National Committee on Vital and Health Statistics

Comments Received in Response to Draft Considerations for Review & Discussion for the NCVHS Standards Subcommittee Listening Session Held June 9, 2022

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Input on Standardization of Information for Burden Reduction and Post-Pandemic America "Convergence 2.0"

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June 24, 2022

Richard W. Landen, MPH, MBA
Denise E. Love, BSN, MBA
Co-Chairs, National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards
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Submitted via email to NCVHSmail@cdc.gov

RE: Potential recommendations on to support the "Standardization of Information for Burden Reduction and Post-Pandemic America"

Dear Mr. Landen and Ms. Love:

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

[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.

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.

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 standard 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 (202) 778-3246 or at dlloyd@ahip.org.

Sincerely,

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

Donna Campbell, HCSC, Product Manager – Provider Portal and Connectivity: sharing commentary as a 270/271 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 standard 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.

SUBMITTED TO:
DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS SUBCOMMITTEE ON STANDARDS
June 9, 2022
Submitted By: Pamela Grosze, Product Manager Lead, PNC Bank Healthcare
Board Chair, Cooperative Exchange: *The National Clearinghouse Association*

Members of the Subcommittee, I am Pam Grosze, Board Chair of the Cooperative Exchange (CE), representing the National Clearinghouse Association and Product Manager Lead, PNC Bank Healthcare. I would like to thank you for the opportunity to provide feedback on behalf of the Cooperative Exchange membership concerning the listening sessions on Standardization of Information for Burden Reduction and Post-Pandemic America "Convergence 2.0".

Cooperative Exchange Background
Cooperative Exchange is the nationally recognized resource and representative of the clearinghouse industry for the media, governmental bodies, and other interested parties.

Cooperative Exchange's 22 member companies, represent over 90% of the clearinghouse industry and process annually over 6 billion plus claims representing $1.1 trillion, from over 750,000 provider organizations, through more than 7,000 payer connections and 1,000 HIT vendors[1].

The Cooperative Exchange ***truly represents the healthcare industry EDI highway infrastructure*** and maintains hundreds of thousands of highways and the majority of the on and off ramp connections across all lines of healthcare business in this country.

Cooperative Exchange member clearinghouses support both administrative and clinical industry interoperability by:

- Managing tens of thousands of connection points
- Securely managing and moving complex data content including administrative and clinical information
- Receiving and submitting both real time and batch transactions
- Providing interoperability by normalizing disparate data to industry standards
- Providing flexible solutions to accommodate the different levels of stakeholder EDI readiness (low tech to high tech)

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[1] *Disclaimer: The Cooperative Exchange (CE) is comprised of 22 of the leading clearinghouses in the US. The views expressed herein are a compilation of the views gathered from our member constituents and reflect the directional feedback of the majority of its collective members. CE has synthesized member feedback and the views, opinions and positions should not be attributed to any single member and an individual member could disagree with all or certain views, opinions and positions expressed by CE.*

- Actively participating and providing strong representations across all the national standard organizations with many of our members holding leadership positions.

Therefore, we strongly advocate for EDI standardization and compliance within the healthcare industry. We are committed to promoting and advancing electronic data exchange for the healthcare industry by improving efficiency, advocacy, and education to industry stakeholders and government entities.

CLEARINGHOUSE OVERVIEW

Clearinghouses have been major participants in the health care EDI industry since before the HIPAA requirements came into effect. Initially, the industry believed that with the advent of uniform EDI standards in the industry, there would be no further need for clearinghouses –it was expected that providers would send standard transactions directly to payers. However, that has not come to pass, and clearinghouses continue to play a pivotal role.

There are several reasons that clearinghouses continue to service the majority of transactions. Despite the attempts at standardizing transactions, there remains variability within the transactions that requires expert processing and creation of a standard transaction. Transformation of data is a key role that the clearinghouses perform daily. During the transition to new versions of the HIPAA transactions, clearinghouses, as the rails of EDI, are called on to ensure providers and payers can stay on track by facilitating the needs of all trading partners in varying states of readiness. Clearinghouses are able to transform data from one version to another, enabling each trading partner to send/receive versions based on their ability.

Clearinghouses provide a single point of contact for providers and even payers, allowing them to exchange transactions while maintaining connectivity with very few sources. Providers do not want to (nor have the resources to) establish and maintain connectivity with the large numbers of payers with whom they exchange transactions. In turn, some payers do not want to maintain connections for every provider with whom they exchange transactions.

Clearinghouses have the capability of implementing and supporting virtually any format type (ASC X12, HL7, FHIR, NCPDP, XML, proprietary formats, etc.) of transactions for communicating between trading partners. However, we note to NCVHS that there is significant cost for each new transaction or major change in a transaction, for development, implementation, and training of customers. The Cooperative Exchange urges NCVHS to consider the expected adoption rate of transactions, to enable clearinghouses to focus resources on those transactions which will be frequently used by providers and plans. It has been frustrating for our members to build capabilities for customers which are barely used.

Somewhat more troubling is the small percentage of payers who do not support the standard transactions at all, and/or send or require non-compliant transactions. This requires considerable data maintenance for clearinghouses, adding cost and complexity to the system and prohibiting us from achieving some of the goals and return on investment (ROI) of Administrative Simplification.

While a CMS enforcement system is in place, many submitters are either not aware of the process or still somewhat reluctant to file a complaint against a payer for fear of damaging an important business relationship. We would encourage CMS to continue to support the National Standards Group Compliance Review Program. We also encourage CMS to provide additional educational outreach regarding their complaint process and to increase industry awareness of successful complaint resolutions.

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. 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.

- Recognizing the health care industry standards advancements made over the past 20 years, the Cooperative Exchange welcomes opportunities for new and emerging standards to support the needs of the industry and our customers. Clearinghouses support multiple standards and support the many-to-many connections that are required to facilitate data exchange in the industry.
- We also recognize, however, that many of the standards and business processes in use today are mature and work extremely well to accomplish the administrative purposes for which they are designed. Current processes in place for business processes such as claims management, eligibility and benefits, and remittance advice and payment have had significant investment by the industry, and function efficiently. Introducing a new standard to perform these functions that are already performing effectively serves no purpose, would be extremely disruptive to the industry, and would have no return on the investment needed.
    - Per the 2021 CAQH Index, below is the adoption rate of the most widely used HIPAA Administrative transactions:
        - Claim Submission (ASC X12N 837) – 97%
        - Coordination of Benefits (ASC X12N 837) – 87%
        - Eligibility and Benefit Verification (ASC X12N 270/271) – 89%
        - Claim Status Inquiry (ASC X12N 276/277) – 68%
        - Claim Payment (ACH CCD+Addenda) – 76%
        - Remittance Advice (ASC X12N 835) – 64%
        - Prior Authorization (ASC X12N 278) – 26%
        - Attachments (ASC X12N 275, HL7 CDA)– 21%
        - Acknowledgments (not currently mandated by HIPAA, ASC X12N 277CA, ASC X12N 999) – 99%
- Approved HIPAA Exception to test HL7 CRD and PAS IG standards
    - Some of the Cooperative Exchange members are also members of the HL7 Da Vinci Project. While we believe that the root cause barrier toward industry adoption of systematic and automated prior authorization workflow is not a “standards” issue, we look forward to supporting the exception testing and the outcome of the reported results and cost-benefit analysis.
    - The HL7 PAS IG supports some use cases, but not all. X12 supports PAS and other use cases. Neither standard has wide adoption. Required industry stakeholder engagement and technology is not supporting the existing standards, even though both standards have been available for a long time, and business processes are not adapting to include the new technology available.

- Existing standards can be, and have been, API-enabled or used in a variety of applications based on industry needs/demand. The underlying issue is not with the current technology standards, or a lack of standards, but rather with business challenges and fragmentation. We also see inconsistencies in

process and competing technologies that deter fully interoperable, systematic, and automated data exchange. There often is continued reliance on manual data entry and human intervention.

- Business processes within all stakeholder groups (providers, health plans, Practice Management System (PMS) vendors) are not changing to support the technology available. Even with existing regulations, there has not been sufficient business interest to support them and adapt existing processes to take advantage of new technology.
- Rather than simply adopting multiple new standards, CMS may wish to consider allowing a new, fully developed and tested standard as an option for Health Plans to offer while continuing the use of the current standard. This would give providers the opportunity to use and test new technologies if they choose.

Action Item 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.

- The Cooperative Exchange recognizes the need to support multiple versions of adopted standards, particularly as transitions are made from one version to the next as trading partners make the transitions at varying paces based on their resources and funding.
- Clearinghouses enable these transitions from one version to a newer version. A main function of clearinghouses is facilitating the exchange of data between trading partners who may be in varying stages of readiness for newer versions. Clearinghouses are able to "upconvert" or "downconvert" as needed to ensure that each trading partner is able to send/receive the version they are able to support. This clearinghouse value-add helps to reduce overall industry costs.
- An important note, however, is that too many versions being supported does not provide cost avoidance and causes industry disruption. An optimal scenario would be to support two versions, the current adopted version, and the next newest version, with a documented sunset date for the current version and required date to move to the newest version.
  - This encourages trading partners to move to the latest version as they are able, and prevents entities like clearinghouses from supporting older versions for many years (as is the current state – clearinghouses are still supporting version 4010 of the HIPAA transactions)
  - Supporting too many versions, more than two, takes us back to pre-HIPAA days when trading partners could use any version and data exchange was extremely difficult.
    - Entities may be reluctant to make the investment to update their systems (Provider PMS systems or Health Plan adjudication systems) if they are able to continue to process as-is indefinitely. Typically, entities have a significant cost to perform these upgrades, so will be reluctant to do so if not necessary.
  - This scenario of current version and next newest version eliminates the "big bang" transition model, where all entities must convert on the same date. This model has proven very challenging and costly to support.

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. 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.

- The Cooperative Exchange supports the use of pilot programs to identify the return on investment including estimated cost, best practices for implementation, challenges with implementation and success results. Given the success, broad adoption, and maturity of existing standards, we believe the exception process is working as designed, i.e., current standards are in general meeting industry needs, thus few exception requests are being submitted.
- Many members have participated in pilot activities for prior authorization and attachments, investing in technology and solutions, and presented ROI results; however, the recommendations made to HHS have not been followed through with a federal mandate. **As an industry, we are losing credibility in our boardrooms to request investments for future pilot programs**.
- Funding is an issue for any pilot testing. Bigger entities can participate in programs like Da Vinci that require commercial participating organization funding, but smaller entities are unable to make that same contribution. Their interests are then not represented, and the pilot test then does not represent all facets of the industry.
- With the above proposed item for consideration, it is unclear what value is added by the exception process. With no review or approval, the application becomes merely an administrative burden and impediment to pilot testing.
    - The issue appears to be with the complexity of conducting a pilot process outside of normal production processes, engaging trading partners to participate in pilot processes, funding for the initiative, and then in adoption of the new process/technology after the pilot is completed.
    - An example is the Da Vinci project, which used the exception process for Prior Authorization. We look forward to the increasing the level of industry participation and reporting outcomes of this process.
- Given the expense and complication of pilot testing, a well-designed and controlled system must be in place. We would also recommend some sort of cost sharing arrangement between CMS and pilot test participants.

Address Standards Integration and Collaboration

Action Item for Consideration #4:

Identify options for improved integration of health information standards, including base standards plus standard 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.

- As indicated in prior testimonies and stakeholder feedback sessions, some SDO's and the Operating Rule Authoring Entity are working in silos and as competitors which introduces even more complexity to implementation and slows down the regulation process. As indicated previously by WEDI, "*it is recommended that SDOs share roadmaps and work products with the other SDOs to improve harmonization and minimize overlap of work*". The Cooperative Exchange agrees with this statement.
    - Some improvement has occurred in this area, as we see some SDO's collaborating, for example HL7 and X12, to ensure integration of data and synchronization of standards.

Continued and expanded collaboration is needed to ensure that SDO's provide information that complements each other's standards and facilitates exchange of data for the industry rather than introducing conflicting requirements or impediments to implementation, particularly when the business purposes may not completely match up.

- Clearinghouses facilitate integration and transition between SDO's and versions of standards (as mentioned above). Clearinghouses can assist with moving the industry towards best practices and updated standards adoption. Clearinghouses can also provide metrics based on the wide range of data available.
- SDO's should ensure that standards produced provide interoperability of the business content (semantics) included. Common definitions and terms, business concepts, and process definitions are vital to ensure integration of the standards. As mentioned above, clearinghouses facilitate exchange of data, regardless of syntax or standard, but must have semantic interoperability to ensure the ability to perform those transitions.
- HHS Agencies and Offices (such as those mentioned above) should lead by example, ensuring that standards and requirements produced are collaborative and do not introduce conflicting priorities or requirements.

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.

- For consideration and to promote standards harmonization and interoperability, we would recommend that SDO's named under regulation work towards functioning under a regulated common agreement. Like TEFCA, including a "Coordinating Entity" as part of this common agreement may work well in this situation to enable SDO's to cooperate, collaborate, and integrate well, rather than compete.
  - The current regulations contain some guidance on criteria for the use and evaluation of standards (preamble to the original transactions rule, the evaluation of pilot tests). These could be used as a starting point for the guidance framework.
- In order to ensure that all requirements imposed on healthcare stakeholders are in sync, the Operating Rule Authoring Entity (currently CAQH CORE) should be included in this framework as well.

Conclusion

The Cooperative Exchange members are firmly committed to standards that enable fully electronic exchange of data, eliminating the need for human intervention in the administrative processes we support. The unique position of clearinghouses allows us to see across the spectrum of constituents, enabling the flow of information across those constituents. As clearinghouses, we are standards-agnostic, facilitating the low-cost exchange of data that allows automation and allows business processes to function in the most efficient manner.

We believe that change just for the sake of change is not only disruptive, but extremely costly to the many entities currently using the standards in place today that are widely adopted and working well. Focusing on areas with the most need, and on the true challenges in those areas (technology and business processes), moves the industry further ahead in complete automation of costly manual processes.

In closing, we would like to thank the members of the Subcommittee for their time and attention. We appreciate all your efforts to bring clarity and consensus to the process. We hope this information will be useful to you. The Cooperative Exchange is available to provide metrics and other information that may be useful in evaluating this and other future recommendations. Should you have questions or need any further information, please do not hesitate to let us know.

Respectfully Submitted,
Pamela Grosze, Board Chair
Cooperative Exchange

HL7 International

June 22, 2022

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Submitted electronically to:
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RE: NCVHS Subcommittee on Standards Request for Additional Feedback Regarding June 9, 2022 Listening Session on Standardization of Information for Burden Reduction and Post-Pandemic America "Convergence 2.0"

Dear NCVHS Subcommittee on Standards Co-Chairs Love and Landen:

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)[1], Documentation Templates and Payer Rules (DTR)[2] and Prior Authorization Support (PAS)[3]. Recognizing the most current versions of these initial three IGs, supports other federal policy[4] 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.

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

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

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

[4] 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 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.
- 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 or 734-677-7777. We look forward to continuing this discussion and offer our assistance to NCVHS.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
HL7 International

Andrew Truscott
Board of Directors, Chair
HL7 International

Key recurring themes expressed by stakeholders during the June 9 listening session and related, relevant HL7 comments are outlined below.

- **Public-Private Sector Partnerships –** HL7 agrees with other June 9 listening session speakers that ongoing meaningful collaboration between the public and private sectors is essential in the interoperability journey and in particular, is improved through more input from industry stakeholders and continued collaboration among Standards Setting Organizations (SSOs). When public and private sector stakeholders collaborate, challenges can be efficiently and productively solved. HL7 FHIR Accelerators are meaningful examples of this collaboration, which brings together industry and government thought leaders, to modernize thinking about technology investment in Health Information Technology (HIT). The HL7 Da Vinci Project is fundamentally re-imagining data exchange in health care is enabled, as well as accommodating existing investments in technology. The Da Vinci Project uses private industry investment, paired with our ANSI accredited standards development structure and a consensus approach, augmented with support from the federal government. The very experts implementing these exchange challenges are partnering to compete on service, differentiated offerings and establishing the best practices of data exchange among a diverse body of collaborators.

- **Cooperation Across Government –** HL7 enthusiastically supports Consideration 4 to identify options for improved integration of health information standards, including legacy technologies augmented by implementation guides, more broadly than those presently available. Furthermore, HL7 encourages strategic collaboration across U.S. Department of Health and Human Services (HHS) agencies and offices, including state, local, tribal & territorial governments. HL7's diverse project portfolio consistently enables the primary record, and supports the fundamental respect of patient preferences, as well as nurturing privacy and security policies. As the government programmatic and policy evolves, HL7 will continue to be a committed technical resource and collaborator to advance data exchange capabilities across national and international governmental partners.

  HL7 is committed to the principal that collaboration and information integration is critical with non-HHS agencies and offices that impact health services, equity, and security of food, housing and transport as well as digital literacy. In fact, HL7 has partnered with the U.S. Department of Defense (DOD), Department of Veterans' Affairs, Department of Housing and Urban Development (HUD), Social Security Administration (SSA), Department of Transportation (DOT), United States Department of Agriculture (USDA) and the United States Digital Service (USDS). Lack of alignment among different agencies in both health policy and protocol is a notable burden and can adversely impact health care quality and equity. A recent JAMA Health Forum article -- *Addressing Social Determinants of Health in Federal Programs* --sheds light on this issue. More information can be found at: https://jamanetwork.com/journals/jama-health-forum/fullarticle/2790811.

  Perhaps most relevant is the fundamental embrace of the global community, by which HL7 underscored in its July 2021 letter to the NCVHS Subcommittee on Standards. "as humans and diseases continue to travel globally, international coordination between jurisdictions will be increasingly important regarding electronic data such as that represented in USCDI, US Core, and specialized Implementation Guides (IGs)".

- **Value Proposition and Incentive Alignment –** HL7 recommends additional federal incentives, funding and support for testing, implementation and maturing of standards in this area. All ecosystem participants must be considered, and should benefit areas identified as HIPAA administrative, financial, and clinical frameworks which increasingly intersect. Return on investment, including societal benefits, and both accrued stakeholder value, as well as recognizing both underlying cost structures, as viewed through a holistic perspective. Several

resources to aid advancement of public-private agreed upon framework include HL7's white paper *The Case for FHIR-Based Quality Measurement and Reporting* and it's outlined Value Metrics Framework. Explored elements are: expressivity, alignment, fitness, liquidity, community, extensibility, conformance, tooling, agility, re-usability, implementability, and value metrics. More information can be found at: http://www.hl7.org/documentcenter/private/standards/FHIR_GUIDE_QUALREPORT_INFORM_2020OCT.pdf and https://confluence.hl7.org/display/FA/Value+Metrics

- **Standards Exceptions Process: HIPAA Covered Entities –** HL7 strongly supports Consideration 3 to 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. Such a modified approach should require attestation of 'willing trading partner' participation, improve current exception guidelines and transparency through website posting. Insights from the current exception granted to the Da Vinci Project participants supports the view of the opportunity to refresh the exception process approach, as well as to address the potentially extraneous obligation by demanding that a revised business agreement be put in place before proceeding with granting the exception. The barriers to investing in modern approaches should be minimal, in order to encourage early and meaningful testing of emerging standards while ensuring appropriate and reasonable partnering is occurring. Interoperability proving ground experiences and opportunities to access emerging standards information publicly should be considered.

- **Standards Transition Policy** – HL7 recommends adequate, additional policy be in place for more agile standards transitions involved in HIPAA administrative transactions and explicit detail about guardrails and sunsets that are a part of this process to ensure efficiency and transparency. A focus on investing, advancing and aligning both federal frameworks and tools is critical, as underscored by the *FHIR Roadmap for Trusted Exchange Framework and Common Agreement (TEFCA) Exchange*.

  HL7 believes that it is critical to accelerate investment in technical tooling and education, in order to extend existing efforts to coordinate and align regulatory and sub-regulatory methods to advance health IT frameworks. This effort will more effectively support the industry in applying clinical and administrative regulations, guidances, and create clearer understanding of timing and triggers mechanism. This approach also provides a better use of resources for developing, vetting, adopting, implementing and maturing standards that support interoperability in Health IT services, products and related use by end-users.

  For example:

  The Standards Version Advancement Process (SVAP) methodology of adopting base standards. Allowing newer versions to be voluntarily adopted should be extended. Emerging capabilities, such as the Interoperability Standards Advisory (ISA), can be examined as a model that aids the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the US healthcare industry to address specific interoperability needs. This process should include, but not be limited to, interoperability for clinical, public health, and research purposes. The ISA already contains HIPAA administrative transactions standards and operating rules.

  Moreover, a relevant concept that was included in HL7's June 9 listening session remarks emphasized that much of the health care industry is hesitant to make financial and operational investments to test or use an updated or new standard without a federal mandate. Early reporting on use, then increasingly to qualitative and increasingly quantitative measures could be a valuable strategy. In terms of global alignment, HL7 urges an examination of the Digital Square Global Goods Maturity Model, which can be accessed at: https://wiki.digitalsquare.io/index.php/Global_Goods_Maturity https://wiki.digitalsquare.io/index.php/Global_Goods_Maturity#Digital_Square_Maturity_Model_Details.

Global Goods are the most prevalent classification and packaging of digital health tools outside of the U.S. context and particularly in Lower and Middle Income Countries (LMICS).

- **Standards Versioning –** HL7's wisdom, lessons learned and current state thinking regarding standards versioning are detailed below. We stand available for additional questions and eager to partner in finding viable ecosystem wide solutions.

  Regarding standards versioning, first and foremost, a distinction must be made in standards versioning between addressing an expansion of choices where there is a nonfunctioning, lightly adopted named standard and scenarios in which there is not a named standard, but one is needed. The focus should be on optimal advancement in each scenario.

  Secondly, complex interdependencies exist between standards and implementation guides (IGs) that are developed by SSOs, adopted then implemented as national standards and included in federal certification programs. There is no clear cadence for HIPAA transaction standards related upgrades. Methodologies related to healthcare operations related initiatives, as led by Office of National Coordinator, have benefited from the HIPAA experience. Today, there is a pressing need to craft a balanced, cohesive signaling and predictability approach as we move forward.

  Lastly, the current process of naming required standards in regulation for every instance (tied to regulatory methods, as is done today) is not meeting nor keeping pace with societal and business demands. Upgrade approaches should leverage the Standards Version Advancement Process (SVAP) for HIPAA administrative standards. Progress involves public-private partnership(s) working to solve these challenges as well as converging frameworks.

  Other relevant standards versioning comments included in HL7's June 9 listening session remarks are noted below:

  As technology evolves, it is rapidly transitioning from transaction-based industry architecture to an environment that embraces modern API based standards for more real-time workflow and access to information. Our HIPAA standards need to follow this model, which has been proven to work by other industries for more than two decades. 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 that is demanding accurate, patient-centric data when and where it's needed in a manner that is with little to no friction.

  Today there are challenges that reflect upon how standards are developed then adopted as national policy. These specifications often require a uniform versioning framework, such as the Standards Version Advancement Process. However, if the industry expects to adapt and to enhance data exchange, whether transactional or purely clinical, we must enable implementers to advance and innovate, while maintaining a floor that each component of the community can support. Extending existing efforts to coordinate and align regulatory and sub-regulatory methods to advance health IT frameworks is essential. With clear mapping and crosswalk, the use of multiple standards or versions of a standard occurs across many industries today allows for advancement of technology capabilities independent of herculean upgrade efforts. Now is the time to fully integrate the administrative and financial requirements with the clinical frameworks in order to keep pace with societal needs and expectations, as well as the power of technology.

At HL7, we recognize the complexities and the burden of supporting multiple versions of adopted standards. Such an undertaking requires the capabilities and commitment of HL7 to develop and maintain needed versions. HL7 must and will do so in partnership with key stakeholders, end-user, technology developers, government agencies and others. HL7 has been and continues to transform in response to lessons learned and the needs of its community. HL7 FHIR Accelerator Programs have already shown a very different approach to standards adoption. It is no longer an expectation that "if you build it they will come". HL7 FHIR Accelerators have successfully demonstrated that if you provide the right environment and enable truly relevant rationale for development, innovators will coalesce around mutually beneficial deliverables, in order to build, test, implement and mature these industry-changing capabilities.

No one at HL7 believes that the complexities and burden of supporting multiple versions is an easy one. We do not expect to have answers to every problem. We recognize that our community will create solutions to problems within our sphere to address many of these obstacles. In order to become a reality, the process requires a robust governance, sound methodologies and, most importantly, the trust to enable the right people to collaborate on defining and solving those problems. This approach enables modifications based on real-world use both before and in tandem with the SSO ballot processes. This is the basis of the modern agile development process.

As a result, standards processes are able to establish their own operational guidelines and instructions with rich examples in a self-contained manner, in between formal regulatory (version) updates. In fact, HL7 FHIR does this today with supplemental Implementation Guides, at the heart of every Accelerator. In an ideal world, the implementers will be able to work with other SDOs to establish the floor and ceiling across a timeline, and any interim, supplemental guidance can be maintained, supported by the active implementer community with support of the standard owner. Ultimately, the community creating the design, and implementing and operating the standards, are best able to mature and curate them.

- **Increased Standards Testing –** HL7 agrees with the need for increased standards testing that was mentioned by multiple speakers at the listening session. Connectathons and more standards pilot testing were offered as examples. HL7 supports and can facilitate more Connectathons and standards pilot testing with adequate assistance. As HL7 stated in its July 2021 letter to the NCVHS Subcommittee on Standards, "successfully transitioning from the current state to a new state of standardized interoperability requires focused programs that involve both human and financial resources." A few points are important to highlight here. First, there is value in increased documentation as well as increasing the transparency of tracker items emerging from the testing process. Connectathons most effectively enable the sharing of significant learnings and substantially reflect the depth and value of testing characteristics tools, participants and results. Secondly, more sandbox testing with robust proof of concept and peer-to-peer learning, as well as ideal facilitation, documentation and resource sharing, is needed and requires additional federal monies. The HL7 Gravity Project has funding from the Office of the National Coordinator for Health Information Technology (ONC) to do this within their domain. The Gravity Project's efforts could potentially be scaled for other HL7 FHIR Accelerators.

- **Standards Guidance Framework –** HL7 supports and highlights Consideration 5 to develop and publish a standards guidance framework with recommended definitions, metrics, templates, and pilot test procedures. HL7 observes that there can be a valuable role for WEDI, HHS and others to maintain the framework, updates, and validation, but the content should emanate from the community of implementers to assure alignment. The framework should evaluate the standards and specifications, and evaluate and resolve the impediments to implementation, as well as provide a consistent library of best practices. This framework can contain examples for industry stakeholders utilize and modify in order to support a continuous learning

process around the value and importance of standards adoption and participation in the development processes.

- **SOGI, SDOH and Public Health Issues** – As was mentioned at the June 9 listening session, greater insight is needed on Sexual Orientation and Gender Identification (SOGI), Social Determinants of Health (SDOH) and public health issues in this space. Moreover, federal, state and local policy should be better aligned. HL7 emphasized in its July 2021 letter to the NCVHS Subcommittee on Standards that, "development and adoption of common data standards is foundational to identifying inequities, identifying potential interventions, coordinating interventions across agencies, measuring progress, and conducting research and evaluation. Requiring that health systems collect standardized data elements indicative of social determinants of health, and report these data, are key to improving the ability to share data that helps our society address inequities."

  HL7 Accelerators, such as the Gravity Project and Helios, and HL7 Work Group initiatives focused on Public Health and Gender Harmony, can aid significantly in lending details, knowledge and insight on these issues. We stand ready to help. We would also recommend the development of knowledge aggregation processes. One such approach would be to constitute NCVHS hearings featuring SSOs and relevant stakeholders that discuss SOGI, SDOH and public health issues. The role of standards and electronic data transport and interoperability in the area of health and disability is also an important, emerging issue.

  In closing, HL7 looks forward to speaking with NCVHS and it's Subcommittee on Standards regarding the issues outlined in this letter. We would be happy to offer additional information and rationale. Specifically, we are very committed to expounding on our recommendation that NCVHS formally recognize HL7 FHIR as an alternate standard to applicable, existing mandated HIPAA transaction standards. We believe that this will ultimately advance the nation's journey of integrating clinical and administrative frameworks and related interoperability objectives.

Squire, Marietta (CDC/DDPHSS/NCHS/OD)

From: Christopher Gracon <Christopher.Gracon@independenthealth.com>
Sent: Wednesday, June 22, 2022 6:32 PM
To: NCVHS Mail (CDC)
Cc: Jonathan Fox
Subject: Comments on NCVHS Subcommittee on Standard Questions June 9, 2022

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

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 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	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.

policy directions of ONC's interoperability and information blocking initiatives.	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 a 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 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	Pros: • Multiple versions of the same transaction could allow for willing trading partners to make use of newer functionality • Ease introduction of newer versions

components: locally unnecessary updates; avoidance of cost and disruption; easier management of update implementations?	• 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.
The NCVHS Subcommittee on Standards suggests three versions simultaneously in production would be the maximum. How many simultaneous version 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. • Standard 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.
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.

Christopher Gracon
Solution Architect
Independent Health

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CDC/National Center for Health Statistics
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Hyattsville, MD 20782-2002

June 23, 2022

Via: NCVHSmail@cdc.gov

Re: Follow-Up to the June 9 Listening Session

Dear Mr. Landen and Ms. Love:

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 standard 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.

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 improvments/ 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.
Sincerely,

/s/

Nancy Spector

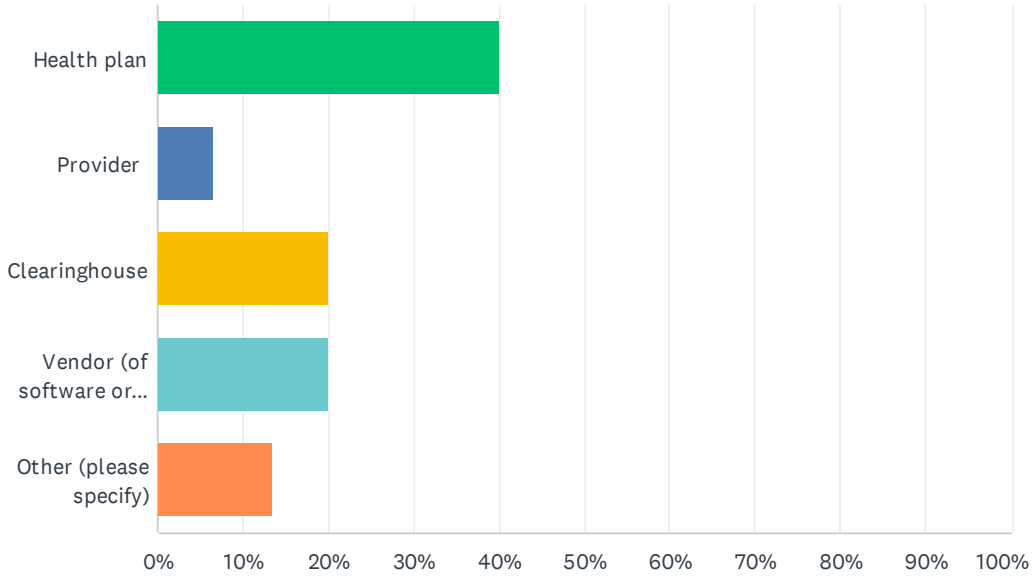
Chair, WEDI

cc: WEDI Board of Directors

//attachment

Q1 Which of the following industry stakeholder best describes your organization?

Answered: 15 Skipped: 0



ANSWER CHOICES	RESPONSES	
Health plan	40.00%	6
Provider	6.67%	1
Clearinghouse	20.00%	3
Vendor (of software or hardware products or solutions)	20.00%	3
Other (please specify)	13.33%	2
TOTAL		15

#	OTHER (PLEASE SPECIFY)	DATE
1	Consultant to Health Plan/Payer.	6/7/2022 5:00 PM
2	Technology Service Provider (Clearinghouse plus Vendor)	6/6/2022 11:23 AM

Q2 For providers, would availability of choice between an app-based standard and an X12-based standard be of value? Why or why not?

Answered: 7 Skipped: 8

#	RESPONSES	DATE
1	Abstain	6/7/2022 5:49 PM
2	The APP-based standards make so much sense since that is the way the world is moving. The X12 standards are so out dated that they don't work effectively anymore.	6/7/2022 11:57 AM
3	No, it is likely to cause confusion. Also, the variation will cause to longer interoperability integration.	6/7/2022 11:18 AM
4	Most providers usually aren't bought in to, or knowledgeable about, a particular standard -- they just want a solution that works. Their choice is really the solution(s) provided by their vendors. For larger providers, additional standards would be valuable.	6/6/2022 11:23 AM
5	No. Make it one standard fir all. We should give them the easiest to implement choice. Put the burden on the payers. They are the ones bringing in billion dollar profits.	6/4/2022 12:19 PM
6	N/A	6/3/2022 2:38 PM
7	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.	6/3/2022 2:34 PM

Q3 For health plans, 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.)

Answered: 13 Skipped: 2

#	RESPONSES	DATE
1	Abstain	6/7/2022 5:49 PM
2	No, there is no significant offset. The industry has failed to eliminate prior standards and/or technologies following the adoption of a new standard. The only exception to this was when the x12 4010 standard was replaced by the 5010 standard, and a single standard remained. Adopting new standards and/or technology 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, and no one appears interested in eliminating any of the prior "solutions".	6/7/2022 5:00 PM
3	This would increase the cost of customer support as there'd be more than one way to receive and process transactions, which could fall on different areas doing the same operational support activities. It would be less valuable to allow the option of more than one solution, but it would be advantageous to be consistent and standardize the solutions so as not to provide more than one way to interpret or implement multiple solutions, which is contrary to the concept of administrative simplification and cost savings by doing standardization.	6/7/2022 4:36 PM
4	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.	6/7/2022 4:20 PM
5	No, unlikely. It is likely to cause more confusion and support times.	6/7/2022 11:18 AM
6	Yes. The current first-pass success is very high (>90%). Technology must enable first-pass transmission of all necessary data.	6/6/2022 11:23 AM
7	No. There needs to be more partnership in care. Customer service is the goal of most business. Why would someone need an offset by doing what they should be doing anyway. Again, look at the overall cost structures. They need to be more balanced to decrease overall healthcare costs in the US.	6/4/2022 12:19 PM
8	We're going for paperless as much as possible. So a reduction in customer service report, at least for first pass processing would be great.	6/3/2022 6:10 PM
9	No. IMO I don't see multiple standards reducing cost of Customer Support.	6/3/2022 2:46 PM
10	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	6/3/2022 2:42 PM
11	no. the hipaa transactions are very well penetrated in the healthcare industry and adopted by both payers and providers, adding an additional standard would only shift that volume and increase costs to payers. Provider system vendors, and providers should optimize the adoption and utilization of the standards already in place. 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 and example of significant payer expense (both in terms of dollar cost and development time spent) with very little current traffic. Those early FHIR functions are not delivering ROI compared to the cost of development.	6/3/2022 2:42 PM

12	N/A	6/3/2022 2:38 PM
13	Many health plans have limited budgets and have not fully implemented the current standards. So adding to that will increase the burden on health plans and potentially cause implementations that do not fully meet the need. A current example is the use of portals by health plans to technically meet some of the requirements, but cause additional manual work for providers.	6/3/2022 2:34 PM

Q4 For system vendors (including providers and health plans 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.

Answered: 8 Skipped: 7

#	RESPONSES	DATE
1	Clearinghouses will continue to support whatever standards are adopted by the Secretary to provide compliant service to payers and providers as needed. Each clearinghouse will need to negotiate with their trading partners to support multiple formats based on return on investment and simplify that connectivity for their provider clients. 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 so that providers may focus on care. X12 standards for administrative transactions today support millions of transactions per day and are fully interoperable. Adding FHIR API transactions does not change the need for providers to access many different payers and to maintain connectivity for those connections. The technology is not widely accepted or understood in the administrative arena today and would require translation to X12 standards to meet the needs of the adjudication systems at payer. As versions, standards and operating rules for those standards continue to change in the future, work needed to maintain all the implemented standards would increase substantially over today.	6/7/2022 5:49 PM
2	Adopting additional alternative standards will increase complexity and cost. Technical support, software maintenance, software licensing fees, people resources, help desk, audit support, training fornew 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.	6/7/2022 5:00 PM
3	No. More standard releases with different release schedules and will take a lot more effort to keep up to date.	6/7/2022 11:18 AM
4	Yes, the cost would increase but can provide more value.	6/6/2022 11:23 AM
5	As more integration takes place, we need to make sure we are looking at total cost and not just one sides cost. We should probably set a timeline for moving to one standard for everyone within the soonest time frame possible and certainly within the next few years.	6/4/2022 12:19 PM
6	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.	6/3/2022 3:04 PM
7	In the short-term it will increase complexity but in the long-run it will decrease and simplify options and methods.	6/3/2022 2:38 PM
8	Multiple standards would very much increase the complexity of systems and cost of maintaining. It may make the systems more flexible towards meeting various customer needs.	6/3/2022 2:34 PM

Q5 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?

Answered: 15 Skipped: 0

#	RESPONSES	DATE
1	Local updates will still occur based on local business needs or agendas regardless of 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. Essentially, multiple versions allow providers to avoid upgrading systems unless there is a true cost benefit for the added functionality of a new version. This allows industry leaders to experiment and prove beneficial capabilities while allowing others without the means to experiment with new technology to remain on cost effective systems. In theory, if the implementation of new versions comes on a set and predictable time scale, implementation challenges due to contracting, upgrading EDI systems, managing versions, and onboarding can be overcome. If versions progress at a faster timescale, but are not implemented as standards, we will continue to see challenges similar to the 5010 implementation. We recommend supporting no more than 2 versions for a limited timeframe to support transition to the new standard and sunset the old.	6/7/2022 5:49 PM
2	Use of a common version provides the easiest means for ensuring a "standard" and most error-free solution for any data exchange. Utilization of a single version provides the most easily supported environment for all trading partners to employ, removes a barrier to entry, and simplifies market adoption of new entrants. If adoption of a new standard or technology is integral to the use of new functionality, then that functionality can be developed and adopted with that standard embedded as part of the new solution. Entities deciding the new functionality is worth the investment can make a reasoned assessment and decision to commit to the new solution along with that new standard.	6/7/2022 5:00 PM
3	It's always best to allow for multiple versions to keep up with industry and healthcare landscape. However, it's going to need to have guardrails as payers will likely require their consumer communities to change when they want to move forward, which could provide a cost implication to existing consumers. It's best to say they can support multiple version, but at a minimum have to always have the "mandated" version (i.e., 5010) in place while experimenting with newer more current versions.	6/7/2022 4:36 PM
4	The main pro is being able to transition over to a new version gradually rather than a big bang approach. For the 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.	6/7/2022 4:20 PM
5	I believe multiple versions could be successful if payers would not contractually require providers to use a certain standard.	6/7/2022 11:57 AM
6	Much better to improve current standard. New standards do not solve the underlying problem. They will create complexity and require ability to move between standard which is costly and not sustainable.	6/7/2022 11:18 AM
7	Pros - gives stakeholders choice and different use cases may be more appropriate for different standards. Also promotes modernizing. Cons - adds complexity. Neither pro or con: Heavier reliance on technology enablers.	6/6/2022 11:23 AM
8	We need to stop having multiple versions and ways of doing things. That is a main reason for the excessive costs in the US. Put everyone on the same standard and you open the system up to cost savings and innovation like other top tier countries do. One system with everyone in	6/4/2022 12:19 PM

	has been proven better in every other industry. How would finance happen if everyone was on different standards. We need consolidation on standards. Find the best and use it everywhere.	
9	It would be great to be consistent. For example, by 2025, everyone be on version 8020 - 275 attachments, and accept both the 2 different CAT02 elements = HL or IA.	6/3/2022 6:10 PM
10	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 are to know what version of the standard is currently implemented, there are better ways to handle this than having two versions in flight at the same time.	6/3/2022 3:04 PM
11	Con: 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 so support the lower standards to ensure can deal with all partners, so there is little savings and increased support.	6/3/2022 2:46 PM
12	Unless there is a consensus as to which versions to support, I do not see any pros to this opportunity. Providers interact with multiple payers and if those payers offer support different versions, it could be a burden on providers to themselves support multiple versions. This could also result in more painful transitions between versions if providers (or payers) decide to delay adoption of newer versions.	6/3/2022 2:42 PM
13	pros - undetermined cons - added maintenance, multiple copies of code sets that need to be synchronized, multiple locations of security and provider identification locations in the architecture	6/3/2022 2:42 PM
14	Supporting multiple versions is the only way to transition from the current world to ta new world. There has to be overlap to allow legacy transactions while enabling innovators to move forward. Then everyone will move over-time.	6/3/2022 2:38 PM
15	Supporting multiple versions if allowed but not required allows innovators to move ahead as their schedule requires, but does require coordination with business associates like clearinghouses to bridge the gap between trading partners in various stages of readiness. If a health plan allows multiple versions of a transaction, then as providers are ready, they can move to that version, which may ease the transition. Clearinghouses have historically provided "upconvert" or "downconvert" processes to help facilitate between trading partners are varying stages of readiness during transaction transitions.	6/3/2022 2:34 PM

Q6 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?

Answered: 14 Skipped: 1

#	RESPONSES	DATE
1	The wide array of mandates placed upon healthcare stakeholders is a common generator of complexity as is the presence of insurance between the consumer and the vendor of services. Factors such as the No Surprises Act mandated requirements for a Good Faith Estimate and Advanced Explanation of Benefits place demands on standards of communication and the capability of those standards between providers and health plans. These requirements or other present or future mandates, more than choice, may dictate the use of the version of the standard based on the capability of that standard. For instance, the 5010 version of the 837 claim standard does not support pre-adjudication, whereas the 8020 does. This difference in capability may become a mandatory requirement for compliance with future rulemaking making the 5010 version all but obsolete, not at the choice of the provider, but demands from industry regulation. Versioning therefore, is only useful to the degree of difference in capabilities between the versions. During the 5010 implementation and after clearinghouses regularly accepted 4010 versions of transactions and upconverted to send to payers. In cases where data fields could not be automatically mapped, providers would need to manually enter the data after the conversion in the applicable fields. Maintaining multiple versions of the standard thus 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.	6/7/2022 5:49 PM
2	Yes, multiple versions pose complexities and barriers in Health Care. If one entity adopts the latest X12 standard, for example, and other entities do not, processing capabilities can be different between the adopter and the non-adopters. Non-adopters cannot avail themselves of the benefits of the newest standard and will not be able to respond "in kind" to the adopter entity. Uniform adoption of a common standard provides a level playing field and standardizes expectations for all entities. Entities will not need to train, support and maintain multiple versions that are intended to perform the same function.	6/7/2022 5:00 PM
3	This would depend on whether or not there's the ability to toggle between versions or not. It's possible that the front-end EDI standards could change, and the processing behind the scenes still be on the lagged version. It's best to outline the expectations of not just enabling EDI capabilities to support newer versions, but to require that the backend, underlying applications must also show some advancement to clearly take advantage of the newer capabilities in the transactions. "Lipstick on a pig" will not be good enough. However, it must be said that supporting multiple versions may have disadvantages as well. It's good to "POC" the newer versions, but there should be some form of an incentive to doing so otherwise, the larger, more "customer" focused organizations will be selective in what they're going to spend their money on and POC's likely won't make the top of the list without some incentivizing.	6/7/2022 4:36 PM
4	This has the potential to be a great burden. Health Care's administrative transactions have historically been based on implementations of a standard transaction, as opposed to the base standard itself. This adds complexity to the differences that may occur between implementation versions. When an implementation makes significant changes in the way the transaction works (reference differences between 5010 and 8010 270/271 for example), the work is labor intensive and costly.	6/7/2022 4:20 PM
5	At least 6x. 1x = current standard; 2x = new standard; 3x = exchange / interoperability between 1st and 2nd standard. Then add 4x and 5x because typically there is current and n-1 version. Now apply that to 2 standards.	6/7/2022 11:18 AM
6	The burden is on the technology enablers (vendors, clearinghouses, and to some extent health plans). There will be a flow-down of cost to providers. Technology providers typically do	6/6/2022 11:23 AM

	support multiple versions already. There is always complexity initially with the introduction of a new standard, which lessens over time. It's very important to agree on the codes and other semantics, versus syntax (format).	
7	Yes. It is more complex and other industries do not have multiple versions. Finance, food supply, manufacturing, airlines all have a single standard fir transactions. Only healthcare lags.	6/4/2022 12:19 PM
8	It's costly to maintain, e.g., 5010 attachments and 6020 attachments. It's nuanced and different for healthcare - because of the additional HL7 standard involved.	6/3/2022 6:10 PM
9	Healthcare is not the same as other industries. Other industries do not have base standards, national guides, federal mandates, companion guides and then CAQH guidelines - not to mention WEDI rules to follow - to add the layer of complexity of multiple versions of the standard would be onerous at best. Please describe the other industries which mirror this level of complexity.	6/3/2022 3:04 PM
10	The entity with lower versions could not do business with the more advanced entity unless entity with higher version also had to be backwards compatible, so little saved by going to higher version, and unnecessary complexity.	6/3/2022 2:46 PM
11	Potential increase in infrastructure costs to develop & maintain multiple workstreams with different processing requirements	6/3/2022 2:42 PM
12	Due to the complexity of healthcare information and multiple systems being in play in order to feed information to operational datastores (administrative data systems are not the same as clinical data systems) many payers have had to develop in-house developed systems to satisfy mandates (or have many compenents that are in-house developed). Multiple standards would increase that complexity by adding multiple entry points into the organization (clinical integration points are often different than administrative). For a given function it should not be considered burdensome for regulatory bodies to pick one standard and stick with it and allow minimum development cost to be spent, and allow the maximum ROI to be delivered on a solution. Multiple standards would mean a spread of the volume of transactions across systems, but not mean an increase in adoption or utilization. A preference would be to pick a standard for a function and be clear on the requirement to adopt that.	6/3/2022 2:42 PM
13	Its not significant. See above - it's required to support transition and allows plans and providers to bridge at different times. Orchestrating a mass start with a new set of standards is prone to disaster.	6/3/2022 2:38 PM
14	In situations where the variance between versions is large, the burden of supporting multiple versions may be large as well, as separate processing may need to take place depending on the version used. If the variance is smaller, then a single system may be able to manage those variances during processing. From a provider perspective, vendor (PMS/ A/R systems) must have the same requirement and be able to manage multiple versions, or again a clearinghouse may be required to do an "upconvert" or "downconvert" to get the appropriate version of the transaction to the provider.	6/3/2022 2:34 PM

Q7 The NCVHS Subcommittee on Standards suggests three versions simultaneously in production would be the maximum. How many simultaneous versions should be allowed? Why?

Answered: 14 Skipped: 1

#	RESPONSES	DATE
1	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. While there should be a limit on any number of allowed versions for practicality of maintenance, the real question is the difference in capabilities between the versions and the needs of the industry. If the purpose of versioning is to move away from the one size fits all concept to differences in capability in the versions, perhaps that really needs to be addressed through more specialized implementation guides, rather than versioning.	6/7/2022 5:49 PM
2	Two. One that is the commonly-adopted "production" form; and a second that is the "next generation - under-development" form.	6/7/2022 5:00 PM
3	3 maximum could be extreme for small providers who cannot afford vendor intermediaries, or multiple integrations; could pose problematic for huge payers who have too many fires to spend on "nice to have" implementations unless something requires them to do so.	6/7/2022 4:36 PM
4	We understand the concept here 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 what has been stated in previous question responses.	6/7/2022 4:20 PM
5	It should be limited to current and current minus 1 version back for backward compatibility till it is phased out.	6/7/2022 11:18 AM
6	Three is okay, but two is ideal. The complexity of supporting multiple standards is not cost-effective. It is also imperative to increase the speed from development to adoption.	6/6/2022 11:23 AM
7	One. Find the best and move to it based on what works for the smallest. We need to start taking care of our rural and underprivileged. Everyone deserves excellent care and the ability to afford it. We need to start looking at decisions from a total country perspective.	6/4/2022 12:19 PM
8	2: 6020 & 5010 for attachments - so the cost burden wouldn't be as high. Also not everyone uses all of the CAT02 elements. For example, just to start out, some Payers and Providers only want to use the non-HL7 standard, just to get up and running with attachments. Then learn the rest of the HL7 later on and add that in, in the future.	6/3/2022 6:10 PM
9	One. Please see the answer above. Healthcare implementations have already been made too complex. If you could remove the complexities, then perhaps this is a possibility - but until this can be done with one singular implementation of a new X12 standard, this is not a feasible statement.	6/3/2022 3:04 PM
10	1	6/3/2022 2:46 PM
11	1 version should be allowed except when a new version is being adopted; then there should be a temporary overlap period where the outgoing and incoming version are allowed.	6/3/2022 2:42 PM
12	1 standard. Maximize the ROI for the developement of a given function, our goal should be to reduce administrative expense, multiple standards could add costs without increasing adoption or utilization, current systems are architected towards one standard and are already mulit-million dollar investments, don't make them more expensive than they really need to be. Think LEAN.	6/3/2022 2:42 PM
13	Three seems reasonable in today's world.	6/3/2022 2:38 PM
14	Two versions (current and next future version) should be supported to allow innovators to move forward and provide feedback on that future version.	6/3/2022 2:34 PM

Q8 If your organization has considered participating in testing emerging or alternative standards, was 162.940 [the HIPAA Exceptions Process] an impediment or not? Did it ever discourage you from even considering participating in testing?

Answered: 11 Skipped: 4

#	RESPONSES	DATE
1	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.	6/7/2022 5:49 PM
2	N/A	6/7/2022 4:36 PM
3	We have not considered participating	6/7/2022 4:20 PM
4	It is better to have established standards rather than allowing exceptions. Exceptions lead to variations which lead to disjointed industry adoption.	6/7/2022 11:18 AM
5	We believe it is working as designed. However, the exception process should require support of the existing standards as well.	6/6/2022 11:23 AM
6	HIPAA needs to be updated to look more like GDPR. There are too many tech companies controlling data that should belong to the patient. The exception process should not be necessary. People should know up front what they can and cannot do and build their solutions around that. Less focus on payer profit and more on making it easier to do the right thing.	6/4/2022 12:19 PM
7	N/A	6/3/2022 6:10 PM
8	N/A	6/3/2022 3:04 PM
9	n/a	6/3/2022 2:46 PM
10	The short-term nature of the exception timeframe and the onerous reporting requirements has discouraged us from seeking this option.	6/3/2022 2:38 PM
11	N/A	6/3/2022 2:34 PM

Q9 If 162.940 [the HIPAA Exceptions Process] were revised as described, do you think that would make your attitude toward participating in testing more favorable, less favorable or unchanged?

Answered: 13 Skipped: 2

#	RESPONSES	DATE
1	It would likely not change the attitude toward participation that exists today as the administrative hurdle is not the true burden of testing.	6/7/2022 5:49 PM
2	Allowing an exception to current standards for those entities engaging in development of an alternative pilot solution should be initially granted for a period longer than three years, to insure sufficient time for development, deployment, and a Live Test and Demonstration period. How long have the HIPAA standards been approved, and in place, and yet the industry has still not uniformly adopted them as a common "production" solution? About 25 years?	6/7/2022 5:00 PM
3	N/A	6/7/2022 4:36 PM
4	A simple, streamlined exceptions process may encourage more participation- perhaps something more akin to a registration process, rather than a request for exception.	6/7/2022 4:20 PM
5	Less.	6/7/2022 11:18 AM
6	Unchanged.	6/6/2022 11:23 AM
7	Unchanged	6/4/2022 12:19 PM
8	We're thinking about being part of a CAQH attachment pilot in 2023. So I don't know at this time. N/A.	6/3/2022 6:10 PM
9	Always willing to move forward if it makes sense.	6/3/2022 3:04 PM
10	do not have enough info regarding this process to answer question	6/3/2022 2:46 PM
11	adding flexibility at the cost of clarity is not a win.	6/3/2022 2:42 PM
12	Unchanged really.	6/3/2022 2:38 PM
13	potentially more favorable, depending on the reporting requirements	6/3/2022 2:34 PM

Q10 Are there other approaches you would suggest NCVHS consider in lieu of or in addition to changing 162.940 [the HIPAA Exceptions Process]?

Answered: 11 Skipped: 4

#	RESPONSES	DATE
1	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.	6/7/2022 5:49 PM
2	N/A	6/7/2022 4:36 PM
3	See question 9	6/7/2022 4:20 PM
4	Be more nimble, create and adopt new HIPAA transactions in more timely manner.	6/7/2022 11:18 AM
5	Federally supported funding/piloting would help.	6/6/2022 11:23 AM
6	Mentioned above. Change the rule to a more modern version without exception. All formats for standards can now be tested with anonomized data. Find the best way and cut out all this other nonsense. Be a leader in changing our laws to present time.	6/4/2022 12:19 PM
7	Haven't considered yet.	6/3/2022 6:10 PM
8	NCVHS should consider simplifying the standard to one and only one standard which supports all of the business and content needs. If this means moving away from X12, then perhaps this is the correct answer.	6/3/2022 3:04 PM
9	do not have enough info regarding this process to answer question	6/3/2022 2:46 PM
10	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.	6/3/2022 2:38 PM
11	If the previous questions, 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. Emphasis on WILLING, must be voluntary, not required, to use the next version.	6/3/2022 2:34 PM

Q11 How might a revised exception process impact the number of versions simultaneously your organization could support (as per Consideration 2)?

Answered: 12 Skipped: 3

#	RESPONSES	DATE
1	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.	6/7/2022 5:49 PM
2	Current costs for staff and technology counter the benefits of being an early adopter of a solution which 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.	6/7/2022 5:00 PM
3	N/A	6/7/2022 4:36 PM
4	Additional participants conducting more pilot implementations would give great data that could support the business case for newer versions.	6/7/2022 4:20 PM
5	allow exception as long as they remain on the same standard, i.e. HIPAA.	6/7/2022 11:18 AM
6	Again, federal funding is critical.	6/6/2022 11:23 AM
7	If we modernize the system there would not need to be multiple versions or exceptions. Time to update our thinking and quit being the most costly and lowest outcome provider in the first tier country world. Think about major change, not outlier bandaids.	6/4/2022 12:19 PM
8	Maybe or 3 max versions.	6/3/2022 6:10 PM
9	We do not believe having more than one version or more than one standard is a correct vision.	6/3/2022 3:04 PM
10	do not have enough info regarding this process to answer question	6/3/2022 2:46 PM
11	It may increase it if the process was simplified (lower burden of participation).	6/3/2022 2:38 PM
12	no change to answer	6/3/2022 2:34 PM

Q12 Are the business needs currently being 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.)

Answered: 13 Skipped: 2

#	RESPONSES	DATE
1	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.	6/7/2022 5:49 PM
2	The problems with standards are two fold: 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)	6/7/2022 4:36 PM
3	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.	6/7/2022 4:20 PM
4	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.	6/7/2022 11:57 AM
5	Yes, the issue is in adoption of new versions and new transactions. Issue is not with the standards.	6/7/2022 11:18 AM
6	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.	6/6/2022 11:23 AM
7	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.	6/4/2022 12:19 PM
8	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.	6/3/2022 6:10 PM
9	No.	6/3/2022 3:04 PM
10	If they are being captured it is not a defined, simple process--but adhoc in nature.	6/3/2022 2:46 PM
11	yes.	6/3/2022 2:42 PM
12	I don't think so. They are happing in small pockets but without a real framework or set of	6/3/2022 2:38 PM

	guidelines for measurement.	
13	There are currently challenges with measuring success of the standards in place. CAQH CORE publishes their information on standards usage; however, that is dependent upon the entities that participate in their evaluation, so may not completely reflect all entities. CMS receives information on implementation success based on complaints received or audits performed, so again, may not reflect overall industry success.	6/3/2022 2:34 PM

Q13 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.)

Answered: 13 Skipped: 2

#	RESPONSES	DATE
1	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.	6/7/2022 5:49 PM
2	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.	6/7/2022 5:00 PM
3	Unknown	6/7/2022 4:36 PM
4	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.	6/7/2022 4:20 PM
5	Yes, CAQH index does a great job.	6/7/2022 11:18 AM
6	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.	6/6/2022 11:23 AM
7	No. It is based on the current system, which we all know is very poor. Use this time to make it right.	6/4/2022 12:19 PM
8	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.	6/3/2022 6:10 PM
9	No.	6/3/2022 3:04 PM
10	I am not aware of guidance framework components for standards	6/3/2022 2:46 PM
11	yes.	6/3/2022 2:42 PM
12	Not really. The guidance framework need to be adaptable and agile enough to accommodate variations of the use- cases and results of pilot testing.	6/3/2022 2:38 PM
13	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.	6/3/2022 2:34 PM

Q14 How could a guidance framework be created and maintained(i.e., how do you see the alternatives for the public sector or private sector)?

Answered: 9 Skipped: 6

#	RESPONSES	DATE
1	Unknown	6/7/2022 4:36 PM
2	Industry groups, engaging their constituents should collaborate on these definitions, metrics, templates and procedures to gain consensus.	6/7/2022 4:20 PM
3	Do connectathons similar to Da Vinci but for HIPAA.	6/7/2022 11:18 AM
4	Private and public sectors need to work collaboratively, from start to finish.	6/6/2022 11:23 AM
5	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.	6/4/2022 12:19 PM
6	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).	6/3/2022 6:10 PM
7	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.	6/3/2022 3:04 PM
8	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.	6/3/2022 2:46 PM
9	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.	6/3/2022 2:38 PM

Q15 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?

Answered: 11 Skipped: 4

#	RESPONSES	DATE
1	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.	6/7/2022 4:36 PM
2	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.	6/7/2022 4:20 PM
3	Require reports from connectathon use cases.	6/7/2022 11:18 AM
4	Outline at the start of the program what metrics you wish to measure, in advance, and create a reporting system around those metrics.	6/6/2022 11:23 AM
5	Create the measurement system when you establish the framework. Build the metrics on ease of use, cost reduction and consistency.	6/4/2022 12:19 PM
6	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.	6/3/2022 6:10 PM
7	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.	6/3/2022 3:04 PM
8	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 improvments/ 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.	6/3/2022 2:46 PM
9	an 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.	6/3/2022 2:42 PM
10	There would need to be simple reporting mechanisms to capture key metrics like time savings per transaction, etc. Very similar to how CAQH collects it's index metrics for administrative transactions use, cost and savings opportunities.	6/3/2022 2:38 PM
11	it must be automated and done in a standard way or this would not be successful.	6/3/2022 2:34 PM