared to 44.5 to 59.0 percent in Texas, New Mexico, and Colorado. Similar regional differences are evident in the rates of emergency department visits for non-traumatic dental conditions of adults with Medicaid coverage. Whereas California and Utah exhibit rates of 939 to 1,649 visits per 100,000 adult beneficiaries, Georgia and Florida exhibit rates of 2,705 to 3,925 per 100,000 adult beneficiaries. When an individual cannot access preventable dental services, their only option may be the emergency department. However, emergency departments only provide palliative (e.g., antibiotics) and a recommendation to contact a dentist for future care—at an average cost of $900. The lack of connectivity between hospital systems and dental providers is a significant challenge, leaving the burden of coordinating care to the individual. Each year, approximately $2.7 million is spent because of this lack of health care access and coordination.

In 2019, approximately 42 percent of Medicare beneficiaries living in the community received a dental exam. The majority (47.9 percent) of these beneficiaries were White, followed by 33.8 percent Hispanic, 17.9 percent Black, and 33.3 percent another race/ethnicity. Beneficiaries with higher incomes were more likely to have had at least one dental exam in 2019. These statistics indicate that income and health disparities, play a major role in access to dental services.

Prior to 2023, Medical PFS dental services payable as physicians or hospital services that may be provided by oral health professionals included (1) professional work involved in the inpatient restructuring of the jaw in connection with accidental injury, (2) oral examinations, but not treatment, performed prior to kidney transplants or cardiac valve replacement, (3) reconstruction of a ridge when it is performed as a result of and at the same time as the surgical removal of a tumor, (4) wiring of teeth with done in connection with the reduction of a jaw fracture, and (5) extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease.

In January 2023, CMS issued a Final Rule to update the Physician Fee Schedule (PFS) related to dental and oral health services. Section 1862(a)(12) of the Social Security Act's statutory dental exclusion states that

> "no payment be made under part A or part B for any expense incurred for items or services…where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services."

The CMS rationale for the 2023 PFS update is as follows:

> "…there may be instances where medical services necessary to diagnose and treat the individual's underlying medical condition and clinical status may require the performance of certain dental services, we believe that there are instances where dental services are so integral to other medically necessary services that they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to the clinical success of an otherwise covered medical service, and therefore, are instead substantially related and integral to that primary medical service."

The Final Rule also established a process through which CMS can review public recommendations for Medicare payments related to dental services that are potentially analogous. In addition, effective in 2024, CMS will finalize Medicare payments for dental exams and necessary treatments prior to receiving care related to head and neck cancers. The Final Rule also states that the exchange, and facilitation of the exchange, of information between dental and medical providers is key to the health care system as a whole. Thus, any policies and updates to standards that can help improve the exchange of information are supported by CMS.

Ferris Marone, Tennessee Medicaid

Mr. Marone has worked with the Tennessee State Government for nearly 20 years in contractor and consultant capacities. He has also worked with clearinghouses, providers, and payers to help implement versions 004010 and 005010. He expressed several reservations regarding the X12 proposal. State governments can only begin to perform a cost/benefit analysis after NCVHS publishes a Final Rule. Implementing version 005010 was highly resource- and cost-intensive for Tennessee, and Mr. Marone expects a similar experience for a transition to version 008020. He emphasized the importance of maintaining interoperability during version transitions, which can be a major undertaking during the implementation process (particularly if the claims forms being used do not match those being received). Finally, the Tennessee State Government does not support the use of two standards at the same time. Mr. Marone emphasized that the goal of Tennessee Medicaid is to provide quality health care for all members and that performing a cost/benefit analysis of X12's proposed updates will help to accomplish this goal.

Discussion

Ms. Love asked panelists to describe the potential costs to organizations of not moving forward with X12's proposed updates. Mr. Marone reiterated that his organization cannot complete a cost/benefit analysis until NCVHS publishes a Final Rule, so the potential costs are unclear. Dr. Chalmers emphasized that the primary goal of each panelist's organization is to serve and support patients, and thus analyses of these updated transactions must prove their benefit to patients and the health care system as a whole.

Panel 4: Health Plan Perspective on Proposed Updates to X12 Transaction Standards

Moderator: Denis Love, Standards Subcommittee Co-Chair

Gail Kocher, Blue Cross Blue Shield Association

The Blue Cross Blue Shield Association (BCBSA) is a national federation of 34 independent community-based and locally operated companies or plans that collectively provide health care coverage for one in three Americans. For more than 90 years, BCBSA companies have offered quality health care coverage across the United States, serving individuals who purchase coverage on their own or through an employer, Medicare, or Medicaid. BCBSA continues to strongly support the goals of HIPAA administrative simplification to promote efficiency and reduce the cost of administrative transactions. Unfortunately, the summaries of X12's proposals do not provide the level of detail needed for BCBSA to answer each of NCVHS' questions. BCBSA, along with each of its plans, needs to conduct a detailed gap analysis using X12's Glass tool to determine (1) the impact of the proposed updates on reducing administrative burden and (2) the estimated costs of implementation.

BCBSA is cautious about beginning to plan for updates to systems and operations before the Final Rule is published. Such an effort is not inconsequential and requires creation of a project, resource allocation, determination of the appropriate teams, and funding. Given the current set of requirements under the Consolidated Appropriations Act (CAA), interoperability rules, and other federal and state requirements and strategic initiatives, the industry is very active in regard to implementation. Obtaining resources for even preliminary planning will be difficult, especially when the version of transactions could change between the release of an NPRM to a Final Rule. BCBSA believes that insufficient information is available to draw conclusions about costs, benefits, and ROI.

BCBSA is not opposed to moving forward with X12's updated standards. However, BCBSA has strong concerns about the concept of reviewing and commenting on one version under an NPRM when different versions may be named in the Final Rule. Finally, BCBSA supports the ability to normalize the publication and adoption of cycles for updating standards, noting that the revisions should be based on a business need.

BCBSA supports not only NCHVS' work related to adoption of standards and operating rules under HIPAA but also establishment of a roadmap to ensure the limitation of private expenditures imposed on stakeholders in order to comply with administrative simplification regulations. This roadmap should balance and account for all federal and state mandates, not just administrative simplification, as well as other mandates such as CAA and the consumer transparency.

Ginny Whitman, Alliance of Community Health Plans

The Alliance of Community Health Plans (ACHP) represents a unique nonprofit partnership model in health care that brings together plans and providers on behalf of the patients and communities they serve. ACHP advocates for practical solutions that improve health care, with the goal to provide high-value coverage and care for all.

Overall, ACHP is generally supportive of the X12 updates because many will likely improve health plan processes. However, some of the updates pose concerns. Regarding administrative processes, the rapid evolution of policy and technology within the HIT space is a significant operational challenge for health plans with the potential to worsen without intervention. ACHP, therefore, looks forward to consistent and rolling updates for standards and rulemaking, as well as to evaluating in future years the recommended X12 annual updated process.

ACHP appreciates the need to update standards but anticipates that implementation of these updates will be a significant undertaking for ACHP's member companies, particularly because several other interoperability efforts are currently under way. Smaller health plans will likely experience more challenges adopting these updates, because they may need to strategically reallocate resources to address the transition and best serve their beneficiaries. Some ACHP members continue to struggle to find appropriate personnel to implement and operationalize the growing demands of HIT. ACHP echoes earlier comments made by WEDI regarding the need for a comprehensive strategy to allow health plans to prioritize and manage the varying personnel and financial resources required in this space.

ACHP also has concerns regarding the timing of X12 updates related to other regulatory initiatives, including the recent Proposed Rules related to attachments and electronic PA interoperability. Version 008020 may become outdated before its full implementation, leading to the proposal of new standards. The current process of adopting ICD-11 serves as an example of how misalignment in standards development and rulemaking can cause future issues. ACHP believes that X12's plan to address this issue should be more fully developed.

ACHP believes that sufficient lead time for implementation should be provided if the X12 standards are adopted. If the current and new versions of the standards are both available for some time period after Final Rule publication, then the transition will be less disruptive transition. ACHP also supports large-scale pilots during the first year of the transition to help identify, troubleshoot, and resolve any issues.

In addition, ACHP supports the Administration's progress towards a FHIR-based health care system—the success of which depends on FHIR crosswalks that are necessary for payer-related exchanges. ACHP members have expressed mix reactions to the FHIR transition due to the lack of maturity. Crosswalks could address these concerns, but they must be tested to ensure that payers do not incur additional burden.

Regarding value-based arrangements and alternative payment models, ACHP members expect the proposed updates to 835 claims to improve health plan capture and sharing of provider reimbursements. Although health plans can support value-based payment (VBP) arrangements through traditional claim transactions, ACHP is optimistic that the ability to access and receive supplemental data on encounters will lead to innovative strides in VBP arrangements. Finally, ACHP appreciates that X12's proposal includes an increase from 12 to 24 diagnoses, which improve a providers' ability to adequately report SDOH measures.

Christol Green, Elevance Health

Elevance Health aims to advance health beyond health care. Elevance Health employs nearly 100,000 associates serving more than 1.19 million people. Elevance Health is a member of WEDI, X12, HL7, CAQH CORE, America's Health Insurance Plans (AHIP), BCBSA, and other related health care industries. Over the past 20 years, Ms. Green has worked to improve the efficiency and usage of electronic health care transactions, which ultimately benefits Elevance Health members and the system as a whole.

Elevance Health will conduct a cost assessment once the NPRM is published because systems may change before then. For example, the NPRM may recommend the most recently published version of transactions, which may differ from the version currently under consideration. Elevance Health recommends that NCVHS provide additional time to learn from anticipated pilot testing and implementation plans before submitting the cost and value estimates. Elevance Health also intends to conduct an operational assessment once the NPRM is published.

X12's proposal includes the use of XML and alternative syntaxes. Ms. Green stressed that standards should not be limited to XML and recommended consideration of FHIR, which enables representation of

multiple formats. FHIR also includes other syntaxes, such as JSON. If allowed, multiple syntaxes should be semantically interoperable. FHIR crosswalks support implementation of newer technology and may decrease costs incurred by stakeholders to enable rapid, efficient development and implementation. However, these systems must be fully developed and tested to ensure that X12 and HL7 FHIR processes can work together seamlessly.

The use of UDI provides opportunities for additional data analysis. UDIs will enable identification of a specific device and association of that device to a specific patient to track outcomes, device defects, recalls, and the patient's experience. However, Ms. Green noted that primary responsibility for device recalls should remain with the manufacturers so that recall information can be quickly disseminated to patients.

In relation to alternate payment models, VBPs can use the same set as non-value-based claims. Thus, version 008020 would inherently support VBPs. Alternatively, payment model support is provided through the use of existing claim data elements, such as diagnosis codes, procedure codes, and provider identification.

Elevance Health encourages an implementation window of at least 2 years after publication of a Final Rule. This window will provide sufficient time for development, implementation, and adoption. Elevance Health also recommends inclusion of a safe harbor in the event of testing issues, which have occurred in the past. In addition, Elevance Health suggests selection of a date other than January 1, because several programs and other changes launch on that date. If an alternate date is selected, Ms. Green recommends that the 2-year implementation window be maintained and not truncated due to a staggered start date.

Elevance Health recommends that entities have the option to adopt concurrent standards. A mandate to use both version 008020 and version 005010 would require additional and burdensome maintenance by health plan. Newer X12 versions tend to address unique claim scenarios and data needs, and plans may not be able to fully support and return needed information on the response transaction in a compliant manner. For example, X12 version 008020 837 transactions include the 277 Claims Acknowledgement (CA) transactions that support the return of information beyond standard code set values, which will benefit additional business scenarios. Plans would lose the opportunity to do so early during implementation of version 008020, if the 837 transactions are forced to use an older version of the 277 CA transactions. Closely aligned transactions should follow similar implementation schedules to ensure consistency of data elements.

Discussion

Ms. Love noted that the public health system has expressed the urgent need to increase the number of diagnosis codes and asked how that effort would be impacted if X12's proposal is not adopted. Ms. Whitman responded that ACHP would capture VBP arrangements within the current claims standards. Ms. Whitman added that the major benefit of the proposed standards relates the capture of SDOH data through diagnosis code reporting.

Panel 5: Vendor and Clearinghouse Perspective on Proposed Updates to X12 Transaction Standards

Moderator: Debra Strickland, Member of the Standards Subcommittee

Pam Grosze, Cooperative Exchange

The Cooperative Exchange includes 23 clearinghouse members representing greater than 90 percent of the nation's clearinghouse organizations. The Cooperative Exchange's members process more than 6 billion health care claims, reflecting more than $2 trillion in billed services annually. The members enable nationwide connectivity between more than 1 million provider organizations, more than 7,000 payers, and 1,000 HIT vendors. This organization represents the U.S. health care electronic data interstate highway system, enabling connectivity across all lines of electronic health-related commerce in the United States. Cooperative Exchange member clearinghouses support both administrative and clinical industry interoperability by

- managing tens of thousands of entities and connection points,
- exchanging complex administrative and clinical data content in a secure manner,
- supporting both real-time and batch transaction standards,
- enabling interoperability by normalizing disparate data to industry standards,
- delivering flexible solutions to accommodate varying levels of stakeholder readiness, and
- providing strong representation and participation across all national health care standard and advocacy organizations with many of our members holding leadership positions.

The Cooperative Exchange agrees that X12's proposed transaction updates will satisfy new business requirements and resolve significant gaps in business processes and administrative functions. The Cooperative Exchange also supports the non-substantive updates, which decrease misinterpretation and ambiguity and promote precision in deployment across all stakeholders and thus reduce the overall operational costs to support the updated IGs. The Cooperative Exchange is also supportive of the version 008020 standards.

Federal regulatory processes have hindered the ability of health care industry stakeholders to embrace innovation, whether operational, technical, or editorial, in support of administrative simplification and efficiency. The solution lies not with a potentially different standard, syntax, or data exchange method, but with fixing the cumbersome and time-consuming regulatory review and rulemaking process that continues to stifle innovation and advancement of the industry. The Cooperative Exchange strongly advocates for a change to the current regulatory review and rulemaking process and its known challenges and supports a federally established known and predictable version update cycle.

NCVHS recently recommended the potential concurrent use of multiple versions of a standard over an extended period of time. The Cooperative Exchange supports allowing early adoption of new functionality via updated standards, as well as continued use of existing standards, to ease burden and provide sufficient time to implement updated standards. The Cooperative Exchange strongly recommends that only two versions of a standard be allowed to coexist. More than two active standards significantly increases technical and operational complexity. This new process would present some challenges. If a version update is not compatible with the previous version, clearinghouses and payers would be required to support two distinct workflows. Software vendors acting as a business associate of a provider would be required to accommodate updated versions in their software solutions and transition their provider customers to updated standards within the effective cycle window for a given version.

Transitioning from the current federal effective date cycle, which involves a cumbersome and time-consuming regulatory review and rulemaking process, to a federally established and predictable cycle of updates every 3 years would enable the industry to realize innovation and apply version updates in smaller incremental changes. The Cooperative Exchange does not support multiple regulatory effective dates for sets of logically grouped transactions for a given version of a standard. Traversing and

maintaining a phased regulatory approach for logically grouped transactions for a given version would be very costly, complex, and confusing.

The Cooperative Exchange believes that with a federal SDO/Operating Rule Authoring Entities (ORAEs) guidance framework in place under a federally established and predictable version update cycle, industry stakeholders can more easily acclimate to the framework requirements. This process also provides a consistent means for stakeholders to participate and comment on proposed standards and operating rule updates. A known and predictable version update cycle would also allow stakeholders to plan, budget, and resource effectively and to introduce changes in a flexible cadence.

A. Richard Temps, Chiapas EDI Technologies, Inc.

Founded in 2010, Chiapas EDI Technologies is a health care integration software vendor. Licensees of its software create custom in-house EDI solutions. As an X12 licensing partner, Chiapas EDI Technologies was invited to participate in X12's version 008020 POC pilot program. Chiapas EDI Technologies has successfully incorporated X12's technical materials on version 8020 and shared observations from that process during this presentation.

Chiapas EDI Technologies first sought to understand the level of difficulty related to implementing X12's proposed updates. It found that changes to outbound claims can be implemented fairly easily, but changes to inbound remittance files require additional work to reconcile claims. From the provider perspective, these changes are not too complex and tie remittance codes directly to the appropriate adjustment. Under the current processes, information about payer adjudication of claims is split across multiple code segments, with the Medicare Outpatient Adjudication (MOA) segments providing the remittance advice reason codes and the CAS providing the claim adjustment information. In the proposed update, the MOA and CAS codes are compiled into the RAS and, in turn, provide more information. In addition, for scenarios involving the implementation of UDIs, providers and payers will likely require deeper engineering solutions. X12 has also recommended incorporating XML as an alternative method to transmit and receive complaint transactions. The contents of the transactions does not change with this update, but the XML formal removes the need to create a custom 008020 parser, which help to smooth the pathway toward adopting these new standards.

The need for a new set of standards is underscored by the fact that the 005010 IGs were authored nearly 17 years ago. National EDI infrastructure must meet the current business needs of the public and health care industry. The proposed changes reflect the needs of the modern health care system as it exists now.

Stephanie Fetzer, HCL Software

Ms. Fetzer works at Actian, a division of HCL Software, and serves as the Chair of the X12 Board of Directors. HCL Software is participating in the X12 POC pilot program. Ms. Fetzer previously worked as a product manager at IBM Sterling on several products, including the Transformation Extender, Trading Manager, and Mercator.

In addition to the core of HIPAA transactions, most of HCL Software's customers use infrastructure that involves other X12 transactions and versions other than 005010. Some customers continue to use the 004010 addendum, as well as versions 006020 and 005010 for clinical attachments. In other industries, using one version of X12 transactions is relatively uncommon. However, the benefits of X12's recommendations stem from the ability to introduce more stability and enable progress. These recommendations build on existing EDI frameworks, allow for functional needs and refinements to be addressed, and provide extension points for additional innovation and interoperability (e.g., FHIR crosswalks and XSD).

Ms. Fetzer commented that one opportunity cost of delaying adoption relates to the Request for Interpretation (RFI) Portal. Any individual can submit an RFI Portal and impact a given standard. HCL Software developers help to review the RFI submissions and answer questions from new business partners and organizations. Often, these developers are asked the same question over and over again—a process that will likely be repeated as new standards are adopted and that stymies pursuit of new and innovative work.

The major implementation costs associated with adopting the new standards stem from the need to build upon current infrastructure and introduce incremental changes to existing transactions. This incremental, phased approach will help reduce risk and provide stakeholders sufficient time to stabilize after each change. This approach will also distribute costs incurred by stakeholders over a longer period of time. From a vendor's perspective, X12's recommendations may not be promising at first glance because most vendors prefer that an entire suite of standards is replaced at a time with new technology. However, the health care industry requires some balance, which can be achieved with the incremental approach. Overall, HCL Software is in strong support of X12's proposed recommendations.

Sherry Wilson, Jopari Solutions

Jopari Solutions is a national corporation that provides technology solutions and clearinghouse services to medical providers and their software solution vendors and payers in the property and casualty lines of business. Jopari Solutions is recognized within the property and casualty industry as a leader in the field and processes more than 60 percent of the claims, attachments, and remittance advices through direct payer connectivity and channel partners. Jopari Solutions is actively engaged with the following SDOs: Cooperative Exchange, Accredited Standards Committee, WEDI, Healthcare Information and Management Systems Society, and International Association of Industrial Accidents Boards and Commissions.

Property and casualty lines of business include worker's compensation and auto insurance. The property and casualty industry is state-regulated and not covered by HIPAA. Many stakeholders in this field are the same entities that are processing version 005010 transactions today. Numerous states have adopted electronic claims, attachments, and payment standards through statute or administrative rule, version 005010 transaction sets, and companion guides that address use cases not supported by version 005010 transactions.

The X12 version 008020 transactions represent more than 15 years of stakeholder efforts to address new business use cases, workflow automation gaps, and administrative and financial efficiencies across all lines of business. Version 8020 addresses property and casualty data content requirements and business use cases that are not supported within version 005010 through the following actions:

- Eliminating the need for individual state companion guides
- Reducing administrative burden to comply with multiple state electronic billing mandates
- Automating regulatory data content requirements (e.g., Remittance Advice: State Jurisdiction)
- Standardizing implementations across all stakeholders
- Increasing workflow automation and administrative efficiencies

Jopari Solutions supports X12's recommendation to adopt version 008020 transaction standards and include XML representation. Jopari Solutions also recommends allowing other industry applications, such as JSON, based on business needs. The use of XML and XSD enables stakeholders to manipulate data with application programming interfaces (APIs) and other tools that accommodate different business use cases and facilitates workflow automation, interoperability, and modernization.

Jopari Solutions also supports the recommendation to implement FHIR crosswalks for version 008020 because these crosswalks will accommodate different stakeholder business needs and workflows, as well as enable interoperability between the two versions of standards. Jopari Solutions suggests a 3-year implementation timeframe and a June or July effective date to accommodate other regulatory or business priorities that typically occur at the start of a new year. Jopari Solutions also stresses the need for a gap analysis to identify data content and other business use cases that could be impacted when other 005010 transaction versions are used simultaneously with 008020 versions. Finally, Jopari Solutions supports the recommendation to streamline industry regulatory processes to accommodate new or updated HIPAA transactions as referenced in the March 2022 NCVHS letter to HHS, "Modernize Aspects of HIPAA and Other HIT Standards to Improve Patient Care and Achieve Burden Reduction."

Arthur Roosa, Healthcare Business Management Association

Mr. Roosa presented testimony on behalf of the Healthcare Business Management Association (HBMA), which is a not-for-profit professional trade association and a major voice in the revenue cycle management (RCM) industry. The RCM industry is highly reliant on the 837 and 835 transactions, and changes to those transactions can greatly impact the ability to perform regular services. Overall, HBMA is generally supportive of the changes proposed by X12.

One topic within the X12 proposal that is important to the RCM industry is the extended provider assignment claim identifier. In the RCM environment, where multiple providers and legal entities can be involved in a single 835 transaction, the ability to align payment information with the claims submitted becomes critical. In addition, HBMA is very supportive of the proposal to exchange the CAS with the RAS, which will greatly improve the ability to identify particular actions for a given claim. HBMA supports moving forward with the implementation of version 008020, with the primary caveat that adequate time for testing and piloting the standards is provided. Testing is needed to ensure that investing funds into development, adoption, and implementation over the next 5-10 years will be practical and feasible. HBMA is also supportive of the recommendation to create a roadmap related to future standard adoption processes; this roadmap could allow organizations to better plan and budget for adoption cycles and to estimate ROI.

HBMA is concerned about the ability to have multiple versions activated at one time and about how those versions will impact interoperability. Mr. Roosa highlighted the need to identify a default format that can be efficiently received by any trading partner. Mr. Roosa also recommended that CMS further investigate transactions that involve virtual credit cards and the typical fees associated with those transactions. Finally, Mr. Roosa emphasized the importance of effective enforcement of adopted standards and policies, noting that new updated standards and practices are not effective if not enforced.

Discussion

Ms. Strickland asked whether panelists, other than those participating in the POC pilot program, have completed a gap analysis. Ms. Fetzer noted that HCL Software completed a gap analysis for the version 008020 transaction standards and found that the differences between versions 005010 and 008020 are similar to those between 005010 and the 004010 addendum.

Ms. Banks asked panelists to share their opinions about most significant value added by X12's proposed updates. Dr. Wilson responded that the most significant update relates to workflow automation and the interoperability between different lines of business. Ms. Grosze commented that the shift from CAS to RAS will greatly benefit providers and that the expertise and refinements gained through the RFI Portal and incorporated into the proposed changes is also of significant value. Mr. Roosa added that the shift

from CAS to RAS will help to reduce administrative burdens through automation. However, Mr. Roosa and Ms. Grosze agreed that this shift alone will not provide a sufficient ROI.

Ms. Banks asked whether panelists believed version 008020 standards will align with the proposed Attachments Rule, or if version 005010 transactions are sufficient for the proposed Attachments Rule. Dr. Wilson noted that the transitions from versions 005010 to 006020 and from 006020 to 008020 will not be major undertakings, adding that level of effort needed to transition to 008020 and achieve a high level of compatibility will be minimal.

Ms. Banks asked the panelists to identify the information their organization's clients would require to ascertain the value associated with transitioning to an upgraded standard. Dr. Wilson noted that Jopari Solutions' stakeholders would appreciate the ability to leverage existing intellectual property investments using version 005010 standards and to automate those resources in version 008020.

Subcommittee Discussion and Q&A

Ms. Sheppard thanked Subcommittee members and participants for the feedback received on X12's proposal and noted that her organization may contact individuals who provided specific feedback to further discuss possible updates to the proposal. She added that, based on lessons learned during the version 005010 transition, X12 POC pilot participants underscored the need to adopt a streamlined, established process for future version implementation. Real-world pilot testing is important, but she cautioned against significantly delaying the adoption process because the federal rulemaking process itself is long.

In response to a question from Ms. Love, Ms. Sheppard confirmed that updates to 276 and 277 transaction standards will likely be included in X12's next proposal.

Ms. Banks asked when the results of X12's POC pilot study will become available and whether individuals can suggest use cases for testing in the study. Ms. Sheppard noted that X12 does not plan on developing one report of results, but several reports as participating organizations work through all the updated transaction standards. These reports will be available on X12's website. Suggestions for use cases can be shared with X12 via its feedback form.

Ms. Love asked for more information regarding X12's work with HL7 to validate FHIR crosswalks. Ms. Sheppard noted that X12's subject matter experts have been employed to validate these processes from various stakeholder perspectives. Ms. Goss noted that HL7 and X12 have established a very collaborative process to develop and validate the crosswalks.

Ms. Banks noted that the technical aspects of the proposed updates are well documented, but the overall compilation of proposed changes and impacts can be difficult to visualize. Ms. Sheppard noted that X12 has developed a visualization that illustrates the lifecycle from health care coverage enrollment through the claims submission process. However, this visualization does not (but could) illustrate cross-SDO processes. Ms. Sheppard suggested revisiting this topic with WEDI, other SDOs, and CAQH CORE.

Ms. Strickland asked whether future standard versions will move forward one at a time or in batches. Ms. Sheppard noted that X12 will likely move forward any standard that has been validated within a given cycle, and if a standard is not finished before the upcoming cycle, then it will be released in the following cycle.

Day 2: January 19, 2023

Welcome, Call to Order, Roll Call, and Review of Proceedings

To open the meeting on Thursday, January 19, 2023, Executive Secretary and Designated Federal Officer Ms. Hines welcomed Standard Subcommittee members, panelists, and public viewers and called roll. The Subcommittee members introduced themselves and stated possible conflicts of interest. Ms. Love reviewed the hearing's agenda.

NCVHS Presentation Regarding the Proposal from CAQH CORE on Updated and New Operating Rules

Per Section 1104 of ACA, which amended Section 1173 of HIPAA, the HHS Secretary shall adopt a single set of operating rules for each transaction, with the overall goal to create uniformity during the implementation of electronic standards. ACA requires that these operating rules be consensus-based and reflect the necessary business rules affecting health plans and health care providers in how they operate to support the standards adopted under HIPAA.

NCVHS has several roles in making recommendations to HHS on operating rules. These roles include the following:

- Advising the HHS Secretary on whether a nonprofit entity meets requirements to serve as an authoring entity for operating rules
- Reviewing the operating rules developed and recommended by this nonprofit entity
- Determining whether operating rules represent a consensus view of health care stakeholders and do not conflict with other existing standards
- Evaluating whether proposed operating rules are consistent with electronic standards adopted for HIT
- Submitting a recommendation to the HHS Secretary regarding the adoption of the proposed operating rules

CAQH CORE has proposed updates to the following four current rules: (1) Eligibility & Benefits (270/271) Data Content Rule, (2) Claim Status (276/277) Infrastructure Rule, (3) Payment & Remittance Advice (835) Infrastructure Rule, and (4) Eligibility & Benefits (270/271) Infrastructure Rule. CAQH CORE has also proposed six additional operating rules: (1) Connectivity Rule vC4.0.0 (to replace existing connectivity requirements and add new requirements to all operating rules), (2) Eligibility & Benefits (270/271) Single Patient Attribution Data Content Rule, (3) Attachments PA Infrastructure Rule, (4) Attachments PA Data Content Rule, (5) Attachments Health Care Claims Infrastructure Rule, and (6) Attachments Health Care Claims Data Content Rule.

NCVHS has met with multiple stakeholders to review the proposed operating rules. CAQH CORE presented an overview of the proposed operating rules to the Standards Subcommittee in July 2022. NCVHS is also collaborating with WEDI, which was named as an advisor to HHS in the HIPAA statute. NCVHS published an RFC regarding the proposed rules and received more than 630 responses. NCVHS has also consulted with the CMS OBRHI and NSG, as well as ONC.

The purpose of Day 2 of this meeting was to gather input from health care industry stakeholders on multiple aspects of the proposed rules, including (1) expected value and business process improvements resulting from these rules, (2) benefits and applicability to HIPAA standards to which these proposed rules apply, (3) availability of cost/benefit information for the proposed rules, (4) changes to the

companion guide template and benefits of these changes, (4) implications of the proposed rules on PAs and claim attachments, and (5) impacts of not adopting the proposed rules. Following this meeting, the Standards Subcommittee will consolidate and discuss stakeholder inputs, and then present recommendations to the full NCVHS Committee. Then, the Standards Subcommittee will finalize and send a recommendations letter to the HHS Secretary.

CMS Presentation Regarding Adoption of Operating Rules under the Affordable Care Act

Mr. Kalwa reiterated from Ms. Love's presentation that ACA requires these operating rules, including requirements for consensus-based rules developed by a nonprofit entity. He noted that the proposed rules do not alter implementation specifications for electronic transactions. For example, these rules do not provide an ability to add data elements not currently present in the implementation specifications. Similarly, the proposed operating rules do not adopt require implementation of specifications that normally fall under the HIPAA standards rulemaking process.

Mr. Kalwa also highlighted that some SDOs and standards-setting organizations develop their own operating rules that are not incorporated into the CAQH CORE rules. For example, NCPDP developed its own operating rules that are not used by X12 and other SDOs, so NCPDP operating rules are not addressed by CAQH CORE's proposed rules.

Mr. Kalwa noted that CMS NSG is often required to undergo a rulemaking process for updates, even relatively minor updates. Thus, updates to existing HIPAA rules are still required to go through the full rulemaking process. In addition, new rules do not have the same time requirements for adoption as modifications to existing rules, providing more flexibility on when new rules will become mandated.

Discussion

Ms. Love asked about the process by which industry partners can voluntarily adopt proposed operating rules that are undergoing review in the NSG rulemaking process. Mr. Kalwa responded that, prior to completion of the NSG rulemaking process, NSG would not comment on operating rules required under that standard. Similarly, NSG would not require compliance with associated operating rules until the relevant standard completed the rulemaking process and was implemented. During the rulemaking process, health care industry partners can update their systems voluntarily in preparation for the new standard.

Presentation from CAQH CORE Regarding Proposals for Updated and New Operating Rules

CAQH CORE Overview

CORE was founded in 2008 through a collaboration among health care industry stakeholders to develop business rules for the effective and efficient use of electronic transactions. CAQH CORE has more than 100 participating organizations, include health plans, provider organizations, vendors, government entities, clearinghouses, and SDOs. CAQH CORE's mission is to drive the creation and adoption of health care operating rules that support standards, accelerate interoperability, and align administrative and clinical activities among providers, payers, and consumers. CAQH CORE strives to be an industry-wide facilitator of trusted, simple, and sustainable health care data exchange that evolves and aligns with market needs. In 2012, HHS designated CAQH CORE as the ORAE for all HIPAA-mandated administrative transactions.

CAQH CORE is led by a Board, whose membership includes health care providers, health plans, vendors, regulatory advisors, and SDO advisors. Health plans participating in CAQH CORE include commercial, governmental, and integrated health plans that provide coverage for approximately 75 percent of Americans with health insurance. The diversity of Board membership ensures that proposed rules reflect consensus across health care industry stakeholders, minimize the use of proprietary solutions, and reduce administrative burdens for all industry stakeholders.

Ms. Weber presented a history of CAQH CORE since 2010, highlighting how ACA established the regulatory role of electronic transaction operating rules. In 2012, HHS adopted CAQH CORE EFT/electronic remittance advice operating rules following recommendation by NCVHS. Between 2016 and 2020, voluntary implementation of CAQH CORE operating rules by many industry stakeholders created significant ROIs, leading many industry stakeholders to embrace emerging technologies, such as APIs. During this same period, NCVHS recognized significant variability in implementation of operating rules by stakeholders across the health care industry, leading NCVHS to recommend that new operating rules remain voluntary. Based on this recognition, CAQH CORE revised its operating rules to further align with current business needs and standards.

CAQH CORE uses a predefined rule development process that pertains to the proposed operating rules discussed during this meeting. CORE's rule development process begins with extensive environmental scans to identify opportunities, which are then discussed in workgroup calls, straw polls, and ballots in order to develop and refine requirements. All CAQH CORE members vote on the requirements, followed by a vote by the Board for final approval. For the current proposed rules, CAQH CORE engaged with more than 140 organizations. Each proposed rule received no less than 88 percent approval by CORE members and unanimous approval by the CORE Board.

Connectivity Rule

The CAQH CORE Connectivity Rule vC4.0.0 builds upon the Phase I and II CORE Connectivity Rules, which are currently federally mandated and cited in HIPAA requirements. Thus, many organizations continue to operate under these decade-old connectivity rules solely for compliance reasons. The updated Connectivity Rules incorporate current cybersecurity technologies and requirements, including OAuth 2.0 and digital certification requirements. Version 4 of the Connectivity Rule also supports usage of representative state transfer (REST) APIs, and CORE members unanimously supported this inclusion. Implementing this rule is estimated to not exceed $350,000 per provider. Implementation costs will be primarily shouldered by health plans and vendors, because both are required to support both REST and Simple Object Access Protocol (SOAP) electronic transactions, while providers are required to only support one of those two formats. Providers can continue to use other Safe Harbor methods (e.g., Secure File Transfer Protocol) if the format is mutually agreed upon between a provider and the trading partner (e.g., health plan).

Infrastructure Rules

The updated Infrastructure Rules upgrade weekly system availability requirements from 86 percent to 90 percent, resulting in an additional 364 hours of system up-time per year. During rule development, many CAQH CORE members, including providers, sought higher availability requirements (e.g., 95 percent), and many stakeholders reported they already meet the 90 percent threshold. However, CAQH CORE decided to set the requirement at 90 percent based on cost/benefit assessments and in recognition of complexity across the health care industry.

Eligibility & Benefits Data Content Rules

Mr. Kaja then presented the proposed Eligibility & Benefits Data Content Operating Rules, noting that the current EDI 005010 standards are obsolete and do not align with current technologies and transaction processes used by the health care industry. The proposed Eligibility & Benefits Data Content rules add granularity to eligibility and benefits transactions through multiple means. The rules add 71 discretionary and 55 mandatory service type codes (STCs) and require that place of service codes specify when a service is available for telehealth. The proposed rules also require eligibility and benefit information at the procedure code level for physical therapy, occupational therapy, surgery, and imaging services. CORE also included the requirement for single patient attribution to support the usage and growth of value-based care models.

A regional health plan estimated that implementing the proposed Eligibility &Benefits Data Content Operating Rules would cost $2.4 million over the course of 2 years, but this cost would be offset by a 60 percent decrease in annual maintenance costs and an 80 percent reduction in eligibility-related call center volume for the impacted STCs. While updating electronic transaction systems would require additional personnel during the implementation period, CAQH CORE estimates that this temporary increase in full-time equivalent (FTE) costs will be offset by the long-term reduction in FTE costs currently spent on manually verifying eligibility information and related call center support. These rules are expected to produce significant long-term cost savings.

Full adoption of electronic Eligibility & Benefits transactions can produce significant cost savings by eliminating the need to manually verify benefit limits, tiered benefits, and procedure-specific eligibility. CAQH CORE estimates that the potential cost savings associated with adopting these rules was $8.64 per transaction prior to the COVID-19 pandemic. During the pandemic, increased usage of telehealth drove these potential cost savings to $15.09 per transaction. Because more than 18 billion transactions occur annually, automating these transactions can save more than $10 billion annually. Similarly, the automated single patient attribution requirements enable attribution in seconds, whereas current manual methods can take hours. The proposed Eligibility & Benefits Rules also automate the process of receiving PA approvals, including for telehealth eligibility, significantly reducing the administrative burden on providers.

Attachments Operating Rules

Ms. Reed then presented an overview of the proposed Attachments Operating Rules, which establish a standard-agnostic framework that can support both X12 and HL7 standards as well as SOAP and REST headers, to ensure support for providers using different exchange methods. In addition, these proposed rules are designed to apply to multiple data formats and reduce costs associated with manual processes for resolving attachment requests. The Attachments Operating Rules also align with previous recommendations from NCVHS regarding attachments, including file size requirements and applications for both claim and PA transactions. These rules also recommend using Logical Observation Identifiers Names and Codes (LOINC) or other standard and publicized reference data to support claim transactions.

A regional health plan associated with CAQH CORE estimated that implementing the proposed Attachments Rules would cost approximately $2.2 million and require 18-24 months. However, this implementation cost would be offset by a nearly 50 percent reduction in annual maintenance costs and 40 percent reduction in call center and fax volume for resolving attachment requests. Similar savings were observed by a national health plan currently conducting a pilot program of the X12 275 attachment rules; adopting these rules is projected to save that plan more than $300,000 during the processing of 76,000 attachments over 8 months.

Ms. Reed presented the benefits of the proposed attachments rules at different steps of an attachment request workflow. Under current operating rules, processing attachments is hindered by multiple barriers, including unclear submission requirements, varying acknowledgement timeframes, system unavailability, attachment rejections, and requests for additional information. The proposed Attachments Rules address many of these barriers, including acknowledgement timeframe requirements, standard attachment formats, and minimum file sizes.

Conclusion

Ms. Weber concluded the presentation by emphasizing that the proposed operating rules were developed through industry consensus to drive automation and interoperability across business processes. She encouraged NCVHS to recommend the proposed operating rules, which align with previous NCVHS recommendations and can significantly improve many types of electronic transactions (e.g., PAs, eligibility verification).

Discussion

Mr. Landen asked for additional information on proposed changes to the Infrastructure Rules' companion guides. Ms. Weber replied that the current CORE Master Companion Guide references version 005010 of X12 standards, and the updated Master Companion Guide removes this reference to enable the usage of other X12 standard versions (e.g., 006020). Mr. Landen asked for additional detail on why CAQH CORE developed rules to be standard agnostic given that the proposed rules only apply to transactions and IGs adopted under HIPAA, which are almost exclusively based on X12 standards. He also encouraged SDOs from Panel 1 to comment on this standards-agnostic approach, particularly for attachments, because the proposed Attachments Rules allow both X12 and HL7 standards. Ms. Weber responded that many non-X12 standards are either currently adopted or proposed for coverage under HIPAA. For example, CMS has proposed HL7 Consolidated Clinical Document Architecture (C-CDA) as an additional attachments standard. Similarly, the Cash Concentration and Disbursement standard is a non-X12 standard currently mandated under HIPAA for EFTs. Ms. Weber noted that both X12 and HL7 are SDO advisors on the CORE Board, enabling them to receive regular updates on CAQH CORE's rule development process. Many of CAQH CORE's Subgroups (e.g., Updated Eligibility & Benefits) are co-chaired by X12 or HL7 representatives. The collaboration between CAQH CORE and these SDOs ensures that proposed rules do not conflict with existing HL7 and X12 standards.

Mr. Ferguson noted that the CAQH CORE's proposed Connectivity Rule involves secure hash algorithm 1 (SHA-1) as the security standard for envelope metadata. However, the National Institute of Standards and Technology retired SHA-1 in 2022, and ONC requires certified provider systems to use secure hash algorithm 2 (SHA-2). Mr. Ferguson asked why the proposed rule included SHA-1 rather than SHA-2. Mr. Bowman responded that CAQH CORE developed the proposed Connectivity Rule 2 years ago, prior to NIST's decision to retire SHA-1. In addition, CAQH CORE typically references base standards and allows future iterations of those standards in its proposed rules. Thus, the updated Connectivity Rule requires compliance with SHA-1 or more recent SHA iterations (e.g., SHA-2).

Ms. Love asked about how the Single Patient Attribution Rule applies to payers that do not use VBP models. Ms. Weber responded that the rule only applies when attribution is required (i.e., for a VBP), so the rule would not apply to payers who do not use VBP models.

Advisory Committee Report on Member Survey and Position Advisory Event Outcome

WEDI is composed of multiple stakeholders, including health plans, providers, SDOs, and state and federal government agencies. SDOs on WEDI's Board include HL7, X12, NCPDP, and the American Dental Association (ADA) Standards Committee.

WEDI has an MPA process designed to solicit WEDI member input on specific topics. For the proposed CAQH CORE rules, WEDI polled its members on the NCVHS RFC questions through three methods: (1) polling members of its Workgroups and Subgroups, (2) a written survey of members conducted in September and October 2022, and (3) a virtual MPA event in November 2022. Mr. Tennant highlighted that all three methods were limited to WEDI members, but the results can be viewed as a snapshot of different industry stakeholders. Among the 58 survey responses received, 15.5 percent came from providers, 43.1 percent from payers, 19.0 percent from clearinghouses, and 22.4 percent from vendors. Dr. Tennant summarized findings from the survey and MPA event poll respondents.

Identify your level of familiarity with the CAQH CORE initiative to create updated and new operating rules in support of electronic transactions.

- 39.2 percent are CAQH CORE members and participated in the development of updated and new operating rules.
- 5.6 percent are CAQH CORE members but did not participate in the development of these operating rules.
- 22.2 percent have reviewed the proposed operating rules.
- 29.6 percent are aware that CAQH CORE has developed updated and new operating rules but does not know the details.
- 7.4 percent have no familiarity with these proposals.

Please rate your level of agreement or disagreement with the following statements regarding the impact that the updated CAQH Core Connectivity Rule cC4.0.0 will have on your organization and/or the industry.

- 35 percent responded that they agree or strongly agree that "these operating rules will reduce cost, enhance utility, and improve quality of care delivered"; 22 percent responded that they were unsure at this time; and 38 percent responded that they neither disagreed nor agreed with the statement.
- 46 percent responded that they agree or strongly agree that "these operating rules take an important step to standardize operational challenges within VBP models"; 15 percent responded that they were unsure at this time; and 23 percent responded that they neither disagreed nor agreed with the statement.
- 58 percent responded that they agree or strongly agree that "these operating rules lay the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption"; 18 percent responded that they were unsure at this time; and 20 percent responded that they neither disagreed nor agreed with the statement.
- 58 percent responded that they agree or strongly agree that "this update to existing federally mandated rules will respond to immediate industry needs to align requirements with current and emerging business, operational security, and connectivity best practices, while promoting technological advances within the industry"; 15 percent responded that they were unsure at this time; and 18 percent responded that they neither disagreed nor agreed with the statement.

Rate the level of potential benefits associated with the new Connectivity Rule.

- 62 percent responded "Significantly or Somewhat Improved Benefits."
- 15 percent responded "No Change in Benefits."
- 4 percent responded "Somewhat Decreased Benefits."
- 4 percent responded "Significantly Decreased in Benefits."
- 15 percent responded "Don't Know."

Please rate your level of agreement or disagreement with the following statements regarding the impact of the updated CAQH CORE Infrastructure Operating Rules will have on your organization and/or the industry.

- 36 percent responded that they agree or strongly agree that "these operating rules will reduce cost, enhance utility, and improve quality of care delivered"; 24 percent responded that they were unsure at this time; and 24 percent responded that they neither disagreed nor agreed with the statement.
- 39 percent responded that they agree or strongly agree that "these operating rules take an important step to standardize operational challenges within VBP models"; 21 percent responded that they were unsure at this time; and 21 percent responded that they neither disagreed nor agreed with the statement.
- 54 percent responded that they agree or strongly agree that "this update to existing federally mandated rules will respond to immediate industry needs to align requirements with current and emerging business, operational security, and connectivity best practices, while promoting technological advances within the industry"; 12 percent responded that they were unsure at this time; and 21 percent responded that they neither disagreed nor agreed with the statement.
- 56 percent responded that they agree or strongly agree that "these operating rules lay the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption"; 15 percent responded that they were unsure at this time; and 15 percent responded that they neither disagreed nor agreed with the statement.

Rate the level of potential benefits associated with the updated Infrastructure Operating Rules.

- 65 percent responded "Significantly or Somewhat Improved Benefits."
- 13 percent responded "No Change in Benefits."
- 0 percent responded "Somewhat Decreased Benefits."
- 0 percent responded "Significantly Decreased Benefits."
- 22 percent responded "Don't Know."

Please rate your level of agreement or disagreement with the following statements regarding the impact the updated CAQH CORE Eligibility & Benefits (270/271) Data Content Operating Rule vEB.2.0 will have on your organization and/or the industry.

- 66 percent responded that they agree or strongly agree that "this operating rule takes an important step to standardize operational challenges within VBPs"; 18 percent responded that they are unsure at this time; and 21 percent responded that they neither disagreed nor agreed with this statement.
- 39 percent responded that they agree or strongly agree that "this operating rule will reduce cost, enhance utility, and improve quality of care"; 24 percent responded that they were unsure at this time; and 15 percent responded that they neither disagreed nor agreed with the statement.

- 54 percent responded that they agree or strongly agree that "this update to existing federally mandated rules will respond to immediate industry needs to align requirements with current and emerging business, operational security, and connectivity best practices, while promoting technological advances within the industry"; 12 percent responded that they were unsure at this time; and 21 percent responded that they neither disagreed nor agreed with the statement.
- 54 percent responded that they agree or strongly agree that "this operating rule lays the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption"; 12 percent responded that they were unsure at this time; and 21 percent responded that they neither disagreed nor agreed with the statement.

Rate the level of potential improvement in efficiency that the Eligibility & Benefits Operating Rules would contribute to your organization.

- 47 percent responded "Significantly or Somewhat Improved Efficiency."
- 30 percent responded "No Change in Efficiency."
- 7 percent responded "Somewhat Decreased Efficiency."
- 0 percent responded "Significantly Decreased Efficiency."
- 17 percent responded "Don't Know."

Rate the level of potential benefits to VBPs that would be associated with the new Eligibility & Benefits Operating Rules.

- 39 percent responded "Significantly or Somewhat Improved Benefits."
- 30 percent responded "No Change in Benefits."
- 0 percent responded "Somewhat Decreased Benefits."
- 8 percent responded "Significantly Decreased Benefits."
- 42 percent responded "Don't Know."

Please rate your level of agreement or disagreement with the following statements regarding the impact the updated CAQH CORE Eligibility & Benefits (270/271) Single Patient Attribution Data Content Rule vEB.1.0 will have on your organization and/or the industry.

- 27 percent responded that they agree or strongly agree that "this operating rule will reduce cost, enhance utility, and improve quality of care"; 27 percent responded that they were unsure at this time; and 30 percent responded that they neither disagreed nor agreed with the statement.
- 33 percent responded that they agree or strongly agree that "this update to existing federally mandated rules will respond to immediate industry needs to align requirements with current and emerging business, operational security, and connectivity best practices, while promoting technological advances within the industry"; 24 percent responded that they were unsure at this time; and 30 percent responded that they neither disagreed nor agreed with the statement.
- 33 percent responded that they agree or strongly agree that "this operating rule takes an important step to standardize operational challenges within VBPs"; 27 percent responded that they are unsure at this time; and 27 percent responded that they neither disagreed nor agreed with this statement.
- 36 percent responded that they agree or strongly agree that "this operating rule lays the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption"; 27 percent responded that they were unsure at this time; and 21 percent responded that they neither disagreed nor agreed with the statement.

Some MPA stakeholders have completed an analysis to determine the impact and value of implementing this operating rule. In addition, some health plan representatives indicated that only a small percentage of members are currently using VBP models, thus limiting the potential impact of this operating rule.

Please rate your level of agreement or disagreement with the following statements regarding the impact the new CAQH CORE Attachments Operating Rules for health care claims will have on your organization and/or the industry.

- 30 percent responded that they agree or strongly agree that "these operating rule takes an important step to standardize operational challenges within VBPs"; 21 percent responded that they are unsure at this time; and 27 percent responded that they neither disagreed nor agreed with this statement.
- 39 percent responded that they agree or strongly agree that "this operating rule will reduce cost, enhance utility, and improve quality of care"; 24 percent responded that they were unsure at this time; and 15 percent responded that they neither disagreed nor agreed with the statement.
- 42 percent responded that they agree or strongly agree that "this update to existing federally mandated rules will respond to immediate industry needs to align requirements with current and emerging business, operational security, and connectivity best practices, while promoting technological advances within the industry"; 18 percent responded that they were unsure at this time; and 24 percent responded that they neither disagreed nor agreed with the statement.
- 45 percent responded that they agree or strongly agree that "this operating rule lays the foundation for creating common expectations to enhance the exchange of attachments to drive electronic adoption"; 15 percent responded that they were unsure at this time; and 27 percent responded that they neither disagreed nor agreed with the statement.

Rate your level of agreement for the following statement: new attachment operating rules should be nationally mandated and implemented at the same time as the Electronic Health Care Attachment (275) transaction standard to decrease industry burden and cost and increase the value of the transaction.

- 62.5 percent agreed or strongly agreed.
- 12.5 percent neither agreed nor disagreed.
- 6.3 percent disagreed or strongly disagreed.

Many MPA participants also expressed value in moving forward with an Attachments Rules and supporting operating rules (e.g., updated Connectivity Rule) at the same time, which could shorten the implementation process.

Rate the level of potential benefits to VBPs that would be associated with the new Attachments Operating Rules.

- 55 percent responded "Significantly or Somewhat Improved Benefits."
- 3 percent responded "No Change in Benefits."
- 3 percent responded "Somewhat or Significantly Decreased Benefits."
- 39 percent responded "Don't Know."

Overall, should WEDI recommend adoption of the updated and new operating rules?

- 32 percent responded "Yes—All of the operating rules."

- 20 percent responded "Yes—All of the operating rules except for the Attachments Operating Rule."
- 20 percent responded "No—WEDI should not recommend adoption of the operating rules."
- 28 percent responded "Don't Know."

Discussion

Mr. Landen noted that some of the percentages did not add up to 100 percent. Mr. Tennant responded that WEDI will recalculate the percentages to ensure their accuracy.

Ms. Love asked whether WEDI has a position regarding the proposed rules. Mr. Tennant replied that WEDI does not have an organization-wide position and highlighted the level of disagreement among WEDI members, with many responding as unsure to multiple questions. Despite these disagreements, the majority of WEDI participants support moving forward with the proposed operating rules.

Panel 1: Presentations from Standards Development Organizations and Code Content Committees on CAQH CORE Operating Rules

Moderator: Denise Love, Subcommittee Co-chair

Cathy Sheppard, X12

X12 has collaborated with CAQH CORE since 2014 to ensure that proposed Data Content Operating Rules do not conflict with X12 IGs and standards. Many of CAQH CORE's rules have been integrated into new versions of X12 IGs. As CAQH CORE develops new operating rules, X12 provides feedback on how proposed rules would interact with existing X12 standards. X12 has also participated in the rule development process as subject matter experts.

Both X12 and CAQH CORE have received extensive feedback on the proposed operating rules, including input from NCVHS hearings and working sessions. Much of this feedback recommended more direct and explicit references between X12 IGs and CAQH CORE's operating rules. In response, X12 IGs have been updated to include highlight references to mandated operating rules. X12 has also begun adding cross-references to FHIR resources as supporting information for X12 IGs. If the proposed operating rules are adopted and mandated, X12 will add similar cross-reference information into X12 IGs and supporting material. X12 and CAQH CORE are facilitating webinars that clarify how CAQH CORE's operating rules interact with X12 EDI standards and IGs. These webinars have been well received and attended by many health care industry stakeholders.

Ms. Sheppard concluded her presentation by noting that X12 has no objections regarding the proposed operating rules. X12 has provided recommendations on these rules based on feedback from WEDI and other health care organizations, but these recommendations are limited to the instructions rather than the requirements themselves.

Viet Nguyen, HL7

HL7 is an ANSI-accredited nonprofit SDO that was founded in 1987. HL7 develops a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information. HL7 aims to automate clinical workflows by defining syntax and semantics of the information exchange, including requirements for authentication, authorization, and transport. Additionally, HL7 standards and underlying infrastructure are developed to preclude the need for separate operating rules. HL7 has developed three families of standards: FHIR, Version 2, and V3/CDA. HL7 has more than 500 corporate members and 1,600 individual affiliates in more than 50 countries.

Members include health care providers, payers, vendors, federal agencies, international organizations, and industry associations. HL7's members contribute wide-ranging and invaluable subject matter expertise, business workflows, and technical environments to our standards.

Dr. Nguyen presented a timeline for the development of the FHIR standard and adoption by federal agencies. Key events include (1) ONC requirement for open APIs in 2015; (2) ONC inclusion of FHIR and Da Vinci IGs in their final rules for interoperable data flows between payers, providers, and patients in 2015; (3) implementation in 2022 of the CMS Patient Access and Provider Directory APIs, which enabled Medicare and Medicaid patients to access their data and find providers on mobile devices; and (4) HL7's response in 2022 to the NCVHS RFC regarding the proposed operating rules, which supported immediate adoption of all rules except the Attachments Rules.

Dr. Nguyen then discussed HL7's standards development lifecycle, which engages providers, payers, vendors, and policymakers. Industry subject matters in both administrative and clinical processes define transaction and data requirements and collaborate with FHIR and implementation experts to identify modifications to FHIR standards to meet these requirements. HL7 then constructs reference implementations to test the feasibility of updated requirements. HL7 and Da Vinci IGs and their associated use case work products are also published for feedback from both members and non-members.

Implementers can continually provide feedback through the FHIR Chat website, implementer community forums, HL7 connect-a-thons, and other forums. Comments or corrections submitted by implementers are addressed by IG authors and HL7 workgroups. Based on evaluation and public feedback and suggested corrections, selected changes to the standard are incorporated into planned updates of IGs.

Dr. Nguyen highlighted three recent IGs that focus on electronic PA transactions: Coverage Requirements Discovery, Document Templates and Rules, and PA Support. These three IGs provide specifications for translation into and out of X12 278 standards, allowing for greater interoperability. HL7 collaborated with X12 to map and align the syntax and semantics of both FHIR and X12 278 standards to ensure interoperability. HL7 continues to collaborate with X12 and other SDOs to provide greater levels of automation and interoperability to reduce administrative burden on clinicians, improve business workflows, and enhance patient care.

Discussion

Dr. Nguyen confirmed that the X12 EDI 278 transaction envelopes can carry attachments in different formats, including C-CDA and FHIR.

Ms. Banks asked about X12's collaboration with HL7 to coordinate the ability to support different transaction standards if the proposed rules are implemented. Dr. Nguyen responded that the ability to use C-CDA standards remains in production and should not be affected by the proposed rules. However, LOINC codes alone may not provide sufficient detail to request attachments without additional communication. Alternatively, payers can request additional documents using either FHIR or U.S. Core for Data Interoperability data elements. Compared to LOINC, FHIR enables payers to include additional details regarding their requests for additional information. Using FHIR also enables the exchange of structured data through APIs, providing additional information to the attachments process. Using this FHIR approach creates a more seamless and automated approach that does not require clinicians to retrieve and upload data to RCM systems. Compared to C-CDA, using FHIR attachments and API-driven processes provides greater flexibility as technologies continue to evolve.

Ms. Banks asked whether HL7 supports adoption of proposed rules regarding X12 transaction standards. Mr. Nguyen responded that HL7 does not have a position on X12-specific rules. Instead, HL7 encourages NCVHS to consider more modern API-driven paradigms that do not require as many operating rules. Mr. Nguyen agreed that adopting the X12 transaction standards does not hinder the ability to use C-CDA attachments, but that limiting the proposed attachments rules to claims only (as opposed to including other clinical attachments) may limit future innovations.

Panel 2: Presentations from Providers Regarding CAQH CORE Proposals

Moderator: Jamie Ferguson, Standards Subcommittee Member

Terry Cunningham, American Hospital Association

AHA recommends immediate adoption of five of the proposed CAQH CORE updates: (1) updated Infrastructure Rules, (2) updated Eligibility & Benefits Data Content Rule, (3) Single Patient Attribution Data Content Rule, (4) Master Companion Guide templates, and (5) updated Connectivity Rule. Mr. Cunningham outlined the benefits of these five rules. First, the updated Infrastructure Rules for eligibility, claims status, and remittance advice transactions increase the weekly system availability requirements from 86 percent to 90 percent. Because health care is an around-the-clock industry, system downtimes can lead to treatment disruptions. For example, if a health care provider cannot verify a patient's coverage and eligibility information, they may be unable to schedule follow-up care. Updating system availability requirements is also necessary for complying with the No Surprises Act, particularly the short turnaround times for cost estimates.

Second, the updated Eligibility & Benefits Data Content Rule significantly improves the quality and granularity of information available to health care providers and patients. This information includes relevant telemedicine benefits, remaining coverage benefits, tiered benefits, and procedure-level information. Many industry partners have expressed particular interest in information on telemedicine benefits given the significant increase in telemedicine usage during the COVID-19 pandemic. This updated rule also aligns with greater health care industry focus on enhanced cost transparency and usage of tiered benefits.

Third, the Single Patient Attribution Data Content Rule improves the ability of health care providers to identify whether patients have VBP coverage. Although VBP usage is currently limited, AHA expects this updated rule to provide additional clarification and standardization for VBP plans and coverage.

Fourth, the Master Companion Guide templates provide greater consistency for organizations to comply with new standards. The proposed templates also prevent loss of existing standardization (e.g., 005010 HIPAA transaction standards) of different guides as organizations transition to the new standards. Fifth, the updated Connectivity Rule improves transaction security by using X.509 digital certificate-based authentication. This rule also streamlines Safe Harbor methodology across transactions.

Mr. Cunningham noted the benefits of these rules in creating uniformity of health care attachments, thereby increasing process efficiency for some claims and PAs. The Attachments Infrastructure Rule establishes maximum response times and an acknowledgement process, and the Attachments Data Content Rule provides more specific reassociation requirements and establishes the usage of LOINC for requests for information. However, AHA recommends delaying adoption of the proposed Attachments Operating Rules based upon multiple concerns. Unlike the other proposed rules, the Attachments Operating Rules were not created to improve an existing HIPAA standard, although these rules build upon the electronic attachment standard published by HHS in December 2022. AHA's major concerns are related to harmonization of standards, particularly a potential conflict between the PA and electronic attachments standards. Thus, AHA recommends delaying adoption of these rules, because they may require revision to resolve conflicting standards.

Heather McComas, American Medical Association

AMA's mission is to promote the art and science of medicine and the betterment of public health. AMA aims to remove obstacles that interfere with patient care, lead the charge to prevent chronic disease, confront public health crises, and drive the future of medicine.

AMA has long advocated for the adoption of electronic transaction and code set standards and operating rules to reduce the administrative burden on health care providers. AMA actively participated in the development of the proposed CAQH CORE rules. These rules will increase consistency in transactions, address unmet business needs, and capitalize on emerging trends across the health care industry. Thus, AMA recommends immediate adoption of four of the CAQH CORE rules: (1) updated Infrastructure Rules, (2) Updated Eligibility & Benefits Data Content Rule, (3) new Eligibility & Benefits Patient Attribution Rule, and (4) updated Connectivity Rule.

The updated Infrastructure Rules recognize that health care practices need to electronically communicate with health plans whenever care is provided, including outside of normal business hours. The updated Infrastructure Rules increase system availability requirements from 86 percent to 90 percent, which will directly improve patient care because system downtime prevents electronic coverage confirmation and scheduling of follow-up care. These rules bring the health care industry closer to the goal of 95 percent system availability or greater.

Similarly, the updated Eligibility & Benefits Data Content Rule addresses the increasing volume of data that physician practices need to assess unmet business needs and recent health care industry trends (e.g., growth in virtual care and complex benefit structures). This rule adds key additional details to eligibility confirmation, including (1) telehealth coverage, (2) maximum and remaining benefits for specified service types, and (3) tiered network status and associated benefits. Health care practices also need improved data granularity and specificity, particularly for PAs and compliance with No Surprises Act requirements. The proposed rule requires health plans to indicate whether a specific service type or procedure requires a PA, increasing transparency of the PA process. This rule also allows physicians to determine good faith estimates for uncovered care, which is required under NSA. This rule will also improve reassociation of transactions between X12 and other formats and establishes LOINC as the recommended format for requesting supporting documentation, which provides greater transparency regarding plan requirements for this documentation.

Many physicians face significant challenges obtaining accurate, timely, and actionable patient attribution data, which is required for participation in value-based contracts (VBCs). The Patient Attribution Rule addresses this challenge by requiring health plans to provide patient attribution information in the electronic eligibility response. Adopting this rule will enable more physicians to transition from traditional fee-for-service payment models toward VBCs and other innovative payment models.

Finally, the updated Connectivity Rule supports modernized security, authorization, and authentication practices for protecting patient health information. Updated security requirements in this rule relate to encryption protocol of Transport Layer Security rating of 1.2 or higher, digital certification based on X.509, and OAuth 2.0-compliant system authorizations. This rule enables the usage of new and emerging technologies (e.g., REST APIs). Under this rule, partnering organizations with existing agreements and connections will be able to exchange data under HIPAA Safe Harbor provisions.

AMA also supports adoption of the Attachments Operating Rules for PAs and health care claims but believes these rules require further evaluation and harmonization prior to implementation. AMA, along with many health care industry stakeholders, have long advocated for standardized approaches for electronically exchanging supporting documentation and attachments, which would prevent care delays and reduce administrative burden. To improve the consistency and efficiency for health care electronic attachment exchange, the proposed infrastructure rules (1) update system availability and connectivity requirements; (2) create consistent minimum files sizes for most health plans; and (3) implement requirements for maximum response times, acknowledgements, and error handling.

AMA has closely followed the development and analysis of these proposed rules, including assessing their impacts on different stakeholders in the health care industry. Based on these analyses, AMA recommends further evaluation of recent regulatory developments, particularly the CMS PA and NPRMs, prior to adopting the Attachments Operating Rules.

Kirk Anderson, Cambia Health Solutions/Regence

When HL7 first began to develop standards for API-driven transactions, Regence capitalized on API-driven verification as a method to increase automation and reduce administrative burden in health care practices. This interest in automating Eligibility & Benefits transactions also led Mr. Anderson to collaborate with other technologists to form the HL7 Da Vinci Project. Cambia has continued to collaborate with health care providers and electronic medical record (EMR) vendors to implement additional API-driven automation for different health care administrative processes, including patient attribution. In 2022, this collaboration with EMR vendors achieved the first real-time electronic PA request and approval that used REST APIs for data exchange.

Mr. Anderson described how API-driven PA requests and approvals can provide a significant opportunity to advance the health care industry, relieve significant administrative burdens on providers and payers, and provide patients with quicker approvals. REST APIs enable software (e.g., EMR systems) to directly communicate without human intervention, enabling payers and providers to view PAs as a single, interoperable workflow. In this system, a health care provider can click submit a PA request directly through the EMR system rather than having to use a separate payer portal, and the provider can directly upload relevant clinical data for this PA request. Providers can view the payer's care guidelines and eligible patient benefits in real time. Many PA requests can be automatically approved. For PAs requiring human review, an EMR can provide both the patient and provider with status updates during the approval process.

Using the HL7-Da Vinci IGs, Regence collaborated with Multicare Connected Care to conduct a pilot project on electronic PA requests and approvals using APIs rather than manual processes (e.g., faxes, phone calls). This pilot project was successful, and starting in summer of 2022, Regence put the API-driven electronic PA system into production, where it is being used by patients. This PA approval system operates based on FHIR standards and Da Vinci IG requirements, enabling Regence to avoid the need for using X12 278 transactions. As a payer, Regence's ability to electronically capture data for PA decisions has allowed the company to significantly reduce the amount of time spent on PA reviews and approvals.

Anna Taylor, Multicare Connected Care

Multicare Connected Care engages with more than 25 different payers and 20 separate EMR systems in its clinically integrated network, so reducing administrative burden across payers and EMRs is a necessity that requires scalable solutions that provide consistency for transaction workflows. API-driven administrative workflows have provided the level of automation and scalability needed to meet these requirements.

Multicare Connected Care has realized significant cost savings by implementing API-driven transactions. For quality reporting, Multicare implemented an API-driven post-discharge reconciliation system based on the Da Vinci Data Exchange for Data Quality Measures IG, resulting in a 175 percent improvement in medical reconciliations. This system has also enabled Multicare to eliminate the need for its employees to conduct extensive patient chart reviews (i.e., chart chasing), which costs Multicare approximately $50 per chart reviewed. Multicare has redirected these cost savings into improving patient care and care management. For PAs, Multicare codified PA processes for 10 surgical procedures, for which Multicare has been able to authorize request responses with 2-3 minutes. This process significantly improves patient care by reducing the amount of time needed for PA approvals. Ms. Taylor highlighted how

implementing API-driven PA approvals and electronic post-discharge reconciliations has benefited Multicare's overall ability to function as a value-based care company.

Margaret Schuler, Aspen Dental Management, Inc.

Aspen Dental Management, Inc. (ADMI) is a dental support organization that provides nonclinical business support and administrative services to more than 1000 ADMI-branded practices in 43 states. ADMI's mission is to reduce barriers that doctors and patients face when interacting with dental care services in order to improve patient care. To address this mission, ADMI focuses on facilitating administrative simplification, which will allow doctors to focus on care delivery. Overall, the dental industry has lagged behind other areas of health care in terms of administrative simplification, and the proposed CAQH CORE rules are crucial in closing this gap and improving patient dental care. Thus, ADMI supports immediate adoption of all proposed CAQH CORE rules.

In 2021, the dental industry sent 40 million attachments, 80 percent of which were manually processed and dependent on third-party solutions. The lack of mandates related to attachments has impeded widespread adoption of electronic attachment processing across the dental industry; thus, mandating electronic processing of attachments will stimulate rapid, large-scale implementation and compliance. Uniform attachment guidelines across the dental industry will significantly reduce attachment rejections and manual processing for claims adjudication. Based on CAQH estimates, full adoption of electronic attachments would save approximately 3.2 million hours and $99.2 million per year.

The updated Eligibility & Benefits Operating Rule will streamline eligibility verifications, which are frequent because many dental insurance plans set limits on specific services (e.g., crowns, tooth extractions) within certain timeframes. Eligibility verification is currently a manual process in which administrative staff often call dental plans to verify coverage, creating a significant administrative burden. CAQH estimates that each electronic eligibility verification saves $9.12 compared to a manual transaction; given the millions of verifications conducted each year, full adoption would provide significant cost savings. The updated Eligibility & Benefits Operating Rule also introduces an expanded subset of dental STCs, which will provide greater coverage detail to dental providers and reduce surprise bills. Similarly, the updated Infrastructure Rules will support ADMI's ability to care for its patients by increasing system availability requirements to 90 percent, thereby strengthening and increasing predictability of system governance and coverage verification.

HIPAA CEs are currently required to maintain outdated security protocols, which increases potential cybersecurity risks and hinders adoption of current security technologies. The updated Connectivity Rule expands support for APIs and enhances security, digital certification, and authorization requirements to protect patient data. The new security standards build upon Safe Harbor requirements, allowing ADMI and other dental support organizations to optimize current relationships without the need to overhaul existing connections.

Ms. Schuler re-emphasized ADMI's support for all proposed rules and recommended aligning the Attachments Operating Rules in a final rule for an attachments standard.

Discussion

Mr. Ferguson asked panelists about how they currently provide good faith cost estimates, as required under the NSA. Mr. Cunningham replied that the updated Eligibility & Benefits Data Content Rule does not specifically address good faith estimates. Instead, the rule provides additional granularity for determining eligibility for current processes. Mr. Ferguson asked how providers currently obtain information on telehealth eligibility. Mr. Cunningham highlighted the lack of consistent processes for determining this eligibility. Although SDOs have outlined methods for determining eligibility, these

methods have not been universally adopted by health plans. Thus, many providers are forced to make phone calls to obtain this information, creating significant administrative burdens.

Mr. Ferguson asked about the consequences of not adopting the proposed CAQH CORE rules for VBP plans, including current methods for patient attribution. Ms. Taylor replied that Multicare uses the Da Vinci IG for attribution. She described how FHIR-compliant REST APIs enable Multicare to exchange attribution data more consistently across different workflows. Ms. McComas noted that patient attribution information is often currently verified through health plan rosters, and she agreed that the proposed rules would enable real-time attribution, reducing administrative time required for this process.

Ms. Love noted that compliance with the proposed rules will likely not be mandated until several years after initial adoption and asked how payers will address administrative burdens during the first few years of implementation. Mr. Cunningham responded that adopting the proposed rules will incentivize many payers and providers to begin implementing upgrades and other solutions prior to full mandates coming into effect, and many health plans have already voluntarily upgraded their systems to incorporate the proposed requirements. Mr. Anderson agreed and noted that Regence already adopted Da Vinci IG requirements for API-driven patient attribution, which has already produced significant cost savings compared to previous manual attribution methods. Ms. Taylor provided a similar example of how Multicare currently uses a FHIR-compliant Beneficiary Claims Data API (BCDA) built on a Da Vinci API construct for PAs. This BCDA is currently used in the Medicare Shared Savings Program and has enabled Multicare to conduct fully electronic PA transactions without established PA operating rules.

Panel 3: Presentations from Health Plans Regarding CAQH CORE Proposals on Operating Rules

Moderator: Tammy Banks, Subcommittee Co-chair

Christol Green, Elevance Health

Ms. Green has been involved in administrative simplification and implementing electronic health care transactions for than 20 years, including as a liaison to both CAQH CORE and HL7 and an operating committee member for both the Da Vinci and Flexible, Appropriate, Standard, and Transparent accelerators. Elevance Health recommends against immediate adoption of the proposed Attachments, Infrastructure, and Eligibility & Benefits Data Content Rules. Instead, NCVHS should seek public comments after associated standards (e.g., FHIR) have been finalized.

Regarding the Single Patient Attribution Data Rule, Ms. Green noted that many VBP plans use retrospective attribution methods to assign patients to providers based on claims data; thus, providers are often not attributed until the end of the year in which the services were provided. Although some VBP plans use tentatively (i.e., prospectively) attributed patient lists that are later reconciled, these lists only update semi-annually or quarterly. Payers have established methods to communicate patient attribution data to providers. Payers may also use other methods for identifying the provider responsible for care, such as through purchases of certain products or selection by patients. In some cases, population-level lists of patients under relevant VBP plans are sent to providers at the start of a plan's contract period. Real-time patient-by-patient attribution is not useful given the usage of retrospective attribution, limited number of updates to patient lists, and necessary reconciliations. Patient lists with VBP plans do not change with enough frequency to require re-performing the analysis associated with these files on a daily basis. Thus, implementation of individual enrollee status checks as envisioned in the proposed operating rules would only refer to the latest file, which could be almost a quarter old. Moreover, implementation will likely require more cost and burden than derive benefit.

Under the proposed Eligibility & Benefits Rules, payers will be required to return maximum and remaining benefits for 10 STCs. Providing this benefit information electronically would require updates to electronic transaction systems used by payers, providers, EMRs, and clearinghouse systems to capture information and receive responses. Supporting procedure code inquiries and mapping these codes to service types would require significant changes to payer systems. Thus, Elevance asks NCVHS to recommend against the adoption of the proposed Eligibility & Benefits Rules, and permit payers to rely on existing systems customized to specific contracts with their providers.

Ms. Green stated that the current CAQH CORE Companion Guides are burdensome to create and have limited value to many payers. Elevance Health recommends that NCVHS collaborate with CAQH CORE to simplify and streamline these Companion Guides. Current FHIR IGs address many of the underlying data exchange connectivity concerns raised by CAQH CORE; thus, Ms. Green recommended that NCVHS also collaborate with HL7 to harmonize current FHIR IGs with the proposed Connectivity Rule prior to adoption.

Elevance Health agrees with the overall need for adopting Attachments Operating Rules but does not support immediate adoption of the proposed Attachments Rules as currently written. The current CAQH CORE Attachments Operating Rules will be burdensome and costly to implement and may conflict with the updated standards in the current CMS proposed rule and pending ONC proposed rule. CMS has proposed the development of an FHIR-based API requirement that automates the process for providers to determine whether an authorization is necessary and what information is required, and that facilitates the electronic exchange of both requests and responses. Whereas CMS requirements would only apply to federal plan programs, Elevance Health supports aligning requirements where reasonable with different insurance product lines. Thus, Elevance Health encourages NCVHS to collaborate with CMS and align Attachments Operating Rules prior to adoption. In addition, the proposed Attachments Rule's requirements for service-level responses will be challenging for many payers. Similarly, the PA Attachments Rule requires providers to list exact services within PA workflows, which will be expensive for many providers.

Lastly, Elevance Health suggests that NCVHS work with stakeholders to clarify transactions for which FHIR or X12 standards are most appropriate and transactions for which either standard is applicable, rather than requiring payers to support both standards for all transactions.

Gail Kocher, Blue Cross Blue Shield Association

BCBSA strongly supports administrative simplification of HIPAA-covered transactions to promote efficiency and reduce health care and administrative costs. Whereas BCBSA plans vary in size, markets, and geography, these plans report consistent challenges and barriers for electronic transactions, and the overall adoption rate of mandated standards is fairly consistent across BCBSA plans.

Ms. Kocher highlighted three major considerations regarding the proposed operating rules. First, operating rules should support the implementation of existing standards rather than supplement requirements already defined by SDOs. Operating rules should not replace requirements in established standards or conflict with general usage information contained in IGs. The proposed CAQH CORE infrastructure requirements meet these criteria by creating requirements not currently addressed by standards or their associated IGs.

Second, IT and interoperability requirements, including the proposed operating rules, must be considered in the context of the broader environment of mandates and other requirements that payers must follow. BCBSA plans have consistently reported that implementing new standards and operating rules concurrently often requires significantly more time and resources than the business value achieved by adoption. The timing for adopting additional provisions for administrative simplification should

consider implementation and mandate schedules for other regulatory requirements (e.g., CMS mandates).

Third, estimating potential benefits of the proposed operating rules requires examination of the collective impacts of all relevant mandates and requirements, rather than of the benefits of one standard or operating rule by itself. Many health plans operate under safe harbors, so these plans may never use many of the electronic transaction types relevant to the proposed operating rules. BCBSA strongly encourages NCVHS and CAQH CORE to develop a roadmap that shows other relevant federal and state mandates (e.g., CAA, NSA) to prevent bottlenecks and overlapping resource commitments for industry stakeholders.

Ms. Kocher then discussed BCBSA's recommendations regarding specific proposed rules. She began by noting that the proposed Connectivity Rule addresses the concerns previously raised by health care stakeholders in 2020. Although BCBSA recognizes the need for higher minimum connectivity requirements, the organization is concerned that its health plans, vendors, clearinghouses, and other intermediaries that act as both a client and a server must implement both REST and SOAP while providers and vendors can implement one or the other. Requiring health plans, vendors, and other intermediaries to implement protocols that are never or rarely used creates unnecessary costs and burdens.

Regarding the data content requirements under the Eligibility & Benefits Operating Rules, X12 plans to propose additional transaction standards that address these requirements, and the proposed operating rule does not account for X12's updates. Thus, updating data content requirements prior to X12's updates is premature and may result in changes that later must be modified or removed to accommodate future versions of X12 standards. Instead, NCVHS should consider updating current HIPAA-mandated transactions before addressing changes to operating rules.

Similarly, BCBSA believes that adopting the proposed Operating Rules related to claims and PAs is premature because these Rules have not yet been widely adopted and implemented across the health care industry. Thus, the business requirements, potential benefits, and implementation costs remain unclear. Instead, the business uses cases, costs, and benefits need further definition. Stakeholders must be given the time to evaluate whether proposed standards adequately address business requirements and provide sufficient ROI.

Barry Hillman, Blue Cross Blue Shield of North Carolina

The proposed Eligibility & Benefits and Data Content Rules address many items and services that frequently require phone calls under current requirements. The proposed rules will ensure that sufficient detail is exchanged between providers and payers as insurance companies increasingly adopt tiered benefit structures and specific benefits for physical therapy, occupational therapy, imaging, and surgery claims. Verifying this eligibility information electronically rather than through a call center would create significant long-term cost savings. The proposed rules will also establish greater consistency of electronic transactions across different insurers.

Proposed updates to the Infrastructure Rules establish minimum criteria for response times, availability, and acknowledgment requirements, which will create predictable timeframes and processes for eligibility verification, system availability, and electronic claims. In addition, the proposed Connectivity Rule enables software vendors to create applications that can work with different entities without custom programming. Costs associated with custom programming for electronic transactions are often incurred by many HIPAA CEs, which disproportionately impacts many smaller CEs with fewer resources for custom programming. Greater consistency shifts the burden of custom programming from CEs to software developers, resulting in significant cost savings to CEs. Mr. Hillman emphasized that the

Infrastructure and Connectivity Rules should be mandatory rather than voluntary to create and enforce greater consistency by enabling the use of common approaches between organizations.

The updated data content requirements within the Eligibility & Benefits Operating Rule will provide significant savings to many payers by shifting eligibility and benefits verification from manual and phone-based processes to electronic methods. Whereas phone calls to verify eligibility can be lengthy, this same information can be provided electronically within 3-5 seconds.

Mr. Hillman then described how the updated attachments- and PA-related operating rules are long overdue. Adopting these rules and transaction standards will enable fully electronic workflows for PAs and claims attachments. Consistent standards will enable software developers to create readily usable applications rather than requiring stakeholders to pay for custom programming. Similarly, shifting toward electronic PA transactions enables integration with EMR systems rather than perpetuating the use of separate payer portals.

Mr. Hillman concluded by re-emphasizing that Blue Cross Blue Shield of North Carolina (BCBSNC) supports immediate adoption of these rules. BCBSNC was involved in the CAQH CORE's multi-stakeholder and collaborative operating rules development process. Furthermore, the implementation costs will be exceeded by long-term cost savings for both providers and payers.

Discussion

Ms. Banks asked Ms. Green to clarify her organization's position regarding the proposed rules. Ms. Green confirmed that Elevance Health opposes immediate adoption of all proposed operating rules except for connectivity response time requirements, for which her organization abstained from commenting.

Ms. Banks noted that conveying member attribution can be difficult under current operating rules, particularly when members join during the middle of the year. She asked Ms. Green whether the use of FHIR-compliant APIs would resolve many of the challenges with attribution. Ms. Green agreed that member attribution can pose significant challenges, and Elevance Health is exploring different approaches to these challenges, including participation in the HL7 Da Vinci project. She agreed that member attribution should be simplified but remains concerned about the proposed rule's approach and requirements for attribution.

Panel 4: Presentations from Health Plans Regarding CAQH CORE Proposals on Operating Rules

Moderator: Debra Strickland, Member of the Standards Subcommittee

Nora Iluri, athenahealth

The mission of athenahealth is to create a thriving ecosystem that delivers accessible, high-quality, and sustainable health care for all. athenahealth aims to achieve this mission through its medical record, revenue cycle, patient engagement, and care coordination service offerings. athenahealth is highly aligned with CAQH CORE's vision to bring together health care industry organizations to make sharing business information more automated, predictable, and consistent. Athenahealth participates in operating rule development as a member of CAQH CORE working groups.

athenahealth provides a leading platform for ambulatory practices with integrated solutions to optimize the physician workflow. These solutions include (1) athenaCollector, which is a technology-enabled RCM solution to manage administrative and financial interactions with payers and patients (including

eligibility, claims, submissions, denials, appeals, posting, payment tools, and practice management); (2) athenaClinicals, which provides clinical experience and support through comprehensive clinical solutions including encounter workflows, quality management, longitudinal patient records, care management, and telehealth; (3) athenaCommunicator, which includes patient engagement tools to facilitate patient outreach, scheduling, check-ins, results delivery, and medication adherence; and (4) athenahealth marketplace and ecosystem, which includes a growing set of partners with access to the athenaOne portal to facilitate connectivity. athenahealth currently serves more than 155,000 providers on its athenaOne portal and hosts more than 170 million unique patient records.

CAQH CORE's operating rules address the most impactful needs that will help athenahealth better serve patients and reduce overall administrative costs. The adoption of new and updated operating rules can improve digital data exchange and transactions, driving the quality and timeliness of care and reduction of costs. In 2022, athenahealth processed 300 million claims, more than 700 million eligibility requests, and more than 5 million Service Eligible Orders.

Currently, the industry has insufficient means to communicate, requiring payers to use error-prone expensive manual portals, instead of automation. In addition, the health care industry is hindered by missing information, so that practices have an unclear view of coverage and costs. The current lack of sufficient standards leads to the return of data to vendors in unstructured fields or standard fields that are used differently by payers. For these reasons, athenahealth supports the Data Content Rules related to Eligibility & Benefits (to improve transparency into coverage and cost for practices and patients), Attachments for Prior Authorization and Claims (to help advance automation and improve quality and timeliness), and Single Patient Attribution Data (to support the expansion of value-based care contracts). The most impactful requirements found in these Data Content Rules are the following: (1) requirement to use specific codes to indicate what service or benefit is available for telemedicine, (2) expansion of discretionary and mandatory STCs and procedure codes to enable more accurate responses for coverage and cost, (3) indication of whether a prior authorization is required, (4) requirement of specific codes and reference data to improve data interoperability, and (5) path to codifying and exchanging single patient attribution information to support a growing value-based care population.

In addition, the attachments standards establish a necessary foundation for the electronic exchange of health information, and the operating rules ensure a consistent construction of solutions. The adoption of the attachment standards related to prior authorizations and claims are estimated to provide $828 million in savings per year according to the CAQH Index Report. Electronic attachments would not only reduce administrative burden and costs, but also improve claim and prior authorization quality and turnaround time—significantly benefiting patients. athenahealth encourages NCVHS to recommend that HHS include the Attachments Operating Rules in the Final Rule because implementation of these standards would support faster and higher quality responses for patients, reduce administrative costs, and aid in the adoption of non-X12 methods that support new technologies.

Operating rules directly support technology advancements and provide a platform for driving industry adoption. athenahealth currently uses X12 and modern non-X12 standards and acts as a pioneer of newer technologies. Movement from X12 standards to HL7 standards would require significant time and effort, and guidelines must provide a framework that supports the alignment of old and new technologies. CAQH CORE's proposed operating rules provide a uniform pathway without being overly prescriptive, thus establishing a scenario wherein stakeholders can gradually implement new requirements and move away from old modalities.

Federal adoption and infrastructure and connectivity of operating rules help to ensure the consistency and fairness of resulting patient care, improve the speed of adoption, and reduce the cost to maintain.

athenahealth serves practices nationwide and observes a significant variation in state-to-state data, connectivity, and business processes. This variation creates significant burden for payers, vendors, and practices to build and maintain solutions that serve stakeholders, leading to inconsistency of and inequality in patient care. As a result, athenahealth supports the adoption of Infrastructure and Connectivity Rules that can reduce the cost to build and maintain systems and services, and to improve the quality and timeliness of transactions.

Arthur Roosa, Healthcare Business Management Association

Overall, HBMA is generally supportive of the operating rules proposed by CAQH CORE. HBMA is particularly supportive of the content related to 270 and 271 transaction sets, copays, deductibles, telehealth, eligibility by procedure code, and maximum benefit data. Mr. Roosa noted that these changes may be extensive and expensive but will only require a one-time implementation to produce significant benefits.

Currently, information related to the 271 transactions is provided to vendors through proprietary and ineffective methods. Adopting the ability to share this information electronically is crucial, particularly for RCM companies that are responsible for billing.

HBMA also supports the proposal's content related to attachments, which will improve the uniformity in which attachments are transmitted to payers. Mr. Roosa noted that HBMA is often asked for additional information related to attachments when processing a claim, and therefore being able to electronically search for such information would significantly improve current procedures.

HBMA agrees with the updated Infrastructure Rules' upgrade in weekly system availability requirements from 86 percent to 90 percent. However, many of HBMA's trading partners already far exceed these percentages. HBMA also agrees with the proposed use of SOAP transactions and REST APIs, which will give providers more flexibility. Further, the Safe Harbor procedures included in the proposed rules are critical to providers; if recommended to HHS, NCVHS must clearly define those procedures to ensure effective communication with payers. In addition, adopted standards and operating rules must be followed and used appropriately. Thus, HBMA strongly suggests that NCVHS consider enforcement methods when developing its recommendations.

Pam Grosze, Cooperative Exchange

Ms. Grosze provided testimony on the federally mandated Infrastructure Rules, the Eligibility & Benefits (270/271) Data Content Rule (including, Connectivity Rule, Single Attribution Data Content Rule, and the attachments operating rules). Stakeholders have been operating under federally mandated Infrastructure Rules for nearly a decade. Increasing the system availability for eligibility and claim status is definitely a benefit and a logical step toward improving availability. The Cooperative Exchange agrees that the CAQH CORE Master Companion Guide Template also offers benefit because it standardizes information flow and format and enables payers and clearinghouses to convey their specific requirements around the IG for their trading partners. This template has been a very effective means to communicate trading partner–specific information. The Cooperative Exchange supports updates to this guide. However, Infrastructure Rules updates continue to include requirements for acknowledgement transactions, which have not been adopted under federal regulation and were specifically excluded in the current mandated rules. The rule updates also reference confusing certification requirements. For example, "CORE-certified organizations" are referenced in Eligibility & Benefits Rule Section 1.1 and conformance requirements for "HIPAA CEs or their agents" are referenced in Section 1.2, which is confusing to organizations using the rule. Further, voluntary certification requirements should be separate from the federally mandated requirements for HIPAA CEs or their agents. Overall, the Cooperative Exchange supports the majority of the updated Infrastructure Rules. However, because the

updated rules continue to refer to acknowledgements and voluntary CAQH CORE certification requirements, the Cooperative Exchange does not support the proposed update to federally mandated Infrastructure Rules as published.

In addition, recent legislative and regulatory actions support a higher level of information at the point of service to inform and protect patients. Updating the Eligibility & Benefits Data Content Rule would support these actions. A robust eligibility response will alleviate the burden on patients, providers, and payers by providing needed information at the time of service regarding benefits, pricing, patient cost, and prior authorization. However, supplying additional information comes at a cost. The exchange of more robust eligibility and benefits data between providers and payers requires systems modifications. Assuming a net positive benefit, the Cooperative Exchange supports the updates to the Eligibility & Benefits Data Content Rule.

The Connectivity Rule is a hybrid rule because it contains both updated and new rule requirements. To address known security vulnerabilities in the current CAQH CORE Connectivity Rule, the Cooperative Exchange supports the operating rule updates outlined in Question 5 of the NCVHS RFC. These updates accommodate secure internet-based REST API and authorization connectivity. The Cooperative Exchange recommends that NCVHS solicit a wider perspective from health care industry stakeholders and the at-large technical community regarding the specification of normative naming conventions for API endpoints and the base set of metadata required for the exchange of REST messages, to ensure that the rule supports technology advances and future standards updates. For this reason, the Cooperative Exchange does not support the inclusion of the naming conventions for API endpoints and base metadata as specified in the updated Connectivity Rule at this time. Because the rule includes a mix of beneficial updates and new requirements that pose concerns, the Cooperative Exchange does not support federal adoption of the updated Connectivity Rule as published.

In general, clearinghouses already support the requirements of the new CAQH CORE Eligibility & Benefits Single Patient Attribution Data Content Rule and the exchange of patient attribution data content when present in eligibility workflows. As with the Eligibility & Benefits Data Content Rule, to be able to exchange more patient attribution data content between providers and payers, companies will be required to incur costs to modify systems. The Cooperative Exchange believes that providers, payers, patients/patient advocate organizations, and other interested stakeholders are better positioned to address the question of administrative simplification improvement and potential adoption under federal regulation.

As stated in 42 USC § 1320d–2, operating rules shall support standards under HIPAA regulation. Because attachment transaction standards have not yet been finalized in federal regulation, the Cooperative Exchange believes that proposing attachments operating rules for federal mandate is premature. The Cooperative Exchange recommends that SDOs and ORAEs coordinate to ensure that regulated transaction standards and operating rules are aligned as appropriate and that industry adoption occurs in a pragmatic and synchronized manner.

Consistent with the NCVHS recommendations in the July 2022 letter to the HHS Secretary, the Cooperative Exchange recommends the establishment and deployment of federally regulated operating rules and a known and predictable version update schedule within a SDO and ORAE guidance framework. The Cooperative Exchange believes that a predictable update schedule for both standards and operating rules would benefit the industry by providing the ability to plan, budget, and resource to ensure that updates are made appropriately.

The Cooperative Exchange recommends that, when published, federally mandated operating rules include only the requirements subject to federal mandate. For example, rule publications or

specifications that list requirements for acknowledgments that were excluded in federal rulemaking causes confusion within the industry at large. CAQH CORE should be required to publish operating rules that fully align with federal rulemaking requirements and can alternatively publish non-mandated certification requirements that include other requirements, such as acknowledgments for purposes of voluntary certification. Voluntary CORE certification requirements should be published separately from federally mandated operating rule requirements and should be clearly noted as such.

Discussion

Ms. Strickland acknowledged the Cooperative Exchange's concerns regarding the proposed CAQH CORE operating rules and asked whether the Cooperative Exchange was involved in the CAQH CORE rule development process. Ms. Grosze responded that, as a CAQH CORE member, the Cooperative Exchange provided input during the rule development process.

Subcommittee Discussion and Q&A

Ms. Weber responded to the concerns raised about the proposed CAQH CORE operating rules. Regarding the Single Patient Attribution Data Content Rule, she agreed that many payers have established processes for exchanging attribution but highlighted the lack of consistency across payers, which creates significant administrative burden for providers. Current plan rosters may be sent to the previously attributed provider, but because patients often see multiple providers, other providers may not know whether their services are also attributed. Thus, the proposed Single Patient Attribution Data Content Rule establishes consistent processes and provides greater transparency to all providers involved.

Ms. Weber described how the CAQH CORE Connectivity Rule vC4.0.0 allows for attachments in multiple formats (e.g., X12 275, C-CDA) on both SOAP and REST transaction messages (e.g., responses to requests for information). Providers often send attachments to multiple data exchange partners (e.g., payers, clearinghouses), and individually formatting attachments per each trading partner's system poses an additional administrative burden. The proposed Attachments Rules mitigate this burden and complement the proposed Connectivity Rule by ensuring that providers can send the same attachment to multiple plans, clearinghouses, and other data exchange partners. Similarly, the CORE Connectivity Safe Harbor network allows for seamless interoperability between providers and health plans, streamlining the process of sending attached data and images to different health plans.

Ms. Weber noted CAQH CORE's analysis of its proposed attachment- and PA-related rules for potential conflicts with other standards did not identify any conflicts. However, CAQH CORE can review its proposed Attachments Rules following finalization of CMS Attachments Rules to ensure alignment between these rules.

Ms. Weber emphasized that CAQH CORE's rule development process was collaborative and involved more than 140 organizations, including providers, vendors, clearinghouses, and government agencies. Greater than 88 percent of members supported adoption of the proposed rules, demonstrating approval across different types of health care organizations.

Ms. Love noted that some panelists supported eventual adoption of the proposed operating rules but suggested changes to specific requirements and protocols. She asked Ms. Weber about the difficulty of changing the proposed rules to address these specific concerns. Ms. Weber responded that the difficulty depends on whether the changes are substantive, which CAQH CORE defines as requiring significant changes to health care organizations' electronic attachment systems. Many of the changes proposed by stakeholders in this meeting were not supported by the CAQH CORE rule development process, and the

current proposed rules reflect the consensus among CAQH CORE members. During the rule development process, CAQH CORE collaborated with CMS to avoid potential conflicts between CAQH CORE and CMS rules. For example, some of the acknowledgment and certification requirements are not included in the proposed CMS rules. She agreed that similar changes (e.g., certification requirements) can be made to the CAQH CORE rules. NCVHS can also contact CAQH CORE with any additional concerns or questions before developing its recommendations to the Secretary of HHS.

Closing Remarks and Adjournment

Ms. Hines invited additional written public comments to be sent to the Subcommittee before January 19, 2023 (see Appendix C).

Ms. Hines thanked all speakers, moderators, and attendees for their participation and adjourned the hearing.

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.

/s/
Jacki Monson, JD, Chair — August 30, 2023
National Committee on Vital and Health Statistics — Date

Appendix A: Meeting Participants

Invited Panelist Speakers

Kirk Anderson, Vice President and Chief Technology Officer, Cambia Health Solutions

Robert Bowman, MA, Director, CAQH CORE

Natalie Chalmers, DDS, PhD, MHSc, Chief Dental Officer, Office of the Administrator, CMS

Terrence Cunningham, JD, Director of Administrative Simplification Policy, AHA

Stephanie Fetzer, Product Manager, HCL Software

Alix Goss, Chair of Policy Advisory Committee, HL7

Christol Green, E-Solutions Senior Business Consultant and Advisor, Elevance Health

Pamela Grosze, Board Chair, Cooperative Exchange, and Vice President and Senior Product Manager, Healthcare Division, PNC Bank

Barry Hillman, Director of Digital Strategy, BCBSNC

Nora Iluri, PhD, MPhil, MEng, Vice President of Product Management, athenahealth

Tim Kaja, MBA, CAQH CORE Former Board Chair, and President, Optum

Dan Kalwa, Deputy Director, National Standards Group, OBRHI, CMS

Beth Karpiak, JD, Health Insurance Specialist, CMS

Jocelyn Keegan, Program Manager of Da Vinci Project, and Payer Practice Lead, Point-of-Care Partners

Katherine Knapp, Program Analyst, Department of Veterans Affairs

Gail Kocher, MPA, Director of National Standards, Blue Cross and Blue Shield Association

Ferris Marone, Architect, TennCare

Heather McComas, PharmD, MA, Director of Administrative Simplification Initiatives, AMA

Viet Nguyen, MD, Chief Standards Implementation Officer, HL7

Andrea Preisler, JD, Senior Director of Administrative Simplification Policy, AHA

Linda Reed, RN, MBA, CHCIO, FCHIME, CAQH CORE Board Chair, and Senior Vice President and Chief Information Officer, St. Joseph's Health

Arthur Roosa, CHBME, Chief Executive Officer, SyMed Corporation, and Member, HBMA

Tara Rose, Strategic Product Manager, Optum

Cathy Sheppard, Executive Director, X12

Margaret Schuler, MBA, Senior Vice President of Practice Support Operations and Revenue Cycle Management, Aspen Dental Management, Inc.

Nancy Spector, MSC, Director of Coding and HIT Advocacy, AMA; Board Chair, WEDI; and Chair, NUCC

Steven Sundrud, Vice President of Software Development, SyMed Corporation

A. Richard Temps, Chief Executive Officer and Founder, Chiapas EDI Technologies, Inc.

Robert Tennant, PhD, MA, Vice President of Federal Affairs, WEDI

Dan Vreeman, DPT, MSc, Chief Standards Development Officer, HL7

Erin Weber, MS, Vice President, CAQH CORE

Virginia Whitman, MS, Senior Manager of Public Policy, Alliance of Community Health Plans

Sherry Wilson, Executive Vice President and Chief Compliance Officer, Jopari Solutions Inc.

Patricia Wijtyk, Senior Associate, EDI Team, Cognizant

Zoom Attendees

Darcey Adams, Booz Allen Hamilton
Sadaf Ali, CMS
Tom Anjy
Sarah Arceo, CMS
Barbara Atherton, Kentucky Medicaid
Morris Auster, Medical Society of the State of New York
Teresa Autery, TIBCO Software Inc.
Stacey Barber, Gainwell Technologies
Michelle Barry, Availity, LLC
Gary Beatty, American Specialty Health
Susan Bellile, Availity
Peter Benziger, CAQH
Marlene Biggs, CMS
Jacob Black, Mississippi Division of Medicaid
Angie Bleibaum, CareSource
Kim Boyd, Point-of-Care Partners
Mayra Bramasco, PRNLINK
Paul Branch, HHS
Denny Brennan, Massachusetts Health Data Consortium
June Bronnert, IMO
Kristine Burnaska, CAQH
Camryn Burner, Texas Association of Health Plans
Mary Lynn Bushman, National Government Services
Jason Butterhoff, Johns Hopkins HeathCare LLC
Gia Byra, R1 RCM, Inc.
Michael Cabral, Peraton
Laura Caldwell, General Dynamics Information Technology, Inc.
Bill Campbell, VIA Consulting
Donna Campbell, Health Care Service Corporation
Vanessa Candelora, Point-of-Care Partners
Emily Carroll, AMA
M. Carter, VA
Ana Castro, New York Urology Specialists

Lynn Chapple, Optum
Jamie Chesakm Common Spirit
Michael Cimmino, CMS
Beth Connor, CMS
Jeff Coughlin, AMA
Crystal Cubias, Experian Health
Karl Davis, CMS
Mike Denison, Change Healthcare
Veena Dawar, Oracle
Lisa Dix, Delta Dental of Wisconsin
Geraldine Doetzer, CMS
Mary Dooley, Deloitte
Donna Doneski, National Association for the Support of Long Term Care
Andy Donton, United Concordia
Dawn Duchek, TriZetto Provider Solutions
Brandi Enrietti, Commonspirit Health
Dorothea Evans, Mind Finders, Inc.
Crystal Ewing, Waystar
Rebekah Fiehn, ADA
Andrew Fitzpatrick, Washington Publishing Company
Andrew Flood, General Dynamics Information Technology
Rachel Foerster, Rachel Foerster & Associates Ltd.
Frank Freeman, Common Spirit
Diana Fuller, Michigan Medicaid
Mollie Gelburd, AHIP
Tanya Getz, Capital Blue Cross
Larissa Gill, Johns Hopkins HealthCare
Debra Gilliam, CASET Associates, Ltd.
Kelli Gilmore, Mind Finders, Inc.
Melody Glaub, Experian Health
Jackie Gonzalez, PRNLINK
Trey Gordner, HHS and U.S. Digital Corps
Christopher Gracon, Independent Health
Eric Grindstaff, Allscripts Payerpath
Ed Hafner, Change Healthcare
Shanna Hartman, CMS
David Haugen, Minnesota Department of Health
Camille Haywood, CMS
Marilyn Heine, AMA
Kei Helm, CMS
Geanelle Herring, CMS
Bonnie Hockaday, CMS
Paul Hogle, North Carolina Department of Health and Human Services
Hong Huang, Cambia Health Solutions
Cameron Huff, American Association of Oral and Maxillary Surgeons
Noah Isserman, CMS
Christine Jackson, Medtronic
Charles Jaffe, HL7
Jeff Jennings, California Department of Health Care Services
Michael Johnson, CMS
Christine Kadtke, HealthCare Partners IPA/MSO

Crystal Kallem, Point-of-Care Partners
Thomas Kessler, CMS
Amy King, BCBS Michigan
Eric Kirnbauer, Vyne Dental
Donna Knight, Mind Finders, Inc.
Paige Kobza, Maverick Health Policy
Indira Konduri, FDA
Erik Kramer, Highmark Health
Susan Langford, BCBS Tennessee
Patricia Lapenn, PRNLINK
Celine Lefebvre, AMA
Cindy Leonard, Arizona Advanced Surgery
Amelia Liarakos, CMS
Kyle Lieneck, Johns Hopkins HealthCare
Zoe Lockhart, Maverick Health Policy
Jacqueline Lopez, NexGen Healthcare
Douglas Lucente, ProMedical, LLC
Mary Lynam, Retired
Jessica Malsom, BCBS Kansas
Erica Martin, AMA
Maureen Masturzo, Otolaryngology Plastic Surgery Association
MaryKay McDaniel, Markam
Lisa McKeen, New York General Dynamics Information Technology
Connor McLarren, R1 RCM, Inc.
Michael McNutt, WEDI
Joan Melendez, Xcelerate UDI
L. Meyers, Medical Coding Educators
Brenda Mitchell, Cambia Health Solutions
Cindy Monarch, BCBS Michigan
Jamie Mosteller, Oracle Cerner
Kimberly Mueller, Ripple Effect
Alexandra Mugge, CMS
Christine Nee, ProMedical
Michael Nolan, Automatic Identification Systems, Inc.
Uchenna Nwangwu, HHS
Jameelah O'Neal, Medical Mutual
Charlene Parks, CMS
Madhuri Patel, Avalon Healthcare Solutions
Janet Peak, CMS
Barb Pecoraro, CMS
Stephanie Pfann, Quadax
Lai Pham, Johns Hopkins HealthCare
Michael Phillips, CAQH CORE
Cezary Podkul, ProPublica
Michelle Polyak, CMS
Brian Poteet, Blue Cross and Blue Shield of Tennessee
McConnell Preston, Symmetric Health Solutions
Monica R.
Michael Radeos, NYC Health & Hospitals/South Brooklyn Health
Meredith Ray, CMS
Matt Reid, AMA

Maura Reilly, ASPE, HHS
Matt Reiter, Capitol Associates, Inc.
Robert Richter, Retired
Stephane Robison, Meritage Medical Network
Fred Rooke, CMS
Michael Ryan, FDA
Julia Sakhnov, Edifecs
Philip Sayles, Summate Technologies, Inc.
Tyler Scheid, AMA
Melinda Schwarten, Ripple Effect
Patricia Serpico, American Association of Oral and Maxillofacial Surgeons
Elizabeth Sharp, Cook Group
Carla Shoff, CMS
Ian Shomper, United Concordia
Mike Schiller, AHA
Alex Shteynshlyuger, New York Urology Specialists
Rupinder Singh, CMS
Michael Simpson, FDA
Kathy Sites, Availity
Gwyn Smith, Department of Veterans Affairs
Dawn Sprague, Trizetto Product Division at Cognizant Health Sciences
LeeAnn Stember, National Council for Prescription Drug Programs
Daphne Stevison, DS Health Solutions
Merri Stine, Aetna
Tricia Stuto, General Dynamics Information Technology, Inc.
Dennis Sullivan, Mass General Brigham
Walter Suarez, Kaiser Permanente
Robin Thomashauer, CAQH
Sarah Tilleman, ADA
Susan Titterington, Alpha II, LLC
April Todd, CAQH
John Travis, Oracle Health
Angela Ulsh, United Concordia Dental
Richard Verderamo, CMS
C Veverka, Kunz Leight & Associuates
Dan Vu, United Concordia Dental
Pat Waller, Cambia Health Solutions
Gladys Wheeler, CMS
Amanda Grimm Wiegrefe, American College of Rheumatology
Paula Wimsatt, Kentucky Medicaid
Mary Winter, PrimeWest Health
Chantal Worzala, Alazro Consulting
Kelly Zak, American Association of Oral and Maxillofacial Surgeons
Mariza Zocalo, Zocalo Health

Appendix B: Agenda

National Committee on Vital and Health Statistics (NCVHS)

Subcommittee on Standards Hearing on
Requests for New and Updated Transaction Standards and Operating Rules

Wednesday, January 18, 2023

Time	Panel	Participants
10:00 a.m.	**Welcome, Call to Order, Roll Call**	Rebecca Hines NCVHS Executive Secretary/Designated Federal Officer
10:05 a.m.	**Opening Remarks/Agenda Review**	Tammy Banks, Rich Landen and Denise Love, Co-chairs Subcommittee on Standards
10:10 a.m.	**NCVHS Presentation Regarding the Proposal from X12 and Next Steps**	NCVHS Subcommittee on Standards Co-Chairs
10:25 a.m.	**Presentation from CMS Regarding Process to Adopt Updated and/or Modified Standards under HIPAA**	Dan Kalwa, CMS, OBRHI, NSG
10:45 a.m.	**Presentation from X12 Regarding the Updated Transactions**	Cathy Sheppard, X12 Patricia Wijtyk, Cognizant
11:15 a.m.	**X12 Pilot Phase on Use of Version 8020**	Tara Rose, Optum
11:35 a.m.	**Panel 1: Designated Standards Maintenance Organizations and Code Content Committees**	Terry Cunningham, DSMO Committee Chair HL7 NCPDP X12 ADA NUCC NUBC
11:55 a.m.	**Break**	
12:35 p.m.	**Advisory Committee Report: WEDI Member Survey and Advisory Event Outcome**	Rob Tennant, WEDI
12:55 p.m.	**Panel 2: Provider Perspective on Proposed Updates to X12 Transaction Standards**	Andrea Preisler, AHA Nancy Spector, AMA Katie Knapp, VA
1:35 p.m.	**Panel 3: Health Plan Perspective on Proposed Updates to X12 Transaction Standards**	Natalie Chalmers, CMS Medicare Dental Program Ferris Marone, Tennessee Medicaid

Time	Panel	Participants
2:00 p.m.	**Break**	
2:15 p.m.	**Public Comment: Updates to X12 Standards**	Rebecca Hines NCVHS Executive Secretary/DFO
2:35 p.m.	**Panel 4: Health Plan Perspective on Proposed Updates to X12 Transaction Standards**	Gail Kocher, BCBSA Ginny Whitman, ACHP Christol Green, Elevance Health
3:00 p.m.	**Panel 5: Vendor and Clearinghouse Perspective on Proposed Updates to X12 Transaction Standards**	Pam Grosze, Cooperative Exchange A. Richard Temps, Chiapas EDI Technologies Stephanie Fetzer, HCL Software Sherry Wilson, Jopari Solutions Arthur Roosa, HBMA
3:55 p.m.	**Subcommittee Discussion and Q&A**	Co-Chairs, Subcommittee on Standards
4:15 p.m.	**Closing and Adjourn**	Co-Chairs, Subcommittee on Standards

Thursday, January 19, 2023

Time	Panel	Participants
10:00 a.m.	**Welcome, Call to Order, Roll Call**	Rebecca Hines NCVHS Executive Secretary/DFO
10:05 a.m.	**Opening Remarks/Agenda Review**	Tammy Banks, Rich Landen and Denise Love, Co-chairs Subcommittee on Standards
10:10 a.m.	**NCVHS Presentation Regarding the Proposal from CAQH CORE on Updated and New Operating Rules**	NCVHS Subcommittee on Standards Co-Chairs
10:25 a.m.	**CMS Presentation Regarding Adoption of Operating Rules under the Affordable Care Act**	Dan Kalwa, CMS, OBRHI, NSG
10:45 a.m.	**Presentation from CAQH CORE Regarding Proposals for Updated and New Operating Rules**	Erin Weber, CAQH CORE Linda Reed and Tim Kaja, Board Members
11:20 a.m.	**Advisory Committee Report on Member Survey and Position Advisory Event Outcome**	Rob Tennant, WEDI
11:40 a.m.	**Panel 1: Presentations from Standard Development Organizations and Code Content Committees on CAQH CORE Operating Rules**	Cathy Sheppard, X12 Viet Nguyen, HL7

Time	Panel	Participants
12:15 p.m.	**Break**	
12:45 p.m.	**Panel 2: Presentations from Providers Regarding CAQH CORE Proposals**	Terry Cunningham, AHA Heather McComa, AMA Anna Taylor, Multicare Connected Care Kirk Anderson, Cambia Health Solutions/Regence Margaret Schuler, Aspen Dental Management, Inc.
1:30 p.m.	**Public Comment**	Rebecca Hines NCVHS Executive Secretary/DFO
1:45 p.m.	**Panel 3: Health Plan Perspective on Proposed Updates to X12 Transaction Standards**	Christol Green, Elevance Health Gail Kocher, BCBSA Barry Hillman, Blue Cross Blue Shield North Carolina
2:20 p.m.	**Panel 4: Presentations from Health Plans Regarding CAQH CORE Proposals on Operating Rules**	Nora Iluri, athenahealth Arthur Roosa HBMA Pam Grosze, Cooperative Exchange
2:50 p.m.	**Break**	
3:05 p.m.	**Subcommittee Discussion and Q&A**	Co-Chairs, Subcommittee on Standards
3:45 p.m.	**Closing and Adjourn**	Co-Chairs, Subcommittee on Standards

Appendix C: Live Public Comments

Arizona Advanced Surgery

Cindy Leonard, Chief Operating Officer

Hello, I am Cindy Leonard, and I am the Chief Operating Officer for Arizona Advanced Surgery. We are a private practice group of 70 surgeons and about 20 mid-levels in 17 locations in the greater metro Phoenix area. We have been aware and making all efforts to push back against these EFT and VCC fees and uses that we are now realizing to the tune of close to $40,000 last year. So we do not support the adoption of this standard, and it just raises cost and we have not seen any benefits for it.

Xcelrate UDI

Joan Melendez, President and Chief Executive Officer

My name is Joan Melendez. I'm from Xcelrate UDI. We appreciate the opportunity to share our view on the utilization of UDI in the claim form. Xcelrate UDI is a leading global provider of barcode scanning solutions and patient safety based solutions that drive effective decision making and outcomes. The recommendations from us really, the UDI element, the data element represents a critical medical device information essential to patient safety. The UDI is currently required in ONC cert regulations for providers, and FDA UDI regulations for both providers and medical device manufacturers. It is the vital next step for the inclusion of UDI for your consideration. Again, thank you so much for your time.

New York Urology Specialists

Anna Castro, Practice Manager

Hi, my name is Anna Castro, I'm the Practice Manager at New York Urology Specialists. We do not support the adoption of new standards or standards modifications, as they do not lower the cost of healthcare due to failure of the National Standards Group to enforce compliance. There is rampant non-compliance with already adopted standards. The proposed standards are not equitable to healthcare providers. HIPAA standards for electronic transactions is a bait and switch. While the standards are adopted and sold to healthcare providers with the promise of cost savings and administrative simplifications, because of rampant non-compliance and CMS failure to enforce standards, the promise of cost savings does not live up to the promise.

CMS National Standards Group created HIPAA Administrative Simplification requirements enforcement with what they call an informal compliance mechanism. But you are smart enough to know that when something is informal, voluntary, or without repercussions, there is no compliance. CMS National Standards Group has not imposed a single penalty for non-compliance with adopted standards. In fact, it would not even call a violation a violation. CMS's own data shows that for the eight health plans that completed a full audit of 835 transactions there is a greater than 100 percent non-compliance rate as there are numerous violations of the standard. Health plans are not compliant with the 8010 version of 835. We have not received the promised benefits. CMS failed to enforce standards. CMS closed thousands of valid complaints, and continues to receive hundreds of new complaints monthly, eight years after the 2014 due date for compliance. Unless CMS creates a real enforcement mechanism for transactions that are already adopted as the standard for the past eight years, there are no justification for adopting these costly revisions and new standards going forward. The informal compliance mechanism is a sham that holds billion-dollar health plans immune from punishment and repercussions. It is public knowledge that CMS closes 80 percent of valid complaints as invalid. Mr. Dan Kalwa, the interim Director of CMS Division of National Standards at the CMS Office of Burden Reduction imposes onerous burdens on healthcare providers to file complaints, requiring that an 835 source file is presented within 10 days, and closes complaints without resolution. On the other hand, Mr. Kalwa at the CMS accepts verbal reassurance from health plans that they are compliant. No validation of health plan compliance is required.

We do not support the adoption of any new standards or standards modification until existing standards are meaningfully and fairly reinforced. Thank you.

New York Urologist Specialists

Alex Shteynshlyuger, Director of Urology

Thank you. My name is Dr, Alex Shteynshlyuger, I'm the Director of Urology at New York Urologist Specialists, a sole business proprietor. I'm an advocate of HIPAA Administrative Simplification Requirements and an advocate of national standards. However, we do not support the adoption of X12 proposed standards or standard modifications, as they do not lower the cost of healthcare. They're unwanted and unneeded. The proposed standards are not equitable to healthcare providers. As you are well aware, over 500 comments opposing the X12 proposed addition of card payments information to 835 transactions were received from practicing physicians and medical practices. Card payments means virtual credit cards.

As a Change Healthcare study that we submitted for your review demonstrates, fewer than two percent of healthcare providers would choose to accept card payments as a payment method. And that's before they even know the true cost of accepting card payments. Yet somehow X12 managed to push this proposal through the so-called consensus adoption process. How could a proposal that is unwanted by 98 percent of providers be a consensus? But yet X12, XL7, and WEDI came out advocating for this unwanted, unneeded, and illegal addition to 835 standards. Worse than that, and more shameful, is that XL7 submitted with the comments to NCVHS endorsing the addition of card payments to 835 transactions. I ask you to ask the following question to XL7: what expertise does HL7 have about the 835 transactions or card payments for that matter? Why is HL7 even advocating this change? What is the basis for HL7 recommendations to adopt the addition of card payments to the 835 transactions? It seems that it is part of an organized RICO-type conspiracy, because there are no buyers for card payments. No healthcare provider wants that. It is important to remember that United Healthcare, Optum, Vpay, is a center of unwanted upcount virtual credit cards, with a seat on X12, WEDI, and NCVHS.

Zelis is another center of unwanted credit cards, a board member of WEDI. Change Healthcare, now part of United Healthcare Optum is another vendor of virtual credit cards in partnership with Echo Health and PCM Bank which also holds board seats at WEDI and are represented on X12. I think you will agree that it is very curious that despite the fact that X12, and curiously enough Hl7, vigorously advocate for the adoption of this addition, not a single health plan or vendor came out in support of it. This raises a question: What is the function of standards organizations? How do they manage to propose consensus based recommendations that no-one will publicly endorse, take ownership of, or stand behind? What interests do the standards organization represent? Whose interests? The X12 proposal to add card payments information to 835 is the biggest crime perpetrated by the capture of standards setting organizations by private interests.

Independent Health

Christopher Gracon, Solution Architect

Thank you. My name is Christopher Gracon, I'm with Independent Health, a payer out of western New York, and also our organization member of the X12 and a participant within X12. I would like to argue for, as a payer, the advancement of these standards, including for the additional data fields like UDI, the additional remark codes. But also for the increase of number of diagnosis codes that we'll see, particularly as we need to be able to get more things like SDOH data.

HL7

Alix Goss, Chair of Policy Advisory Committee

This is Alix Goss, the Chair of the Policy Advisory Committee of HL7. I just wanted to clarify that our submission in the request for comment indicated that the X12 835 was updated to support different payment models, including virtual card. The 835 has many front matter revisions to support COV and recoupments. These two developments alone are significant pain points for the industry, and suggested updates will help streamline the use of it in reporting. Overall, we are not necessarily an advocate of virtual cards, but I think we also need to understand that industry has the ability to participate in the consensus-based processing. We encourage all key stakeholders to actively engage in all standards development organizations. Thank you.

Appendix D: List of Acronyms

ACA	Affordable Care Act
ACHP	Alliance of Community Health Plans
ADA	American Dental Association
ADMI	Aspen Dental Management, Inc.
AEOB	advanced explanation of benefits
AHA	American Hospital Association
AHIP	America's Health Insurance Plans
AMA	American Medical Association
ANSI	American National Standards Institute
API	application programming interface
BCBSA	Blue Cross and Blue Shield Association
BCBSNC	Blue Cross and Blue Shield of North Carolina
BCDA	Beneficiary Claims Data API
CA	Claims Acknowledgement
CAA	Consolidated Appropriations Act
CAS	Claim Adjustment Segment
CAQH	Council for Affordable Quality Healthcare, Inc.
C-CDA	Consolidated Clinical Document Architecture
CDC	U.S. Centers for Disease Control and Prevention
CE	covered entity
CFR	Code of Federal Regulation
CMS	Centers for Medicare & Medicaid Services
COB	coordination of benefits
CORE	Committee on Operating Rules for Information Exchange
DFO	Designated Federal Official
DI	Device Identifier
DSMO	Designated Standards Maintenance Organization
EDI	electronic data interchange
EFT	electronic fund transfer
EMR	electronic medical record
FAHIMA	Fellow of the American Health Information Management Association
FDA	U.S. Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
FTE	full-time equivalent
HBMA	Healthcare Billing and Management Association
HL7	Health Level 7 International
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIT	health information technology
ICD-11	International Classification of Diseases 11
IG	implementation guide
IT	information technology
JSON	JavaScipt Object Notation
LOINC	Logical Observation Identifiers Names and Codes
MOA	Medicare Outpatient Adjudication
NCHS	National Center for Health Statistics
NCPDP	National Council for Prescription Drug Programs
NCVHS	National Committee on Vital and Health Statistics
NPRM	Notice of Proposed Rulemaking
NSD	National Standards Developer
NSG	National Standards Group
NUCC	National Uniform Claim Committee
OBRHI	Office of Burden Reduction and Health Informatics

ONC	Office of the National Coordinator for Health Information Technology
ORAE	Operating Rule Authoring Entity
PA	prior authorization
PFS	Physician Fee Schedule
POC	proof-of-concept
RAS	Reason Adjustment Segment
RCM	revenue cycle management
REST	representative state transfer
RFC	Request for Comment
RFI	Request for Interpretation
ROI	return of investment
SDO	Standards Development Organization
SDOH	social determinants of health
SHA-1	secure hash algorithm 1
SHA-2	secure hash algorithm 2
SOAP	Simple Object Access Protocol
STC	service type code
UDI	Unique Device Identifier
USC	U.S. Code
VA	Department of Veterans Affairs
VBC	value-based contract
VBP	value-based payment
WEDI	Workgroup for Electronic Data Interchange
XML	Extensible Markup Language
XSD	XML Schema Definition