Subcommittee on Standards Listening Session on Standardization of Information for Burden Reduction and Post-Pandemic America

Meeting Summary

June 9, 2022

National Committee on Vital and Health Statistics (NCVHS)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

This report was written by NCVHS consultant Martin Sabandal, PhD, and Nancy Tuvesson, MBA, at Rose Li and Associates, Inc., in collaboration with NCVHS members and staff.

NCVHS Members and Staff in Attendance

Jacki Monson, Sutter Health, NCVHS Chair

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

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

Tammy Banks, MBA*

Jamie Ferguson*

Margaret A. Skurka, MS, RHIA, CCS, FAHIMA*

Debra Strickland, MS*

*Member of the NCVHS Subcommittee on Standards

Lorraine Doo, MPH
Lead Staff to the Subcommittee
Senior Policy Advisor
Health Informatics and Interoperability Group
Office of Burden Reduction and Health Informatics
HHS/Centers for Medicare & Medicaid Services (CMS)

Rebecca Hines, MHS
NCVHS Executive Secretary/Designated Federal Officer (DFO)
Health Scientist
National Center for Health Statistics (NCHS)
HHS/Centers for Disease Control and Prevention (CDC)

Sharon Arnold, PhD
Associate Deputy Assistant Secretary for Science and Data Policy
HHS/Office of the Assistant Secretary for Planning and Evaluation (ASPE)

See Appendix A for complete list of meeting participants.

NCVHS—The National Committee on Vital and Health Statistics

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) (42 U.S.C.242k[k]). 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 of health care services, integrated digital health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. The HHS Secretary appoints 16 of the 18 committee members to 4-year terms. Two additional members are selected by Congress. The NCVHS website provides additional information at https://ncvhs.hhs.gov/

Table of Contents

Welcome, Call to Order, Roll Call

To open the meeting on Thursday, June 9, 2022, Executive Secretary Rebecca Hines welcomed Standard Subcommittee members and public attendees and called roll. The Subcommittee members introduced themselves and stated possible conflicts of interest. Jamie Ferguson recused himself from any discussions that pertained to Kaiser Permanente.

The goal of this meeting is for the Standards Subcommittee to obtain input and learn from stakeholders on the draft considerations developed by the Subcommittee pertaining to standards adoption, standards integration, and measuring value. Findings from this Listening Session will be reported by Subcommittee co-chairs Richard Landen and Denise Love during the next Full Committee Meeting, scheduled for July 20-21, 2022.

Agenda Overview and Review of Proceedings

Landen emphasized that the draft considerations are broad, high-level policies—a fundamental step in NCVHS' vision to standardize health and wellness information for all. The five considerations pertain to standards adoption, advancement, integration, collaboration, and value metrics. These considerations do not yet provide detail about the policies' assembly and implementation. Instead, the Subcommittee aims to obtain insights from stakeholders on ways to robustly transform considerations into actionable recommendations for HHS and other relevant agencies. The agenda is organized into three panel sessions, each composed of a brief presentation by the moderator, followed by panelist reactions, and subsequent public comment. A Subcommittee discussion will review considerations and perspectives from all panel sessions. (See Appendix B for Agenda.)

CMS Standards Update

Mary Greene, MD explained that the goal of the Centers for Medicare & Medicaid Services (CMS) Office of Burden Reduction and Health Informatics (OBRHI) is to enable efficiencies across the health care enterprise that include stakeholder engagement, Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification, and interoperability.

Stakeholder Engagement

OBRHI engages with stakeholders to understand and address health care burdens that require health policies or operational solutions. OBRHI is particularly interested in beneficiary experiences of providers that care for underprivileged and underserved communities. Some of these experiences include access to care, health equity, social determinants of health, inequities in technology availability, and data transparency.

HIPAA Administrative Simplification

HIPAA Administrative Simplification seeks to improve efficiency and achieve cost savings across the health industry. OBRHI has been focused on three actions: (1) disseminating rules and regulations, (2) raising awareness of the HIPAA standards exception request process, and (3) bolstering enforcement function. The OBRHI's National Standards Group updates the health industry on current rules and regulations; this information is published twice a year. The exception request process enables organizations to temporarily implement an alternate, modified standard in a controlled setting in order to assess the effectiveness of this proposed standard. OBRHI bolsters its function through a comprehensive compliance review, increased transparency of issues that arise from the review, and civil monetary penalties. Overall, OBRHI believes that compliance enables efficient transactions. All three actions generate data, which are essential to develop, finetune, and standardize regulations.

Interoperability

OBRHI promotes interoperability to advance opportunities for health data exchange. Dr. Greene provided the following updates:

- In May 2020, the CMS interoperability and in-patient access rule was finalized, with policies now in effect. However, Dr. Greene noted that feedback about the lack of technical specifications for the payer-to-payer data exchange requirements are creating challenges including different implementation across the health industry, poor data quality, and increased administration burden.
- In December 2021, OBRHI published a *Federal Register* notice that OBRHI will not enforce the payer-to-payer policy at this time; the policy will be revised in future internal meetings.
- The CMS interoperability and prior authorization proposed rule, published in December 2020, is not finalized and is in a state of flux. OBHRI has incorporated use of application programming interfaces (APIs) with Fast Healthcare Interoperability Resources (FHIR) to enable faster, better, and safer data exchange.
- OBRHI included a Request for Information in the recent release of the In-Patient Prospective Payments rule to solicit public input on how best to leverage the Trusted Exchange Framework and the Common Agreement structure.
- CMS and the Office of the National Coordinator for Health Information Technology (ONC) continue to combat information blocking. The 21st Century Cures Act gives the Department of Health and Human Services (HHS) the authority to institute appropriate disincentives on providers who are found guilty of information blocking.
- On July 19-21, 2022, OBRHI will hold its third annual CMS/Health Level 7 International (HL7) connect-a-thon virtual event. The virtual event will implement HL7 FHIR that support various interoperability use cases in health care.

Greene forecasted the goals of OBRHI for Year 3, which starts on July 1, 2022: collaborate with federal partners such as the United States Core Data for Interoperability (USCDI), upgrade digital quality measures, update provider directories, and continue public health work. Importantly, OBRHI is excited to participate in the Standards Subcommittee and industry stakeholders Listening Sessions.

Greene also offered the Subcommittee four additional considerations: (1) engage with HHS to identify qualitative and quantitative approaches to evaluate standards and develop guidance to appropriate stakeholders for real-world implementation; (2) engage with HHS to determine approaches to identify subject-matter experts, and fund and conduct appropriately timed research related to *International Classification of Diseases* 11th revision (ICD-11); (3) convene subject-matter experts to address specific topics as identified by HHS as significant issues; and (4) expedite adoption of the national HIPAA standards.

Planning for Tomorrow's Administrative Interoperability Landscape

Landen described the evolution of the Convergence Program, ongoing progress, and lessons learned. The Standardization of Information for Burden Reduction and Post-Pandemic America, or Convergence 2.0, is a two-year Subcommittee project. He noted that the Phase 1 interoperability landscape assessment is complete, and steadfast progress is being made in Phase 2, which encompasses analysis, deliberation, report, and potential recommendations. Furthermore, Landen attributed shaping of the predictability roadmap to the following components: (1) development and adoption of industry-driven standards; (2) frequent but smaller updates; (3) enhanced pre-adoption testing; (4) building in value assessments such as return on investment (ROI), burden, and societal benefits; and (5) increased emphasis on enforcement and conformance.

Landen listed the top 10 public comments or themes from the Standards Subcommittee Listening Session in August 2021, in no priority order: (1) test standards, evaluate ROI before federal adoption; (2) adopt health care attachments standard; (3) adopt acknowledgements (HIPAA) standard; (4) publish prior authorization API (HL7) regulation; (5) improve regulatory process for adopting standards under HIPAA; (6) implement a patient education campaign; (7) implement training programs for providers on data exchange to support bidirectional data exchange; (8) identify, implement, and adopt standards for payers and other organizations to exchange data bidirectionally; (9) develop a universal solution for patient matching; and (10) consider expansion of HIPAA to non-covered entities.

Importantly, Landen emphasized that the Subcommittee aims to update, not replace, standards to meet the evolving needs of the health industry and conduct effective stakeholder education for implementation. The Subcommittee must understand HHS priorities to support development of the recommendations.

Panel 1: Advance HIPAA Standards Adoption for Administrative Transactions

Moderator: Rich W. Landen, Subcommittee Co-chair

Panelists: Kirk Anderson, Cambia Health; Terry Cunningham, AMA; Charles Jaffe, HL7; Jocelyn Keegan, Da Vinci Project; John Kelly, Edifecs; Gail Kocher, BCBSA; Patrick Murta, BehaVR; Heather McComas, AMA; Erin O'Rourke, AHIP; Arthur Roosa, HBMA; Cathy Sheppard, X12; Nancy Spector, WEDI; Sarah Tilleman, ADA; April Todd, CAQH CORE; Margaret Weiker, NCPDP

The purpose of this panel was to learn how to update, mobilize, and implement the HIPAA standards to serve business functions and administrative transactions.

Landen explained that in 1996, HIPAA envisioned one universal standard per business function. Initial efforts to perform batchwise transmission and processing of claims were constrained and expensive, but ongoing technological advancements have enabled real-time processing to be a common practice. However, business needs continue to evolve. Value-based, instead of fee-for-service, purchasing has significantly penetrated the market, and clinical data are increasingly integrated into administrative process requirements. Since the Subcommittee's 2021 Listening Session, industry stakeholders have requested an update to the HIPAA standards and have noted the following concerns:

- The HIPAA-adopted standards have not kept pace with industry change.
- Updates to the standards need to be more frequent, smaller, and more predictable.
- Workforce demographics are changing; finding and training workers for older technologies is difficult.
- Broad standards must be custom mapped and programmed by each implementer.

Action Item for Consideration #1

Landen stated that industry input to NCVHS strongly indicated that updates to the HIPAA transaction regulations are not keeping pace with industry need for new data fields/codes. Further, the regulations do not affirmatively encourage industry innovation. Infrequent updates tend to be massive, disruptive, and very costly. How can the process be redesigned and managed to ensure maximum efficiency and value to the industry?

To reduce provider burden and support technological innovation, NCVHS is considering the net value to the health care industry of allowing a strictly limited number (i.e., two or three) of alternative standards for the HIPAA-named business transactions. Much like batch and real-time standards, an app-based standard might co-exist with an electronic data interchange (EDI) standard. For example, an HL7 FHIR standard could be an adopted allowable alternative to an X12 standard. Provider organizations could choose the type of standard that best suits their business needs and workforce (or vendor) constraints. The different standards could be used stand-alone or in conjunction with another type of standard (e.g., a FHIR-based electronic Prior Authorization transaction alone or in conjunction with an X12 278 [authorization] or an X12 275 [attachment] standard).

The Subcommittee proposed the following draft language for Consideration #1: Update relevant HIPAA policies to allow the adoption and use of more than one standard per business function. Health plans would be required to support all adopted standards for their industry sector. Providers could choose which other proposed or adopted standard(s) to conduct with their health plans.

Question and Answer Session

For providers, would availability of choice between an app-based standard and an X12-based standard be of value? Why or why not?

O'Rourke noted that providers value having the flexibility to choose between the modern app-based standard and the traditional X12-based standard. O'Rourke and Cunningham agreed on the need to balance innovation with standardization. Todd confirmed that the health care industry currently can use both app-based and X12-based standards, which has enabled the industry stakeholders and their respective organizations—of different sizes—to advance their interoperable technology.

Spector and Anderson emphasized that providers rely largely on electronic health record (EHR) and practice management system vendors, and thus simply want a solution that works. Spector noted that the availability of multiple standard types for a specific business need may enhance interoperability, which Anderson added may drive innovation. Anderson also stated that providers operate on three principles: (1) undisruptive use of EHRs is paramount, (2) fix prior authorization, and (3) amend prior authorization so that provider investments in technology will translate across all payers regardless of vendors. Anderson noted that Cambia Health has launched a pilot study to allow providers to complete the entire prior authorization process without having to leave their EHR workflow, which has enabled providers to make real-time API calls within the system. This level of real-time integrated experience was possible because providers could choose to use both FHIR APIs and X12 standards.

Tilleman clarified that dentists are open to multiple standards. She remarked that standards were initially developed without the dental industry in mind, which has caused severe revenue implications for practices and has damaged dentist-patient relationships. Dental benefits are limited; thus, patients must accept a cost estimate before accepting a treatment plan. Roosa and McComas expressed concern, however, that a choice and use of multiple standards would be costly and burdensome for small and under-resourced providers. Roosa suggested a mandate for a single standard with other standards remaining optional or negotiable (i.e., providers should only be required to support one standard). McComas proposed institution of strict guardrails that would prohibit payers from contracting with providers that use a specific standard. Finally, Weiker stated that the two standards, X12 837 and National Council for Prescription Drug Programs (NCPDP) Telecommunication Version D-zero, require pharmacies to support the two different standards, forcing them to contract with a third party for data exchange and increasing administrative burden.

For payers, would the increased cost of supporting multiple types of standards be offset by reduced cost of customer service support?

Kocher indicated that payers support use of emerging technologies especially when it makes business sense. She expressed that it is unfair to compare the cost of customer services support to the cost of multiple infrastructures in order to have multiple standards available. Kocher further suggested prohibition of mandatory use of multiple standards by payers. Spector explained that customer support requires payers to understand the cause of their current customer service volume, which has not decreased since implementation of X12. Spector urged payers to confirm whether their providers are using current standards that may address their customer service issues. In addition, Murta suggested consideration of the total cost of ownership and not just the cost of implementation.

For system vendors, would multiple alternative standards increase or decrease the complexity and cost of maintaining all the systems over the next 5-10 years?

Jaffe and Murta noted that the use of multiple alternative standards (e.g., FHIR Open-APIs, X12/FHIR), which are contemporary models, enable the health care industry to keep pace with its growing standards needs. Murta added that these alternatives are complementary and do not replace the traditional standards in place. Using these contemporary models fosters interoperability of models in the same ecosystems and eventually makes health care more affordable, yields better patient care, and produces robust solutions to security and privacy.

Sheppard supported innovation but not de-standardization; multiple alternative standards may allow vendors flexibility to consume standards while improving interoperability. Sheppard suggested that, to accomplish innovation and reduce costs, federal processes should leverage the capacity of standards development organizations (SDOs) to build new functionalities. In contrast, Spector explained that adopting multiple alternative standards will increase complexities and costs (e.g., technology support, software maintenance and licensing fees, help desk, training personnel, regression testing). Moreover, use of numerous standards reinforces the need for third party support to manage the high volume of data. Roosa mentioned that vendors choose standards based on their business needs and not the providers' business needs—underscoring the importance of a single standard. Kelly proposed having one or two standards that establish the lexicon on how to automate businesses from start to end. Federal agencies, such as CMS, must place value creation at the heart of information exchange, thereby protecting providers, payers, and vendors from becoming primary arbiters of value-based decision making.

Action Item for Consideration #2

Landen explained that prior input to NCVHS strongly indicated that updates to the HIPAA transaction regulations are not keeping pace with industry need. Infrequent updates tend to be massive, disruptive, and very costly, leading to the question "How can the process be redesigned and managed to ensure maximum efficiency and value to the industry?" Some industry segments (e.g., long-term and post-acute care providers, specialty and sub-specialty providers) may not be affected by changes made from one standard version to the next, but they are nonetheless required to bear the cost and effort of implementing the new version.

If provider organizations were permitted to determine whether an updated version of a standard is warranted based on their business needs, then those with no business need could avoid a costly and resource-intensive transition process that returns no value. An added benefit of multiple versions would be elimination of the industry-wide date-certain cutover to a new version: industry segments, payers, providers, and their intermediaries would have more flexibility and longer timeframes to move their trading partners onto the new version.

The Subcommittee proposed the following draft language for Consideration #2: Enable HIPAA covered entities to support multiple versions of adopted standards for business functions. This provides an opportunity for innovators to be one version ahead of the current adopted version.

Question and Answer Session

What do you see as the pros and cons of allowing multiple versions? To what extent do you see multiple versions successfully addressing the problem statement components: locally unnecessary updates; avoidance of cost and disruption; easier management of update implementations?

Todd mentioned that vendors routinely maintain more than one version, which encourages innovation. However, Cunningham raised the possibility that allowing multiple versions could create confusion and decrease interoperability efficiency. Several panelists stated that standard versions should be backwards compatible. McComas suggested creation of strict guidelines for the version in process to prevent widespread use of different versions. O'Rourke stated that flexibility offsets burden and encouraged ONC and CMS to work with SDOs and stakeholders to anticipate timeline, costs, and workflow disruptions—an approach, Jaffe added, that requires collaboration and trust.

McComas expressed concern that upgrading to new versions can be costly, slow down business practice, and interfere with patient care. Spector added that cost burden will disproportionately affect smaller provider practices. For example, the app-based transaction may move data between organizations rapidly, but receivers may be limited in their processing capacities. Spector proposed to pilot which version works best, via an elimination process, for smaller and under-resourced practices.

Todd expressed interest about the process for deprecation, determination of the criteria for the lowest version, and management when pieces of data are stored in different versions.

What is the magnitude of the burden of supporting multiple versions of a standard? Are there complexities or barriers that multiple versions pose to healthcare?

Keegan acknowledged inequitable access to technology but believes that modern API-based infrastructure offers a good alternative for providers who are not information technology–rich. Cunningham remarked that success rates may be inconsistent between industry types (i.e., physician providers versus dentists, who have different billing cycles and associations, and experience different price fluctuations). Kocher added that two production environments may be required to support two standard versions, which is not accommodating.

Sheppard forecasted that stakeholders will need to upgrade and incur costs, but smaller and more frequent updates may lessen the associated burdens. Sheppard suggested using industries with successful implementation of multiple standards as models, without strictly following their paths. Murta emphasized that multiple contemporary interoperability is moving in agile fashion and seems to be solving more problems than it is creating.

How many simultaneous versions should be allowed? Why?

Roosa stated that multiple versions spur innovation and improves predictability in technology investment. He suggested determining the duration of support of previous versions rather than focusing on the number of versions.

Action Item for Consideration #3

Landed explained that input received prior to this Listening Session strongly indicates that updates to the HIPAA transaction regulations (e.g., SDO development and/or federal adoption of updated transaction versions) are not keeping pace with industry needs. In addition, the regulations do not aggressively encourage industry innovation.

At the same time, industry has expressed a strong desire that emerging standards be subjected to more rigorous pre-adoption testing. The Subcommittee believes that the Code of Federal Regulations (CFR) 162.940 exception process has been used only twice. Based on its review of the testimony, the Subcommittee hypothesizes that changing 162.940 from an "apply for permission" to a "notify and publish" approach would (1) better support those cutting-edge organizations who want to push the standards farther and faster; (2) provide detailed timely feedback to SDOs; and (3) provide significant value, cost, and impact data that CMS needs in its rule promulgation process.

The Subcommittee proposed the following draft language for Consideration #3: Revise the standards exception process for HIPAA covered entities who apply with the required justification and business case to automatically authorize them without waiting for review. Willing trading partners would automatically be authorized to use different standards for the same transaction and for the same business purpose(s). Reporting on the use of alternative standards would be required of the willing trading partners.

Question and Answer Session

If your organization has considered participation in testing emerging or alternative standards, was 162.940 an impediment or not? Did it ever discourage you from even considering participating in testing?

Anderson explained that testing of emerging standards fosters collaboration with new partners; but, he added that these collaborations slow progress because legal teams must be involved during the trading partner negotiations and agreements. However, the slow progress also provides an opportunity for pilot testing, UX design, and consideration of feedback from providers.

Weiker shared that educating stakeholders on eligibility and identifying specific providers who can apply for the CFR 162.940 exception process are two challenges.

If 162.940 were revised as we described, do you think that would make your attitude toward participating in testing more favorable, less favorable, or unchanged?

Keegan and O'Rourke agreed that balancing standard mandate and standard flexibility can streamline the process, which, in turn, will mitigate administrative burden and make data exchange more predictable. Kocher suggested removal of superfluous information to increase efficiency. Keegan and Spector noted that prodigious amounts of resources and funding will enable more frequent pilot testing and potentially early adoption of standards.

Are there other approaches you would suggest NCVHS consider in lieu of or in addition to changing 162.940?

Todd suggested that NCVHS consider defining expectations for measurement and ensuring that these expectations align with each other and are established before testing. Furthermore, Todd encouraged NCVHS to shorten the timeline for review and completion of the exception process so that providers can quickly receive feedback and address the gaps in their applications. Todd and Cunningham stated that federal resources must support pilot versions to spur innovation.

How might a revised exception process impact the number of versions simultaneously supports (as per Consideration 2)?

McComas noted that the exception process is still new. McComas and Cunningham strongly cautioned against skipping the application review process just to move the pilot forward more rapidly. This review step is valuable because it rigorously evaluates the alternative standard. McComas urged HHS to increase funds for smaller provider practices to participate in testing to ensure that new technology works for all.

Public Comment for Panel 1

Pamela Grosze suggested that NCVHS look for areas that require functionality improvements. For example, clearinghouses facilitate transition of data between trading providers at different states of readiness. Grosze also supported implementation of a sunset date for older standards, which will encourage all providers to adopt newer versions. Moreover, she emphasized that the content of information is critical for interoperability. Providers may not be aware of current available standard versions because they depend on their vendors and are hesitant to invest significant funds. Grosze also expressed that vendors often do not quickly use new versions because there is no business need to do so.

Rajesh Godavarthi supported innovation because people are relocating globally. He also underscored the importance of patient outcomes and needs when considering the transport of consistent data exchange.

Lisa McKeen suggested incorporating an industry-specific floor standard.

Stanley Nachimsom offered a three-tiered approach to incentivize stakeholders to test standards: (1) run a pilot test of a new standard for 6-12 months in a controlled setting; (2) when successful, reclassify it as an option standard; and (3) consider this new standard to be eligible for adoption as the main standard.

Christopher Schaut noted that efforts should be concentrated on ensuring access to the technology capabilities. He also mentioned that providers should only use a single standard even when other standards are allowable.

Panel 2: Address Standards Integration and Collaboration

Moderator: Denise Love, Subcommittee Co-Chair

Panelists: Tom Giannulli, AMA; Julia Skapik, NACHC; Jennifer Stoll, OCHIN; Walter Suarez, Kaiser Permanente; Charles Jaffe, HL7

The purpose of this panel was to learn how to foster standards integration and collaboration between and across the health care system. Information from this panel addresses the heart of Convergence 2.0.

Action Item for Consideration #4

Love explained that data standardization is vital to the success of efforts to address health equity and to improve interoperability among health care organizations or between health care organizations and other entities including public health agencies. The Subcommittee is interested in learning more about the coordination of standards between and across the system, including those pertaining to HIPAA and non-HIPAA data, social service data, and public health data. Challenges include the following:

- Social determinants of health (SDOH) data are not consistently defined across data sources;
- Public health relies on data systems that are often inconsistent across federal, state, and local programs, or not harmonized with clinical care data standards;
- It is difficult to track and understand all of the unique data and reporting standards requirements for organizations across the health care system.

The Subcommittee proposed the following draft language for Consideration #4: Identify options for improved integration of health information standards, including base standards plus standards development organization (SDO) implementation guides, more broadly than at present, and fostering relevant collaboration across HHS Agencies and Offices (e.g., CMS, ONC, CDC, NIH, Indian Health Service [IHS]) include State, Local, Tribal & Territorial Governments.

Question and Answer Session

We have an existing framework of data standards harmonization between HITECH and HIPAA led by ONC and CMS. Can this approach to data harmonization be extended to harmonize data needed in all the other related areas demanding relevant data, or would a different approach speed up and broaden data harmonization, and if so, how should it work?

Giannulli, Skapik, and Stoll concurred that the Subcommittee should first explicitly delineate the "existing framework of data standards harmonization." The health care industry, health equity, and data exchange are transforming rapidly. However, harmonization of data content format is limited. Suarez emphasized the important distinction between harmonization and alignment of data content versus harmonization and alignment of data exchange. Stoll expressed that the high volume of data variation received by the Oregon Community Health Information Network, for example, impairs harmonization efforts, which underscores the need to accelerate standards adoption.

Another major concern is the lack of a centralized governance body to drive a consensus across federal agencies and stakeholders. Suarez suggested that the regulatory framework of HIPAA and Health Information Technology for Economic and Clinical Health (HITECH) perpetuates fragmented interoperability. Skapik noted the need for frequent, rapid cycle improvements, which will require prodigious amounts of resources to generate community participation, demonstrate quantitative success, and stimulate measurable changes within months. Giannulli suggested a focus on the agile model and base standards (e.g., USCDI) and encouraged NCVHS to draw inspiration from the FHIR accelerator program that transformed interoperability from years to months.

With a focus on innovative technologies, how can all areas of standards development, standards adoption, and standards implementation meet demands for timeliness while also improving collaboration and maintaining data quality?

Poor data quality harms the ability to interoperate. Giannulli and Skapik stated that USCDI should specify technical language to enhance interoperability and maintain good data quality. Skapik further indicated that both standards and data content compel proper governance and centralized framework support. Jaffe suggested development of testing that enables translation of a single implementation guide to other accelerators and implementation entities. He also suggested that implementation guides undergo vigorous assessment before implementation within the broader community.

Suarez and Stoll underscored the constraints posed by the regulatory process and associated timelines. For example, ONC advances the process for standards certification, while CMS establishes the functional requirements and regulatory expectations to use these standards. Stoll noted the large disconnect between innovation and the regulatory process, which is prominent in underserved and under-resourced communities. She encouraged NCVHS to increase innovation and standards testing in real-time.

What are the barriers to consistent use of data standards at the federal, state, and local levels, and how could those barriers be mitigated? What policy or operational levers might be appropriate to support change?

Skapik stressed the need for strong, centralized federal governance to ensure adherence to a single data standard. The lack of firm, top-down communication renders local and state communities confused. Stoll urged translation of federal standards and public health monetization to state and local levels to foster alignment and harmonization. Stoll stated that federal leadership must provide proper education, resources, and tools—especially to under-resourced communities—to support change.

Panelists also encouraged greater collaboration between public and private agencies. Skapik advocated for live bidirectional testing of products and contents, certification framework, and robust repositories. Love and Suarez commented that data formats for SDOH and sexual orientation and gender identity (SOGI) are fragmented and varied, especially at the local and state levels. Suarez added, however, that the Digital Bridge Initiative and the Gravity Program facilitate efforts by public health partner organizations to pursue harmonization and alignment for bidirectional data exchange.

Public Comment for Panel 2

Lisa McKeen advocated for uniformity in data classification, criteria, and purpose within each industry.

Panel 3: Measure the Value of Standards

Moderator: Tammy Banks, Subcommittee Member

Panelist: Kirk Anderson, Cambia Health; David Degandi, Cambia Health; Alix Goss, HL7; Ed Hafner, WEDI; Jocelyn Keegan, Da Vinci Project; Erin O'Rourke, AHIP; Lauren Riplinger, AHIMA; Cathy Sheppard, X12; April Todd, CAQH CORE; Margaret Weiker, NCPDP

The purpose of this panel was to learn how to best measure the value of standards implemented in real-world settings.

Degandi presented an example of how both the monetary and nonmonetary value of a standard could be determined through a value guidance framework. This framework spans two phases—ideation and execution—and provides tangible results (e.g., value type, value definition, real-world experiences, value recipient) that are specific to the end users (e.g., standards reviewers, standards organizations, regulators, implementation guide creators, implementers, industry stakeholders). The next steps for this Cambia Health project are to determine (1) where this framework should exist; (2) some form of custodian governance; (3) how the value guidance framework can be used to further encourage organizations to implement standards-based solutions; and (4) how the framework can remain open to future content contribution and expansion. Degandi noted that this value guidance framework enables comparability of different standards across different use cases.

Action Item for Consideration #5

Banks explained that industry input to NCVHS strongly indicated a need for publication of standardized ROI and non-monetary value metrics and methodologies. A publicly available guidance framework will assist industry stakeholders in appropriate assessment of emerging and revised standards. HHS has requested SDOs and Operating Rule Authoring Entities to provide ROI metrics for new and updated standards and operating rules that are being considered for adoption under HIPAA.

The Subcommittee proposed the following draft language for Consideration #5: Develop and publish a guidance framework with recommended definitions, metrics, templates, and pilot test procedures, including methods for reporting on standards readiness, standards cost, results of real-world testing, and metrics essential for evaluation of standards. This would enable better measurement, management, and understanding of standards maturity, standards implementation success, and the net value of standards.

Question and Answer Session

Are the business needs captured or understood for evaluation of standards across the industry?

Anderson stressed the importance of monitoring activity, tracking the parties involved, and measuring results during the early stages of a complex innovation project. Hafner urged stakeholders to voice their needs regarding establishment of net value (e.g., cost savings, business value propositions). The development and adoption of new technology standards that create uniformity are paramount. However, Riplinger noted that new standards often favor larger organizations, are not rigorously evaluated for real-world experiences, and fail to consider the implementation pathway prior to mandated usage. O'Rourke emphasized that small providers are resource limited. This constraint coupled with the lack of ROI guidance hinders their participation in pilot studies of standards testing.

Are the guidance framework components sufficient to measure and manage emerging and revised standards?

Several panelists commended Cambia Health's ongoing development of an ROI calculator. However, Degandi and Goss mentioned that the framework requires effective user-interface. Keegan suggested creation of common terminology across the industry for the definitions and use of values (e.g., accuracy, efficiency, security), which will

drive widespread use, implementation, and investment. Moreover, Goss emphasized the need for greater governance leadership to mitigate administrative burden.

Hafner and Todd stated that standards testing should address the potential effects on business need and workflow. Furthermore, Todd emphasized that testing must be scalable and comparative—focusing on the three major components of cost, volume, and time. Hafner and Sheppard commented that unique metrics associated with the pilot standard should be developed before testing (i.e., new use case through real-world testing to identify ROI and missing elements). Sheppard reiterated that large implementation steps are costly, are intimidating for the industry, and may invite disastrous errors.

O'Rourke remarked that the guidance framework must recognize and align the changes to standards and operating rules in proportion to the anticipated size of change—rather than seek a one-size-fits-all solution. Increased use of common templates and metrics can expedite the process and allow organizations to conduct testing more frequently. Riplinger suggested that the guidance framework require that the standards (1) demonstrate that they engage end users (e.g., providers, health IT personnel) throughout the standards development process; (2) support end user engagement to maximize their ability to provide effective input; (3) mandate commitment and active participation by end users; and (4) assure that SDOs will not dismiss end user's input.

Weiker raised the possibility of using two different frameworks: one to address the existing standard and another to address modifications against that standard. She noted the importance of determining the value of transaction implementation versus the value of upgrading technology with defined modifications.

How could a guidance framework be created and maintained, i.e., how do you see the alternatives for the public sector or private sector?

Panelists concurred that a framework must be created and maintained collaboratively. Degandi proposed establishment of a custodian group to ensure the content's usability, which must be normalized to conform with framework specifications; results and value will depend on industry contribution. Goss articulated that abundant, yet targeted resources will enhance the breadth and depth of implementation and supplemental guidance. She suggested, for example, that NCVHS start with business requirements that drive the entire SDO process (i.e., proven, tested, validated, matured, and deployed).

Riplinger suggested establishing metrics in advance by creating a vetting process of standards and alternative standards, and by comprehensive public reporting of standards testing. Furthermore, she advised that federal governance must support the participation of underserved or marginalized groups and ensure that representation of end users is proportional to participation of all entities.

If a guidance framework was created, how do you envision the collection and reporting of metrics would occur to streamline the evaluation of standards – regulatory and nonregulatory?

Hafner stated that efforts to create a framework should be driven by partnerships between the public and private sector and supported by CMS regulation. He encouraged NCVHS to hold regular Listening Sessions with SDOs and to invite public testimony aimed at evaluating these standards and well-researched ROI studies. Goss remarked that, because the framework will engage different organizations, there will be resistance and thus the need for strong governance and support (i.e., the 21st Century Cures Act needs to harmonize with HIPAA). Riplinger concurred that standards that have not completed robust real-world testing and whose comprehensive reports are not public are not suitable for mandated use for health policy.

O'Rourke stressed that qualitative and quantitative measures are imperative to understanding the ROI of standards; some standards may immediately demonstrate reduction in cost, while other standards may first enhance patient care and staff satisfaction. Weiker raised several questions about quantifying standards: How will they be scored? What will the scores infer? What will be scoring impact on industry?

Public Comment for Panel 3

Julia Skapik urged NCVHS to consider the value proposition as important to end users. She also suggested that NCVHS foster collaborations between regulatory organizations and health care providers, by involving end users throughout the standards development process.

Stanley Nachimson noted difficulty experienced in distinguishing between the groups that invest in standards implementation and those that reap benefits when standards are implemented. NCVHS needs to specify which organizations pay versus who benefits.

Discussion

Landen outlined next steps for the Subcommittee:

- Review discussion from Listening Session and consider any updates to the considerations;
- Continue discussions during internal biweekly meetings; and
- Present outcomes to Full Committee as recommendations to HHS Secretary.

Panel 1: Advance HIPAA Standards Adoption for Administrative Transactions

Landen noted the interest in, although no clear commitment to, having multiple standards in effect simultaneously. One major concern relates to proper management of multiple standards. Regardless, NCVHS recommendations must ensure uniform data content across all SDOs, different technologies, and distinct standards and versions. In addition, Strickland underscored the many strong suggestions to establish backwards compatibility, guardrails, and sunsets for utilizing multiple standards or versions. Ferguson added that several comments received about the multiple standards approach frequently addressed a hypothetical environment, which did not address the question asked.

Landen highlighted the prominent discussion regarding willing trading partners, particularly about the potential imbalanced power distribution in favor of big health plans over small providers. However, Ferguson explained that "legacy organizations" would generally not recommend change nor see problems, and that "non-legacy organizations" highlighted opportunities for improvement, efficiencies, and effectiveness. The Subcommittee must deeply investigate the power distribution and identify ways to provide protections for parties with weaker negotiating positions.

Landen and Strickland highlighted a general conclusion that the exception process is not broken. Mr. Landen questioned whether investment in additional tools is required because the main objective is to change the structure to encourage innovation; the Subcommittee must revisit this issue.

Panel 2: Address Standards Integration and Collaboration

Doo highlighted the many comments about the fundamental requirement for good quality data. Love emphasized the fragmentation of data content and structure (e.g., emerging data elements, SOGI, SODH) and the rapid need for new standards. USCDI fails to address this fragmentation robustly; thus, additional technology standards are required to serve all user types across the national and local levels. Ferguson encouraged NCVHS to recommend an outreach plan to encourage state public health departments and agencies to use other federally supported standards (e.g., Gravity Program), to foster centralized federal governance and leadership.

Hines offered that several comments related to Digital Bridge's role in moving the field toward standardized elements for SODH and SOGI. She added that the Subcommittee could seek expertise and input (e.g., regulatory process, data harmonization, data alignment) from Digital Bridge, whose Chair is also Chair of the NCHS Board of Scientific Counselors. Hines noted that this expertise could help to mitigate complexity and prevent the scenario of 50 different state solutions. Skurka expressed the need for deeper discussions about SDOH and the associated documentation.

Panel 3: Measure the Value of Standards

Banks suggested consideration of all perspectives that arise from emerging standards. Standards are needed, but the processes to address how standards should be developed continue to evolve.

Landen noted the end user dichotomy: some end users are subject matter and technical experts and therefore should be involved throughout the standards development process, while others are primarily interested in the end result. The Subcommittee must reconcile these two perspectives.

Landen also noted that no silver bullet can address all ROI permutations for smaller and larger organizations. However, the tyranny of the majority must not prevail (i.e., excessive costs forcing small practices out of business), nor can the tyranny of the minority (i.e., the ability of certain smaller organizations to prevent the adoption of new standards that could produce national-level benefits). He stressed the importance of considering the potential benefits and value relative to the resources invested to update modern infrastructure.

Public Comment

Hines and Landen opened the floor to public attendees and panelist speakers for additional comments pertaining to the five drafted considerations.

Skapik (panelist) provided the following comments:

- Limitations on SDOH include the proliferation of data splintering and minimal technology investment.
- Gravity appears to be an encyclopedia rather than a robust standards implementation.
- Federal agencies should hold meetings to discuss the framework referenced in Panel 2 because they fail to recognize the need for a matrix approach to standards.
- Time should be devoted time to identify proper federal governance, address the values and requirements of that organization of standards in general, and address to accelerate the pace such that it leads to increased data quality while reducing implementation burden.

Donna Campbell (public attendee) provided the following comments:

- Identify common content requirements when introducing formats of like-capability (i.e., prior authorization, X12 versus DaVinci) so as not to disadvantage either side.
- Improve maintenance request capabilities so that all organizations are at the table when requesting new functionality, data, or new specifications.
- Agilify the legislative and regulatory process by delimiting local and state requirements.
- Regulate and require time limit on standards version development timelines.
- Enforce use of standards.
- Resurface Strategic National Implementation Process (SNIP) validation to enforce SNIP levels inclusive of code sets.
- Minimize duality of standards versions to avoid disruption and costly operational period.
- Subsidize and incentivize the proof-of-concept process to collect real-world data and prove ROI.

Closing Remarks and Adjournment

Mr. Landen invited additional written public comments to be sent to the Subcommittee before June 24 (see Appendix C).

Mr. Landen thanked all speakers, moderators, and attendees for their participation and adjourned the Listening Session.

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

Jacki Monson, JD, Chair
National Committee on Vital and Health Statistics

October 13, 2022
Date

Appendix A: Meeting Participants

Invited Panelist Speakers

Kirk Anderson, Chief Technology Officer, Cambia Health Solutions, and Chair of Da Vinci Project Steering Committee, Health Level 7 International

Terry Cunningham, Director of Administrative Simplification Policy, American Hospital Association

David Degandi, Senior Interoperability Strategist, Cambia Health Solutions

Tom Giannulli, Chief Medical Information Officer of Integrated Health Model Initiative, American Medical Association

Alix Goss, Chair of Policy Advisory Committee, Health Level 7 International

Ed Hafner, Board Chair-Elect, Workgroup for Electronic Data Interchange

Charles Jaffe, Chief Executive Officer, Health Level 7 International

Jocelyn Keegan, Program Manager of Da Vinci Project, Point-of-Care Partners

John Kelly, Principal Business Advisor, Edifecs

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

Heather McComas, Director of Administrative Simplification Policy, American Medical Association

Patrick Murta, Chief Platform Architect, BehaVR

Erin O'Rourke, Executive Director of Clinical Performance and Transformation, America's Health Insurance Plans

Lauren Riplinger, Vice President of Policy and Government Affairs, American Health Information Management Association

Arthur Roosa, Chief Executive Officer, SyMed Corporation, and Member, Healthcare Billing and Management Association

Cathy Sheppard, Executive Director, X12

Julia Skapik, Medical Director for Informatics, National Association of Community Health Centers

Nancy Spector, Board Chair, Workgroup for Electronic Data Interchange

Jennifer Stoll, Executive Vice President of External Affairs, Oregon Community Health Information Network

Walter Suarez, Executive Director of Health IT Strategy and Policy, Kaiser Permanente

Sarah Tilleman, Senior Manager of Credentialing and Third Party Payer Advocacy, American Dental Association

April Todd, Senior Vice President of Committee on Operating Rules for Information Exchange, Council for Affordable Quality Healthcare

Margaret Weiker, Director of Standards Development, National Council Prescription Drug Programs

Public Attendees on Zoom

Monica Andrews, WPS Health Solutions
Daphne Asteriadis, CAQH CORE
Teresa Autery, TIBCO Software Inc.
Anmer Ayala, ONC, HHS
Pooja Babbrah, Point-of-Care Partners
Alexander Baker, HHS
Donna Baker-Miller, MCG Health
Michelle Barry, Availity, LLC
Gary Beatty, American Specialty Health
Ryan Bell, McLaren Health Plan
Tony Benson, Blue Cross and Blue Shield of Alabama
Sue Bowman, AHIMA
Robert Bowman, CAQH
Kim Boyd, Calibrate
Samantha Burch, OCHIN
Michael Cabral, Peraton
Laura Caldwell, General Dynamics
Donna Campbell, Health Care Service Corporation
Bart Carlson, Azuba Corporation
Lynn Chapple, Optum
Kristol Chism, Change Healthcare
Ellen Clewett, Illinois Public Health Institute
Branden Cordeiro, Capitol Associates, Inc.
Jessica Czulewicz, CMS
John D'Amore, More Infomatics
Mike Denison, Change Healthcare
Tuyet DesJean, AMA
Debra Dixon, California Department of Health Care Services
Mary Dooley, Deloitte
Dawn Duchek, TriZetto Provider Solutions
Eric Edwards, Ohio Department of Medicaid
Crystal Ewing, Waystar
Bettina Experton, Humetrix
Bill Finerfrock, HBMA
Andrew Flood, General Dynamics Information Technology
Rachel Foerster, Rachel Foerster & Associates Ltd.
Evert Ford, UnitedHealth Group
Diana Fuller, Michigan Medicaid
Ticia Gerber, HL7
Christine Gerhardt, CMS OBRHI
Debra Gilliam, CASET Associates, Ltd.
Rajesh Godavarthi, MCG Health
Michael Gould, BCBSA
Tina Greene, Enlyte/Mitchell
Eric Grindstaff, Allscripts Payerpath
Pamela Grosze, PNC Bank
Freida Hall, Quest Diagnostics
Nick Hatt, Redox, Inc.
David Haugen, Minnesota Department of Health
Laurel Havenner, CompuGroup Medical

William Hayes, Computer Programs and Systems, Inc.
Geanelle Herring, CMS
Barbara Hillock, Harris
Hong Huang, Cambia Health Solutions
Susan Jenkins, HHS
Jeff Jennings, California Department of Health Care Services
Daniel Kalwa, CMS
Beth Karpiak, CMS
Thomas Kessler, CMS
Jessica Kilgore, The SSI Group
Katie Knapp, Department of Veteran Affairs
Boyd Kreeck, Utah Health Information Network
Patrice Kuppe, Surescripts
Ogi Kwon, R1 RCM, Inc.
Susan Langford, Blue Cross and Blue Shield of Tennessee
Celine Lefebvre, AMA
Robbyn Lessig, Clinithink
Jay Lindsey, The SSI Group
Tim Lopez, Blue Cross and Blue Shield of Minnesota
Codrin Lungu, National Institute of Neurological Disorders and Stroke
Deb McCachern, Change Healthcare
Lisa McKeen, New York General Dynamics Information Technology
Michelle Miles, California Department of Public Health
Dana Moore, California Department of Public Health
Devaiah Muccatira, North Dakota Department of Health
Alexandra Mugge, CMS
Gwen Mustaf, CDC, NCHS
Stanley Nachimson, Nachimsom Advisors, LLC
Shilesh Nair, General Dynamics Information Technology
Jean Narcisi, ADA
Isserman Noah, CMS
Robin Omata, Kaiser Permanente
Swapna Pachauri, Medical Group Management Association
Adam Pellillo, CMS
Michael Pettit, New York State Department of Health
Alexander Pirhalla, UnitedHealth Group
Cathy Plattner, Kaiser Permanente
Brian Poteet, Blue Cross and Blue Shield of Tennessee
Andrea Preisler, AHA
Richard Price, AdvaMed
Don Quackenbush, TriZetto Provider Solutions
Nick Radov, UnitedHealth Group
Molly Reese, AMA
Matt Reid, AMA
Matt Reiter, Capitol Associates, Inc.
Margaret Richardson, Centene Corporation
Scott Robertson, Kaiser Permanente
Tara Rose, Optum
Rosalyn Ryan, HealthFOX US
Christopher Schaut, Epic Integrations
Meredith Schram, Ohio Department of Medicaid

Avinash Shanbhang, ONC, HHS
Nichole Small, Ohio Department of Medicaid
Keli Smith, Ohio Department of Medicaid
Charles Stellar, WEDI
LeeAnn Stember, NCPDP
Merri Stine, Aetna
Sandra Stuart, Kaiser Permanente
Scott Stuewe, DirectTrust
Tricia Stuto, General Dynamics Information Technology
Emily TenEyck, CAQH CORE
Robert Tennant, WEDI
Amber Thomas, R1 RCM, Inc.
Tracey Tillman, The SSI Group
Susan Titterington, Alpha II, LLC
Andrew Tomlinson, AHIMA
Rita Torkzadeh, District of Columbia Department of Health
Griselle Torres, Illinois Department of Public Health
Jennifer Travis, The SSI Group
Elizabeth Tremblay, Peraton
Amy Turney, Blue Cross and Blue Shield of Michigan
Sheryl Turney, Anthem
Shay Vaughan, Allscripts
C Veverka, KL&A
Pat Waller, Cambia Health Solutions
Erin Weber, CAQH CORE
Patricia Wijtyk, Cognizant
Stacie Wilcox, Change Healthcare
Mary Winter, PrimeWest Health
Chantal Worzala, Alazro Consulting

Appendix B: Agenda

National Committee on Vital and Health Statistics (NCVHS)

Subcommittee on Standards Listening Session on
Standardization of Information for Burden Reduction and Post Pandemic America

Thursday, June 9, 2022

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.	**Agenda Overview & Review of Proceedings**	Rich Landen and Denise Love, Co-chairs Subcommittee on Standards
10:10 a.m.	**CMS Standards Update**	Mary Greene, Director Office of Burden Reduction and Health Informatics, CMS
10:30 a.m.	**Planning for Tomorrow's Administrative Interoperability Landscape** Convergence 2.0 Workplan Update & Timeline	Rich Landen and Denise Love, Co-chairs
11:00 a.m.	**Panel 1: Advance HIPAA Standards Adoption for Administrative Transactions** **Action Item for Consideration #1:** Update relevant HIPAA policies to allow the adoption and use of more than one standard per business function. **Action Item for Consideration #2:** Enable HIPAA covered entities to support multiple versions of adopted standards for business functions. **Action Item for Consideration #3:** Revise the standards exception process for HIPAA covered entities who submit an application with the required justification and business case to automatically authorize them without waiting for review.	Moderator: Rich Landen, Co-chair
12:30 p.m.	**Public Comment for Panel 1**	Rebecca Hines NCVHS Executive Secretary/DFO
1:00 p.m.	**Break**	

Time	Panel	Participants
1:30 p.m.	**Panel 2: Address Standards Integration and Collaboration** **Action Item for Consideration #4:** Identify options for improved integration of health information standards, including base standards plus standards development organization (SDO) implementation guides, more broadly than at present, and fostering relevant collaboration across HHS Agencies and Offices (e.g., CMS, ONC, CDC, NIH, IHS) including State, Local, Tribal & Territorial Governments.	Moderator: Denise Love, Co-chair
2:20 p.m.	**Public Comment for Panel 2**	Rebecca Hines NCVHS Executive Secretary/DFO
2:30 p.m.	**Panel 3: Measure the Value of Standards** **Action Item for Consideration #5:** Develop and publish a guidance framework with recommended definitions, metrics, templates, and pilot test procedures, including methods for reporting on standards readiness, standards costs, results of real-world testing and metrics essential for evaluation of standards, to enable better measurement, management, and understanding of standards maturity, standards implementation success, and the net value of standards.	Moderator: Tammy Banks, Subcommittee on Standards, NCVHS
3:30 p.m.	**Public Comment for Panel 3**	Rebecca Hines NCVHS Executive Secretary/DFO
3:45 p.m.	**Break**	
4:00 p.m.	**Discussion**	NCHVS Members
5:00 p.m.	**Public Comment**	Rebecca Hines NCVHS Executive Secretary/DFO
5:15 p.m.	**Closing Remarks and Adjournment**	Rich Landen and Denise Love Co-chairs, Subcommittee on Standards

Appendix C: Written Public Comments

AHIP

Danielle A. Lloyd, Senior Vice President, Private Market Innovations & Quality Initiatives

Patients deserve high-quality, equitable, and affordable care, with everyone working together. This requires safe, efficient sharing of data that patients, their care teams, and their health insurance providers need to make informed health care decisions. AHIP[1] appreciates the opportunity to provide input to the Subcommittee as you discuss potential recommendations on to support the "Standardization of Information for Burden Reduction and Post-Pandemic America" (Convergence 2.0).

Our member health insurance providers are committed to offering coverage for consumer-centric care that helps maintain wellness and improve health outcomes. Data and technology are integral to our members' offerings, allowing them to furnish patients and their doctors with the information they need to support care and make informed health care decisions. Health Information Technology (HIT) is rapidly evolving, and we appreciate the need to ensure data standards do not hamper efforts to improve the flow of information and to reduce the burden of current processes on all stakeholders.

However, we must also balance innovation with the value of standardization and the increased burden of maintaining and using multiple standards and versions. We urge the Subcommittee to preserve what is working in the current standards while allowing stakeholders the flexibility needed to innovate and meet the transparency and interoperability requirements outlined by the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC). With that perspective in mind, we are pleased to share the following feedback on the Subcommittee's draft considerations.

Consideration 1: Standards adoption policy

Update relevant HIPAA policies to allow the adoption and use of more than one standard per business function. Health plans would be required to support all adopted standards for their industry sector. Providers could choose which other proposed/adopted standard or standards to conduct with their health plans.

AHIP Response:

We appreciate the recognition that technology is changing. However, we must balance innovation with consistency and ensure that stakeholders are not subject to undue burdens caused by requirements to support multiple standards. We urge the Subcommittee to look at these policies on a use case by case basis to determine if the use of multiple standards should be permitted and consider transition policies so that multiple standards would only be required on a temporary basis. Such policies would allow the industry to maintain what is working and support innovation when improvement is needed.

We appreciate the flexibility that permitting multiple standards could provide and recognize that such a policy would allow health insurance the ability to solve complex business cases. However, we must balance these factors with the burden of implementing and maintaining multiple standards. We see a key difference between allowing the use of multiple standards and requiring health insurance providers to support multiple standards. We urge the Subcommittee to revise this Consideration to make it voluntary for a health insurance provider to support multiple standards given the significant resources this will require. We also ask the Subcommittee to consider the number of standards that would be supported. There is a significant difference in the resources required and associated costs to support a discrete number of standards (e.g.; one or two) as opposed to supporting multiple standards. We'd also encourage the Committee to explore ways to distribute the burden of supporting multiple standards across the industry rather than focusing the burden on health insurance providers.

[1] AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone.

We encourage the Subcommittee to consider the method of transaction (e.g.; document-based, controlled-access, web-based) first and then define a standard for each method available. Such a process could allow the Subcommittee to consider one standard for each method. We strongly urge the Subcommittee to avoid developing policies that would force data to be interpreted back and forth between different standards because of regulatory requirements. For example, health insurance providers are actively working to meet the potential requirements of the expected revised CMS Interoperability and Prior Authorization rule. However, organizations that wish to pursue a Fast Healthcare Interoperability Resources (FHIR)-based solution but do not have an exemption are required to temporarily transfer the data to the X12 278 standard. We strongly support policies that would allow those who choose to do so to implement FHIR-based solutions end-to-end.

Finally, we would emphasize the need to consider interoperability and consistent data regardless of which standard is used. This will be essential for both administrative and clinical data. We appreciate current efforts to crosswalk the data content between X12 and the DaVinci Project as well as the coordination of content with National Council for Prescription Drug Programs (NCPDP). These efforts will be essential to ensure consistent data for information exchanges.

Consideration 2: Standards adoption policy

Enable HIPAA covered entities to support multiple versions of adopted standards for business functions. This provides an opportunity for innovators to be one version ahead of the current adopted version.

AHIP Response:

As with Consideration 1, we would ask the Subcommittee to consider allowing multiple versions of adopted standards on a use case by use case basis and to consider how many versions an organization would be required to support. Again, we urge the Subcommittee to allow flexibility as organizations will have varying abilities and infrastructures to implement updates. We ask the Subcommittee to consider a process that allows innovation but balances it with the resources required to update and the potential burden. Again, maintaining a smaller, discrete number of versions for specific functions is a different ask than maintaining multiple versions. This is another area where the Subcommittee would first consider the transaction method and then determine if multiple versions should be supported.

We strongly encourage the Subcommittee to ensure policies support interoperability and note that backwards compatibility will be essential so these policies will work for all organizations. We encourage the Subcommittee to consider CMS and ONC processes to name standards and versions as well as to work with CMS, ONC, and the Standards Development Organizations (SDOs) to develop transition plans when versions are updated. Clear and consistent plans would allow organization time to plan for updates and the associated costs and potential disruptions to ensure smooth transitions between versions.

Consideration 3: Standards exception process

Revise the standards exception process for HIPAA covered entities who submit an application with the required justification and business case to automatically authorize them without waiting for review. Willing trading partners would automatically be authorized to use different standards for the same transaction and for the same business purpose(s). Reporting on the use of alternative standards would be required of the willing trading partners

AHIP Response:

We appreciate the Subcommittee stating that the exception process would be between willing trading partners. As noted in our responses above, implementing alternative standards can be burdensome and organizations will have differing capacities and resources to make such changes. A voluntary, opt-in process allows organizations that are prepared to innovate to do so while respecting the longer lead-time that some organizations may require. We firmly believe there are key differences between mandating the support of multiple standards and allowing the flexibility to support innovation.

We support the Subcommittee's vision to simplify the exception process. Managing regulatory provisions such as 45 CFR 162.940 through an exception process imposes undue process burdens (e.g.; applying, seeking approval, documenting, etc.) that can be onerous and unnecessary. The regulation should instead be open and permissive to support innovation.

It is important that the Subcommittee work quickly to recommend simplification of the exemption process as both technology and the related standards are changing rapidly. Moreover, the regulatory environment continues to change, and health insurance providers are facing new requirements under the advanced Explanation of Benefits (AEOB) policy. Many health insurance providers had assumed this would be done under the X12 standards; however, health insurance providers are also exploring building these tools in FHIR. We must also ensure that the regulations created by the expected revision of the CMS Interoperability and Prior Authorization rule are feasible. When implementing such policies, we currently face a tension between a slow and stringent process to develop and update standards with new regulations with accelerated implementation dates. When that happens, health insurance providers are forced to build workaround that cost extra time and money. Simplifying the exemption process would allow organizations to avoid such issues.

Consideration 4: Integration

Identify options for improved integration of health information standards, including base standards plus standards development organization (SDO) implementation guides, more broadly than at present, and fostering relevant collaboration across HHS Agencies and Offices (e.g., CMS, ONC, CDC, NIH, IHS) including State, Local, Tribal & Territorial Governments.

AHIP Response:

The COVID-19 pandemic has shown the need to integrate data from multiple sources. We appreciate the Subcommittee's efforts to develop strategies to foster collaboration to support public health. Better data flow will allow the healthcare system to adapt and respond to future emergencies. We encourage the Subcommittee to consider ways that improved integration of health information standards could support health equity and provide better data to help address social determinants of health.

Consideration 5: Value Metrics

Develop and publish a guidance framework with recommended definitions, metrics, templates, and pilot test procedures, including methods for reporting on standards readiness, standards costs, results of real-world testing and metrics essential for evaluation of standards. This would enable better measurement, management, and understanding of standards maturity, standards implementation success, and the net value of standards.

AHIP Response:

We appreciate the Subcommittee's work to consider how metrics to evaluate standards could be implemented in a uniform and consistent manner. We agree that the use of consistent definitions and metrics could allow better measurement and produce more accurate and actionable data on the standards. However, we request that the Subcommittee provide clarification on what its vision for a guidance framework for value metrics. While we support the concept of a guidance framework in theory, additional information is needed on what metrics would be included, which entities would be accountable, and how data to support the metrics would be captured and collected. AHIP strongly supports ensuring all stakeholders derive value from the standards and additional information on the Subcommittee's vision for a guidance framework and how uniform measurement would be implemented would inform better stakeholder input.

AHIP and its members look forward to working with the NCVHS Standards Subcommittee to continue to advance interoperability to empower patients and support patient care. If you have any questions, please contact me at dlloyd@ahip.org.

Donna Campbell

Industry subject matter expert and not on behalf of HCSC

A few observations and points I hope will be considered when moving to the next steps:

I feel there are several gaps that should be addressed as we've experienced years of adoption activity with HIPAA, Administrative Simplification, Interoperability, each of which, understandably, has occurred at varying points in time which does not allow for alignment, however, because each is somewhat siloed and overlap to some degree, my observations below have been take aways that I have captured over the course of the last 20 years, since 4010 was mandated to today's date where we're discussing the possibilities of building future state protocols for a number of business capabilities that are in place today.

Some of my findings over the last several years, mostly since 5010 was mandated for use but more recently with the direction of including DaVinci/FHIR specifications and interoperability needs: With the concept of different standards, such as FHIR/DaVinci and X12 HIPAA and non-HIPAA TR3s:

A need exists that would identify common content/data requirements if introducing multiple formats of like capability (e.g., PAs in X12 vs. DaVinci) so as not to disadvantage either side, incent the use of one format over the other, and level the support/service/operational activities playing field. When one specification can provide more data ingestion/capability than another naturally the migration to the more sophisticated protocol will prevail. This should not become a competition with who can make the most robust, verbose, or convoluted specification.

A need exists to improve the maintenance request cycle process-so there's one avenue to submit requests for changes and those changes can be vetted and agreed to take shape, where all organizations are at the table when such requests for new functionality, data or new specifications are needed. This would allow all to have the ability to update their respective specifications via their standards development processes consistently and collaboratively to not disadvantage one format over the others. Furthermore, there seems to be a lack of representation by organizations to look ahead and participate by making the requests for needed changes. I see/hear a lot of people taking about the lag with the X12 TR3s but also do not see the same organizations generating discussions at the onset of the maintenance request cycles, thus putting the development in the hands of the few who represent their own needs. More industry involvement is needed and must not be one-sided with respect to format. There should be a streamlined protocol for maintenance representing "business needs" and the standards organizations can address those needs on a case-by-case basis, uniformly. This then allows the SDO's to share their feedback and generate conversation where discrepancies or deviations may be needed. It's my opinion that X12 has been "beaten" up and accused of taking such a too much time to produce their specs, when in fact, the development process in every SDO are not any more speedy in producing their documents. If we try to race the clock we either cannot entertain the same number of changes, or we have to announce deadlines for change requests with enough time given to allow SDOs to analyze and make said changes. Therefore, it would behoove the industry as a whole to have a more "managed" change process, governed by regulation, on a more frequent and yet somewhat fastidious cycle so as to anticipate change and work the timeline backwards.

Need to "agilify" (as in make more agile) the legislative and regulatory process; The development of specifications such as the HIPAA named TR3s has continued for the last decade, despite being required to only support 5010, there's been several published versions. These versions should be exposed via routine and regular implementation & adoption timelines so as not to force providers, payers, and vendors to seek alternative solutions. This can be done by putting limits on the state requirements that sometimes impede the ability to be progressive (i.e., the Texas House Bill 3459, where there is prior authorization exemption requirements for certain care categories which seems to be contrary to the required use of the 278 for the purpose of prior authorization). Agility in regulation adoption can offset the lag and stagnancy of current day specifications and will then possibly negate the need for an exception process.

It's evident there's also a need to regulate and require a time limit on version development timelines. The updates to SDO specifications should be provided annually, so that the future of business capabilities is not held hostage for a decade, there will only be a short time between the business need ideation to the publication of solution capability, allowing for the faster, more flexible support of the healthcare footprints. This then too negates the need to be backwards compatible, as there will be a building on the current structure. If something is vastly

different, it would be recommended that a “new” specification be drafted, proven via a conceptual trial before proposed for adoption and key performance indicators of success be used to determine ROI.

A need exists to enforce use of the standards. It’s disappointing, but there are several in the healthcare industry still supporting 4010.

A need exists to resurface the idea of SNIP validation to enforce the SNIP levels —inclusive of code sets. This can promote the standardized usability of the transactions and will allow for uniformity when implementing.

A need exists to minimize the duality of versions to avoid disruption/costly implementation and operational periods. Mentioned several times by the panelists; supporting multiple formats, and then recognizing there will be updates via versioning to those formats, such as a version 5010 to 8020 then possibly one day to 9040 migration, and if required to support a FHIR specification, could be a Release 4 to Release 5 to Release 6, all with varying timelines, and complexities will increase the costs, reduce the efficiencies, and require multiple testing platforms to support in parallel. At the end of the day, if the data is the same (via my first point above) it will prove to be a “content vs format” discussion and if one does not offer more than the other, it can be determined which best fits the use case (mobile services, vs. portal services, file based vs. real-time, clinical vs. administrative, provider/payer vs member/provider vs. member/payer vs. provider/provider vs. payer/payer focuses). When it’s all said and done, implementors will still have proprietary applications within their organizations building the data ingestion/consumption capabilities, and regardless of the specification being an API or an implementation guide specification, there is still a lot of work within the organizations to transform and transport data in a manner that can be interpreted and acted upon, with little to no intervention. The API focus and the EDI standards, again, at the end of the day, are all generally electronic data interchange, with scalability and flexibility.

A need exists to subsidize/incentivize the proof-of-concept process to garner the ability to collect real data and prove ROI. Many organizations have business strategies that build on membership growth, self-service capabilities, artificial intelligence, etc. These organizations are looking for ways to improve their capability matrices and provide value add functionality via projects. When requiring standardization whether it be FHIR or X12, it’s effort and time that does not seemingly have a value-add cost benefit to it. There are few organizations that can and will pursue, voluntarily, migrations to new versions or different formats without legislation demand it so. With that, it would be beneficial if the government could provide incentives or subsidize costs of implementations, with a set of metrics that are (as mentioned on the call) useful and comparable between organizations to provide the insight into the level of complexity, cost (dollars and hours), number of resources, adoption rate, volumetrics between “transactions” and phone calls, to determine if there’s value to the updates/migration.

Lastly, it’s very evident that organizations are not as involved in the ideation process, and thereafter requesting of change(s). As a SDO workgroup member, I find there are limited requests for new or modified changes for transactions/workflows as related to the 270/271 Eligibility and Benefits, yet in my day to day career it’s very clear that opportunities exist for strategic alignment to create the basis for new capabilities or functionality and thereafter maintenance or change requests to SDOs. There needs to be some responsibility on the part of the industry to make sure they are looking ahead so that SDO’s can be positioned in a timely manner to provide support. It would behoove the healthcare community of implementors to be change agents and find ways to support outreach and solicit those who are insisting that one format is less flexible than the needs require, to be a party to the development by initiating the change requests to allow SDO’s to be adaptive and supportive of industry’s strategic capabilities and needs. Otherwise, we are always going to be playing extreme “catch up” with the healthcare landscape.

Thank you for your time and consideration of my comments.

HL7 International

Charles Jaffe, MD, PhD, Chief Executive Officer; Andrew Truscott, Board of Directors, Chair

Health Level Seven (HL7) International welcomed the opportunity to speak at the June 9 NCVHS Subcommittee on Standards Listening Session and values providing further written feedback with this correspondence. As you know, HL7 is the global authority on health care interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries, including 500+ corporate members representing health care consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

HL7's Chief Executive Officer (CEO) Charles Jaffe, MD, PhD emphasized three important overarching points during his June 9 remarks:

First, HL7 urges NCVHS to formally recognize HL7® FHIR® as an alternate standard to existing mandated HIPAA transaction standards, furthering the nation's journey of intersecting of clinical and administrative frameworks and related interoperability objectives. While the information requirements of health care data are extremely complex, the HL7 FHIR standard aids in removing many of the barriers to health care data exchange. FHIR itself, now 11 years old, is no longer an emerging standard but a global phenomenon and well supported by an interconnected health care ecosystem, demanding accurate, patient-centric data when and where it's needed. The time is now to make these tools more widely available starting with the prior authorization related implementation guides (IGs), including those related to: Coverage Requirements Discovery (CRD)[2], Documentation Templates and Payer Rules (DTR)[3] and Prior Authorization Support (PAS)[4]. Recognizing the most current versions of these initial three IGs, supports other federal policy[5] to reduce burden through technology and policy-related enhancements.

Second, a critical part of the HL7 mission is to provide a comprehensive framework and related standards for electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7 and its Work Groups produce a family of standards, including FHIR, as well as Implementation Guides and Specifications, which enable both routine and cutting-edge health care functions. HL7 actively supports cross-community terminology and value set needs to further benefit data driven policy and operational needs. Our HL7 FHIR Accelerators drive groundbreaking cross-sector innovation in interoperability and bridging historical investments through partnerships to provide end-to-end capabilities needed in today's modern health care eco-system. One such example, showcased by their June 9th testimony, is the Da Vinci Project, addressing value-based care data exchange efficiencies. Other HL7 FHIR Accelerators contribute to the interoperability journey such as FAST for infrastructure and connectivity, the Gravity Project for social determinants of health, and Helios for public health.

Third, HL7 supports all five considerations below that were examined by the NCVHS Subcommittee on Standards on June 9, including:

- Consideration 1: Update relevant HIPAA policies to allow for the adoption and use of more than one standard per business function.
- Consideration 2: Enable HIPAA covered entities to support multiple versions of adopted standards for business functions.
- Consideration 3: Revise the standards exception process for HIPAA covered entities who submit an application with the required justification and business case to automatically authorize them without waiting for review.

---

[2] HL7 Da Vinci Project, Coverage Requirements Discovery Implementation Guide, December 2020

[3] HL7 Da Vinci Project, Documentation Templates and Payer Rules Implementation Guide, December 2020, https://confluence.hl7.org/pages/viewpage.action?pageId=21857604

[4] HL7 Da Vinci Project, Prior Authorization Support Implementation Guide, December 2021, http://hl7.org/fhir/us/davinci-pas/

[5] U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria, RIN 0955–AA04; FR 2022-01309, January 24, 2022, https://www.federalregister.gov/documents/2022/01/24/2022-01309/request-for-information-electronic-prior-authorization-standards-implementation-specifications-and

- Consideration 4: Identify options for improved integration of health information standards, including base standards plus implementation guides, more broadly than at present, and fostering relevant collaboration across HHS Agencies and Offices.
- Consideration 5: Develop and publish a guidance framework with recommended definitions, metrics, templates, and pilot test procedures. The specific areas of work include such methods for reporting on standards readiness, standards costs, results of real-world testing and metrics essential for evaluation of standards.

Complementing these points above, and contained in this letter are HL7 perspectives on key themes emerging from the June 9 Listening Session:

- Public-Private Sector Partnerships
- Cooperation Across Government
- Value Proposition and Incentive Alignment
- Standards Exceptions Process Revision - HIPAA Covered Entities
- Standards Transition Policy
- Standards Versioning
- Increased Standards Testing
- Standards Guidance Framework
- Sexual Orientation and Gender Identification (SOGI), Social Determinants of Health (SDOH) and Public Health Issues

Comments detailed in this letter reflect the combined perspectives of HL7's leadership, the Policy Advisory Committee and the Da Vinci Project HL7 FHIR Accelerator. Should you have any questions about the attached document, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org. We look forward to continuing this discussion and offer our assistance to NCVHS.

Independent Health

Christopher Gracon, Solution Architect

I am submitting comments on the questions the NCVHS Subcommittee on Standards had raised for their June 9, 2022 meeting.

Question	Comment
Consideration #1 Standards adoption policy	
For providers, would availability of choice between an app-based standard and an X12-based standard be of value? Why or why not?	N/A
For payers, would the increased cost of supporting multiple types of standards be offset by reduced cost of customer service support? (This assumes better data and better first-pass processing success if providers select a technology more compatible with their business requirements and capabilities.)	Working for a payer, I would see that costs could be increased if we had to support multiple types of standards and that there would not be a decreased cost of customer support. We would have to have support for each standard and have to increase our published documentation to cover the additional standards. Prior to working in healthcare, I had worked in the transportation industry for an international carrier. At that company we had to support multiple transactions (X12, EDIFACT) and multiple versions of these transactions. While this company tried to have a common standard process for similar transactions, there was a cost to maintain each additional transaction and version. Another challenge of multiple types of standards has to do with different meanings that could occur to data fields which means

Question	Comment
	when that when a company tries to use a common standard process Also I have seen from my experience in another industry where with flexibility to allow someone to send (or require to receive) data that is not in limited by a guide there is added cost in that there is additional cost to handle this data that is outside of a guide and there usually needs to be a discussion between trading partners to understand what this data is (definition and specifications). With FHIR, their guides allow extensions, so there can be unexpected data which a receiver needs to handle.
For system vendors (including providers and payers who develop or maintain their own systems), would multiple alternative standards increase or decrease the complexity and cost of maintaining all the systems over the next 5-10 years? Please use a forward-looking evaluation to reflect further integration of administrative and clinical systems, as well as recognizing the policy directions of ONC's interoperability and information blocking initiatives.	Working for a payer who develops internal processes for consuming and generating transactions, I can state that having to process multiple alternative standards would increase the complexity and cost to maintaining our systems. From a simple QA perspective, the more alternatives there are the more tests which have to be run for each test case to validate any system changes. This would be apply when having to validate any upgrades or patches. From what has been talked about, of possibly having a mix of X12 transactions and FHIR resources, the systems needed to support these two are different as X12, even if processed in a real-time mode is not 'conversational' while FHIR is 'conversational'. What I mean by 'conversational' is that typically the model for X12 is that a transaction is sent and one or more responses are returned. Under FHIR most of the implementation guides figure on there being a series of sends and receives (eg, request for member info, member info returned, request for additional data based upon member info returned – say for a provider resource, that data returned, additional data requested and returned until a full data set is obtained). These different types of interactions require different types of processing at a payer and have different considerations when making system changes and for testing Another challenge to using multiple standards is whether the data in each standard uses a single common vocabulary and rules. Currently X12 has its established definitions for data and actors which for claims is in coordination with NUBC and NUCC, including for how long each common data element would be. I am not so sure that HL7 has the maturity that its names and rules for data elements and rules is in alignment with X12/NUBC/NUCC. While a payer processing multiple alternative standards could do its own bridging so that it can process fields which might be different, this becomes a huge issue when the payer has to send data onto another entity, such as an All Payer Claims Database, or other reporting agency, where there is a single reporting format which might not be in alignment with each of the multiple alternative standards in use. For example, the Post Adjudicated Claims Data Reporting (PACDR) 837 is in alignment with the 837 and 835 Standard Transactions so the vocabulary and data elements can be easily matched and populated. If there were an alternative standard where the vocabulary and data elements, especially data element

Question	Comment
	requirements, were different, a payer might have a problem in populating their PACDR 837 submission due to having a required output data element that they might not have if the data element was optional on the claim they received and not sent. A final thought on multiple standards, if FHIR guides are required, until the FHIR At Scale Taskforce (FAST) solves the scale connectivity issue there is an increased cost to all parties involved to connect to each additional provider/payer. Unless there are Clearinghouses (or other intermediaries) which facilitate a hub & spoke connectivity, FHIR connections end up being all point-to-point so there is technical effort involved for each additional connection.
Consideration #2 Standards adoption policy	
What do you see as the pros and cons of allowing multiple versions? To what extent to you see multiple versions successfully addressing the problem statement components: locally unnecessary updates; avoidance of cost and disruption; easier management of update implementations?	Pros: • Multiple versions of the same transaction could allow for willing trading partners to make use of newer functionality • Ease introduction of newer versions • Might lead to more requests to be made to transactions as they could be available within a year or two. Currently few enhancements are made to X12 possibly due to changes not becoming available until many years after requested. Cons: • Payer has to support multiple versions or could be seen as being an impediment to powerful providers. Need to support a version or lack of supporting a version could be used during negotiating contracts. • Software vendors for EDI might not support every version which is not named in regulations. So a payer might have to pay for support or might not be able to exchange a version that a provider would like to use. • If a payer decides to no longer support a non-named standard, then any providers using that version will then have to either go back to the Standard version or move to a version the payer will support. This could lead to different payers supporting different versions and the providers possibly needing to use more versions than payers.
What is the magnitude of the burden of supporting multiple versions of a standard? NCVHS has been told that multiple versions are common in other industries. Are there complexities or barriers that multiple versions pose to healthcare?	Multiple versions of the same transaction could be small burden if all the versions could be easily mapped into a common internal data structure. If there are structural changes between versions then this becomes much more difficult. For example, mapping between 5010 837 and 8020 837 can be a more difficult task than between 7030 837 and 8020 837 due to the change from using the CAS segment to the RAS segment for conveying prior payer claim processing. Another transaction which would be a challenge to merge different versions would be the 820 where there were significant structural changes between 5010 and 7030. This might be seen in FHIR resources too until resources get to the Normative stage.

Question	Comment
The NCVHS Subcommittee on Standards suggests three versions simultaneously in production would be the maximum. How many simultaneous versions should be allowed? Why?	I think two should be the number of standards to allow with three for extenuating circumstances or at times of transitioning from 1 version to another. The reason being that each version supported has a maintenance cost, and the more versions you have the fewer providers a payer would have on each version.
Consideration #3 Standards exception process	
If your organization has considered participation in testing emerging or alternative standards, was 162.940 an impediment or not? Did it ever discourage you from even considering participating in testing?	My organization has never considered participating in testing of emerging or alternative standards. Looking at 162.940, the requirements to request an exception would probably dissuade my organization if we were to consider participating in testing of emerging or alternative standards. My organization would likely be averse to spending time and money to a limited test which might not have a use after the testing was completed.
If 162.940 were revised as we described, do you think that would make your attitude toward participating in testing more favorable, less favorable or unchanged?	It would be unchanged.
Are there other approaches you would suggest NCVHS consider in lieu of or in addition to changing 162.940?	No
How might a revised exception process impact the number of versions simultaneously supports (as per Consideration 2)?	Uncertain
Consideration #4 Integration	
We have an existing framework of data standards harmonization between HITECH and HIPAA led by ONC and CMS. Can this approach to data harmonization be extended to harmonize data needed in all the other related areas demanding relevant data, or would a different approach speed up and broaden data harmonization, and if so, how should it work?	The approach could be extended but would require very clear vocabulary and data specifications (data type, lengths, and code sets, if any) in order to have a common data set across all standards. This would require a consensus body of industry members who understand the implications to the various standards as what is defined could require modifications to one or more standards.
With a focus on innovative technologies, how can all areas of standards development, standards adoption, and standards implementation meet demands for timeliness while also improving collaboration and maintaining data quality?	The challenges to timeliness for these are: • Standards adoption, the prescribed process takes well over a year even if the shortest time elapses occur between each step and the NPRM is of the shortest time allowed. • Standards development can be a challenge to come to consensus depending upon how clear the new requirement is and how much agreement there is in the approach across the industry participants. Unfortunately there tends to be a limited number of people who participate and might be no participation from people who might have industry knowledge about lesser known sectors such as ambulance or dental or chiropractic.

Question	Comment
What are the barriers to consistent use of data standards at the federal, state and local levels, and how could those barriers be mitigated? What policy or operational levers might be appropriate to support change?	There is a barrier to consistent data standards at the state level for All Payer Claim Database reporting. There is not a consistent set of transactions used across the states which have these. New York uses the NCPDP Post Adjudicated History, PACDR 837, Plan Member Reporting 834, and 277 Data Reporting Acknowledgement transactions. These transactions follow the same data definitions and rules as the Standard Transactions payer use and facilitate regular (even daily) reporting. This is the only state using all of these though Ohio Medicaid is adopting several of these. Those state using the APCD Council's Common Data Layout (CDL) use this set of data structures differently and typically as a bulk data submission such as quarterly or annually. There are also states using their own defined data structure. A policy lever that could be used to allow for consistent data reporting would be to name as Standard Transactions the NCPDP and X12 suite of transactions for reporting which align with the already named Standard Transactions. This could facilitate state and federal data collecting.

Independent Health

Nancy Spector, Chair, Board of Directors

WEDI is pleased to submit the following letter in response to the National Committee on Vital and Health Statistics (NCVHS) Standards Subcommittee Listening Session entitled Standardization of Information for Burden Reduction and Post-Pandemic America "Convergence 2.0" held on June 9, 2022. We appreciated the invitation to participate at the Listening Session and the opportunity to provide additional comments and recommendations regarding improving the identification and implementation of standards that will streamline communications between patients, providers, health plans and other health care stakeholders.

Our responses will be augmented with the results from a membership survey WEDI conducted in advance of the Listening Session. While there were limited responses (14), we believe many of the comments were illustrative of broader industry perspectives.

WEDI, formed in 1991, is the leading authority on the use of health information technology (IT) to improve health care information exchange to enhance the quality of care, improve efficiency, and reduce costs of our nation's health care system. WEDI's membership includes a broad coalition of organizations, including hospitals, providers, health payers, vendors, government agencies, consumers, not-for-profit organizations, and standards development organizations. WEDI was designated in the 1996 Health Insurance Portability and Accountability Act (HIPAA) legislation as an advisor to the U.S. Department of Health and Human Services (HHS).

Consideration 1: Update relevant HIPAA policies to allow the adoption and use of more than one standard per business function. Health plans would be required to support all adopted standards for their industry sector. Providers could choose which other proposed/adopted standard or standards to conduct with their health plans.

Question 1: For providers, would availability of choice between an app-based standard and an X12-based standard be of value? Why or why not?

WEDI Response:

- There are broader considerations that need to be explored, for payers as well as providers, as to what it means to have a choice between an app-based standard and an X12-based standard. For

example:
  - Providers may find value in some app-based transactions but may also find value in continuing its current business practices, workflows, and practice management system for X12-based transactions.
    - Is it possible to mix and match which standards are used for the different business needs?
    - How do the different systems work together?
    - Has this been tested in an operations environment?
  - Providers must rely on their electronic health record (EHR) and practice management system vendors to conduct any data exchange.
    - Will their EHR and practice management system be able to accommodate both app-based and X12-based transactions in one software package?
    - What will the costs be to support the app-based and X12-based software packages?
    - Will providers need two separate workflows for the app-based transactions vs. the X12-based transactions and what will that administrative burden be?
  - Providers have contracts with multiple payers and are concerned about the potential of being required to use different standards and different combinations of standards for different payers, which would be counter to the overall goal of administrative simplification.
- We need an overarching principal that any regulatory flexibility does not lead to additional administrative burden and costs. We will need guardrails put in place to prevent this.
- WEDI is willing to convene industry stakeholders to identify the business processes and workflows necessary to support the use of multiple standards for various use cases.

We received the following responses from our survey respondents:

- *For business processes that already have an implemented, well-used X12 standard, adding a new standard is not only not of value, but adds complexity and challenges with changing what already is working. For those processes that do not have a well-used process in place (e.g., attachments, prior authorization), an additional standard may be of benefit if it opens more options with vendor solutions that can be adopted easily.*
- *No, it is likely to cause confusion.*
- *Most providers just want a solution that works. Their choice is really the solution(s) provided by their vendors.*
- *The APP-based standards make so much sense since that is the way the world is moving. The X12 standards are so outdated that they don't work effectively anymore.*

Question 2: For payers, would the increased cost of supporting multiple types of standards be offset by reduced cost of customer service support? (This assumes better data and better first-pass processing success if providers select a technology more compatible with their business requirements and capabilities.)

WEDI Response:

- Again, there are broader considerations that need to be explored beyond a potential reduction in customer service costs for payers.
- Payers need to understand the cause of their current customer service volume. We have heard from payers that their customer service volume has not decreased since the mandating of X12 transactions and with some transactions the volume has actually increased. We know from the CAQH Index that not all X12 transactions have been widely implemented by providers. Payers may want to ask:
  - Are their providers using the current standards? If not, why?
  - Is better information available by calling their customer service vs. using the standard?
  - Is this an issue with the current version of the standard not allowing for richer data to be exchanged in the transaction with the provider?

    - Will a different standard solve these problems?
- Similar to the providers, payers will need to determine the business flow and operations of supporting multiple standards.
    - Is it possible to mix and match which standards are used for the different business needs based on what the provider chooses to send?
    - How do the different systems work together? Can two data "streams" be effectively merged?
    - Has this been tested in an operations environment?
    - Is there evidence that app-based transactions are more successful in exchanging the necessary information with the provider thus decreasing the need for phone calls?

We received the following responses from our survey respondents:

- *This would increase the cost of customer support as there'd be more than one way to receive and process transactions.*
- *While we are always interested in technology that improves the data and quality of the transactions we receive, it is not clear how additional technologies can demonstrate these efficiencies if they are based on the same data at their core.*
- *I don't think so; at best it might break even. Even if there was a decrease in costs for customer service related to processing, there would still be an increase in costs related to supporting multiple standards.*
- *No. The HIPAA transactions are very well penetrated in the healthcare industry. Adding an additional standard would only shift that volume and increase costs to payers. Payers already bear a burden of being mandated to deliver a function without the providers being mandated to use it. The CMS mandate to use FHIR for the Patient Access API and Payer to Payer API is an example of significant payer expense with very little current traffic. Those early FHIR functions are not delivering ROI compared to the cost of development.*
- *No, there is no significant offset. The industry has failed to eliminate prior standards following the adoption of a new standard. Adopting new standards results in layering additional levels on top of existing standards and requires the payer community to support the new level in addition to all preceding levels. For example: phone, hard copy, email, web portal, x12 electronic exchange, and APIs all continue to require support.*

Question 3: For system vendors (including providers and payers who develop or maintain their own systems), would multiple alternative standards increase or decrease the complexity and cost of maintaining all the systems over the next 5-10 years? Please use a forward-looking evaluation to reflect further integration of administrative and clinical systems, as well as recognizing the policy directions of ONC's interoperability and information blocking initiatives.

WEDI Response:

- While we do not have any specific insight into how vendors will handle the development and maintenance necessary to support multiple standards, logic suggests developing and maintaining systems for more than one standard will be more complicated and more costly than developing, deploying, and maintaining systems for one standard.
- It is possible that smaller vendors that tend to have smaller organizations as clients, will make the business decision to support just one standard. This would result in these smaller organizations being limited to the one standard or being required to engage with a second vendor for support of the other standard.
- The Office of the National Coordinator for Health Information Technology (ONC) has signaled in the electronic prior authorization (ePA) request for information (RFI) that it is exploring incorporating administrative transactions into its software certification program. WEDI does support this direction, as it will offer providers assurance that their vendors can support FHIR-based electronic prior authorization and electronic attachments.

We received the following responses from our survey respondents:

- *Adopting additional alternative standards will increase complexity and cost. Technical support, software maintenance, software licensing fees, people resources, help desk, audit support, training for new personnel, and regression testing must remain in place for all previous technologies and will continue to require funding for resources into the foreseeable (5 to 10 year) future.*
- *This would increase the support costs of software development to support multiple standards for the same business processes and content. The purpose of a standard is to NOT have multiple formats and content to support for the same business processes. This would be a nightmare.*
- *In the short-term it will increase complexity but in the long-run it will decrease and simplify options and methods.*
- *Creating multiple options simply reinforces the need for third party technical support between providers and payers to leverage the capabilities and manage the complexities of a large array of payer connection points. As versions, standards, and operating rules continue to change in the future, work needed to maintain all the implemented standards would increase substantially over today.*

Consideration 2: Enable HIPAA covered entities to support multiple versions of adopted standards for business functions. This provides an opportunity for innovators to be one version ahead of the current adopted version.

Question 4: What do you see as the pros and cons of allowing multiple versions? To what extent to you see multiple versions successfully addressing the problem statement components: locally unnecessary updates; avoidance of cost and disruption; easier management of update implementations?

WEDI Response:

- The pros, as we see it, would be:
    - The opportunity to fully test a new version of a standard in production.
    - The ability of the industry to migrate to the version of the standard that has the least burden and better return on investment (ROI).Allowing providers to choose the version of the standard, and combination of them, that best meet their business needs, so long as their systems support this set up and their payers are able to support this set up.
    - Making version mandates easier for the industry, if the provider can support the one-back version until they are ready, as long as the payers are mandated to meet the version mandated date.
- The cons, as we see it, would be:
    - Additional administrative costs for health plans, vendors, and clearinghouses to support multiple versions of standards.
    - Organizations will need to manage the different versions of standards for the different standards, along with their related business processes and workflows.
    - Costs will disproportionally impact smaller organizations.
- It is highly debatable that allowing multiple versions of standards with address concerns with "locally unnecessary updates; avoidance of cost and disruption; easier management of update implementations." Multiple formats could in fact lead to the opposite of increased costs, disruptions, complexities, and barriers.

We received the following responses from our survey respondents:

- Pros:
    - *The main pro is being able to transition over to a new version gradually rather than a big bang approach.*
    - *Gives stakeholders choice and different use cases may be more appropriate for different standards.*

- *Promotes modernizing.*
- *Undetermined.*

- Cons:
  - *Multiple versions of a single transaction would still need to feed from and to the same set of systems. There may be extensive changes as a transaction implementation moves from version to version. This may result in large system changes to accommodate the support of different structures feeding into and from the same system. This is magnified by the number of versions being supported.*
  - *Adds complexity.*
  - *Confusion to juggle multiple standards. The entity with the 'lower' standards could not do business with those of 'higher' standards -- the higher standard entities would have to also be able to support the lower standards to ensure can deal with all partners, so there is little savings and increased support.*
  - *Added maintenance, multiple copies of code sets that need to be synchronized, multiple locations of security and provider identification locations in the architecture.*
  - *Neither pro nor con: Heavier reliance on technology enablers.*
  - *Unless there is a consensus as to which versions to support, I do not see any pros to this opportunity. Local updates will still occur based on local business needs regardless of the standard but will be multiplied by the number of standards and versions supported. Support for multiple versions adds costs for all trading partners in maintenance, downtime, support, development, and education resources. We recommend supporting no more than 2 versions for a limited timeframe to support transition to the new standard and sunset the old.*
  - *This would be a nightmare for any vendor implementation or development situation, not to mention the support of companion guides or edits based on the standard. Again, the intent of standards is to know what version of the standard is currently implemented.*
  - *Supporting multiple versions is the only way to transition from the current world to a new world. There has to be overlap to allow legacy transactions while enabling innovators to move forward.*

Question 5: What is the magnitude of the burden of supporting multiple versions of a standard? NCVHS has been told that multiple versions are common in other industries. Are there complexities or barriers that multiple versions pose to healthcare?

WEDI Response:

- Other industries may find that the use of multiple versions of a standard works well and does not increase their costs or add burden to their process. We need to remember that the purpose of HIPAA was to move away from multiple versions of solutions and workflows and create a single standard. After 20 years of experience with the HIPAA transactions, the industry still struggles with conducting business using only a single adopted standard.
- The complexities of using multiple versions of an adopted standard will be managing which version is being sent and of which standard if multiple standards are also allowed. Each organization could realistically have its own set of standards and versions of standards it has implemented, and their trading partners will need to be able to accommodate all variations of the versions and standards. Is the industry prepared to manage its business processes and workflows to accommodate all potential variations?
- Operationalizing multiple versions of a standard will likely prove challenging. We believe there will need to be extensive piloting to understand the workflows of using multiple versions of a standard and WEDI is willing to assist in convening industry stakeholders to do this work. We think the prior authorization transaction is a prime candidate for piloting.
- Allowing more than one version of an adopted standard may not address current business process issues. These issues need to be solved irrespective of the version of the standard being

used. For example, an app-based transaction may move data more quickly between organizations, but that does not mean the receiver can respond any faster to the transaction. If the goal is to have more real- time requests and responses, that is often a business function and not necessarily within the scope of the function of the transaction.

We received the following responses from our survey respondents:

- *Yes. It is more complex and other industries do not have multiple versions. Finance, food supply, manufacturing, airlines all have a single standard for transactions. Only healthcare lags.*
- *Maintaining multiple versions of the standard increases not only the maintenance and cost for vendors, clearinghouses, and health plans, but also runs the risk of increasing manual work for providers to negotiate differences in the standards or choosing which version supports their use case.*
- *It's not significant. It allows plans and providers to bridge at different times. Orchestrating a mass start with a new set of standards is prone to disaster.*
- *Yes, multiple versions pose complexities and barriers in Health Care. Uniform adoption of a common standard provides a level playing field and standardizes expectations for all entities.*
- *The entity with lower versions could not do business with the more advanced entity unless the entity with higher version also had to be backwards compatible, so little saved by going to higher version, and unnecessary complexity.*
- *Potential increase in infrastructure costs to develop & maintain multiple workstreams with different processing requirements.*

Question 6: The NCVHS Subcommittee on Standards suggests three versions simultaneously in production would be the maximum. How many simultaneous versions should be allowed? Why?

WEDI Response:

- There will need to be extensive pilot testing prior to any federal mandate requiring multiple versions of a standard. WEDI believes adopting two versions of a standard would be extremely challenging. Three would be exponentially more difficult.
- There will need to be specific guardrails around what "multiple versions of adopted standards" will mean. The consideration statement says, "for innovators to be one version ahead of the current adopted version." This implies that the maximum number of versions will be two – the adopted version and a newer version.
- Suggesting the allowance of three versions raises the question of what additional version would be allowed beyond the suggestion in the consideration statement for an adopted version and a newer version. Does allowing a third version open the door for organizations to remain on an old version and not move to a newer version whether adopted or not?
- The CAQH Index continues to show that it is a challenge to get providers to fully adopt the X12 standards. It is our understanding that a significant number of the standard electronic transactions start out non-compliant and are routed through clearinghouses to make them compliant. Getting providers to adopt multiple versions of standards will be even more difficult.

We received the following responses from our survey respondents:

- 5 responses were in favor of 1 version with comments that included:
    - *Find the best and move to it based on what works for the smallest.*
    - *Our goal should be to reduce administrative expense, multiple standards could add costs without increasing adoption or utilization.*
    - *1 version, although there should be a temporary overlap period when a new version is being adopted.*

- 5 responses were in favor of 2 versions, with comments including:
    - *Two commenters supported having the two versions be the current and next/under development version.*
    - *One commenter supported having the versions be the current and 1 version back for backward compatibility until phased out.*
    - *One commenter said three is okay, but two is ideal because the complexity of supporting multiple standards is not cost-effective.*
- 1 response was in favor of 3 versions. Other comments included:
    - *3 could be extreme for small providers who cannot afford vendor intermediaries, or multiple integrations; could also be problematic for huge payers.*
    - *If the purpose of versioning is to permit some within the industry to make use of more advanced capabilities while permitting others to continue to use what works for them, the number of versions seems less like the solution. The real question is the difference in capabilities between the versions and the needs of the industry.*
    - *We understand the concept is to support the version being retired, the current version and the next new version, and there are merits to the concept. The difficulties are the complexities to manage three versions at the same time.*

Consideration 3: We urge the HIPAA exception process be revised to allow an expedited approval process for organizations that submit an application with the required justification and business case. Reporting on the use of alternative standards would still be required of the applicant and willing trading partners.

Question 7: If your organization has considered participation in testing emerging or alternative standards, was 162.940 an impediment or not? Did it ever discourage you from even considering participating in testing?

WEDI Response:

- We have heard from our members that the current HIPAA exceptions process does not facilitate easy testing of new standards or newer versions of standards. WEDI recommends that the Centers for Medicare & Medicaid Services (CMS) develop an expedited review and approval process.

We received the following responses from our survey respondents:

- *Our organization has largely not considered testing implementations requiring a HIPAA exception. We've determined the solutions are simply not scalable if the innovations cannot be adopted into permanent use by or near the end of the exception period because of the delay in adoption of updated standards. Standard modification and adoption would have to be more predictable to make this a worthwhile endeavor.*
- *The short-term nature of the exception timeframe and the onerous reporting requirements has discouraged us from seeking this option.*

Question 8: If 162.940 were revised as we described, do you think that would make your attitude toward participating in testing more favorable, less favorable or unchanged?

WEDI Response:

- WEDI has concerns with the proposed idea to allow HIPAA exceptions without a review. Organizations should not be permitted to test non-standard transactions without formal approval of a HIPAA exceptions project. This could result in even more variations in the standards and versions of standards being used throughout the industry adding additional complexity to business processes, workflows, and systems' development and maintenance. We believe a better solution would be for CMS to develop an expedited review and approval process.
- WEDI agrees that a more efficient and timely review process for HIPAA exceptions would encourage

additional covered entities to test new standards and versions of standards.
- The current connect-a-thons are helpful but having pilot testing of standards in production and will yield better real-world data.

We received the following responses from our survey respondents:

- 3 “unchanged,” 1 “less favorable,” and 1 “more favorable.” Other comments included:
- *It would likely not change the attitude toward participation that exists today as the administrative hurdle is not the true burden of testing.*
- *Allowing an exception should be granted for a period longer than three years, to insure sufficient time for development, deployment, and a Live Test and Demonstration period.*
- *A simple, streamlined exceptions process may encourage more participation- perhaps something more akin to a registration process, rather than a request for exception.*
- *Adding flexibility at the cost of clarity is not a win.*

Question 9: Are there other approaches you would suggest NCVHS consider in lieu of or in addition to changing 162.940?

WEDI Response:

- WEDI believes there are additional approaches that should be considered. We have heard that a barrier for some covered entities applying for a HIPAA exception is the limited time in which they are permitted to use the non-standard format. To make the investment produce a higher ROI, the organizations participating in the project should be permitted to apply for extensions of the time period when they can use the non-standard format.
- Another barrier to HIPAA exceptions is the financial commitment by the participating organizations for systems development and changes in workflow. WEDI recommends that CMS make funding available for organizations participating in HIPAA exceptions projects.

We received the following responses from our survey respondents:

- *The true limitation on participation in testing is the return on the investment. If innovations are found, but never implemented, the effort could be viewed as largely wasted. The change needs to allow for willing trading partners to continue to make use of the innovations found through the tests until such time as the changes are implemented in adopted standards or changes in adopted standard require a new exception request to be reviewed and approved. Providing federal funding for testing could be a way to encourage additional participation in testing.*
- *Federally supported funding/piloting would help.*
- *Rather than calling it an 'Exceptions Process' I would lean toward an 'Innovator Exception' that applies to all that meet certain criteria like using the evolving standards and agreeing to sharing / participating with standards reviews.*

- *If allowing more than one version of the standard, is adopted, then not sure the value added by this exception process. It seems like it overly complicates the process and impedes willing trading partners from moving to the version that works best for them.*

Question 10: How might a revised exception process impact the number of versions simultaneously supports (as per Consideration 2)?

WEDI Response:

- Revising the HIPAA exceptions process and getting more organizations to participated in these projects will be critical for gaining real-world experience with using multiple standards or multiple versions of standards and the impacts of that. It will be important for the industry to test and report on new standards and test and report on the simultaneous deployment of multiple

standards and multiple versions of standards and their associated workflows prior to any national mandate.

We received the following responses from our survey respondents:

- *The number of versions supported would largely depend on the cost and value those versions bring to the company. As it stands, the changes proposed to 162.490, would not increase our likelihood of participating in testing.*
- *Current costs for staff and technology counter the benefits of being an early adopter of a solution that might not materialize as a new approved industry standard. A minimum number of versions is preferable until the realistic benefits and costs of a new alternative either make migration to that alternative worthwhile or justify the migration costs in order to obtain the defined advantages of that alternative.*
- *Additional participants conducting more pilot implementations would give great data that could support the business case for newer versions.*
- *Federal funding is critical.*
- *We do not believe having more than one version or more than one standard is a correct vision.*

Consideration 4: Identify options for improved integration of health information standards, including base standards plus standards development organizations (SDO) implementation guides, more broadly than at present, and fostering relevant collaboration across HHS Agencies and Offices (e.g., CMS, ONC, CDC, NIH, IHS) including State, Local, Tribal & Territorial Governments.

Question 11: We have an existing framework of data standards harmonization between HITECH and HIPAA led by ONC and CMS. Can this approach to data harmonization be extended to harmonize data needed in all the other related areas demanding relevant data, or would a different approach speed up and broaden data harmonization, and if so how should it work?

WEDI Response:

- We recognize the growing level of convergence of administrative and clinical data. Optimally, standards should be leveraged for both administrative and clinical uses (i.e., attachments). ONC's recent ePA (and attachments) RFI signals the agency's intent to support the forthcoming CMS ePA regulation.
- We strongly support this type of collaboration between CMS and ONC to integrate standards harmonize implementation requirements. To improve the process, we encourage CMS and ONC work in partnership to engage directly with WEDI and others in the private sector in the identification of data harmonization opportunities and the development of appropriate implementation timelines and processes.

Question 12: With a focus on innovative technologies, how can all areas of standards development, standards adoption, and standards implementation meet demands for timeliness while also improving collaboration and maintaining data quality?

WEDI Response:

- The current standards development and adoption process is overly complex and unnecessarily protracted. A more streamlined development and approval process from standards development organizations (SDOs) and operating rules authoring entities could still meet industry's need for high quality standards but be nimbler in meeting emerging business needs. CMS can also contribute to this improved process.
- The agency should expedite the promulgation of standards regulations when there is clear private sector support and recommendations from the NCVHS (i.e., attachments).

Question 13: What are the barriers to consistent use of data standards at the federal, state and local levels, and how could those barriers be mitigated? What policy or operational levers might be appropriate to support change?

WEDI Response:

- Variation can serve as a barrier to consistent use of data standards at the federal, state, and local levels. If a standard is developed that permits entities to develop proprietary approaches, consistency will be compromised, and efficiency will not be achieved.
- Further, the lack of standards enforcement can serve as a barrier to consistent use of standards. We urge CMS to increase enforcement of non-compliant HIPAA covered entities.

Consideration 5: Develop and publish a guidance framework with recommended definitions, metrics, templates, and pilot test procedures, including methods for reporting on standards readiness, standards costs, results of real-world testing and metrics essential for evaluation of standards, to enable better measurement, management, and understanding of standards maturity, standards implementation success, and the net value of standards.

Question 14: Are the business needs captured or understood for evaluation of standards across the industry? (e.g., better measurement, management, and understanding of standards maturity, standards implementation success, and the net value of standards)

WEDI Response:

- As standards are being developed, we recommend they address a specific business need and that SDOs involve all appropriate industry stakeholders in the development process. It is imperative that stakeholder voices are equally heard and that SDOs utilize a standardized approach to establish the net value of standards, including cost savings and business value propositions, to assist CMS to consider for adoption.
- Often, we just see costs specified. To bolster the case for adoption, an ROI calculator for each stakeholder group would be appreciated and would assist in establishing a compelling business case. In some cases, unique metrics associated with the proposed standard should be designed before pilot testing begins.
- For new standards whether it be a new transaction or a use case, we encourage pilots be conducted in a real-world testing environment. Reporting of these results would be invaluable to discover missing elements or resources and a great source to help identify ROI.
- Adopting a real-time approach has reduced meaning if the responder is not mandated or willing to respond in real-time for at least a percentage of the responses.
- In general, we hear from health plans, "if we build it – will they come?" If a rule is only mandated on plans, we do need to consider resistance associated with assuring participants that the standards rule adheres to the privacy of patient data and that there is trust between participants for their participation particularly for clinical exchange.
- Addressing the question on public and private efforts, we believe the guidance framework should be the work of a partnership between the public and private sectors culminating with a regulation or sub-regulation from CMS establishing the framework whether the public or private rule drops first. Commercial practices and health plans often follow CMS innovation.
- SDOs, operating rules authoring entities, and other private sector organizations could leverage the guidance framework to test new standards readying for the commercial side.
- We also encourage NCVHS to hold hearings on a regular basis and invite public testimony all aimed at evaluating these standards and encourage well researched ROI studies. This evaluation would be a component of any NCVHS recommendation to HHS regarding the adoption of new or revised standards.

We received the following responses from our survey respondents:

- *The CAQH Index Report is largely capturing similar data through willing participants. CAQH CORE is developing operating rules to bridge the gap in standards implementation through consensus-based improvements.*
- *The problems with standards are twofold: one, they're developed at a point in time that does not really take into consideration the speed at which "business" changes; two, it takes too long to document, draft and then mandate standards. While the "hot" item may be FHIR, this is still "EDI" and it still requires development cycles that are still "young" to the industry as a whole. A happy medium needs to exist-such as, mandating newer X12 versions for HIPAA purposes that satisfy the administrative burdens, require more frequent publications by ASC X12 to keep up with healthcare changes, but require clinical standards, such as FHIR, for items that are more care and clinical management focused. This will allow the exercise of familiar and new concepts and can share the participation and development so as not to compound one organization and development with all expected outputs. It's becoming evident that it feels like it's a competition of sorts between standards development organizations. It might be beneficial to get a gauge of the concerns to date (i.e., the long development cycles between versions, the limited exposure in a production environment prior to regulatory required use, etc).*
- *This is an area that the industry could improve. While the CAQH Index goes a long way towards evaluating current standards, we do not have anything in place to consistently and accurately measure new and emerging technologies and standards. Something that seems to be a good idea may not be beneficial to administrative processes and in practice. If there were a consistent, standard evaluation process, there would be less trepidation from management to move forward.*
- *I believe the business needs are being evaluated by the industry but unfortunately HHS has let the industry down. Standards have not been rolled out as promised many years ago.*
- *Yes, the issue is in adoption of new versions and new transactions. Issue is not with the standards.*
- *We need more pilot testing with standardized metrics and reporting. Also, we need a better definition of what success is--i.e., what is of value to measure? Pre-define measurement of success, then measure. Additionally, each SDO should be required to submit to NCVHS metrics.*
- *No. There is no consistency and no real standardization across the whole system. We need to look at the whole picture and modernize it all.*
- *Still trying to understand HL7 mixed in with X12 for attachments. Need framework with what consulting would look like - for the HL7 attachment component for CAT02 = HL, TX, and MB and the use of HL7 C-CDA R2.1 instead of CDA R2. Just starting to be a part of the learning curve in this area. Once we do the work, we'll need to measure it. I won't have an idea until it's done, other than get volumes, and provider cycle time numbers - should improve. First pass claims and PAs with attachments should also improve.*
- *If they are being captured it is not a defined, simple process--but adhoc in nature.*

Question 15: Are the guidance framework components sufficient to measure and manage emerging and revised standards? (e.g., recommended definitions, metrics, templates, and pilot test procedures, including methods for reporting on standards readiness, standards costs, results of real-world testing and metrics essential for evaluation of standards.)

WEDI Response:

- The guidance framework components as outlined would be extremely beneficial to the standards development process. Establishing a standardized process for pilot (real-world) testing and reporting of results would be invaluable for CMS to determine whether or not to mandate a standard and for building support (establishing a business imperative) within the private sector for the new standard.
- We also urge CMS to consider the following when developing a process to identify the cost of a new standard: (i) does this standard simply have optional new elements or resources that will not disrupt ingestion or transmission? (ii) Does this new standard require redoing mapping? (iii) Does this new standard require significant new mapping? (iv) Does this new standard require a new technology?

(v) Does this new standard require heavy backend integration?

- When establishing potential benefits of a new standard, CMS should explore the net value to the patient, sending party, and receiving party. CMS should also consider the potential value of transmitting/receiving data and consider the value associated with the of integration of the sending app and receiving app.
- We do recognize that resistance to testing could occur. Resistance could be associated with assuring participants that the privacy of patient data is being maintained and that there is trust between participants for sending the correct data. There could also be resistance from payers and providers working together due to past relationships and trust issues.

We received the following responses from our survey respondents:

- *There should be a defined pathway for continuous improvement through cooperation with the SDOs from lessons learned. There also needs to be a direct comparison of the old version to the new version so that metrics may be evaluated on the benefits of migrating to the new version.*
- *Caution should be employed to ensure pilot standards address more than a limited ad-hoc problem statement and can be extrapolated to address overall industry data-exchange needs.*
- *Unknown*
- *We don't have any suggestions for additional components. The importance here is setting the standard along with transparency. Standard definitions, measures, processes and transparency of results and metrics will create a level field where everyone is speaking the same language and able to access the same data.*
- *Yes, CAQH index does a great job.*
- *If we are doing testing, it should be from application to application vs gateway to gateway. End-to-end and production pilots are critical. Challenge is finding participants.*
- *No. It is based on the current system, which we all know is very poor. Use this time to make it right.*
- *I think because of the CAT02 = 4 elements: HL, TX, MB, and IA - causes a larger variability x # of versions = # of EDI maps that need to be created. I think it creates more complication unless I'm not understanding it correctly.*
- *No.*
- *I am not aware of guidance framework components for standards*
- *Yes.*
- *Not really. The guidance framework need to be adaptable and agile enough to accommodate variations of the use- cases and results of pilot testing.*
- *Success depends not only on real-world testing, but on on-going results as well, which should be taken into account. Some of the existing required standards have never been implemented by health plans or providers, or are implemented poorly, and these components would not reflect that.*

Question 16: How could a guidance framework be created and maintained, i.e., how do you see the alternatives for the public sector or private sector?

WEDI Response:

- We believe the guidance framework should be the work of a partnership between the public and private sectors culminating with a regulation or sub-regulation from CMS establishing the framework.
- This cooperative approach will ensure that sufficient public input is incorporated into the framework and that the framework has the weight of regulation behind it.
- We believe this approach would discourage entities from developing a proprietary framework. In terms of maintenance, it could be the NCVHS that, on a regular basis, holds hearing on the frame, invited public input, and issues recommendations to HHS regarding needed modifications to the framework.

We received the following responses from our survey respondents:

- *Unknown*
- *Industry groups, engaging their constituents should collaborate on these definitions, metrics, templates and procedures to gain consensus.*
- *Do Connectathons, similar to Da Vinci but for HIPAA.*
- *Private and public sectors need to work collaboratively, from start to finish.*
- *Get all stakeholders together and let them talk it out with other industry professionals and those with other country solutions that work great and get to consensus. Do not follow status quo and be innovative.*
- *1) how to handle documents vs images - will there be 1 EDI map or 2 (up to 4 maps based on CAT segment, etc.) and version 2) have industry decide that there can only be 2 versions - but up to 8 EDI maps max OR 3 versions and up to 24 maps max (that's a lot to think about) as it relates to attachments (either claim or PA).*
- *Organizations represented from all over the country, representing all types of providers, payers, and vendors must have a voice in this process. Unfortunately only the same voices are heard in this process, which leads the industry to the same unimplementable solutions.*
- *Communicating to stakeholders simple ideas regarding looking out for possible standard improvements in the future. Ask entities to review all of their EDI support tickets once a year and flag issues that could have been avoided if data was organized differently on the inbound EDI transactions. If this was done annually 'e.g. Feb is EDI Support Pulse month', the committees would likely obtain more ideas for layout changes/standardization updates. It would need to be flexible and adaptable to varying use-cases and applications of the standards. There will be many various adaptations of the approaches to adopting new standards.*

Question 17: If a guidance framework was created, how do you envision the collection and reporting of metrics would occur to streamline the evaluation of standards - regulatory and nonregulatory.

WEDI Response:

- SDOs, operating rules authoring entities, and other private sector organizations could leverage the guidance framework to test new standards.
- We recommend NCVHS continue to hold hearing on a regular basis and invite public testimony all aimed at evaluating these standards. This evaluation would be a component of any NCVHS recommendation to HHS regarding the adoption of new or revised standards.

We received the following responses from our survey respondents:

- *Would require a standardized set of metrics to be required to be captured, and it would be beneficial to require that as part of any mandate/regulation to compare like for like.*
- *A centralized repository (ONC facilitated, perhaps) that contains all the elements previously discussed would be the best way for this to occur. It should be possible to differentiate between those standards that have been mandated versus those that are subject to willing trading partners' support.*
- *Require reports from Connectathon use cases.*
- *Outline at the start of the program what metrics you wish to measure, in advance, and create a reporting system around those metrics.*
- *Create the measurement system when you establish the framework. Build the metrics on ease of use, cost reduction and consistency.*
- *Have standard metrics for attachments - 1) volumes that CAQH captures 2) revenue cycle time from provider - and 1 or 2 different calculations 3) capture 5010- 837 PWK02 values - are they using EL only (and/or something else) 4) attachments by Line of Business: Commercial, Medicaid, and Medicare, etc.*
- *A guidance framework needs to be created in collaboration with local organizations which reach a larger audience, perhaps local HIMSS, AMA, AHA, etc - to build the broad consensus based*

information gathering - from that the collection of metrics which can accurately gather the evaluation of standards both regulatory and non- regulatory can begin in earnest. Beginning small and working up to the national level will make sure a larger audience is heard from and hopefully get the attention this topic deserves.

- *Run the metrics off of the last year's worth of EDI support tickets. Determine for each ticket if an upgrade to the EDI format (standard) may prevent it in the future. It may be only 1%, but then take that 1% and breakdown improvements/ communicate to WEDI. So, some kind of annual requirement to provide the industry with support metrics along with ideas for new standards based on those metrics.*
- *A third party/independent organization like CAQH CORE could be tasked with surveying the industry and reporting findings. CAQH is doing this currently and provide non-biased information on adoption and utilization for the HIPAA transaction, this role could be expanded without a "mandate" being forced.*
- *There would need to be simple reporting mechanisms to capture key metrics like time savings per transaction, etc. Very similar to how CAQH collects its index metrics for administrative transactions use, cost and savings opportunities.*
- *It must be automated and done in a standard way or this would not be successful.*

WEDI appreciates the opportunity to submit these supplemental responses to the questions posed by the Standards Subcommittee during the Listening Session.

Attachment 1 is the complete report from the industry survey we conducted for the questions for Considerations 1, 2, 3, and 5. We look forward to continued collaboration with NCVHS and stand ready to assist in clarifying our responses to your questions as needed. Please contact Charles Stellar, President and CEO of WEDI, at cstellar@wedi.org with any questions pertaining to WEDI's comments.

Appendix D: List of Acronyms

ADA	American Dental Association
AHA	American Hospital Association
AHIMA	American Health Information Management Association
AHIP	America's Health Insurance Plans
AMA	American Medical Association
API	Application Programming Interface
BCBSA	Blue Cross and Blue Shield Association
CAQH	Council for Affordable Quality Healthcare, Inc.
CORE	Committee on Operating Rules for Information Exchange
CDC	U.S. Centers for Disease Control and Prevention
CFR	Code of Federal Regulation
CMS	Centers for Medicare & Medicaid Services
DFO	Designated Federal Official
EDI	electronic data interchange
EHR	Electronic Health Record
FDA	U.S. Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
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
HITECH	Health Information Technology for Economic and Clinical Health
ICD-11	International Classification of Diseases 11
IHS	Indian Health Service
IT	information technology
NACHC	National Association of Community Health Centers
NCHS	National Center for Health Statistics
NCVHS	National Committee on Vital and Health Statistics
NCPDP	National Council for Prescription Drug Programs
OBRHI	Office of Burden Reduction and Health Informatics
OCHIN	Oregon Community Health Information Network
ONC	Office of the National Coordinator for Health Information Technology
ROI	return of investment
SDO	Standards Development Organization
SDOH	social determinants of health
SNIP	Strategic National Implementation Process
SOGI	sexual orientation and gender identity
USCDI	U.S. Core Data for Interoperability
WEDI	Workgroup for Electronic Data Interchange