National Committee on Vital and Health Statistics
Standards Subcommittee Listening Session
Standardization of Information for Burden Reduction And Post-Pandemic America
"Convergence 2.0"

Transcript

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Virtual

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Welcome, Call to Order, Roll Call

Rebecca Hines: Good morning to today's Listening Session of the Standards Subcommittee of the National Committee on Vital and Health Statistics, on the topic of Standardization of Information for Burden Reduction and Post-Pandemic America.

A warm welcome to our members and committee staff, members of the public in attendance with us here today. I hope everyone is well. My name is Rebecca Hines and I serve as the executive secretary and designated federal officer for the committee.

Today the committee is convening this listening session to hear input from stakeholders on draft considerations developed by the Subcommittee, and they are available on the website here. For those who may not have seen them, I am going to place the link in the chat so if you have not seen the considerations, here they are. I want to especially thank those who will be offering input and feedback today, both the invited panelists and those who plan to participate in public comments.

Note that the next meeting of the Full Committee is scheduled for mid-July, the 20 and 21st, where our Subcommittee co-chairs Rich Landen and Denise Love, will bring back findings from today to the full committee membership.

With that, let us take care of roll call now starting off with the committee chair, Jacki Monson. Good morning. State your name, your affiliation, your status as a special government employee and any conflicts.

Jacki Monson: Good morning. Jacki Monson, Sutter Health, Chair of NCVHS, no conflicts.

Rebecca Hines: Rich Landen.

Rich Landen: Good morning. Rich Landen. I am self-employed. I am the co-chair of the Standards Subcommittee, on the Executive Subcommittee, and I have no conflicts.

Rebecca Hines: Denise Love.

Denise Love: Denise Love. I am an independent public health data consultant. I am a member of the Standards Subcommittee and a member of the Full Committee. No conflicts.

Rebecca Hines: Deb Strickland.

Deb Strickland. Hi. I am Deb Strickland. I am a member of the Full Committee and the Standards Subcommittee, and I have no conflicts.

Rebecca Hines: Jamie Ferguson.

Jamie Ferguson: Good morning. I am Jamie Ferguson with Kaiser Permanente, a member of the Full Committee and of the Subcommittee on Standards. I have no conflicts. But I would note that we will have a panelist today from Kaiser Permanente. I will recuse myself from any discussions specific to Kaiser Permanente.

Rebecca Hines: Thank you, Jamie. Margaret Skurka.

Margaret Skurka: I am Margaret Skurka. I am a member of the Standards Subcommittee. I am Professor Emerita at Indiana University. I have no conflicts.

Rebecca Hines: Tammy Banks.

Tammy Banks: Tammy Banks, independent, member of the Full Committee, member of the Subcommittee of Standards, and no conflicts.

Rebecca Hines: Very good and I believe that is all of the membership on today. Have I missed any members? No. Okay.

Let us move over to staff. We have our Executive Director here today, Sharon Arnold.

Sharon Arnold: Hi. I am Sharon Arnold. I am the Associate Deputy Assistant Secretary for Science and Data Policy in ASPE. I am happy to be with you. Thank you.

Rebecca Hines: Thank you, Sharon. And none other than Lorraine Doo, who makes this all possible. Lorraine.

Lorraine Doo: Good morning. Lorraine Doo, policy advisor with the Health Informatics and Interoperability Group in the Office of Burden Reduction and Health Informatics, and lead staff for the Subcommittee on Standards.

Rebecca Hines: Thank you. A quick note on today's agenda for the members of the public. There are four periods of public comment as noted on the agenda. If you need the agenda, I am going to place it in the chat so you can find it. Rich Landen will go into detail on the process in a moment here.

Just a quick note that it is possible that the timing on the agenda may shift somewhat. The times listed are our best estimate of when public comment will take place. If you are planning to make a public comment orally, you will need to monitor the timing of the proceedings and feel free, as you see here on the slides, to send an email if for some reasons you cannot be here during the public comment period where your comment is relevant, at NCVHSmail@CDC.gov. We will read your comment aloud into the record.

With that, Rich, I will turn it over to you.

Agenda Overview & Review of Proceedings

Rich Landen: Thank you, Rebecca. First off, we will just do an overview of what we are going to do today and then the sequence and talk just a little bit about process. This is a session that the Subcommittee on Standards of NCVHS is looking to get some industry reaction to some of the considerations that the Subcommittee has put together based on earlier public input into the kind of vision that we need to ensure that the standards that we use in health and wellness for data interchange stay up to date and meet the industry needs.

Previous testimony has indicated there are some rough spots and there are some good spots. We listened very carefully to what you said. We put together a set of consensus considerations from the Subcommittee. And today, we are looking to get your reaction to those considerations.

They are, of course, at a necessarily high level because they are more of a vision or policy. They do not provide the detail of how they would be assembled and implemented. But the first step in this whole process for NCVHS is at a vision and policy level. Are we headed in the right direction?

Today, we will divide the recommendations into three groups, and we will have – for each of the three groups, we will have a short presentation by the moderator just to talk through what the consideration is and the implications and what problem we are trying to solve in a little bit more detail than what you saw in the agenda and in the questions that we sent out. We will have reaction to that from the panelists and then after each panel, we will have a public comment section. As Rebecca mentioned, at the end of the day, we will have another one.

But before we get started, there is so much going on in health care in standards and related issues that we are delighted that Dr. Mary Greene, the director of the Office of Burden of Health Informatics and Burden Reduction at CMS will be presenting a brief overview of some of the things that her department is working on and they are very engaged in the standards and the whole data flow thing and working with the Office of the National Coordinator in trying to make a lot of things happen.

After we hear from Dr. Greene, we will go into a little background on what has led up to these considerations by the Subcommittee. We will talk about the Convergence 2.0 workplan. That is available on the website for those of you who may want to do a quick refresher. That has a very well-defined discussion of what the purpose and scope of this whole process is.

Then we will go into the panels, after each panel, as I mentioned, public comment, we will break. The first panel will talk about standards adoption process and administrative transactions. The second panel will talk about standards integration and collaboration. And the third panel will talk about value metrics. We understand that this is coming at the panelists and at the industry at a very high level without a whole lot of detail.

I want to stress and I will be repeating several times during the day that the hope for today is not only for the subcommittee members and by extension then the Full NCVHS but also for industry to listen to discussion, think about not only our considerations but think about the reactions that you will hear from the panelists and the public comment and then follow up with the Standards Committee by email or by letter after you have had a chance to digest it again. If you want to reconsider or modify or expand on any of the statements that you make or hear today, we would welcome that.

The caveat is that, as Rebecca mentioned, there is a meeting of the Full NCVHS the third week of July. The Subcommittee needs time to digest any input. We would appreciate it if you could get any further correspondence to us within about two weeks from today.

I think that is an overview of the agenda. Denise or any of the other subcommittee members, anything to add?

Denise Love: No, I think you covered it. Thank you, Rich.

Rich Landen: Alright then, we will move into the first agenda item then and I am delighted to have with us Dr. Mary Greene from CMS. Dr. Greene.

CMS Standards Update

Mary Greene: Thank you, Rich. I appreciate it and thank you for inviting me to speak with you all. I am delighted to have the opportunity to help kick off today's listening session. We appreciate the work of the Subcommittee, and we appreciate the industry representatives who are participating in the panel today. Thank you, all, for that. You all provide the depth and breadth of experience, and your input is critical to the transparency of the standards development process in and of itself.

In the few minutes I have with you this morning, I would like to say a few words about the Office of Burden Reduction and Health Informatics, give you an update on our HIPAA Administrative Simplification work and our Interoperability work. And I will finish with a few remarks about the next year. And if there is a little time left, a couple of suggestions for your consideration.

Let us start with the Office. The Office is almost two years old at this point. Our job is to enable efficiencies across the health care enterprise. In addition to HIPAA Administrative Simplification and Interoperability, we also do a lot of work with stakeholders to understand and address burdens that often require policy or operational solutions beyond health IT or in addition to health IT.

This administration is particularly interested in beneficiary experience and the experience of providers that take care of underserved populations. That includes issues around access to care, health equity, social determinants of health of course, and also inequities in technology availability and data transparency.

We have gotten more engaged with the Gravity Project because of the work they are doing to develop tests and validate standardized SDOH data for clinical human services and public health use cases. Think about equity in the work that you are doing. We look through that lens for all of our work.

Let us talk about HIPAA Administrative Simplification. As you all know, the ultimate goal of HIPAA Administrative Simplification is to improve efficiency and to achieve cost savings across the health industry. We have been focused on three things: getting our rules out, raising awareness of the HIPAA Standards Exception Request Process and bolstering our enforcement function.

Regulation development is one of the National Standards' groups most critical functions and we urge you to keep abreast of the unified agenda to know what regulations are in development. It is published twice a year. Currently, you will find our Attachment Rule and our Pharmacy Standards Rule is on the agenda. There has been considerable progress on them over the last six months. I want you to know that.

The data to support the proposal is essential to developing these regs. Some of that data comes from your proof of concept or other informatics pilots that test standards and figure out implementing the standards in the real-world setting.

We really need the data from real-world experience, implementing the standards, and operational environments. It is incredibly important to the decision-making process. That is where the exceptions process comes in as well. It allows organizations to request an exception from using a standard so they can test and propose modification to that standard. The use of the process not only allows for testing and refinement of a potential standard, but it produces what that valuable data from the real-world setting.

The exception enables covered entities to implement new standards on a temporary basis in a controlled setting in order to evaluate their effectiveness and part of that process is to report back the data that could be used to support the proposals to adopt the standards.

Our approach to bolstering our enforcement function is three parts. First, we did a review of our current processes and are sorting through the recommendations that come from that and we will figure out from there what actions we can take regarding the function itself.

Second, we are working to increase transparency of the issues we are seeing from complaints that are filed and from comprehensive compliance reviews so everyone can learn from them. Outputs of that will include guidance letters like the ones we issued for virtual credit cards, EFT, and for the remittance advice policies, FAQs, as well, to support the guidance letters addressing the questions we received. Information bulletins alerting industry to specific problems coming up most frequently in the compliance review program and provide clear information on how to properly apply standards, and then fact sheets to provide useful information and links on various topics.

In the third area of focus, we are looking into our authority to levy civil monetary penalties.

Our goal is to help the health care industry successfully comply with the requirements. This is not a gotcha exercise. It is with the firm belief that compliance enables efficient transactions to happen. That is why we are bolstering that function.

In addition to that, this coming year, we are going to restart listening sessions with stakeholders that we had to stop because of the pandemic. We are working on the schedule. And if your organization is interested in participating, please contact our HIPAA and Simplification Team. We will be happy to include you on the schedule.

One other thing I will mention is that NCVHS, as you know, has recommended a number of research projects to develop data that would help determine if the adoption of the ICD code set should be recommended to the Secretary. We are currently pursuing how to conduct the research projects and make the results available to the NCVHS for consideration.

Let us switch over to interoperability and data exchange. Our team, our high G team, is working across the various programs and components at CMS to begin to align the health IT and interoperability work that we are already doing and to foster new work where we see opportunity for advance data exchange in the use of families.

While we do a lot of this work within CMS and among our programs, a significant part of our work is to collaborate with other federal agencies. Rich mentioned, for example, the Office of the National Coordinator. We do that to help align our programs to the broader health IT and federal interoperability mission.

The CMS Interoperability and Patient Access final rule that you are aware of was finalized in May 2020. It is a full two years ago now. And the policies of that rule are now in effect. The rule was published the same day as the ONC's 21st Century Cures Act Final Rule and that was done intentionally to show alignment across the federal agencies.

I just want to mention the peer-to-peer data exchange provision in that rule. Since the rule was finalized in May 2020, we heard from multiple impacted payers at the lack of technical specifications for the

peer-to-peer data exchange requirement is creating challenges for implementation, which may lead to differences in implementation across industry and then coordinate quality operational challenges and increase administrative burden.

In December 2021, we published a federal register notice announcing an enforcement discretion and stating that CMS would not be enforcing the peer-to-peer policy at this time, but also encouraging those payers who have already developed FHIR solutions to support peer-to-peer data exchange to continue to go forward with the implementation. For those not capable of implementing a FHIR solution at that time, we stated that this enforcement discretion would alleviate some of the tension regarding the peer-to-peer policy. We will revisit this in future rulemaking.

Now, some of you may have seen in December 2020 – we published a CMS Interoperability and Prior Auth Proposed Rule. That rule has not been finalized and is in a bit of a flux right now at the moment in our processes. But I will give you a little bit insight in what we try to do in that rule just to remind you.

The new proposed rule took those FHIR-based APIs we had previously established in the first rule to the next level and continued to build on our policies of data sharing. But it also went beyond that to start using APIs to enhance data exchange and that is bidirectional exchange. Not just sending data from one place to another but really using APIs to facilitate data exchange in this case or in that rules case prior authorization.

We believe that APIs can facilitate faster, better, and safer data exchange. And we include it in a lot of discussion around that in the proposed rule. There is more to come on that soon.

Let us talk about TEFCA for a second. In support of ONC, CMS included an RFI in the recent release IPPS rule. That is the Hospital Inpatient Prospective Payment Proposed Rule. It is called advancing the trusted exchange framework and common agreement. And the purpose is to get public input on how CMS could leverage the TEFCA – the comment period is still open. I believe it closes June 17, I think. Please consider providing your thoughts on that.

CMS and ONC are working together to combat information blocking. The 21st Century Cures Act gives the Department of Health and Human Services the authority to institute appropriate disincentives on providers who are found to be guilty of information blocking. We are actively working with our colleagues in HHS to help define those disincentives.

The majority of the complaints ONC has received regarding information blocking are about providers. This will be a significant step in making progress against the practice of withholding information.

The last thing about interoperability. Just a remind, July 19 to 21, CMS will be hosting the third annual CMS HL7 Connectathon. It will be a virtual event again. This event brings together a diverse group of stakeholders from technical developers to policy leaders from across the health care industry to hear from CMS on the first day and then those folks will spend the following two days testing HL7 FHIR implementations that support various interoperability use cases in health care.

Registration is open and it has been extended to June 30. Consider participating. We can provide you the link to the event. Actually, Lorraine can provide you the link to the event to let you know.

That is a quick summary of the work we are doing and what we are working to achieve.

Year three for our office starts essentially July 1. This work that I just described will continue. We are involved in cross-agency discussions and discussions with our federal partners around USCDI, USCDI+, digital quality measures, provider directors, and some public health related work as well.

Most importantly for our year three, we look forward to hearing from the Subcommittee as well as industry stakeholders through formal public comment opportunities through regs and RFIs, for example, or through listening sessions and through direct communications to inform our work. For example, let us know about the realities of implementation in the real-world setting. Please look for opportunities to provide your thoughts.

I think we have a few more minutes here. I would like to end with a few suggestions for the Subcommittee that I would appreciate if you would consider. The first is engage with HHS in its efforts to identify approaches to evaluating standards and developing guidance to appropriate stakeholders for the data we need about real-world implementations and pilots. For example, qualitative and quantitative metrics to demonstrate value.

The second one is to engage with HHS on its efforts to determine approaches to identify, fund, and conduct appropriately timed research related to ICD-11. The Subcommittee could also support HHS in identifying subject matter experts to assist in understanding necessary communications and relevant communication strategies.

In general, the Subcommittee could serve in an advisory capacity in a variety of other related issues pertaining to ICD-11 code set such as providing contacts and information about resources. That is the second one.

The third is to convene subject matter experts to address specific topics as identified by HHS as significant issue. For example, some of you might recall. NCVHS had an ad hoc hearing on the health plan ID back in 2019 based on a specific HHS request when it had a pressing need to obtain input on rescinding the plan ID. This would be a good opportunity for the National Standards group to identify any area of need for industry input on administrative simplification topics.

And the last one is we have heard from time to time and just last night again about expediting the adoption of HIPAA National Standards. That is not just about the governance clearance process although I know that has been an issue. But some of what we are hearing proceeds our process and some of it relates to implementation after standards are adopted. In year three of our office, let us collectively surface those issues and what we may be able to do about them. Those are the four things that I can make available to you too if you want them directly.

Thank you, everyone. Enjoy the listening session. Happy to take any questions if there is time; otherwise, we can talk again.

Rich Landen: Any questions for Dr. Greene, please raise your hand.

Rebecca Hines: From members only just to clarify.

Rich Landen: I am not seeing any so let me just thank you, Dr. Greene, for your presentation. A ton of stuff going on in there. I am sure you just hit the – not even the tip of the iceberg but the tip of the tip of the iceberg. We do appreciate you and your staff's efforts. It is making a difference in the industry.

As far as the four points, absolutely. All I can say is amen to that. The Subcommittee members know. The public probably does not. But we have recently set up a scheduled series of meetings between the Standards Subcommittee and Dr. Greene's office and we hope to be able to explore that.

But the concerns that Dr. Greene said and kind of what we need to work on together. Absolutely agree that we have common interest and there are certainly ways that we can work together to both take advantage of each other's strengths and also to help each other out in terms of the weaknesses. The biggest one that comes to mind is NCVHS and the Standards Subcommittee is not an operating group, so we do not have the ability to do a lot of things in the detailed world, or actually running projects. That being said however, there is a ton of stuff that we can and will be actually happy to do to further the objectives that were described. Very much appreciate it.

Mary Greene: Great. Thank you, Rich. And thank you for holding this session today. Just looking at the agenda and how you all described it. I am very much looking forward to what you learn. I think it is going to be enormously helpful. Thank you for that.

Rich Landen: Moving along then.

Margaret Skurka: I would like to say one quick thing.

Rich Landen: Yes, Margaret.

Margaret Skurka: I would like to thank our speaker for referencing ICD-10 and mentioning ICD-11. We need to keep that on our plates, and as other countries are doing, and start to do that analysis and that research because it is coming. Thank you.

Rebecca Hines: Rich, Denise Love's hand is up.

Denise Love: Never mind. I was just going to reference our research questions and make those available to CMS and Dr. Greene, but she may already have those.

Mary Greene: Thank you for that. I will look out for them.

Rich Landen: For those listening in on the Zoom session, NCVHS has submitted in the past – all our letters go to the Secretary of HHS. We have submitted letters recommending a research program on ICD-11 and the communications plan. Everything that Dr. Greene said is consistent with where the NCVHS wants to go and we have some more thinking as far as current updating. There will be a lot of fruitful discussion that will lead us down a path to assess the value of ICD-11 and talk about the opportunities and challenges when we consider ICD-11 adoption here in this country both for morbidity and for mortality and hopefully bringing to the table with us lessons learned from the not-so-distant past implementation around ICD-10.

Planning for Tomorrow's Administrative Interoperability Landscape

Rich Landen: Let us move into the next part of the agenda. This is talking about the Convergence 2.0, the process that is behind that, and where we have come from and where we are going.

As I mentioned earlier, the project scoping document for what we – the long title of Standardization of Information for Burden Reduction and Post-Pandemic America, which is shorthanded to Convergence

2.0, convergence referring to the coming together of the administrative transactions and code sets historically under HIPAA but as modified to other pieces of federal legislation and that coming together with the clinical data flows that largely happened under the HITECH American ARRA. I am blocking on what the first R stands for and again subsequent legislation on there like 21st Century Cures.

But the administrative transactions in HIPAA when HIPAA was first passed back in 1996 were pretty much standalone from any clinical data. Clinical data at that time was a little bit too far for industry because the adoption rate of electronic health records and standards in clinical data were not as advanced or ready for prime time as were the relatively more Simple Use Cases around claims, eligibility, claims payment, and the other standards that were identified by the Congress in the HIPAA legislation and subsequently promulgated in adoption rules by CMS.

The Convergence 2.0 project is a two-year project of the Subcommittee on Standards of NCVHS. Last year we conducted a landscape assessment, what it is that we knew, what it is we did not know. Many of you participated in our listening session last August and we thank you for that. That listening session then – we went over the testimony. We went over the panels. We went over the public comments. We went over the materials submitted pursuant to the request for information. When I say we there, I mean the members of the Subcommittee on Standards.

This year we got more into the analysis deliberation, how we would report the findings of what we learned in landscape assessment and started to identify potential recommendations. The potential recommendations are in process. These, what we are calling, considerations, the five considerations that we are focusing our three panels on today are the first of the potential recommendations. There will be more. The recommendations or considerations, as they still are at this stage, all fit into a larger vision of where the Standards Subcommittee sees the industry going in the future. These are some of the more near-term potential recommendations that we have identified, as we move forward through these potential recommendations and as I mentioned earlier, depending on the analysis of all the input received today and for many subsequent correspondences, the Subcommittee will move these forward to recommendations for the Full Subcommittee or for the Full NCVHS Committee to consider toward the end of July. Assuming concurrence by the Full Committee, which is not necessarily given, that would then – the considerations as modified would become recommendations from NCHVS to the HHS Secretary.

Some of the history of the Convergence 2.0 is we built on earlier efforts of the NCVHS and the Standards Committee. What came out of those early efforts that we refer to as the Predictability Roadmap had some visions in it. We had a vision that the standards development adoption would be more industry driven, in other words, looking more at business use cases and the timing of the need for modifications or updates to the standards to achieve the business use cases as those use cases evolve.

To us in our vision, again, this is draft. That would require more regular updates to the transactions, meaning more frequent updates but smaller, more digestible updates rather than a massive update once every ten years or so.

It also implies enhanced pre-adoption testing. We will talk – in a few more slides, we will talk about some of the key things that we heard from the listening session last year but the importance of pre-adoption testing. By pre-adoption means pre-adoption of testing prior to the promulgation of proposed and final rules, not just the pre-implementation testing.

We also concluded that we need to build in a value assessment, including both return on investment, recognizing burden, but also recognizing societal benefits. There are sometimes where I think, as Dr. Greene mentioned, it is not simply a quantitative put the green eye shades on and do the debits in one column or the credits in the other. But it is also a societal value assessment as well and those are qualitative, but still need to be somehow figured into the process for making a determination of the value of the updates and upgrades.

And then finally, the last big piece of the picture emerging from last year's session was an increased emphasis on conformance. Conformance in our lexicon usually means conformance documents arising from the standard development organizations themselves but then coupling that with enforcement. Dr. Greene touched on a couple of those questions where in order to institute an enforcement process, it has to be clear what needs to be enforced so the combination of conformance with enforcement emerged as a pretty important concept and something we, as the Subcommittee on the NCVHS, need to help find solutions that work that are effective, are efficient, and that work for industry.

These next two slides are just a summary of some of the top ideas we have heard at the listening session both orally and in writing a year ago. This is the listening session last August. I will not go into them in detail. But again, I will stress. There is no priority order here. It is just these are the ten end things we heard that we think are the most impactful.

Testing and evaluating the standards, including return on investment before adoption. The need for adoption of the health care attachment. Acknowledgments, which is not currently a mandated standard under HIPAA. Prior authorization, both the industry and the ONC's federal advisory committee. HITECH has been looking into this. Prior auth. And as you heard from Dr. Greene, there had been rules under development by CMS.

Improve regulatory processes for adopting standards under HIPAA and as an example only. Food for thought example is to look at what ONC does with its standards version advancement process. The acronym is SVAP. Dr. Greene also mentioned the IPPS, which is the Hospital Inpatient. There is a companion function for the professional side of the industry and rate setting for Medicare for the coming year. That is also a potential thing to look at. Again, it gets into standardizing the process, making the updates more predictable and reliable so that the stakeholders and the business associates of the stakeholders and clearinghouses, IT developers, and reliably and effectively do their budgeting both the financial development process and the planning for the implementations.

Patient education. When HIPAA started out, it was exclusively business to business. There was not a role for the patient. That has changed particularly as we get into the patient's apps and privacy policy and as we get into prior authorization as a specific use case, there is more a patient in the data flow that we need to take a look at and figure out how we work that into the other standards.

Number seven was training programs for providers on data exchange to support bidirectional data exchange. Just how to make the best use of what is available from the standards and from the technology.

Eight. Identify, implement, adopt standards for payers and other organizations to change data bidirectionally. This is a little bit complicated, but it is no longer simply a business model where data flows from either a payer as point A to provider's point B or the reverse through any intermediaries. There is a lot of downstream entities that are participants in the data flow, not just receiving but also sending. As we accomplish more toward what ONC laid out probably a good ten years ago about having

the data follow the patient and being available to the patient at the point where it is needed irrespective of what that need is a provider-based need or a health plan payer-based need.

Nine. Developing a universal solution for patient matching. This goes beyond just talking about some sort of national patient identifier. The real challenge is to how do we know that at any point in time that that patient is the patient for whom the data that is moving is all about so we do not have someone else's data being used for a patient to whom it does not belong. That is a challenge.

And then number ten. Consider expansion of HIPAA to non-covered entities, for example, holders of data from covered entities. As you are probably all well aware, HIPAA and the privacy protections generally were formulated initially to apply just to the payers, the providers, and the clearinghouses that is the covered entities under HIPAA.

But in the real world, data flows beyond those and even in legitimate data flow, once that data legitimately leaves a covered entity to go to some other entity that is not a HIPAA-covered entity then the HIPAA privacy regulations do not necessarily apply. It is a big topic, and I am staying very general in that. There are a lot of nuances, as you drill down in that. Please just consider my remarks at a high-level policy or a vision level but that is the challenge that the data flows to more than covered entities. And once the data is legitimately out of the realm of control of covered entities then the HIPAA privacy protections may not necessarily apply. What opportunities are there to ensure that we do the appropriate privacy protection for the data and for the patient? That obviously is only partly in the scope of the Standards Subcommittee of NCVHS.

NCVHS also has a Privacy and Security Subcommittee. There is a lot of other organizations that will have an involvement in the discussion of the privacy area. That is not on the agenda for the considerations for today or for the panels today but is always something that we keep in the back of our mind and we understand clearly that it is one of the challenges that we need to be taking a look at.

In all the listening sessions, the exercises, the hearings that we have had either under Convergence 2.0 or the Predictability Roadmap or even prior to Predictability Roadmap, we brought the concepts forward into what we are talking about today.

These are some of the takeaways by the Subcommittee. First, the nature of electronic commerce has changed dramatically since 1996 what HIPAA was enacted. The words here are a little bit harsh. We are describing the HIPAA framework as obsolete and dysfunctional. Now, we mean no criticism. We are just observing that it is 25 years later. Things have changed. And to expect something particularly in the role of technology to remain stable over two and a half decades is, I think, an unrealistic expectation. Ignoring the negative connectivity of these two words, obsolete and dysfunctional, and look at the issue from the solution standpoint, how do we make it more meaningful and functional, as Dr. Green said, achieve the objectives for which HIPAA was actually passed, effective and efficient? How do we do that? How do we move from where we are now to where we get back on track or achieving the objectives of the HIPAA framers?

The evaluation would be appropriate to determine whether legislative remediation or regulatory modifications provide the better – path. We are throwing out today the considerations. Once we get industry feedback and know we have some degree of confidence that we are on the right path then we can start looking at can we do this just working with industry or can we do it just working with CMS and the regulation side of that or some combination or do we actually have to work with CMS and HHS and

involve Congress to some extent. Those are possibilities. I am not pre-judging which is the path we will need to take. But we will have to answer those questions as we work through this with industry.

Next point. Some standards developed activities are not meeting the needs of the regulated industry. Some standards are moving a pace, meaning that things like the claims transactions when you kind of recognize that the version updates have not been accomplished as regularly as we think they are needed. The basic function is working and working well. It is achieving the HIPAA objectives and there is – the Subcommittee sees no need to change those functions that are working. What we need to do is focus more on what is not achieving high rates of success, which is not being well adopted by industry, which is not meeting industry needs.

The processes need to be amended. We need to talk about best practices in order to meet industry expectations. I want to emphasize very clearly that the Subcommittee is not embarking on a philosophy of rip and replace. We are very clearly in consensus that there are major pieces of the standards that have been adopted and supporting structures that need to be maintained and protected. It is only in the areas that are not working as well that we are exploring alternatives that we think may better meet the industry needs and accomplish the objectives as stated by HIPAA.

The third bullet. Standards development organizations could collaborate more to conduct effective stakeholder education for implementation. There is sometimes a gap between what the SDOs intend and what the stakeholders perceive. There is always room to improve the process of education.

Finally, the Subcommittee understands – needs to understand the HHS priorities to support development of recommendations. That point goes back to what Dr. Greene was bringing and this is a complex – the scale of this is just immense because it is national, and the health industry is huge in its own right but understanding that the health industry is comprised of many sub-segments and the individual needs of each of those sub-segments makes it really difficult when you talk about standards and uniformity. It is about how do we move that into the equation and the Subcommittee's thinking. As you see in the considerations, we think we need to do a little bit of moving away from the one size fits all philosophy that was actually industry through the WEDI reports that recommended to Congress that we do that, that we do the one size fits all with everybody converting to the same standard at the same time.

That was a bit of the background. For those of you who have been through the industry, there is no need really, talking about the evolution for those of you who are joining us. To some extent, the history is mute because what we need to do now is assess where we are and figure out how to move forward.

The purpose of the day is to obtain reaction from stakeholders to the five considerations that we are putting forward at this time. Those pertain to standard adoption and advancement, pertain to integration and collaboration, and pertain to value metrics.

The Subcommittee on Standards will use the reactions and the information that we get during today's discussion to obtain insight into whether panelists believe that these considerations should become recommendations to be sent to the Department of Health and Human Services. Whether or how these considerations could be actionable whether that is for Health and Human Services, CMS, or for other parties. Other parties could be payers, providers, standard development organizations, other third parties.

Whether or how the considerations could be used to support action and/or changes by relevant organizations. As I stressed earlier and will continue to stress, this is not rip and replace. This is about evolution to meet business needs and achieve the defined objectives.

And then finally, the ubiquitous open question. What other opportunities could be addressed? Interested in hearing what our panelists and what the public comment will say as to are there other key objectives that the Subcommittee needs to consider along with these five that we have on the table today.

Logistics for the panels today. The moderators will explain the background and talk through the problem statement behind each consideration and then we will review the initial question set for the discussion. Panelists may raise other issues not included in the questions provided. We would like to get feedback, kick the tires. Again, as I mentioned earlier, we want to get everything on the table that we can today, but we recognize that everyone will probably want to do further reflection on what they hear and learn today, points they may have not considered. We, as the Subcommittee, would welcome letters or emails and will provide contact information later within two weeks to flesh out or to update any of the positions that you will raise today.

During the panels, the panelists, the invitees will raise their hands on Zoom to respond to questions or raise other issues. Each moderator will create a queue and call upon the panelists to speak. Zoom has a feature where it will list who has their hands raised first. Each panelist will have three minutes to speak, and we will have a timer that will be visible on the web. We ask you to minimize your talking time. We need to hear what you say. We want to hear what is important. Please if you can finish in shorter than three minutes, there are a lot of people we have to hear from on the panels in a lot of time. We want to hear from the public. Please tell us a little bit about the organization you are representing and why you are a stakeholder in this. But do not expand on that. I think all the Subcommittee members are very familiar.

Most of our panelists, and I think all of the organizations, have testified to us or presented to us before. There is no need to take a lot of the three minutes to tell us what your organization does. Just be quick. More for a reminder to the public and for the Subcommittee members. Once you have used your three minutes, you can certainly queue up again. The moderators then will as time allows call on you a second time.

After the two rounds, after two or so rounds, the committee members will ask additional follow-up questions to the panelists as time permits. Because we have a lot of things to accomplish today, we will try our best to stick to the maximum time limits for each panel as on the agenda. We will try and keep on track for the times of the public comment. But again, with public comment that is subject to change. If you intend to do a public comment, please keep track of where we are in the agenda.

As Rebecca Hines mentioned earlier, we will have public comment after each panel. Those comments – we request that the comments be specifically focused on the content matter of that panel and then the public comment at the end of the session this afternoon will be open to any topic.

Our three topics. Panel 1. Three considerations all related to advancing HIPAA standards adoption. Panel 2 will address standards integration and collaboration. Panel 3 will talk about metrics, how do we measure the value of standard?.

Let me pause here and see if there is anyone on the Standards Subcommittee who wants to make a comment about the background that we presented, anything I missed or anything you would like to add, underline, or add more emphasis to. We will start with you, Denise Love.

Denise Love: Thank you, Rich. You did a great job of covering the train. I just wanted to give a shout out to the Subcommittee because this group has worked long and hard, going through scads of information from – starting with the Predictability Roadmap and on through listening sessions. These considerations that we brought forth are not the only considerations we looked at. There will be more. But these are the ones we felt were the most urgent or feasible.

I also am encouraged by the growing collaboration with CMS and ONC and it is just going to take all hands-on deck as things become more blurred in the sector relative to data systems and the complexity increases. I think you did a great job of capturing that and I just wanted to give a nod to the committee and our staff.

Rich Landen: Thanks, Denise. Any other subcommittee members? Seeing none. Any whole committee members? Jacki, did you want to say anything? Jacki Monson.

Jacki Monson: I am good. Thank you.

Panel 1: Advance HIPAA Standards Adoption or Administrative Transactions

Rich Landen: Let us move into Panel 1. Advancing HIPAA Standards Adoption. Background and implications. Some of this I have alluded to before. It is a little bit more detailed here. But this is kind of the background where the Subcommittee is coming from, and both are based on our experience and the input we have gotten from the various listening sessions over the years.

As I mentioned, HIPAA is 1996. At that time, paper claims were the norm. Providers used computers to print forms. I am generalizing here so there are always exceptions to it. But I am trying to describe – not the leading edge of the industry but where the middle of the industry is. There were paper forms. Computers were used to print forms. The payers then scanned or keyboarded them into their systems, systems for the larger payers and then were mostly mainframe.

There was, however, significant use of electronic submission. There were electronic formats based on the Uniform Bill 92, maintained by the National Uniform Billing Committee and the HIPAA, now CMS, 1500, the professional billing that was maintained by what is now the National Uniform Claim Committee. But the electronic formats were not necessarily consistent from payer to payer. The implication there being that the provider needed to fill them out one way for each of its major payers.

HIPAA came along and envisioned one universal standard per business function. That is a single standard to replace each of the paper forms, hospital, professional, pharmacy, and dental. You see that the three X12 837 claims, implementation guides and the NCPDP guides that were adopted under HIPAA, plus automating the eligibility inquiry. Eligibility was deemed a common cause of the claim denial and then the other standard was on the payment-related transactions.

Transmission and processing were predominantly batched. Bandwidth was constrained and expensive. Large health plans processed on mainframes. Real-time processing was relatively rare. That is the background.

Standards were introduced to the health care industry. I am talking about administrative standards here, not clinical at this point. And standards were something that industry leadership, hospital administrators, health plan executives were skeptical of. There was not a whole lot of trust. There was no experience. But it is a vision that was led by WEDI among other groups. Congress recognized the value and enacted HIPAA after about four years, I think, for the legislation to go from the drafting to actually being approved and signed. I believe it was President Clinton who signed that.

Twenty-five years later, technology has changed. Bandwidth is mostly available. There are some real exceptions. Inner-city exceptions. And relatively inexpensive. Processing speeds are much faster. Real time is now commonplace. Certainly, batch is still a major contributor. As I said several times already and will say again, this is not rip and replace. We are protecting the infrastructure that is in place. And if something is working, we are not going to mess with it.

Business needs have evolved. The single biggest change at least in my mind is that there are alternative payment arrangements. Fee for service is not as exclusive as it once was. Capitation, value-based purchasing, other alternatives have achieved significant market penetration. The types of coverages and reimbursements will continue to evolve and change, and our system needs to – our standard system needs to evolve and change not only to follow it but to anticipate it. My editorial there on the anticipation. But what we adopt as standards and what we implement as standards needs to be there to serve the business needed. The business needs cannot be – should not be subservient to a standard that has been adopted.

Finally, clinical data is increasingly integrated into administrative process requirements. For example, but not limited to prior authorization and claims attachments. I think that is pretty clear to most of the organizations that we have done on the panel.

What we have heard about advancing this HIPAA standards adoption is that – and then what we have heard from industry. The adopted standards have not kept pace with industry change, neither with the evolving data requirements nor the technology changes.

Updates for the standards need to be more frequent, smaller, and more predictable and reliable, again, for budgeting purposes, not just the financial budgeting, but the system design and implementation and the human resource planning.

Workforce demographics are changing. New entrants into health information technology are trained on newer technologies in our universities, colleges, and technical schools. Finding and training workers for older technologies can be difficult. That is what we have heard.

HIPAA introduced a one-size-fits-all concept of standards, as I mentioned earlier in my presentation, at that time, again, going back to the early ‘90s. That was the best of available options to get us away from paper. But it may no longer be the optimal alternative.

Very broad standards carry a lot of overhead and standards have to be very broad because again it is a one size fits all. It is not tailored to an industry subsegment specific business case. It is a broad business case for the entire industry. Very broad standard carries a lot of overhead that must be custom mapped and programmed by each implementer. Newer technologies, however, can support narrower standards, easing the programming requirements and burden, especially in small and more specialized provider practices. As I mentioned earlier, part of this visioning by the Standards Subcommittee and NCVHS is consistent with the federal policy goals of reducing burden and reducing burden in general applies to all

parties but specifically to the providers who tend to practice in smaller organizations relative to health plans and clearinghouses.

Rich Landen: Here is consideration number one. This is the language that the Subcommittee has drafted, and this is what we are expecting the panelists to react to.

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

It is a little vague but what that means is in essence, right now, we have an X12 standard, an NCPDP standard with implementation guides that are specific for some industry segments within a function to the transaction. And what we are saying is if other technologies and the main thought right here is APIs, which we have talked about earlier and which Dr. Greene talked about. If we can use an API, that might be better for the smaller entities. I will pick on X12 here because it is a more diverse set of implementers than NCPDP. But it could be easier on the implementers to use an API rather than an X12-based EDI standard for a specific transaction. Again, this envisions a universe where if a transaction and we called out the claims and the eligibility and the remittance. If they are working well, no changes. If there are some challenges, changes would come sooner. But it would be a provider option.

The problem statement here is that industry input to us strongly indicated that updates to HIPAA transaction regulations are not keeping pace with industry need for data fields or codes. Nor do the regulations affirmatively encourage industry innovation. Again, innovation and the ability to evolve with the needs of the business. Again, everything to benefit the patient. Regulations are not – the way the regulations are structured now – it is not doing a good job of keeping pace with the need. There are many reasons for that. We are not challenging – we are not trying to allege that anybody is not doing what they can do achieve – it is just very complicated, and the effort is massive.

When we are doing the one-size-fits-all industry updates, they tend to be massive. Again, we only have a couple of experience – updates since the original 4010 and 4010a1 were promulgated. But our experience has been that they have been massive disruptive and very costly. Our question is how can we redesign the process and manage the process to encourage maximum efficiency and value to the industry.

To reduce provider burden, to support tech innovation, we are considering the net value to the health care of allowing a strictly limited number. And the number we have in mind is two or three alternative standards to the existing HIPAA-named business transactions.

Much like batch and real-time standards variants of the transaction, an app-based standard might co-exist with an EDI standard. For example, but not limited to, HL7 FHIR, which I think all of us agree has potential. Where we disagree is the maturity, the readiness across all industry segments and the applicability of the limited in a number of use cases that HL7 and FHIR have at the present time. But the concept of an API or an HL7 FHIR standard could be adopted as an allowable alternative to an X12 standard.

Provider organizations could choose the type of standard that best suits its business needs and its workforce or its vendor constraints. The different standards could be used stand-alone or in conjunction with another type of standard. Again, for example, HL7 FHIR-based EPA, electronic prior authorization

transaction, where it works, and it is valuable to trading partners. It could be used self-sufficiently alone or again where the value is better, the efficiency better or the in-place infrastructure, the installed base is better. It could be used in conjunction with an X12 278 authorization or an X12 275 attachment standard. There are a lot of assumptions in there.

But the basic thing is to get away from HIPAA's concept of one size fits all standard and allow a limited number, very limited number, very constrained number specifically adopted with guardrails around the number of alternatives available to prevent the risk of proliferation, which is kind of an anathema to the concept of a standard. It is a balancing act. One extreme or the other does not appear to be the answer. Again, throwing it to the panelists in just a second. How we find a place in the middle. What do you think of this concept, this consideration, and getting away from the one size fits all?

Food for thought. The Subcommittee has put out these questions. When I finish going through these questions, we will invite the panelists to rise their hands and comment on one or more of them. First, for the providers, would availability of choice between an app-based standards and an X12 standard be of value? Why or why not? Again, we are looking for real feedback. If it is available, would you implement it? Do you see value? Do you not see value? What else would you have to know before you could make your decision on it and whether or not there is potential value?

Second question for the payers and health plans and their vendors. 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.)

This question also reflects something we have heard in input from the industry that the transition between versions was a massive undertaking and was very difficult for the health plans to manage converting their clients, their provider partners from the older version to the new version, all within a very narrow date specific window.

Then the third question mostly for the system vendors, which also includes providers and payer who development or maintain their own software systems. Would multiple alternative standards increase or decrease the complexity and cost of maintaining all the systems over the next five to ten years? Please use a forward-looking evaluation to reflect further integration of administrative and clinical systems, again, looking forward. We understand that the data flow, the administrative and the clinical, are coming together. In some transactions like claims, they are going to be barely separate except for claims attachments but in things like electronic prior authorization. The clinical data is a key part of the transaction.

Forward looking, assume the further need to integrate administrative and clinical data systems, as well as recognizing policy directions. The slide said ONC but as you heard from Dr. Greene, also CMS, the interoperability and information blocking and again moving the data to where the patient needs it safely and securely and privately. That is the background. Again, it is high level.

The panelists that we have invited here for this include, and in no particular order. Again, panelists please begin to raise your hands if you want to speak. But to introduce the panelists to the public listening on the websites. We have the American Dental Association represented by Jean Narcisi, American Hospital Association represented by Terrence Cunningham, American Medical Association represented by Heather McComas, Medical Group Management Association, Claire Ernst, Blue Cross Blue Shield Association, Gail Kocher, and Bill Finerfrock from HBMA and Bill, pardon me if I cannot

remember what HBMA stands for, but please tell us when you join us, John Kelly from Edifecs, CAQH CORE, April Todd, Da Vinci Project, Jocelyn Keegan and Viet Wen(ph.), National Council for Prescription Drug Programs, Margaret Weiker, X12, Cathy Sheppard, WEDI, Rob Tennant. Ladies and gentlemen, welcome. I see Cathy Sheppard has her hand up first. Cathy Sheppard from X12.

Rebecca Hines: Timer please.

Cathy Sheppard: Now, I am not on mute. Sorry. Too many muting options. Can you hear me now? Okay. I just want to start by saying very clearly the same thing that X12 has said in numerous settings and that is that we say yes to innovation but no to de-standardization. Whatever choices that we are going to put into play to benefit the industry, we agree at X12 that people – to be able to consume and transmit things in different formats, but without standardization of the data content and the business rules. What we have worked so hard to accomplish with interoperability goes out the window. We need to move forward to more alternatives that support the industries very carefully so that we do not go back to the times Rich was discussing when there were 350 formats for submitting a claim.

The SDOs have begun to clearly demonstrate in real-world settings that we can work together to define ways to improve interoperability and still allow people the flexibility to consume the standards. X12 and Da Vinci are working on several projects. X12 is working with NCP on other things. We will be able to do some of this without much industry disruption. Let us say that.

The part about saying we just need different standards and we do not know how many. That is a question that is never going to end because technology is going to improve and options for transport are going to improve. Whatever we do so, whatever set up now needs to be forward thinking enough that we do not have to start over again.

We need some guardrails. We cannot have free for all standards adoption. But I think we all recognize that we do need to do things together. It does not all have to be with the hammer of federal requirements. We can do things together with federal support that are good for the industry and that can be done more quickly.

The other part is no matter how much we come up with brilliant ideas here, if we do not change some of the federal processes, then we are not going to change the fact that it is expensive to upgrade because it only is permitted every five or ten or six or whatever the number is, number of years, not based on when the SDOs can develop a new functionality and whether the industry needs that functionality. Thank you.

Rich Landen: Cathy, the three minutes have gone. Are you wrapped up?

Cathy Sheppard: Yes.

Rich Landen: Thanks very much.

Next in the queue, I see Margaret Weiker, NCPDP.

Margaret Weiker: Thanks, Rich. Back in 2009 on January 16, 2009, HHS released a final rule that updated the HIPAA standard transactions. In that rule, it named for the retail pharmacy supplies and professional services two standards that could be used, the X12 837 and the NCPDP telecom standard version D.0. These were done by trading partner agreements to where the payer did not have to implement both.

They could choose which one if either one. And then the provider would have to be able to support the two different standards because one payer may say I want NCPDP. Another payer may say I want X12.

What we found is with the NCPDP standard, obviously, that is part of the pharmacy workflow because that standard is used for claims, eligibility, et cetera. The 837, however, is not part of that workflow. Because the volume of the 837 type claims is not huge, pharmacy systems do not have that incorporated into their actual systems. What they have to do is they contract with a third party that takes the data, transforms it into an 837 and then sends it to the appropriate payer. That is also a batch standard, or it is used in a batch standard in this way where NCPDP is real time. You get a request and a response. Was the claim paid? Whatever. Where in the batch, you do not get that unless they have implemented the 837 in real time and they have it.

It would be wonderful if the professional service, et cetera, would also implement the transaction because that would alleviate an expense from the pharmacy and also allow the real time interchange. This has already happened, and it is in place today. Typically, the 837 is used if the benefit falls under the medical benefit where the pharmacy transaction is used if it is under the pharmacy benefit.

Also, as part of that rule, in Section 162.103, the definition of a standard was changed, which allowed more than one standard to be named for a particular business function. I just wanted to call that out. There may not be a lot of HIPAA modifications to do that because it was done as part of the rule that was released on January 16, 2009.

In regard to some of the other comments in regard to allowing multiple standards, as I have said, we have had experience in doing that. We would say for more allowing multiple versions of a standard to be adopted at the same time versus multiple different standards for a particular business function.

Rebecca Hines: Rich, do you want to call on the next person? The three minutes are up.

Rich Landen: Thank you, Margaret. Some good points there. It looks like Kirk Anderson.

Kirk Anderson: Good morning. Thanks, Rich. Thanks to the committee for having me today. My name is Kirk Anderson. I am the chief technology officer at Cambia Health Solutions and also chair of the HL7 Da Vinci Project Steering Committee.

Rich, I wanted to answer if I could to your question about the value for providers and being able to use apps or APIs in addition to the X12 transactions. In my experience and this both in hearing from the provider community of Da Vinci but also as a payer responding to the needs of our provider partners. In my experience, the answer to that is a very emphatic yes. There are a few reasons for this. I think throughout the time that I have spent in health care interoperability with Da Vinci, there are really three messages or three themes that I consistently hear from the provider community. It is essentially, number one, never make us leave our EHRs to interact with payers. We do not want to have to log into your portals. We certainly do not want to call or fax you for information.

The second message is fix prior-auth. I think we can all identify with that.

And then the third message is fix it so that the investments we make as providers in technology are going to work across all the payers, we have to interact with regardless of the vendors we have chosen for our EHRs and regardless of what technology vendors our payers have chosen.

And all three of those value themes are encompassed in some work that Cambia is doing right now to pilot FHIR API-powered prior authorization pilots, which we are engaged in delivering with two of our provider partners here in the Pacific Northwest. That is Oregon Health Sciences University or OHSU and multi-care.

And these pilots, which are following the Da Vinci Burden Reduction Implementation Guides for Prior-Auth, together with CMS waiver, that has exempted us from having to use the X12 278 transaction, are allowing us to innovate together with our provider partners on what is a pure end-to-end FHIR API solution for prior-auth.

These pilots are scheduled to go live later this month and they are going to allow a provider to complete the entire prior-auth process without ever having to leave their EHR workflow. That was the first theme. It allows to make a real-time API call from within their systems, in this case, Epic. The calls to a Cambia-hosted FHIR API to check if prior-auth is even required for a given treatment procedure. If the answer is no, they have that answer immediately --

Rich Landen: Kirk, can you wrap up, please?

Kirk Anderson: Yes. The last point I would make is that this level of real-time integrated experience for providers. It is not possible with X12 type data format standards alone. We need the ability to create experiences that are calling out to different entities in health care, breaking down those silos in real time in a standard-base way using FHIR APIs. Thank you.

Rich Landen: thanks, Kirk.

Next in the queue is Terrance Cunningham, American Hospital Association.

Terrance Cunningham: Thank you so much and thank you to the Subcommittee for hearing from me. I am Terrance Cunningham. I am from the American Hospital Association, as mentioned.

I guess before I get into a specific answer to this question, I wanted to generally state that both technology standards and methodologies have changed. The concepts of uniformity and consistency remain just as relevant today as they did in 1996 when HIPAA was passed just as it was a hassle for practice to have to print each payer specific form and fill it out. So too is it inefficient to require providers to sign on multiple portals or utilize different technical standards and fill out widely varied forms of different information.

Additionally, I wanted to jump in on some of the questions. This concept of there being – and I guess the way I view it is there being a floor of one standard and then the ability of other available standards. I guess it is not really a floor but they are being multiple. But the provider being able to choose is great.

I think one set of careful controls that have to be put in place is to ensure that the provider is able to choose without undue pressure from external forces. What I mean by that is oftentimes let us say you have a situation where there is one or two insurers in a provider's area. If one of those insurers says we are going to switch and you need to use this transaction, that provider's choice is not really just a free and willing choice. Again, I hear the term willing training provider thrown around a lot. I think it is just important to in order to ensure that providers can adopt technology and really have this choice that you mentioned in the beginning, I think there are careful considerations that need to be put into place to

ensure that the provider is not being unduly influenced or forced to adopt a standard that they otherwise would not be interested in undertaking.

In terms of the specifics to what you mentioned, I think there are a couple of things that I highlight that should be considered. One is again in what way can providers be incentivized to utilize an alternate method. Again, I just mentioned this, but I would say that one specific – I do not think it can be part of the contract process for all the reasons I just mentioned. I think there needs to be some other way to ensure that providers are completely willing to undertake this what I guess would say a testing or this new technology approach.

Additionally, do each standards contain the same information? Does one standard permit more data to be transmitted than others? How does this impact such things as coordination of benefits and multiple insurers and things like that? I am sure these are on the table, but I think there are very careful things that need to be sorted out and tested before they are put in place.

And then final, you talk a lot about specific use cases or transactions, not replacing those that are working. I agree completely. I do not want to replace transactions that are working. But this concept of being able to pick and choose individual transactions that are API is great, but it also could be complicated because a lot of our transactions are inter-reliant. For example, could you adopt a claim status in an API format but then have the claim be an EDI transaction? Or could a provider be allowed to use API for remittance but an X12 for claims? Again, I do not think these are necessarily the considerations that are on the table right now. I know we are at a high level.

But I think when you get into the idea that people can choose each individual piece to implement, we need to make sure that that is actually in practice makes sense and that utilization of API versus utilization of API for certain small segments of your revenue cycle functions makes sense and are not going --

Rich Landen: Your time is up. Thank you very much.

Jocelyn Keegan, Da Vinci.

Jocelyn Keegan: Thanks, Rich. And actually, I agree with everything that folks have talked about thus far and acknowledging the challenges. Sort of building on Terry's comments about the floor and Kirk used the example of prior authorization and the work that is happening there, I am going to talk a little bit about clinical data exchange because if we think about this idea of convergence, I think it is incredibly important to acknowledge that where we are moving as an industry or technology is headed in general is to this ability to be able to abstract the complexity and the differentiation to the very closest point between trading partners and be able to leverage the benefit that we get out of normalizing and standardizing the core transaction sets and the core APIs that we are using.

If we talk about this in the frame of clinical data exchange, there is no one standard to do all of the things that we need to do to get value-based care data from happening so payers and providers can be successful in their contracts. There is a plethora of ways that payers and providers in their supporting vendor community move "documents of data" around today.

Because it is primarily document driven, it requires really costly subject matter, heavy technologies and technologists, and it lacks really often the semantic and the syntactical interoperability that we want to get to even after we have made these investments. The ability for us to move to newer, more discrete

data exchange models will reduce the time to market, the reusability of these components. I think this is important for the payer, provider, and the vendor community.

Really, if we look at a RESTful Model that is built into FHIR, it has been proven across all different industries and it is designed in the ground up for it to be easier to implement, less costly to maintain, and provide a level of the ability to get into workflow functionality and efficiencies that is not available in our classic transaction models. That being said, we have an amazing base and investment in the industry today, but we need to be honest to the fact that most of the work that we are talking about here is being done in Excel files, custom files, faxes and proprietary data exchange and documents. FHIR is capable or FHIR-ready C-CDAs will be capable and critical for us to be able to make these changes.

We need to meet the industry where it is. We need to put the tools, the right advisement and set expectations for people to be able to transition at time at their own pace, again, getting back to this concept of the floor.

I want to talk about the power of what we are doing in the FHIR accelerators and what happens when you bring communities together to solve things at a use-case basis. As a program owner of Da Vinci in addition to being a management consultant. I see that this world and I get to spend a lot of time in a number of accelerators and other multi-stakeholder projects that we are shifting how we are talking about data exchanges in industry and this private industry investment that is happening paired with the power of that consensus-based SDO structure in consensus building approach has really allowed us to unleash people, the people in your organizations to be able to solve problems at a pace that we have not been able to today and to get to that specific differentiated workflow that is needed to solve the actual business problem, as you heard Kirk describe.

Rich Landen: Jocelyn, your time is up. Please wrap up.

Jocelyn Keegan: No problem. I think that what we want to look at here is that to me it is about the timeline for the adoption and testing, recognizing that our ability to deploy FHIR APIs is fast. That deployments are happening in months and that it is happening alongside and in conjunction with colleagues from NCPDP and X12 to be able to take advantage of the existing investment that is already out there.

Rich Landen: Thanks.

Next up is Gail Kocher, Blue Cross Blue Shield Association.

Gail Kocher: Thanks, Rich, and members of the Subcommittee. I appreciate the opportunity to be here today. I am going to focus on the question that you ask of us from a payer perspective. First, I will say that we fully support the use of emerging technologies especially when it makes business sense. Also, if it is working, there is no need to replace it. Things like claims, claim payment. Those things work and work well. There are other opportunities, other areas where other emerging technologies might be more useful.

I do not think you can compare however the cost of customer service support to the cost of multiple infrastructures and systems that would be needed to support having multiple standards be available and then on top of that, you make two things available at one time, but no one uses one of them. That is a lot of time and effort and money and resources that does not get used. I would encourage looking for a way to not just blanketly say payers have to do both but there has to be the appetite on the provider

community to use it if the payers are going to build it because again you cannot – customer service support is different dollars than dollars for systems and standards.

That is all I have on the topic at this point in time. Thank you.

Rich Landen: Thank you so much, Gail.

Heather McComas, American Medical Association.

Heather McComas: Hi there. I am Heather from AMA. Thanks so much for including us in today's discussion. I will start out by saying that we fully appreciate what we think is the underlying intention of this recommendation to allow flexibility and choices for providers. But we think there is a real misunderstanding about how things work for boots on the ground, physician practices, and the actual power dynamics in place between physicians and health plans and contract negotiations. While in theory, a provider could choose to use one standard as suggested in the recommendation. In reality, we would fully expect that payers would require one standard via network contracting, which would force essentially the physician to use that – standard.

And then obviously, if different payers choose different standards, this will essentially force the physician to be supporting two or three standards, whatever would be adopted. This would obviously be extremely costly and burdensome for physician practices, particularly those that are small and under sourced to begin with. Even if they were not supporting multiple standards themselves, they would have to pay as Margaret was mentioning earlier, an intermediary to do the translation between standards.

We really urge caution on this because we feel at the end of the day even though the choice might look attractive on paper, in reality, we expect providers would actually have to be supporting all the standards that had been adopted.

If NCVHS does pursue this recommendation, there would have to be really strict guardrails around it and that would not allow a payer to contract – require under contracting that a physician or other provider use a specific standard. We think that is really critical.

And then also just – very much what Gail just said. When we are talking about adopting new standards, we think it is really important to take a measured analytical approach and to first of all not break what is working already. We should not waste our scarce resources on business functionalities. The functioning technologies have just claims.

We should identify the unmet business industry needs. Prior authorization is obviously something we have been talking about already a lot this morning. And then before we adopt any new standards, we need to ensure that they are sufficiently tested and piloted and will work in the real world across provider settings of all shapes and sizes. Following this approach will ensure that we are using our HIT dollars to the best effect. Thank you.

Rich Landen: Thank you, Heather.

April Todd, CAQH CORE.

April Todd: Thank you, Rich. I am April Todd at CAQH. Thank you for inviting us today. I wanted to make a few comments. One is to share the experience that CORE and the industry has had. Actually, it was

something similar to this since the eligibility transaction operating rules were adopted quite a while ago now. Some of you may remember that there is a connectivity rule that is associated with our eligibility transaction and actually our connectivity rule is used pretty broadly even well beyond our eligibility transaction. Actually, our connectivity rule is phrased exactly this way where there were two standards that were allowed for connectivity and that the plans were required to support both and the provides were able to choose.

I would say that this rule is very popular. It has been used throughout the industry and it has actually helped the industry transition at a pace that different sized systems can help advance their technology. There is a way to do this and I wanted to offer that as an example of something that has been adopted and is already under HIPAA.

It would also acknowledge where others have – I think others have as well that there is a way to do this under HIPAA. There is flexibility there. I do not think we need necessarily new laws to do this.

I would also mention that we are also talking a similar approach, have taken a similar approach with our attachment rules. We have rules that apply to the X12 standard as well as the non-X12 standards. And in particular, we did that to meet the industry where they were and where they wanted to have rules applied to standards. But the intention was also to help those standards interact with each other. There are particular requirements that help create some alignment and consistency across that. Those are things such as metadata, the size of data and files that can be transmitted as well as connectivity requirements that are there as well.

The other point that I will make is if we go down this path, there are going to be needs to create alignment whether the standards interact with each other or there are more than one used. When there are differences in data content, there is going to need to be some rules around what does that mean when data is not available or is available, and how is that interpreted.

There should also be some common rules around response times, around connectivity, and meta data, those types of things. It would be important to – if we do this, have those business rules, operating rules around that to help the industry function.

And then the last thing that I would mention is that and we have made this comment many times before but creating different standards or options for different standards by line of business will not help the industry. That will be actually very harmful, particularly for our providers who would need to support a different way of doing things for Medicaid versus the commercial line of business. We have heard that very regularly from our providers that that would create a lot of burden. I wanted to add that as another comment.

And then lastly if I have a few seconds, I would say we also have been testing some of this in our PA pilots that have shown some high ROIs. I would say there is a way to do this but there are some things that we need to do to create alignment to help facilitate this and to use this as a way to improve innovation – thank you.

Rich Landen: Thank you, April.

Erin O'Rourke, AHIP.

Erin O'Rourke: Thanks, Rich. And thank you so much to the committee for the opportunity to join you today. I am Erin O'Rourke, Executive Director of Clinical Performance and Transformation at AHIP. We are the national association whose members provide health care coverage and services.

We really appreciate the committee's consideration that technology is changing, and we agree that there is a need to balance innovation with standardization. We need to look at these policies on a use case by use case basis and consider as well, transition policies so that if multiple standards are required, that is only temporary. Piggyback on what Heather and Gail and others have said about maintaining what is working and innovating where things are not working. You should consider each use case and determining whether to allow the use of more than one standard.

We certainly appreciate the flexibility that allowing more than one standard could provide. This could provide payers and providers the ability to solve some complex business cases. But we also need to balance that with the implementation burden. We see a key difference between allowing the use of multiple standards and requiring plans to support multiple standards. We think it should be voluntary if more than one standard is allowed. Requiring plans to support multiple standards can be an undue burden and it is going to take significant resources to implement that. We need to accommodate ways to normalize the data and then implement and support each individual standard.

In particular, we urge the Subcommittee to consider the number of standards that would be supported. Our members have said there is a significant cost different in supporting three or more standards as opposed to one or two.

We would also encourage the committee to explore ways to distribute the burden of supporting multiple standards across the industry. We also think it is important to consider not just the standard per se but also the method. Perhaps we should first consider the method of the exchange and then consider if there should be one or more standards for each method. We strongly urge the committee to avoid forcing back and forth between different standards just because the regulation defines one. In the case of the prior authorization without an exemption requires going back and forth between FHIR and X12. It does not allow FHIR end to end without the exemption.

Finally, I would like to echo some of the points on considerations for interoperability. Consistent data regardless of which standard used is key. We see this as essential for both administrative and clinical data. We know that there are efforts underway to crosswalk the data content between X12 and Da Vinci as well as coordination of data content with NCPDP. We support those efforts to gain consistent data for information exchanges.

Rich Landen: Thank you, Erin.

Next up is Arthur Roosa, HBMA.

Arthur Roosa: Thanks, Rich. Bill Finerfrock by the way, is an alias that I use sometimes. The HBMA is the Healthcare Business Management Association. We represent revenue cycle management companies.

I wanted to – a lot of things have been said and I agree with them. But I want to emphasize the issue of multiple standards and that for most providers, there needs to be a single standard with the ability to have other standards developed. The ability to innovate is important. I think there needs to be a regulation that says that there is one standard that everyone must support. Other standards could be supported around it.

There has been talking about provider choice. But for most – particularly small providers. But unless you are a large provider, it is unlikely that you are going to have the ability to make that choice. When providers are choosing, very often it is not the provider who is choosing but rather the provider's vendor who is choosing and that provider vendor is often choosing based on their business needs, not necessarily the provider's business needs. I think it is important to recognize that. If you have a discussion that sounds great that providers can choose among multiple standards, most providers are not in a position to do that. Particularly the smaller providers certainly are not going to focus on the technology and the details around that choice.

Basically, you have vendors choosing or you have providers being trapped into choosing whatever the payers are choosing. Again, that is where I see the importance of having a single standard that all payers must support in addition to whatever other development that they could do in terms of other ways of communicating data back and forth, which may advance health care and the technology. But it needs to be something which is negotiated and optional for providers to participate in.

The idea of narrow standards – it is something that is attractive except that I do not know if payers are going to be able to support a great many of those or even several of those. I am not sure if that is something that works long term.

I think that is it for my time. Thanks for the opportunity.

Rich Landen: Thank you, Arthur.

Next up is WEDI, Workgroup for Electronic Data Interchange, Nancy Spector.

Nancy Spector: Yes. I wanted to start by saying thank you for inviting WEDI to participate today. We do have a multi-stakeholder membership of payers, providers, and vendors. I am going to try to speak to all three questions, starting with the first question around providers. We do see that providers – they find value in some app-based transaction but may also find value in continuing with their current business practices. The one question that we have heard is the same that Terry raised, which is around the idea of is it possible to mix and match which standards are used for different business needs and how will these different systems be working together.

The other point is that providers largely rely on their EHR and their practice management system vendors. The question is how will providers' systems be able to accommodate both app-based and X12-based transactions and what will be the cost to support those software packages?

We think that there needs to be an overarching principle in general as we look at this idea of regulatory flexibility that does not lead to additional administrative burdens and costs.

WEDI did put out a brief survey, using these questions that were posed to us to get some feedback from our membership. We are willing to share those results with you. But I just wanted to point out, as I go along, some of the comments we got back in the survey based on the questions. For this particular one, I thought one question that was of interest was that most providers just want a solution that works. Their choice is really the solution provided by their vendors.

Moving on to question number two about payers and their customer support, Gail spoke well about this. I will just add that we also see a need for payers to understand the cause of their current customer service volume. We have heard from payers that customer service volume has not decreased since the

X12 transactions went into place and we know from the CAQH index that not all X12 transactions have them widely implemented by providers. Payers may want to look at whether or not their providers are using the current standards and then what will a different standard do. Will that actually solve the problems that they are seeing within their customer service?

In terms of comments from our survey on this particular one, the one quote I pull out was that their comment was I do not think so. At best, we might break even. Even if there was a decrease in cost for customer service relating to processing, there would still be an increase in cost related to supporting multiple standards, which goes back to what Gail had raised.

For the final question about the system vendors and the alternative standards, again, just to bring out some of the quotes that we got from the survey, adopting additional alternative standards will increase complexity and cost, technical support, software maintenance, software licensing piece, people resources, help desk, audit support, training for new personnel, regression testing must remain in place for all previous technologies and will continue to require funding for resources into the foreseeable five to ten-year future. And that creating multiple options simply reinforces the need for third-party technology support between providers and payers to leverage the capabilities and manage the complexities of a large array of payer connection points.

Again, I just want to reiterate what some of the others have said. We appreciate that this work is focusing on what is not working and what is missing and that there is not an effort to try to fix what is not broken. Thank you.

Rich Landen: Thanks, Nancy. We will definitely take you up on your offer to share the survey results.

John Kelly, Edifecs.

John Kelly: Thank you, Rich. Just quick context. I am with Edifecs, a vendor, but I have had a long career. I do not want to talk about how long but roughly split, a third, a third, and a third between provider operations, payer operations, and vendor now. The context is my comments reflects some of all that experience.

First thing I think I would like to say is we are living in between this world right now between change at all costs and really do not screw up something that is working. Don't try to fix what is not broken. That world we are in though is very different from that situation in 1996. Machines are really smart now, and some people certainly have heard me say this before, but I think the standards competition here is kind of a red herring. That the machines – your mobile, your laptop, your iPad, all support multiple forms of music that can move back and forth. They can support PDFs, docs, text files, whatever you exchange. The machine says I know what this and organizes it.

What is really critical to understand about standards is not about the loops and the segments or the posts and the puts and all that stuff, whether it is RESTful, whether it is XML Soap. It is that each of these standards and this is where I think X12 and NCPDP need credit for what they have done. They defined a set of barter components. Every provider, every payer cannot build a business relationship, a business process, a contract that includes data elements outside of what they have defined in the transaction.

Rich, earlier when you said maybe it is not – it is APIs but maybe not FHIR. The key thing about FHIR is not necessarily how the IGs are written. The key thing about FHIR is it is rooted in USCDI. A payer cannot

request data that is not being captured by the EMR. If they do, the process cannot be automated. And the value creation from automation is the heart of this.

I think it is really important for us to understand, yes, we need to have a floor. Your iPhone does not support 100 different music standards. It supports probably 15 or 20. But it does it without any additional cost. You do not pay extra to support a WAV file in your iPhone.

I think understanding that the multiple standards conversation is not at the heart of it but understand that we need to have a few standards that establish the lexicon of how we are going to automate these businesses end to end is critical.

I think the other major thing is the pivot that CMS did is making value creation, putting value creation for the consumer at the heart of information exchange and thereby not making payers, providers, vendors the primary arbiters of what is going to be a value because they are going to change kicking and screaming as a short-term business interest as opposed to long-term value creation for consumers.

Rich Landen: Thank you, John.

Next up is Patrick Murta.

Patrick Murta: Thank you, Rich. And thanks to the Subcommittee for having us here today. I am Chief Technology Officer at BehaVR, a developer of digital therapeutics. Before that, I spent 25 years at Humana until very recently, most recently as Chief Interoperability Architect, and also has worked with Da Vince since day one.

Coming from both a payer perspective, and also the perspective of an IT vendor, I am going to hit on a couple of things there and echo a lot of what John was just describing as well. I think we need to recognize that in today's world, we support multiple standards today. We have different types of – we have FHIR. We have X12, NCPDP. This pattern exists. I think it is important to recognize that the newer contemporary models, FHIR, SMART on FHIR, CDS, those types of technologies are built to allow folks to ease into the brave new world of interoperability without abandoning stuff that we know works. These are basically built to solve problems that are not solvable using previous technology.

An example of these co-existing and working together is the work that we have done from Da Vinci from a prior authorization perspective. We are basically combining the X12 model and also the FHIR model and seeing very good positive results for those of us that have implemented at least pieces of it.

It is key to understand that what we are doing from a contemporary perspective is focusing on issues that have not been solved yet in workflow iteration, allowing apps to run EHRs, providing single integration of data from payers, providers, and other IT vendors that, again, they are simply not doable using previous versions or classic styles of interoperability. I think recognizing that these are complementary to each other as opposed to competing is something that is really key.

Getting onto to the customer support and the cost perspective, I think we need to take the view or recommend folks to look at it from a total cost of ownership, not just the additional implementation cost because in the implementations that I have been involved in, although you certainly have to spend a little bit of money or some money to implement, the cost of ownership or the benefit of the overall increase in the experience outweighs the cost. For example, prior authorization, taking that from 17

minutes to a couple of minutes using a SMART on FHIR app much outweighs the cost of implementing that particular app as well.

The benefits that we see with putting providers in front of patients as opposed to doing paperwork is key with some of the core technologies that we are bringing out here today.

We talked about the fact that these are complementary and that they are meant to work together. But I also want to call out that in addition to that, the ability to use these contemporary models allows others in the ecosystem to interop with each other. For example, I call it the great equalizer in the sense that if we are working with contemporary technology, those actors, which previously struggled to interop using older standards now have much more of available playing field with contemporary standards to start sharing information, providing innovation, and allowing folks from a competitive perspective to choose the right solution for their needs. Thank you.

Rich Landen: Thank you, Patrick.

Next up is Charles Jaffe from HL7 International. Dr. Jaffe.

Charles Jaffe: Hi. I am Chuck Jaffe. I have been a clinician, a researcher, an informatician for more than a decade, the CEO of HL7. I think it is fair to say that HL7 has evolved more than I have. Over the past 20 years, the landscape of the way we share information has changed dramatically. I fear more that we are not changing than we are changing too fast. Some of the challenges that we have are related to some cost and other issues that chain us to technologies that are outmoded.

At HL7, we have no interest in supplanting existing technologies that work. We are simply committed to providing the change necessary that is embedded in agile development process which HL7 embraces as well as the new capabilities for the health care industry that FHIR and OpenAPIs provide. This is not limited to the landscape of API technology. It goes much broader than that.

Henry Ford famously said if I gave my customers what they wanted, I would have invented a faster horse. Today, that seems a silly analogy, but it really hearkens back to some of the challenges that we face.

When I sit in my car seat and I push the button on the dashboard, my car starts. Hundreds of standards are evoked when I push that button. I have no idea what they are because I am the end user. I recognize that the car fob has afforded me security and the ability to start my car when others cannot.

The capabilities that this evolving technology provide is really remarkable. Again, it is not a replacement. It is an addition to the capabilities that we now serve. The foundations of this have been driven by the accelerator projects, initially led for more than five years by Micky Tripathi, who understood that OpenAPIs was really speaking to the future of interoperability.

Now, we have an opportunity to bring that to bear in a much larger scale that FHIR accelerators now include eight, most recently Helios from the CDC. And to bear upon that is really the notion of making health care more affordable, better care for our patients, and better solutions for security and privacy.

Rich Landen: Dr. Jaffe, if you can wrap up, please.

Charles Jaffe: I acknowledge the capabilities that we embraced two decades ago, and I ask you to unburden yourself and look at the opportunities ahead. Thank you.

Rich Landen: Next up is American Dental Association, Sarah Tilleman.

Sarah Tilleman: Thank you. I am stepping in for Jean Narcisi today. Thank you for allowing me to be here. I will not spend too much time repeating what many of the good points that have already been made.

I just wanted to take a moment to point out that the dentist's perspective is a little bit different given the dental benefits are much more limited. That cost estimation is crucial before the acceptance of a treatment plan. Therefore, we are open to multiple standards. I think excellent points have been made today about the need for a floor, about making sure the burden is not on the provider, about considering the need to bring in current noncovered entities maybe to be part of this to make it all work better for the provider.

Our main focus is, and the reason we are so open to new technologies and what else may be out there is that quite frankly, the eligibility and benefits transactions are not working for dentistry. They were not designed with dentistry in mind. It is causing severe revenue implications for practices but more importantly, it really damages the dentist-patient relationship.

We are open to whatever is out there that would work to make eligibility and benefit transactions or what new technologies are out there to make those real time down to the procedure level at the tooth level, things like that. We have annual maximums and other restrictions on benefits. All that kind of information that just currently is not contained in the 270/271 as implemented.

With that being said, I want to just yield the rest of time back. Thank you.

Rich Landen: Thank you. Arthur Roosa, your hand is up but you have spoken once and we have 20 minutes left to get through the other considerations. If you will hold your question later on to the public comment, be most appreciative and I apologize for that. We do need to keep on schedule.

Rich Landen: Let us move to Consideration 2, so if you could advance to the next slide, please. I am hoping that the discussion or the comments will be – that we have already aired a lot of the fundamentals underlying the issues. The next consideration. I have not seen the slide move, please. If you go to Consideration 2. There we go. I am hoping for a lot of the discussion underlying the first conversation will apply to this. Again, I ask panelists to recognize we have a half an hour left to complete these next two considerations.

Consideration 2 talks about the possibility of the industry supporting multiple versions of an adopted standard or business functions. This would provide an opportunity for innovators to be one version ahead of the current adopted version. Again, from a high level, what the Subcommittee is looking about here is the – from what we have heard in the industry input so far is the concept of cutting over from one and only one version to one and only one updated version has been proven burdensome to the industry, difficult to manage, and that for some of the industry, the updates are critical. For others in the industry, the updates are not very relevant. Again, that is our input and that is our frame of reference.

What we are suggesting is in perpetuity that we look at allowing multiple versions, again, two, perhaps three of any given standard at any time. The assumption here as we have heard from some of the panelists already that the software could take care of handling whichever version comes in.

The problem statement. Prior to NCVHS strongly indicated that updates that the regulations are not keeping pace with need. Updates are massive, disruptive, and costly. How can we redesign and manage to ensure maximum efficiency and value? Some segments, for instance, long-term and post-acute care specialty and subspecialty providers may not be affected by the changes made in any particular version update. But they are nonetheless required to bear the cost and effort of implementing the new version.

If provider organizations were permitted to determine whether they needed the updated version of a standard based on their business need, those who had no business need could avoid a costly transition process that returned them no value. A more flexible HIPAA policy allowing multiple versions would ensure those who needed a critical update would get it while avoiding significant cost, resources, and disruptions for those who did not. An added benefit of multiple versions would be to eliminate the industry-wide date-certain cutover to a new version. Industry segments, payers, providers, and their intermediaries would have more flexibility and longer timeframes to migrate their trading partners onto the new version.

Here are the questions we threw out. In the interest of time, I will not read them. Let us go to our queue list and it looks like we are starting with CAQH CORE, April Todd.

April Todd: I will be brief. I just wanted to mention some of the additional points that were not related to number one, particularly related to pros and cons. One is I think on the pro side. In the software industry today, vendors are routinely maintaining more than one version. This is not unusual to do that.

I think one of the benefits of this is that it does encourage the industry to innovate because you have folks that are on newer versions of standards that can establish an ROI from actual implementation that can be used to help move the rest of the industry forward and innovate.

One of the cons I think we are just going to really need to grapple with is what is the process for deprecation. What are the criteria for when you can stop supporting the lowest version? It just creates another question for us to consider as an industry.

I would just reiterate when there are multiple versions if there are certain data elements in one, not in another, we still need common expectations around that. What does that mean? It creates other business type needs to think about when folks are engaging with each other. What does that necessarily mean? Thank you.

Rich Landen: Thank you. Jocelyn Keegan.

Jocelyn Keegan: Hi. Thanks. I agree with much of what April just said and I think we covered really this concept of the floor in the last session.

I think there are a couple of things I would like to pull out as we were discussing as a group before we got on the phone today. I think that this idea that we need to acknowledge of having a single standard has been a rate-limiting step for us in the industry and that we need to really own and acknowledge that all the organizations don't have the same access to technology enablement. I think we saw this in the chat in some of the comments.

Disability for people to pick and choose over a period of time, their upgrade in their advancement path is critical, and where government and industry support is required and can provide alignment is really important.

If we look at this idea of moving to more modern standards-based API infrastructures, we fundamentally believe that this will allow the folks that are less IT rich to be able to play at a more equal level to be able to better integrate additional vendor partners than they can today. I think that if we look at the terms of national standards really setting that effective floor rather than the ceiling that it artificially creates today will be able to pull on the innovators and state, regional, and private sector partnerships to get to that level of progressiveness.

We did have feedback from the Da Vinci membership from a number of parties around the concept of actually removing the government from the naming of versions and allowing SDOs to own their own process within guidelines, to allow the industry to maintain a pace of innovation but without being burdensome and really allow the implementers in this community around specific business problems to set the pace. But if they were going to continue in a model where the government is naming these standards that we need to make sure that that is being done in the way that is incremental, testing is included, so when standards are coming out, we make sure that they are fully formed. I think we have headed that way across a number of initiatives today.

I think the work that is being done in SVAP over on the ONC side and with the ISA, the Interoperability Standards Assessment, is really important in investing in tools like that. As new partners come into the community, they really understand what is available and where the maturity is around particular standards. I have encouraged folks, if you are not going to stick around this afternoon to come back and listen to the update that Dave DaGandi is going to give on the Value Framework that Cambia Grove worked on last year with the FHIR accelerators to really start to understand what does it really mean for standards to be ready and mature and having common industry terminology and concepts around how we measure value in the implementation of these technologies. Thank you.

Rich Landen: Thank you. I will remind the panelists that we are facing a time crunch. Please try and keep your remarks as narrow as you can, focusing on this particular topic. Much appreciate it.

Arthur Roosa, HBMA.

Arthur Roosa: Thank you. I think primarily I am supporting what I am hearing so far. Having multiple versions does help in terms of the supporting innovation and involving technologies. It also handles predictability and also it protects investment.

I think I would like the committee to think about the support of multiple versions in terms of rather a specific number but in terms of how long if in fact a new version is adopted. How long do you support a previous version and sort of have that defined? Is it like three years, two years after something is adopted?

Having a large number – when I say large, like four or five different versions out there at the same time. You would have the danger, I believe, of somebody who was let us say under version 1.0 and now you have 4.0 out there and they move to 2.0 rather than a move up to where the current version is. If you have a lot of versions, I think you would have people moving from one older version to another older version and you probably want to discourage that. But basically, the idea of multiple versions I think is important and it does enable predictability. I will stop there.

Rich Landen: Thank you.

Heather McComas, AMA.

Heather McComas: Hi there. Thanks. In the interest of time, I will basically reiterate what I said for the first question, but I would say turn my response dial up to 12. Basically, what I said before. The same concerns about providers really not having a choice on the version they would need to use or compounded by the idea of having multiple versions.

In theory on paper on the previous slide, it said the provider could choose whether or not to stick with an old version or move to the next one if it suits their business. But in reality, a health plan could require under network contracting that a physician practice use a particular version of a standard. We would have a situation where there would be – the practice would be required to support multiple versions of multiple standards and essentially, we could have a situation of version explosion, which would be extremely expensive and cumbersome for a physician practice to support.

Also need to realize that upgrading versions for a practice can be obviously very expensive. But if something goes wrong, it can basically bring the business or the practice to a crawl, which is very concerning. It can interfere with patient care. That is a concern.

And even if the practice itself was not upgrading a version but it was using a mediator like a clearinghouse to convert to a new version that is expensive for the physician practice.

If NCVHS is going to pursue this consideration, we would urge them to at least require that the multiple versions be backwards compatible. That is just essential. And there would also need to be strong and strict controls around the versioning process and transition so that we would not have a free for all essentially in the market where everyone was using a lot of different versions and different standards. Thank you.

Rich Landen: Thank you, Heather.

AHA, Terry.

Terrance Cunningham: Thank you, guys. In the interest of time, I share a lot of the same comments that Heather said so I will not belabor the points. But I do agree with her stance that allowing multiple versions could be problematic in that it leads to the proliferation you talked about earlier. If you have several standards and several versions of each standard, you could have a situation where a provider plan is required to be supporting a large number of different ways of performing the same function, which really gets away from the initial goal of the HIPAA, which is to again improve the efficiencies by not having the same function be completed in multiple ways.

I agree completely with – she mentioned the backwards compatibility being if the pursuit of new versions is pursued, it needs to be done in a judicious and careful manner particularly to ensure that there is no breakdown in the system to a lack of backwards compatibility or interoperability between these different transaction versions.

And then finally, I will respond to – I see in the second question that other industries are using multiple versions of the same standard. I think everyone in this call knows that health care is inherently a different industry. We have more than two parties involved. We have a lack of transparency as to how price is going to be affected. We have different prices. There are a whole bunch of different things that are involved. I am always a little bit leery when we try to say it works in this industry. It is not to stifle innovation. It is just to recognize that what works for a different industry very possibly might not work for this industry because of how complex our billing cycles tend to be because of the multiple parties,

the multiple ways in which prices are changed, controlled, or differed and the multiple ways in which they are adjudicated.

With that, I will yield the rest of time. Thank you.

Rich Landen: Thank you, Terry.

Patrick Murta.

Patrick Murta: Yes, thank you again, Rich. I will be brief. I think it is important to keep in mind that if we go into this with thoughtful planning from an architectural perspective, supporting multiple versions is not the burden that we are maybe convincing ourselves that it is.

I recognize after talking with the previous speaker, that this health care has some uniqueness from other industries. But a lot of patterns that we built FHIR and contemporary models on were learned in other industries. It does not mean they cannot be applied here as well. We are seeing some of that take ground in the work that we are doing as it relates to some of the implementation guides. I keep talking about prior authorization just because it is a great example. We are bringing different versions and different protocols together to solve a common problem. I think we should maybe consider the fact that health care can learn from some of the models that have been developed in other industries.

Going really quickly here. I think recognizing that even if that level of complexity that is an order of magnitude better than having multiple proprietary models that do not talk to each other and provide even more cost complexity and enable you to share information.

Again, recognizing that quite transparently, the industry is already moving in this direction. We see, and Dr. Jaffe mentioned a second ago, Eight Plus Accelerators from a FHIR perspective, writing implementation guides that are being adopted by the industry. The stuff is moving forward.

We need to recognize that the desire especially from a value-based care perspective to share information is going to advance. It is not going to slow down and talking about some of the real-world examples. Some of the stuff that you mentioned a second ago or a couple of minutes ago about payers and EHRs integrating with SMART on FHIR to ease the burden of prior authorization CDS Hooks returning aggregated medication profiles, liberation of data. Dr. Greene mentioned this early on. CMS-9115. Basically, using FHIR to serve up data and putting patients in control of their information. UDAP protocols that were developed or grown in FAST, FHIR at Scale Taskforce now being implemented by Commonwealth. The list goes on and on.

I think again, not sounding like a broken record, but the role of contemporary interoperability is built upon a model in which things go incrementally. They are developed in an agile fashion and the fact that if something were to move forward, it does not mean you break backwards compatibility. That is just part of the overall model.

The web browsers. I know that is probably not a great example. But there are many different web browsers out there. There are different versions. They are not limited to only three. I think limiting it to three can be very constrictive. Allowing SDOs to choose or to basically govern themselves as it relates to when something should be deprecated but we see as part of the contemporary model that do not mandate a certain number of versions because you are limiting innovation and allowing folks to move forward to solve real-world problems but having the industry govern itself and determining that if

something truly needs to be deprecated that we can certainly do that but not at the expense of limiting innovation for folks that can certainly benefit from it.

Rich Landen: WEDI, Nancy Spector.

Nancy Spector: Yes. I am not going to reiterate all the pros and cons. I think from the WEDI membership, we are hearing what others have already said about opportunities to fully test new versions in the standard production, ability to migrate to new versions as pros. And then the cons being additional administrative costs. The one point though is that costs will be disproportionately impacting smaller organizations.

In terms of the number of versions to allow simultaneously. In our survey when we asked this – and I should say that we had limited number of responses in the survey because we just did it over a couple of days. But we had five responses there were in favor of one version and the comments included find the best version and move to it based on what works for the smallest organizations or one version that allowed temporary overlap period while a new version is being adopted.

There were five responses in favor of two versions. Interestingly, the two versions that were different views of what they should be. Some it was the current and the next one under development and a couple of the comments were the current and the previous version until it is phased out. And then only one of the responders was in favor of having three versions at the same time.

But one comment that I wanted to pass along that sits a little outside but is touched on through these questions is that allowing more than one version of an adopted standard may not actually address the current business issue that is going on. The example given was that an app-based transaction may move data more quickly but between organizations. But that does not mean that the receiver can respond any faster to that request or that transaction. If the goal – to achieve is to have more real-time requests and responses that business is a business function and is not necessarily within the scope of the function of the transaction itself.

I will pass it along to the next person.

Cathy Sheppard: Thanks, Nancy. I think the next person is me. I am going through my notes to try to make sure I do not repeat anything. But I do think that there is an important consideration that needs to go related to the comment about unnecessary updates and avoiding them if they are not directly applicable to you. What I am afraid is that that kicks the cost down the road. It does not really eliminate it because eventually you are going to have to upgrade. It is just a matter of when that cost is going to be incurred.

Perhaps a better approach would be to try to find a way as we have been saying for many years to really allow smaller and more frequent updates because those incremental changes are not as much of a burden on the industry and they can be handled in a way that will give people more comfort about being able to upgrade without significant costs.

There is one thing that I will repeat and that is Terry's comment about this industry is different. X12 is the only SDO that supports multiple industries. I can vouch for his statement. What works in one of our verticals does not work at all in others. We should look to other industries for ideas but not necessarily for a path that we can follow. Thank you.

Rich Landen: Gail Kocher, BCBSA.

Gail Kocher: Thanks, Rich. I think there is value in multiple versions but for a period of time. The concept of moving to a next version is there because additional business needs are being met. There are additional needs, data needs that are being accommodated. It is not just moving to a new version to move to a new version. Having to continue for a long term to maintain multiple, it is actually hurting those that are not migrating because there is data that they either are not able to get if they are the recipient or they are not sending, which is needed if they are the sender.

It is also not as simple as the software will handle it. Depending upon how an entity's infrastructure is and this is not just payers, it is also the provider community and any of the vendors, it may actually require having two production environments to support two versions, et cetera. It is not always something that is accommodatable just through a software. There is additional infrastructure and downstream system and other impacts when we have multiples.

I agree with a lot of the other comments that were made but I definitely think the timing is really critical to understand. Thank you.

Rich Landen: Thanks, Gail.

John Kelly.

John Kelly: Hi. Thanks. Quickly, really two points. Number one, alluding to a couple of comments earlier, I think the idea that the industry and the organizations and the SDOs and the stakeholders complete themselves. Maybe I am a little more skeptical than others. After HITECH, we spent probably close to or north of $100 billion of public and private money, all largely governed to achieve interoperability by the industry participants and then we have JSONs come out in 2014 and said what the heck were you guys thinking. Did you forget about the internet? I think we have a little bit of history to tell us that the gentle hand of NCVHS and HHS maybe in our favor.

As far as versions are concerned, I think that – how many times did your iPhone update itself for the version? The thing is it does not break. Occasionally, it does. But then they jump on it and fix it. I think the notion of reverse compatibility is something when you are inside the system's development organizations, the people inside are always looking for greater, better, faster capability and sometimes they make decisions that might break.

I think more importantly about versions is it is not about the technology in the version itself. It is about does the business process break. Some orchestration I think on the part of either NCVHS or CMS or ONC or somebody to work with the SDOs and saying we know that there is a cost to reverse compatibility, but it is an important value that we really want to maintain as we go forward mandating standards.

And then the idea for the vendor community and the providers that people do need to be investing just like I am stupid if I do not update my iPhone because of privacy concerns and hacks. We do need to be investing and maintaining our systems of always moving, never being one more than one version behind so to speak or two or whatever the number is. But I think those are really the two points. There needs to be coordination and a little bit of sticks and carrots to make sure that all the SDOs and everybody are looking at maintaining reverse compatibility and also looking not just at the transaction version compatibility but at the business process compatibility of changing a version.

Rich Landen: Thank you, John.

NCPDP, Margaret.

Margaret Weiker: Thanks, Rich. Today when a standard is updated in HIPAA, there is a point in time where both versions of the standard are supported. There is a beginning. You can send one or the other and then there is an ending date. Perhaps we get rid of the ending date as a suggestion.

We would love the SDOs to determine the versions and have said this on numerous occasions. But as I understand it, that is a change to the Administrative Procedure Act. I was always told that it is highly unlikely that would occur. But if that cannot occur then I do agree. We need to come up with some rules around the versions and keep in mind data content, coordination of benefits, how do you determine what to deprecate and what to move forward. Those are just a few comments.

And a comment that I failed to mention in the first panel was until some of the federal processes change, we are stuck. Thank you.

Rich Landen: Thank you, Margaret.

Dr. Jaffe, HL7.

Charles Jaffe: Very briefly, I recall the argument about whether we would use VHS or Beta. Most people who listen to music or videos have no idea what tape systems/standards were all about. My laptop once had a port where I could put in a CD. That is an anachronism now although I can buy a device to connect to my laptop that will enable me to play CDs. The important thing is not to abandon the other technology but to move forward.

I want to remind everyone that FHIR is backward compatible. FHIR R4, which will be a requirement for all certified EHRs in December of this year, is backward compatible. 4B, which is currently under testing, is backward compatible but it provides new capabilities that will be addressed in R5, again, backward compatible. This does not mean that you have to abandon the old technologies. It just needs to move ahead to the newer ones that provide more capabilities.

At the end of the day, we cannot forget that it is the patients who are the beneficiaries of the decisions we make. Again, I ask you to focus on two words, which are collaboration and trust. Thank you.

Rich Landen: Thank you. You did mention video disks or vinyl.

Erin O'Rourke, AHIP. Last comment.

Erin O'Rourke: Thank you. I will be brief. Again, we ask the Subcommittee here to consider allowing multiple versions on a use case by use case basis and to consider how many versions an organization would be required to support. I certainly appreciate Jocelyn's comment that not all organizations have the same ability and infrastructure to do these updates and we need a process that allows early adopters to innovate and balances that with the resources that it requires to update and the potential burden.

I would certainly emphasize other points that backwards compatibility is essential so that we are not leaving anyone behind. We say that we could use the CMS and ONC processes to name standards and

versions but again ask that we balance flexibility and burden. We would encourage CMS and ONC to work with the SDOs and stakeholders to plan out these transitions to make sure we are allowing organizations time to plan for updates and the associated costs and potential disruptions.

With that, I can concede the rest of my time.

Rich Landen: Thank you. Much appreciate it.

We have one more question to go. We are going to modify the agenda a little bit. We will finish the discussion on consideration number three and then we will go to our 1 o'clock break. We will have the public comment period after we return from the 1 o'clock break.

If we could go back to the slide deck, please, and advance the slides to Consideration 3. This consideration talks about the testing process otherwise known as the exception process. The wording is 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 CMS/HHS review. Willing trading partners would automatically be authorized to us different standards for the same transaction and for the same business purpose or purposes. Reporting on the use of the alternative standards would be required.

A little clarification here. The current process does not require registering the project if you are just testing like a connectathon. What is requires is when you actually put it into production and are using something other than the adopted transaction. This consideration does not change the connectathon type testing, the alpha testing, the beta testing. It does not include exchanging live data in a production environment. This only talks about use of live data and real results. I hope that scope clarifies this a little bit.

Problem statement. Prior input to us strongly indicated that the updates to the HIPAA transaction regulations are not keeping pace with needs nor do the regulations – I use the term aggressively here but I think we mean assertively encourage industry innovation. How can we redesign the process and manage it to ensure maximum efficiency and value?

We have received a lot of testimony that SDO development and/or federal adoption so there are two distinct parts to that plus some interrelationships. The SDO development and federal adoption of updated transaction versions does not keep pace with the need for change. At the same time, testimony indicates a strong desire that emerging standards be subject to much more rigorous pre-adoption testing than they get now. To our knowledge, the exception process that is codified there has been used only twice since it was created. And based on a review of the testimony, we are hypothesizing that changing the requirement from a "apply for permission" approach to a "notify and publish" approach would better support those cutting-edge organizations who want to push the standards farther and faster. It could also provide detailed timely feedback to the SDOs. Finally, it could provide significant value, cost and impact data that CMS needs in its rule promulgation process.

Here are the questions. Let us go to our panelists. Kirk Anderson.

Kirk Anderson: Thank you. As I mentioned previously, Cambia received exceptions to implement a pure FHIR-based prior authorization process using the Da Vinci Reduction Implementation Guides. First of all, I just want to state how appreciative we are that there is such an exception process so that we were

able to move forward collaboratively with our provider partners, innovating a completely new approach for creating a seamless, real-time experience for providers doing prior auth.

As to our specific experience at Cambia, navigating the exception process, it did take several months for us to finalize that due to the need of having to modify and bring our legal teams together from payer and provider to modify the terms in our various trading partner agreements. We have six different affiliated plans at Cambia so working with two providers. We had 12 trading partner agreements that needed to go back and forth through redlining, et cetera.

This certainly did slow down a little bit our progress. We are able to move forward in testing and UX design and feedback from providers while we were navigating the trader partner during that. That was good. As I mentioned, we are on the cusp of going live this summer with the solution.

In sum, I think that the process as it exists today works fine. Burdensome – to the extent that there is a lot of back and forth with legal teams, which never goes quickly. But I think it works fine for very limited pilots to prove out concepts. But moving forward as we look to expand the solution across our other providers and for our providers to expand what they have invested in across the other payers that they are working with, I would support, as you mentioned, Rich, a model where you can allow innovator to attest that they are implementing an innovative solution according to what has been laid out for them in guidelines versus getting permission and signing a bunch of legal agreements before that roll out can begin.

I will yield back the balance of my time. Thank you.

Rich Landen: Thank you.

CAQH CORE, April.

April Todd: Thanks. A few comments here and some of them actually will tie in – for some of the comments that we have there. A key point we wanted to make here is that for this process, we really need to define expectations for measurement and that needs to be specified for organizations before they are going to be doing the testing. Those measurement expectations really need to match with what we are hopefully going to come up with guidance for a measurement just – between standards and versions later on in the – today. That highlights a point that I had for later.

Also, I want to emphasize that we want to make sure that organizations are still maintaining a floor during this test. And then there are some points that was actually submitted in a joint letter I think late last night from WEDI, CORE, HL7, NCPDP, and X12 around this particular point around the exemption process and the need for it to be shorter and for that testing so we can learn to fail fast and also for there to be a recommendation – federal resources for a limited number of tests to support pilots and innovation for new standards and new versions to encourage innovation with industry. Thank you.

Rich Landen: Thank you, April.

American Hospital Association, Terry.

Terrance Cunningham: Thank you. I just want to touch on a couple of things in this space. I guess I will clarify by saying I think the testimonies can depend on the entity that is testifying. It might be a very different experience from a provider versus a plan or a vendor. But from the provider perspective, I am

not sure I adhere to the hypothesis that this clause has been the issue. I have certainly never heard from any of our members about this type of issue.

Largely, it might be that providers are not interested in having to support multiple standards and multiple workflows during their practice. Again, this whole notion that you have different health plans that are going to be requiring information in a different standard and it is a huge lift because you have to train staff to interact with both functions, et cetera.

It might be not that there was necessarily a flaw in the nitty gritty of the exception process but it might just be that it is an enormous lift for a provider to inherently take on what is inevitably some inefficiencies because you are going to be doing the same thing two different ways in order to do this.

I am not sure how to solve that. I might be something – if the exception process is to be explored, it might be something that these things that are considered to be formal pilots and then, if need be, there might need to be some sort of incentivization to get people involved. Again, I had not really fleshed that idea out but I am just trying to think what might be the obstacle if it is in fact this clause. I think it might be something else.

Additionally, I would disagree with the idea that we skip the approval process. If it is slow, let us figure out a way to get it sped up. Let us move forward without some of the things that the previous speaker spoke of such as like sorting out all the legal issues. That seems unwise. I would just say let us figure out a way to speed it up rather than skip or rather than move ahead before all of the issues are sorted out appropriately.

With that, I yield the rest of my time. Thank you.

Rich Landen: Thank you, Terry.

American Medical Association, Heather.

Heather McComas: Hi there. Thanks. I think this consideration seems to presuppose that there is a major problem surrounding the current exception process. As the previous slide showed, this option has only been exercised twice. Actually, before Kirk was talking today, I had not heard a lot of people talking about problems with the process. Not to put words in Kirk's mouth, it sounded to me he did reference that there was a delay of a couple of months. That did not sound to me like it was a CMS review process though that slowed things down. That was legal work between trading partners.

To Terry's point, I think if there is a problem with the review of the exempt exception application at the federal level, that is one thing. But I think we need to tease out what the actual barriers are to using this process because maybe we are trying to fix something that is not broken right now.

Like Terry just said, I think I would strongly caution against getting rid of that review of the application before allowing the pilot to move forward. That is a valuable step. That process ensures that there is true value to the expected cost of using additional standards. That is part of the evaluation process. I would really urge NCVHS not to recommend getting rid of that process.

Also – some of the things that Terry was referencing. But we keep talking about this concept of willing trading partners and yet again I will urge us all to realize that that is really in reality not a fair reflection

of most physician practices interact with their payers especially for smaller practices. They kind of have to accept contract terms. They do not have sufficient power and negotiation ability.

Again, the concern is that they would be forced to participate in the pilot even if they did not want to by their contract terms. That could be quite expensive particularly for a small practice.

And then the last thing I would recommend is that ensure that these technologies are really viable in the real world that NCVHS should recommend that HHS provide funding to allow smaller providers to participate and needs to make sure that this technology will work in all practice settings across the board. Thank you.

Rich Landen: Thank you.

Nancy. We are running out – please limit your remarks.

Nancy Spector: Yes. I just want to say that WEDI also agrees with the concern about doing away with a review process with the HIPAA exception process. Our concern would be that you could end up having even more variations within standards and versions of standards being used throughout the industry, which would add to obviously the complexity of business practices, workflows, system development, all of that. We agree that the idea should be to look at CMS to have a more expedited review and approval process if that is where the slowdown is.

One of the other points that I wanted to make was the idea that there are the connectathons that happen today, which are usually around the FHIR-based transactions and maybe there would be a way to expand the connectathons to include X12 transactions or these other variations of business processes and how to use different standards and different versions of standards to test out some of what we have been talking about here in terms of whether or not those situations are viable within that connectathon environment.

I just wanted to reiterate within our survey around the HIPAA exception process. We got multiple comments about federal funding and the need for that to help support this work. And the comments were around that organizations have not tried to follow this process because the cost of standing up the technology and the staffing changes workflow and all that to support a HIPAA exceptions project is too costly compared to the value that comes back to the organization in doing that. Thank you.

Rich Landen: Thanks, Nancy.

BCBSA, Gail.

Gail Kocher: Thanks, Rich. I have not ever heard from any of the plans that the provisions in the current regs are an impediment. I think it is a valuable concept because if we are going to do something new and different, it still needs to be on the record and everyone needs to be aware of what is happening. I do not think completely going to you can automatically start. Just tell us and you can start is the right place. I think we need to find something in the middle and look at what is it about the current process that takes so long. Can we fix that? Are there things – is there information that does not really need to be submitted or does not need to be part of that process?

I think the focus should be on revising the process but still maintaining some level of review. Just maybe perhaps the detail level of review may not be as necessary. But I do not think just you send it in and you

are good to go. I do not think that is going to help any of the trading partners across the spectrum. Thanks.

Rich Landen: Let me step in and put my co-chair hat on here. It is sounding to me from everybody that has spoken that there is a fairly good consensus that the current system while it may have some – may not be entirely optimal, it is not really a problem. I know I am putting words in everybody's mouth, but I am looking at the agenda. I do not want to take time away from the other panels this afternoon.

Let me ask the remaining folks with their hands up. Do you have anything that would take us in a direction other than telling the Subcommittee that this perhaps is a process that is not really broken so do not try and fix it?

Margaret, NCPDP.

Margaret Weiker: Yes. NCPDP assisted the CMS Medicare Part D group and the national facilitator as submitting an exception process application for an updated eligibility inquiry. It would allow any willing provider to submit one of those.

We spent a great deal of time educating the department on eligibility and real time and how it all works. But the showstopper was because we wanted to allow any willing provider. We had to name these specific providers of who would be doing this. And Medicare Part D wanted any provider that would be able to do it to do it. That really became the showstopper there because if we went to any then the national facilitator would have had to come up with a process to get the appropriate agreements in place to acknowledge that they were technically creating a HIPAA violation but that was okay because they were doing this exception process. That became the showstopper is when you had to name the specific entities that would be participating.

Rich Landen: Thank you.

John Kelly.

John Kelly: Just quickly. I think listening to the conversation and some of the goals you had talked about earlier in terms of driving innovation, I think the exception process as it currently stands, it is like okay. Do HIPAA mandate or anything else. I think if you want to look at changes in terms of expediting and making auto exceptions, you need to make a distinction between just anything crazy versus I am going to be an early adopter for these emerging standards. I think that might help you expedite most of the projects that you want to get going while at the same time allowing the review process for things that are just really maybe creative and out there and really a part of the future.

Rich Landen: Thanks.

Jocelyn Keegan, Da Vinci.

Jocelyn Keegan: Rich, I will be as brief as possible. But I am more than happy to follow up on this conversation in more detail with the folks that have been through the process.

We heard from Kirk who successfully navigated actually getting the exception in place with his trading partners. I have talked to probably ten times more providers and payers that were interested in joining in participating in the process. I think if I were going to set them up sort of the feedback or sort of the

challenges that folks have had, I think it is that the process today is opaque. It is not really well documented how it works. Da Vinci worked very closely with the National Standards group to figure out what it needed to look like for our particular project. There are some specific areas of feedback I think that could be helpful that would allow it to be wider, more broadly used and known but not doing the tradeoffs that I think people are fearful of, really making sure that people are not expanding the use of standards.

I think the first is how do we streamline it and make it predictable what you are signing up for, when you have to do what. Because even though you are not required to have the exception until you go into production, most organizations would not start and the idea that you had to start your project with a provider on the other side as a willing partner to go with you was really a non-starter for many of our payer partners that wanted to get involved.

The other thing that was challenging was the exception was only named to Da Vinci. And because Da Vinci is a privately funded project, we did not necessarily have the ability to scale to other organizations that were interested in participating but did not happen to be Da Vinci members and they wanted to use our guides that are publicly available. That limitation of making Da Vinci having to own and house all of the reporting around this particular exception made it so other participants in the market really were not able to participate. Being able to more broadly allow people to participate once an exception has been named for a specific set of standards, I think, would be important.

At the end of the day, I think people are really excited about the idea of really solving this nut that is prior authorization, and all of the upfront transparency – to get there. But it is really hard, and everybody would probably agree to get pilots and early adoption projects started inside the organizations. I would implore us. If there is anything we can do to streamline this and make it lighter weight and make it so it is more known and people are taking less of a trust fall to start the project, funding always helps on that front. I think that those are the sorts of things that we want to think about about why aren't we getting the throughput, why aren't we getting people testing more standards? We have probably 20 organizations we have talked to over the last year since we got our exception but I am more than happy to put in front of the right folks to talk about why it has been so hard.

Rich Landen: Thank you, Jocelyn.

Last is AHIP, Erin.

Erin O'Rourke: Thank you. Again, I will try to be as brief as possible. We appreciate the language that this would be between willing trading partners to use alternative standards, again, highlight the difference between mandating, supporting different standards as well as the different – allowing flexibility to support innovation.

I echo what others have said that we agree there is a need to explore ways to streamline the process so that those who do want to pursue an exception can do so without an undue burden.

We have heard from our members that there is a tension between some of the stringent processes to develop and update standards as well as the desire to implement new technologies. And when that happens, plans are forced to build work arounds that are costing extra time and money.

As Jocelyn mentioned, we are facing new requirements under transparency rules as well as the potential for the new interoperability rules. We need to ensure that these regulations have policies that are feasible and that plans can work with other stakeholders to build viable solutions.

With that, I can yield.

Rich Landen: Thank you. That completes the list of the panelists who have their hands up. I thank you all very much. Very excellent feedback. Again, I am looking forward to getting any follow-up communication from you all if you have time to digest and think about the things.

We will now go to our lunch break. We will resume at 1:30 when we will take the public comment for this group of the considerations.

Rebecca, anything to add?

Rebecca Hines: That sounds like a good plan, Rich. So 1:30 Eastern Time we will reconvene. That is in 25 short minutes.

Rich Landen: See you all then.

(Lunch Break)

Public Comment for Panel 1

Rebecca Hines: It is 1:31 p.m. I think we are in good shape. Let us have the public comment slide, please. For our panelists who are in the queue for Panel #2, please remember to rename yourself with your organization to the right of your name if you would not mind. Thank you.

We have here the instructions for the public comment period. Just to reiterate, Rich Landen, the co-chair. This public comment is specific to considerations number 1, 2, and 3 that were just discussed. If you have a general public comment, please hold that until the end of the day or pertaining to one of the other considerations, there is a public comment period after each one of those panels. On Zoom, you can use the Q&A to request an open line. You can raise your hand. Some of you are on the phone. You can press *9.

Greg, I see that we have had one person in the Q&A. Stanley Nachimson would like to have an open line. We will need the timer. Stanley, when your line is open, can you please state the organization you are with and then share your feedback for the committee.

Stanley Nachimson: Certainly. I am here and I hope that you can hear me.

Rebecca Hines: We can, loud and clear. Thank you.

Stanley Nachimson: Wonderful. My name is Stanley Nachimson. I with the Nachimson Advisors, an independent consulting firm. I want to thank the committee for this opportunity. It is always a pleasure to address some of my old friends and colleagues and some of my new friends. Rich, I perhaps took a little bit of offense to hear that the HIPAA process is obsolete, but that is okay.

I do want to address I think a solution to the considerations that were raised, Considerations 1, 2, and 3. There is actually already an option for floor and an optional standard in the original HIPAA rule.

You recall the direct data entry option in the original rule allowed payers to support direct data entry as an option as long as it was equivalent data. This was put into place because many hospitals already use that DD option rather than X12.

From what I see, we could have a tiered approach to standards updates. First, a pilot test for a new standard. Perhaps the last 6 to 12 months to prove that it works at least in a small set of plans, providers, and clearinghouses. And then move that forward to an option, not a requirement, but an option for payers and providers to support. And then based on the experience that we have in both the pilot test and the use of that new standard as an option, consider that new standard to be eligible for adoption as the main standard if it appears to be better than the existing standard in place. I think this gives more of an incentive to test standards because there is a pathway to move from the pilot test and the option to having adoption as a full standard.

Thanks very much.

Rebecca Hines: Thank you.

I also want to say that Lisa McKeen – you put a comment in the Q&A before the break. Are you here and would you like to have an open line? It does not appear she is on so I will --

Lisa McKeen: Hi. I am Lisa McKeen. I am with eMedNY of New York through GDIT. I am the Privacy and Security Officer.

Thinking about the structure that they are speaking of and knowing HIPAA and the CFRs and the desire for innovation that we see in interoperability, it might be better if they do like a floor standard for each industry like categorize it by industry because providers – their needs and desires and their capabilities are different than let us say with the clearinghouse or a vendor and just set it up by a vendor, clearinghouse, and provider and then public just to have – consider addressing the industry and what their regulations stipulate for them within their state.

Rebecca Hines: Thank you very much.

Pamela Grosze, your hand is up.

Pamela Grosze: Thank you. I am Pamela Grosze from PNC Bank. Today, I am wearing my hat, representing the Cooperative Exchange, which is the National Clearinghouse Association. I am the Board Chair of the Cooperative Exchange.

Just a couple of comments that I would like to make regarding the discussion we had this morning. I agree with most of the comments that have been made and especially discussion around not breaking something that is working today, continuing the use of the significant investment that we have all made in some of the standards today but looking for the areas that may not be working as well and what options we might have to improve functionality there or make those business processes operate more efficiently.

I would like to state that clearinghouses – the role of the clearinghouse in these situations is really pivotal to what we have been discussing whether it is multiple standards that we have the option to support or multiple versions that we are trying to support. Clearinghouses facilitate transition of data between trading partners that have varying states of readiness. We might have providers that might not be able to send a newer version but payers are asking for that. And clearinghouses can help facilitate that transition of data and movement from one version to another, again, between trading partners that have varying states of readiness.

We fully support that idea but also support the idea of having a sunset date for the previous version or the older version that is being supported so that it is not indefinite, which would then encourage alternating partners to ultimately move to the newer versions as they are being supported.

I would like to echo the statement that was made earlier about the content of the information is really critical to allowing this process to occur so that the syntax is not as important as making sure the content is interoperable, which then facilitates a clearinghouse being able to do that to up convert or down convert and facilitate that data exchange.

Then a final point I would like to make is around the concept that providers often are limited by what their vendors will support, which is absolutely true. Providers may not even be aware of what versions are available or what version they are sending because they are very dependent on their vendors and what is supported there.

We often see that vendors may not be willing to move to the latest versions as rapidly as would be beneficial simply because there is not a business need for them to do so. And when they do make those changes, providers have to invest dollars in order to upgrade to a later version to support those newer standards. Providers often are hesitant to upgrade to a later version of their practice management system or EHR, for example, because they do not want to invest the dollars. That is just something else to consider as we look at the cost of having to do this for all the stakeholders involved.

That is everything I have to say. Thank you.

Rebecca Hines: Thank you. At this time, I do not see any other hands up on the attendee side. Again, the information was just up on the screen. Here we go. Yes, you raised your hand, Christopher Schaut. And we actually have after him Rajesh Godavari. Please leave the public comment slide up. We still have some people ready to give public comments.

Christopher, please introduce yourself and the timer will be set for three minutes.

Christopher Schaut: Good afternoon. This is Christopher Schaut. I work with Epic. I just wanted to emphasize a couple of things. I have one other comment that I hadn't heard brought up. As Dr. Jaffe noted, users really care about the capabilities and not what is under the hood. All of our efforts should be focused on making sure that the users get the most capability as they can.

If we want to expect support for multiple standards even if there is a supposed choice between those standards, there will be demand across all parties to have each of those standards' updates. I would encourage that as far as a mandate goes to really focus on one standard being what is expected even if other standards might be allowable.

For both considering transitions across standards or versions, I would also support the idea of having a sunset date to ensure that everyone understands where we should be moving as an industry and not having an expectation of supporting multiple versions or standards in perpetuity.

But one other thought about in bringing in new standards or new versions of a standard because you want to make sure that that new standard is mature and will meet the business needs. You may want to allow a period of a pilot for a given version or a given standard and make sure that it really fulfills those business needs before naming it as the direction where it will become a future floor for all parties.

Thank you.

Rebecca Hines: Thank you.

Next up we have Rajesh Godavarthi.

Rajesh Godavarthi: Thank you very much. My name is Rajesh. I am from MCG Health, part of the Hearst Health network. For full transparency, I am also part of the ONC HITAC Committee membership.

Thank you very much for the opportunity to listen in the wonderful conversation so far. My few comments are very much around what is important to the patient. I live in the technology space and I have been dealing with prior authorizations and interoperability for many years, but many times, we forget or unintentionally ignore how these things would help a patient. If anything has become apparent to us in the last two years. A patient is stuck in a place with his or her allergy information is not transportable and the people who are administering medications probably not having the information, unintentionally harming the patient. These things happen and will happen.

We have the greatest opportunity to look at it from the patient's side of what is important for my family and your family, and then think about technology. And then think about standards. And then think about everything else. The perspective is important. I think it was brought up in the earlier slides with the organizer. We need to have the patient outcome in mind.

The burden direction comments made by organizers and the CMS and others, and many other initiatives are heading in the direction. These are, of course, complex. But it ultimately benefits a patient, ultimately benefits somebody life.

Keeping that in mind, we have to continue to innovate and open to adopt the processes and whatever it takes to do it because people are moving globally, not anymore restricted to one place. We probably will come across situations like other pandemics in the future and having this information available to somebody who is somewhere in Europe, as an example, would save a life. I think it is all worth it if you think from that perspective.

Thank you very much.

Rebecca Hines: Thank you very much. Let us wait a few more moments here on the attendee side or any of our panelists who have an additional comment to make. Please raise your hand. For the five people on the phone, if you would like to make a public comment, please press *9 to request unmuting of your phone.

Rich, it looks like we may be done. If that is the case for now then we can move to Panel 2.

Rich Landen: Let me make one or two more comments and then we can move to the next panel. First, I would just like to address Stanley Nachimson's comment with the direct data entry and to let everyone know that the Subcommittee is looking at direct data entry, DDE, and that exception to the HIPAA process. The Subcommittee discussion on that was still shall we say fluid and we know it is an area we want to address. It was not ripe enough to include in this first list of considerations. We, the Subcommittee, will continue to work on that. There are issues, a lot of the issues that do go back to some of the same concepts we have heard about different ways of doing things across providers and across plans. But that is on the table that was part of the input we got from the public. We will address that along with some other considerations as we walk down this path in the future. This is not a once a done thing. This is a vision and a lot more work to be done.

Last point. Let me ask any of the committee or subcommittee members if they want to raise any issues, make any comments, or ask any questions at this point. Seeing none, let us move to Panel 2. Thank you all very much.

Rebecca Hines: Thank you, Rich. And for our panelists, I know some of you were not on this morning. Please remember to rename yourself with your organization and once Denise Love launches the panel discussion, there is going to be a timer up and you will have to scroll through the thumbnails. The timer will be there a little down the set of thumbnails. Just know that that is there when it is your turn to speak.

Over to you, Denise.

Panel 2: Address Standards Integration and Collaboration

Denise Love: Thank you. Can you hear me?

Rebecca Hines: Perfectly.

Denise Love: Welcome to the Consideration 4 for Panel 2. We will follow the same format as the previous panel. For those of you who were not on, I will do some introductory remarks, introduce the consideration, and then we will go through each question sequentially and give our panelists some time on the timer, three minutes, to speak.

I am just so pleased to have the following on the panel. Tom Giannulli from the AMA, Julia Skapik from the National Association of Community Health Centers, Jean Stoll. I believe it is Oregon Community Health Information Network. Elisabeth Myers, HHS ONC. And Walter Suarez, Kaiser Permanente and other entities that he will recognize.

We are going to shift gears a little bit. This consideration really is at the heart of convergence. As we bring multiple data sources together in order to obtain a more full picture of an individual's health, population's health, and get a full holistic view of health and health status.

The committee's recommendation is to identify options for improved integration of health information standards, including base standards plus standard development organization implementation guides, more broadly than at present, and fostering relevant collaboration across HHS agencies and offices, including state, local, tribal, and territorial governments.

It is clear that data standardization is vital to the success of efforts to address health equity and efforts to improve interoperability among health care organizations and interoperability between health care entities and others, including public health agencies.

The Subcommittee is well aware of much is happening at every level and at HHS. We just wanted to acknowledge that there is a lot going on. In fact, that is part of the issue is to keep track of that and know what is going on. The Subcommittee is interested in learning more about the coordination of standards between and across the system, including HIPAA and non-HIPAA data, social service data, and public health data.

Some of these challenges include social determinant data are not consistently defined across data sources that in play today. Public health relies on data systems that are often not consistent across federal, state, and local programs, and may not be harmonized with clinical data standards.

There are many unique data and reporting standard requirements for organizations. It is difficult to track and understand all of these across the health care system. It is really difficult for – just an example for states that are developing reporting initiatives such as all-payer claims databases. They are not aware of what is in the pipeline; yet the standards for these reporting systems are updated – a year and they may not know what is in the pipeline and it is very difficult to change when you make a data policy at that level. It also increases burden on those supplying the data to these reporting systems.

We will do our round robin, kind of speed dating format. We have these excellent panelists. We will just talk to the first question. And the first question is 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?

I see Walter's hand up now. We will start with Walter Suarez.

Walter Suarez: Yes. Thank you. First of all, can you hear me okay?

Denise Love: Yes.

Walter Suarez: Excellent. Thank you. Thank you so much for inviting us. It is truly a pleasure to be a part of this panel and participate in this listening session. Excellent comments in the previous panel. Lots of really good points.

I wanted to start by saying that I think throughout the pandemic, one of the things that we really experienced was the speed at which things are changing. I think the world, not just the US and not just health care, is going through a major transformation in terms of things like digital health. We are all experiencing this concept of digital health transformation. And certainly, health equity is at the center of a lot of this conversation and a lot of public health exchanges and need for faster, better, cleaner, more quality, timely data is at the center of all this. We are moving at the speed of light in many ways. The good news is that we have methods and mechanisms to do that.

Let me address the question itself. Do we have a good collaboration and framework? I do believe that we have a great collaboration and coordination between CMS and ONC. I would even add OCR and CDC

and other agencies. I think they are having a lot more conversations. They are clearly looking at how to harmonize different elements.

However, I do believe that when it comes to standards, we still have much fragmentation and relatively limited harmonization with respect to things like data content, data structure, data format between all the different types of exchanges, administrative transactions and standards and clinical exchanges and standards, federal and state and local public health data exchanges and other purposes, research, and others. We still see a lot of fragmentation and somewhat of limited harmonization.

I do think that one of the other realities that we have is that we are still segmenting things along different business lines, business functions, business types, even SDOs that have some specialized business work focusing on certain lines of business and the regulatory framework of HIPAA versus HITECH seems to have been perpetrating some of these fragmentations. I think we still have fragmentation and segmentation across all these components when it comes to standards.

What can we pursue?

Denise Love: I am going to play timekeeper and I want you to hold that thought because I want to know more about how we solve some of this fragmentation but in the spirit of the roundtable speed dating format.

Walter Suarez: Okay. I did not see the watch.

Denise Love: I have to be harsh, but we are going to circle back to you. You are not done.

Julia, I think it is your turn. I will turn it over to Julia Skapik.

Julia Skapik: Hi. Julia Skapik. I am a CMIO at the National Association of Community Health Centers. We represent over 1400 federally qualified health centers that make up the nation's health care safety net.

I have a deep appreciation for all the work that is being done and all the partners on this call. I really appreciate their work. But I think my first question here would actually be I am not really sure what is being referred to in this comment. What is the existing framework of standard harmonization? Because even as a person who has worked with these agencies and inside this process, I do not know that it is fully understandable still to me. I am imagining that the public would have much less understanding of that.

I think the approach to data harmonization to date has been really slow moving and that there is a lack of centralized governance body and a lack of a process that really drives to a consensus with both the federal agencies and with the external private stakeholders that should be involved. I appreciate that there are a lot of those kinds of organizations at present today and commenting today.

The pace at which the current process is moving is a pace that will take decades to reach a place where we really have plug and play interoperability in the way that is needed to support point of care learning health system and that is just not fast enough.

We really need to shift the way that we do these things and start doing rapid cycle improvement until we get to a place that we are making measurable differences in a matter of months to a year and not over periods of decades.

I think part of that is we need a lot of tooling to help support participatory action by the community and a lot of tooling that demonstrates success and feasibility of these things.

Denise Love: Thank you, Julia. Are you done? Do you need a little more time?

Julia Skapik: I did not see a timer either so I will save it for the next one.

Rebecca Hines: I apologize, panelists. The timer is in the thumbnails with your names or if your camera is on, your photos. Depending on whether you have them to the right of your screen or above your screen, you are going to have to use the arrow to scroll through the thumbnails and the timer is there. You can see it right now. It is set at three minutes. When it is your turn, you might want to make sure you can see that.

Denise Love: I had a little hiccup here. I had an oversight. I think Chuck Jaffe from HL7 is also part of this panel and I just did not recognize that. I apologize. Is he on? I do not see his name here.

While that sorts out, I will go to Jennifer Stoll from OCHIN.

Jennifer Stoll: Thank you. Good morning. Good afternoon. I am Jennifer Stoll. I lead External Affairs for OCHIN. We are a national, not-profit health IT innovation and research network. We support over 1000 care delivery sites, 22,000 providers in 47 states, really working through with federally qualified health centers, public health departments, school-based health centers, tribal clinics, clinical access hospitals, and many other organizations serving the nation's most medically and socially complex patient population.

I am really pleased to be here today for this important discussion on standards, integration, and collaboration to bring visibility to the challenges and opportunities we experience as an organization across the country. We specifically support the needs for federal leadership and data and standards coordination. Again, I appreciate this conversation.

Because we operate in 47 states, we have a unique lens on the complexity that is what happens when you have every state doing something different, every municipality doing something different in the thousands of reports and very specific and unique things that have to be generated as a result of lack of coordination and data standardization.

I would agree with the comments Julia made earlier around the framework and clarity around the framework. OCHIN would support more transparency around that. And while we believe that a lot has advanced over the last few years, we need to accelerate the need for data standardization and go beyond what is required by HIPAA and federal programs and accelerate the need for standards adoption.

And to give you a specific example of that, OCHIN helps our organizations collect social determinants of health information. Let us just say, it is extremely varied all across the country on how that data looks, how it is presented, how it is collected and never mind being able to move the data.

Ultimately, we think we could go a lot further than what is here. We truly appreciate the efforts of what is happening, but we would love to have more transparency and we would love to accelerate the need for data standardization as well, and we look forward to being part of this conversation and being a resource moving forward. Thank you.

Denise Love: Thank you, Jennifer. And all of you are getting at some of the heart of our Subcommittee discussions over the past months.

I will go next to Tom Giannulli, AMA.

Tom Giannulli: Thank you. I am the CMIO of the Integrated Health Model Initiative at the AMA. I am a physician. I have also been past CMIOs for companies like Epocrates and other HIT digital health companies. We are currently one of the founding members of the Gravity FHIR Accelerator and also have the seat on the CAC with Da Vinci.

I think the question you raised – again, I agree with the other speakers. It is unclear to me what framework you are referring to and how successful that framework is and what are the gaps and how do we need to change that. It maybe easier to answer if that was known.

I would also point out, however, that harmonization is often overused. In this particular discussion around social determinants, I think it is probably best referred to a base set of standards, those typically within USCDI, US CORE, and maybe USCDI+ as that gets developed and say that is the base for which we want to operate.

I think by focusing on that rather than trying to figure out how to harmonize a set of other either data standards or terminologies or both, it would be easier to focus people on what has been adopted and proven as a leader. I would point to USCDI in that case.

I believe the pace for which USCDI is evolving could use some acceleration. I would point to the FHIR Accelerator program. It has a really interesting model that is successful in my view of taking a process that had taken years and moving into months. Our work there, I think, has traversed the process in ways that I could not anticipated. I was much more pleased than I would have assumed going into it. I think there is a lot of learnings that could be translated. Those are my key points.

I think staying abreast of how to improve things, using the Agile model, looking at the FHIR Accelerator model as a good reference are all the recommendations I would make at this point.

Denise Love: Thank you.

Walter, will you be speaking for HL7 at this go around?

Walter Suarez: Not really.

Alix Goss: Let me weigh in here. Chuck Jaffe is on the call. He is thoughtfully considering the dialogue to weigh in when it makes most sense for him to do so.

Denise Love: That is fine. I just did not see his hand or his name.

Alix Goss: He is under Charles not Chuck.

Denise Love: Okay.

Chuck Jaffe: Thanks, Alix and Denise. I am here listening quietly.

Denise Love: Just raise your hand. I just kind of did not mean to give you an oversight and then I was looking for your name. We are back to the discussion.

I think what we will do and then we will circle back. I hope to have some time for a more robust discussion. The second question. 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?

Julia Skapik: I will start by just making a comment off of the end of previous comments, which is I agree that USCDI and USCDI+ are good ideas, an approach to take content and – content itself magically interoperable. But the problem there is that the specificity of that content is not adequate to ensure interoperability. We really need to have building blocks that we can take and plug and play and they meet clinical use case needs and requirements.

When we say something in USCDI like do SDoH, that is far too broad. It actually could have the effect of hindering interoperability. That content interoperability is the foundational limitation to all the standards development adoption and implementation. It hinders interoperability when you say just do something like this because that is not specific enough. Two machines will see the same thing and be able to recognize it. It puts people always between the machines and each other. There is still this process constantly of doing this manual mapping and manual connection. That manual work is always going to be one to one in a lot of cases.

We can move to a data model or a coherent set of content that the standards can reference. If you look at HL7 standards, no offense to my wonderful colleagues and I am on the board of HL7 and HL7 Europe. You will find that value sets will often be totally inappropriate for the use case, and that is not really recognized to the standards level. But the standards developers don't necessarily want to create value sets. They want to point to the content that is already in use and be able to reference that and have it be reused.

There are two layers really. There is the standards layer and then the content layer. Both of those simultaneously have to have the right governance and the right support if we are going to get to plug and play and if we are going to get to data quality because (inaudible) right now has millions of patients' worth of data that people literally have to go through every spreadsheet by hand because – and it comes directly from EHRs because that data quality is so poor at the EHR level and that data extraction therefore yields back quality data and that back quality data just goes up every level back to the government.

Denise Love: Thank you.

Walter.

Walter Suarez: Very quickly since the clock is just starting, I think what I wanted to say in the previous section was I think there is an important distinction to be made between harmonizing or aligning data content and then trying to harmonize or align the data exchange method or exchange standard. I think with respect to data content, I do believe that there are value and that there are important benefits of having better alignment of the data content. I would argue that the goal would be to establish a common base set of data elements that can be applied to all types of the information exchange regardless of the purpose of the transaction. We do not have any more separate data definitions on data elements for administrative transactions, for example, and clinical transactions or public health

exchanges. We all have lived through all the different implications of having to tweak the data to report a particular data element on a particular transaction in a particular way because someone wants it in a concrete, defined way and content definition. I think the content part is a very important one and I do see that. USCDI, for example, is a good way to try to align. But the USCDI data elements are not used or aligned completely with the administrative transaction. That is one.

And then the next question is harmonizing the transactions themselves, the method of exchange. And here, I think that the key element to understand is what I call goodness of fit. I think there will be some instances and some transactions where certain types of approaches, for example, FHIR-based API standards would make all the sense in the world. Other transactions would probably still be more appropriate to use document-based exchange rather than control access and yet some will have the opportunity to have different types of approaches. I think it is important to consider that.

And I think when it comes to the life cycle of standards, I think standard development adoption and implementation is not necessarily the issue here. I think the issue is really more about regulatory process and timeline that has been applied to this. I think in many ways, what we have seen and learned from exercises and examples like ONC standard version advancement process for certification and then CMS establishing functional requirements and regulatory expectations to use some of those new functional capabilities in an EHR are good examples of alternative ways to adopt this.

But I think what we have experienced with, for example, FHIR-based standards are the whole life cycle of standard development, adoption, implementation, and maintenance can be accelerated and can be compressed to fulfill the business need and the problem or the real constraints are the regulatory process. Thank you.

Denise Love: Thank you, Walter.

We will go next to Jennifer.

Jennifer Stoll: Thank you, Denise. The point I wanted to make on this item was that OCHIN would like to encourage ONC and CMS to continue to push out testing and do more innovation around being able to learn specifically by driving more testing and create more opportunities to test data standards and giving a real-world example of why it is so important to accelerate the adoption of some of these standards or even just try and see what we are learning from it is in partnership with HL7 and Gravity. Right now, we are in partnership and innovating around social determinants of health and being able to exchange some of that data, looking at USCDI V1. As you know, we are in comments and thinking about V2, USCDI V3. The disconnect between testing and innovation and what is happening in the field and what is also happening in regulatory side is pretty big. The more that we can continue to test in real time and innovate in real time is something we would love to see ONC and CMS continue to do.

Because what is also happening is states are taking this and other jurisdictions are taking this into their own hands, adding confusion and complexity to the underserved communities because there is no alignment and there is no acceleration on a federal side. To drive health equity, we really need to be thinking about this and accelerating the testing and trying new things and innovating them. Thank you.

Denise Love: Thank you, Jennifer.

Next, we will go with Tom.

Tom Giannulli: I just want to make a follow up on the comment about USCDI. I think it is by definition by nature implementation agonistic. It is a bit of a generic descriptor. However, I think when you move towards US Core, look at the FHIR IGs that are then referenced or subsequent to that, you will find the specificity granularity that makes a lot of sense.

Now, within those IGs, you will have terminology bindings. I do agree that there are some issues in the quality of the value sets and/or terminology bindings. And that is an area where quality could be improved as part of this refined process around accelerating, development of these standards as well as the bound terminologies and value sets. I think the structure is good. I think it can use some improvement and investment. With that, I think we could actually get to a point where you can move things quickly and maintain that level of quality that we are looking for.

Denise Love: Thank you.

Next is Julia.

Julia Skapik: Yes. I just wanted to jump on to what Jen had said about tooling and maturity because to Tom's point, you can go into an IG and find some more specificity. But the problem is there is no framework to put all of these pieces together in a single place and see if they interoperate and if they integrate successfully.

The thing that we see is one IG is dealing with the same concept as this IG and the way that they have described that profile with extensions is very different. But from a clinical perspective, there is no difference. I am a primary care provider. I am in my clinic right now. I think about these things in one way. It does not make sense to me that there are so many expressions of them in the standard. If we have those building blocks pre-defined and I think that that can go up to the USCDI level. It does not mean that you cannot add additional optionality. But there needs to be a level of core functionality there within enough metadata that I can do clinical reasoning off it. We have seen recently even with things like lab data, a large academic medical center said that 85 percent of the lab results they got sent to them from externally, they had thrown out because there was not metadata that allowed them to do clinical decision support based on that. They could not trust 80 percent of the lab results that they got and lab results are significantly less complex than some other concepts in this.

Denise Love: Thank you, Julia.

Charles, I see your hand.

Charles Jaffe: I just wanted to expand very briefly in support of what Tom and Julia have said. The value that will bring as the implementation division matures is the kind of testing that assures that the meaning within a single implementation guide can be translated to other accelerators and other implementation entities.

I think the real key which this NCVHS hearing cannot address is the lack of data quality that comes from different sources as Julia described from outside labs, for example. I do not want to pin the blame on them – use it as an example. I think the data quality harms the ability to not only interoperate but to make risk assessment, quality measures, clinical decision support and the like.

I think the future will be defined when we are able to test the implementation guides more fully before the specification is rolled out or the implementation is given to a broader community. Thanks.

Denise Love: Thank you.

I have some other questions, but I think in the interest of time, we will go right to the last question and then hopefully we can get at some of these loose ends. What are the barriers to consistent use of data standards at the federal, state, and local levels? How could those barriers be mitigated? Are there policy or operational levers that might need to be pulled or established or changed?

Jennifer Stoll: Thank you, Denise. I want to respond to this question with two different perspectives. One is around the work that we do in public health and the other is around the need for workforce. We work with over 40 unique public health departments. During the pandemic, I can tell you we have produced thousands of reports and we connected to lots of things where there was not the ability to even read data, only files at state or local levels. It was due to the fact that we have very clearly defined lack of public health modernization and tools at the public health side. The continued investments within public health modernization and the one thing that I would also emphasize is being able to translate federal standards to state and local levels and the need to harmonize data standards across the playing fields. As I said, we had so many different versions of the same thing happening through the pandemic in the reporting structure and moving data elements and everyone wanted something different and it became extremely complex.

The more that ONC, CMS, HHS can work with in partnership with CDC and also be able to help the states and local understand how harmonization means. It really ties into the workforce piece because workforce has been decimated within the OCHIN network of the organizations we support. We lost one-third of the operational staff that understand data and technology and work in the EHRs. We have to keep it clear, be able to provide the guidance of what we are looking for in terms of harmonization, standardization. I think that is something the Federal Government can really lead on with the states and especially in our rural public health departments, being able to be very clear and help them with guides and education and tools and resources to be able to support the work.

Denise Love: Thank you, Jennifer. This sort of gets at that framework issue because what I struggle with is the standards as top-down development and approach versus a bottom up and there is a huge gap that you just referred to. I think that is what we are fishing for. Is there a new kind of framework to close that gap?

We will go to Julia next.

Julia Skapik: I will piggyback on Jennifer's comment. At the federal level, I think there really has to be some governance body that has real teeth to it that says it is not acceptable to have multiple representations at the same information. We need to agree on a single set of standards, and we need to adhere to that and there needs to be someone who is actually doing review of context coming out of different agencies. This is usually unwittingly. They unwittingly are redoing things over and over again in different agencies that have already been done in other places in the government with taxpayer money in addition to that not being efficient.

To Jennifer's point, she has a huge burden on organizations especially when they cross state lines and when they work in multiple contexts. That really needs to happen at the federal level in regard to federal regulatory policy and federal program content.

In regard to state and local levels, I actually spent 20 minutes explaining to folks at ASTHO that the US Government OMB requirements for race and ethnicity for 20 minutes a few weeks ago. They said they

cannot understand why people cannot get race and ethnicity data and my point back to them is if you guys are not aware of what this centralizing standard should be, no wonder that your members are going out and making new standards. There has to be a direct engagement of all the stakeholder communities in the standards process and education that tells them these are the gold standard sources and repositories. You have to go here first. You cannot just make something up on your own.

If you have a use case that you need to fill and you do not think these standards fill it, there should be a process to actually request that to go through larger bodies. When we build that content, it becomes easily sharable, and it spreads easily across the different regulatory contexts.

The last piece I will say – we work with a lot of health centers. We have products that are not conformant to 2012 meaningful use requirements. And I think that that problem is two-fold. One, we do not test actual live products. Two, the ONC certification standards back from a decade ago did not go far enough to ensure the full extent of implementation of the intent of 2012 standards. We have several regulatory requirements since then. If they are not conformant to 2012, the likely that they are getting to the more modern standards in a timely basis is unlikely.

We need to build not only a certification program that is like several orders of magnitude more stringent than the one we currently have, one that does live bidirectional testing in the way that we want to see it happening all over the industry. But we also want to build testing tools so people can work with other partners. They can work with the service virtualization, a virtual EHR, if you will, to test products and to test content and make sure that that will be able to be shared successfully so that when they deploy it, that data just falling into a black hole. It is not that product grinding to a halt and having a long unintended down time. That is what we are seeing in the field.

Building these testing tools and the certification framework and these repositories can put people back to a centralized location and they normalize to that. They will be successful in normalizing to other products as well.

Denise Love: Thank you, Julie and Walter. Are we up with our time, Rebecca? I lost track.

Rebecca Hines: We are fine. We are supposed to start public comment so basically in the next few minutes. I think we are fine to continue one more person if we have one more.

Denise Love: Walter.

Walter Suarez: Thank you. I just want to emphasize a couple of points. I think I mentioned earlier the need to really align and harmonize data content. I think this is an example where we have a lot of issues. We all experienced during the pandemic the challenges of having different local, state, and federal agencies request data, not just actually case reports but data like resource availability in different ways, in different formats, in different content. We are seeing it not just in this but we are seeing a proliferation really of clinical and administrative data requests from states with a number of states asking, for example, for data under something related to sexual orientation and gender identity, using their own set of standards. I think that is a big challenge.

I think the good news in some ways is that we do have a national collaborative in place. It is called Digital Bridge initiative that brings together ASTHO, NACCHO, APHL, CSD, CDC, and all the other federal and state public health partners along with providers, health plans, and vendors to pursue the

opportunities to harmonize and align public health data exchanges and seek truly bidirectional exchange opportunities.

We are currently undergoing a re-envisioning process to look at what would be the focus of these next three years for the Digital Bridge initiative and align it and consistency of data requests is a clear element there.

Similarly with respect to health equity and social determinants of health, as has been mentioned, we have multiple programs, multiple efforts, collecting data from multiple different places and sources using different ways. Again, here fortunately we have a national program like Gravity that garners really the attention of all critical groups, government consumers and others, community-based organizations, networks and others in helping define those standards.

I think we still have here important work to be done in terms of aligning different types of, for example, social health need assessment forms and tools that are used because at the end, all these tools are generating data in different ways and are less comparable across systems. I think we are seeing it is very important. It is going to be part of the development of metrics that will help us set the performance of health systems in achieving health equity goals, the efforts that are being led by CMS, NCQA, and others.

I think there are opportunities to really help advance alignment of this data standards in both public health and health equity. Thanks.

Denise Love: Thank you, Panel. I wish we had longer, but I think we got exactly what we needed to hear with these excellent comments. You mentioned fragmentation. It surely is. And the need to tie it all together. I work closely with state and local entities and they are investing heavily right now in IT and data modernization. And those rules are being promulgated in the absence of a place to go, a clearinghouse for some of these emerging standards. We are seeing proliferation.

This will not be the last of this kind of conversation. I think this is just the beginning. But we, as the Subcommittee, thank you all. And we have some things to deliberate going forward. I appreciate it very much.

Public Comment for Panel 2

Rebecca Hines: Thank you, Denise. Now, we have time for public comments specific to consideration number 4 and the instructions are on the screen. For those of you in the audience, you can raise your hand or use the Q&A. If you are on the phone and we have three phone listeners, you can press *9 to request unmuting of your phone and you can email us at ncvhsmail@cdc.gov to have your comment read into the record this afternoon.

Lisa McKeen: I had made a comment earlier in the Q&A that I wanted to correlate with this and – draw all the industries that the scope and purpose in the classification of data should probably measure with the industry that is utilizing it. When you say getting collaboration, if we took into account the data that is needed in each industry and classified it because a lot of places believe or not or a lot of entities have not done data classification as of thus far. They do have a lot of questions about data classification when they are working in projects. If we did data classification according to industries and use like the hospitals have certain reports that are reportable that report certain data standardized to the state, you have payers, providers, all of them might be reporting to social determinants. And the criteria for those reports will not necessarily align with having to standardize across the board data or reminding the data.

To do better collaboration, I am just thinking that the classification and the criterion purpose should match the industry that is utilizing it. In this way, there is no doubt what classification or what metadata is going to be used and make sure that it is uniform throughout by industry. I think that would stop a lot of the questions that many affiliations have that question all the time. It is not something that is new – and some people do not even understand some of the – federal regulations regarding minimum data sets even though they have been out there. They still question sometimes the criteria that they need to abide by.

Rebecca Hines: Thank you, Lisa. Can you remind us of your organization that you are with?

Lisa McKeen: I am sorry. New York State eMedNY.

Rebecca Hines: Thank you.

Anyone on the panelist side who would like to add a comment to the discussion. There is some time. I do not see any comments. I will remind you all again this afternoon that Rich Landen, co-chair, mentioned that you are welcome to send additional follow-up written comments or any modifications to the comments you made here today. You can send them at any time. But if you would like to be considered for this next round of Subcommittee deliberations, please have them to us by Friday, June 24. And then the Subcommittee can take your additional input into account when preparing for the July meeting of the Full Committee.

With that, I think we are done with this public comment period number 2.

Denise Love: Thank you, Panel.

Rebecca Hines: It is all yours, Tammy.

Panel 3: Measure the Value of Standards

Tammy Banks: I am so excited. I don't know if I should be excited that I am the last panel or a little concerned, but I hope you guys are still with me. I am really appreciative to everybody who has served on the previous panels, as well as this one. I think no matter what your experience or background is, it is always wonderful to learn the different perspectives that are out there because it just really helps us look at this from a full cross-stakeholder perspective. Which is definitely needed in order to achieve the efficiencies that we are looking for.

With that I am heading up the panel, Measure the value of Standards. I want to initially thank those who are going to serve on the panel. In the interest of time, I would like to ask the panel to introduce themselves when initially speaking. We look forward to gaining your feedback and expertise.

Just for a little background purpose, the topic is a continuation of the robust discussion that occurred at the last NCVHS Listening Session this past August. The industry input to NCVHS strongly indicated a need for the creation and development of a standardized ROI and a standardized non-monetary value metrics and methodologies to be published to assess emerging and revised standards.

As more standards are developed to meet similar business needs of publicly available guidance framework and pilot test procedures were mentioned that could be developed to assist the

stakeholders to consistently collect these types of metric results, pilot tests and standardized procedures for pilot tests, to evaluate and compare again the emerging standards.

I would like to manage this panel a little bit differently than the previous ones by first requesting David DeGandi to briefly describe the Cambia Health Value Framework he created in response to a senior leadership question. What is the value of one or more standards? What is the value or priority of these standards within its roadmap?

David DeGandi is a senior interoperability strategist and Kirk Anderson serves as the vice president and chief technology officer at Cambia Health Solution, who is also represented on this panel.

I just want to be clear that this presentation is intended to be only thought provoking, as it provides an example of a private sector initiative to create a value metric framework to show the value of standards from as we had discussed previously, and ROI and a non-monetary perspective that is currently being vetted within the health care industry.

We will not have a Q&A period after this presentation for the Cambia Value Framework, however those of you who would like to dive deeper into the specifics, are encouraged to reach directly out to David. He has included his email in his presentation. Also an url will be provided for more information in the chat.

But I just want to give you that reminder that this presentation is intended to be a brief introduction to one example of how monetary and non-monetary value of a standard could be determined through a value guidance framework. Again, after the brief presentation, we will dive into our draft consideration and panel questions.

So with no further ado, David, would you be willing to take it over?

Rebecca Hines: Can we have the slides up, please.

Tammy Banks: I think that is what David is waiting for.

Rebecca Hines: We cannot hear you, David. We should have done an audio check.

Kirk Anderson: If necessary, this is Kirk Anderson, I can probably speak to these slides if Dave is unable to come off mute.

Rebecca Hines: Give him a sec.

David DeGandi: Is that any better?

Rebecca Hines: Yes. You are on.

David DeGandi: Sorry about that. Thank you for the introduction, Tammy. If we can go to the next slide, please, I will try to make this quick. As Tammy said, this idea came out of an ask from our leadership here at Cambia, saying what is the value of these interoperability initiatives that we are rolling out? I took the idea and said I am sure all organizations are going to have the same question about all their use cases and thought that a framework might serve that purpose. A framework that is intended to provide insight to others considering use case implement to help encourage adoption. Insight to those needing

to determine the value of an implementation. Different aspects that they might look at and consider when they are trying to understand the value.

Also the means for organizations to share real world experiences – more subjective value content. And then provide guidance towards measuring the points of value.

This framework is supplemental information and not part of the balloted content. Ideally, it would be open to future contribution to increase the amount of content and the value that it provides.

Next slide, please.

So, and this whole approach was we went to Da Vinci and proposed that we create this value metric framework. They said yes, go ahead and do a pilot with two of our use cases, retribution and data exchange for quality measures. We went away and did that and came back with a framework. They said, this is great. Let's go ahead and do all of our use cases.

Next slide, please.

This is what we came out of this initial pilot process with. The process we went through was we select use case of interest, the two I mentioned. Then we gathered a group of use case experts to have the discussion and gathered what I call points of value. In the spreadsheet they will be called measurement of value column. Then tried to normalize the data by determining a qualified type and description combination, which enables the point of value.

It takes a couple of minutes of thinking about this to really get it, but hopefully it will make sense.

So the characteristics are columns on the spreadsheet. So measurement of value – tangible definition of a point of value. Then we came up with different types, abrasion relief, accuracy, clinical value, efficiency, financial, and the other ones listed here. Take a second to look at those.

The description of value is enables that point of value to be true. Real world experiences where people share their content. Value recipients and then per use case framework aspect on how value would be equated to in a use case. So just hang with me on this content here – I will show a spreadsheet example later in this presentation and hopefully it will make more sense.

Next slide, please.

So Cambia has an innovation hub called Cambia Grove. I was talking to them and learned that they have this Fellowship Program and they needed a project to work on. I mentioned this to them. They thought it was a great idea. This allowed us – they had six resources that we were able to use. This allowed us to expand our scope beyond just the Da Vinci use cases and we were able to include all the expired accelerated use cases of interest, which gave us a better marketing sampling to represent the exercise of framework.

Next slide, please.

This is a bit of an eye chart and not meant for anybody to understand the detail, but it is more the concept here. I filtered this screen on the down arrow, the Data Exchange for Quality Measures Use Case. You can see in orange, that there are other use cases that also have a Y in the box. That would

mean that the measurement of value column, which was the point of value that we determined through interviews with the subject matter experts, applies to multiple use cases. You can see there is value recipients that can apply to a varied number of value recipients also.

So just generally understand the concept of how this framework kind of looks at a high level. Go the next slide, please.

This is kind of diving into the detail level on that same use case data exchange for quality measures. You can see here there are nine different value recipients. I am just showing three for sake a readability on a presentation. The measurement of value that we got from the experts that we interviewed were reduction of errors due to manual processing of data files. So we say, what enables that? It is the automatic ingestion of data in the downstream systems, and we would qualify that as a type of accuracy.

A real world experience was each system in the past required different layout, and they are now able to just use a single layout and get much more – the automation of the data ingestion the accuracy increased there.

Another example for data exchange quality measures is using standard based solutions for data exchange turns that functionality into a commodity and opens the door for innovation at the business process level. We consider that a foundational, where we can build other functionality upon. An example of that would be because now we are automated – we've automated the data exchange, we are able to manage that measure for say population out of the regulated Medicare scope for this certain measure. Hope that kind of makes sense a little bit.

Another example we had was a financial type of value, where we are saving a number of hours from doing manual chart chasing and non-scalable reporting. The real world of Cambia we are able to save $20 to $50 per chart chase. Which is something tangible, hopefully someone would find the value.

Next slide, please.

This is a sample list of users and why they might be interested in using this content. For example, for regulators to identify values offered by a specific use case to resolve industry problems. They might filter and sort and get into this spreadsheet and be able to make their determinations on what is the best path to go.

A wide range of users are what I call, promoters. Anybody looking for potential points of value when considering to implement a specific use case. It can be a wide range of users from business leaders, architects, to vendors creating products, even to reporters looking for supporting content for a story to write.

Next slide, please.

Next steps, this needs to be managed by some type of governing custodian body. I have not determined what or who yet, but it really belongs – it needs some governance for it to be reusable and valuable. I think you guys can read the points here. I have made a little diagram of who uses and contributes and governs and the different roles of the different actors there.

If anybody has any questions on this, feel free to reach out and I will do my best to answer them. Back to you, Tammy.

Tammy Banks: Thank you David. Really appreciate this. You did a lot of work on trying to address that standard value question. We again, had a huge discussion, what should non-monetary value metrics be. Typically the focus is on ROI and in our industry there is so much other types of efficiency and accuracy. I think you took your value metrics and backed into your nine buckets. I think that was really informative the different types of non-monetary value that we need to consider, right, in where these standards address.

I really appreciate that Cambia's work proves that it is possible to create this robust value metric framework in order to assess the value of standards that goes further than the ROI metrics.

David DeGandi: Right, and storing it in that framework allows for comparability across standards and different use cases, terminologies, leveling, that kind of thing.

Tammy Banks: Exactly. There are a lot of other uses than just comparing the emerging and standards that are considered for adoption, as you said, as more standards come out there is going to be the comparability question. There is going to be a lot of other uses in creating a framework for multiple purposes is always a little bit more efficient than creating one and then adapting, right?

So, again, really appreciate your work. Appreciate Cambia for putting the time and effort into this and working with the industry to really assess the value of the approach that you have come up with.

I just want to reiterate again, we won't have a Q&A session on this, but I did want to raise awareness of this effort that is going on. If you want more information, please reach out to David. His email is on the slides, as well as I believe, there is going to be an URL placed in the chat that you can also dive deeper in a presentation. So again, thank you.

As previously stated, Consideration 5, was drafted after hearing your comments during the past listening session and reviewing written comments, to gain your input on related questions. We heard loud and clear that the health care industry ask was to 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.

I know we have a limited time, what I was planning on doing is walking through the two content validation questions and then allow more time to build on the exploration into the how and by what organizations could this type of guidance framework be created and maintained, as well as how the collection and reporting of these metrics could occur to streamline the evaluation of standards with the consideration of what are the regulatory and non-regulatory topics to be addressed.

I want to remind the panelist that the two minute – three minute, right, rule still applies so brevity is encouraged. The timer is going to be right in with the panel – attendee bar or whatever. We also welcome written comment. So if anybody prefers to hold off or is not able to get their comments in, we definitely want them. Public comment period is going to occur at 3:30.

So the first two questions, it is purely just regurgitating back to those participated in the previous panel. Is there anything that should be included or revised? Don't feel you have to comment if you are comfortable with the language as written.

Are the business needs captured or understood for evaluation of standards across the industry? We captured business needs listed were better measurement, management, and understanding of standards maturity, standards implementation success, and the net value of standards.

And for the guidance framework components, what we captured was it needed to be sufficient to measure and manage emerging and revising standards through recommended definitions, metrics, templates and pilot test procedures, which include the methods for reporting on the standards readiness, standard costs, results of real-world testing and metrics essential for evaluation of standards.

So could we start with those two, and then leave the other two for a second go around? I am trying to see if there are any hands up.

Rebecca Hines: Lots of takers, Tammy.

Tammy Banks: I am trying to see why I am not seeing them online.

Rebecca Hines: If you open your participant box, Ed Hafner, WEDI chair elect is first up.

Tammy Banks: Excellent. Why don't you go first and I will figure out my screen here.

Ed Hafner: Thanks Tammy. Again, this is Ed Hafner representing WEDI. WEDI encourages standards to address specific business need and how it impacts providers, health plans, and as Raj mentioned earlier, patients, such as Good Faith Estimate and Advanced DOB does within the No Surprises Act.

As standards are being developed, we recommend ensuring that all industry stakeholders provide input and represented well enough that their voices are equally heard and utilizes a standard approach to establish the net value.

When it comes to net value, we are looking at cost savings in business value propositions that are difficult to quantify, contrasted with implementation costs for CMS to consider adoption. Often times when we see a standard, we look at those regulations, we just see the cost specified. But having for example, and ROI calculator for each stakeholder type would really be appreciated.

In some cases, unique metrics associated with a proposed standard should be designed before the pilot testing begins because they are so unique.

For new standards, whether it be a new transaction or a new use case, we encourage pilots be real-world testing, just like Cambia suggested just previously. Reporting on these results would be invaluable not only to identify ROI, but also to discover missing elements to make the standards or the use case work better.

Also, as Nancy Spector mentioned, adopting the real-time approaches to some of these standards has reduced meaning that if the responder is not mandated or willing to respond at a real-time way, or at least for a percentage of those responses.

So that is my feedback, Tammy.

Tammy Banks: Excellent. Thank you, Ed. Alix.

Alix Goss: I think Lauren was next. Maybe not. I will go ahead. Thank you, Tammy. From an HL7 perspective, we've been very proud to participate in this body of work within our FHIR accelerator and support across our accelerator community, into the Cambia Grove effort.

At this point the HL7 community is reflecting on moving this body of work into a more formal recognized process as a part of our ecosystem. So we are still in that community deliberation. So I think that this framework that we have seen represented by the Cambia model that was showcased here, gives us an ability to work across the aisle of the standards organizations, along with our federal partners to really bring forward that kind of ROI calculator that Ed just spoke to.

And that we would likely need some kind of an effective user interface, as well as a governance structure to help us all collaborate within our respective organizations, understanding that it falls often to volunteer communities and business representatives, to lean into providing the facts and the time and effort and manpower, to really use such a tool and build that out for quantitative and qualitative information.

Because we are not only helping business entities understand the value of picking up standards and implementation guides and the supplemental artifacts, such as those that exist in the HL7 realm of work products. We are also looking to help regulators get through their administrative hurdles with justifying the reason and the value for uptake that really is for societal benefit overall.

Thank you.

Tammy Banks: Thank you, Alix. Margaret.

Margaret Walker: Thanks, Tammy. I think there would need to be – I am not sure if it is two sets of a framework or a framework divided, because you would have a difference in the value if the standards an existing standard, and then you're moving it to a next version because you have a set of modifications that were done to that standard. So what is the value of increasing the dollar field? So what is the value of increasing the number of the product ID, to link to that field? Versus, I have a new transaction and what is the value of implementing that transaction?

So I think there would be a little bit of a difference between its existing and I am upgrading with a set of defined modifications, and then this is a brand new function that exists, how we are going to try and standardize it. I think there would be two different metrics and values associated with that.

You hear where people say, oh, yes, it is going to cost me X to implement the new version of whatever, but a lot of times in that equation they don't look at say, what am I also going to save. Some do, some don't.

Then getting this information could be problematic in some instances, as companies may not want to share information. How is it going to be used? Is it deidentified? Who is going to see it? All of those type of things would also need to be addressed.

So, thank you.

Tammy Banks: Thank you, Margaret. Lauren.

Lauren Riplinger: Thank you. I want to share I represent the American Health Information Management Association and so we represent health information professionals that work with health data for over a billion patients a year. So we come to this conversation really from the context of the end user.

Certainly, we agree that the development and adoption of new health IT standards into the regulatory environment, can bring tremendous benefits by addressing specific challenges and creating more uniformity in how that information is collected, shared and used.

However, our concern is that new technical approaches are not necessarily grounded enough in real-world experiences and don't always consider the implementation pathway before really mandating use.

So our kind of thinking on this is that the Guidance Framework really needs to require that a standard demonstrate that it captures the business needs of the end user. To do so the framework needs to ensure that the Standards Development Organizations identify their end users, including whether the standard is applicable across all types of end users. That it articulates whether the end user was included in the development of that standard and provide the analysis that was undertaken to demonstrate that that standard meets the end user's business needs.

Beyond that, better capture and understanding of the business needs for evaluation of standards across the industry, really requires making sure that we are involving health IT end users in establishing the goals and priorities for setting those standards across different care settings and use cases.

It also includes input from the health IT end user in every phase of the standards development process, from scoping to the real-world testing itself. That requires support for the end user engagement to maximize their ability to provide effective input and also a commitment on our end users or their professional organizations to be active participants in this process.

There also needs to be assurances from Standard Development Organizations that this input from the end user is taken seriously and it is not dismissed as simply out of scope or a matter of policy for purposes of standards development.

Finally, I will just also note as it relates to the testing of a standard, we need to make sure we are including real-world implementation production pilots and the collection of metrics regarding the effort needed to implement, as well as the training needs of staff, and the extent to which the standards achieved the stated goals and estimates of the cost and benefits of that implementation.

So this includes thinking about such issues as scoping, conceptual development, use cases, standards testing, pilot testing, return on investment has been mentioned, and an assessment of the impact on different provider types that might have different resources.

So, thank you.

Tammy Banks: Thank you, Lauren. April.

April Todd: Hi everyone. Thank you for the invitation. April Todd, CAQH Core, but actually this afternoon I am putting on my CAQH exploration's hat on some of our points and comments here.

I am talking from the perspective of the work that we have actually done on our CAQH Index, which is going into its 10th year, of the work that we have done. So this is just going to be a high level there. I could spend hours on this with people. I would be happy to get into more depth on this. We have a lot of thoughts and ideas around how this could work.

But what I want to offer is our experience and recommendations, and this is based on the work that we have done in combination with we have an industry advisory council that works with us every year on our index and provides extremely valuable feedback on the work that we do as well.

So first off, one of the things I wanted to highlight, which is one of the things that Lauren had just mentioned, is that it is extremely important that what we do from a measurement perspective is measuring activity in a real-world setting. That means that we are not just measuring whether the technology works, but that we are measuring the impact that it has on the business need and on the workflow. So our first key point.

Second key point is that however we set this up, this needs to be scalable, and it needs to be comparative. If we have just one-off pilots and one-off studies that we are looking at, it is hard for us to think about that as an industry across the board in how we are moving forward. It needs to have key components to it that we can make sure are not taking significantly increase industry resources to actually collect this information and that it is something that we can compare over time.

With that, the key things that we look at from an index perspective that are extremely important and should be I think, in anything that we do, are key components of we need to be looking not just at the cost, but we need to be looking at the volume and we need to be looking at the time.

So for example, even if you are looking at cost, if the cost of something is cheaper, it may not be that valuable if the volume of which you are going to anticipate of what is going to be used is not that significant, that may not justify the investment. So it is important to look at all of those three things and to make sure that we have definitions of what that is that are clear enough, but also broad enough to cover different components of what we are measuring.

So for example on costs, we spend a lot of time on this on the index. Are you measuring the implementation cost? Are you measuring the ongoing operational cost? What components are included in that? So it is very important to be able to delineate that.

What was also mentioned was non-monetary cost. We have also incorporated that in work that we do on our pilots that is based on an index framework and using a standard methodology around user satisfaction and the user satisfaction scale, when we are asking those users how is this impacting the work that it is that they do.

Tammy Banks: April, I apologize, I have to ask you to wrap it up.

April Todd: I can keep some of my comments to somewhat later, but also just issues of comparison point timeframe and representative sample. I am happy to talk about those in the next two as well.

Tammy Banks: Thank you, April. Cathy.

Cathy Sheppard: Hi Tammy, thanks for having us. I wish I could just chant amen to much of what has been said before. I am going to try not to repeat any of that either.

But I think the point of pilots, that maybe we are making too simple, is maybe one step is not enough because we have all been talking about real pilot, real data, real trading partners, real examples of how this is going to be. I think that there is so much focus on that because we are finding that our canned, so to speak, pilots, with controlled data and preplanned scripts of who is going to move something from what to what the next.

That is not as helpful as we had hoped once we rolled those things out into the real world and there is not clean data and there is not a clear path from place to place.

Maybe just calling things pilot tests is too simplistic and we need to do something else to cover both sides of that. First it has to work in a sterile environment, but then it also has to work in the real world.

Also, I think I am going to channel part of what Dr. Jaffe said the last time we talked about this, but sometimes there is value in moving forward for other than some of the metrics that are measured here. For example, we have talked a lot today and over the past I don't know how many years, about the fact that large implementation steps, large steps forward, are costly, they are intimidating for the industry, and there is a lot of room for error.

So we have said along today and virtually in all of our other roadmap sessions, that incremental bites forward are better for the industry. So then we can't use only functionality improvements or correction of show-stopper errors or those things, as the reasons for moving forward. So we have to include the intangibles.

Those are hard to measure, and we may find that we don't know what we don't know right now. What struck me with these questions is they are asking if we know what we need to know, but we are not really sure until we know. That is my word salad contribution for today, by the way.

An example, right, we can measure A batteries against C batteries all day, but if what we really want to know if the flashlight is going to come on when we use those batteries, then that better be the test that we are looking at.

I have other comments too, but I think that they can be held until we can submit them in writing, so we can make sure that everybody has a chance to talk.

Tammy Banks: Thank you, Cathy, appreciate it. Kirk.

Kirk Anderson: Thank you. Just a little bit more on the genesis of this work to hopefully provide some more context into the problem we were trying to solve as we developed this at Cambia and worked with various accelerator groups.

This is very much intended to show the overall business value for investing in a API approach to solving problems that today, in many cases, have no standard that govern them. For example, data exchange for quality measures is something that is core to our value base arrangements, but the way that data was coming into us prior to the implementation of the Da Vinci Use Case that allowed for automation of that data, comes in all types of forms, spreadsheets, emails, et cetera.

As we moved into our implementation of the work that we did, we were able to then realize the value, our provider was able to realize the value, of 175 percent improvement in their HEDIS scores as a result.

The other point I wanted to make just briefly, is that whenever you are starting a complicated innovation project, in the early stages it is important to measure the activity, it is important to measure who is trying it, who is implementing it. But over time, you have to move beyond just measuring activity and start to measure the results.

That is what we have intended to create here is a menu of – I kind of think of it as value levers, value categories, that a payer and a provider can look at and can determine where to start. Which of these use cases can address the specific needs that they have?

Everyone's mileage is going to vary. For some, what they really want to do is reduce the amount of staff that they have manually shuttling data back and forth across all of their payers. For a smaller provider, they might not have a floor full of humans who do that, but it might be very important for them to improve their patient experience in something like a prior authorization use case.

So it is again, intended to be a framework of different categories for implementors to look at and then to measure. If they chose to, report out their actual results, but it doesn't have to include the sharing of those specifics.

Thank you.

Tammy Banks: Thank you, Kirk. Jocelyn.

Jocelyn Keegan: I just want to add a couple of points to what Kirk said because we spent a lot of time talking about this really from the inception of Da Vinci. As folks can imagine, I talked to folks both in my day-to-day job and my Da Vinci world, about the – I almost refer to it as the secret decoder ring of which one of these guides should they pick up and use first.

What we are seeing is there is high level of interest to solve these business problems, right. Every one of the implementation guides that we built was critically important and solved a real business problem between payers and providers today. The link between that and people getting projects approved and being able to create – and this is where I think the value is of the work that we are doing here, this ability to be able to say at a point in time, as Kirk described where it is in its deployment, as a new standard or as an existing standard that is evolving. Being able to create a common vocabulary within the industry about how and what types of value people might drive, individual organizations are going to make different decisions, but being able to create this common vocabulary in way to discuss and think about what one gets out of APIs beyond the cost to implement and the reduction of potential workforce in replacing the mythical human beings we are going to replace with this work, I think that there is so much for us to explore as an industry about what you really get out of – often it is not the first user, as the example that Kirk just gave with the multi-care team. It is the ability of the second that code was in production, it can be used again for 10 more payers and Cambia can use it with 10 more providers, and you unleash this value that you haven't been able to get to.

So being able to get to a point where we have a way to discuss these challenges and how we solve these challenges with technology in a common way, I think is really why this investment makes sense in this work. And I don't think it is just FHIR API question, to Margaret's point, I think we should be asking these questions across all of the things we are implementing because there are so many places where because the standard can't get the buy in to get to the next evolution, people are going off and doing all of this one-off investing or keeping people in Excel files and PDFs and faxes, which are dragging our ability to care for patients more effectively.

So I think moving forward to develop a common framework terminology wise, I think is incredibly important for us to be able to give the tools to the implementors so they can get these project approved inside their own organizations.

Tammy Banks: Thank you. Erin.

Erin Weber: Thanks. I just want to build off a couple of things other speakers have said and add a little color from the CORE perspective. The lack of an ROI guidance framework across industry really does hinder organizations from participating in pilots and testing, as well as resource constraints. But it also reduced the consistency of the definitions of measurements and metrics and decreases the number in frequency of pilot testing that can take place across the industry.

As noted in the letter that went out from the SDOs and WEDI and CORE to HHS earlier this week, all of the standards and operating rules are developed by industry, via consensus-based processes and the level of its support and extensive vetting required for an operating rules be approved via our processes means that organizations supporting it understand the benefit it will bring to their organizations in the industry.

It's then that leap that Jocelyn mentioned to the project planning that can be tough. To Margaret's point, there are both what I term major and minor changes to standards and operating rules that can occur, and any guidance framework would need to recognize and align the investment in the detailed evaluation against the anticipated size of the change. I would argue that one size not fit all here.

At CORE we have already embedded a framework for ROI measurement within our own certification program and through industry pilots, in addition to the work that we do with the Index, as April mentioned.

Common templates and metrics would be very helpful in setting up and designing these pilots as initial planning and scoping can be lengthy when starting from scratch. In the early days of CORE, we conducted pre/post implementation measurement across a number of health plans and providers using pre-defined templates. More recently, CORE has successfully conducted a pilot case study with Cleveland Clinic and Prior Auth now, measuring cost, time saving, volume and impact patient care and satisfaction, to demonstrate the impact of using prior auth standards and operating rules to drive automation.

But the design process for the study took the better part of a year before going live, and we are already using the templates and metrics and surveys developed for that pilot for future planning. So I think a guidance framework that establishes qualitative and quantitative metrics to measure and manage emerging and revised standards could really reduce the time organizations are spending researching, establishing, and agreeing on common metrics. And allow organizations to conduct operational testing in a more streamlined manner, increasing the cadence of which testing and analysis can occur.

I think the final point is we have been looking into regulatory impact analysis guidelines, those do recognize that both qualitative and quantitative measurements are imperative to understanding the ROI of standards and that some change may not immediately demonstrate reductions and costs, but patient care and staff satisfaction may be improved. So we also need to be thinking about how to build that into this framework as well.

Tammy Banks: Thank you, Erin. David.

David DeGandi: I put some content in the chat and I was asked to go ahead and raise my hand and read it out.

My response to question one is in my experience, as standards are created and all attempts are made to engage with business experts for consult and that standards are matured over time as enhancement needs are discovered in business processes involved with industry.

Response to question two, referring to the Value Metrics Framework, is a great start but is in a serious need of a user interface. As of standards themselves, we should expect a mature such a framework, as enhancement needs are discovered.

Response to question two, custodian group will need to be identified to ensure useability. The content must be normalized and in conformance with the framework specifications to make sure it remains useable. The real value of the content will depend upon industry contribution.

Question four, under oversight of the custodian group, the standards creators and reviewers and engaged industry experts, can add perceived value as they create the standards, but only the real implementers can contribute the realized content as experienced.

I think that will be the trick is getting a wide range of people sharing what they are doing and how well it is working.

That is all I have. Thank you.

Tammy Banks: And David, always the overachiever, but as we move into the third and fourth question, I know that some of you have already touched on this. But keep in mind Rich's comments, that this is more visionary than the how, but sometimes thinking through how the framework could be created and maintained and how we envision collecting, can inform how that visionary approach is framed. Would love to hear from the panelist on the second two questions. The third and fourth questions – the two on the bottom.

Anybody have any additional comments on those two points? Ed.

Ed Hafner: Thanks again, Tammy. I wanted to just talk about – just give a topic just in general. We hear from health plans, if we build it, will they come? It is a really good Field of Dreams reference. If a rule is only mandated on the payers, we really need to consider the resistance from the providers related to how it adheres to privacy of their patients, and also the trust between the provider and the payer when it comes to clinical exchange. I think that is a really important note to take.

Addressing your questions, especially the third one, on public and private efforts. We believe that guidance framework should be the work of the partnership between the public and private sectors, accumulating with the regulation or sub-regulation from CMS that establishes a framework whether the public or private rule drops first.

In other words, typically the commercial practices and health plans often follow CMS innovation. So we believe that should be done together. Then the SDOs Operating Rules and entities and other private sector organizations to leverage that guidance framework to test out the new standards for the commercial side.

For the last question, we also encourage NCVHS could hold hearings on a regular basis with the SDOs 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 a new or revised standards. I think you all are in a great position to that. Thanks.

Tammy Banks: Thank you, again, Ed. April.

April Todd: I think I am going to add on a little bit to what Ed said. I wanted to also mention again, kind of the letter that WEDI and CORE and the SDOs had submitted yesterday. That we are committing to work with CMS on creating this framework. So would agree that – would be very interested in working on creating that framework together.

Specifically, from a CAQH perspective and an exploration perspective, we would be happy to lend our expertise as part of this. Just for background, we have industry experts, as well as CMS, that participates on our council. One of the things that we are doing this year as part of our 10th now Index, is we are starting to add detailed questions around API implementations of volume and cost and time associated with that.

Over the past couple of years, we have been asking some qualitative questions to see how things could be answered on the plan and provider side. So we are looking forward to formally adding those questions to the next year. We are happy to be part of this process and lead the history and expertise that we have there.

Tammy Banks: Thank you April. Alix.

Alix Goss: Thank you, Tammy. It is really good to be here today. I come to you, as many of you realize, with multitude of hats having lived in the X12 world and deployed IHE standards and HL7 standards. I am sitting here today as HL7 formally, but I feel like I need to channel a bit of broader view from my time on this committee. In that I think we need to be realistic about the asks on the industry and sort of channeling a little bit about what April said about having a measurement framework that is scalable and comparative.

It is really going to take a private sector joint initiative because we have got a multitude of end user objectives that we are trying to achieve, and that is going to take some focused resources. We have learned within the HL7 community, that the speed to market and the depth and breadth of the implementation guides and supplemental guidance's that really provide the soup to nuts sort of solutions that HL7, as an ancillary accredited organization provides really is benefited by having targeted resources and that stewardship sort of aspect.

I think that when you look at how standards are developed and how a framework might be enabled, it starts at the point of developing of those business requirements that drive the entire SDO process, whether it is the business analysis requirements or the bar format at X12 or the dearth at NCPDP. You start there and there is an obligation to sort of understand what you are trying to achieve but then you go all the way to the end of the real world experience after we have proven it, tested it, validated, matured it, then you are going to have to look at that other end of the process.

This framework is likely to touch upon a lot of different entities and that there are going to be trigger mechanisms and natural resistance that we are going to have to overcome. So that is going to need to

have some strong governance, some leaning into support until we get it to be a cultural norm. That, in this environment, could take quite a long time.

Thank you.

Tammy Banks: Thank you, Alix. Lauren.

Lauren Riplinger: Thanks Tammy. So to this third question, I think our perspective is that the existing frameworks today are not sufficient to ensure that the standards meet the needs of the end user. So really think about how this guidance framework can create sufficient expectations and processes to make sure that all stakeholders know whether the standards work in the real world setting.

I think setting these expectations around accountability early and allowing for that ongoing input by end users, will help ensure that the end product works in the real world.

I mentioned this before, but as part of this effort we need to have a range of end users that are involved in this process. That includes patients and consumers, and a range of provider types across different settings and specialties. That could require federal support to make sure that those who serve communities that are underserved are marginalized are able to participate. But also really making sure that representation from the end user is proportional to the participation of other groups or entities to really make sure that those real world experiences are reflected.

I will also say that the framework needs to evaluate, measure, and encourage comprehensive report-outs of real world testing of all standards. So we are making sure that the most appropriate standards support the end user needs I know other folks have touched on.

The fourth question, I want to say again, really making sure we are establishing the metrics in advance and what metrics need to be reported. That includes creating a vetting process for standards that includes a review of alternative standards and that comprehensive public reporting on the outcome of real world testing.

The other thing I just mentioned real quick, as we set these metrics and they need to be reported on, certainly while an end user has an obligation to participate in every phase of the standard's development, we also want to make sure that the burden of reporting these metrics doesn't fall entirely to the shoulders of the end user. Which I think is an important consideration here.

So, thank you.

Tammy Banks: Thank you, Lauren. Margaret.

Margaret Walker: As April stated in her comments to the last two questions, a letter was sent to the secretary from WEDI, CAHQ, NCPP, X12 and HL7. We all volunteered to assist in the effort. So I just wanted to reiterate that.

I do agree with Alix, it needs to be a public and private effort to get this done if we are going to develop this framework. We need to make sure we are inclusive of all in that process. Which could take a while.

Then we need to decide as part of our measurement and our valuation, and we have this framework, how are we going to score it? What happens if the score is at a certain level? Does that mean that

standard doesn't get moved forward? What is the end result of this? Oh, there is no value in moving this version of the standard. So, okay, you had a business need, it was put in there, but it was a very specific business need for maybe a specific segment.

So then they can't use it because the other said there is no value to me. But there was a value to for example, long-term care pharmacy but there is not a value to retail pharmacy.

So I think the end result, we also need to think about what that is and what does that mean.

Tammy Banks: Thank you, Margaret. I know we are running into public comment shortly here. Is there any other questions on this topic that you would like to add to the record? Any of the panelist? Margaret, go for it.

Rebecca Hines: I think it was a hanging chad.

Tammy Banks: Oh, okay. Anybody else?

David DeGandi: I did post a link to the Cambia Grove Value Metrics Work Product in the chat.

Tammy Banks: Excellent. Thank you, David.

Rebecca Hines: Lauren has got her hand up, Tammy.

Tammy Banks: Lauren.

Lauren Riplinger: Just one more quick point. I want to talk about the intersection of policy and the standards themselves. So I think as part of this guidance framework, what is important to think about is making sure that these policy proposals build from the results of the real world testing and what is the implementation pathway.

We want to make sure that the framework makes clear that standards that have not completed robust real world testing and whose results are not made public, may not be suitable for mandated use of health policy. And really making sure that the conclusion of standards and policy is not necessarily seen as a mark of maturity.

So thank you for letting me make that additional point.

Tammy Banks: Thank you, Lauren. Alix.

Alix Goss: An additional point I would like to make is that if we are looking at a measurement framework for the value of standards that from a policy perspective and a public/private partnership perspective, it needs to stitch together the entire ecosystem. So the work that we have seen from ONC, for Certified Health IT products, needs to be married up. The 21st Century Cures really need to be synced up with the HIPAA world.

I think that if that wasn't said, I just wanted to make sure that it was clearly on the table. A second thought I would like to offer here is that the value of standards cannot just be from a complete real world implementation testing perspective. It has to take into account emerging standards and our prior conversation around the exception process.

Thank you.

Tammy Banks: Thank you, Alix. And just one more last minute request, if anybody has any other comments. Otherwise, I will hand it over to Rebecca for the public comment.

Public Comment for Panel 3

Rebecca Hines: Thank you Tammy. Great panel. We can go to the public comment slide. Thank you very much.

Again, for those of you in the public on the attendee side of this meeting, you can click raise your hand" to have your audio unmuted or use the Q&A to request an open line. It looks like we have a few people on the phone. You can press *9 to request that your phone be unmuted, and you can also send us a written comment to be read into the record this afternoon, at NCVHSmail@cdc.gov.

Let's wait another 30 seconds. While we are waiting, just a reminder, you are always welcome to send public comments to our mailbox, NCVHSmail@cdc.gov. If you send them by Friday, June 24th, the Subcommittee can take them into account when preparing for the July Full Committee meeting. I will say that one more time this afternoon when we get to the final public comment.

Believe it or not, we are now a little bit ahead of schedule. There are no public comments, as far as I can tell. Oh, here we go. Julia, you are up.

Julia Skapik: I just want to make a comment that I think that there is a lot of value in standards, but I don't know that the standards process really goes about like thinking about the value proposition. I don't know that the implementation of standards necessarily – or the regulatory and implementation of standards is necessarily required to demonstrate that value. I think that is what our end user want, our care teams and our patients, and maybe involving them more in the process at all levels would help to ensure that the development of use of standards delivers that value.

I think that the standards community really wants to do that, but there is a disconnect in there being several levels away from the work on the ground and we need to foster that sense of connection between the work that we are doing in the clinic everyday, and the work that we are doing in the SDOs and the regulatory bodies.

I do think that the HL7 implementation division will help, and I know several other people had commented about using accelerators and maybe an accelerator for that purpose would further benefit.

Rebecca Hines: Thank you very much. On the attendee side, Mike, can you please open the line for Stanley Nachimson. I don't think he has his hand raised but he is on the attendee side. First name Stanley, if you could open his line. There you go. I think you have an open line, Stanley.

Stanley Nachimson: Thank you very much. Just to comment on both the benefits and the cost of the value of standards. We have had some difficulty assigning the value, the benefit to different groups, and it being very different from the groups that are necessarily spending the money to implement the standards. I think it will be very important that you break out in any valuation of standards the group to whom the benefit applies and the groups to whom the cost applies. They are not necessarily equal. Thanks.

Rebecca Hines: Thank you. Anybody else? You are hesitating. Now is your moment. We do have time.

(Pause)

Rebecca Hines: I don't see anyone on the attendee side. I do not see anyone on the panelist side. So you will have one more bite at the public comment apple after the break and the discussion.

Rich, Denise, do you want to have the break moved up or do you want to have us reconvene at 4 o'clock? What is your preference?

Rich Landen: I think we should stick with a 15-minute break and then reconvene a little prior to the published time on the agenda.

Rebecca Hines: Okay. So let's reconvene at I guess, 10 till 4:00 Eastern and we will resume the Subcommittee discussion then. When that is over, public comment. For those of you in the public, just take note that if that discussion does not entail a full hour, public comment may indeed be sooner than 5 pm. So just for awareness. See you all in 15.

(Break)

Discussion

Rebecca Hines: Rich, we were going to bring up the slides. You were going to discuss next steps to lead us into the Subcommittee discussion.

Rich Landen: It has been a really, really good day. I want to thank everybody who has participated, just a really good discussion and the Subcommittee will be taking a lot away from listening today and again anticipating any follow-on comments that you will be submitted to us.

As I mentioned at the outset, the Subcommittee on Standards will review the discussion from today and follow-on communications and then we will make a determination of what to bring to the Full NCVHS Committee meeting in the second half of July as far as recommendations to HHS.

There is a lot to speak about. Some of the things I heard from the conversations today from the panelists and the public comment was expected. There is nothing we can do in a world of the HIPAA transactions that is clearcut, crystal clear, cut and dry and win-win for all participants in the system.

Yet HIPAA started a process to achieve at a national level, standardization for certain functions in the administrative community, and to a large extent, that has been really, really successful. We are going to build on that. Again, no rip and replace. But technology has changed in the 25 years. We have to be open to evolution, to innovation, and look at some things. We have to take the pain now, make the investment now to build the proper future for the national system.

In a minute, I will open it up for Subcommittee discussion. But I think the highlights that I heard today talking about again back to the first panel, the number of standards and effect at one time. There was interest but not any clear commitment. There were concerns about having multiple standards and how to manage whether that is just a software thing, or it means running different systems for each standard similarly on the versions. What does it really mean? I think the Subcommittee is going to have to take a deeper dive into that and in formulating our path forward.

I think the consensus was there was an explicit need to include a statement like whatever we do irrespective of standard, we have to have the same data content across all the different SDOs and across all the different technologies, different standards, different versions that may be in place.

There was a discussion that to me personally I was a little bit surprised about how much the concept of willing trading partner came up. I know in the early days of HIPAA going back to essentially the WEDI reports that became the basis on which Congress built the administrative simplification and the administration simplification section itself and the subsequent regulations. There was a lot of infrastructure that was built in order to recognize what some call the asymmetric distribution of power. Mostly we think of in terms of small providers versus big health plans. But the reverse is also true when you have a dominant provider in a region. The health plan may not be able to negotiate. From our perspective, it is a question we need to grapple with.

It is clearly from all the discussions of the Subcommittee, the concept of willing really meant willing and not involuntarily willing to do something. We will have to take a closer look at that and see if there is something we can do now that would give the protections to the parties with the weaker negotiating positions.

Nonetheless, there is a compelling need to move forward and to do this kind of testing and to – again, one of our fundamental views is that the one size fits all may not be the best solution in 2020. We are going to have to take a look at that pretty hard.

Another theme was being more explicit about guardrails and sunsetting whether we are talking about multiple standards or multiple versions. I think that is well received.

And on the issue of exceptions for the testing, I did not get warm fuzzies that there is a lot of support for that. Again, the Subcommittee will have to take a look at that in terms of the relative value. Is that a tool that we want to have available in the toolset because our major objective is really to change the structure such that the structure itself encourages innovation? It gets back to how do you move forward without being constrained necessarily by asking permission. Although in this case, all the testimony we heard was that asking permission under the existing exceptions process was not all that onerous. It was not that much of a deterrent and in some cases was even helpful. We will revisit that.

One of the things that I think we heard throughout all three panels was what I am describing as the end user dichotomy. On the one hand, it was universally agreed from all the presenters that the end users need to be involved in every step of the process from standards development through the testing, through the consideration of whether to promulgate rules and then implementation. But at the same time, we also heard loud and clear that I think the analogy was the car. It just has to work. The end user neither knows nor cares about what is under the hood and how everything works. How will the Subcommittee reconcile those two perspectives? Yes, we want inclusiveness. Yes, we want all points considered. But when you look at what it takes for an individual organization, it is cost prohibitive with very ill-defined return on investment to have let's say, a provider or even a key staff member attend and do all the work, take all the time that is required to be actively engaged in the development of standards and the testing of standards. We are going to have to take a good, hard look at that. How do we achieve both? We get end user involvement but recognizing that the end users themselves are by and large not subject matter experts in that particular technical aspect of what we are doing. How do we accomplish both ends?

And then my last couple of comments is on return on investment, again, where the Subcommittee is thinking about value. We recognize there is a national scope. There will be those organizations that benefit more or benefit less from any change, any update to the standards. We need to address how we recognize some sort of equity for those that benefit more versus those that benefit less. We cannot have either the tyranny of the majority, meaning forcing a lot of cost that may put small entities out of business nor can we afford the opposite where the inability of certain organizations prevents the adoption of new standards that may carry a very well-defined benefit at a national level. Again, it is something we need to wrestle with. There is no easy answer. There is no silver bullet. But it is a reality that we face.

And then part of the discussion is the return on investment goes to we need to look at more than just the implementation cost of this particular update or this particular version or this particular new standard. We need to view this as part of a larger whole where it is the cost of achieving national efficiencies and the cost of investing today for benefits that we will get in the future. And that again subsumed in that category is who benefits and how much relative to what they have to invest in adopting the updates and operating their systems. Those are my highlights from my takeaways.

The process is going to be --

Denise Love: Can I add one?

Rich Landen: Let me finish, Denise, and then it will be you. The Subcommittee will start the conversation today. The Subcommittee then has its biweekly meetings that we will continue this conversation and then by the July NCVHS meeting, we will have made a decision as to what if anything we present to the Full NCVHS as draft recommendations to go in a letter to the Secretary of Health and Human Services. A lot of discussion yet to be happening. No decisions today on what is in, what is out, and the language around it. But I am looking forward to a very good committee discussion where we can capitalize on all the information we heard today. End of my soap box. Denise Love.

Denise Love: You summarized it nicely. On the emerging data elements, the social determinants and SOGI, I heard beyond the agreement that there is fragmentation and diversity and rapid need for new standards. We need a common base but there are gaps, gaps that the USCDI does not cover and an entity or some new way of thinking for some central place to pull this all together that will serve all kinds of users from public health, local, to small providers and on up and fill those gaps between the national and the local. That jumped out to me in Panel 2.

Rich Landen: Other members of the Subcommittee and if there is anyone on, member of the Full Committee, by all means, please join in.

Rebecca Hines: Just noting for the members of the public and panelists right now, this is a Subcommittee discussion, and we will have the opportunity for more external input when the Subcommittee is ready. Thank you.

Jamie Ferguson: I did want to make a comment here. Just a couple of observations. I took notes during the day. But a couple of highlights to add some perspective perhaps. I was not completely surprised that in Panel 1 that generally a lot of the legacy organization with vested interest would recommend no change generally or see no problems in a lot of the things we were asking about but what I would call non-legacy organizations mentioned opportunities for improvement and efficiency and effectiveness.

It kind of just led me to think about a broader perspective and trying to put the questions we were asking, looking at health information and health information management and sharing and information transactions across health care overall.

Of course, most of health care is not related to health plan administrative functions. I was looking up actually benchmarking. I think health information resources are applied roughly 70 percent to patient care and care delivery, including public health, and about 30 percent to coverage, financing, and the administrative functions.

In most of health care, having multiple standards for the same function actually is the norm. This is the case for care coordination where, for example, Medicare hospitals and physicians have to support at least three different ways of information sharing, using different standards and technologies for care coordination.

We have multiple standards for the same reporting of public health, lab reporting, et cetera. And then also payments outside of health care also use multiple standards and multiple technologies. Just thinking on this. The HIPAA payment administration really is the outlier in terms of having the one-size-fits-all approach.

And then I think we also have objective evidence that the HIPAA payments framework is broken and that it has not been updated meaningfully for many years. And currently, if we look at the alterative technologies, it takes many times more resources to implement this framework compared to APIs and newer information architectures. I just wanted to add that perspective and thoughts that I had taken note of during Panel 1.

Another thing on Panel 1. I noted that some of the comments that we received with concerns or identifying issues with the multiple standards approach frequently address a hypothetical environment like the Wild, Wild West, which is not what we were asking about. They sort of set up and knock down a straw concept that is really very different from the controlled environment of having a few different standards that we were asking about. I think that is it for notes on Panel 1 I wanted to mention.

I did want to mention also on Panel 2. As I think Denise just mentioned, there was a lot of support for USCDI. In looking at that, to my knowledge, the states and the state agencies are not involved in that process. I wonder if we might consider engaging with HHS to recommend more of an outreach plan to state public health departments and other state agencies for greater involvement in Gravity and USCDI and the other federally supported standards to try to create more of that central place that the people were talking about. I think some of the comments also supported this kind of – a need for this kind of federal leaders. That was my point on Panel 2. Thank you.

Rich Landen: Anybody else? Deb Strickland, observations you would like to share?

Deb Strickland: I found it very interesting that we heard a lot about the exception process not being broken. It is not used very much but I guess it is really just not broken. We certainly do not want to do anything – touch anything that we do not need to where we cannot be of value.

We heard a lot about making sure that the standards are backwards compatible. That was resounding. We know we need to make sure that that is part of the whole methodology moving forward.

We also want to make sure that we are not breaking the business processes as we go through this, making sure that everybody is able to function. Do no harm I guess is what we want to do and make sure that we can leave the industry with the things that are working and just fix the things that are broken.

Rich Landen: Tammy, do you want to add anything? Tammy Banks.

Tammy Banks: Just with Panel 3, I think the comments were right on point. There are a lot of different perspectives that we need to look at as we look at the emerging to the mature standard and how is value measured in each of those different sectors of the continuing quality process. I really look forward to going through the transcript because I think there are some really good insights on things which should be considered in all those different cycles.

Again, I really appreciated that panel. I do not want to give a summary because I think there was a lot more that was shared than could be consumed at that point in time. I really appreciate the panel. I think it was very clear. It is needed. The question is the how. But one step first.

Rich Landen: Thanks, Tammy.

Margaret Skurka, anything you would like to share?

Margaret Skurka: I was in listening mode as I always am for this side of the work for the most part. I certainly am understanding it and much better. I wish I would have heard more today on more specifics. We mentioned SDOH a lot and then nothing seems to go forward. And we have the ability if that information documented to start gathering that data. It is good data. It would be good data for the institutions, for physician practices. The codes are sitting there waiting to be used but there has to be documentation. I am always looking for more in that area.

Rebecca Hines: Rich, can I just echo something Margaret just said? Would that be okay?

Rich Landen: Absolutely.

Rebecca Hines: So we do have -- the committee now has a workgroup that is looking at SOGI and SDOH data, and I was impressed with the comments made on Panel 2 about the role of Digital Bridge in trying to move the field forward on standardizing the content of elements for SDOH and SOGI.

When our workgroup, when the committee's workgroup moves forward, I think it might be worth engaging with Digital Bridge for their input because it seems like they really are already in it. It turns out that the chair of the board is also the chair of the NCHS Board of Scientific Counselors. We have a direct line to the Digital Bridge in addition to those who are here today, and if it would be helpful to get their insights and input on the processes or cooperative efforts that could be established to move this sooner rather than later so we do not have 50 different state solutions, as somebody said, just adding to the complexity. Then I think that might be an outcome of those comments we heard today.

Rich Landen: Thanks, Rebecca.

Anybody else from the Subcommittee or the Committee want to say anything? I think we have heard from all the Subcommittee members. Just one member of the Committee, the Full Committee here.

Seeing not then, Lorraine Doo is staff to the Committee. Any comments you would like to make?

Public Commenter: I raised my hand.

Rebecca Hines: Hold on please. We are not at public comment yet.

Lorraine Doo: I think what Julia was going to say during public comment may be apropos of what Margaret was saying and a couple of the others. When we go back to the transcript, it will be relevant. But Margaret and many other people are very eager to get at data but good clean data. There were a number of really important comments related to the quality of the data that is available. That was, I think, one of many very compelling comments that I heard today.

While we want data, we want it to be exchanged. We want the states to have it. Public health organizations to have it. We want this data. It is either not there or the quality of that data is not there. That was one of the things that resonated with me in part from the commentary today but also because of some work from a colleague at FDA when they are looking at some of the COVID statistics and prior and trying to do some analysis. I think that as much as we want this data, there are some very important issues that we cannot just want it. There are some other very significant back-end issues that we have to wrestle with.

I thought all the panelists and the diversity of the comments were really good. I think there were a lot of rich things we are going to have to cull through in the transcripts with respect to the considerations. The questions were great. Just a few of them. But they really generated a lot of good intel. I think it will be a terrific follow-up discussion with the committee to understand what happens next with those and how they get reconstituted. I thought it was great. You all did wonderful.

Rich Landen: Thanks, Lorraine. Again, thanks to you and Rebecca for all your support along with Rose Li and Associates and pulling off this production today. Much appreciated. A lot of value. And thanks to all the people who participated as panelists or public comment. Unless there is something else from Subcommittee members, then Rebecca, I think we are ready to go to public comment. Subcommittee members will have our usual meeting two weeks from today. Think about it. Exchange emails if you want to share thoughts and ideas between now and then. As mentioned, we have asked the public to send us any updated comments or further thoughts by Friday June 24 for the Subcommittee to consider before it moves its – before we report out and potentially make recommendations to the Full NCVHS Meeting July 20 and 21.

Rebecca, public comment.

Public Comment

Mike Kavounis: This is Mike here from Rose Li and Associates. To submit public comment on Zoom, just click the raise your hand to have your audio muted or use Q&A to request an open audio line. By phone, press *9 to request to be unmuted and *6 to raise --

Lorraine Doo: I think Rebecca is frozen, so I think we do finally have our first comment from Julia.

Julia Skapik: In regard to SDOH, I actually spent all day yesterday at the Michigan State Primary Care Association in a full-day meeting on social determinants of health data. There are a number of limitations on SDOH. One is data quality. I can tell you in NACHC's data set for just like a million patients, we had 6000 unique question and answer pairs come out of our EHR data set. Most of the EHR data complete SDOH is somewhere south of 10 percent. We have organizations that have above 90 percent.

But the big gap there is what is the workflow and the reimbursement and resourcing model to have people actually take time with the patient and address that. It takes time because there is an emotional burden on the patient and on the person doing the interview as to what the needs are and how they are going to be met. There is the time it takes to explain why we are asking for the information. There is the time it takes to go through all of the questions and then there is a burden of following up on that. It is just not fair to patients to ask them about their needs and then do nothing. But there are a lot of pieces that are not directly related to standards.

That being said, you look at the contents come out of Gravity. It is really more of an encyclopedia than it is an implementation guide or a toolkit. It has not taken the pieces and put them into usable chunks. As I said earlier, I worry that as we push forward telling people to do SDOH without giving them clear guidance and tested use cases, they will make up things and it will cause splintering of the data and it will be a really low value investment in getting things wrong before we get them right.

But I think there really does need to be an intelligent thinking about how are we going to approach this both as the federal government but also as an industry so we do learn from our previous limitations. I will not say mistakes. But our previous limitations out of meaningful use and quality measures and all the spaces where we have tried to move towards coherent measurement of something across very broadly different stakeholder organizations and settings of care.

I actually would as my final comment to that suggest that the government do have an in-person convening to talk about this framework that was referenced earlier in Session 2 because, as I said before, I think a lot of agencies sort of act on their mission and their silo without the recognition that there needs to be this matrix approach toward some things, which will be cross cutting. And standards are definitely one of them.

Maybe taking some time out to identify who are the people who could participate in this governance and create this framework. What are the values and the requirements of that organization of standards in general? And then how do we move towards doing that in a way that does accelerate the pace and that does lead to higher quality data and it reduces the implementation burden at the same time?

Rebecca Hines: Thank you for the suggestion. I am back, Rich. I had a little mini crash, luckily of the virtual kind. Members of the public, this is your last bite at the apple to engage orally with the committee in today's listening session. You can raise your hand to have your audio unmuted, put a note in the Q&A to request an open line.

While we are waiting, just a reminder that June 24 is the date by which the committee would like to have any additional feedback, input, insights into any of the questions under the considerations today. You can always send comments to the committee at NCVHSmail@cdc.gov. Anything we have by June 24 can then be considered for the next Full Committee Meeting July 2022. I do not see any additional requests for public comments. My goodness, we are 45 minutes ahead of schedule.

Donna Campbell has asked us to read this into the record. Donna, if you want to add who you are with, just your role. She has a series of comments that cover a multitude of considerations. We definitely need to capture these. For those who are on the phone and in the audience, I will briefly read these. We need to identify common content requirements – introducing multiple formats of like capability, i.e., prior authorization and X12 versus Da Vince so as not to disadvantage either side, indent the use of one over the other and level the support service and operational activities.

Need to improve the maintenance request capabilities so all organizations are at the table when request for new functionality, data, or new specifications to allow all have the ability to update their respective specifications consistently and collaboratively to not disadvantage one format over the others. That is a nice long sentence.

Need to agilify the legislative and regulatory process. Donna, in the future, if you want to send us comments on what you mean by agilify, that might be helpful. Need to put limit on the state requirements that sometimes impede the ability to be progressive, i.e., the Texas 3459 bill where there are prior authorization exemption requirements, which seem to be contrary to the required use of the 278 for prior auth.

Need to regulate and require a time limit on version development timelines. Need to enforce use of the standards. Need to resurface the idea of SNIP validation to enforce the SNIP levels exclusive of code sets. Need to minimize the duality of versions to avoid disruption and costly implementation and operational periods. Need to subsidize and incentivize the POC process to garner the ability to collect real data and prove ROI. And for the record, Donna is a product manager overseeing the eligibility and benefits and claims data spaces for the Heath Care Service Corporation. Thank you, Donna Campbell.

Do we have any other comments from the attendees? Thank you, Donna. You are welcome to send written comments that might add a little more detail to some of your points there.

One last time. NCVHSmail@cdc.gov. We have not received anything in the last few hours other than to re-emphasize the date is June 24 to have your comments considered in the next period. You can send them any time and they will be considered. But to have them for the Subcommittee's consideration for July, we need them by June 24.

Rich, back over to you. Donna just said she will send in her comments in written format.

Rich Landen: Thank you, Rebecca. Just one word on the anything you want to follow up by email or letter, no later than June 24 but earlier is better. Don't feel there is any prohibition about getting it in sooner rather than later.

With that again, my thanks to all who have participated today. I think the work of the Subcommittee over the last years and particularly the last year since our listening session last August, we have made some great progress. We have been trying to align well with the efforts of CMS and (inaudible) and particularly with ONC with the clinical data, HITECH, the ICAD Task Force, the Electronic Prior Authorization Task Force. There is no lack of groups, organizations, and initiatives to coordinate with and be aware of. We have some really good suggestions. We will follow up with other groups that have an interest in this.

Just for the information of the public, the Subcommittee deliberations do recognize that while our recommendations go to the Secretary of Health and Human Services, there is no prohibition that we cannot make suggestions or recommendations for other actors in the industry. We have done that in the past. We will certainly consider that here as well.

Our role is mostly thought leadership vision. We are not an operating entity. We do not executive anything but to the best of our ability, we will identify partners to work with who have those abilities to move us forward as we identify specific recommendations and publish those with the approval of the full NCVHS membership.

Unless somebody else on the Subcommittee wants to add anything then we stand adjourned. Thank you all very much.

Rebecca Hines: Thanks everybody. Take good care.

(Whereupon the meeting was adjourned at 4:45 p.m.)