National Committee on Vital and Health Statistics

Joint Meeting of the Subcommittee on Privacy, Confidentiality, and Security and the Subcommittee on Standards

Transcript

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Virtual

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Sarah Lessem	**DHHS**	**Executive Director**
Naomi Michaelis	**NCHS**	**Executive Secretary/Acting Chair**
Angela Alton	City of Hope	Member
Steve Wagner	Individual	Member
Jamie Ferguson	Kaiser Permanente	Member
Michael Hodgkins	Consultant	Member
Lenel James	Blue Cross Blue Shield Association	Member
Catherine Donald	Alabama Department of Public Health	Member
Tammy Banks	Principal/ImpactQue	Member
Valerie Watzlaf	University of Pittsburgh	Member
Wu Xu	University of Utah	Member
NCVHS Staff		
Name	**Organization**	**Role**
Maya Bernstein	ASPE/OSDP	Staff
Lorraine Doo	CMS	Staff
Grace Singson	ASPE	Staff
Marietta Squire	NCHS	Staff
Shirley Castillo	NCHS	Staff
Presenters		
Name	**Organization**	**Role**

Timothy Noonan	Office for Civil Rights	Deputy Director for Health Information Privacy, Data and Cybersecurity
Michael Cimmino	CMS	Director, National Standards Group
Edward Hafner	WEDI	Chair
Merri-Lee Stine	WEDI	Chair-Elect

Call to Order/Roll Call

Naomi Michaelis: All right, let get started. Welcome, everyone, to day two of the National Committee on Vital and Health Statistics, NCVHS, joint meeting of the Privacy, Confidentiality and Security Subcommittee and the Standards Subcommittee.

My name is Naomi Michaelis, I am the executive secretary, designated federal officer, and acting chair for NCVHS. We will begin with our roll call. Please state your name, your status as a special government employee, and any potential conflicts you have with today's work, starting with Angela.

Angela Alton: Good morning, my name is Angela Alton, and I work for city of Hope. I'm a member of the full committee and serve on the Privacy, Confidentiality and Security Subcommittee, and I have no conflicts.

Tammy Banks: Tammy Banks, principal, ImpactQue, member of the full committee, member of the executive committee, co-chair of the Standards Subcommittee. No conflict.

Catherine Donald: Good morning, Cathy Donald. I'm with the Alabama Department of Public Health, I'm on the full committee, the Subcommittee for Privacy, Confidentiality, and Security, and the ICD-11 workgroup. I have a conflict with reproductive health, so if there are any discussions on reproductive health, I will recuse myself. Thank you.

Jamie Ferguson: Jamie Ferguson, Kaiser Permanente, a member of the full committee, serving as chair of the ICD-11 workgroup. Also a member of the PCS and standards subcommittees. I have no conflicts.

Michael Hodgkins: Michael Hodgkins, independent consultant, member of the full committee, member of standards, subcommittee member of the ICD-11 workgroup. I have no conflicts.

Lenel James: Lenel James, Blue Cross Blue Shield Association, I'm a member of the full committee, active with the standards subcommittee, and I have no conflicts.

Steve Wagner: Steve Wagner, former enterprise architect, now retired, I'm a member of the full committee, executive committee, and I co-chair the standards subcommittee, and I have no conflicts.

Wu Xu: Hi, my name is Wu Xu, a member of full committee and also ICD-11 workgroup. I have no conflict.

Valerie Watzlaf: Valerie Watzlaf, I'm with the University of Pittsburgh, I'm a member of the full committee, the chair of the Privacy, Confidentiality and Security Subcommittee, and a member of the ICD-11 workgroup, and I have no conflicts.

Naomi Michaelis: Thank you. We will move on to our staff, Sara Lessem.

Sarah Lessem: My name is Sarah Lessem. I am a senior data policy analyst at the Assistant Secretary for Planning and Evaluation, and the executive director of NCVHS, and I am a regular government employee with no conflicts.

Maya Bernstein: Good morning, my name is Maya Bernstein, I'm the senior advisor for privacy policy in the Office of The Assistant Secretary for Planning and Evaluation, and the lead staff to the subcommittee on Privacy, Confidentiality and Security. Government employees have no conflicts. We can't be conflicted.

Welcome Remarks/Agenda Review

Naomi Michaelis: And Lorraine will be joining us later today. She is our lead staff for the standards subcommittee.

Our additional staff, we have Grace Singson and Shirley Castillo.

We will be having our public comment today around 3 p.m. Eastern. If you are planning to participate in the public comment, please be attentive to where we are in the agenda, as we may or may not be running early or late.

As you can see, there is an email address on the screen. If you are not able to make it for the oral public comment, you can always send us an email and we can read it into the record. And if you haven't done so already, you can also sign up to receive email notices from the committee on our home page.

We are now going to review our agenda for the day. We're going to start with an update from Jamie Ferguson on the work of the ICD-11 workgroup. We will then move on and have an update from the Office for Civil Rights, followed by an update from CMS and WEDI.

We will then take a lunch break and then after lunch we will be going over updates from the subcommittee on standards, and we'll have a review of their two requests for information that they are planning on. We will then follow that with our public comment before adjourning.

I will now turn it over to Jamie.

Update from the ICD-11 Workgroup

Jamie Ferguson: Thanks, Naomi. Could we please bring up the ICD-11 update slides?

This is just what I'm going to talk about. We only have half an hour for this update. I'm going to talk about the timeline and just remind everybody how we got to where we are. We haven't published yet an update on the analysis of the second RFI that actually happened at the end of last year, and the additional expert input that we've had. We do have a report in process, but I'll give you an update on that.

And then I wanted to walk the group through the thought process and the deliberations and analysis that the workgroup has undertaken following both the second RFI and the additional expert input, because we have some plans for how to attack what we see as the most important next steps to get the information we need in order to present good findings to the full committee. So I'll talk about those in the next steps.

I'm going to spend a couple minutes on this slide, because this goes back to how did we get here? The study and analysis and development of committee recommendations on ICD-11 is not a new activity. This has been going on for quite a while. It started under Chairman Bill Stead

with an expert roundtable back in 2019. I was not on the committee yet, I didn't participate in that roundtable, but I did have a chance to talk to Bill Stead about it, and obviously, from that roundtable back in 2019 -- five years ago, my gosh -- there were a set of recommendations issued. Then we had a little thing of a public health emergency, pandemic happened, and so there really wasn't any action on those.

So in 2021, the committee got back together on this and said, wow, this is really important, we want to reiterate really many of the same recommendations. So the 2021 letter of recommendations to the Secretary supported all the previous recommendations of 2019, and actually prioritized some of the work to be done and some of the analysis, research and communications that were called for in the previous letter.

Then ongoing discussions in the committee, the committee decided that a workgroup needed to be chartered, so in 2022 the workgroup was chartered and formed, and really wasn't fully populated until the early part of 2023.

Then the first actual work product that was done both by the workgroup members and by staff, mostly by staff, was an environmental scan to really understand what are all the different research papers that have been published on ICD-11, what are the implementations, how is ICD-11 being used around the world, outside of the United States, and at that point there were -- I don't remember if it was one dozen or two dozen -- countries that had implemented ICD-11, and had a number of published studies about those implementations.

So we learned a lot from that, and we issued an RFI. Due to some issues with the publication cycle, the comment period for the first RFI was very limited, and so even though we did get some very important responses from both industry trade groups and others in the analysis, in the first RFI, we didn't have the full 60- or 90-day comment period that we would have liked to have had for the first RFI.

Then in the summer of 2023, we held the second expert roundtable, and this was -- I would even call it a major event -- it was a daylong in-person event in Washington D.C., and we gathered experts, I think we had 50 participants, all experts in different areas talking about the various use cases, the benefits as well as concerns and unknowns, identified research that needed to be done. Also identified some of the key drivers for the adoption of ICD-11 in areas like mental, behavioral, and neurodevelopmental health information, in terms of safety and quality measures. And other areas where the current ICD, which has actually already been deprecated by WHO, it just doesn't meet our needs.

So after that the workgroup published a phase one report of findings, that was last fall, and got together to issue a second RFI with a full 90-day comment period. So I think the comment period actually even stretched even into January of this year.

Of course we've done a lot of analysis, and I'll talk about that analysis of that second RFI, and we've also reached out and gotten additional expert input, mostly from the participants in the second roundtable. We went back to those experts with questions that were formed based on the responses to the second RFI, and we've come up with some analysis that I'll talk about in just a minute.

But I just wanted to review kind of the history of how we got here, and do any of the committee members have any questions about the timeline or how we got here? Okay, so we're all on the same page then.

In the second RFI, there are two pages on this, a lot of the responses actually aligned with the previous recommendations from the first two letters. I think a majority, if not all, of the responses, encouraged stakeholders and the Department to start planning for ICD-11, to provide education and communication, and analyze costs and benefits. So cost-benefit analysis turned out to be a big driver of support for the adoption of this classification system, and it's both financial and nonfinancial costs and benefits that need to be analyzed.

Further analysis of these responses showed several different things. One is that there are a number of expected benefits, they're listed here, I'm not going to read the list, but there are a lot of expected benefits from the future adoption of ICD-11. And commenters really believe that ICD-11 will support improved healthcare quality and safety, and also, and this was something actually that came up in a little bit of the discussion yesterday about the ability to capture more granular information on the social determinants of health and factors affecting health equity, so that those kinds of programs could be more successful.

A number of the responses indicated a belief that automation and AI would drive burden reduction. Some of the responses were concerned about the cost of this new technology, but I don't think there were any that said it won't work, but there were some that said we don't know. There were other responses saying we're using this and we're finding that it does drive burden reduction, increased accuracy, and so forth, in the coding process. But of course we don't have that process in ICD-11 yet, because we're not using it yet.

A big thing is the lack of understanding of ICD-11. ICD-11 is structurally and syntactically very different from ICD-10 and 10-CM. It's based on an underlying ontological framework. It features polyhierarchy. It has the ability to do post-coordination or concatenation of different concepts, to get greater specificity. So these are all very fundamental differences from the existing coding system, and consequently there's a lack of understanding of how this new system is structured, how it would work, how it would be implemented. So this drives really a need for not just training but actually education and understanding.

I'll also say that we looked at these responses and grouped them by stakeholder categories or groups of stakeholders with common interests, and then we found that doing it that way, different groups of stakeholders had different specific concerns, whether they were financial concerns about the cost of implementation, or the benefits of automation, or different technical or operational concerns.

Moving forward from that analysis, the workgroup identified an array of key use cases for ICD-11, including things like claims and reimbursement, public health reporting, interoperability, quality and safety measures, and we also then identified stakeholder groups such as large providers, small providers, large health plans, small health plans, system developers, public health, and so forth, and then we used the participants in the previous roundtable and our other previously identified experts to reach out to stakeholder group representatives to get their input on a list of questions about these use cases from each stakeholder perspective.

So we were able to create sort of a matrix, if you will, of the different identified benefits or costs, or concerns or opportunities, for each of the stakeholder groups in each of the use case categories. So it was very interesting to see the commonalities as well as the differences in that analytical approach.

We found from that that actually -- it's not on this page, but I will say that the number one thing that was on every stakeholder's list, and this actually goes back to one of the previous slides on the RFI analysis, that everybody wants training and education. So training and education was the one thing that was most in common across all the different stakeholder responses on all the use cases.

But having said that, we also were able to identify a critical -- I don't want to call it a barrier -- but it's a critical dependency, and this is information that really is needed before all the other research questions can be analyzed, and that is really what is the specific linearization or subset of the international underlying framework that's going to be implemented in the United States? How will it be structured, and how will we use post-coordination to achieve the kind of specificity that we need off of that underlying framework?

So this really is a different way of saying this, is to identify an overriding question: what is needed in the U.S. morbidity linearization subset for ICD-11? There is an existing linearization subset published by WHO called the MMS, the morbidity-mortality subset. That is intended to be used or is used for final records reporting, for cause of death reporting, statistical reporting, and such like. But we found in the analysis done by the National Library of Medicine, which we have analyzed carefully, showed that that really is not going to meet the needs for the other morbidity coding use cases.

So we need to now understand what has to be in, what are the different requirements of different stakeholders, different specialty areas, different subject matter areas, what are the requirements for this linearization of subset of the entire ICD-11 framework?

Through a whole series of meetings, we've identified an approach to this analysis, and it's these three bullets in the middle of this page. First, we want to identify what's not in ICD-10-CM that's needed for the ICD-11 use cases. There's some examples of this that we know right off the bat. We have information that's needed for healthcare quality and patient safety measures that is not readily available or not structured appropriately in 10-CM. There's a lot of information in the mental and behavioral and neurodevelopmental subject area that's not in 10-CM, and it's structured completely differently in ICD-11. In ICD-11, it matches the way that those professionals really need to identify and code for their diagnostic information.

So those are examples of things that are not in 10-CM that are needed, but that needs to be much more fully explored in all the different medical specialty area and find out what's needed. Because after all, if everything we needed was in 10-CM, there wouldn't be any need to change. We'd just keep using 10-CM. But there are a number of areas that aren't in 10-CM, and so we want to make sure we understand those.

Secondly, we also want to identify what's in 10-CM, which is of course the U.S. modification of the international standard. What are the things in 10-CM that are and are not needed in a U.S. linearization? So 10-CM is vast, it's huge. I don't know the exact number of elements in it, but I'll say something like 75,000 codes in 10-CM. But an initial analysis of that using hospital data

that was done by one of our workgroup members showed that I think 22,000 of those 75,000 codes in 10-CM have never been used for hospital reporting in the United States in the last five years, ever.

So it's likely that we will be able to identify things in ICD-10-CM that really are not needed to be carried over and represented and brought out into ICD-11. Some of those things might be things the United States added into ICD-10, such as some of the laterality or some of the sequence or progression information that was added. So those things, in some cases, if they haven't been used, we have to wonder is it really needed? Obviously, there are going to be somethings also in 10-CM that have not been used, that really still are needed, that might be needed for rare disease coding, and we haven't seen it yet, or they might be needed for other research purposes other than clinical documentation. So that second part of the analysis is very important, so this is to compare the needs versus 10-CM.

The third part is to look at the WHO MMS linearization, because again, if this is another subset that's intended for morbidity and mortality classification, and if it had everything we needed than we could use that, but I think also the initial analysis has already shown there are things that are not there that are needed, but that needs to be better understood.

In each of these three parts of the linearization analysis we're going to have to reach out to a variety of different stakeholder groups. We're going to have to reach out to not only different kinds of researchers, different kinds of clinicians, different kinds of health systems, payers. The variety of needs are driven by programs for things like health equity, safety, and quality and so forth, so we're going to have to reach out to all of those different stakeholder groups and get a lot of expert input on each of these parts of the analysis.

And then in addition to identifying what's needed in the linearization, at the bottom of this page, there are some of these sort of subsidiary questions that need to be answered. One is about post-coordination. One way of achieving specificity is to add more precoordinated terms into the actual ICD-11 product. Another way of achieving specificity is to group or cluster codes together in order to achieve the right level of specificity that's needed and to really group those concepts together.

So this might be a way to capture some of, for example, what's in 10-CM in terms of laterality. That's an example where post-coordination could be an approach to that, but then we'd have to have rules or consistent guidance for the syntax of how that post-coordination clustering will occur so that the resulting codes would be standardized in a consistent way and would work in terms of interoperability and could provide system specifications both for EHRs and other kinds of systems.

Similarly, we'd have to have an analysis of the extension codes. So after you look at the linearization of what's in 11 that you want and figure out how to use post-coordination, there is expected to be some number of things that still are needed that would not be covered, and this is where we get into a hopefully small number of extension codes that are needed for the United States.

So all these parts of analysis really are in the future plans for the workgroup, to seek expert input on this, and I think if we go to the next page we can talk about how we want to do that. I'll get to that in just a second.

I did want to mention, I think I might have mentioned this at the top, we do have a subset of the workgroup that's developing a draft update report. This will be a report to the full committee. We had an update report a little over a year ago. We'll have another update report coming up, and this second update report will cover the analysis of the second RFI, the other expert input, and everything I'm talking about here.

In order to address the kinds of analysis that I was just talking about, we plan to hold virtual panel discussions, really where I call them panels, we're not sure if it's going to be another expert roundtable, a virtual workshop, virtual panel discussions; we're of course working within budgetary constraints, so we want to make sure that we do this efficiently and without trying to apply resources that we don't have to help facilitate these kinds of things. You know I think at some points in the past we might have had more budget than we would have brought everybody to meetings in person, in the Humphrey building. But that's not going to happen, I think, in the near term, so we're looking at virtual panels, and we want to figure out how to do that to capture the range of stakeholder input from all the different medical specialties and the other kinds of stakeholders that we need to get that input from. Then we would of course report the results of those panels and use that information to report back to the full committee.

So this is the immediate work that we're doing in the workgroup to support that path forward, to get this expert input. So we're in the process of identifying both the U.S. representatives to the WHO family of international classifications groups and subgroups, as well as U.S. participants in those groups who are not official U.S. representatives and other key subject-matter respondents who previously have been working with the workgroup, to start to address the key questions about the morbidity linearization. So we want to use these representatives to help us form the panels for those virtual events that I just referred to on the previous page, and then we want to understand also -- this is a separate activity that is going on within the workgroup -- we want to understand in terms of the ICD-10-CM, which is our current classification system, how did we get to where we are?

What were the rationales that were used for adding things that in many cases ended up not being used, and what are the usage patterns? So we want to understand that so that we have a better feeling for the base from which we are planning to shift, if you will, so that we can really understand what's needed in ICD-11 based on the processes that were used in 10-CM. Then we're also starting to look at scheduling for those expert panel events.

I think the next slide just is for discussion, and we've got maybe 10 minutes for discussion. I'm happy to take any questions, comments, committee discussion. A lot of the workgroup participants actually are on the call, so anything you all want to add.

Valerie Watzlaf: Jamie, I just want to commend you for the work and the whole committee when you look at that timeline that you put up, it is just amazing how much has been accomplished, as you said. I think a lot of people think that this has just been happening, when really we have been working on it since, as you mentioned, 2019. And I just hope we can continue. Yeah, applaud, because it is amazing, I think, the work that's been done. And I hope that we continue to get the support, that's really what I -- that this won't end, and that we get the support that we need to continue the work of the workgroup and the wonderful subject matter experts that we get on this, is really important, and I just hope that continues. So thank you for all the work that you're doing.

Jamie Ferguson: Thanks, Val. Other comments?

Maya Bernstein: Are your workgroup participants -- I don't think they have been elevated into panelist status so that they could speak, but they could raise their hands, and you can recognize them that way. Our team can elevate them so that they can speak, but I don't think we have a way to put their questions.

Jamie Ferguson: I do see a few of them on the participant list. Any of the workgroup members who are on the line, please if you want to make a comment, please raise your hands.

Michael Hodgkins: Thanks, Jamie. Very well done. This is more of a question. I probably missed it at some point, because I know I've missed some of our meetings. Some time back we sent a letter asking for urgent action to appoint someone as a lead, a point person, for the United States. I'm just curious if we ever heard back on that.

Jamie Ferguson: We have not had a response to date. I don't know, Sarah, if you know of anything in process. Tammy.

Tammy Banks: I was just going to ask, because I know we're focused on mortality and there's also a morbidity piece of this. Do you have any insight on the morbidity which is a required implementation for ICD-11?

Jamie Ferguson: Other way around. It's the mortality that's required. Actually we had a presentation on that to the committee I think last year from NCHS. I think it was Bob Anderson who's running that. Talked about how they're in the process of analyzing and doing a dual coding study on mortality reporting for cause of death reporting and how they're planning to shift that to use ICD-11 for the internationally required national reporting.

Now, all of the mortality coding for cause of death is done in NCHS. It's not done locally or anything. It's all done centrally in NCHS, so they're doing that, and that is using the WHO's MMS subset. That's the one that's required for internationally comparable cause of death reporting. That work is underway, but that's really separate from the morbidity coding that we would use for all the other use cases, ranging from quality and safety and research to reimbursement and so forth, in the United States.

Tammy Banks: And Jamie, if I can just add, because sometimes people who aren't familiar with ICD-11, that there is use cases there -- the WHO has been doing this for a long time, and it is implemented in other countries, so if anybody wants use cases, implementation guides, the works, all that education is up on the World Health Organization, so be sure to use those, as others who aren't familiar with this become familiar, because why recreate what's already been done.

Jamie Ferguson: Thank you. I see a workgroup member, Vickie Mays, has her hand raised.

Vickie Mays: One of the things that I wanted to comment on -- Vickie Mays, I'm a member of the workgroup, no conflicts -- one of the things I want to raise is really elevate what you and Valerie said about the need for this work to move forward and kind of a sense of urgency in some of it moving forward.

Part of what we really need to do is get the panels underway and be able to get the feedback that we're going to send to WHO and others, because things are moving along, and I think we don't want to find ourselves kind of too late to the party in the sense that other countries are making their decisions and I think we need, for the United States, which has some very different needs than some of these other countries, to step forward, give our thoughts, find the way to be the most effective, and also to find a way to get our point person within HHS to kind of clearly be the lead for this, so that they're sitting at the table as discussions go on.

I just wanted to support and emphasize that if it's a resource issue, if it's a timing issue, we really need to see -- because we've been doing a lot of work, and I applaud Jamie for his leadership in this, but if we miss windows, then I think we're going to find ourselves not in the best place.

Jamie Ferguson: Thank you, Vickie, and just to support what you say, the window that Vickie's talking about, a part of that is determination by WHO with the other member countries who are implementing ICD-11, determination of the licensing terms and the requirements for national subsets or national linearizations that are going to be supported and licensed by WHO. So that is the work that's going on now, and the United States does not currently have a lead representative at the table for that that encompasses all the different use cases that we're talking about.

Michael Hodgkins: This lead representative issue has been hanging out there for a while, and to Vickie's point on the urgency that we believe exists, is there any way to push for a response to the letter that we sent?

Jamie Ferguson: I would ask for staff to address that.

Maya Bernstein: I can only tell you that the response to the committee is being actively discussed.

Lorraine Doo: This is Lorraine, and I'll also check with our executive officers to see the status of it. Last I knew it was in the Secretary's office. But I'm following up on that.

Jamie Ferguson: Thank you. Thank you, everybody, very much. So if there are no other questions or comments, I'll give you just a couple minutes back.

Office for Civil Rights Update

Naomi Michaelis: Thank you, Jamie.

I'd like to welcome Tim Noonan to give us an update from the Office of Civil Rights.

Timothy Noonan: While the slides are being prepared, hello, everyone. I appreciate the invitation to OCR to speak today. I always like attending these meetings. I always catch a little overlap at the beginning or the end with other speakers, and always find that fascinating and wish I had more time to track and listen to all the discussion that occur at NCVHS.

I think the last time OCR spoke was back in April, we spoke about the new final rule we had published at the time, the confidentiality revisions for part two, and since then, OCR has been busy; so today I thought to speak on OCR's recent policy activity, the final rule on the HIPAA privacy rule to support reproductive healthcare privacy.

We'll talk a little bit about some of our activity in rulemaking. I can also share some information on trends that OCR sees in the large breach reports that we receive, such as the amount of large breaches that are being reported, the numbers of individuals affected, the types of breaches that are occurring and the location of the breaches. And then as time permits, we can talk a little bit about some recent enforcement activity and perhaps discuss a recent investigation that I think is illustrative of some of the issues we see with respect to cybersecurity in the healthcare sector.

This is the HIPAA privacy rule for reproductive healthcare privacy, final rule. It was displayed at the Federal Register on April 22 and then published on April 26. It had an effective date of June 25, 2024. What does that mean? That's the date that entities affected by this rule, the covered entities and business associates within the healthcare sector, are expected to implement the requirements of the rule. The compliance date is December 23, 2024, except for the notice of policy practices provisions. The compliance date is the date on which OCR can then begin investigations and if necessary take enforcement action.

So that date, as I said, is December 23 for everything except the changes that we made to notice of privacy practices. The compliance date for the notice of privacy practices is February 16, 2026. Why is that? It's the same date -- it wasn't chosen by accident or randomly -- as the 2024 part two rule on the confidentiality on substance use disorder patient records. So the idea is that regulated entities would only need to have to change their notice of privacy practices once to address the changes that are contained in both regulations.

The new final rule, it contains the prohibition. It prohibits regulated entities from using or disclosing protected health information to conduct a criminal, civil, administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive healthcare. It also prohibits the imposition of criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive healthcare, and it also prohibits identifying any person for either of those purposes.

When we did the proposed rule, we had provided some examples that continue to apply and we think remain helpful in illustrating the operation of the prohibition and how it continues to permit uses and disclosures for legitimate interests. So for example, the prohibition does not restrict a regulated entity from using or disclosing protected health information to a health oversight agency conducting health oversight activities such as investigating whether reproductive healthcare was actually provided or appropriately billed in connection with a claim for such services or investigating substandard medical care or patient abuse. And the prohibition generally does not prohibit the disclosure of protected health information to an inspector general, where the health information is sought to conduct an audit aimed at protecting the integrity of the Medicare/Medicaid program.

The prohibition has very specific limited applicability, which takes us to our next section. There is a rule applicability. The prohibition applies where a regulated entity has reasonably determined that one or more of the following conditions exists.

The first one is the reproductive healthcare is lawful, under the law of the state in which such healthcare is provided. So for example if a resident of one state traveled to another state to receive reproductive healthcare, that is lawful where such healthcare was provided. That would

be an instance where the prohibition applies because the healthcare received was lawful in the state where it was provided.

Number two is, the reproductive healthcare is protected, required, or authorized by federal law within the U.S. Constitution, regardless of the state within which such healthcare is provided. So here as an example, if reproductive healthcare such as contraception, that's protected by the U.S. Constitution, I think the Griswold and Eisenstadt decisions, if you're up on your caselaw.

And third is whether reproductive healthcare was provided by a person other than the regulated entity that receives the request for protected health information, and the presumption which I'm about to describe applies.

Here, this is probably the biggest change from the proposed rule to the final rule. When we did the proposed rule, we had a public comment period, of course, and we received a lot of comments explaining that regulated entities are often not in possession of information about the circumstances surrounding the provision of healthcare, if they didn't provide such healthcare. So in response we added a presumption that we believe reduces the burden of the new prohibition on regulated entities while still maintaining the same levels of protection.

So where a request for protected health information is made of a person that did not provide the reproductive healthcare at issue, such reproductive healthcare is presumed to be lawful unless one of the following circumstances exists.

So the exceptions, if you will, are the regulated entity has actual knowledge that the reproductive healthcare was not lawful, and so here, if an individual were to disclose to their doctor that they obtained reproductive healthcare from an unlicensed person and that doctor knows that the specific reproductive healthcare that was provided must be provided by a licensed healthcare provider, that could be an instance where the doctor has actual knowledge.

The second is the regulated entity is in possession of factual information supplied by the person making the request for protected health information, perhaps the patient, that demonstrates a substantial factual basis that the reproductive healthcare was not lawful due to the circumstances in which it was provided. So an example here would be where a law enforcement official provides a health plan with evidence that the information being requested is reproductive healthcare that was provided by an unlicensed person, where again the law requires that that healthcare be provided by a licensed healthcare provider.

Next is the attestation requirement. A regulated entity must obtain a signed attestation when it receives requests for protected health information potentially related to reproductive healthcare, that the use or disclosure is not for a prohibited purpose. The attestation is required when the request for information is for any of the following purposes: health oversight activities, judicial and administrative proceedings, law enforcement purposes, or it's about decedents to coroners or medical examiners.

Assuming the attestation is not facially deficient, a regulated entity upon receiving a request and an attestation, they must consider the totality of the circumstances surrounding the attestation and whether it's reasonable to rely in those circumstances on the attestation that the request for the information is not for a purpose prohibited by the new rule.

This attestation requirement, it provides regulated entities with a way to obtain written representation from a person requesting the health information and documenting that the request is not for a purpose prohibited by the final rule. And after we published the final rule, we did publish a model attestation that's available on our website that entities can use. I think it's two pages, one page instructions and then one page of the actual attestation itself that should help facilitate this.

Lastly, I want to talk about notice of privacy practices -- we carved that out at the beginning as having a different timeframe -- so this 2024 HIPAA privacy rule addresses the proposals related to the notice of privacy provisions made in both the part 2 rulemaking that we did earlier in the year, as well as the proposed changes we had made in the 2023 proposed rule for HIPAA.

As I said earlier, the compliance date for these changes is February 16, 2026, and the provisions have been revised to require a covered entity to, among other things, provide the following information, and what's new from the current notice of privacy practice is, now they'll be required to include descriptions and examples of the types of uses and disclosures that the new final rule prohibits and those for which an attestation is required.

And then a statement putting the individual on notice of the potential for information disclosed pursuant to the privacy rule to be subject to redisclosure by the recipient and potentially no longer protected by privacy rules, so that a patient can understand how their health information can leave the safety of HIPAA, depending upon where health information is redisclosed.

Here is just some resources that if there's anything that I've said today that sparks your interest or you want to read up more on, so it can be viewed or downloaded at the Federal Register. We have a fact sheet on our website that goes through the major provisions of the new rule. There's a couple of videos, both in English and Spanish. And then if you like what I'm saying today and wish I were saying more about it, perhaps there's good news for you. I did a webinar. I spoke for over an hour really getting into much greater detail, providing much more examples of each of the provisions of the new rule, and so the webinar is on our YouTube channel, and so the link to that is also there. And then as I mentioned earlier, we also published the model attestation that entities can use to comply with this rule.

Some of the trends that I'd like to discuss. We spoke about trends last time, in April, so some of this will be a continuation of the trends that we see, and some numbers have changed. Here we see the large breach reports received by OCR. A large breach report is a breach affecting 500 or more individuals, and you can see there's been a substantial increase in the large breach reports that we've received over the past five years from 2018 to 2023. It's a 102 percent increase.

And then more notably, there's been a substantial increase in the number of individuals affected by large breaches. I'll say the number twice -- 950 percent, 950 percent from 2018 to 2023. It went from 15.2 million to over 160 million. A 186 percent increase just from 2022 to 2023, and with some of the large breaches that have occurred this year, in 2024, we expect the total of individuals affected in 2024 to surpass what was reported in 2023, setting yet another unfortunate new record.

Here we see the type of large breach reports that OCR receives and how that has changed over the years. The pie chart on the left is cumulative data, the historical record, if you will, from 2009 through December 31 last year. And you can see the prominence of hacking, it's the

largest percentage, 51 percent, a little more than half. Unauthorized access or disclosure at 23 percent and theft at 18 percent are also significant.

And then the chart on the right shows just this year's data, 2024, through August 31. Here you can see that hacking is by far the most common type of large breach report reported to OCR, at 80 percent, and it's really what's driving the increase in reported large breaches to OCR. It's all about hacking.

And you can also see there's a trend movement, as theft has significantly decreased, both large breach report that is reported. This data is part of an overall trend. Over the last couple of years, we've seen the same thing, that hacking at the end of the year ends up being about 79 percent of the large breaches reported to OCR, and so this year is continuing that trend, as well.

Here's another way of looking at what's driving the increase in large breaches and hacking, and in particular is a subgroup within hacking, ransomware. As we said, hacking is the most frequently reported large breach reported to OCR. You can see here 89 percent increase in large breaches reported to OCR involving hacking, from 2019 to 2023. And within that, though, ransomware is 102 percent increase for the same timeframe.

So if you're an entity and you're going to experience a large breach, the overwhelming statistics are it's going to be hacking or ransomware specifically, is the most frequent common occurrence.

PARTICIPANT: Can you talk about how you guys define hacking? Because this seems like a change from previous reports we've had where it was like a lost laptop was the main driver of lost data or various kinds of breaches. This seems to be a shift to something more nefarious.

Timothy Noonan: Well, it is. You now have third party threat actors that are driving the increase in large breaches as opposed to perhaps the negligence of an entity vis-a-vis a stolen or lost laptop. Hacking, from OCR's perspective, is an intrusion into a health information system that contains electronic protected health information that results in an impermissible disclosure. In many instances, it's exfiltrated out of the healthcare system and often appears on the dark web. Many times when there's a ransom attached to it, even if it's not ransomware, so that the actual mechanism wasn't encrypting and locking down the data, it was just a straight up exfiltration, then it's a stickup. It's we're giving back your data or we, quote, promise to destroy it if you pay this ransom. That often appears on the dark web where they will send a regulated entity a snapshot showing that you've lost containment, you've lost control of your information. So we view all that as hacking. Any time there's been an intrusion into the system.

PARTICIPANT: Let me just clarify. You mean like an outside third party -- so we're not talking about insider threat from someone who would otherwise have access but is using it wrongly, and we're not talking about negligence, as you said, losing the laptop or doing something --

Timothy Noonan: Correct. Hacking requires a third-party actor. I suppose there's an edge case somewhere where if an insider was part of a hacking ring and hacked it, perhaps it could be in multiple categories. But yeah, I'm generally talking about a third-party actor that's breaking into their system electronically and accessing the health information.

PARTICIPANT: I'm just remembering briefings from your office in past years to this committee, where the mix was quite different. It was more on the negligence side, and this really is a significant shift in the last few years that you're describing.

Timothy Noonan: It is an unfortunate shift, and if we have time to talk about it today, it's highlighting perhaps the general unpreparedness of healthcare entities. So when the intrusion occurs and we conduct an investigation, as you perhaps heard me say over the years, the most common violation we find is a risk analysis. The hack, the intrusion into their healthcare system didn't cause their failure to not have a risk analysis. There's no cause and effect there. The hack casts a spotlight, if you will, on the entity. We conduct an investigation, and in the course of the investigation we find they hadn't done their risk analysis.

And often, the problems begin to multiply from there, that because they hadn't conducted a risk analysis, they weren't aware of issues involving remote desktop protocol, or they were not aware that multifactor authentication was not implemented on all of their systems, or they weren't aware of weak passwords or overuse of administrator credentials, and so anyone could access all of the information, it's not segmented, you don't have role-based access, and what-have-you.

PARTICIPANT: These are some of the things that the committee has written to you about in the past year or two, and hopefully I know that you're aware of those. Hopefully you found those comments and recommendations useful on this topic.

Timothy Noonan: Yes, indeed. Continuing along, I think the last chart we have, here we see where the reported large breaches are occurring. Again, historical versus this year, you can see the changes. Network servers, historically, were at 36 percent, email at 22 percent. These are the largest locations, historically. Paper records still fairly significant at 14 percent.

However when you move to the 2024 data, you can see that network servers are even more dominant, 66 percent. So two-thirds of all large breaches involve network servers. Slight drop in email at 20 percent, and then paper records is greatly reduced at 6 percent, as that's not such the attractive target anymore.

In sum, network servers and emails account for 86 percent of the large breaches reported to OCR this year. Again, if you're an entity, you can anticipate if you're going to experience a breach, it's probably going to be involving your emails or your network servers. A good best practice would be to make sure your risk analysis, if it's not fully complete, is really honing in on those areas.

Here, I'll just go through this quickly, you see the rise in network servers. As Maya was saying, it's all connected to hacking. That's the major point of intrusion, and then here you can see that this is the preferred location, and that's just gone up 325 percent since 2019. And it can also include, though -- we've been talking about hacking, and rightly so -- but network servers, it can also be instances where it's unforced error, it's negligence. Health information is just left exposed without any access controls in place on the internet. That would still also fit in this category, as well.

Finally, here we see perhaps the rise and fall of email, although email is featuring prominently in 2024, so it's yet to be determined how this trend, if there's a meaningful trend to be had here.

But until this year there was a 35 percent decrease since 2019 through 2023 in email, also it is a broader category outside the realm of just hacking and installation of malware. Email can also be an instance where negligence, somebody sends out an email to a group of patients and each of the patients can see one another. That would be an instance where there was a breach involving an email account. So it isn't always a hacking, but it most often is.

Here we have a list of the recent OCR enforcement actions. All these cases were resolved with settlement agreements, corrective action plans, and monetary payment or the imposition of a civil money penalty. I'll run through them, just give you an idea of what each case was about very generally, being mindful of the time.

The issues reflected on this list involve the mis-mailing of health plan ID cards. Everybody someone else's ID card, not their own. That was the LA Care Health Plan case. Ransomware that featured prominently, that's the Doctors' Management Services case. Greenridge Behavioral Health, and then Heritage Valley Health System.

Disclosures to the media. We saw a little uptick in this during the COVID period where folks were bringing in the media, and they would have access to individuals' protected health information. We had issued some guidance on that. However, this issue still remains, that is the St. Joseph's Medical Center case.

We had a phishing attack, also a very common attack vector used. Sometimes to install malware and extract health information. That was the Lafourche Medical Group. Malicious insider identity theft ring that was operating at Montefiore Medical Center. And OCR's right-of-access initiative where we're still pursuing enforcement actions to get individuals access to their records. That's still been a major problem. It's the largest source of complaint for OCR; individuals still don't get timely access to their health records. And so those are cases involving David Bente(ph.), United Healthcare Insurance, Optum Medical Care, Phoenix Healthcare, Essex Residential Care, and American Medical Response.

I'll spend a minute speaking about a recent case, and then open up for questions. One of our most recent announcements of a complete enforcement action was our investigation involving Heritage Valley Health System, you can see them on the list. OCR had received a media report concerning a data security incident and a potential ransomware attack. We initiated an investigation, and as I mentioned earlier, with violations we found in the case involving the security rule, this is pretty standard, typical of what we see in investigations.

First was risk analysis, which is again, as I said, by the far the most common that we see. You have to be able to identify potential risks and vulnerabilities for the electronic health information, and this continues to be the biggest stumbling block. And if you haven't implemented that provision, it's very hard to really have a good cybersecurity posture, and so we continue to flag it.

Last time I was here, I spoke about we created an enforcement initiative to focus just on the risk analysis provision to try and increase awareness as well as the number of completed enforcement actions, so we have a number of those type.

The biggest failing we find is risk analysis is required to be accurate and thorough. It's not thorough. It doesn't account for everything. So all the devices, mobile devices, that are hooked

up or have access to an information system, doesn't account for all the information systems. Often entities have multiple locations, but their risk analysis is confined to only one or two locations, and not all 10, or it doesn't include all of the information systems where electronic protected health information is flowing. So the thoroughness is often the major stumbling block.

This case also involved a violation of the contingency plan, so this is something that I think is raised in prominence as a result of ransomware cases. Often, they don't get the data back, either it remains encrypted or the thief doesn't honor their word, surprisingly, and doesn't give it back to them. So having data backup plans, disaster recovery, emergency mode operation, all those things, are necessary in order to ensure the continued availability and integrity, for that matter, of health information. The purpose of a contingency plan is to allow an organization to be able to return to its daily operation as quickly as possible following an unforeseen event. And failing to have a contingency plan in place to address those types of things -- which can be natural disasters, hurricanes, tornado, anything like that -- or it could be what we've been talking about today, cyberattacks, malicious software, whatever the event is, that they have to be able to restore systems and be able to have access to all the health information that they previously had, and they have to make sure it hasn't been corrupted, otherwise its integrity has been violated.

Then the last violation we found in this case was access controls, which of course you're required to limit access to only those individuals that should have access to it. It's again a common pattern that we often see simple passwords, the word password is the password, or if you go to workforce members' social media page or Facebook page, you can figure out their local sport team, their spouse's name, something, and you can quickly deduce their passwords. So unsophisticated passwords, lack of multifactor authentication, that continues to be a problem.

In this case, following OCR's investigation, we found those three violations, Heritage Valley agreed to settle with OCR. Settlement was for $950,000 and they agreed to implement a corrective action plan to address the items I've discussed. And they agreed to three years of OCR monitoring, and that's where we provide technical assistance, producing documentation of how they've implemented things. If there's things that they've implemented that we don't believe fully comply with the law, then we point that out during the monitoring period to hopefully put them in the best possible posture so future events don't lead to a similar outcome.

With that, I will stop there, and if anyone has questions, happy to take them.

Valerie Watzlaf: Thank you so much, Tim, for being with us today, and I think congratulations on I think it's OCR's 28th anniversary or something, last month. So it's been a long while that they have been with us and doing such great work.

I wanted to mention something that Maya kind of mentioned, and that's that we did provide a letter to the Secretary on recommendations to strengthen the security role, and we do include as you went through step by step of what the risk analysis should include. So thank you for going through that again.

My question really deals with something that we heard yesterday from our panelists. We had two very interesting panels that focused on privacy and security issues around health data

access, and we asked them kind of what are their concerns, what keeps them up at night, and they had a few things. I won't go through all of them, but two of them that came up that I think I'd like to hear your perspective.

One was the lack of regulations around health data apps they feel is huge and that maybe we need a national campaign on the issue to really educate consumers, to educate app developers, providers, all of them, so that they know what can occur when their information is on an app that may not be covered by HIPAA.

And then the other issue was, which I think you just mentioned about, was the 42 CFR Part 2, one of them had mentioned that it's still impeding their ability to share that data, the substance use disorder data, because it still requires consent I believe, for treatment, payment and operations. So I didn't know if you had any clarification around that or any additional things that you guys are thinking about in relation to those two areas.

Timothy Noonan: Sure, I appreciate that thoughtful conversation. Would have loved to have heard it, but alas. I think on the first concern, health apps, you have direct-to-consumer products that individuals can use to facilitate gaining access to their medical records. These health apps don't meet the definition of a covered entity or a business associate, so they're unregulated by HIPAA, and there may not be great awareness -- when you talk to people, sometimes there's just this presumption that HIPAA protects health information, everywhere it goes. Well, that's not really the case, right?

So we did some guidance a few years ago about the use of health apps and flagged the warning about the buyer beware, if you will, that the use of this app, you're introducing a risk or a danger. From the covered entity's perspective, if an individual wants to use this third party that's not regulated by HIPAA to facilitate access to their health information, the covered entity has to facilitate it. You would be violating the right of access provisions to object to it, so there isn't a great remedy for the healthcare entity on the other side to do anything for the consumer.

We have included that as part of some of our outreach events to make consumers aware, but I think what they're flagging, and I tend to agree, it is an area, this group that appears to be unregulated, certainly not by HIPAA, and that could benefit from being addressed. There isn't anything we can do in the HIPAA space. Congress would have to issue a new statute, creating new jurisdiction for OCR to be able to do something with that.

We do have many meetings with FTC, and so they are involved in this space. They also have a health data breach rule, and they often get involved in cases where misrepresentations are made. We see a lot of entities saying HIPAA-compliant. But if you're not a HIPAA entity, that really doesn't mean anything, and it also gives the impression that you are regulated by HIPAA, and so that would be more of an area for the FTC. But I share the concern. It's something that we've seen and we're not able to -- our jurisdiction is set by Congress, so that's not something we can cure on our own with rulemaking.

Valerie Watzlaf: I think they did also say that the FTC, they don't feel they're doing enough. But I know that's not something that you can deal with, I guess.

Timothy Noonan: I am sorry, your second --

Valerie Watzlaf: The second one was that the 42 CFR Part 2 is still impeding the ability to share that data, I think particularly because they said you still need a consent for treatment, payment. It still requires consent for TPO.

Timothy Noonan: The modifications we made were consistent with the CARES Act, so that was the driving force. There is the opportunity to get a single consent so you don't have to go back to the patient for each future one, and that was the mechanism that was set up in the authorizing statutory authority. But I'm not sure -- so OCR wouldn't have the last or final word on this. SAMHSA administers Part 2, so I think it would be more fruitful and productive probably to have conversations with them, and I think they'll be able to do more about that. We assisted with the rulemaking, because the idea behind the rulemaking was to bring it into greater alignment with HIPAA, and we know a little bit about HIPAA, but they still administer Part 2, and so they're best situated to manage that.

Maya Bernstein: Could I just tweak that before we leave that topic? I think there might have been some misunderstanding yesterday about what the rulemaking does. As Tim explained, there's one consent that's permitted now to move data from the Part 2 realm to a provider that would be HIPAA-covered, and then from there -- correct me if I got it wrong, Tim -- but I think what happens from there, it's thereafter covered by the HIPAA rules, which do not require consent for treatment, payment, or operations.

So there is a requirement for that first consent, but after that it runs like HIPAA. That's my understanding. Is that right? That is, if you're talking about Part 2 data that's covered by Part 2, you need the consent of the patient for the first time for it to move, say, to a provider that's provided by HIPAA, but thereafter it's covered by that provider's HIPAA rules and not the more stringent Part 2 rules.

Timothy Noonan: Right. So the redisclosure by a HIPAA entity, the backstop is the privacy rule. So they can make redisclosures of that information once they've received it, consistent with the privacy rule, and you're correct, you do not need the patient's consent under the privacy rule to disclose health information for payment, treatment or healthcare operations.

Valerie Watzlaf: So maybe there is that misunderstanding around it, from that group who brought it up. So I don't know if there's more education that might be provided, because I don't think they were understanding that, and the groups that they deal with. I think this was looking at public health and so forth.

Timothy Noonan: It could be. Now there's a nuance; if the disclosure is not to an entity regulated by HIPAA, then the HIPAA privacy rule doesn't apply to entities that are not HIPAA, and you would be limited by whatever language was in the original consent. Without knowing more, it can get fairly nuanced. As I say, if there's more information on that that could be brought to bear and let us know, I'm happy to engage with SAMHSA. Any time there's a rulemaking, a final rule in particular, we always envision having to do some sort of suite of guidance to help clarify as people start to identify some of the rough spots or some of the things that aren't as easily understood as we thought it was in our heads.

Valerie Watzlaf: Thank you, appreciate it.

Michael Hodgkins: Thank you for the presentation, Tim, and you may not be able to comment, but the recent Change Healthcare hack, which was obviously so disruptive to the healthcare system in general, there were small physician practices that were teetering on going out of business as a result. They're still trying to recover from this. And one of the things that came up in yesterday's discussion was just the whole topic of auditing.

I'm just wondering are we ever going to be able to get out ahead of these obviously very impactful breaches? I'm not talking about third parties now or outside actors hacking systems. I'm talking about really irresponsible corporate behavior, which I think is the example of the Change Healthcare situation that they hadn't put the necessary security measures in place.

Timothy Noonan: So, the Change Healthcare matter is under investigation, so I won't speak to that, but speaking generally about the issue you've raised. The trends I showed, the risks to health information have changed dramatically, and what it's highlighted is there's entities within the industry that have failed cybersecurity 101, if you will. The current security rule was published more than 20 years ago, and so entities should not be tripping over basic foundational, fundamental requirements, having proper authentication and access controls in place, managing your risks, regular system activity review, audit controls on all the information systems. Many times they're not able to, after an intrusion, you often have a forensic analysis and start to peel back what happened, and if they don't have audit controls in place, it's like somebody broke into your house, and you don't have security cameras, you're not going to get a complete picture of how it occurred, when it occurred, how long -- and we've had instances where threat actors have been inside the information system for months, sometimes more than a year, and they weren't aware of it.

How is this going to change? The healthcare sector has to recognize the changing threat landscape. That's why we have all these charts, so the risk of a stolen laptop, lost laptop, paper records, that was ten years ago. Now you need to have your cyber defenses in place, and we are working, as I think everyone knows, on a proposed security rule. Because we're in the rulemaking stage I can't say too much about that other than to say we're aware of the change in the landscape and we're proposing modifications to address that changing landscape that we think will -- if fully implemented by regulated entities, will put them in a much better posture, but we can add more details and add more requirements, but if entities aren't going to have a risk analysis and access controls in place, then they're going to continue to be soft attractive targets, and will continue to be exploited until that changes.

We conduct hundreds of investigations a year, but the way we're funded and the availability of our resources, we don't have 500 investigators, and we're not -- so we accomplish I think do quite a bit with what we've got. We do resolve quite a few cases with technical assistance, but it's a growing problem and I think the healthcare entities have to take ownership that if you're going to store individuals' health information, you have to ensure it's protected. This can no longer be ignored.

Sometimes maybe CEOs, they don't want to talk to the IT folks because they're all talking ones and zeros and they're hard to understand. You've got to pay attention to those folks, because we often get that story that we've been warning them of these concerns for years and we couldn't get the front office management to address it.

Naomi Michaelis: Thank you so much, Tim, for your time. We really do always appreciate you coming to speak to the committee.

I am now going to turn it over to Tammy to set us up for next conversation.

CMS Update

Tammy Banks: Excellent. I am looking forward to hear from Michael Cimmino. Michael is the director of the National Standards Group at the Center for Medicare and Medicare Services. The National Standards Group focuses on reducing administrative burdens and advancing interoperability and national standards within the healthcare system. Michael, we really appreciate the collaboration with your department, and thank you for being available to present your update.

Michael Cimmino: Thank you, and thank you for allowing us time to address the committee and the public today. I just want to underscore that we really appreciate the advisement and the recommendations this committee has provided on a number of efforts.

In the past, I've updated on a number of areas that NSG is focusing its efforts, and all of that work right now is continuing, especially our efforts to modernize the HIPAA process framework. So with that, I'd like to actually use our time to do something a little different today.

As many of you know, this past spring, HHS released its unified agenda which lays out the regulatory actions that we planned to take over the course of the year, and one of the items on the agenda for NSG is the pursuance of rulemaking that will propose the adoption of X12's version 8020 for the three healthcare claims transactions, institutional, professional, and dental, and for the electronic remittance advice transaction.

So in support of that effort, I'm actually going to hand over my time to WEDI to have them present on a recent survey they completed with industry where they obtained feedback on 8020. I know WEDI has shared this information to some extent, but NSG felt that this meeting would really be the best forum to bring this to the public as well as to the committee.

So with that, I'm going to turn things over to the folks from WEDI. Thanks.

Edward Hafner: Thank you, Michael. My name is Ed Hafner. I am currently the WEDI chair and recently retired after 41 years mostly working for vendors in the data exchange space. And Merri-Lee?

Merri-Lee Stine: Hi, I am Merri-Lee Stine. I work for Aetna, but I am the chair-elect of WEDI.

Edward Hafner: Great. So, our agenda today is to provide a brief overview of WEDI, our recent participation in past NCVHS meeting, our WEDI summer forum activities, the results of our survey focused on perceived value and cost of migrating to 8020, and take any questions at the end if we have time.

For some of you who may not be familiar with WEDI, we were formed in 1991 by HHS Secretary Dr. Louis Sullivan to advice health services in a nonbiased multistakeholder perspective. As we're also named in the HIPAA legislation officially as an HHS advisor.

Today we have productive close relationships with ASTP, CMS, and OCR, as we provide guidance through our member physician function, as well as through listening sessions. We also provide education and workgroup products to our multistakeholder members that come from health plans, providers, vendors, clearinghouses, government entities, healthcare associations, standard development organizations, HIEs, and patient advocacy groups. So believe it or not, we all get along.

Our aim is to help improve the U.S. healthcare system. Many of our participants are involved in both the administrative and the clinical exchange from both a technical and business perspectives. Also, please check out our member list at WEDI.org.

Among our many workgroups, we'll be focusing on the remittance, advice, and payments sub workgroups and the claims sub workgroup that created this survey. We wanted to further our previous informal survey that we provided to NCVHS in a recent meeting, and we felt that the presentation was received well. So we wanted to get into much more detail.

It was apparent from the meetings that there was a lack of industry knowledge of the content in the 8020 versions. We've come so many different versions since 4010 and 5010, and there's a lack of understanding of the value and the cost impact. So our aim was to both educate people and gather detailed feedback from our members. Our aim is an objective one. We are trying to be nonbiased. We want to help provide feedback to NCVHS and CMS and we value our relationship with NCVHS and hope the content Merri-Lee will present after me will help.

Our survey focused on the remits 835s and the claims 837 transaction sets. We've provided a background within the survey on each major change, and we asked for the perceived business value and the perceived cost of each. The survey was conducted this May through July, and we did use some additional channels to further our reach through X12 meetings as well as our association members.

Altogether, there were 204 participants. Each question had about 80 to 110 responses. Overall, we found it was easier for them to rate the value, and it was a bit more difficult for them to do cost estimates since it requires heavier analysis from other teams, internal teams, that haven't started yet.

We reported the results in our WEDI summer forum. Following that or within the summer forum, we held a listening session with CMS who queried the audience of over 100 in-person attendees as well as over 100 virtual attendees.

I want to thank the co-chairs of the two workgroups that created this survey. Beth, Stanley, Chuck, Pam, and Pat worked so hard with their workgroup participants to shape the survey and we truly appreciate their volunteer efforts.

We'll start the reporting here. I'll take the first slide, and Merri-Lee will give you the rest.

You can see the breakdown of respondents on this slide: 47.6 percent were payers; 18 percent were providers, clearinghouses had 11 percent, 23 percent from the vendors.

Now, Merri-Lee, to get to the real results.

Merri-Lee Stine: These next three slides are going to actually talk about the responses to the surveys, and as Ed described, these are people's impressions of the benefits to the different changes. You'll see across the top, the left column talks about what that change is, and then there's four impressions that they could choose from: highly or moderately beneficial; somewhat or slightly beneficial, not beneficial, or need more information.

Now these are rounded up. If they chose to abstain, we did not include that in our calculations.

So the first one here, this is a very important change. External code sets. In these guides, many of the codes -- and these are not medical code sets. These are codes that are used within the transactions themselves -- have moved from code lists that exist within the transaction to external. What that means is the codes that are used to identify things like the type of plan that's involved or the status of the payment have been moved external to the transaction implementation. And that allows the transactions to be more nimble.

Previously, they would have had to wait for an upgrade to HIPAA standard to be able to report different statuses or different plan types or things like that. The externalization of these code sets.

As you can see by these results, are generally viewed as beneficial. The other thing that I want to point out, and as you look down these results, you will see that most people find these changes generally beneficial and they do seem to be aware of the changes, which I take -- my impression I take is by the fact that they are finding them beneficial.

Moving on through these results on this page, the predetermination has been added back into the 837. It had been moved out for 5010. It has been moved back for the future versions. There are clearer instructions for real-time adjudication in both the 837 and 835. This is something that although adoption is a little bit slow, it is moving forward. There are updates to the allowed amount in the 837 and 835.

The RAS segment, which is the segment that reports adjustments to the submitted amount as far as amounts that are taken off of the submitted amount to get to the end result payment, it was reported in what's called a CAS segment. It is now going to be a RAS segment that allows more finite reporting of remarks. So better information for the provider.

There's updated national drug code and prescription information on the 837 which is valuable for our pharmacy partners. And there's more diagnosis codes on the 837. Many more. And that is very supportive of population health information. As I said, most of these, you can see the value that our stakeholders found in these changes. So let's move to the second slide of our responses.

These survey changes are updates to lengths, element usage. There's addition of the LQ segment for remark codes which is another place to send information regarding the adjudication of the claim. There is a new remark code list and that's used in both the 837 and 835.

The next one, the unique device identifier, is very important. That was requested by the FDA to be able to track devices by their identifier. So far we've had some really good support again for these changes.

The next one is always a controversial topic, but they are used, virtual credit cards, and it's important to be able to attach those virtual credit card payments to the claim that was submitted to the remittance advice that was received. So the virtual credit card payment information will now have a place in the 835. It's been kind of a workaround in the past, and invalid procedure codes that come in on a claim will be reportable on the 835. Again, you can see the support that's received for those changes.

Moving on, again some more changes. New requirements for patient liability in the 835. Source of payment typology code. Support for more DRG types, ability to report corrected priority payers, which has been a pain point; updated reversal and correct process. Again, this has been a pain point for many receivers of the 835, and updated overpayment recovery process. Those last three have been a pain point for a while. Noting on the multiple corrected priority payers, well, actually that and reversal and corrections. We can do a little bit of education, and I think we as WEDI will take that back and look at doing some education as these guides move forward, our remittance, advice, and payment workgroup will look at those to help educate receivers on those two topics.

To summarize, each of these areas allowed input of comments. So our respondents were able to give us some of their thoughts. We did see a general concern about the cost of the externalizing the code sets and the TR3 updates themselves, or the TR3s themselves. 5010 was the first time that the implementers of the HIPAA transactions had to pay for TR3s, which are the implementation guides. There continues to be a concern about having to pay for the implementation guides, and they are charged for them.

They have support for the updates, as we just saw in the previous three slides. They support them to ensure that they're meeting the evolving of the industry.

The stakeholders feel that they will not move to the new version without a federal mandate, and because of that, they won't spend time fully evaluating the changes. They do feel the updates will provide more detailed information for the payers to adjudicate the claim and to the providers on how the claim was adjudicated. So they are supportive of that.

They are concerned that the changes will be expensive to implement, but that's based on experience not on analysis, and they do feel the changes will allow submission of information without the need for note segments, that's an NTE segment, or supplemental files or other workarounds. They feel that this will increase automation.

So, the impact, and this is where it became a little bit more difficult. This is where we are asking -- this was a question: do you feel that there's -- what the cost is compared to the value. We asked it based on different pieces of the implementation process, and you can see that there's not one specific strong trend here. So did they feel that there's lower cost and high value, medium cost and moderate value, so it's middle of the road, high cost low value, to any of these pieces, and I think that this lends itself to the understanding that understanding the cost is just not known at this point, and I'm not speaking on behalf of myself, but my own sense as a payer was exactly that we can't do the analysis ourselves until there's a mandate, because in the payer community, we don't get funding to do analysis and it takes funding to do analysis.

Many of our responses in the summary of comments for this section would have placed this at high or medium cost, but high value, and a downside of those responses, we did not add that as

an option but should have. So they feel that it is high to medium cost but there is high value. So they added that as comments.

There are concerns that vendors may not be prepared to handle the changes, and for so many in the industry, they are very dependent on those vendors to handle those changes for them. There's a concern that costs and staffing will be dependent on the implementation timeframe that's allowed. So the timeframe may drive the cost. If there's a shorter timeframe, it will increase the cost. And there is a high concern about losing the opportunity; as this goes longer, the guides may become outdated.

So, in summary, the respondents feel that the version update is long overdue. The implementation of these standards sets the stage for a regular cadence of transaction updates that would be beneficial to the industry on an ongoing basis but would be much less disruptive. This would then become a process rather than an event, but we need to take this big bite in order to get there.

Moving to a new version would keep the payer costs lower, would result in more affordability for members, because payer costs are reduced, and general administrative simplification would be achieved.

The costs and support of upgrading to a new X12 version, people also feel, the cost and effort of upgrading outweighs the benefits of the upgrades, but this will always be true unless we can get to that incremental upgrade cycle instead of entire transaction versions.

The majority of the survey respondents felt that the changes outlined were moderately to highly beneficial. They clearly indicate a need for additional education on what's being proposed. Regarding implementation time, the majority responded for 2 years or less, but there were significant responses for 1 or more.

Vendor dependency was called out as an impact to implementation time, which I think we already talked about. A strong majority favored having interim milestones during implementation rather than a single deadline.

Overall comments reflect support of the upgrades to get to a point of regular smaller upgrades to prevent costly workarounds and to meet evolving industry needs in a more timely manner.

Any questions?

Michael Cimmino: I just want to reiterate that we felt that it was important for WEDI to provide kind of this larger picture of what they were able to capture from industry regarding the perceptions on 8020, and again, this effort is really relevant and important, given the regulatory efforts and the HIPAA modernization work that we're undertaking. So just wanted to add that. But thank you.

Tammy Banks: That was going to be my first question, Michael, is kind of the background on what your department is doing in regards to this activity and is there an ask for NCVHS or is this just information for the industry?

Michael Cimmino: Again, I think it's just information sharing that we feel is very important.

Tammy Banks: Anybody have any questions for Michael or for WEDI?

(No response.)

I'll pass it back over to Naomi.

Naomi Michaelis: Thank you so much for joining us today. We are now going to take our lunch break; because we are running behind, we're going to go with we will resume at 1:25 for our update on standards.

(Luncheon Break.)

Update from the Subcommittee on Standards

Tammy Banks: I just want to thank the Standards Subcommittee for all of the great work that they've been doing. I always try and do a little bit more than we probably should and these individuals, Steve Wagner, co-chair, Jamie Ferguson, Michael Hodgkins, Lenel James, all put in that extra time in order to bring the work products for NCVHS review.

Also, as always, we can't live without Lorraine Doo and her expertise and really appreciate Lorraine as well as Naomi, really enjoyed the transition with Naomi, Sarah, and Shirley and the rest of the staff. So we appreciate you. We wouldn't be here, again, without all of everybody's efforts.

So the Standard Subcommittee or Subcommittee on Standards report, what we'll hopefully accomplish today is, number one, we'll briefly talk about the work plan, just to refresh everybody's memory on where we're focused moving forward.

Just a quick review of the full committee educational sessions, and as Naomi mentioned in the agenda, we're going to talk about two draft RFIs today and review where we are in that stage and what our expectations are, as well as the next steps.

So as we talked about before, NCVHS as a full committee put together a backgrounder really focused in on what are the issues at large for NCVHS. I'm going to speak directly to the standard piece of that effort. We took a look at the background work that was done by our predecessors, the predictability roadmap, convergence 1.0, 2.0, to come up with the next stage which we call data modernization 1.0.

That focus really is based on the premise that the regulatory process established under HIPAA needs to evolve to meet the current emerging business and clinical needs, that there really is a need to modernize the HIPAA transaction standards adoption framework, enhance the privacy and security requirements which you heard about yesterday, and harmonize clinical, public health, administrative, financial, and other standards.

The need really comes from that we were looking at so many different areas that health information passes now, it's not just between the physician, the patient, and the payer, and that we really need to end up with a comprehensive, well-integrated set of standards across all of health data, from public health, state, territorial, tribal, local government, as well as our traditional exchange of healthcare information.

Again, when we look at interoperability, we're looking at interoperability from a semantic, syntactical, and structural interoperability so that it truly meets the business needs of all of the endpoints of the data being exchanged in addition to the privacy and security.

So our vision is to get to that standard data capture and improve availability of data across, again, that whole ecosystem that I was talking about, to support the expansion of healthcare into wellness, the health policy, healthcare quality and safety, as well as all of the increasing use cases that are being presented, that is a little bit different than when HIPAA originally began.

So with that in mind, the four topic areas that we gleaned out of that background or that we talked about is, number one, always ensure that HHS and other department alignment that the

projects that are coming out support the work that is being done or are thought-provoking to assist with that work moving forward.

We're also looking at examining the mature and emerging standards. How do they coexist? With that first step that we're looking at is going to be the RFI that we're going to talk about in regards to exceptions from standards.

The third one is to review the relevance of HIPAA in the current healthcare ecosystem. The other is harmonization of standards and data requests which Steve will jump on and go through where we are in that project.

Real quickly, those of you who weren't on our April 11 to 12 session, we had three educational sessions, standards for SDOH data elements, value-based care, models versus fee for service, and TEFCA gave us an update on their common agreement.

I'm just going to go through three slides real quickly that include the presenters that took their time out to share their vast knowledge. These are very informative sessions. If you haven't listened to them, please, go to the NCVHS website. You can get access to the slides, as well as the video for the sessions.

But the standards for SDOH data elements, as you can tell, we are still having the conversation. The session at the end of yesterday that Val and Privacy and Security Subcommittee came in really delves into a lot of the issues. One of the things on our work plan is to delve into the collection of SDOH and will be continuing to have those conversations within the work group.

This one was very thought-provoking and we appreciated the takeaway that we put into our work plan, it's really again to understand what I said before, how does the coexistence of the mature and emerging standards work together? I think Erin from CAQH made some very good comments about how the existing standards can support some of the data exchange that's needed.

We know that a lot of the value-based care models are based on the new HL7 FIHR API transactions. So again, those are continued conversations on where we go from here, recognizing the investment that's been made in the industry, and how the new and the mature may work together.

The common agreement, we continue to appreciate the work of the trusted exchange framework and are really keeping the pulse on the administrative side as the administrative and clinical data merge and converge and the use cases merge and converge. There's a lot of interest in understanding, again, how everything is going to coexist. So our subcommittee is also monitoring that as well and appreciate the presentations and the vast expertise of these panelists.

What I'm hopeful to achieve in this section of the presentation is I really want to give a background for those of you who may not be familiar with the request for exceptions from standards, as well as I'm going to be bringing up our RFI questions.

What we're sharing with you is not a total vetted question and answers. It is the questions that we felt would bring enough information in order to help assist the National Standards Group as well as HHS in figuring out how does this process fit as we look at, again, the changing dynamics of standards moving forward? So remember this is not well-vetted, it's not a final work product, it's just to gain everybody's expertise into these RFI questions, as well as educate the industry and ourselves on this process.

I'm going to be looking forward to Lorraine and Michael and others keeping me on track with the correct terminology and the correct process as we go through these.

So what is the exceptions from standards to permit testing and proposed modifications and why is it so important to NCVHS and the industry at large? So 28 years ago, so it's been just a little while ago, this process was created. The reason it was created was to find a way to exempt organizations that wanted to bring forward new or emerging standards that may serve the same purpose as existing HIPAA transactions and code set standards.

I think the easiest way to understand this process is we have an X12 278 prior auth transaction that providers can send to health plans, and they're required under HIPAA to respond to that transaction for the prior auth use case. Recently, we had an application for the exemptions from standards to permit testing and proposed modifications for a prior auth transaction that's based on the HL7 FIHR API technology or syntax or whatever.

The point is, in order to put in for a test or get an exception to the enforcement under HIPAA for the prior auth transaction, this process was created so that there could be an exception. This could be tested, and it could be determined if there was value in revisiting the use of the prior auth transaction.

So when we go through this, just think about that scenario as I go through what that approved application went through and what is the end result, because the importance of this to NCVHS is we took a look at the claims, the ERA that WEDI was explaining that they did their survey on, and we provided recommendations to the Secretary in regards to those transactions.

That's one process where the designated standard maintenance organizations, which we'll talk about a little bit later, will create or update a standard, and then they'll go to a designated standard maintenance organization which is all of the different standard SDOs and determine if that standard is ready to come to NCVHS to be reviewed, and then those recommendations go to the secretary and then the process is in place for regulation.

This exception from standards to permit testing and proposed modification is independent of that process. So this is any organization out there who wants to test a standard that may serve the purpose or function of a HIPAA transaction, can utilize the standard. Now, there's not that many HIPAA standard transactions, so this is not something that would be used frequently, because there's always seven or nine different HIPAA-designated standard transactions.

So that sort of tries to set up the stage on why we care, because if a standard goes through this process, there are a lot of open questions on what would happen when this exception is completed. So let's go to the next slide and continue this conversation.

So an organization may request an exemption from the use of a standard from the Secretary, remember that would be from the HIPAA-mandated standard, to test a proposed modification. The purpose is to test whether that modified standard is an improvement to the current standard and increases the efficiency and effectiveness of data exchange for electronic administrative transactions. So an organization feels there is a better alternative way, and they ask for a group of people to test that in order to make that assumption.

The process this organization would need to go through is they need to request it. Then they go through the basis for granting an exception. The Secretary will make a decision on it. If approved, the organization is going to report on test results in their specific listing of what needs to be included in those test results, and then if that's approved, then they also have the opportunity to request to extend that use.

So the request for the exception, what that includes is an explanation of how the proposed modification would provide that significant improvement, the specifications of that modification, how the organization intends to test the standard, and then agreements, written concurrences from the trading partners.

Then assessment occurs, whether the modification does indeed represent a significant improvement and the extent and length of time of the exception testing, and then when the exception may be granted, there are consultations that occur with designated standard maintenance organizations and that could be with HL7, X12, NCPDP, which would be more of the standard bodies, or the code set organizations, as well.

Then when the Secretary makes a decision, what the Secretary provides back to the organization is the length of time for the exception, approve the trading partners and geographic areas that would be participating, and then the other conditions for the approval. Within 90 days of completing the testing, then the organization submits the results, the cost benefit analysis to the Secretary.

When that exception test is completed, they can ask for an extension of time for those who are participating. It does not mean that the standard will be adopted. There is the option if they choose to work with the DSMO and submit or request that it be considered to be mandated under HIPAA. That is an option. It is not required. They can have an extension of time, and then they keep the same conditions of the testing and continue that testing.

But in the guidance that HHS is given, it's said that it is expected that a successful test conducted through the exception authority and resolved in a comprehensive and compelling data would facilitate the movement of modification through the DSMO and the processes put in place.

Now, with the exception process, there are 10 principles that the organization needs to provide evidence of, and this is included in the testing results: that it improves the efficiency and effectiveness of the healthcare system, meets the needs of the health data standards user community, has low additional development and implementation costs relative to the benefits, and there are additional ones that you can read at your own time. I just highlighted the key ones.

Timely development testing implementation and updating procedures, so that it achieves administrative simplification benefits faster, minimum data collection and paperwork burden,

incorporate flexibility to adapt more easily to changes to healthcare infrastructure and information technology.

So each of those gets determined by the organization on how they respond to those elements within the testing of it to determine the value so the Secretary can determine the value and the impact of the new standard testing. There have been three uses of this process, one for an alternative code set, one for the use of a UDI in planes in one state, and the recent use of the API for prior authorizations.

So HHS has requested that we look at publishing an RFI to obtain industry input on this process. So you're going to see the question set that we currently have developed and really want to, again, get your input to make sure that we've covered all the areas to gain the information so that NSG and NCVHS will have the information to be able to develop more meaningful recommendations to HHS to potentially improve this process to make it more usable moving forward as we're seeing the change in standards down the road.

The request is, again, obtain information from stakeholders to inform our recommendations to HHS. We feel that participants will be HIPAA-covered entities and other interested parties, and we're hopeful to submit this RFI to the Federal Register by the end of the calendar year.

So the way we took a look at this is we thought about the process. The first step for the process is the instruction guidance. Is it clear, is it not?

Then we took a look at questions for the application process itself. So if you choose to move forward, do you have the information you need to complete that application, and does that application support the end result to get the information to the Secretary to make a decision yea or nay?

Then the exception process implementation, so the implementation of it, gathering that information on if it's burdensome, if it's not, if it can be easier, and then taking a look at that exception process overall. Then approved exceptions, what are the next steps? So if an exception is approved, so you as an organization put in for an exception, you run this test, what are the options? What can happen? What should happen? Should there be a list of those transactions or code sets that were approved and went through this process and it can be voluntary used? There are a lot of things to think about.

What's the next step? Because, again, how do we know when something has a value? We already know the difficulties of cost/benefit analysis. Is any of these process steps or exception questions a way to get that information? Those are some of the thought processes to think about. If it is approved, and the testing goes through successfully, what are the options? What are the next steps?

Then the last step, as we said, testing of standards outside of the exception process. Now, what would that mean? So we have the testing of standard through this pilot process, but what about outside? So right now, the way the testing of standards occurs is HL7 has connect-a-thons for their standards; what kinds of testing is available outside this type of process?

Now, I know that was a lot of information, especially for those of you who aren't in the standard industry, not in the weeds, so to speak. Are there any questions or anything I can answer to try

and clarify this a little bit more before we go into the questions, what information we're trying to gather and why? While you're coming up with questions, I can pull up my RFI if that's all right.

The first questions that we came up with, to better understand if the instructions and guidance are clear, is are you familiar with the exception process under HIPAA which permits an organization to request an exception from using a standard to test a proposed modification to that standard?

Then the second is, if yes, is the information clear and understandable, or is there additional information from HHS that is needed regarding a process for applying for and executing an exception from the standards to the permit testing of a modification?

Are there any other types of questions that we should add? Again, I just want to add the caveat, these will change. These are not final. We just want to make sure we pull the information needed that's valuable. They may be condensed. They may be merged in the future working with NSG and their team as well. But does this pretty much capture the question on is there enough understandable instruction and guidance available?

Any comments? If you have questions, just happy to answer any questions, too, if this doesn't make sense. Michael, you always have a good question.

Michael Hodgkins: You have done a very good job presenting. We've gone through this document a bunch of times as a committee. I don't have any questions.

Tammy Banks: Great. I know the privacy and security and at large folks haven't been on those calls, so I want to capture their information, as well.

Naomi Michaelis: I do want to pose the question, if they're not familiar with the exception process, they're not going to proceed. So do you need that first question, or can you merge it with the second question?

Tammy Banks: Or we could take the first question and say, if you're not, refer to whatever other sections we'd like them to look at. Really good point.

Michael Hodgkins: We've been looking at this so much, we forgot the obvious. Thanks, Naomi.

Tammy Banks: Okay, then exception process application, I think a lot of these first ones just kind of make sense when we get more into the thought-provoking ones. But again, Val and others, I just want to make sure that this makes sense and gather your feedback as well.

If you have experience with HIPAA exception process, what went well in your experience and what did not, please provide details in your response. For those who have considered filing and chose not to, what are the reasons? And if there was funding available for completing an exception process, would that increase participation?

Valerie Watzlaf: I am just wondering if you can prompt them at all under some of these. Are there certain areas under there that you specifically want them to address? I'm just thinking of what we did, I think with the ICD-11 one. If there are ways that you can give them a little more

prompts, but I don't know. Is that something that you could do under part three? I'm looking at that under the application.

Tammy Banks: That is a really good point and something that we discussed in the subcommittee because we didn't want to steer the answers because we really wanted to put trading partner agreements, we wanted to put all this other stuff in, but we were afraid that if we do that then we're going to steer it.

Valerie Watzlaf: You know what I mean, you could have other, additional, something like that. I'm just wondering if you will lose it. You won't get enough that you're really looking for, that's all.

It looks great, though, and you did do a wonderful job. I really am thinking I'm getting this. You did a great job explaining it.

Tammy Banks: We'll consider debating that, because we know the people who have gone through, like three organizations have gone through, they're going to know. They went through it, they're going to know what were challenges, what were not. So that's the teeter-totter we keep going back and forth. We'll keep this to continue to consider.

Okay, process implementation, the application is to process written concurrences from trading partners who would agree to participate in this test. Basically, we're trying to get more information on that specific issue, because we know that that was raised in the past. So that was where we did consider listing the specifics about we broke that out as we know, we have heard that that has caused issues.

Sarah Lessem: I think number three, this is just something that I'm observing, I'm not necessarily going to correct or change it, but the first one is the you, so if you have experience with the exception process, what worked well in your experience? The next one is a little more hypothetical for those who have not considered filing for an exception but chose or have. Do we want that to be if you have not or if you have considered but chose not to, what is the reason you didn't file. The difference is one would include maybe hearsay, like all of my colleagues told me that, and the same for the third one. Like what would increase their participation versus what would increase your participation.

I just think it's something to think about. Are we asking specifically what their experience is, or are you asking what you think the industry thinks? Does that make sense?

Tammy Banks: I am so glad that you volunteered to go through this and put it in that same voice.

Sarah Lessem: I'll do that after the content there, but just something to think which is it we're asking?

Tammy Banks: We will put that on there when we go back and get that revised. Very good point.

Michael Hodgkins: Listening to Sarah's comment, I guess I'm also wondering now do we want to specifically only ask if funding was available, would it increase participation, or do we want to be more general and say what would -- these aren't the words, but what would it take to get you to

participate? Funding obviously might be an example of that, but is it the only example? I don't know. Did we want to be as specific as only focusing on whether there was funding available? I'm asking; I'm trying to remember --

Tammy Banks: I don't have any answer, Michael. It's a very good question, because funding was mentioned as needed, right? And who knows what source type of funding.

Michael Hodgkins: We could offer funding as an example, but I guess I am wondering if we're being too prescriptive by not making it more open-ended in terms of what might cause you to participate; an example could be funding but there could be other reasons.

Lenel James: Tammy and Michael, the other thing that it could be could be in kind resources, because I believe the process of doing this is technically challenging, but whether it's HL7 or X12 or some other resources that might be able to help with that process, that might be another, and maybe there's some federal agency resources that can't give you money, but they could give you some --

Michael Hodgkins: I mean, funding is an obvious one. Just resource constraints is an obvious one, you're right, Lenel. And where might they find those resources outside their organization? I just think certainly some organizations are just resource limited. So they're just never going to participate, and funding actually wouldn't solve that problem, because they're not going to hire a bunch of resources just to do that.

Lenel James: Let's not forget we're talking about an exception. So someone's familiar with X12, using HL7 or using a different approach, they may not have the resources to understand and learn that approach, but if someone or some group would help them get up to speed to be able to understand and use that technology, that to me is one example of the kind of in-kind resource that's feasible. Many of the standards bodies have training. So maybe there needs to be some training so that they can do the exception and maybe that training could be provided without it being a low-cost or some kind of discount.

Michael Hodgkins: I think you're onto something, because it seems to me that it's only the heavy hitters that are going to participation in the exception process because of the complexities, and I guess it begs the question would smaller players seek exceptions if they only had -- if they didn't have the resource constraints of a small organization?

I don't know, Tammy, are we creating too much chaos here?

Tammy Banks: No, I think this is really good, and I think we have enough here so we can continue that debate.

Any topic areas or any type of subject matter response do we want to get in those sections, or have we captured that? And we're just thinking high level, because we're going to go back and wordsmith and get survey experts and all the other good stuff, take a look at this. Pulling the content out is what's important for us. I'm sorry to give you an assignment there. That was really good.

Okay, let's look at the impact. So is the exception process to test a modification to a standard an effective policy tool to update HIPAA standards, and this is to understand is this process as a

whole, is it meaningful to getting to understanding what standards could possibly be used to update the HIPAA standards or, again, work in collaboration with the standards. That's the stuff that we're trying to pull out. If not, what other policy tools might HHS use, and remember, the Standards Subcommittee said in the recommendation that we really needed to have criteria for the cost benefit analysis. Is this process a place to pull some of that criteria? Those are the questions, the impact of this process, on HIPAA standard transactions overall, how meaningfully is this, when we look at it from that lens?

Nine is for what other purposes might the exception process be used. I'm just going to throw something to help you guys -- this is all to be thought-provoking. This is not -- that's it.

If we had more than one standard go through this process and be approved for different reasons, is it something that we would want to have a listing or merge it with the ONC listing of standards that it has been tested and has been vetted, and if the Secretary would approve its use in a certain area or whatever reason, is that something -- would that help be another step that we don't have today that may be helpful as people are moving forward looking at mature and emerging standards? What would prohibit that? Is that something needs to be looked at? Is it not? These are just all thoughts to think about, right? How to make this more effective and user-friendly for its intended purpose.

Michael Hodgkins: This is probably just me, because I'm not as sophisticated with respect to the whole standards process in general, but I'm still struggling a bit with conflating both new and updated. An exception process seems to me something that you used for existing standard that you want to make changes to. Is the exception process also used for new standards that are completely new that are just changes requested for an existing standard?

Tammy Banks: You raise a really good point. What is new and what is updated? Maybe that's a question that we need to figure out what the definition is. In my opinion, again, just a conversation, this is just for thought, the X12 278 standard versus the API would be -- the API would be a new standard, because it's not just taking that X12 standard and changing a few things. It's a new one. But now, if you would take that X12 278 standard and add -- make a change to that and want to test it, so we have the 5010 version in play now, and you'd want to test the 6030 or 8020, that would be an updated standard that you could test through here. It's not a mandated standard, because it's an updated version, but there could be a test of the updated version as an option.

Lorraine Doo: Tammy, can I just make a little modification? So, no, it's a perfect question. So the exception process, the pilot that's going on now under the HL7 Da Vinci pilot to test the prior authorization API is a modification to an existing adopted standard for that purpose. So it's the prior authorization saying rather than the X12 adopted standard, we have this other standard to modify the existing standard. So it's using this process for exactly what is intended. So to answer your question, Michael, that's what its intended purpose is.

If someone came up with a new standard that they wanted updated under HIPAA, that's part of the question is is something not envisioned? I can't even think of a good one, but some new financial transaction that they wanted here; should they go through this testing process, or would it go through some other methodology to determine whether or not it's a necessary standard to be adopted under HIPAA? I just don't know what an administrative transaction would be that's missing right now.

Michael Hodgkins: Thank you, Lorraine. That's helpful. I guess I just -- and this is just me, because I'm not as familiar, but when I hear exception process, that seems to me something where you're making a change to something and so you're creating an exception. It seems like new standards come out of SDOs, presumably, and don't they have their process before they can be adopted? Or do they go through the same process?

Lorraine Doo: Well, they have their own process for coming up with new or updated standards, and that's what you just went through with the -- an updated version of an existing standard, which is what you did with 8020. But what HL7 has done with the prior authorization API is said we have a different version of an existing standard that has been adopted. It's not an X12 version. It's an HL7 version. And they haven't asked for it to be adopted yet. They have asked for it to be allowed to be tested.

Michael Hodgkins: Which seems to me, but that example seems to me where you are creating an exception. It's just a different way of doing a standard transaction, because you're doing it with an API. So that does seem to be an exception, not really something that's new. Although I can understand how one might interpret it as new, but it's just another way of doing an existing standard.

Tammy Banks: I think we do need to think about defining what new and updated and add clarity, because there's going to be others that are looking at it from different lenses.

Val, did you have anything you wanted, and then I'll switch it over to you, Lenel?

Valerie Watzlaf: You might have said this and I might have missed it, I don't know, will most people know some of these things that you're talking about or could you provide a definition of terms or something that further defines some of these areas? And you could attach that or something, or link it? I don't know. I know you have a lot of links in there, but I still don't know that everybody will read, because I think some of those are pretty extensive.

Tammy Banks: Really good point, Val, and I am thinking some of the conversations that we had is that you have your RFI in the Federal Register, that we would have one laid out a little bit differently on our NCVHS website, and then we could provide those definitions. So it's something that we as a committee will need to talk about, but I don't see why. I think it's going to be important based on our conversations today. Good point.

Lenel?

Lenel James: I wanted to respond to what Michael said about the fact that you've got an X12 and then you have an HL7 transaction in WEDI, and that it's the same business purpose. That's true, but it's a completely different standard from a standpoint of the technology, how you store the data, how you exchange the data. It may be the same function, but it is not the same thing, and that's the whole reason we have the exception. It ain't the same. It looks the same, it acts the same, but to the technology people, it's a brand-new animal that no one understands the mechanics of operations workflow because it seems to work the same to the user, but to the real world of the IT guys, completely different thing, which is why we want to kind of explore what are the barriers to getting exceptions, because these things in a business mindset sound the same, but once you get into terminology, technology, and operational workflow, they're not the same and that's why we need an exception. It's relative painful to figure out how to

implement it and test it to make sure the feds would agree this is a reasonable way to solve the same problem that has been named in a federal rule, but it never named APIs. It named an X12 transaction.

Michael Hodgkins: Lenel, that was very helpful for me, thank you. So what you are saying is it's not an update. It really is new, but it's appropriately treated as an exception.

Lenel James: The same problem, different solution that looks to a businessperson to be, oh, that looks neat, that looks nice, I'd like that. That looks new. Except it's not what the rule approved, and we need to prove that it is as efficacious as people think it is and understand what it really means to try to do it, in a controlled manner.

Michael Hodgkins: That finally gets me over the struggle I've been having with this new and updated differentiation. Thank you, Lenel.

Tammy Banks: Another question, and Lenel, this is kind of based on what you're saying, is when is -- when should a transaction be tested, right? So I'm just going to take a simple one like we did the operating rule, the eligibility, where you can say if a prior auth is needed or not. If you're going to do an API just to pull that type of information, it's kind of a bad example, but should that go through this process so that it can become standardized overall, or those are the kind of questions, right?

Where do you deal with some of these new -- where you just grab part of the information within a HIPAA standard. Is this a process that should be put in place so that it gets done the same way? Or is that wholly independent of this process and we don't even need to think about it? Or things are going to change, how are they going to change is the big question and how do we pull that out?

Lenel James: I think one of the challenges we have is we do -- it's easy to say but hard to do, and right now, the way the exception process is built, it treats everything the same so that you have a relatively laborious process to request the exception, to do the exception, to report on the exception, but in a world with AI and new technologies and APIs, that level of overhead is a thing we want to try to figure out how to make less burdensome for the industry, but yet respect the fact that you do need some paperwork to ask for it. You do need some paperwork to document what you did and how you did it.

But the experience at Da Vinci was doing it between the lawyers and the process and the paperwork and the backend reporting when you were done, that's too onerous right now, but how do we bridge where we are to where we want to get so that this process becomes documentable but doesn't become a real major expensive complex effort. We're trying to find a middle ground so that we can create a process that could work better, because the current one that we've currently experienced to the Da Vinci process isn't going to work if we expect AI and technologies to advance fast. We don't have a fast way to do exception processes.

Michael Hodgkins: I guess I'd love to hear from someone who's been more involved in the whole standards environment than I have. How much of this is inside baseball, and by that I mean is the best vehicle to address this an RFI, or are there so few players involved that it's simpler to just go directly to players and have a conversation? Or is an RFI sort of a requirement just from a process standpoint, and I don't know if I'm being clear.

Tammy Banks: Very good question, because we as a subcommittee debated that, right? Should we have panels, and we invited three sets of stakeholders, but after we kept talking about this and also with input from NSG, we decided an RFI first to really pull out the information of those who considered but didn't forward, because we can't capture that. We know who the three groups that went through this process, so the RFI is a predecessor to get as much information as we know, then develop the panel to pull out more information, because we want to spread that net wider for those who may have considered and didn't do it versus just those who did. So it's step 1 into step 2.

Michael Hodgkins: As a committee member, I'm familiar with that. I guess I am not being very clear. I am just wondering how big an audience there is for this RFI, and might there be a more direct way of doing it? But that might not be permitted under the rules that guide us. I don't know.

Lenel James: Let me state something really quick. Don't forget, one of the reasons we need to do this RFI process is lawyers are in the room. Lawyers are involved on the provider side, the vendor side, the payer side. You don't want to touch anything that's going to involve legal review and policy and law without doing some really careful homework, and the RFI is kind of our way to carefully document everything we're doing so that it's a well-viewed process and no one can claim later they didn't get a chance to get their two cents in.

Michael Hodgkins: Lenel, you answered my question very appropriately, thank you.

Catherine Donald: I was just going to say I think we don't know what we don't know, and it sounds like you want to get to the folks who may have tried and didn't go through with this process to see what those barriers are that some of questions, and so I would say the RFI would be the best way to get to those people who may have tried this and have been unsuccessful or just felt like I don't want to do this.

I also appreciate what Lenel said, CYA.

Tammy Banks: I have 10 more minutes, and then I have to get it over to Steve. So the last couple questions are on next steps. After an exception testing is completed, again, where do they go next and these are the five questions that we came up based on the conversation that we're having today, is there anything missing?

NCVHS understands that approval of an exception report or permission to extend an exception by the Secretary does not mean that a standard tested during an exception process will be adopted and that it does not require the organization or SDO to submit the standard. In your view, should an SDO be required to submit a request to HHS for adoption within a certain period after the test results have been evaluated and approved, why or why not?

The second one is if an exception study has been completed, should such modifications be permitted voluntarily by other covered entities that may include updating their trading agreement? Do you consider an exception from the standard to permit testing of modification to be the same as testing a new standard, and that's again paralleling the SDO process with this process.

Do you believe that the results from an exception project are sufficient to demonstrate that the tested standard should be considered for adoption to replace an existing standard? So again, we're talking about the process, the typical review process through NCVHS, and this is outside that process coming through the exception process into the DSMO and regulatory process.

What other changes to HIPAA statute or regulation are needed to allow for updates to approved standards that may be different than those typically adopted under HIPAA process to promote innovations? For example, ONC regulations support routine updates, tie with USCDI updates, that kind of thought process. Is there any other options that could occur that we should phrase here, or do we catch all the different options based on if an application was put in, it was approved by the Secretary, and then these are the next steps, what could happen after that?

Who has some good thoughts, or did we capture -- we really thought about this pretty carefully.

Okay, with that, then we will take this back to the subcommittee and continue to refine this RFI, but again, I hope that you have a better understanding of what this process is, what it means to us in the review process of updated new standards as well as the industry at large.

So thank you. Really appreciate it.

If you don't mind putting up the slides for Steve, starting at the harmonization, that would be fabulous. Thank you, everybody, for your participation, really appreciate it.

Steve Wagner: So, I am going to start off by having a little overview here, look at background, purpose, goal, project scope, harmonization approach. So giving you information on how we arrived at doing a harmonization RFI. And then I'm actually going to walk through the RFI document itself, paragraph by paragraph, so that we can look at what it actually says, and then at the end I just have one slide related to next steps.

So let's begin. NCVHS has determined that there is a broad industry requirement to modernize the standards adoption framework. This is something that we've worked on the last couple of years or more, I guess, including enhancing privacy and security, harmonizing clinical, public health, administrative, financial and other standards. That's one basic statement.

Those previous committee information gathering sessions have identified harmonization and collaboration issues between standards organizations. They don't always work together as well as we would like them to. They have some overlaps. They have some gaps. They have other things, other issues.

The current U.S. harmonization efforts appear to be ad hoc and somewhat inconsistent. They don't seem to have an actual regular group who support doing harmonization efforts. It's (audio drop) something with somebody else on this area. So let's set up a special little group to do that, and then it disbands and goes away.

These efforts lack a permanent support structure, and such a structure could support and promote timely and efficient harmonization activities, which in turn could reduce the burden placed on health organizations that are required to implement the standards, and that's one of the main things we want to try to focus on as reducing the burden on the implementers. There

actually was a collaboration group under ONC previously, but that has gone inactive at this point in time. So it's one possibility of reestablishing it.

The purpose here for doing an RFI is to identify existing and emerging harmonization efforts related to healthcare standards and data to support interoperable data exchange and the diverse business needs that are out there. The goal here is identifying strategies to modernize the standards-driven information infrastructure across the healthcare ecosystem, in partnership with the key federal and industry stakeholders. An RFI is a very good way to begin achieving that goal and meeting that purpose.

The scope is very broad. This RFI is meant to look at harmonization of standardizations and data across SDOs and across what we call strategic areas, and I'll list those in a moment. So it's really based upon findings that we've had in the past from previous work that we've done that the healthcare industry needs a comprehensive well-integrated set of standards that fully support health information interoperability, and this includes things like semantics and tactical and structural interoperability. It includes data privacy and security, and that includes across your public health, population health, your research, administrative, your remote monitoring, patient wearables, et cetera. So lots of users and lots of products and so forth.

The other thing that we recognize is that this harmonization of standards across standards development organizations, users and state and federal regulatory agencies, will be necessary to achieve the objectives, and we've got to reach out to a lot of fairly broad groups here in order to achieve what we're looking at.

When we look at -- this comes from our strategic plan document that was produced previously -- when we look at harmonization efforts, that we can categorize them into seven strategic areas here. So you have a regulatory framework that has to be there, that's mainly handled by HHS and NCVHS and ONC. You have information and data elements, the terminologies and code sets; security/trust framework; and the data privacy; and then you have an information exchange framework. These are all the different exchange formats and things that are used by the different SDOs.

And then you have a common standards development and implementation methodology, which would be very beneficial to harmonization. Right now we don't really have something like that. It's very much each SDO kind of does whatever they want to do based upon their own stated requirements and so forth.

So the rationale here for the harmonization RFI is to gain information to assist NCVHS in making thoughtful recommendations to HHS on the current and future process for harmonization of standards and data, and our target groups are all the standards organizations, the standards-specifying agencies, private and public, and their efforts to coordinate and collaborate with other standards organizations to harmonize standards and data, and the implementers and the challenges or potential opportunities they have when implementing new or updated standards.

At this point, what I wanted to do is actually walk through the harmonization RFI document. So the first three sections or paragraphs in here are basically boilerplate that the staff pretty much takes care of. We've reviewed those and left some red highlights for the staff to actually fill in once we've completed the rest of the content for this document.

So the purpose of this RFI, we've pretty much identified some of that in stuff that I covered in the slides, so we want to identify existing and emerging harmonization efforts. We want to look at strategies to modernize the standards-driven infrastructure. We want to -- the healthcare industry, again the statement that we have in a number of documents, needs a comprehensive, well-integrated set of standards that fully support health information interoperability, data privacy and security across public health, population health, state/territorial/tribal/local government, research, administrative, and clinical systems. Harmonization of standards across these SDOs, users and state and federal regulatory agencies will be necessary to achieve the objective.

I'll stop there. Is there any feedback or questions related to this section? The purpose.

Lenel James: So far so good.

Steve Wagner: So part of this I also covered. The previous committee information gathering sessions have identified harmonization and collaboration issues. The current harmonization efforts appear to be ad hoc and inconsistent. These efforts lack a permanent support structure. Such a structure could support and promote timely and efficient harmonization activities which in turn could reduce the burden placed on the health organizations that are required to implement the standards.

There's a footnote here that I'll get to in a moment. Actually, let's go down to the footnote and then we'll come back up.

Okay, so as I said, there was a previous group, this Health Standards Collaborative, which is no longer active, that was doing some previous harmonization of standards and data activity. It was an all voluntary group. They had appointed someone, and they had to step down almost immediately after they were appointed, and then they weren't able to get another volunteer, and so they just basically inactivated the group at that point.

We have just received comments from ONC a few days ago, and one of their comments was that they wanted to add some information here to this footnote. So we had that -- we still have -- USCDI is an existing activity that supports harmonization efforts, and they wanted to add, expand that, and add a little more information about the USCDI ONC expanding its name out to the New Data Element and Class Submission System that supports a predictable, transparent, and collaborative process, allowing the health IT community to submit new data standards and classes for future versions of USCDI. So we added that in there.

So is there any comments so far on that portion?

(No response.)

No. All right, so let's look at the request for information. This notice serves as a request for information. The committee is interested from hearing from standards organization and standards specifying private and public agencies about their efforts to coordinate and collaborate with other standards organizations to harmonize standards and data. The committee is also hearing from implementers about the challenges and potential opportunities when implementing new or updated standards. The committee is interested in any harmonization efforts related to the following areas.

We had identified seven strategic areas where harmonization needs to occur. Two of those, we didn't feel needed to be in this harmonization RFI, because we're looking at things that are very broad, high level here. But the most important ones are the ones that the SDOs primarily are responsible for, and those are things such as information and data elements; terminologies and code sets; security and data privacy; information exchange formats; and methodologies used to support harmonization efforts.

So we're specifically looking for them to provide input at this level, at a high level, on these different areas. And the committee is also interested in hearing from standards organizations and implementers about -- if you could scroll up, that's right. Okay, so whether the coordination and collaboration efforts are temporary ad hoc efforts or continuous efforts. The advantages and disadvantages of having a group or organization that could support continuous coordination and harmonization efforts. Any recommendations concerning an existing group or organization, government/nongovernment, that could support continuous coordination, collaboration, and harmonization efforts across standards organizations, and what subject matter expert member composition would be needed to support successful harmonization efforts.

And whether there are any current or innovative tools or technologies available that could help reduce the level of effort to harmonize, such as map, convert, standards/data or identify where harmonization, mappings, and conversions should occur, and what NCVHS can do to help with coordination, collaboration, and harmonization of standards and data. Anything that they can think of that would be beneficial for us to do that falls within our realm, of course. So those are the basic things that we are -- high level things -- that we want them to think about and comment on as they go through, and then we have a little more specific questions down below.

Before we get to those specific questions, is there are comment on the other section above?

(No response.)

All right, can we scroll down to where it says questions for implementers? So we have divided the groups of organizations that we're hoping to receive comments from into -- it was four groups. It's now three groups. One was implementers. One was standards-specifying organizations, and you can see that that portion is all struck out, because we removed that based upon comments from ONC, which we found out were quite appropriate in that the government organizations who were the ones who really do the specifying here, such as NIST and CMS and ONC, don't actually report or reply to Federal Register requests. They are the ones who originate them. They have the ability to simply speak directly with each other and don't have to actually reply to these things, and they said ONC made the point that they probably won't get any comments from them.

So the better way to do that would be to have some educational sessions after we get the feedback from the RFI and pull in those standards-specifying organizations, government agencies, and get their input at that point. So that was just deleted out.

The other thing they said was we should probably ask for comments from these other groups, the implementers, the SDOs, and the terminology developers, about -- and you can see in red what they recommend we add, what should the role of federal agencies in regards to harmonization of standards and data efforts?

So the questions we have here, besides the one we added for ONC, for implementers are: are there challenges or potential opportunities when implementing new or updated standards? What are you currently doing to address the challenges you encounter, i.e., harmonization, testing, mapping, or other challenges? Are you pursuing specific opportunities? And what are your highest priorities that would positively improve efficiency and reduce costs?

Any comments on the questions for implementers or removing the questions for the standards specifying organizations?

(No response.)

Well, I'm sure somebody will figure out a question here.

Let's scroll down, see if we can fit in the last few here. The other two organizations out of the three that we're doing are questions for standards development organizations, so these are the HL7, X12, et cetera. What are the incentives and challenges for organizations to work together? What are the existing points of coordination/current activities? What mechanisms might increase efficiency and reduce work across standards organizations? What do you hear from the end users about compliance challenges when implementing your standards? And of course, the fifth question which ONC wanted to add to all of them: what should the role of federal agencies be in regards to harmonization of standards and data efforts?

Any comments, feedback on that portion?

(No response.)

We've already gotten comments from the standards subcommittee. So I think we had some input from the security and privacy. But these are at high level, so we're not actually trying to get down into specifics about security and privacy versus other kinds of standards and so forth, looking at standards as a whole here.

All right, let's scroll down to the questions for terminology organizations. For the terminology organizations, they're basically very similar to the SDOs, because the terminology organizations are developing terminologies, and they become standards, and most of them end up being specified by ONC and the USCDI. So again, what are the incentives and challenges for organizations to work together? What are the existing points of coordination and current activities? What mechanisms might increase efficiency/reduce work across your standards organizations? What do you hear from end users about compliance challenges when implementing? And what should the role of federal agencies be in regards to harmonization of standards and data efforts?

Anything else that we should add here?

Naomi Michaelis: Steve, I actually have a question. Can we identify nongovernment agencies in our examples? Because right now you have three different government agencies.

Steve Wagner: Well, AMA is not government.

Naomi Michaelis: Right, but NCHS, NLM, and CMS are all government.

Steve Wagner: Yes, they are. Well, we can eliminate them if we wish. Probably would be an idea.

(Cross-talk.)

Steve Wagner: ADA does something and mental health area does some terminology, I believe. So yeah, we can find at least a few others that we could add here and eliminate the government ones.

Other suggestions? All right, if we could go back to the presentation at this point, and go to the second to the last slide.

Tammy Banks: Slide 50. Unless you want proposed questions for others.

Steve Wagner: There we go. So, once we've published this, and we hope to have it submitted to the Federal Register at least by the end of the calendar year, possibly fairly soon, how long it will the Federal Register to actually publish depends on how much of a backlog they have and things of that nature. So we don't know. Might be towards the end of this calendar year, beginning of next, we'll see. But that's the next step, and the compiling the RFI responses after the period of time for responding is closed, consider them together with input from subject matter experts. We very likely will hold education sessions afterwards, especially for federal agencies that we want to receive more specific input from mostly likely on terminologies and on the actual standards development. That is our next steps so far.

Any other feedback or questions?

Valerie Watzlaf: Steve, great job with this, as well. You have, I was just going to -- I think your previous slide back up? I just wondered how, who will compile? Who will do the compilation of the responses? Will that fall on you guys, or will you have some support there? It seems like a lot, for both of them.

Steve Wagner: We expect that we would be doing this since we're the ones technically issuing it, but we're happy to have other participation.

Tammy Banks: We are under discussion to see if there is or is not resources for those. Like, when we did the other RFI with the standards group we had, Lorraine had an organization that was able to do that through the department. We're unsure at this time.

Steve Wagner: We could try out AI.

Valerie Watzlaf: Thank you.

Tammy Banks: Val, you made a really good point about timing and that we really need to make sure there's enough of a response time. Now, what timeframe did you think was enough? Because I know you had a shortened timeframe with your RFI. Ninety days?

Valerie Watzlaf: I think what we did -- I don't know, and Jamie might be able to know exactly what we did for ICD-11. I think it was -- did we do 60 and then we extended it to 90? I'm not positive, but I think when we did the first one, we didn't have enough time. So we can check that for you and make sure.

Jamie Ferguson: On ICD-11, the first one was cut short. It just took too long to get through clearance or something like that, but the second one, we made sure we had the full 90 days, which I would recommend the 90-day period. I think it gives people time to put together thoughtful responses, and I don't think this is -- these aren't really timebound RFIs right now, are they?

Steve Wagner: All right, last slide again.

Tammy Banks: We're just going to do a quick summary, Steve, just again, I always like to remind people to go to our NCVHS website, access the meeting summaries, educational presentations, work products, all this is here for you to also glean and gain expert information as you are able. So thank you, full NCVHS committee and staff for helping us work through these RFIs. Those are the top priorities on our workplan as we continue to gather information to made educated recommendations and thoughtful recommendations to the Secretary.

Any questions, additional questions on other topics for standards?

Then please note, we are early. We typically run long. So I'm not sure where you want to go, Naomi, since 3 o'clock is public comment.

Michael Hodgkins: I was going to say, you know, this particular RFI, this topic, just seems such great importance, and I certainly would echo giving 90 days so that we get the broadest possible input. But this is moving the needle, I think, to have this RFI and to hopefully we'll get some very robust responses. Where it will lead us, who knows, but we've got to start somewhere. So I just wanted to express my appreciation as a committee member.

Naomi Michaelis: Thank you. Thank you, Tammy and Steve and the Standards Subcommittee. Having sat on many of the meetings where these RFIs have been discussed, they've come a very long way and it's very impressive to see where they are now.

So we are running a couple of minutes early, but because we did say it was approximately 3 o'clock would be the public comment period, we're going to get started. So please raise your hand. We can unmute you, if you would like to speak during public comment.

Again, a reminder, you can also send comments at any time by email. I see Stanley has raised his hand.

Public Comment

Stanley Nachimson: Thank you. I wanted to address my comments particularly on the ICD-11 work that the committee has undertaken and just to let you know that I've been appointed as the ICD-11 subject matter expert for X12. So feel free to contact me for any information you might need from federal organization. To let you know, we've already begun looking at how to incorporate ICD-11 in our standards and some of the work to see which standards would be impacting and what potential changes we might need to make.

I did want to suggest that in the analysis that you continue to do that you include the impact on all of the interoperability standards in your research and what changes and the time for making those changes have to be done to accommodate ICD-11 and all of our data exchange standards.

Jamie talked a lot about the impact analyses and education for the industry, but just a reminder that it's hard for a lot of organizations to begin their impact analysis and even participate in education first until more of the final decisions on the U.S. linearization are made, but even more importantly, that there's a much better idea from the Department of HHS what the final deadlines would be or frankly if there will be that move to ICD-11.

I understand all the work that you're doing, but there just as was mentioned in the discussion about the upgrade to the X12 standards, many organizations don't pay attention, many vendors don't put the resources into their work, until there are proposed rules or even final rules from the department. So that's an important consideration in figuring out the timing for implementation and the work that needs to be done.

And just one additional suggestion, that the coordination of the ICD-11 implementation with some of the other medical code sets like CPT or ICD-10 PCS, with the understanding that these are not diagnosis codes, but they're procedure codes, but they work hand in hand, so I think it's important that any impact on those other medical coding sets be considered as we move to ICD-11 and what information that's included in them may not be necessary to include in ICD-11.

So just a couple of items there, and I appreciate the opportunity to provide my comments. Thank you.

Naomi Michaelis: Thank you so much.

Janice Karin, your line is open.

Janice Karin: Hi, this is Janice Karin from the Massachusetts Health Data Consortium. I just wanted to thank you for the efforts on the RFI on the HIPAA exceptions and to comment that we actually are an organization that looked at doing an exception and decided not to, and we would welcome the opportunity to comment on that RFI and provide our feedback on our thoughts on the current exception process and ways that it could be improved. Thank you very much for your time.

Next Steps & Wrap Up

Naomi Michaelis: Thank you so much, Janice.

If there are no more comments, we will wrap up for the day. I once again want to thank all of our NCVHS committee members and our staff, Sarah and Maya, Lorraine, Grace, Marietta, and Shirley, for all the work that they have been doing in front of and behind the scenes to help getting everyone prepared for today. I want to especially thank our team at RLA, Ella, Mike, and Greg, for making sure everything has run smoothly today.

With that, we are officially adjourned.

Michael Hodgkins: Thank you, Naomi. Let's not forget you.

(Whereupon the meeting adjourned at 3:00 p.m.)