National Committee on Vital and Health Statistics

Transcript
November 29, 2023 10:00 a.m. – 5:00 p.m. ET
Virtual

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Jacki Monson	**Sutter Health**	**Chair**
Sharon Arnold	**DHHS**	**Executive Staff Director**
Rebecca Hines	**NCHS**	**Executive Secretary**
Angela Alton	City of Hope	Member
Catherine Donald	Alabama Department of Public Health	Member
Debra Strickland	Conduent	Member
Denise Chrysler	University of Michigan	Member
Tammy Feenstra Banks	Healthcare Consultant	Member
Jamie Ferguson	Kaiser Permanente	Member
Michael Hodgkins	Healthcare Consultant	Member
Richard W. Landen	Individual	Member
Valerie Watzlaf	University of Pittsburgh	Member
R. Lenel James	Blue Cross Blue Shield Association	Member
Steven Wagner	Healthcare Consultant	Member
Wu Xu	University of Utah	Member
NCVHS Staff		
Name	**Organization**	**Role**
Maya Bernstein	ASPE/OSDP	Staff
Lorraine Doo	CMS	Staff
Shirley Castillo	NCHS	Staff
Presenters		
Name	**Organization**	**Role**
Steve Posnack	Office of the National Coordinator for Health Information Technology, HHS	Deputy National Coordinator
Michael Cimmino	National Standards Group, CMS	Director
Daniel Kalwa	National Standards Group, CMS	Deputy Director
Jami Lookabill	National Standards Group, CMS	
Bob Bowman	Interoperability and Standards, CAQH	Principal
Cathy Sheppard	X12	Chief Executive Officer
Dan Vreeman	HL7 International	Chief Standards Officer
Margaret Weiker	National Council for Prescription Drug Programs (NCPDP)	Vice President

Call to Order/Roll Call

Rebecca Hines: It is 10:02. Let us go ahead and get started. Mike and Stephanie, if you could take down the slide so I can see everyone, that would be great. Good morning and a warm welcome to members of the National Committee on Vital and Health Statistics, NCVHS, for short. Welcome to committee staff and members of the public in attendance with us today. This is our late fall/winter meeting of the committee. My name is Rebecca Hines and I serve as executive secretary and designated federal officer for NCVHS.

Our last meeting of the Full Committee, as you might recall, we met in person at the HHS Humphrey Building and it was the first meeting for our five newest members of the committee. For them today is your first meeting of the Full Committee held virtually. You will see that we are picking right up where we left on in July except today you will need to make friends with your "raise hand" button. Make sure you can find that. That is a great way to keep ourselves in good working order here.

In July, we heard from the HHS Office for Civil Rights, heard from their leadership. And this morning, we will be starting right off with discussion on six new proposed recommendations to strengthen the HIPAA Security Rule just to show that the committee can work efficiently when there are clear time-sensitive issues in play.

I also want to remind everyone that tomorrow we will be hearing from the NCVHS workgroup on timely and strategic action to inform ICD-11 policy and there is an open request for information, RFI, that was published in the Federal Register on October 16. We very much welcome your input on the new version of ICD, ICD-11, and hope that you will take advantage of this opportunity to send input for the workgroup's consideration. You can see the link here. Thank you, Shirley, for making that available to everyone. The input is due January 12, 12 days after the New Year's holiday. We look forward to getting everyone's input.

Let us take care of roll call now. We will start off with our chair, Jacki Monson.

Jacki Monson: Good morning, everyone. I am Jacki Monson, Sutter Health chair, NCVHS, no conflicts.

Rebecca Hines: And then alphabetically, starting off with Angela Alton.

Angela Alton: Good morning. My name is Angela Alton and I work for City of Hope. I am a member of the Full Committee and serve on the Privacy, Confidentiality, and Security Subcommittee. I have no conflicts.

Rebecca Hines: Thank you, Angela.

Catherine Donald.

Catherine Donald: Good morning. I am Catherine Donald and I work for the Alabama Department of Public Health. I am a member of the Full Committee and the ICD-11 Workgroup. I do have a conflict with any discussions on reproductive health. I will recuse myself if any of those discussions occur.

Rebecca Hines: Thank you, Catherine.

Debra Strickland.

Debra Strickland: Hi. I am Debra Strickland. I am a member of the Full Committee and member of the Standards Subcommittee as well.

Rebecca Hines: Any conflicts?

Debra Strickland: No conflicts.

Rebecca Hines: Thank you, Debra.

Denise Chrysler.

Denise Chrysler: Good morning. Denise Chrysler. I am with the Network for Public Health Law. I am a member of the Full Committee and the Privacy, Confidentiality, and Security Subcommittee and I have no conflicts.

Rebecca Hines: Thank you.

Jamie Ferguson.

Jamie Ferguson: Good morning. I am Jamie Ferguson. I work for Kaiser Permanente. I am a member of the Full Committee, the Subcommittee on Standards, the Subcommittee on Privacy, Confidentiality, and Security, and I chair the ICD-1 Workgroup and I have no conflicts.

Rebecca Hines: Thank you.

Lenel James.

Lenel James: Hi. My name is Lenel James with Blue Cross Blue Shield Association. I am part of the Full Committee, active on the Standards Subcomittee and have no conflicts.

Rebecca Hines: Thank you.

Michael Hodgkins.

Michael Hodgkins: Good morning. Michael Hodgkins. Independent consultant. I am a member of the Full Committee, the Committee on Standards, and the Subcommittee on ICD-11 and I have no conflicts.

Rebecca Hines: Thank you.

Rich Landen.

Rich Landen: Rich Landen, member of the Full Committee, member of the Standards Subcommittee. I have no conflicts.

Rebecca Hines: Thanks, Rich.

Steve Wagner.

Steve Wagner: I am Steve Wagner. I am a former health information architect. I am a member of the Full Committee and the Subcommittee on Standards, and I have no conflicts.

Rebecca Hines: Thanks, Steve.

Tammy Feenstra Banks.

Tammy Feenstra Banks: Tammy Banks, independent consultant, member of the Full Committee, Executive Committee, chair of the Subcommittee on Standards and no conflicts. Thank you.

Rebecca Hines: Val Watzlaf.

Valerie Watzlaf: Good morning. Val Watzlaf. I am with the University of Pittsburgh. I am a member of the Full Committee, co-chair of the Privacy, Confidentiality, and Security Subcommittee, and also a member of the ICD-11 Workgroup and I have no conflicts.

Rebecca Hines: Thank you, Val.

And Wu Xu.

Wu Xu: Good morning. My name is Wu XU. I am adjunct faculty with University of Utah. I am a member of the Full Committee and ICD-11 Workgroup. I have no conflicts.

Rebecca Hines: Thank you. We have a quorum with all 13 committee members.

Let us move over to staff. I see we have here with us our lead staff for the Standards Subcommittee. Lorraine.

Lorraine Doo: Good morning. Lorraine Doo with the Centers for Medicare and Medicaid Services, Health Informatics and Interoperability Group and lead staff to the Standards Subcommittee.

Rebecca Hines: Thank you, Lorraine.

And Maya Bernstein.

Maya Bernstein: Good morning, everyone. I am Maya Bernstein. I am the senior advisor for Privacy at the Office of the Assistant Secretary for Planning and Evaluation. I am the lead staff to our Executive Director Sharon Arnold, who is not able to be here this morning but will brief you tomorrow and I am also the lead staff to the Subcommittee on Privacy, Confidentiality, and Security. Thank you.

Rebecca Hines: Thanks, Maya.

And Shirley Castillo. Good morning.

Shirley Castillo: Good morning. My name is Shirley Castillo. I am with NCHS, National Center for Health Statistics, and I am support staff for the NCVHS Committee.

Rebecca Hines: Welcome to the committee. Thank you, Shirley. We are delighted you are able to join us. I believe that is the staff that are here with us this morning.

Before moving over to our chair, I just want to say that if you have not already, you can sign up to receive email notices from the committee and to subscribe, you can visit the home page of the NCVHS website. I just wanted to make sure you are aware of that and note for this afternoon and we will be going through the agenda. The comment period is scheduled for 5:15 p.m. Eastern. We will aim to have public comment at this time. In the unlikely event, we are so efficient that we can wrap up earlier than that time and you are planning to participate in public comment, you might want to be attentive to the proceedings starting around 4:30 Eastern p.m. or so. For members of the public, we will show you this slide that you can see up on your screen on how to make a public comment. You can also email them to us at NCVHSmail@cdc.gov. We have actually already gotten one this morning, which I will share with the members. I think that is everything.

Jacki, I am turning it over to you.

Agenda Review

Jacki Monson: Great. If we can pull up the agenda, please. While we are waiting to pull up the agenda, just a couple of comments. We had two members roll off since the last meeting. I just want to recognize and thank those individuals. Melissa Goldstein and Margaret Skurka both have ended their commitment to NCVHS. We are extremely grateful for all that they did for us over the last several years and the many contributions to NCVHS. I just wanted to publicly thank them again for their work for the committee.

Then I also just wanted to mention that Rich Landen, who has been a long-time member of NCVHS, this is his last meeting, the next couple of days. Rich, expect all the contributions to be high par today and tomorrow. On a lighter note, we are just extremely grateful to have you for two more days of NCVHS and just your long-time commitment to all the work here.

With that said, I will move into covering the formal agenda. We covered roll call already. Next is what I am doing right now, which is reviewing the agenda. We will then move into strengthening the HIPAA Security Rule discussion that Val will lead. And we do have actions, both a discussion and deliberation on proposed recommendations. We will then take a lunch break and then in the afternoon, we have ONC, the evaluation and assessment of the readiness of the new and updated standards. We then have an update from the Standards Workgroup and CMS, and then we go into CORE Operating Rule Enforcement Process and recent activity. And then we will move into assessing new and updated standard's business value and technical risk across standards. There are many individuals, as you can see on the side, who will be participating throughout the afternoon on these discussions.

We are going to take a break and then the Full Committee and invited panelists will continue the discussion on assessing new and updated standard's business value and technical risk across the standards. We will take a break and then we will move into NCVHS workplan development, the project scope discussion, modernizing standards driven information infrastructure across the health care ecosystem. And then we will move to public comment at 5:15 and schedule to adjourn at 5:30 today.

I will cover the agenda for tomorrow. Let us officially kick off the first agenda item today and Val, I will turn it over to you.

Strengthening the HIPAA Security Rule

Valerie Watzlaf: Great. Thank you, Jacki. If I could pull up the slides for the recommendations. Thank you. Good morning, everyone. The draft letter of recommendations to strengthen the HIPAA Security Rule is in your eAgenda book. I believe it is starting on page 23 so please feel free to refer to that letter.

Before we walk through the recommendations and the letter, I want to also thank the current and some previous PCS Subcommittee members, that took part in the development of the letter and the recommendations. Very special thanks to Jamie, Vickie, Jacki, Cathy, Angela, Denise, and Melissa, for all of their input into this letter as well as special thanks to Maya and Rebecca for all their hard work and support on this letter as well.

I also want to thank all of the you, the Full Committee, for your input as well. We strongly encourage all of you for the entire committee to provide comments and any possible refinements as we discuss these recommendations.

And the way we will go through this is I will provide a brief presentation that led to the recommendations and then we will go over the six recommendations to see if there are any refinements. After that, we will walk through the entire letter to capture your comments and any changes you might have.

One of the important charges of our Full Committee is to research and identify privacy, confidentiality, and security measures to protect individually identifiable health information. We have found from previous reports that there has been a dramatic increase in cyberattacks, causing disruption to the health care continuum and these reports also list health care as the third-most frequently targeted sector of the cyberattacks. In the last few years, we have had several reports of patients' deaths due to ransomware attacks that have been reported in major news outlets.

Also, we have found from previous research that cyberattacks may have had a major effect on increasing patient's severity of illness due to delays in needed procedures and tests as well as being more likely to cause longer lengths of stay, increases in complications from medical procedures, and even increases in mortality rates.

The committee sought to understand the scope and breadth of security risks and how best to address these challenges in protecting the safety of patients and the entire health care system itself.

NCVHS held hearings on July 14ht of 2021 and again July 20th of 2022 to better understand the cybersecurity landscape and to really explore how best to protect health information in our patients. And then on May 10th of 2022, the committee submitted a Letter of Recommendations to Strengthen Cybersecurity in Healthcare. The committee went on then to hear presentations from the director of the Office for Civil Rights and the deputy director for Health Information Privacy Data and Cybersecurity. This was July 19th and 20h of this year and that was during our public meeting.

Then our PCS Subcommittee met on September 26, 2023, to address follow-up questions to the deputy director of OCR.

And throughout all of these meetings, the panelists, the OCR officials, they consistently voiced their concerns about the major increase in cybersecurity incidence and the lack of a robust risk

analysis on the part of some covered entities and business associates.

Therefore, today, we want to bring forward this letter with the purpose to strengthen the security rule by encouraging covered entities and their business associates to really focus on ways to decrease cybersecurity incidence and then adopt strong risk management programs that really do include a robust risk analysis.

Also, it was found in the most recent HIPAA audits industry report, OCR found that covered entities and business associates were not consistently compliant in implementing the Security Rule's requirements for a risk analysis and a risk management program.

The committee is aware that OCR has provided multiple tools and guidance on risk analysis. However, in the OCR audit findings and from the previous hearings and meetings, many covered entities and business associates failed to comply with the existing regulations, leading to the conclusion that what constitutes an accurate and thorough enterprise risk assessment may not be clear or the guidance resources that are provided might be too numerous or too voluminous and somewhat difficult and to follow or the expense could be burdensome, especially for some of the smaller entities and business associates.

It was with this premise in mind that we proposed the following six recommendations. I will read through the recommendations first and then we can move on to the letter and we will walk through that together as well.

These are the first three recommendations. I will read through them and then if we could have your – any changes or refinements that you have, please feel free to speak up and make those because we are really looking to see. We definitely want to make sure that we get these correct before we move forward.

The first recommendation and specifically we say that NCVHS recommends that HHS require in the HIPAA Security Rule that all covered entities and business associates implement a security program, and that the rule specify the same minimum security controls for all covered entities and business associates. I know one of the changes was, I think, we need to capitalize the word rule throughout here, I believe. Right? Security and rule. Is anyone recording any changes for me or should I just be doing this?

Maya Bernstein: I am recording. I am not doing it on the slides, but I am doing it in the letter. If you make changes here in the letter, I will put them in the letter.

Valerie Watzlaf: We can move to the letter if that would be easier. Would that be easier for you, Maya?

Maya Bernstein: If there is nothing else in your slides.

Valerie Watzlaf: It is just the recommendations, I think.

Rebecca Hines: I think it would be good to review them in whole with all of the members who have not been on a daily basis looking at this just to make sure that –

Maya Bernstein: I have them up on my screen so I think we can do that all in one place. You will see some other changes in the letter. Is that okay with you, Val?

Valerie Watzlaf: Yes, that is great. Thank you. And I do encourage – we had so much wonderful input from all the members of PCS, our subcommittee. Please feel free to make comments as well.

Maya Bernstein: Can you all see this? Is it large enough? Do you want me to make it bigger? Here in bold are the six recommendations that Val was – do you want to talk us through those, Valerie.

Valerie Watzlaf: Sure. As I mentioned, the first one is – it is the same as what was on your slides. Require in the HIPAA Security Rule that all covered entities and business associates implement a security program and that the rule specifies the minimum-security controls for all covered entities and business associates. Any changes? If not, I can move on to the second one.

The second one states require in the IPAA Security Rule that covered entities and business associates adopt a risk-based approach in their security program. Any changes to number 2? Rich, go ahead.

Rich Landen: A question about clarity here. Covered entities and business associates adopt a risk-based approach. In the current rule, there is a risk-based approach specified. I think the term that it uses is addressable. I am not real clear on what this recommendation as is worded now would be adding.

Valerie Watzlaf: I think with this one what we were trying to do is to have those covered entities and business associates that might have lesser scope of PHI that that is where they might want to then be able to specify that in the rule so that they could then choose a risk-based approach.

Jamie, go ahead if you have further –

Jamie Ferguson: Just to amplify and clarify on that. It is not to say that the risk-based approach would reduce the minimum control requirements. This is what you would do on top of the minimum. In other words, as the first recommendation would have it, all covered entities and business associates have the same minimum security requirements that would be specified in the rule. That would make potentially some of the things that are now addressable make them required. And then what you would do on top of that is to have the risk-based approach for a layered security on top of the minimum.

Valerie Watzlaf: Go ahead, Lenel.

Lenel James: My question was on the risk-based approach. Is there additional information in the appendix because in the preamble to starting the discussion, it seemed that one of the concerns is not large, multi-million, multi-billion-dollar companies know what to do with risk. This is more about small providers, rural providers, people that may not have some of the sophistication. Is there guidance to as people see this and maybe did not realize we all think everybody understands the HIPAA rules. For that audience we are targeting, are we providing some guidance so that they know where to go to find more about risk-based assessments in the appendix is my question.

Valerie Watzlaf: We do not break it out in that second recommendation. We do provide more I would say a step-by-step risk analysis procedure in the third recommendation. But we just say that – we do say that – we talk about the minimum security requirements that should be

followed, and we specify those. We also talk about how the addressable items I think have been too many and many people do not always abide by that at all. And then we do talk about again what that risk-based approach would include but it is very general. We do not go into detail in that second recommendation.

Lenel James: Valerie, I just do not know whether we ever – because again everybody can Google everything but that does not really always get them the right official answer. I am not so sure to what extent we, in our recommendations, since it is going to HHS, they know what we need but again for people new to NCVHS or new to security of which there are many people. We have people retiring, new people coming. And all the new people that are in health care IT do not have a lot of the history of HIPAA. I just worry that as many of these new employees and new health care come in, we might want to provide some more cookie crumbs, not for HHS, but people who read this and realize they should be doing more of this work. But that may be more than we need to payload but just throwing that out as a concern.

Valerie Watzlaf: We do I think, in the following recommendations, we also offer compensating controls. We tell them there should be more examples for that. We just do not break it out as much, I believe, in this second one.

Go ahead, Jamie.

Jamie Ferguson: I guess two things. One is to respond to Lenel. In the explanation or exposition of these recommendations in the appendix, we do call for the guidance that you are talking about and that it should be explicit.

Lenel James: Thank you. Not having read that part, I was not sure.

Jamie Ferguson: The other point I wanted to make separately is it might be helpful in the second recommendation to clarify that that is in addition to and not instead of the minimum requirements in the first recommendation just to say – maybe to add the phrase in addition just as simply as that.

Valerie Watzlaf: In the first paragraph? Is that what –

Jamie Ferguson: Yes. I think just where Maya had it. In the security programs or in addition to the minimum controls.

Rebecca Hines: That is a nice clarification.

Valerie Watzlaf: We are okay then with that just to say – because we do say in the second paragraph that the end guidance should specify acceptable options for the security controls, but you do not want any detail listed out. I guess that is what I just wanted to clarify with Lenel.

Lenel James: Correct. Thank you.

Valerie Watzlaf: Okay. Go ahead, Maya.

Maya Bernstein: I just wanted to clarify if it is helpful for the committee. Rich raised a question earlier about the current rule, calling these things addressable, which means that you must document, that you looked at them but you do not actually have to do them if you have some

justification for why you are not doing that. And this change, as I understand what the committee's intention is, is to make those things required and not addressable as in the current rule.

There are a bunch of expositions in the appendix that talk about what we mean by this. These are really just summary recommendations. There is a discussion of why in the rationale for these things in the appendix that you may want to take a look at and that as Jamie and Val have said, would ask for OCR to provide in one place guidance that would be helpful to people. Right now, as Lenel mentioned, there is guidance all over the place. You have to Google. You get multiple different sources. It is not clear for people, especially perhaps smaller or less sophisticated entities, where to find that guidance. The idea is to allow people to have one go-to place where they can find guidance. Those are written out and taken together or these recommendations taken together would lead us to that eventuality where minimums are required, and guidance is in one place. I hope I did not – that is what I understand the committee's intentions were.

Valerie Watzlaf: I think Rich had his hand up.

Rich Landen: I thought I was clear when Jamie talked about addressability and what Maya said then did not sound like the same thing I heard from Jamie. I am not a security expert, but my understanding of addressability is essentially it is a risk-based approach. As Maya was explaining, you do view as an entity, a covered entity or business associate, you do your risk – your threat analysis. And if a threat is not applicable to you, you just stay away. We looked at it. It does not apply to us. We do not have to do it.

But I just heard Maya say – I think I heard her say that even if it is not applicable, you have to do something, and I am a little bit unclear then. Again, my concern is – and it does not have to be in the recommendation. It can be done in the explanation that we are clear about just what it is about this current approach to risk base and addressability that we are clear on our recommendation about what it is new we are looking for. Thanks.

Valerie Watzlaf: I think too what we – because we did say and that was in the first recommendation that we would like to see covered entities and business associates should be required either to be in full compliance or to adopt a reasonable documented alternative. I think this was because we saw so many times when we heard from the panelists. We talked to the OCR officials about how so many covered entities and business associates were not meeting these minimums. These are minimum security controls. I believe that is why we – I know this was also presented in the previous cybersecurity letter that went out last year as well. There was different information there as well.

Go ahead, Jamie.

Jamie Ferguson: Just to respond to Rich. I would not confuse addressability with the risk-based approach. I would say that that may be a part of a way to have a risk-based approach. As we explained in the exposition, we are talking about layered security controls on top of a minimum where the addressability says, as I think Maya said, in some cases, you just do not have to do it. You have to just say that you looked at it. We are not saying that you would do something that does not apply to you. But I think the kinds of requirements for encryption and access controls and so forth and having done a full risk analysis and documented that, those are the kinds of minimum-security controls that we are talking about. And those would apply whenever you

have a PHI.

Valerie Watzlaf: Thanks, Jamie. Excellent clarification. Thank you for that. I am getting thumbs up. I hope you can see those.

I believe that there are no other changes to number two. We could move on to the third recommendation, which just states include a step-by-step risk analysis procedure within the Security Rule. We do outline that procedure. That is included in the exposition.

Again, Michael.

Michael Hodgkins: I was just wondering if it would be helpful from a clarification standpoint to insert the word required.

Valerie Watzlaf: On number three?

Michael Hodgkins: No. In the discussions that we were having on the first two.

Valerie Watzlaf: It does say require. On the first two, we do have the word require.

Michael Hodgkins: Yes, but specify the same required minimum-security control, for instance – it is not a big deal but this whole discussion back and forth about addressable versus required. I think the intent here is to require minimum security controls. I thought it might be worth inserting that.

Maya Bernstein: Do you mean instead of the word specify?

Michael Hodgkins: Specify the same minimum – specify the same required minimum security. I guess you could just say require the same minimum-security controls. That is probably more direct.

Maya Bernstein: Does that work?

Michael Hodgkins: I do not want to complicate things. The back-and-forth discussion –

Valerie Watzlaf: That is fine. Now it would say require in the HIPAA Security Rule that all covered entities and business associates implement a security program and that the rule requires the same minimum-security controls for all covered entities and business associates. Is that better?

Maya Bernstein: Does that address your concern, Michael?

Michael Hodgkins: It works for me if it works for others.

Valerie Watzlaf: Thank you, Michael.

Rich Landen: Back to recommendation number three. I would like to ask the subcommittee if they have thought through what it means to place a specific procedure within the rule. One of the lessons learned from the HIPAA code sets and transaction experience is if something is embedded in a rule, the advantage is if immediately raises the floor for the entire industry. The disadvantage, however, is it locks that floor and creates a ceiling because you cannot modify the procedure without a change to the rule, which can take years, even decades. I do not know the

answer to this question, but I just want to make sure that the subcommittee considered whether embedding a procedure in the rule that may well lock industry into that procedure for a decade or more is – will that bite us as the threat environment changes over the years? The alternative obviously is to put something in the rule that points to something external where that external procedure could change over time.

Valerie Watzlaf: I know that we did discuss what this should be called. We did talk about that, what you are bringing up. I think because we had seen so much where covered entities and business associates are not always complying with risk analysis that we thought if OCR could come up with some type of procedure. We do list out what we are recommending but it certainly does not have to include that. But we tried to do the minimum again and hoping that they would be able to come up with something that would be applicable to both large and small entities is what I think we were moving towards in this one.

Any additions from our committee or subcommittee? But we did think about it, I believe, and had those discussions in our subcommittee.

Lenel James: I think this is a good discussion and we have tweaked it and I think we all better understand the intent because again this is going to HHS to execute as a recommendation.

Valerie Watzlaf: Thank you.

Maya Bernstein: I think, if I may, the intent was to have something in the rule that was not going to be technology specific, for example, or something that would raise the concerns that Rich had, very legitimate concerns about putting into a rule making something that cannot be changed. The topics, for example, that you must address in an order may be – I do not think we got to that level of detail, but we would leave it to the department to figure out how to put some kind of procedure in place that would get to all the steps that you need to get to in order to have a robust risk analysis. I think that is the phrase that gets used in the exposition later is a robust risk analysis.

Valerie Watzlaf: And I think it was also because there is a lot of guidance out there but there is so much of it, and I think there are so many organizations that do not know what they should be following. It is too much for them. We wanted something that could synthesize that and be helpful.

Go ahead, Tammy.

Tammy Feenstra Banks: I was just wondering because it is such a big point and obviously, we are really struggling with it in the Standards Subcommittee. Is there any way in the notes that we can incorporate that question and concern to make sure that it is addressed, and the secretary really determines if it should be placed within or placed within guidance or another type of external format.

Maya Bernstein: They are recommendations. The secretary of course has the discretion to do with them what he wants. This is providing your sense to the secretary of what you think the best course is but they are still just recommendations.

We can go look – do you want to look in the discussion?

Tammy Feenstra Banks: I just need to explain this issue, this question, not just say we are just basically saying put it in the rule but that is a question. Should it be in the rule? Should it not be in the rule? Just include that narrative of that consideration that needs to be decided. Should there be an external vehicle for this?

Rebecca Hines: And you might handle that by changing the first verb to consider including a step-by-step risk analysis procedure within the Security Rule and/or guidance or something like that.

Valerie Watzlaf: It is already in guidance. That is the thing.

Rebecca Hines: Consider then –

Tammy Feenstra Banks: How to enforce or how to – the big thing is how to get people to do it but still have the flexibility to increase and change according to how the health care ecosystem changes. That is more the recommendation.

Valerie Watzlaf: Are people okay with saying consider including a step-by-step risk analysis procedure within the Security Rule?

Tammy Feenstra Banks: How about consider a way?

Jamie Ferguson: I am not okay with consider because the whole point is to make it required. I do not know about if the procedure could be either amended or enhanced through guidance or some way that there could be a basic structure. But I think the whole point of the recommendation is to make a risk analysis required. And if it is not in the rule, it is not enforceable. That is the issue that we have had, putting it in guidance.

Rich Landen: I would agree. Consider is the wrong word for there because consider says maybe put it, maybe not. And we want to be strong. We want it there. We want it enforceable. The question is if we put it in the rule, what happens in 2035 with the development of artificial intelligence and that and will that embedded procedure be a millstone that is actually doing harm to the industry. The question is what is the solution? Is there a way to require it without embedding it in the rule and again without knowing what the procedure is going to be? And as a non-expert, I cannot answer that question. We need to be cognizant of that.

I liked Tammy's suggestion that we put something in here that at least flags the issue for the regulators. There is certainly an opportunity for us to chime in on if and when a rule is published as draft and we can do a public comment on the rule so it is not something we have to solve today but let us at least flag the issue.

Valerie Watzlaf: Thank you, Rich.

Michael.

Michael Hodgkins: I guess to Rich's point because I appreciate his concern. Do we want to explicitly state that the risk analysis procedure should be tied to an external source or a reliable external source? There are other entities outside of government who continue to update risk analysis procedures. Is that a consideration?

Valerie Watzlaf: I think again I think the reason we had said, no, we wanted it in the rule was just that would make people do it.

Go ahead, Jacki.

Jacki Monson: I am an expert in this area and I do have strong opinions on it. I think the purpose or the intent behind it is what Jamie articulated, which is we have to get to a point where people actually do risk analysis. Today, the big entities are doing risk analysis. The small entities do not have the bandwidth. And most importantly, the third parties who we are doing business with do not do it, do not take it seriously. It is creating massive cyberattacks across the United States and even nationwide. As a result of that, it is a patient safety issue. I do not see any other way than it being in the regulation to get to a point.

I think it is generic enough that it can contemplate any kind of new technology whether it is cloud, whether it is AI. There are lots of things that are going to continue to evolve. The Security Rule itself has not been updated for a long time. It is old. I think my perspective is that we really do need risk analysis as a mandatory requirement for folks to do and evaluate it. If you cite other guidance or send it to a third party, then it does not have the impact that it is going to have if it actually said in the HIPAA Security Rule.

Valerie Watzlaf: Thank you, Jacki.

Tammy.

Tammy Feenstra Banks: I guess what I am just trying to say is lay all the issues. Some recommended language I threw on the chat is to maybe include a required step-by-step risk analysis procedure, uncovered entity, and business associates that can be updated as HIPAA changes within the security rule or other options. Option is not the right word. But again, that has to be thought because we need to have that requirement, but it cannot be a stale requirement in ten years. This is too important. Is there language? I could not come up with anything except our other option or other rule making. I do not know.

Jacki Monson: I think you are taking it too literally. It is not that prescriptive. Risk analysis is still going to be subjective in evaluation and factors. I am not sure that we want the out to contemplate new technology because as a part of that risk analysis, you are going to contemplate new technology. You are going to go through the factors and evaluate that risk. My perspective is that it is already covered with what is articulated. If we add a second loophole, it just gives people the opportunity to use their discretion to do something differently.

Valerie Watzlaf: Thank you. Would it help for us to go down to the recommendation so you could see what is there on number three? I do not think that is the issue but if it would –

Maya Bernstein: I could scroll down there.

Jamie Ferguson: In terms of the recommendation itself, we might use the word require instead of include. Require a step-by-step risk analysis in the security rule.

Maya Bernstein: Say that again.

Jamie Ferguson: Just to use the word require instead of include.

Maya Bernstein: I was sort of saying in the comments that you could point to a governmental type of source like CISA, who we heard from, or NIST, who we have heard from. It would be awkward to point to a non-governmental entity. As I was saying in the chat there, I do not know observers can see but it implies an endorsement of an outside entity.

Valerie Watzlaf: But the guidance is from – the guidance documents – they do refer to NIST.

Maya Bernstein: That is right.

Valerie Watzlaf: But I think Tammy had her hand up.

Tammy Feenstra Banks: No, I was just going to say then you are not going to have the specific step-by-step risk analysis procedure if you just do require. But I hear what you are saying because you are still debating that point. Where should that step-by-step risk analysis procedure be? I am fine with require but if you are strong on having it in the rule, then you are going to have to say require and include it so either/or.

Jacki Monson: Or you could say request a step-by-step within the Security Rule that aligns with any updates from NIST and CISA, which are the government sources. If you had some technology changes, it would accommodate that.

Valerie Watzlaf: I like that. But what do others feel?

Jamie Ferguson: I like that too.

Participant: I like that as well.

Participant: I support that.

Valerie Watzlaf: Thank you.

Maya Bernstein: Someone remind me what CISA stands for.

Jacki Monson: Cybersecurity and Infrastructure Security Agency.

Valerie Watzlaf: For number three then, it reads require a step-by-step risk analysis procedure within the Security Rule that aligns with guidance from the National Institute of Standards and Technology of the Department of Commerce and the Cybersecurity and Infrastructure Security Agency of the Department of Homeland Security. Is everyone okay with that? Any questions or changes?

Maya Bernstein: Is aligns the right word? I am seeing thumbs up. I have never seen that phenomenon before in Zoom. I have never seen them travel up the screen like that.

Valerie Watzlaf: Steve has his hand up. Steve.

Steve Wagner: It was not quite the name of the agency. It is Cybersecurity and Infrastructure – I do not think it was security. It was something else.

Valerie Watzlaf: Cybersecurity and Infrastructure Security Agency. Thank you.

Rebecca Hines: I am glad someone is paying attention to the details. Thank you, Steve.

Maya Bernstein: It is funny. There are two securities in there. Is aligns the right word? Is there anything about this that gives anyone any heartburn?

Jamie Ferguson: Aligns or conforms.

Maya Bernstein: People like that better?

Participant: Conforms, I think, is stronger.

Maya Bernstein: Is that a good thing?

Valerie Watzlaf: Do you want it to be stronger there? Okay.

Maya Bernstein: Just so you know, when we finish figuring out exactly what the language is here, we will make it match with the appendix. It is part of the editing that we will do after we make all these things match and make sure that it gets changed in all the proper places of the letter.

Valerie Watzlaf: Everyone is okay with number three. Let us move on to number four. Define compensating controls more specifically in the Security Rule and provide examples. Any questions, changes, comments on number four? I am not hearing any.

Maya Bernstein: I personally never remember what compensating controls are.

Valerie Watzlaf: I think we do define them in here, I believe. We do say that there are those controls that can be put in place by covered entities and business associates as an alternative control when the original control is too burdensome or costly. We do define that one and we do give some examples of how, for example, the entire State of Maine, how they were impacted due to the MOVEit software vulnerability in here. Any changes to this one at all? We just would like them to provide more specific examples.

Hearing none, we will move on to the fifth one and that reinforces the need to evaluate artificial intelligence systems and data within the Privacy and Security Rule as part of risk analysis for all and any new technology. Any changes, comments? Anything on number five?

Steve Wagner: How much do you want this reinforced? Do you want to say strongly reinforced since we are talking about AI now?

Valerie Watzlaf: I like that, Steve. You would like it to say strongly before reinforce.

Participant: Why can't we use require as we have used – why can't we say require –

Jamie Ferguson: It is already required. This is communicating reinforcing the existing requirement.

Maya Bernstein: Can you say a little more about that, Jamie?

Jamie Ferguson: If you are doing risk analysis, you are going to do risk analysis on any new technology that you bring in and AI is just one of those. If you are already requiring a risk

analysis, then you are already required to do this. But to communicate that as you buy or build artificial intelligence tools, remember that you have to do your risk analysis on the software and data.

Valerie Watzlaf: Which some do not do. Right? They forget about – that that is a new technology as well.

Jamie Ferguson: There have been examples of that. Yes.

Tammy Feenstra Banks: I would support strongly or prioritize or something like that to just really emphasize it due to the climate we are in.

Valerie Watzlaf: Everybody okay with just saying strongly reinforce?

Jamie Ferguson: We might consider instead of the word evaluate say take into account.

Valerie Watzlaf: I like that because that is really what we were trying to say. Do not forget about this, which is so important.

Maya Bernstein: You are basically asking them to call it out specifically even though you think it would already be included if people were reading carefully. You like consider, take into account, address.

Valerie Watzlaf: I do not like consider there. I should see what other people like. I think consider makes it softer. What do others think? Cathy?

Catherine Donald: I was just going to say I would take out consider and just flat out say they should take into account. I like that. I think that is stronger.

Valerie Watzlaf: Tammy? Thank you, Cathy.

Tammy Feenstra Banks: That is fine. I would either use evaluate or take into account. Do we need a "the"? I hate to be nit – between as part of the risk analysis in the last –

Valerie Watzlaf: The risk analysis for –

Jamie Ferguson: I would take out evaluate again.

Jacki Monson: I second that.

Participant: Take into account, is fine. One or the other.

Valerie Watzlaf: It now reads strongly reinforce the need to take into account artificial intelligence systems and data within the Privacy and Security Rules as part of the risk analysis for all and any new technology. Thumbs up again, Maya. At least we are getting thumbs up and not down.

Any other changes on number five? Excellent. Thank you so much for these refinements here. We will go on to number six, which says standardize cyber incidents reporting in the HIPAA Security Rule and harmonize any such requirements in HIPAA rules with incident reporting provisions applicable to health care critical infrastructure actors and health care federal

contractors. Any changes there?

Maya Bernstein: I am having a grammar issue with harmonize requirements with actors.

Jamie Ferguson: You are harmonizing the provisions that are applicable to actors and contractors. If I could just offer – commentary on this. The reason why the extension is there on standardizing cyber incident reporting for those two groups. CISA currently has guidance in effect and is required to publish rules for cyber incident reporting by critical infrastructure actors, which includes, for example, hospitals and health plans. It is currently in guidance but they are required by the CIRCIA Act. They are required to publish that in regulations.

At the same time, the current proposed revisions to the Federal Acquisition Regulation or FAR would have all federal contractors including, for example, Medicare or Tricare providers and plans follow the CISA cyber incident reporting. That would apply to the vast majority and most of the health care sector but not all of the covered entities and business associates. By putting it in the rule, you would have a consistent floor of cyber incident reporting for all covered entities and business associates.

Valerie Watzlaf: Great explanation because they are doing it anyway for some.

Jamie Ferguson: They are doing it for the critical infrastructure and they are doing it for federal contractors but that is most but not all adult care.

Valerie Watzlaf: I do like that consistent floor. Are you thinking we should put that in somewhere –

Maya Bernstein: I like that phrase because that really captures your intention.

Jamie Ferguson: You can put that just after contractors to provide a consistent floor or put it after the Security Rule.

Maya Bernstein: I am thinking establish a consistent floor. Something like that. I think that is more concrete about what your intention is but of course, it is up to the committee but that struck me as really capturing what your intention here is.

Valerie Watzlaf: It states establish a consistent floor for cyber incident reporting in the HIPAA Security Rule and harmonize any such requirements in HIPAA rules with incident reporting provision applicable to health care critical infrastructure actors and health care federal contractors. Any other changes?

Maya Bernstein: Does that work for people?

Valerie Watzlaf: And we need to call out the federal contractors because they include – right, it would not just be health care contractors. Correct?

Jamie Ferguson: The FAR would require all federal contractors, but this would require everybody, not just federal contractors.

Valerie Watzlaf: Is that clear to everyone?

Lenel James: This is Lenel. I think it is clear but I am not sure if everybody will be understanding all the critical health care infrastructure actors because I agree with Jamie. It is more than the federal contractors and because of APIs in health care, there is a whole bunch of vendor entrants that do not consider themselves HIPAA covered and they have health care data.

Participant: Do we have examples of health care critical infrastructure actors down below?

Jamie Ferguson: I think in the exposition of this, we refer to the act that defines the actors.

Maya Bernstein: Do you want to go down there and look at that?

Valerie Watzlaf: You do define. You have the actors in there, Jamie, CISA and what CISA does as well. You even include the elements to share in cyber incident reporting, which they include.

Maya Bernstein: This is the discussion that goes with that.

Jamie Ferguson: The definitions are in there.

Lenel James: The devil is in the details and the details are on Item 6. Good. Thank you.

Valerie Watzlaf: Thank you.

Maya Bernstein: There is more. It goes on. There is the mention of the FAR. There is quite a lot of information in the rationale portions.

Valerie Watzlaf: Any other comments, changes? I did want to just go back up to number four very quickly. It says define compensating controls more specifically. Do we need more specifically if we are saying – or could we just say define compensating controls in the Security Rule and provide examples?

Go ahead, Jamie.

Jamie Ferguson: They are already defined but people do not understand it. That is why we need more specificity.

Valerie Watzlaf: Even though you do say provide – because they do provide examples too.

Jamie Ferguson: It is not sufficient.

Valerie Watzlaf: You want both in there. Great.

Maya Bernstein: Do you want to elaborate on the examples that you want? The examples exist but you do not like them. What would you like to say about better examples?

Valerie Watzlaf: We wanted ones I think that smaller – there are some smaller entities that would not be able to I think afford to do some of them.

Jamie Ferguson: We are looking for more examples to clarify it.

Valerie Watzlaf: For both large and small. A wide variety or wide range. That is nice.

Jamie Ferguson: That is fine.

Maya Bernstein: Does that help?

Valerie Watzlaf: It will say define compensating controls more specifically in the Security Rule and provide a wider range of examples that apply to large and small entities. That is great.

Maya Bernstein: Or a range of – not just small and large but a range of types of entities or –

Valerie Watzlaf: Or all types of entities you could say too.

Maya Bernstein: I think all. For example, you cannot really have all. Something like that. Size might not be the only thing. It could be profit, not profit.

Valerie Watzlaf: Okay. Any other as you look others these, any other comments or changes to any of them?

Go ahead, Rich.

Rich Landen: I have no more comments on the recommendations, but I do have some earlier in the letter when we are ready. Let us not forget to review the letter itself.

Maya Bernstein: Can I just draw everyone's attention to an email that Rebecca sent to you all with an interesting question from a member of the public. I can read it or if you have, Val, you can read it if you choose into the record.

Rebecca Hines: Maya, Jacki also has some thoughts on it.

Jacki Monson: I am fine with us reading it though into the record then we can talk about it.

Valerie Watzlaf: Who would like to read it? I think if this is the right one, I think I got it too.

Rebecca Hines: Why don't you read it, Val?

Valerie Watzlaf: This is from Duke University. Good morning. I am on the NCVHS meeting and wanted to see if the committee is thinking or considering extending HIPAA coverage to EHI releases as well. Having worked to develop our EHI release, I have concerns about patients signing over access to EHI, not recognizing that this is so much more than LMR or DRS access. Improving the HIPAA security is very much in need of an update but hoping we will also recognize the workarounds that I could see might also be in the works very soon.

Go ahead, Jacki, if you have a comment.

Jacki Monson: My thought on this was – and for those of you who do not know what EHI is, it is electronic health information. That is the acronym. I think this is more of a Beyond HIPAA kind of the scope and discussion that we were going into before. I don't disagree with the public comment on this but I am not sure – I do not really see the correlation with what we are doing right now in the HIPAA Security Rule. I see this as something we might want to tackle in either Beyond HIPAA or perhaps the conversation between standards and PCS on this. I understand what they are saying, which is basically if a patient signs an authorization, they might not know

what they are authorizing as far as information exchange. I am certainly open to feedback. I do not see how that correlates to the HIPAA Security Rule.

I got the impression from the author that it was just will you also please consider this, which has been active conversations on Beyond HIPAA that we have had over the last couple of years in how you manage through that and make sure that the patient is aware of what they are doing.

Maya Bernstein: This may be more appropriate for the public comment period. We should say – her name is Eugenia McPeek Hinz. She is an MD from Duke University Health System.

Valerie Watzlaf: And we are thinking about those – doing more on the Beyond HIPAA area too. This is certainly something that we could make note of and consider for the future. That is something we hope to tackle very soon.

Maya Bernstein: Can we just do a time check real quick, Rebecca. Where are we in our schedule?

Rebecca Hines: You are halfway basically through your time on this letter. You might want to get to the body of the letter and I would suggest going broadly rather than line by line. All the members have had this for over a week. Hopefully, if you had any major concerns, you already sent them forward.

Maya Bernstein: We did not receive any comments so we are hoping that people are reasonably satisfied with it but this is an opportunity to go through and figure out if there is something that causes heartburn.

Rich asked us correctly that we should look at the letter itself.

Jamie Ferguson: Can we use the simple markup so that we do not see all of the changes but just the current version?

Valerie Watzlaf: Can we do page by page for time? If anyone has any comments on this first page of the letter.

Rebecca Hines: I think on the letter, I would go paragraph by paragraph and on the appendix, you can go chunk by chunk.

Valerie Watzlaf: Any comments on the first paragraph?

Rich Landen: It looks like the first of my comments has been addressed already by specifying cybersecurity as opposed to just generic security.

Maya Bernstein: I caught. I made some changes when I was reading over this in the last week. One of them was that and also there was an example here from the Ponemon Institute, which I have some issues with. They go out with these fancy reports that are nicely formatted and they have a 3.8 response rate when I go to look at it, which to me indicates that there may be a lot of bias in the report even though they report on that. I would prefer that the committee look at something that might be more reliable in terms of if you are going to survey analysis.

I found some information from CISA, which might be a more reliable source than Ponemon

Institute just to – you want to have something upfront to illustrate the importance of the work that you are doing here and the reason for coming out with this letter now. This is an example. It gives a little bit. If somebody has a different example, that is up to the committee. But I have some issues with the Ponemon Institute because they have marketing level of – 3 percent. NCHS would just look at that and say this is completely unreliable data and they draw a lot of conclusions from that 3.8 percent that I just think are likely to have a lot of bias. And even though they say it is likely to have bias, they still come out with their flasher report anyway. I personally find that objectionable as a government person. We would not accept that kind of research response as something from which you could really draw conclusions. I think the committee can do better than that. That is my bias.

Valerie Watzlaf: That is fine too. I had put that in and I think we were trying to see the effects on patient's direct care is what we were looking for. But we do have those listed out as you have there in the past few years where news outlets – I think it is wired – Washington Post, I think.

Maya Bernstein: You can see the footnotes here. I should mention. We will go through after this meeting our usual procedures to go through and I will fix all the footnotes and make sure that the links work and that people can go back and find the sources that you use to rely on so that it is not just a link because links can die or get moved but that you have the author, the title, the date of whatever the document is so that it can be found later by someone who might be doing research or might want to refer to it and that takes some time. The letter might not be signed out tomorrow but once you have agreed on the substance of it, then we can fix those kinds of things. If there are commas that need fixing – we usually go and clean it up and then Rebecca's staff does an excellent job of making it beautifully formatted, so it is appropriate for transmission and so forth just for the new people to remind you what the process looks like.

Valerie Watzlaf: Okay. And then the second paragraph is just a little bit about the committee. And then any comments on that one? I think we quoted so I do not know that you can change that one.

Maya Bernstein: That just states who we are that we are writing to you, the secretary, and then jumps right into what is this letter about and why – and justifications for why we are writing this letter. That is this kind of information.

Valerie Watzlaf: This is more the research background is the third paragraph. Any changes at all on that one? You are probably just seeing that. That did change.

Maya Bernstein: -- for the first time.

Valerie Watzlaf: That third paragraph is new.

Maya Bernstein: I basically took it directly from that report that – it is from the Healthcare and Public Health Sector Coordinating Committee. That is the sector-specific organization that deals with health care industry in terms of cybersecurity.

Valerie Watzlaf: And you have some other reports too that also support that.

Maya Bernstein: It in turn cites these other reports and says that what we are finding is consistent with these other things, some of which are private sector for here. It itself refers to these other things.

Valerie Watzlaf: I think we can move on. I am not hearing any comments. I do not see any hands up.

Rich Landen: It is for the next paragraph, the one that starts NCVHS held hearings. The fifth line of that. This is an editorial nit. We talked about the PCS Committee. This is first reference so we need to spell out PCS.

Valerie Watzlaf: I thought we did that. Thank you. Any other comments on that paragraph?

We can move on to the next one. It is 2016-2017 HIPAA Audits Industry Report. I am not hearing anything there.

And then the next paragraph starts on May 10.

Maya Bernstein: This talks about the prior letter on cybersecurity from last year on which this is building. It explains I think the focus here – this letter really is focused on risk analysis, as I understand. The committee recognizes that there are other security matters that should be addressed like the important thing that you wanted to focus on was that the problem with the lack of risk analysis feeds into so many of the other problems that we find.

Valerie Watzlaf: And we did even discuss putting that in the title too but then we did remove it. I think it said to strengthen the security role with a focus on risk analysis originally and then we removed that because it went off a little bit. It was not just on risk analysis. I am not seeing any hands up.

The next paragraph, the purpose of this letter. Then we just go into how we want to strengthen the security rule.

Maya Bernstein: Main point here.

Valerie Watzlaf: And the strong risk management, risk analysis. Yes. Any comments? Hearing none, we can move on to the next paragraph.

I think this one then just introduces the recommendations. There they are. The new recommendations. Take a look at those.

Maya Bernstein: They are not all marked up. Do you want to see them all in their glory?

Valerie Watzlaf: If there are any comments or changes, let us know. We appreciate all the input too. Thank you so much. It is very helpful.

Maya Bernstein: The grammar police do not like the way you worded that.

Rebecca Hines: The grammar police are not human.

Valerie Watzlaf: They are not always the best. Any changes to the recommendations?

Participant: Did the grammar police offer a better alternative if you right click on that?

Valerie Watzlaf: It might. It probably says evaluate, which we removed.

Maya Bernstein: Try using a verb instead of a noun phrase to be concise. I think it would say account for instead of take into account or something like that.

Participant: We also thought we might use address, need to address AI systems and data.

Participant: Going once. Going twice.

Valerie Watzlaf: Everyone okay with address instead of take into account?

Rebecca Hines: I do not know. I like take into account, but I leave it all in your good hands.

Maya Bernstein: Or even account for. I have seen some thumbs and some –

Rebecca Hines: To account for. There we go.

Valerie Watzlaf: I like that better myself. How are others feeling? Address or account. We are getting some thumbs here. Anybody feel strongly either way?

Lenel James: No. I think the change worked out well.

Valerie Watzlaf: Okay. Thank you, Lenel. Anything else?

Maya Bernstein: Please do not shy away from nit picking at the language. For me, that is where the policy gets made.

Participant: I come from HL7. We nitpick on everything.

Maya Bernstein: I am a lawyer by training. It is like agreeing on what you want to say is one thing. But getting the language to match what you agreed on is difficult. Do not shy away from if the word is wrong for you, please speak up now because this is your opportunity to get it just precise.

Valerie Watzlaf: I guess we can move into the rationale if we have time. Are we done at noon or 12:15? I should know that. 12:15.

Rebecca Hines: You have about 45 minutes. If you divide that by six, you have maybe seven or so minutes for the recommendations.

Valerie Watzlaf: Why don't we do page by page maybe for this? Anybody have any comments on the first recommendation?

Maya Bernstein: We did make some changes in the first recommendation. With Jamie's indulgence, I am going to show the markup here.

Rebecca Hines: That is good, Maya, because this is Maya's support in getting this cleaned up. Make sure you are okay with these edits because these were edits made after you all reviewed this over the holiday.

Participant: The edits for the recommendation have not yet been carried forward here.

Maya Bernstein: That is correct. We just did that during this meeting. I will carry those forward.

The exposition now we are going to look at. It looks like that was just a leftover placeholder unless somebody meant something else by that so I took it out.

Rebecca Hines: Maya, down below, I would change our to the committee's cybersecurity letter. More detail regarding each of these security controls is provided in the committee's cybersecurity letter.

Maya Bernstein: Again, the footnotes – we will clean up after I put some links. They will be fully fleshed out with dates –

I am going to move forward a little bit. I am going to move to the next page so you can see it all at once. Here you are where you are mapping to NIST. The bullets are a little – guideposts, subheadings.

Valerie Watzlaf: You did say something here, Maya, I think if I – maybe it was a comment about moving up the example to the beginning.

Maya Bernstein: I hit the comments because some of them were – not as diplomatic as I could have been last night.

Valerie Watzlaf: And I do not like it there either. I feel like it is just kind of attached. I was not sure where you were thinking of putting it. The example at the bottom of the encryption.

Maya Bernstein: Do you want to see the comments? As you see, I was – hopefully, I was not too snarky. It was late. My concern is that in general our letters are meant for an educated layperson, someone who is not necessarily -- like yourselves, some of you are experts in security but many of you are not. I am not a security or technologist. I want to read this and be able to understand what is being asked. I think you are going to find the same – thinking about the OCR staff. Clearly, the people writing the security rule are going to be experts in security but they are going to be helped by other members of the staff. The leadership certainly who is going to have to read this and understand what you are asking of them are not going to be experts in security. They have staff that are. With that in mind, I want it to be very clear and plain language.

Rebecca Hines: I have never seen the phrase data in transit, but I guess I see what you are doing there.

Maya Bernstein: Things that are moving from place to place.

Valerie Watzlaf: Jamie has his hand up.

Jamie Ferguson: I just wanted to say that what quantum computing is, what the threats are and the reason why you have to be prepared for it. That is all explained in the NIST-NAS memorandum and the NIST guidance that is cited and footnoted. All the details on that are explained in the footnotes.

Maya Bernstein: It is referred to. You have to go look at that to find that information.

Jamie Ferguson: That is right. You do.

Maya Bernstein: I defer to the committee's thoughts about this. But you could put a sentence or

two that would help people along. If they do not want to read the whole source, which is exactly what we are saying that we do not want people to do. We could give them a sentence or two that says quantum computing means this kind of thing. My sense was when I was reading this that it does assume a lot of knowledge. We could help people along to get through this if we –

Participant: Is it worth having a footnote here referencing the document that Jamie mentioned?

Jamie Ferguson: -- have the footnote.

Maya Bernstein: The footnote is there.

Jamie Ferguson: The National Security memorandum is the document that really explains it best, I think.

Rebecca Hines: Maybe after the meeting, we could put in a little definition, just a one sentence of what is quantum computing so that –

Participant: The footnote does not occur when quantum computing threats are mentioned.

Valerie Watzlaf: It should be right after threats, and it is not. It is earlier.

Maya Bernstein: Here refers to the memo.

Valerie Watzlaf: Put it twice.

Maya Bernstein: Well, here, you could put – in a footnote, you could drop a footnote here that says this is what we mean by quantum computing –

Jamie Ferguson: I do not know how to explain quantum computing and what the threats are in a sentence.

Rebecca Hines: Jamie, I am so disappointed. I thought you could do that.

Valerie Watzlaf: If anybody could do it, Jamie could do it.

Participant: -- leap tall buildings in a single bound –

Maya Bernstein: He can make leaps.

Jamie Ferguson: If we can find a short paragraph that explains that maybe from the NSA-CIS joint memorandum.

Rebecca Hines: As somebody with no knowledge of this, maybe I should find it because if I can understand it, then probably other people could too. I will look up the source and see if I can come up with something.

Maya Bernstein: Please send me, and I will include in the footnotes, whatever sources people –

Valerie Watzlaf: Because we do explain other things. One that we could explain I think – it is just a little more difficult with some.

Maya Bernstein: Some of it is just grammatical silliness.

Valerie Watzlaf: And then I think it was the example that you said – it might be better placed before the recommendation.

Maya Bernstein: I think what I was suggesting here when I read it was we say what we want to do and then we say this is why instead of bringing people along with us and saying here is the problem that we have observed or that other people have observed and this is what we are going to do about it. Here is a problem. Here is how affected the health care industry. Here are some real issues that have arisen that covered entities have to deal with because of this and then here is what we recommend to fix the problem that we just described. That seemed to me as a lay reader, an organization that flowed for me in terms of the logical thinking rather than saying here is what we think you should do and I am like how did we get to there. Then at the end it says this is why. Here is an example of why this is important.

Valerie Watzlaf: You are saying just put it at the top of this paragraph under minimum encryption requirements.

Maya Bernstein: Here is what happened – thing was all over the news. Here is what we think we should do about something like that or here –

Valerie Watzlaf: Not before the full recommendation. Just under this –

Maya Bernstein: Minimum encryption requirements. Here we have this example of what happened with MOVEit. Here is why (inaudible) would have helped avoid that kind of a problem. Does that make sense?

VAL WAZLAF: Yes. I like that change actually because it does look like it is kind of attached on there.

Maya Bernstein: Instead of saying – I would tell a story and then say okay. Based on that story –

Jamie Ferguson: I did put in the chat a couple of paragraphs we might potentially consider. These are lifted from the memorandum issued by NIST and NSA on what quantum is or what the quantum thread is.

Rebecca Hines: You picked out some very helpful texts there, Jamie.

Maya Bernstein: We could expand on this a little bit I think about not just MOVEit impacted things but what exactly it did. Also, other people who are not new to the committee will know that I have a particular antipathy for the passive voice. I think it makes it punchier and more active if you say – instead of it was reported, I would say so and so reported that. But that is not something we need to do right now.

Valerie Watzlaf: Any other – there are more changes down below, I think.

Maya Bernstein: I was starting to work on the footnotes here. I suggested that we say a sentence about what it means to be working on the cloud. That is the kind of –

Valerie Watzlaf: I thought we did have that in. I guess we do not. We do not include that even

later.

Maya Bernstein: I do not see it. It assumes that we know what the cloud is, which is kind of a funny term. Basically, server farms that were out there.

Valerie Watzlaf: I know we mentioned or I mentioned, glossary of terms for some things, but do you think that would just be more difficult to do rather than just putting them right in the body?

Maya Bernstein: The committee could certainly put a glossary of terms. The problem is I do not know whether the group would agree on the terms easily and we have not really left time or we do not even have a draft of it yet. It is possible that among yourselves – competent, interesting, engaged people like yourselves may disagree about exactly what you mean by a particular term and how it is used. I am a little reluctant to suggest creating a glossary now if you want to be able to vote on this letter today or tomorrow.

Valerie Watzlaf: Lenel has his hand up.

Lenel James: I would recommend we not go down this road for terminology because when you get into definitions, we have a whole workgroup at HL7 that spends minutes and days and hours discussing what is the right way. There are many definitions for all these terms. This is going to a pretty sophisticated – I mean I know it is a global audience, but the letter is going to HHS. There are people that understand these terms and if there is any confusion, they will come back to us. I think we should just tackle the outliers because things like cloud and quantum computing, as Jamie said, there are definitions out there. Let us not worry about that unless someone raises that issue and then we can target it to the terms they are concerned about instead of the global list of terms we could come up with. As you said, Maya, that could end up with a lot of discussion on tweaking terms that I am not sure is very valuable use of our time.

Maya Bernstein: One thing I did not mention and Rebecca will correct me if I got this wrong, but usually we will pass a letter and it would go – I cannot remember if this is right. It goes to the Executive Subcommittee just to make sure that it aligned with what got decided at the Full Committee meeting.

Rebecca Hines: Only if they are substantive, something more than smoothing. Smoothing we can handle afterwards if no content is adjusted.

Maya Bernstein: If you wanted me to add a footnote with a definition and you think that might be controversial and all then maybe we would go back and have the Executive Subcommittee look at those footnotes to see whether the definition is really off or is subject to a lot of controversy. But otherwise, I would try to find some NIST, CISA, some reasonably agreed upon footnote to put and maybe for cloud, I would just stick it in a footnote rather than in the text as you wish. I am going to try to make edits that will conform to whatever the committee's goals/wishes are at this meeting and stick with –

Valerie Watzlaf: There is a good definition here of cloud computing from Steve we could possibly put in.

Rebecca Hines: I am going to send all this to Maya so she can put these in the footnote because you all need to keep going. You now have 25 minutes left and you are on page 5 of 12.

Valerie Watzlaf: Let us go to six. Are we hearing any changes on page 6?

Maya Bernstein: I am on page 6. I will clean some of this up where I said that we have a run-on sentence here and there is complicated – we will make it flow better.

Valerie Watzlaf: Then we went into network security, API security. Any changes? Too much jargon?

Maya Bernstein: I thought there were a lot of leaps here that would be difficult to follow for an educated layperson. I did not mean to call out my NCVHS colleagues. Like not everybody is a security expert here. We do have some. I am speaking from my own – I am not a technologist.

Valerie Watzlaf: Steve has his hand up. Go ahead, Steve.

Steve Wagner: We have a little discrepancy here. Application programming interfaces or application program interface, which we say in the next slide. One or the other.

Jacki Monson: I think defense and depth and layers of risk management – I see those as different things. Defense and depth from a security perspective is you have all kinds of different controls in place basically. They would have to break through all of them to get basically to the end game data systems, et cetera. I am not sure that I would call that risk management or layers of risk management. I think they are different.

And defense and depth is a super common terms in the security world. I guess I would prefer we just footnote it and define it and/or cite it.

Maya Bernstein: Where are you Jacki?

Jacki Monson: Right after network security, networks segmentation. We changed it to layers of risk management. It does not mean the same thing to me. I would prefer that we just call it defense and depth and then I can give you a citation. I will find one because I think NIST actually cites it and others, that are credible that we could cite too versus calling it layers of risk management.

Maya Bernstein: This used to say defense and depth with layers of risk management.

Jacki Monson: I would not correlate the two. I would call it defense and depth.

Maya Bernstein: That is not a term that everybody is going to know.

Jacki Monson: I know. It is a technical term, but it is the write term in the context of network segmentation.

Maya Bernstein: I am going to just drop a footnote here. Is this discussion – now we said security controls are critically important following on to the use of the term defense and depth. Does that make sense? It sort of fits the two.

Jacki Monson: They are the same thing. Defense and depth are layering security controls basically to protect your network, to protect – you want to have multiple ways and points of failure basically so that nobody can break it and get in and hack you. NIST actually has a

definition in 7622. I will send this to you.

Maya Bernstein: You just used a phrase that I missed. It was like multiple –

Jacki Monson: Layers.

Maya Bernstein: Layered security controls – layers of something.

Jacki Monson: Security controls.

Maya Bernstein: I am looking for something that explains what we just said, not to use the same phrase. Something like that is –

Jacki Monson: You could say network segmentation is one option where you are basically creating – you are creating layers to protect what I call it your crowned jewels, which is your electronic health record or your most important assets like active directory. And basically, you put number of security controls, privileged access. You have anti-malware, anti-virus, firewalls, all these different things that create the defense and depth.

Maya Bernstein: Is that phrase accurate or helpful or just too much or not?

Jacki Monson: I think it is fine and then I will send you the NIST citation.

Maya Bernstein: Okay. I will go back and ask you if I do not find it.

Now, we are on APIs. Someone – Steve, Michael, somebody pointed out –

Participant: Both of these are wrong. It should be application programming interface, singular, and then you can change the other one. And then change it in the first sentence.

Maya Bernstein: Programming interface, singular. Correct?

Participant: Correct.

Maya Bernstein: Okay. This is currently addressable. We say there are additional hazards but we do not say what. Jamie says they are explained. This is sort of reminding me to go smooth this over truthfully. I have shown you the markup, but do you want to look at simple markup? Is that easier at this point?

Valerie Watzlaf: I think this is fine because we have not seen these changes here. I think you can leave it. But if we are not hearing from anyone, I think we ought to keep moving because it is almost noon. I would really like to make sure we just get through everything just to see or maybe we could even – since we only have about 15 minutes left, does anyone have anything even in the original draft that you received where you wanted to make any changes on the rationale? Let us just keep going then. You might think of something as we walk through.

Maya Bernstein: Is your plan to take a vote now? Do you want to do it tomorrow? I have a little time overnight while you guys are discussing security.

Valerie Watzlaf: And we just vote right now on the recommendations. Is that correct?

Rebecca Hines: You can have two votes or one vote. You can vote on the whole letter, or you can vote on the recommendations or you can vote on them separately. It is your choice.

Maya Bernstein: The recommendations we need to do for sure.

Rebecca Hines: Normally, we do the letter as a whole. It does not look like we are going to have gotten all the way through it by 12:15.

Maya Bernstein: Let us see how we do.

Valerie Watzlaf: I think we can move on to the second recommendation there, which is very short.

Rebecca Hines: I do want to just say that members have had this for ten days. If there were any showstoppers, hopefully we would have heard from people. I do not know that we want to spend too much time wordsmithing. Obviously, you need to get the substance correct.

Valerie Watzlaf: We really did not receive any additional comments, major ones, I would say. Maybe we would like to take a vote on the letter and the recommendations together. Are we ready to do that?

Maya Bernstein: Take a look through the other recommendations. Remember that the bold language is going to match what you said before. Those are the only changes that I have made already. The rest of it – I had not gotten through the rest of the letter so there are not going to be anymore changes in here unless Jamie did something – all going to be the same letter that you have seen in the circulated book.

Valerie Watzlaf: Great. That makes it a little easier. Okay.

Maya Bernstein: I am still planning to go over it though.

Jacki Monson: I did not want to cut you guys off. I just wanted to -- feedback in general, perspective from members before we go too far down this road. Are people ready to vote? Would they like us to turn a draft with all these comments for tomorrow? What is the general feeling of the group? Silence is not an answer either.

Rebecca Hines: Tammy is the co-chair or the chair of Standards right now. What is your comfort level with the quality and content of the letter as it is?

Tammy Feenstra Banks: I really ask the rest of the members to give their perception. This is not my area of expertise. I am very confident with the recommendations and with Maya and the Privacy and Security Committee's composition. I am comfortable moving forward in any way with a vote or whatever the chair recommends.

Rebecca Hines: You have all seen this and this has not been edited since you have seen it. You saw up above what Maya does in terms of going through it. I think if you were to bring it to a vote, you would need to stipulate that no change to the wording of the recommendations and that the content would only be revised for smoothing purposes.

Jacki Monson: -- clarity.

Rich Landen: That seems to be our normal procedure. I think we have had a good discussion and chance to review. Assuming the informing edits are made throughout the document, I have no problem voting the whole package now.

Jacki Monson: Thank you.

Debra Strickland: Same with me. I read through it in advance, so I was ready to go and vote anyway.

Jacki Monson: Does anybody have any concerns that they have not already brought up?

Lenel James: This is Lenel. No concerns. Again, given the source of the original draft, I am comfortable with the content too.

Jacki Monson: Rebecca and Maya, just based on what I am hearing, my perspective is we can call for a vote.

Maya Bernstein: You are welcome to invite a motion as the chair.

Jacki Monson: Is there a motion?

Rich Landen: I will make the motion.

Maya Bernstein: State your motion.

Rich Landen: I move that we approve the letter and the recommendations with the changes to be made as discussed and documented by our diligent scribe and the review of the PCS leadership.

Jacki Monson: Is there a second?

Debra Strickland: Second.

Jacki Monson: I heard Deb first so we will call her second. All in favor, raise your hand.

Rebecca Hines: Please stop sharing your screen, Maya. I need to now track this. Thank you. Thirteen. We have unanimous approval of the letter based on the motion that Rich put forward. Congratulations.

Valerie Watzlaf: Thank you, everybody. We greatly appreciate all of your feedback and everybody's hard work on this. This was truly a group effort. Thank you so much.

Jacki Monson: Congratulation, and I think this calls for a break, Rebecca.

Rebecca Hines: That works for me, and I know we have some of our speakers on for the afternoon session. Stay logged in if you can. Just mute your camera and your video and we will see everyone back here at 12:59 Eastern.

(Break)

Rebecca Hines: Thank you, all, for making it back. We have a little extra time on the front end of

our little break there. Steve, Jamie, Michael – Steve Wagner, Jamie, Michael, if you want to turn on your camera when you are back so I know you are ready to go. It is 12:59. Tammy, when you are ready, you can start off our afternoon session here.

Tammy Feenstra Banks: Excellent. If you can bring the slides back up and just be prepared if you want to go to the first slide. The next three hours are going to information packed with crucial information to assist in committee discussions. The sessions are focused on enhancing the committee's understanding of the ONC and NSG's recent activities and potential collaborations, the status and current activity of standards and operating rule enforcement, how the SDOs assess benefits, readiness, and maturity to minimize risk of new and updated standards for nationwide implementation and certification while also maximizing business cost recovery. And also, we will have a review of the approaches used by the SDOs, the standards development organizations, and certification bodies to evaluate and assess the readiness of new and updated standards prior to release for the national implementation or certification.

Again, just as Rebecca said, I want to thank you, Steve, and thank the rest of the presenters for sharing your time and knowledge with the committee. We have new members and this is always an excellent way to get everybody up to speed on the activities across the departments. Thank you.

Steve Posnack from ONC will kick off the conversation from the certification perspective in the session evaluation and assessment of the readiness of new and updated standards. He will present for about 15 to 20 minutes, leaving time for committee Q&A. We are also going to have a Q&A at the end. If you are able to stay, that is great. But we just want to make sure to be conscious of your time.

Next is the National Standard Group, CMS, presenting today is Michael Cimmino, Daniel Kalwa, and Jami Lookabill. They will be sharing an update from the National Standards Group and also provide an update on their standards enforcement process and recent activity. They too will present 15 to 20 minutes, leaving time for committee Q&A.

Then Robert Bowman from CAQH will present the CAQH CORE operating rule enforcement process and recent activity for approximately 10 minutes, again leaving time for a little bit of Q&A if possible.

And we will hear from the SDOs. First up will be HL7 Dan Vreeman, then will come Margarat Weiker from NCPDP, and following will be X12 from Cathy Sheppard, who will be speaking. The SDOs – they were asked to focus on the primary areas that the committee is interested in. They were asked prior to the session, how does your SDO assess and report on backward capabilities, support the functionality and the impact across mandated standards, assess cost and value of changes within the standard, cost and value of the changes at the time expected to be implemented, and the cost and value of implementation of the standards in the cross-transaction environment where it will be used with other standards, and then also assess the potential risks and impacts of new and updated standards across – in the cross-transaction environment where it will be used with other standards.

We have CORE first. Steve, did you have slides? If you did not have slides, why don't –

Rebecca Hines: Steve does not have slides. I do not know why that is up. That is not the next –

Tammy Feenstra Banks: We are all good. Steve, very excited to have you here. Thank you and we look forward to hearing from you. Thank you, Steve.

Evaluation and Assessment of the Readiness of New and Updated Standards

Steve Posnack: Thanks very much, Tammy. I appreciate it. Hello to all of my NCVHS friends and colleagues. Lots of friendly faces and names in those squares. As was alluded to earlier, Steve Posnack from ONC, Office of National Coordinator for Health IT. I serve as our deputy national coordinator for Health IT. Now that we have gotten all of the titles and superlatives out of the way.

As Tammy just had on the slide and what you all prompted me to present to you all today without slides is a rundown of how we approach things from an ONC perspective. Obviously, with coordination in our middle name, it is both an activity that we lead with our regulatory hat on as well as work that we do with our partners out there in industry, yourselves included, as well as some of the SDOs that you got lined up later on. I will try not to steal too much of their thunder, but I think you will hear a lot of similar themes across the points that we discuss.

When it comes to looking at the – I will call it compatibility of standards and I try to not to use backward compatibility in some cases because I reflect with some personal experience that that is often misinterpreted and/or misapplied and in some cases, we are talking about what may be referred to as forward compatibility in some cases but it bogs down a lot of folks. I would say this is a quick reflection to look at the directionality of the compatibility in some cases based on how the standards are referenced.

I think you will hear from our colleagues leading the SDOs that a lot of times we look at the compatibility of standards relative to whether or not there are "breaking" changes and those would then affect the substantive work and industry efforts to go through and update infrastructure wise, standard performance wise to the specifications.

I thought would be helpful to do as part of my intro remarks and then leave a bunch of time for Q&A as well is to just talk through a few areas where we have direct roles or stewardship responsibilities associated with certain standards related efforts and then give you my take on some of those bullets that we teased up and unpack them as well from our perspective.

In no particular order, many of you may be familiar now with what we call the Interoperability Standards Advisory. I colloquially refer to it as the standards-opedia. Our 24/7, 365 kind of online representation of health IT operability use cases that exist, the standards that we have heard that we know that we have received feedback on that the industry is using. Over time, we try to provide some metadata associated with those standards to give folks a sense of – for each particular use case to which those standards are attributed, what kind of context do people put around those. That includes both the straight on listening of the use case and particular standards as well as any particular limitations or scoping that may be associated with those standards as well.

As you dig into the details there, I am happy to send you the links to some of this information offline. We talk about the standard process maturity and across the SDOs as again – sorry to my colleagues on the SDOs. They have different stages at which they rate or categorize their standards. Some of them maybe "final", fully validated and others may be considered invalid or draft standard for trial use or standards trial use, I should say now. STU is the new lingo in the

HL7 space. And then you may have some that are just under development. They are still kicking around in the various workgroups within the SDOs. There may be a current build of the implementation guide or the standard that is ongoing. But it is really more in that exploratory trial stage of work.

As you start to look at those standards and you pair them with what is the implementation maturity and this is largely any of the ones that have been valid in some form or another. We categorize them in the ISA as either a pilot or production. That is kind of getting a sense of at what scale and at what level of investment the industry is applying to those particular standards or implementation specifications.

A few other metadata that we consider include – we try to assess, which has probably been the most difficult over the many years is the adoption level. That is an imprecise science. And even though a standard may be widely adopted for a particular use case, it does not mean that it is widely adopted for every use case to which it could be applied because there may be other infrastructure or workflow or other dynamics that add into the full utility or use of that standard for a particular use case. And just caution I guess as you are thinking.

Even if a standard is widely deployed for one particular use case, it does not mean that it can always be considered widely deployed across all use cases that it may be considered.

One that we look at both across the board as a general participant in the standards space as well as a regulatory work include the cost and that may relate to needing to purchase license or otherwise obtain some type of membership to access the standards. Our experience has been generally across the health care space that that is not usually an impediment to folks accessing the specifications that they need to use but certainly a factor that we want people to be aware of in terms of different models that exist out there across SDOs and how that may affect the availability of a particular standard.

And lastly, as you all are well familiar with and certainly related to the HIPAA work that our colleagues from CMS lead and you all have as far as part of your charted purview, test tool availability. And this is something that is the other half of our certification program from a regulatory perspective. Not only do we go through the regulatory space to adopt new certification criteria that reference new standards performance requirements, we also support testing tools to do electronic testing, especially for transaction-oriented types of standards performance. As we populate the interoperability standard advisory we like to make sure that where there are resources available either ONC supported or provided or through other private sector stakeholders or collaborations that those test tools are available.

We find that where there accompanying testing components or infrastructure for specifications at any level, it makes a big difference in terms of I would say for lack of a better word, adoptability of those standards in addition to other ways in which the industry can leverage, steward, engage with the SDOs. And certainly, that will vary based on whether or not we are talking about terminology's code systems and that can kind of semantic level, and how those related standards are maintained over time and then comparison to more content exchange standards where there may be transaction-based syntax and syntactic level. That is kind of the interoperability standards advisory. It is a rough backdrop to talk about this.

Many of you are familiar with the United States Core Data for Interoperability and that focuses

on data elements, in particular. But there are some aspects of how we evaluate the data that I thought would be applicable to this conversation as well. Again, looking at the use case scope whether or not it is for a particular type of setting or a particular type of health care providers or health care use cases, whether or not the data elements are included within available transaction standards today or content exchange standards today as I should note. And then also look at the again use from a scale and scope perspective how many types of organizations are engaging with those data elements and exchanging them.

And then lastly, perhaps why you brought me here mostly relates to our certification program and the approach that we take through that. As I already alluded to, the work that we do through our certification program really comes to life through the regulatory process. As you may know, we have a single advisory committee now. In the past, we have had two advisory committees. Your sister agency in HHS, the Health IT Advisory Committee.

As we put together proposals for our next turn of the crank, the next cycle of our regulatory responsibilities, that is really where a lot of these questions that you posed are the rubber that hits the road. When it comes to looking at compatibility, when it comes to looking at the intersection of value proposition or business case, the new functionality requirements, the types of support that exists today versus what we are looking at in the future and understanding potential impacts and risks associated with adopting the newer versions of certain standards or a new standard all together for a particular use case. That is a lot of what we do and a lot of what the regulatory process as perhaps onerous or slow as it is. It is built for and meant to handle, and I think accommodate a lot of these challenges.

I think when it comes to the agency perspective, we are perhaps first out of the gate in doing all the behind-the-scenes work to get a first assessment of those various characteristics or criteria or factors that you noted you are interested in and putting those out as part of the public comment process in the regulation.

And many of you know if you are somewhat fluent in regulations, not only is there the section in the rules that deal with the proposals from a policy perspective, but we also include what are called regulatory impact analyses and that includes work efforts, industry impact, and that is from both a qualitative and quantitative perspective about the proposals that we have included in the rules. That also tees up opportunity for the public and advisory committee, such as yourselves, to weigh the tradeoffs associated with what we propose, which in our space and in the space that you work in, largely has to do with technology and standards updates. I just want to emphasize that the regulatory process is really one of the places to be and to influence this and where a lot of these analyses take place from a cycling and sequence perspective.

I would say just in closing here to keep to my time, one of the other partial answers to a lot of the questions that you all have noted is that there really is this intersection between business interest, policy interest and kind of the tech maturity and direction and where those align most across the three large categories. That is where we I would say see the least amount of friction in terms of getting progress to happen. In some cases, it is already happening organically. If we are crafting our regulatory policy correctly, that serves as an accelerant for the direction that the industry may be already going but provides again that kind of policy foundation, the push, and helps reinforce some of the business interest and business cases.

In other places, this is an intersecting juxtaposition in terms of the policy interest is there based

on the administration and what it is trying to tackle. There may be certain technical maturity that is good enough to put something forward and maybe you wrestle with what is good enough for policymaking, which is always a challenge that we face. That helps to align business interest where there may be some variation across industry and the regulatory process and the public comment process and the structure and the proposals helps to sharpen some direction for the industry to go in.

What I found in my experience in the regulatory work that we have done is that certainty is high – is a factor that our regulated community places a high premium on, as I elaborated on that more clearly now. When we get feedback and as we have engaged with you all and other advisory committees and certainly the health IT development community out there, it is less at times a concern about moving to a new version of a standard, a standard that may have breaking changes and more about the certainty that that is the direction and that it will not be make effort that the – in our case, the government will change at some point in the near future so that there is additional iterative cycles associated with that. It is kind of the pick and stick, if you have heard that saying before, in terms of moving in a direction where there is a little bit more change and there does need to be some greater tolerance for that change.

The other thing that I would note that I think you have seen both out of our colleagues over at CMS through NSG, over time as well as with ourselves is a new thing that I have been using recently, which is space and taste. As we look to make changes that may have more substantive impacts, giving space for those changes to be implemented and pacing them out over time. I think for those of you who have been around for the ICD-9 and 10 conversation, there was some space and pace changes that happened at the beginning and through the laying out a longer compliance period as well as iterative bumps to that deadline as well. But there is also some spacing in terms of sequencing the underlying the 5010 transitions before the ICD-10 transition as well. Looking at those things from a three to five-year, which is normally the regulatory mindset that I operate in, and looking at where things can be spaced and paced helps even when there are more substantive changes relative to the compatibility or other issues that they all have considered as well. Definitely worked closely, as I mentioned, with our colleagues at NSG and their leadership related to the HIPAA standards and modernization there.

Our certification program is obviously a little bit different and focused on other types of transaction standards largely in the clinical side. But I guess I will pause here and conclude my remarks in terms of leveraging the regulatory process as one important track and dimension and really where from an agency perspective we get the deepest feedback associated with the points and bullets that you raised. With that, I am happy to get shot with questions.

Tammy Feenstra Banks: Thanks, Steve. Again, really appreciate it. You gave us a wealth of information, so I am so glad that this is taped.

One thing that we are going to be going through later today and tomorrow is a scoping document as we are laying out that three- to five-year vision. And we would love to get your feedback as well as HITECH's feedback because I think there are going to be some areas of synergy moving forward.

But besides that, I really appreciate you bringing up the ICD-11 conversation and the need to really think about what is the time length going to look like so we do not have the 5010 ICD-10 at the same time. What is ONC's direction? I know you kind of talked about it high level. Are you

considering it? What kind of timeframe are you thinking? Can you just elaborate a little bit more on that importance?

Steve Posnack: Anything related to HIPAA Administrative Simplification standards, code systems, and transactions, I would largely defer it to the policy aspects that our colleagues over at CMS lead. That is a core responsibility for their shop. We follow along.

Just as when they made the transition, which occurred during the earlier stages of what used to be called meaningful use, we reflected those CMS policy changes in our certification program as the 9 to 10 transition became effective and compliance was required for ICD-10. We then reflected that in our certification program. Those are things that we work with them on internally in terms of timing, pacing, structure.

Regarding the overall industry aspects and ICD-11 shift, that would be best for them to discuss and cover as part of their remarks.

Tammy Feenstra Banks: Definitely. I was not trying to put you on the spot.

One of the things you were talking about is testing components, testing tools. What do you look for when you have a new standard coming in or even an updated standard? What makes it palatable to move forward?

Steve Posnack: The testing process really helps illuminate where implementers have different views and interpretations of written specifications. We experience that through the certification program on a weekly basis as best – and I want to thank all the volunteers out there – as best as the efforts that all of them place in writing the clear specifications as it sounded exactly on that day at a workgroup meeting when it goes into the hands of all the community out there and they implement and then they come forward.

When we build a testing tool, we make choices about what conformance means to the specification. And oftentimes like if it is an HL7 specification and as Dan can attest later, as we do FHIR testing for certification programs, there are specific choices that we make in terms of what will pass or fail the testing tool. In some cases where that is not clear to implementers, that is where we find out the ambiguity exists. There is this interesting feedback loop that I think is really important in terms of both how the testing process can help inform better standards, more agile standards development because oftentimes -- and this can be not necessarily changing the specifications at that point but providing more implementation guidance quicker as things go through that testing process even if industry-driven testing say the same benefit exists.

You get feedback on how we see that implementers are actually choosing three different pathways to meet the implementation guide this way. The test tool only lets people go through door number one in the past. Do we need to say that doors one, two, and three are acceptable or only one is really the intent from the workgroup in terms of how the implementation guide was developed.

As you all consider different types of standards, looking at industry availability of testing infrastructure is one thing I would continue to recommend.

Tammy Feenstra Banks: And just for clarity – I know that you are talking about the ONC – it is

called health IT certification now, the former EMR certification just for those on the call. Is there ever any conflict or multiple standards that have to be reviewed when you are making your selection process because I know we are looking more at APIs versus the more legacy types of standards? Can you elaborate on any of that?

Steve Posnack: This is always a dilemma or a challenge in the space in which we operate. It goes across the different standard layers that may exist. Where we have had this in the past and I am sorry to bring this up in case it gives anyone flashbacks. At the content exchange level, I think we take for granted nowadays that industry came together and aligned on a single summary care record standard. But in the past, it was not like that in the beginning, and you had different kinds of flavors of summary care records.

We made an informed choice at the beginning of meaningful use stage one as part of our certification program health IT to allow two different standards. Not to make it in a bake-off situation but more to reflect the current variability that exists in an industry and that there were best fit choices for using one or the other standard in certain cases. And certainly, as you make transitions, that may be important to consider as well especially consider our ecosystem. If there is something – a transition being considered or other use cases that may be more FHIR oriented versus X12 oriented. Giving due considerations to where both of them can coexist until the industry makes a tipping point decision about which direction it wants to go in, seems to be a necessary transition step at some places along our road and that is on a decade-long road or a two decade-long road or a two decade long road. I haven't been in healthcare long enough to say. It is like I have seen these things evolve over ten years where at the beginning, there is a lot of consternation and fist wringing about two different standards. But in a lot of cases, there are valid reasons for use of either one. Most of the time it boils down to two standards, as we have seen in other industries like VHS and Beta and Blu-Ray DVD and HD-DVD. Eventually, other correlated factors shift the industry to move to one direction or the other. In some cases, it would be using case specific.

I would say perhaps not to get too cliché like two standards sometimes is not a bad thing to allow for the industry to have flexibility and move in a transitional way so long as if there is work to provide certainty, provide clarity when one standard may be the better choice than another and to start to evaluate where there needs to potentially be resolution or convergence to a single standard approach for certain use cases. I am getting long winded in my answer here. That is kind of the stream of consciousness associated with multiple standards.

The one thing for those of you that remember our colleagues at a number of different advisory committees, Wes Richelle(ph.). He is perhaps famous for one of these things, which is bilateral asynchronous cut over, which means as nerdy as it sounds, I have to sneak that in. Hopefully, this makes some of you laugh. Understanding that when we move from one standard to another even if it is a different version of the same standard kind of flavor, you have to accommodate those transitions and you have to accommodate that – to use the baseball metaphor here. Pitchers may be on version one and catchers may be on version two or vice versa or that across the community, some proportion of the senders, the pitchers will be on the new version and some will still be on the old version while others are on the receiving side or vice versa, again, on old and new versions.

That type of understanding also applies when you look at shifting from one standard approach to another standard approach across SDOs. And all those things have to be handled. If they

come through the regulatory process, that is where we can again to use my saying earlier, space and pace, the transition. If we had standards A and B at the beginning, maybe that is allowed for the first three years and then standard B will be required thereafter. It would give the industry a way to slowly transition off standard A and move on to standard B.

Tammy Feenstra Banks: One other question, and I know I have been rude and not let the other members have –

Steve Posnack: I thought they were feeding you all the questions.

Tammy Feenstra Banks: I know. I just love pulling information out of you. Do you require any type of materials to prove that the standard is worth reviewing whether it be testing criteria, analysis – what do you require before you can actually take a look at it for national-wide implementation?

Steve Posnack: A lot of that is our engagement with the community especially if we are going through the kind of regulatory process. That includes participation in the various SDOs that you hear from, doing fact finding and other research with our industry partners.

For those of you that are well familiar with the regulatory process, we do not normally disclose what exactly we are going to propose ahead of when we release the proposed rule. There is a little bit of that timing and behind the scenes action. But we definitely engage the community, get an understanding of where things are and how they could be applied associated with their potential use.

The other one thing I would just note – at times and this is an interesting paradox in our space, we hear feedback that in order for the industry to move, they need to see something referenced in regulations. It kind of creates this chicken and egg situation where the standard would certainly have more adoption because then everyone would take it seriously if CMS or ONC or pick your agency put it in a proposed regulation that would focus everyone's attention and then create the momentum for adoption that otherwise does not exist. That is just a general challenge that we face in our space.

I think we are seeing a lot now where there is more organic growth through initiatives like Da Vinci and a few others where the industry stakeholders are pushing forward certain activities to get ahead of where our regulatory updates could ultimately be.

Tammy Feenstra Banks: Excellent. I know we are running a little over time but I do want to say is there anything I missed, members of the Full Committee, that you would like to get a question in because I do not know, Steve, if you are able to stay longer today. I hope you are but I want to make sure.

Steve Posnack: I wish I could but I have other schedules. I am happy to come back another time.

Tammy Feenstra Banks: You are so much fun though. Any other questions that anybody has? Going once, going twice. Again, Steve, please, really appreciate your time and the ability to learn from all the good work that you guys have done. I hope that you will be able to provide some feedback on that scoping document that we will be looking at later on today. Again, thank you and you take care.

Lenel James: Alright, everybody. We are going to move forward and talk with the National Standards Group. Michael, the floor is yours to get started and share some interesting updates I am sure you have. Thank you.

Update from National Standards Group

Michael Cimmino: Thank you, Lenel. Thank you, everyone, and good afternoon. I am Michael Cimmino, director for the National Standards Group at CMS. I want to talk briefly today about the work and the priorities that NSG is pursuing and then I will hand things over to my colleagues to provide an overview of our enforcement work.

Before I go into my remarks, Tammy, I know you mentioned the scoping document. I think the plan is to review that later today. I just wanted to add that while we have not yet had an opportunity to review it closely, we do appreciate it being shared with us and we look forward to being able to provide our feedback and comments and working with the committee so that work aligns with our priorities.

Participant: You beat me to the punch. Thank you.

Michael Cimmino: We definitely will share our feedback with you all on that once we have a chance to look at that closely.

The first area that I want to discuss is our regulatory work. I know many of you are aware of the comment periods for our proposed rule adopting updated retail pharmacy standards and our proposed rule to adopt standards for health care attachments have closed. And NSG is currently reviewing the comments for both of those rules.

Specifically, regarding the rule on attachments, we are reviewing comments received and will consider those as the final rule is developed. But I did want to acknowledge commenters' concerns regarding the proposed rule and potential conflicts with other rules that contain policies pertaining to prior authorization.

And then also on the horizon around our regulatory work, given the latest recommendation from NCVHS to adopt certain CAQH CORE operating rules, NSG anticipates to engage very soon, in rulemaking that likely will propose to adopt updated operating rules for the eligibility claims status and the remittance advice transactions.

And then next, I wanted to address actually the June non-recommendation of 8020 and update to the claims of remittance advice transactions. Specifically, in regard to Version 8020, as regulators are responsibility for adopting and enforcing HIPAA admin simp transaction standards, NSG is carefully reviewing all comments and evidence that is available to us around 8020. We will continue to discuss the viability of adopting the new versions of the claims and remittance advice transactions, including seeking input from industry.

In addition, we are exploring our options regarding a path forward, including potential rulemaking that serves to support the purposes of HIPAA administrative simplification.

And then I also – I know there is a lot of buzz around ICD-11, so I wanted to talk briefly about that. Really, I would like to remind the public about the HIPAA standards and code set adoption process and the steps that are included in that process. The process is directed by statute and

regulation and broadly takes into account a variety of factors that the secretary must consider as well as a formal recommendation, which takes into account sufficient public input.

At this time, NSG has minimal indication from stakeholders on the need, interest, or readiness for the adoption of ICD-11, including to date no request to consider a modification of the standards for code set being submitted to NCVHS or to the secretary for consideration.

With that said, I would like just to caution the public against categorically prioritizing ICD-11 over maybe other long-awaited and important enhancements to the HIPAA transactions.

And then something I think that Steve reiterated too, is we need to think about and we need to ensure that we do not have a repeat of some of the technical problems the industry experienced with the attempted and concurrent implementation of 5010 and ICD-10. I know when the time arrives, the timing and coordination will be very important.

And then finally, with ICD-10, the coordination, communication, and implementation strategy for an updated code set will be overseen by HHS when the Secretary makes the decision to accept a recommendation for its adoption.

And then the last thing and I will be brief, I wanted to just mention what we have called our HIPAA modernization efforts. As many of you know from just our recent engagements, NSG is currently working to modernize the standards development and adoption process. We foresee our efforts moving forward over the next few years and gradually tackling an aging process that no longer meets stakeholder needs. We envision a new process that prioritizes not only a faster channel to get updated standards implemented but also a way to evaluate standards more effectively and earlier on in the process. We will continue to seek your input and your feedback as we work through those efforts.

Thank you for letting me just run through those quickly and then I will hand things over to my deputy director, Daniel Kalwa and Jami Lookabill, from our enforcement team and they will provide some information on our enforcement efforts.

Daniel Kalwa: Good afternoon, everyone. It is good to see you all again. I think I have been here several times to speak to some of you, but I might be new to others. My name is Dan Kalwa and I am the deputy director of the National Standards Group.

We are going to go through somewhat quickly of just a quick overview of what our enforcement process looks like under HIPAA Administrative Simplification. And then my colleague, Jami, will go through some of the more specifics of our process. My job today is just to go over some of the basics and maybe point out some food for thought for the committee as they consider how to interact with enforcement and what it really means.

The first and probably the most important to note is that our authority and the Office for Civil Rights authority both exist in a legal construct under HIPAA Administrative Simplification, but our sphere of effort and action is very much separated. When I am talking about enforcement and any sort of compliance actions today in this, I am only talking about the National Standards Group's activities for enforcing and bringing into compliance rules for things like the electronic transactions, the operating rules, the code sets, and identifiers. Those are what we are responsible for.

Any complaints or compliance issues or breeches of the security and privacy requirements should go to OCR. We do communicate across our organization. If something goes to the wrong place, it does get moved. But it can save you some time and a little bit of confusion to think about those two processes separately.

There are two on our side for the National Standards Group, enforcing HIPAA Administrative Simplification, that we are responsible for. We essentially have two lines of business in that regard. First is responding to complaints about non-compliance. And in that case, that is any entity anywhere in the nation that is interacting with one of our covered entities is able to submit a complaint, which we will then review and then consider acting upon.

The other avenue is proactive compliance reviews wherein we, that is NSG, randomly select different covered entities and then we require them to produce evidence and go through a testing process that ensures compliance with the standard transactions.

I think it is important to note here that our purpose for both investigating complaints when we choose to do so and for conducting these proactive compliance reviews is to ensure compliance with the HIPAA transactions, code sets, and operating rules and unique identifiers.

We may sometimes find ourselves in the middle of things like business disputes or contractional disagreements regarding things like payment or other activities, for example, a particular health plan's covered requirement. We do not involve ourselves as part of the HIPAA enforcement process in those discussions. Our only goal and you will notice as Jamie talks about the specifics of how we approach it is to resolve to our satisfaction as representatives of the secretary that compliance has been achieved and that the entity is in fact compliant.

It is also important to consider as you are considering how we conduct our compliance efforts and how we conduct our complaint review efforts is that we have authority only over the covered entities. Those are the health care providers that conduct electronic transactions, health plans, and clearinghouses. I know there has been some confusion in industry about the role of business associates and requirements for compliance with the business associates. You may recall – I think it is two years ago now – we released some guidance on that topic. It is probably worth reiterating now. It is the covered entities' responsibility to ensure that their business associates are in compliance with HIPAA. If we get a complaint regarding an entity that is more properly considered a business associate, we will in fact investigate long enough to determine who the health plan or the health care provider is that is contracting with that business associate to conduct HIPAA activities on their behalf.

I believe this is the part where Jami will jump in and she will take us through specifically the process of how we consider complaints and as well as the process for how compliance reviews are conducted.

Jami Lookabill: Hi. Good afternoon. Thank you, Dan, for those very valid points to frame the conversation. I will go into a bit more specificity as I move through the practical, I will call them life cycles, if you will, both a complaint and a compliance review, which are outlined in the next two slides. We will be starting with complaints. It is important to note, as Dan said previously, that anyone can file a complaint. That does not mean that each complaint will necessarily end up in a corrective action plan as demonstrated in this workflow. There are a variety of different stages of analysis that I am about to walk through. But it is important to note that indeed

anyone can file a complaint. Now the subject of a complaint is a bit more limited, but I will touch on that as we move through.

Firstly, let us talk about the intake phase. During this particular phase, this is after a complaint has been filed. NSG and I am part of the enforcement team and NSG. NSG will review and assess the complaint. And what that means is the complaint on its face represents noncompliance. It is within our purview to investigate and implicate HIPAA transactional requirements or if there is a violation of an operating rule, et cetera. The initial analysis is on its face, is this something that implicates our authority.

This can be fairly in depth. It typically requires some form of regulatory application and technical analysis. However, we are not always able to answer that question with the information that is provided. It can be quite limited and there may be a need to correspond with the complainant themselves to get additional clarification or information nearly to determine whether the particular complainant and the compliance, which is represented in the allegations of the complaint, are within our purview.

At this point, we are not asking the complainant to prove anything or prove their case or mount an evidentiary proof. That is merely where we are in the intake process.

It may be that we are unable basically to determine that this triggers our authority. We may reach out to the complainant. It may not trigger our authority. We do get complaints that are completely out of scope. As Dan mentioned, much of it is a misunderstanding of the particular type of HIPAA noncompliance, which we and NSG are enforcing.

At that stage, we would indeed be closing the complaint and we would send that notification to the complainant. Sometimes it is in, as Dan mentioned – we need to get additional information related to who the subject – we call them the filed against entity, the FAE, who that is because oftentimes we do find that complaints are filed against business associates. As Dan mentioned, that is not something that we have the authority over so we will find the particular health planner or what have you, the covered entity who is appropriate. We need to engage with a complainant in order to determine that.

At that stage, we will move beyond the intake. Let us say that on its face, we are accepting it for investigation and we are engaging in the contact phase. We will notify the complainant that we have accepted the investigation. I am walking through a more practical application right of the workload. We are going to accept the complaint, send a notification letter to the complainant. We are also going to send a notification letter to the FAE themselves. In that notification letter, we will detail the allegations and the non-compliance, which has been alleged. We will ask that the FAE responds to our initial notice. Within that notice, there are really three avenues for response and we ask that we receive that within 30 days.

And the first would be that this notice and the details within, the FAE could say this is untrue. This is inaccurate. And while they may not end the conversation and we may need to continue to engage with that FAE, that is a response that we receive and sometimes it is a valid response and we are able to close based upon that response from the FAE and some evidentiary showing of such.

Secondarily, sometimes the FAE will say we have rectified this issue. We have corrected the noncompliance. We are no longer engaging in these acts or omissions, described in your

allegations and they would provide documentation to show that indeed that noncompliance is not ongoing.

And then thirdly, the FAE can say this indeed is occurring and we will engage with them to put into place a corrective action plan, which we and NSG will review and approve and then we will proceed through monitoring in phase 4 here in the graphic, monitoring that cap. The length of time that a particular cap may be in place could vary based upon the facts and circumstances so whatever the noncompliance is that needs to be rectified indeed the cap could last a significant period of time if necessary.

In the CAP phase, we are monitoring it and then hopefully , on the happy path we are moving towards the resolution phase. Now, I want to pause for a moment and notate that there are several graphics within this slide that say that we are engaging with the complainant and may imply that indeed we are asking for their concurrence with the cap itself or when we move to the resolution phase whatever the end result is and that, as Dan mentioned, is not how we approach complaints indeed. We are the regulators and we evaluate complaints through the lens of resolving the noncompliance to the secretary's satisfaction. There may be stages throughout various points where we need to engage with the complainant either to get additional information or indeed in the rare circumstance, we may need them to weigh in at the end of the investigation or the end of the cap to show that indeed that noncompliance has been rectified.

But at the end of the day, we are moving to the resolution phase, not based upon a complainant's rights, concurrence on the actions, which have occurred in the investigation and the subsequent right steps that have been taken. I just wanted to flag that for everyone, and Dan already forecasted that as well.

At the resolution phase, the FAE is – we are at the end of a cap if you will. Sometimes it is not as – a formal cap does not need to be put into place, but we have sufficient documentation to demonstrate the noncompliance rate has been rectified. We ask for that proof. We do a regulatory and technical analysis of that. We do verify that.

At that time, we say this is satisfactory. We move to the closure phase and at the closure phase, we will send notifications to both the FAE and to the complainants. This will be our formal notification back to the complainant that indeed we are closing the investigation. There will be information within that notice as to what has occurred in the investigation, what the FAE has put into place to rectify it, and we will send those notifications out for closure. That is in a nutshell the life cycle of a complainant.

We can move to the next slide and talk about compliance reviews and the difference between a complaint and a compliance review. As Dan mentioned, we have the authority to conduct these assessments and carry out these compliance review activities on behalf of HHS. The purpose of conducting the compliance reviews is really to determine if corrective action is necessary and to assist covered entities in identifying vulnerabilities or identifying areas for improvement in policies and procedures, et cetera, but also to identify areas that may be needed for education and outreach, even future development or revision of standards or operating rules. There are a multitude of reasons why compliance reviews are really valuable.

I do want to note that the program was launched in April of 2019, but I wanted to give that

background of what the purpose of these compliance reviews are and the age of the program itself.

But as I did with complaints, let us walk through the practical aspects of a compliance review. Similar in a way to complaints; however, the initial phase is not generated by a complainant and CMS selecting an entity for review and then contacting that entity, which entails identifying points of contact, which will be responsible for the compliance review. Oftentimes that may be a complaint officer, or we engage with legal counsel in order to facilitate the review itself.

Then after we have identified that point of contact and we have sent some initial notices related to the compliance review, we would move into the submission phase where we will be providing these contacts with instructions and resources so that they may submit their transaction files or their required artefacts. We typically ask that they do that within 30 days – extenuating circumstances exist or sometimes it can be a heavy lift and it takes a bit longer.

But once we are in receipt of that information, we review the information and we conduct transaction testing typically within 30 days. It may take additional time. We may need to consult other bodies such as X12, et cetera.

After the transaction testing if indeed perhaps there is no need for corrective action but if there is, then the entity would be responsible for executing it. That corrective action could vary in duration based upon the facts and circumstances such as the number of transactions, the types of transactions, the types of technical fixes that could be required. But the entity would be responsible for executing whatever needs to be done to rectify that noncompliance, which has been identified by CMS.

Once that is complete, we would approve the actions, which were undertaken in the validation phase. As I stated, if indeed there is no corrective action, we would not be in the corrective action, the cap, if you will, phase. We will notify the entity that they are either in compliance or no corrective action is required and close the review.

That was a little bit swifter but we can move to the next slide, which is a general resources slide.

Daniel Kalwa: Could we go ahead and just let the committee take a look at this at their leisure. I think there are some interesting questions and we are almost out of time.

Jami Lookabill: Yes. I do want to flag if you have any interest in the compliance review program findings, there are documents on – that you can find at these links and they will let you know the common transactions, et cetera.

Lenel James: Great. Let me start with a question that I am aware of from several on the group, which is that Jami and Daniel, what are the statistics? How many complaints have you gotten and how many have gotten actually cleared through this process in general? I am not looking for exact numbers but want to have a sense of how many have gone through this process you are talking about and resolved it appropriately. Any statistics you can share?

Jami Lookabill: I do not have those numbers offhand. It is certainly something that I could obtain but I do not have them offhand. Dan, I do not know if you know a roundabout number that we could provide.

Daniel Kalwa: I would not want to quote any numbers, but I can say generally, with our current process, we are resolving complaints fairly quickly and we have gone very far into reducing or eliminating the idea of any backlog in our complaint process.

Jami Lookabill: In terms of submission, I would say we are averaging every week maybe one or two submissions and not all of those go through the valid path, if you will. They are often deemed invalid.

Lenel James: Let me open it up to see for the rest of the commissioners if there are any questions for Michael or Daniel or Jami. Raise you hand and we will recognize you. If you do not have any questions, we are going to get done on time. There is Tammy.

Tammy Feenstra Banks: Michael, I do not have to give the plug because I was going to ask you to please review that scoping document because we really value your feedback and value your partnership as we review a lot of these issues that were all under HIPAA.

I just had one statement and one question. The first question is could you discuss your perspectives on the X12 request 2 that came in as Version 8030 I believe for premium – that set, the claim status and then I forgot the other one.

Michael Cimmino: I think with 8030, as I mentioned, we are working right now on the process, the review process, evaluation process. What I would say in regard to that is let us continue that work and as soon as we can, we can communicate any updates regarding that particular version.

Tammy Feenstra Banks: Thank you, Michael.

And then I just want to mention on the ICD-11 comment, obviously, nothing is in regulation or being proposed for regulation, but I do want to have the members of the public as well as the committee members be aware of the ICD-11 workgroup report out tomorrow where there is a lot of review and analysis that is occurring in regard to ICD-11. Please stay and jump on that call tomorrow.

Jamie, is there anything you would like to add as a promo?

Jamie Ferguson: No. I would say we are not – the committee has not made any recommendations about ICD-11 but based on the timeline of the workgroup. The workgroup is serving the committee by gathering the information that the committee will need in order to make those recommendations. I think we can look forward to the results of our RFI that is currently open for comment. We will have those results back in January. The workgroup will be able to analyze those and hopefully we will be able to equip the committee to make recommendations about adoption of ICD-11 maybe next year. It would have to be part of any planning beyond that timeline.

Michael Cimmino: I just want to add that we do appreciate the work that the committee has decided to undertake around ICD-11. It is obviously separate from our work in the policy right now. We are not yet engaged on that effort. From a policy analysis perspective at least, we do appreciate the work that you are doing.

Lenel James: I think we have another question. Go ahead.

Wu Xu: This question is for Michael. You mentioned – I want you to explain a little bit more – you mentioned currently that they have low interest in adoption. You mentioned there's no request you received. You mean what is your source to assess this low interest.

Michael Cimmino: Just that. I do not think we have really heard much from stakeholders and from industry at all at this point. I assume you are referring to ICD-11. I do not think we have heard much at all from them at this point on again as I said the need. What is the need behind making that move and who is getting value from that?

Wu Xu: Thank you.

Lenel James: Tammy, I turn it back to you.

Tammy Feenstra Banks: Just one last quick question. I think it is for Dan and Jami in regard to the enforcement. On our last – the testimonies that we heard in regard to CAQH CORE or in X12 where really voiced a lot of concern about the compliance of those standards. I will not elaborate on that. But do you feel that the enforcement process has been effective? Is there anything that is needed that can make it more effective? I know there is no monetary penalty similar to the privacy and security. Again, I am not saying there should be or should not be. But do you have any insight on what can be done to alleviate all the concerns that we are hearing in regard to the enforcement process?

Michael Cimmino: I think, Tammy, I would say, one, I think we have been very successful. We have had extraordinary success just in our education process, explaining to complainants exactly what they can actually expect and what a reasonable outcome might be.

One of the reasons both Jami and I brought up to the committee and others listening is to make sure everyone understands that even though it is called the complaint process, it is complaints about HIPAA compliance. Sometimes in that shorthand, people forget that other sorts of complaints are just not in our purview. But for those that have been in our purview, we work with multiple business associates and countless health plans at this point to resolve just those sorts of concerns that you have heard about before and it is at least from our point of view, many of the business associates now have compliance solutions and it is just a matter of ensuring they are applied appropriately.

Tammy Feenstra Banks: Thanks, Daniel. I appreciate that and I know that you presented the overview at WEDI. You presented it here and I will just leave the plug is those who have testified or those who are on the call to spread the word to make sure that if there are any challenges within the exchange of information with the HIPAA standard transactions to make sure that enforcement process continues to be publicly disclosed.

Daniel Kalwa: I just wanted to mention very quickly, just because I know CAQH is right behind us. I believe they are also looking at updating the operating rules regarding enrollment and some other items that have been consistent concerns –

Michael Cimmino: I was just going to add that I think the process – I agree with Dan. The process has been successful so far. But we are always looking at ways to make it more impactful and it is something that we are looking at as part of that modernization work that I mentioned earlier.

Lenel James: For the sake of time, we are going to move on and I want to bring up Bob Bowman

to talk about CAQH CORE. Great timing.

CAQH CORE Operating Rule Enforcement Process and Recent Activity

Bob Bowman: Thank you. I would like to thank you, Lenel, as well, and the committee for the time this afternoon for a quick presentation on the CORE certification enforcement process that we have.

There was mention that there were several new members of the committee on today's session. I wanted to give you a little background of who we are. On the next slide, you will see that CORE is really a committee on operating rules that are made up of over 100 different entities across the industry that have come together, build consensus-based operating rules, that help develop and drive interoperability again through both technology and data content.

We have been federally designated as the National Operating Rule Authorizing Entity by HHS and ten of our operating rules are currently mandated under HIPAA. Those entities that pool together all of their industry knowledge and develop the operating rules, help us drive cost savings throughout the industry as well as many of them pursue CORE certification. And to date, we have over 400 CORE certification seals that have been awarded to health plans, vendors, and clearinghouse organizations.

On the next slide, you will see many of the organizations that make up the body of CORE. There you will see many of the organizations that participate in CORE and help drive the development of the operating rules. Between the government and health plans and the integrated health plan and providers, over 75 percent of American covered lives are parts of that discussion. It is really important for us at CORE that we have the different perspectives. You will see this kind of over and over again between health plans, vendors, and clearinghouses and providers those four key stakeholder groups that help develop the operating rules.

On the next slide, you will see that there are very specific requirements for CORE certification. Any organization that creates, transmits, or uses the health care administrative or financial transaction can become CORE certified if we have a rule for it.

Part of that certification requires the entity to abide by the certification policies and we have a set of those. You have to adopt the CORE operating rules within your systems, within your applications, within the way that you conduct and transmit data. You have to pass the CORE certification conformance testing program. You also attest that you will be in compliance with HIPAA.

Many of the organizations require to become or if you are seeking certification perhaps as a health plan, you may have many of your trading partners will also have to be certified before you can achieve your own certification. We look at national health plans that require the use of a particular clearinghouse. The clearinghouse and the health plan would have to achieve certification before the health plan could achieve certification. It helps to ensure and in that work, a system is built across the country for that data exchange model.

On the next slide, you will see that we do have specific requirements for enforcement. Those ensure and part of the process that we have developed as a body, is to ensure that the industry itself can monitor, regulate, and correct itself. We do have very specific ways of doing that. We will go through that process in just a moment. But this helps to ensure that the industry can

avoid any penalties and prepare for enforcement audits. We heard both Dan Kalwa and Jami Lookabill mention the audits that CMS completes. Becoming CORE certified helps ensure that those audits are not as trial as they could possibly be for you.

Again, it is a progressive and collaborative approach. We do require industry to work together. Again, that is our mission and vision really is to build consensus around the processes that we have within the industry. We do ensure that we work together as industry for any sort of enforcement complaints or issues.

On the next slide, on slide 6, you will see that we do have a very specific process. Who can file a complaint? Most of our complaints do originate from a provider or provider-facing vendor because they are at the end of that data exchange model in most cases. We do receive most of our complaints from providers or provider-facing vendors. That any organization, just as Dan mentioned for CMS – any entity within the data exchange model can file a complaint. Vendors, clearinghouses, and health plans can also file complaints. We just do not have very many from those organizations.

We have had three organizations over the last three years file full complaints that did require the complete remediation process. That remediation process is outlined on the next slide. In just a few steps, we do have to ensure that the entity is CORE certified so it has to be a CORE-certified entity that you are complaining about, the provider is complaint about a CORE-certified entity so we do list all of our certifications on our website so you can track them and we can help you with that as well.

An entity must work first initially privately between the two organizations so perhaps a provider organization and a clearinghouse or the provider and the health plan. The provider has determined that they are not receiving the data or they are not able to exchange the data according to the operating rules. There is an enforcement letter that we post on our site that the provider can complete and share that with the entity that they think is in nonconformance and they can work that out between the two of them.

If that does not happen to the provider's satisfaction, they can then move forward with documenting instances of nonconformance. CORE does require five instances of nonconformance to be completed and attached to the request for review for possible nonconformance. That form will be sent to us along with the examples and then we will initiate the process of working with both the initial complaint as well as who they are complaining against, who they filed a complaint against.

We coordinate and collaborate to help identify the issue in determining litigation steps. We establish milestones to resolve any technical or data content issues that have been identified in the complaint between the three organizations or four, be it a provider, a clearinghouse, and a health plan, for example, and help resolve that issue. We, CORE, take it upon ourselves to actually act as the facilitator and ensure that steps are made, litigation plans developed and it is processed through, milestones are met, reporting back to the provider or the formal complainant whoever initiated that complaint and is completely resolved.

If, however, the trading partner or the health plan in many examples is unable to or refuses to comply with the mitigation plan and milestones that have been developed, CORE can revoke their certification seal. You would lose your seal and you would have to go through the entire

certification process again in the future if they wish to obtain that seal beginning at the very beginning of the process. There are no short cuts to receiving the certification seal.

Again, all of this is pertinent to the industry because we are trying to ensure that both the technology that is available for providers to submit data and the data that they need to operate is available at the health plan. They can receive that data according to the operating rules. Again, most of our operating rules require real-time data exchange. Specific data must come back for the provider to conduct their transactions and operate and facilitate better health care for the members and patients.

With that, we do have another final slide just with some resources that are mentioned here on the presentation. With that, I will hand the call back over to Mr. James for any questions.

Lenel James: Thanks, Bob. For the sake of time, I am going to turn it over to Deb Strickland and Steve and then we are going to have all the questions at the end before the break. Thank you. Deb, Steve, and then hang on, Bob. This question is for you. They will come.

Debra Strickland: Thank you so much, Lenel. The next panel we are going to start with HL7, Dan Vreeman. Thank you.

Assessing New and Updated Standard's Business Value and Technical Risk Across Standards

Dan Vreeman: Hello, everyone. I wonder if you might be able to pull up the slides for my set. Standards that get used get better. This idea inspired by late Dr. Lindberg is one of the ideas I think about often. A world-class standard is one with world-class use. Becoming a world-class standard is a process that requires ongoing evolution and feedback from implementers. On behalf of HL7, international members, we thank you for the opportunity to participate in this panel. I am Dan Vreeman. I serve as HL7's chief standards development officer.

Steve cued this up a little bit but to set the stage for discussing a risk and value of standards updates, let me start with how we think about backwards and forwards compatibility. Our focus is on the compatibility of data instances. We think of forwards compatibility as content that is conformant to an old release, remaining conformant with future versions of a standard. When a HL7 spec reaches a high maturity, our standard development rules are designed to enforce that forward compatibility by limiting what kinds of changes are allowed in subsequent versions.

Backwards compatibility means that they have instances created against a newer version of the spec will interoperate with older versions. And this kind of compatibility is a little bit more brittle. For example, adding a new optional new element to a new version is going to affect backward compatibility or it may. Our rules might allow this if it addresses an implemented need and does not alter existing data's meaning. Thus, our standards like FHIR provide advice to implementers and how they can maximize their software backwards compatibility.

In order to help reflect the degree of consensus review and stability that a standard has, we give it a level and the main levels we assign at HL7 are shown here with normative being content that has had rigorous review under the ANSI standard development process and is considered stable. There are now strict rules in place about what can and cannot change in future versions, provide assurances to implementers.

Trial use is content that has been well reviewed and considered ready for production use.

However, it might not have seen widespread use across the full spectrum of intended environments. Future versions may introduce breaking changes.

Now, our FHIR standard introduced a novel, maturity-level framework that we actually applied to each artefact in the specification. We call this maturity level FMM and it allows implementers to judge how advanced and therefore how stable an artefact is.

On the next slide, I have shown here a summary of the progressively rigorous FMM levels. I want to underscore two key things here. First is that the maturity level is strongly related to stability. Higher maturity means more controls to restrict breaking changes.

Second, assigning this maturity level is influenced by the degree of testing and implementation. For example, at FMM 4, the artefact is considered stable enough to require community consultation for subsequent breaking changes. Getting to FMM 5 adds the requirement of demonstrated implementation in at least five independent systems in more than one country. Once an artefact reaches FMM 6, further change is restricted by introversion change rules.

To illustrate the progressive maturation of artefacts in FHIR across this release history, on the next slide I show here this colorful graphic. Here, each row represents a FHIR release from DSTU published back in 2015, to release five, published earlier this year.

Each cell represents a FHIR resource artifact and it is color coded FMM level. Over time, you see progressive maturation that is driven by implementer testing, feedback, and deployments. As we look ahead to FHIR's next version based on the industry feedback we received, we are intentionally focusing on stability. FHIR release 6 is establishing a broad core of clinical resources at the normative maturity level. We are seeking additional industry input on this approach through a market survey that is coming out soon.

On the next slide, I illustrate here for you how HL7 is dedicated to creating a virtuous cycle of standards development and implementation. Two years ago, we launched the HL7's standards implementation division to focus on closing the gap between having a specification published and actually implementing it.

One key technique for closing that gap is testing. We are subject to HL7 specification testing both before and after publication. Testing events are called connect-a-thons and implementation-a-thons throughout the year.

We also invest heavily in developing software for validating both our specifications and data that conforms to them to make these tools available for everyone under permissive, open-source licenses. We closely coordinate with the ONC as they develop related tools like Inferno and a C-CDA Scorecard.

On the next slide, you will see here an example, validator.fhir.org, a public web interface to our validation tool set. Of course, you can run these tools locally or embed them in cloud pipelines and this validation infrastructure works not only for FHIR but also for CDA and functional models as well.

Now, in the last few years, we have made a quiet, but major standards development advance. Today, most HL7 specifications are developed with corresponding reference implementation software. Creating reference implementation software alongside the spec itself helps the

specification become more practical to implement. Since this software is usually open source, it is also useful as a learning tool and for others to be able to test against. This image shows an example of the reference implementation server for the FHIR international patient specification.

There are four additional mechanisms that we use for assessing the implement ability of our specifications and community readiness through feedback. I would like to briefly mention them. First, we try to keep the barriers to participation as low as possible. We make the standards freely available and have a propose a change link at the bottom of every page so it makes it pretty easy for anyone whether an HL7 member or not to log an issue.

Second, we regularly survey the industry to understand how they use our standards for interest in future versions and their reasons for using particular versions.

Third, HL7 deeply understands that interoperability is a team sport.

Our closing keynote at this year's MEDINFO conference really emphasized the close collaboration happening among standards development organizations and with government agencies such as the nations like the US participating in the global digital health partnership. I facilitated this panel in my role as chair elect of the Joint Initiative Council, which is a collaborative forum of 13 international SDOs. HL7 also works very closely with nationally focused SDOs, including those others on this panel and with the health standards collaborative, a US SDO forum.

We have maintained formal agreements with over 30 organizations, including professional societies, industry groups, open-source communities, and others. And these collaborations are essential for enabling us to align with and gain insights from diverse stakeholders.

Fourth and finally, I want to highlight the HL7 FHIR accelerator program as a key initiative demonstrating our focus on implementing our perspectives. The accelerator program gathers health IT vendors, provider organizations, payers, and others into communities that tackle real-world interoperability challenges in particular domains using FHIR.

For example, the Argonaut accelerator includes participation from the major EHR vendors like companies like Apple and Microsoft and leading provider organizations. One of Argonaut's projects each year is leading updates to the FHIR US CORE specification, which is the standards for implementing USCDI with FHIR. Following ONC's annual USCDI update, Argonaut leads design sessions to help translate those USCDI definitions into FHIR specifications. This work undergoes further testing and review through connect-a-thon, HL7 ballot. But participation from Argonaut's members is crucial to ensuring that it can thrive in real-world contexts.

Thinking about how to characterize the cost and value of implementing standards, we have to recognize that diverse marketplace capabilities and resources to support new and enhanced standards. Although HL7 does not perform detailed cost analyses on its specifications due to resource limitations and the global source of deployments, we do highly prioritize and implement our priorities in our standards development as I have been discussing so far.

Some implementers have shared case studies on clinical and financial benefits like reduced administrative burden or improve patient experience, which we compile in the case study library, and a few of the 500 or so academic studies on FHIR do include economic insights though for sure would like to see more.

We have worked with the Cambia Grove Innovator Fellowship to create what we call a value metrics framework that helps characterize various benefits of a specification, which has sufficiency, security, financial savings. It is a structure for identifying metrics of how different stakeholders might realize value. An early application of this framework appears in the Da Vinci FHIR Prior Authorization Support Specification and we are considering how to apply it more widely.

My final comments will focus on how we are trying to enable HL7's specifications to work well with other standards. On a technical level, HL7 builds its standard on other widely adopted open standards wherever possible like, for example, OAuth for authorization. Similarly, we rely on standard terminologies wherever we can for semantic meaning.

We recognize that complex interoperability challenges require the orchestration of many standards, which is why collaboration among SDOs is key. For example, the Da Vinci FHIR Accelerator developed three FHIR implementation guides focused on the prior authorization process that are referenced in the CMS NPRM 0057.

The prior authorization support implementation guide provides facts for translating into and out of the HIPAA-mandated X12 278 standard. HL7 Da Vinci project members were given a HIPAA exception to be able to implement this. In its development, HL7 worked directly with X12 to map aspects of the X12 transaction to FHIR and we are grateful that X12 has allowed us to use their code sets for testing. We have similar projects underway in collaboration with NCPDP.

Recognizing that the adoption of standard terminologies is complex, I will briefly comment on how HL7 standards could enable the use of ICD-11. One of ICD-11's key innovations is the use of post-coordination. Structurally, this feature is well-supported by HL7's standards across our product families from FHIR, CDA, and B2.

HL7 works with the authorities of major coding systems to develop guidance about using their terminology within HL7 standards. For example, our published guidance for SNOMED CT covers the use of (inaudible) expressions. We have not yet developed our guidance for ICD-11. But as you can see on the next slide, this summer, HL7 and WHO signed a collaboration agreement and we will be working together with them to develop this guidance for use of ICD-11 and HL7 standards. In addition, we are working with WHO to refine their use of the FHIR terminology services API for distributing that content.

The HL7 community has identified one significant limitation in WHO's license of ICD-11, which is that it does not permit organizations to create mappings from other terminologies, including local ones, to ICD-11 without a special agreement.

As I complete my remarks, I would like to again thank the committee for this opportunity today and we will be available for discussion at the appropriate time. Thank you.

Debra Strickland: Great. Thank you so much, Dan. I appreciate that bulk of information.

Next up we have Margaret Weiker with NCPDP.

Margaret Weiker: Thanks, Deb. I am Margaret Weiker, vice president of Standards Development at the National Council for Prescription Drug Programs or NCPDP. NCPDP was established in 1977. It is a not-for-profit, multi-stakeholder forum for developing and promoting industry

standards and business solutions that improve patient safety and health outcomes while also decreasing costs.

The work of the organization is accomplished through its members who bring expertise and diverse perspectives to the forum. As an ANSI accredited standards developer or ASD, NCPDP uses a consensus building process to create national standards for real-time electronic exchange of health care information.

Through our collaborative problem-solving forum, we also develop and standardize best practices for product labeling, dosing instructions, patient communication, education, as well as other practices important in safeguarding patients.

We were asked to address a series of questions that starts out with how does your SDO blank. The first one was how do we assess and report on backward compatibility or specific anticipated issues with version updates. When we moved to a new version of a named standard such as the telecommunication standard or the script standard, NCPDP develops many types of crosswalks between the currently adopted version and the proposed adopted version and as well as other documents.

The example on the slide has one header segment from the telecommunications standard, Version F6. You can see the corresponding header segment in Version D.0. This is just one type of crosswalk that we develop. We also have others as well as produce other documents, which contain data attribute changes, changes to the designations and what I mean by that is mandatory situational or optional, changes to repetitions, added segments or composites, new functionality, segment data element situation modifications, count modifications, new and deleted fields by segment and composite, added deleted modified sections from the implementation guide. As I mentioned, data attributes to modifications to existing data elements, segment note modifications, as well as other notable changes and those documents are all created.

We also have extensive detailed change logs in our implementation guides. And in addition, the NCPDP SNIP Committee creates transition guidance whether it is for the telecommunication standard or the script standard.

Recently, NCPDP provided an educational summit on the telecommunication standard Version F6 as well as a more high-level webinar on the telecom standard Version F6. Both of those are available on demand from our website.

How does your SDO assess and report on backward compatibility or specific issues? This is an example of a transition guidance crosswalk. In Version V6, we split a field, the submission clarification code field, into two fields because it contains multiple concepts. We created a field called submission type code, which we label as what is the type of submission versus the submission clarification code, which is the why you are providing additional clarification on why the transaction is being submitted where under normal circumstances, the claim may not be covered. An example of that is vacation supply or lost or damaged prescriptions.

As I show on the slide, you can see in Version D.0, there was a value of 20. In Version F6, it will move to the submission type code field with a value of AA. Also of note, is we did not change the descriptions when we moved the codes from submission clarification code to submission type codes.

Assessing whether current systems can support the functionality and the impact across mandated standards. As a member-driven organization, NCPDP relies on its members and stakeholders and implementers to determine if any of the proposed changes cannot be implemented from a system point of view, in other words, not technically feasible.

This review is done at the point of change introduction and does not wait until the change has gone through the entire standards update process. NCPDP has a change request form called the Data Element Request Form or the DERF. On the DERF, it does provide a section of which standards are impacted by the request. The submitter completes that section and then members of my team review it to ensure that all impacts are noted as well on the DERF. We also have implemented something called the DERF Harmonization Process and Review.

Once the DERFs come in and are accepted, the Standardization Committee reviews them and looks more at the concepts of the DERF versus the actual change to a specific standard and look at it toward this may impact other standards though not necessarily directly. It may not – that is being referenced but it may have the concept that is being referenced.

For example, we recently had a DERF come in that wanted to change the value from 90 days at retail to extended day supply allowed. That was to the telecommunications standard. However, the real-time prescription benefit standard has a codified data element used in that standard that also has a value description of 90-day retail. That was referred to that workgroup and then to the task group to look at it to make a determination of whether they should also make a change or not.

In regard to cost and value at the time expected to be implemented, in regard to cost as an ASD or SDO, NCPDP does not assess the cost. Members, stakeholders, and implementers determine the cost of the changes. Many entities do not perform an analysis or even begin to budget until there is a final rule.

In anticipation of the final rule, we do have entities that will go ahead and implement the full standard. Others will partially implement a new standard that has been proposed.

We also have a section, as on our DERF, as I mentioned previously, where the submitter describes the business need, or the purpose being addressed by the submission. The section should explain in detail what the requester would like changed, added, or deleted, the reason why the modifications are necessary, and then the business benefit and value of those changes. This allows the reader to understand why the request is being made.

On the screen, you will see – on the slide deck, there is an example that I pulled from some of our DERFs where it did not give a specific cost or dollar value associated with it. But it did mention that these will reduce calls to the provider help desk. It allows to expedite patient access to care because you do not have somebody on the phone calling somebody. It lowers administrative costs and it facilitates compliance with the plan's policies.

I have included three additional changes or examples of what may be included on a DERF in regard to the value and the benefit. You can see where it is to proactively communicate upcoming formulary changes, which would mitigate access to care and adherence risk. But again, not a dollar value but yet the business value of making that change.

The next question had to do with ICD-11 and the standards, et cetera. To our knowledge, there

has not been any analysis on how the transition from ICD-10 to 11 will impact the pharmacy industry. However, the ICD-11 architecture is profoundly more granular than ICD-10 and will have a much bigger impact on the pharmacy industry. While NCPDP can update our standards to support ICD-11, in which cases, it would mostly be updating by adding a code value to an existing data element. The larger considerations regarding the nature of the changes needed to the coding systems and those requirements from the pharmacy industry systems to support an alphanumeric ICD-11. Special characters if we are talking about clusters are also used in ICD-11. It would have a profound effect on those systems.

Education is definitely needed for the industry to understand the changes, the impact, as well as then a timeline and I believe you all have already talked about in regard to when it would be implemented.

Currently, we are focused more on the NDC or the National Drug Code changes. They are in the unified agenda. It is proposed the FDA would release a final rule in January of 2024 for the NDC changes. Based upon what is in that final rule, it will impact the pharmacy industry as well as many other sectors of health care. We tend to be more focused on NDC changes than ICD-11 because we see the NDC changes coming before the ICD-11 changes. Hopefully, the NDC changes can be made at the same time that people are coding for F6.

In regard to reporting and testing, like I mentioned previously, we are a member-driven organization. We rely on our members and stakeholders to determine if any of the changes cannot be implemented. Again, we do this at the point of change introduction and we do not wait until the standards have gone through the whole update process.

Our members vote on when to move to a new version of a named standard. The vote typically takes place every three years. And during that process, the members evaluate all of the changes that have been proposed to be made to the updated version that has been adopted and make a determination of its time to move forward to a new version.

As I also mentioned previously, we develop crosswalks, transition guidance, and other documents. In the aid of transitioning from one version to another, our industry also uses switches, clearinghouses, and health information networks to aid in that transition.

As a side note, NCPDP does have a script testing tool that people, entities, companies, anybody can go out and use to test the script standard. And that same tool is also used for the certification piece of it to certify that your electronic health records are compatible and meet the requirements under script. We are in the process of transitioning that tool over to ONC as well.

We did talk about creating a testing tool for the telecommunication standard with our stakeholders. They were all for it but nobody wanted to pay for it. That is where that stands.

I want to also call out, I did not see this anywhere, is the cost of not promulgating a final rule in a timely manner. It is something that for you all that have been on this committee for many years have heard me say many times. The perfect example of this is the dollar fields. We initially asked in October or actually in January of 2018 to move to a new version of the telecom standard, the batching segregation. A DSMO change request was submitted. The NCVHS held a hearing in March 2018. But because of the changes that were happening in regard to the pipeline on million-dollar drugs, we needed to increase our dollar fields by three digits. We did so. We had

to go back through the process, so we submitted another DSMO change request, sent the letter to the NCVHS of January of 2020. A hearing was held in March. NCVHS sent their letter to HHS in April of 2020. An NPRM was published on November 9, 2022. The comments closed January 2023. According to the unified agenda, the final rule should be released in January of 2024.

But not promulgating a rule in a timely manner has caused workarounds. There is no other way to do it for the dollar fields. NCPDP initially recommended using the paper claim form because you can squeeze it in a box but there are many payers/processors that do not take paper. We have this proliferation of proprietary workarounds being done. NCPDP was asked if we couldn't bring together stakeholders and try to come up with a solution that least violated the standard, which is not something we like to do. It is proposed violations to the standard. But right now, we are trying to find workarounds so the industry can consistently implement a workaround. Since July of 2023, 131.4 hours of volunteer time has been spent on trying to gain consensus on proprietary workarounds.

Thank you for the committee for inviting me and hearing the NCPDP responses to your questions.

Debra Strickland: Thank you so much, Margaret, for your valuable information.

We are going to move on X12. Cathy Sheppard.

Cathy Sheppard: Hi Deb. Thanks for having me today and thanks to you for also putting this group of people together. Good morning or afternoon, depending on where people are today. I am Cathy Sheppard. I am the X12 CEO. I think I will acknowledge the same as many of the previous speakers, there is going to be overlap between many of us have spoken this afternoon and that is good because it does actually mean that we are all fairly well aligned with what needs to be done and where things need to end up.

I also received the information that there were some new people. I wanted to take a moment to give a small tutorial I guess about X12. Similarly, to HL7 and NCPDP, X12 is an ANSI-accredited standards developer, which the official acronym is ASD. Commonly in health care, we have been referenced as SDO. Know that SDO and ASD are synonyms for our purposes.

Basically, being an ANSI-accredited standards developer that you use processes that ensure materially interested stakeholders are represented and that a consensus is reached in accordance with the processes that you have published as what you will follow.

One of the differences between X12 and the other ASDs that have talked today is that we are across industry and our standards support a number of industries, including health care of course, insurance, transportation, finance, government, supply chain and that gives us a large library that we can borrow from when there are new needs in health care that have already been accommodated in our other verticals.

Millions of entities around the world have established infrastructures that support the X12-based transactions and the data exchanged in those transactions is effective, well-defined, and mature. In many cases, those systems have had more than 40 years to mature, stabilize, and become effective.

This vast network of ever-increasing trading partners that process X12 transactions moves

billions of transactions every day across the industries that rely on those exchanges. We have some idea of how to do this and we are always looking for ways to improve it a little bit more.

With that in mind, I am not going to walk through the topics exactly like some of the other presenters did because I think there is a lot of interaction between them and also because many of the things that I would say you have already heard from the other presenters this afternoon.

Like others, we believe at X12 that the concept of backward compatibility has to be accommodated in advancing standards generationally. But there are nuances to what that means and we have seen today that even among the speakers here, there are differences that have to be considered and we are going to have to use particular wording so that we are all talking about apples when we are talking about apples instead of somebody talking about apples and somebody talking about transmission fluid. That does not work out very well.

When we look at background compatibility at X12, we think that sometimes it refers to an approach that says a trading partner who is effectively using Version X of a standard can just keep doing what they are doing and make no changes if Version Y comes in. And what that would mean is that their computer-based systems would just ignore anything that changed in the new version and they would go on with no problem in the systems they have.

If we applied that type of backward compatibility test strictly, ASDs would not be able to make changes to the standard that support the emerging needs of industries as we grow, as our data exchanges get more significant and as the length of data and the specificity increase, we have to be able to expand the links of data items to add repetitions to data that previously had a lower repetition limit and to add requirements for data that just frankly did not exist a year ago or six months ago.

If we require the type of backward compatibility that says somebody can just ignore all the changes and start using the new version without making any system changes, we would be reducing our ability to improve the standards in the ways that implementers need them to be improved.

Another approach to backwards compatibility matches up with the visuals that Margaret just gave you to some degree and that is an ASD can document the enhancements that rely on trading partners to either change their established application systems and their other computer-based solutions or to transform the exchanged information somewhere in the exchange process.

An example would be if currently the standard has a piece of data that transmits to the receiver the number of ounces that someone is sending, and the new version says you can send ounces or you can send pounds. The trading partners would need to do one of three things. They would need to agree to continue only using ounces no matter what the standard says, which is not the preferred approach. They could agree to change the systems of both trading partners so that both trading partners could take ounces or could take pounds and they could each exchange between getting the transaction in the door and their internal systems if they wished. And the third option would be to allow the sender to use both units of measure and have the receiver change their internal systems to convert the information from pounds to ounces on its way in their door.

It is not a simple thing to say something is backward compatible or something is not backward

compatible. We think that in many cases, what we need to be focusing on as a whole is more a cross compatibility discussion. Cross compatibility is what we talk about when we say separate transactions in different versions can interact smoothly and effectively or separate transactions in different standards syntaxes can interact smoothly and effectively as opposed to saying different versions of a single transaction set can have that smoothness.

Of course, we are going to consider both. All the ASDs are going to work to make sure that their new standards do not contradict their old ones but simply enhance them. But we also need to be talking about cross compatibility and that not only requires the same data. It requires in many cases the same business rules because if you do not have the same business rules then you cannot have the same expectations on both sides of an exchange and that means that people have questions that need to be answered some other way. We do not want to increase calls between trading partners because we have not effectively told them how to communicate with each other very consistently.

Related to several of the topics that were laid out for ASDs to answer today, there were many questions about assessing risk, assessing risk, assessing benefit, assessing cost, assessing impact. And all of those things – there are limits to what the ASD can identify and assess itself. I think that will sound like an echo to what Margaret just said. ASDs can certainly quantify the impact of getting a new message version in the door to any trading partners' shop so to speak.

But what happens to it after that is not only outside of our control, it is outside of our understanding. Some trading partners may just load their internal data systems directly form the inbound transaction but others have sophisticated intermediate processes that use different parts of the data depending on where they are going to route that information in their internal proprietary systems that support the business that they want to perform. No ASD can understand the impact of that on every implementer or even to be sure that they can do it for a majority of impactors.

We have hundreds of thousands of people exchanging health care information, but we do not have hundreds of thousands of organizations coming to our industry meetings, to watching this hearing today to see what is going on or participating in other direct ways. We cannot even gather information from everybody, only from the people who choose to engage with us and to a great extent, the people who choose to engage with us, they are the experts already because they are involved enough to understand what we are doing.

What can ASDs do? ASDs can quantify the impact between what they are sending out as the proposed new version and the old. There are no changes here. There are changes here. Those changes are going to have to be evaluated by every trading partner because it might not matter to one trading partner that the unit of measure was going to change to pounds because they do not use that quantity in any of their internal processes.

We cannot evaluate how many people will have to make a change based on a certain piece of information. But we can certainly say someone has to expand the field. And according to best IT practices, you think that X number of hours are consumed when someone does a change of this difficulty level.

We can also provide forums for discussions among the stakeholders and we can provide forums across the SDOs/ASDs, which we have done in the past so that we can make sure that if we are

making a change that impacts NCPDP or if NCPDP is making a change that impacts us that we can get our stakeholders together to make sure that the transition of information is consistent and clear no matter whether it is being exchanged in one of the NCPDP standards or in ours. All of those things are very important to X12 just like they are important to the other ASDs.

The other thing that ASDs bring to the table in these discussions of risk and cost and benefit is we have all been doing this an extremely long time. X12, NCPDP, HL7 have spent decades considering people's data requirements, considering their business processes, considering gaps in what they are doing now and what they could do with new technology and providing change and then learning the lessons from that change. The more transaction sets we have in our libraries, the more experience we have with more implementers about the difficulties that can be encountered and potential ways that they can be resolved. Those are very important contributions even if they are not a dollar figure for how many dollars it would cost somebody to go to a system that accommodates ounces and pounds.

Another thing that X12 has been doing for a number of years is paying attention to the industry and listening and particularly in this forum at NCVHS, they have conducted a number of meetings related to roadmaps and to things that would improve the process for implementers and for standards developers as well as meet the federal government needs in these standard data exchange arenas.

What we have done is put in a new maintenance process that has a predictable schedule and we know we are going to put a new standard out every year and we will know exactly what is in that standard when it is time to go forward.

We have assembled a group of representative stakeholders who are working to provide implementation and benefit assessments in their real-world shops, which will help inform those kind of transition instructions that are needed if something does change between the versions. As a bonus, that also supports our goal of providing a more robust test bed with expected results.

The second stage of that improvement was to put some robust public comment at the front of our process and you will start seeing that roll out in 2024.

Lastly, we are making some changes to our processes for ensuring that we are participating in discussions related to external changes or revisions such as the NDC codes or ICD-11 and you will also hear more about that in the coming weeks and into 2024 as we try to make sure that we are in all the right places at all the right times, which as we all know is very difficult.

One more sentence, Deb, and then I will go. We joined Margaret very strenuously in encouraging NCVHS to put intentional emphasis on the cost of not moving standards forward because the cost of missed opportunities and increasingly non-standard proprietary solutions is very real and has a very significant cost. Thank you for the time today.

Debra Strickland: Great. Thank you so much to all our presenters. I would entertain some questions here before we go on break.

Lenel James: Lenel James. I have a quick question for Rob. It is about CAQH and maybe just my confusion. In terms of CAQH, making sure I understand the difference between your enforcement process versus HIPAA-covered entities that are reacting to HIPAA requirements. I

want to make sure that the understanding where CAQH does or does not interact with HIPAA requirements because I think your CAQH CORE is again your CAQH CORE members for enforcement. Rob, did I get that right?

Bob Bowman: That is correct. The CORE enforcement is specific to those entities that have completed voluntary CORE certification. If you have a CORE seal, then we will track and monitor your compliance with that seal and those requirements for that particular seal. Any entity can receive a seal for any of the transactions. For example, a health plan may have a seal for claims, eligibility, claims status, and remittance advice. They have four seals. A complainant can be filed from a provider against your remittance advice seal so we will track that down and make sure that you are in conformance and compliance for that particular seal.

The same with vendors. Vendors may have three or four different versions of software available for their end users. They may only certify the latest version. But we would only go after or work towards ensuring that that latest version is the one that the provider is using because that is the one that has the CORE seal.

Rebecca Hines: I am wondering if we want to take the break. It has been a couple of hours and come back at 3:15. What do you all think?

Participant: I think I would want to make sure while our guests are here we commit with a couple of quick questions before we take a break while it is fresh in our mind.

Rebecca Hines: The plan was actually to take a break and then ask our guests to hang with us until 4 Eastern. Can our guests do that? Are you all planning to stay?

Debra Strickland: It is 4 Eastern.

Rebecca Hines: Right now, it is 3 Eastern.

Margaret Weiker: I plan to stay, Rebecca. This is Margaret.

Cathy Sheppard: It is Cathy. I am staying also.

Rebecca Hines: It has been a couple of hours and I am sensitive to Zoom fatigue. Why doesn’t everybody just take a ten-minute break and we will resume at 3:15. Does that sound reasonable?

Participant: It sounds perfect. Thanks.

Rebecca Hines: We will see you all in ten minutes. Thank you.

(Break)

Rebecca Hines: Lenel, are you and Deb facilitating the Q&A period?

Debra Strickland: I did have a question, personally. Margaret, you mentioned that you're using a testing tool and that you are transitioning that tool to OCR. I'm interested in that concept, what the tool is, and is it not getting uptake with getting interindustry use and being back in testing?

Margaret Weiker: I am transferring it to ONC, not OCR. As part of the 21st Century Cures Act, and this goes into certification of EHRs, a tool was developed by NIST to test at that point the version 2016 of the SCRIPT standard. That was the initial tool. We updated the tool to version 2017071, which is the current mandated version of the SCRIPT standard. The tool allows any entity to go in and test, it also allows the pharmacy to test, because they're receiving the script transactions. That tool is used by the accrediting bodies, like the Drummond Group accredits and certifies EHRs, and they use that tool for certification. So it has plenty of uptake, plenty of use.

The reason we're transitioning -- there's a couple of reasons. One is we're the only outside entity that has a test tool that's not maintained and owned, and I put that word in quotes, or run by ONC, and in addition, I don't have the skillset to keep updating it as far as an employee, to keep updating it and making changes as we move to the next version of the SCRIPT standard. So those are the primary two reasons that it's transitioning to ONC. But the tool is used by multiple entities, and continues to be used today, because there are EHRs that are not certified yet, and they continue to test using the tool, and then the testing labs actually use it to do the certification.

Debra Strickland: Great, thank you. Anyone else have any questions for this panel? And including Bob?

Steve Wagner: Yes, this is Steve. I have actually two questions, one's a follow-on to the first one. This is for X12 NCPDP and HL7. Do you require a specific level of testing for all your new standards or changes to standards? Like do you specify as number of test sites that you need to have tested, types of test sites, or the size of test sites, things of that nature?

Maragaret Weiker: We don't. This is -- NCPDP does not.

Participant: X12 does not either.

Daniel Vreeman: I described it a little bit in my remarks, I realize we're moving quickly with a lot of information, but to some extent the maturity model grading of resources within the FHIR specification is a reflection of those kinds of requirements, both the sort of number, diversity, and I'll say level, whether production or sort of connective time-based testing that we have documented evidence for. So as we sort of move up that maturity level, those kinds of requirements get added in.

Participant: Okay. You all do testing with test sites in one way or another, I assume. And even if you don't specify certain requirements and things of that nature when you do your testing, I agree with statements that were made earlier, that the SDOs really aren't the ones who can make the determinations of costs and values and things of that nature. It's got to be the implementers who do most of that. You have a piece of it, at least, but most of that, costs and stuff and what the benefits are, are really by the implementers.

So if you do use test sites, at least a number of them, I would assume, you don't just do one or two test sites to test out your standard and everything, it seems to me that those are the appropriate people to help you with defining what the costs and benefits are and even trying to come up with reasonable dollar estimates of those things in their environments. So if you were to test these with a variety of sites, size-wise and type-wise, and number-wise, then that would allow you to actually work with them to capture those kinds of costs and then be able to provide

them as part of your output when you are ready to submit your standards to go forward and stuff like that. So I was wondering if that was an approach that you might be interested in looking into.

Cathy Sheppard: I'll go first this time. This is Cathy from X12. As Maragret said, and as I said as well, that presumes the fact that the implementers are willing to do something in advance of either a firm mandate or a very high expectation that one is forthcoming, and that in this environment, that's not really the case, because as Margaret said, she's been waiting a thousand-and-fifteen years for something that they needed to be mandated.

So we might assemble a group of five organizations, but that is not going to be a statistically accurate representation of any set of individual implementers. But of the groups that we have, the small groups of people who are willing to invest significant time and money not knowing if there will ever be a return on that investment, we have statements that we can make, in general -- in general you can move from version 7030 to 80 -- I'm trying not to use mandated ones -- you could move between two versions in general, it would take less than 10 days of business time, and things like that, but the statistical accuracy of that information is not going to hold true across the whole industry.

Lenel James: Let me add a point wearing my HL7 and my payer hat, Steve, I appreciate your question, but I also know one of the things we all do as SDOs is start out every meeting saying we're not going to do antitrust. Standards bodies collecting cost information from people that compete with each other, that's a problem. I think in the past, the federal government solved that problem, because they would hire somebody who would go talk to people who could collect the information, and there wouldn't be any antitrust disclosure. I think that's a big challenge you accidentally introduced, Michael, that's a problem.

Margaret Weiker: This is Margaret with NCPDP, and I agree with both Lenel and Cathy. We at one point as part of an ONC grant went to try to find number of transactions by versions of all of our standards, costing data, that type of thing, and we couldn't get it. Companies, corporations, were not willing to provide us with that information, even though we said, oh, we'll never name who you are, it'll all be secret, deidentified, and we still could not get it.

Tammy Feenstra Banks: We may be misconstruing what kind of cost data we're talking about, because I think if you're costing out the volume, your call volume will decrease by 20 percent because this additional information will be exchanged in theory, that information is something that can be shared and I'm assuming when a field is being evaluated if it should be put in a transaction, that type of information needs to be provided, right, to show that it is a valuable item and needs to be changed. So Steve, I understand your point and where you are going.

But my question is, we need some help here, right? We have all these regulations that are going to be in play. There is massive amount of implementation that needs to be done over the next three to five years, and I can start naming regulations and effective dates if you want. So when we review these standards, it doesn't matter what standards, from a national implementation, we have to think about what is going to be the cost, what's the cost saving -- Margaret, loved your quantitative rationale why there's a cost not to move forward -- but taking into all these considerations, and I'm hearing from the standard bodies that we can't tell you any type of cost saving or what the value is, other than the category that it will reduce call volume, it will help -- we can't get that granular data of what, just hypothetically, why there's value over all these

other initiatives that have to happen.

In your opinion, can you help us, where would steer us, where would you have us look, so that we can make a thoughtful recommendation based on the impact across all the stakeholders on new versions of standards, or new standards? Can you help us?

Cathy Sheppard: No one wants to answer that question first, I can tell you that. Here's the reason why. There's a different set of requirements at different stages of the federal process, not only by which of the SDOs or OREs is moving something, but also by time that has elapsed. And a requirement for a robust, statistically significant, reliable information on price and resource constraints -- the whole thing, though. We've been asked to provide before is what business benefits are going to be presented? What is an improvement that is going to do something for the implementers?

The ASDs can do lots of things, but one thing we can't do is make people do things, whereas some of the federal agencies or departments that want information do have some hammers. If whoever gets to decide what's required can tell us what that is in great detail, then the ASDs will have a better chance of collecting information, but when it's changeable over time and over scenario, that's really difficult.

Margaret Weiker: Tammy, if you're looking for specific dollar amounts, as I said, we require what's the business benefit? What's the value of this? I think most of my examples talked about reducing the provider help desk calls. Well, for a large national retail drug chain, pick one, that dollar value is going to be significantly different than your local independent pharmacy on Main Street who may have one person helping the pharmacist behind the counter and one person at the front checkout. So the cost is very different between those two, and we've never asked our members to provide us actual dollar figures when they submit change requests. It's typically what's the value, what is the business benefit of doing this? And then the entities that review the DRVs, et cetera, would say, oh, this is going to cost me X dollars. Can I get a return on that investment if I make this change, or not?

But we've never asked. Like I said, the one time we tried to get figures, the door got shut in our face.

Tammy Feenstra Banks: Margaret, you guys have done really nice work in that area, in regard to laying out business value, so I commend you, Margaret, on a lot of work that you've done to make that clear.

Cathy Sheppard: I was just going to say, even if it's not dollar figures, what Margaret said applies to other measures as well, the same concepts.

Tammy Feenstra Banks: Yeah, I think that's where people get misconstrued. They think dollars, and they think the proposed rule -- and that's not, you don't need that, right? What do you need when you have that conversation, to get a field in? Just that type of information. Why is it going to make a difference? But anyway, I think we always kind of -- I won't use a bad analogy -- overtalk it.

Daniel Vreeman: The only other comment I would make to add to this is it's difficult to get kind of a whole-system perspective, because there are investments, time and resources, made by vendors that then translate into deployment costs at organizations, and those organizations are

interacting with their other partners. So sometimes the benefits accrue in different places, and it's hard to sort of characterize them separately. And that's I think a challenge, where we maybe some limited success in having one participant describe the value they received, but that doesn't actually fully capture the full value or the full cost, in the ecosystem perspective. And I think that's where sometimes we certainly feel hamstrung a little bit in what we're able to characterize.

Tammy Feenstra Banks: That's an excellent point, Daniel. You rely on people who are proving testimony to share where the benefit is for them, and when that doesn't come through, and it doesn't come through from the SDO, where should it come through? So it's not an SDO issue; it's all of our issue. The question is how do you make that judgment.

Remember, we're talking community hospitals, we're talking small physician hospitals, we're talking about health systems, we're talking about large payers, small payers. So just kind of understand where the question is coming from will help us help you, and help the industry figure out what really is needed. I don't know if Michael Cimmino is still on the call and if he has any questions, because I know that they are doing a lot of work in this area. So I don't want to jump on that, but just -- this is something that we all have to think about, right? As all these regs are coming down and all these implementation requirements are coming down with ICD-11 coming down the pike. Let's figure this out now so that we cannot keep asking for a roadmap and keep asking -- the questions we're asking are the same one that have been asked, Margaret, you know, 15, 20 years ago, these are the same questions.

So I know it sounds like I'm hammering it. Let's get answers, guys, let's get answers.

Debra Strickland: I think that's the industry challenge. Until you implement it, you won't know. You will have a workflow change over here that will reduce phone calls over here. So you increase some operational expense, but you decrease -- so some things are a wash. But you don't understand the full nuances of changes all the time through the industry until you implement.

And to Cathy's point, people don't even want to test, really, until they have a mandate, and that's always been the way it is. Because they have to change the depth of their systems. We just know this is the age-old problem. They're not going to build it until they are forced to. That is definitely the problem we will always have, because you will not be able to discover the hidden pitfalls, potentially, in an implementation until you build it.

Tammy Feenstra Banks: And I'm going to agree to disagree, because we're coming at it from two different points. You're coming at from a technical perspective; I'm coming at from a business perspective, and Daniel made a really good point. Each individual setting can figure it out. I know when I brought codes or fields to be implemented in X12, I had that data of why it was valuable, because I had to -- there's a lot of different stakeholders you have to convince, and I'm just wondering how can we all get talking about this using the same terms on what is needed, and that includes me. I guess we just have to continue to have this conversation.

Rebecca Hines: We do have someone from Michael Cimmino's office, and I've asked --

Michael Cimmino: I'm actually on, Rebecca. I did want to comment, Tammy, on what you said. I think part of getting at this is how we evaluate a standard, and that's part of the process we're undertaking now, is how can we better evaluate those proposed standards. There's probably a

lot of assumptions that are made in that process, and maybe there were in the past when we were able to do something like that. But we're looking at some of the work that we did in the past and working closely with all of you, to understand how to get to a point where we can get at some of this information.

Tammy Feenstra Banks: Thank you, Michael, I'm glad that you said something. I wanted to ask if anybody from your department wanted to ask any questions of the presenters, if it would be helpful for your work, please feel free to do so.

Michael Cimmino: Thank you. I don't have anything right now, but I do appreciate it.

Debra Strickland: Any other questions for this panel, from the full committee or anyone else?

Lenel James: I usually have questions, but in this case, no.

Tammy Feenstra Banks: I'll ask the standards subcommittee, Jamie, Rich, Steve, Michael, any questions from the stakeholders in regards to review of standards?

Participant: No additional questions, thank you.

Tammy Feenstra Banks: And any of the other full committee members? Any specific questions or clarifications? I know some of you, this isn't in your world, but it's really important stuff. So please, any question is a good question, and we've got the experts. These are really good SMEs.

Valerie Watzlaf: I don't have any questions, but I really appreciate everyone's time, because I think this was so informational for me, so it really helped me to put everything in perspective, so thank you for coming, for being here with us, and explaining it in such good detail. It was very easy to understand, so I really appreciate that. Thank you.

Tammy Feenstra Banks: Deb, do you want to wrap it up? Or before I do that, any of the presenters have any questions for us? Or words of wisdom.

Margaret Weiker: I don't have any questions, Tammy, but Lorraine would know that something was wrong if I didn't wish everyone happy trails.

Debra Strickland: Thank you very much for this panel, everyone. You've been so informative and helpful in presenting to the full committee and keeping the education at a level that folks can understand, even though we're not in the weeds. So appreciate it.

So, Rebecca, how do you want to handle, we're a bit early?

Rebecca Hines: I also wanted to let our speakers know that the next main topic is going to be the committee's overall concept of where to move ahead, and your input is very much welcome, so if you can hang on for another hour or so, that would be really ideal. If you can't, then we will definitely come back and talk with you as this new vision for the next couple of years starts to come into place.

Mike Kavounis, can you bring up slide deck J, please? We'd like to pause our regular agenda here, our regular programming, to recognize Richard Landen who has been with the committee for eight years, two terms plus an extension, so Tammy, take it away.

Rich Landen Commemoration

Tammy Feenstra Banks: I think the best way to sum up our little presentation is that a simple thank you is not enough. Rich has been amazing. Being a co-chair, you do a lot of work that may not always get that thanks and the gratitude, and it's a very time-intensive, and Rich has overdone and has always been so informative, and I'm really bummed I'm losing a mentor, because that historic knowledge is just amazing. So we just wanted to give you a simple thank you, and when I say we, I gathered your two previous co-chairs, Denise Love and Alix Goss, to kind of go through and reminisce how valued you are through your two terms of 2015 through 2023.

Alix, are you on the line?

Alix Goss: I am here.

Tammy Feenstra Banks: I'm just so emotional. I'm really bummed about Rich transitioning off.

Alix Goss: I know what you mean. All of a sudden, I've been listening to the session for many hours, and suddenly got butterflies in my stomach as I knew I was coming on to do a little bit of recognition as a part of our farewell to Rich Landen, healthcare statesman for many years, and a mentor to me. I want to give you a little bit of a snapshot of who Rich is, on this slide, and then I'm going to talk a little bit about one of the projects he and I spearheaded together.

I think it's amazing for me to step back and think about the relationship that I've had with Rich and the impact that he's had on my career and on the industry overall, and I think it's appropriate to start with understanding a little bit more about his background and the numerous roles that he has played across the industry, and although he's retired, he's really continued to give very extensively and able to contribute, starting with his experience as a hospital orderly, advancing to getting dual Masters from Columbia related to his concentration in hospital administration, which then he really exercised at a New York City teaching hospital, before joining a national health insurance trade association -- the blue color might be involved there -- where he was involved in very many industry groups, initially a paper-based and then really helped us over the years in X12, in collaboration with data content committees, to really take it to the next level of EDI adoption, and through his various and diverse leadership roles within the insurance subcommittee at X12, then later building on that in his role with CAQH-CORE.

Along the way he also got to influence the precursors to HITAC and even their earlier incarnation as the Health Insurance Technology Standards Panel, work with WEDI over the years and a number of other groups, that we nationally would recognize, to advance fraud and interoperability objectives.

But he's also brought this perspective of a vendor into the mix. Interesting role for him to pivot into as a director of regulatory affairs later in his career, related to the meaningful use objectives. And that really provided a solid foundation for him to join the committee in 2015 and really bring his overall talents and skillsets to bear.

Some of the pictures you're going to see on this slide and a couple of other slides were from our working sessions at the Hubert Humphrey Building to advance predictability roadmap. With that, I'd like us to go to the next slide.

Some of you will see yourselves as the usual suspects peppered throughout these slides as committee members and regular testifiers, and I affectionately include myself in that description.

Rich and I really advanced the predictability roadmap, building on the work that Nick Coussoule and I had started, and a major focus of Rich's time on the committee was spent advancing this next-generation health information approaches reflecting 21st century realities.

Grounded in the committee's review committee work, as mandated under the Affordable Care Act, and were extended by the framing of the 21st Century Cures Act advisory committee collaboration provision, which helped frame cross-federal advisory committee collaboration with ONC, to thoughtfully intersect clinical and administrative data.

This is just one little example of Rich's capacity to work effectively with others to impact the course of healthcare policy, standards, and community learning. Rich's diverse professional and civic experiences, skills, and genuine caring about making healthcare better aided his ability to garner agreement in challenging situations.

The predictability roadmap encapsulates earnest reflections by the healthcare industry, prepared through many hours and layers of work, to define how HIPAA, federal regulation, and healthcare industry comprised of patients, providers, payers, and vendors, will work together in our more modern governance and technologically advanced and evolving ecosystem.

Furthering this work he brought his expertise to the EHR request for information taskforce HITAC recommendations, and most recently, the Convergence 1.0 and 2.0 efforts to support the changing standards landscape. These are some of the many meaningful contributions Rich brought to NCVHS over his two-term-plus service, and I'm really grateful to have had the opportunity to work with Rich since 1999 and to call him friend and to call him a mentor and my elder statesman.

So thank you. I hope you get to enjoy your retirement fully now. Back to you, Tammy.

Tammy Feenstra Banks: Thanks, Alix. And I'll tell you, Alix and Rich were a dynamo pair, that was really hard to follow in their footsteps, and I hope I'm even doing 25 percent of all the work that you guys did, and Denise Love as well. We're standing on your shoulders.

We just have a couple reflections for you, Rich. Denise wanted to share. Working with you, obviously, was a pleasure. Serving on the Standards Subcommittee was an honor and privilege, especially because I was able to work closely with Rich. Through his willingness to share his vast knowledge and his infinite patience, I and the subcommittee were better able to navigate the intractable puzzle that is HIPAA.

And again, I too want to thank you for your leadership, guidance, and mentorship. I remain hopeful you will continue to be a call away and I can still call a friend for guidance, because you've been an inspiration to us all.

And Alix added, collaborating with Rich starting in 1999, it's been a while, at X12, throughout the years in various industry groups and culminating in co-chairing the Standards Subcommittee to advance the Predictability Roadmap Project was always a pleasure as well as a learning and rewarding experience.

On the next slide, I love how Denise shared our journey, since we worked with you, Rich, because actions speak louder than words is all that we can say -- but we were standards without borders. We did not have an in-person meeting until well into our third year, or my third year, as a committee member, and so she reflected: our co-chair journey during COVID was virtual and sometimes from automobiles as we coordinated call schedules, as traveled from and to our residences in Florida, New Mexico, Utah, and Idaho, Rich always provided wise counsel and common sense along with his technical expertise.

Participant: Tammy, Denise is here.

Tammy Feenstra Banks: Oh, Denise, I didn't know you were on. Awesome. Did you want to add anything? I apologize.

Denise Love: No, I'm just lurking. This is great. I can't really add too much more, except Rich was the wind beneath our standards wings, and he will be missed.

Tammy Feenstra Banks: And I'll tell you, we talk about the wealth of knowledge, the statesman, but this is one gentleman that you always wanted to be a co-chair with because his precision with the English language; he is so detail-oriented, and all of these work products, late at night, quick turnarounds, but after his review everything was clear, concise, accurate, and really would make any grammar teacher proud. So I can't even tell you how much we're going to miss that knowledge and editorial flair.

And if you want to move on just to the last one, I just want to conclude. We're really grateful, I think you can realize that, Rich, for your service, and really want to toast you virtually as you conclude your service here with NCVHS. Alix made a really good point that we really thank you for your thoughtful remarks and deliberations over the years and wish you all the best.

So again, I can't say it enough, Rich, just want to say thank you. You've meant a lot to a lot of people, especially your co-chairs and your members, and you have made a deep influence on the work that has occurred at NCVHS, so thank you.

Rebecca Hines: And I just want to add, Rich, that as staff too, the committee, working with you was so easy. You were so responsive, and you really, as Tammy said improved the quality of the overall end product of things with your clarity, and I think you've trained some other members well, and we're going to do our best to fill your shoes, maybe with an extra pair of socks or two.

Lorraine, did you want to add anything?

Lorraine Doo: Yes. It's fun to see this picture because we all remember and, Alix, we had our sunglasses and our total eclipse, we were at the HHS building, but I think also just a longstanding relationship with Rich for more years than any of us care to count, I agree that he has been a mentor and a voice of reason, and even when debating difficult topics, sort of moving the trajectory forward. It's really been a pleasure, I've learned a lot in the many years that I've been lucky enough to work with you.

So thank you. I know we'll still be in touch. I'm not that far from Santa Fe anymore, so I guess I'll still get to see you. And good luck in harvesting and doing all the things that you now will be able to have time for because we won't be bothering you. I just thank you for all the wisdom and guidance over the years, for the many, many years, even before NCVHS.

Tammy Feenstra Banks: I don't know, I'm not deleting his phone number, so I don't --

(Laughter.)

Lenel James: Rich, I'd be remiss if I didn't acknowledge that 20 years ago Rich pulled me into standards at Blue Cross. He hired me and mentored me and look where I ended up. This is fantastic and wouldn't have happened without Rich being that sparkplug. And then of course, when I started, he turned the HIPAA conference over to me, and trial by fire -- a HIPAA conference for all 34 Blue plans -- here, Lenel. Take it, run with it. And I did, so it worked out great. Thanks again, Rich, for all your input and help.

Rich Landen: I'm touched by all the comments, and I expected a few words today since as of tomorrow night I'm gone, but people have my number. So thank you very much. It was quite the journey. When I look at where we are now with standards, electronic standards, versus where we were when HIPAA was first discussed in 1994, we have achieved tremendous amount of progress, and we have improved the administrative aspects of the U.S. healthcare system dramatically. So congratulations to all of us. I know particularly for Lenel and for Alix, yes, I mentored you, and as your revenge you have got me onto NCVHS, and in Lenel's case, my revenge is now he's on NCVHS.

But NCVHS, for the last eight years, has been one of the anchors in my life. It has been one of the few groups around the country where the members and the staff work collegially toward common goals and objectives, they have frank discussions, and bring all their experience and input and passion, but they never, ever lose sight of what we're trying to do for the common good. So for all of that I thank all of the members and staff of NCVHS, both current and their predecessors over the last eight years.

So again, thank you so much for the nice words and particularly for some of the pictures. I have a fond memory of the current photograph, trying to figure out how we get the beverage for a suitable toast into the HHS building. That goes down into the detail of the making of the sausage, which I won't take any more time. You've spent a lot of national time here on me. I am flattered and pleased, and thank you all very much.

NCVHS Workplan Development - Part 1

Rebecca Hines: Thank you, Rich. Hard to top that, except that the next topic is actually sort of the icing on the cake of where standards has moved, and there is a break on the agenda. Mike, now you can take the final slide down for Rich's commemoration.

Jacki, Tammy, Steve, Lenel, would you like to take a 5, 10-minute break, before we launch into this very important overview that Tammy and Val are going to provide for the next phase of where you all plan to go on data modernization? Would you like to just launch into it now?

We're a little ahead of schedule, so it's really up to you how you want to manage the next few minutes.

Tammy Feenstra Banks: I would love to move forward. But if anybody needs a break, I think that would take precedence.

Rebecca Hines: All right, Mike, if you can bring up deck -- there you go. Perfect.

Tammy Feenstra Banks: Awesome. Now you've got the history, so I can skip over a lot of it, as we go through, but what we're going to be talking about is our scoping document, which we have renamed modernizing the standards data healthcare information infrastructure and ensuring the privacy and security of data exchange -- and the reason I'm reading it is it is a true collaboration, a true full committee project scope document, which I'm very proud of working with Val and the members at large in order to get everybody's feedback in the information I will be sharing today.

What I'm going to talk about very briefly is what the scoping document is, the background, and then we'll have a review and discussion on that. Then we'll go through the proposed topics that each of the subcommittees came up with and how we came up with, and see if we missed anything, if there's agreement. Would like to leave those two conversations with a consensus in support or getting this document placed on the website and continue workplans, depending on how the conversation goes.

Then Val and I, on behalf of our respective subcommittees, would like to propose a joint topic, review relevance of HIPAA in the current healthcare ecosystem. So we'll kind of explain why we're bringing that to the full committee for discussion.

And then hopefully collaboratively we can talk about next steps. I'm not quite sure how much we'll be able to get done today, because there is time on the agenda tomorrow, so we'll just kind of roll with it, and seek your guidance, Jacki and Rebecca, on how far we can go.

What is a scoping document? For those of you who have been following NCVHS for a long time, there's a lot of project scope documents on our website, and they're living, breathing documents that are updated as things change, or the landscape changes. The most recent one, a document was created for a new topic, ICD-11. But the previous versions of this particular project scope, one was March 2020, which focused on the convergence of clinical and administrative data, and then the one that we modeled this one after is the convergence 2.0 work that was discussed, that immediately followed the predictability roadmap.

So we took that project scope and began our review, and if you go to the next slide, for us to take a look at that document. What we did is we really wanted to have a better understanding of the history of what occurred within NCVHS, so we reviewed all the output and work products of the predictability roadmap. We also reviewed all the discussions, notes, minutes, from the convergence 1.0 and 2.0, and the intersection of clinical and administrative data task force, which Alix chaired with the HITAC workgroup, and then review privacy and security as well as standards, reviewed the different letters to the Secretary, the various recommendations, and the recommendations that didn't move forward because of timing, in order to really get a better understanding of the history and the good work that was done before by our predecessors.

The questions that we asked when we were looking at that historic scoping document is what has changed since HIPAA? What's changed since that document was written? What are the industry business models that have changed? What are the dataflows that have changed? The technology. And then we went through the thought process, what issues, considerations, remain relevant? And these are the questions I want you guys to ask, too, and when you review this document, I know that we had discussed it at that time too, so that you could really take a look at this from your perspectives, and so we can get that collaborative thought process in this document for us to look at today.

Then we reviewed the historical documents, testimony, requests for information. Then we had to determine what remains high priority from all the historical thoughts -- what are the different things that our predecessors were going to look at, and then based on our recent testimony and requests for information, we then, the subcommittees, really ranked what were the topics that were of highest priority for us to have this conversation today.

In the document that you reviewed, the contents for those on the call, includes the background, the what has changed conversation. We identify a problem statement, added in some additional challenges, created a project scope, and then the workplan development is basically just a place from the document before, what can an advisory group do? How can we gather information? What is the avenues for us in order to come up with appropriate recommendations or other work products? So that's more of a guidance section of this document.

And then we have two appendixes, each with the areas of interest for each of the different subcommittees.

So the workplan that we're looking at is in fourth quarter. Both subcommittees reviewed this, the members at large reviewed this document. We got everything incorporated. We had discussions with the executive committee. We did send our final draft document to both ONC and NSG and are very pleased that Steve and Michael will be taking a look at that and giving us guidance, as well. And at this committee meeting, again, we just really want to make sure that we have the support to move forward with posting this as a scoping document, as well as getting our directions moving forward.

After this meeting, then, we will take a look at fleshing out whichever topics make sense and determining where we need to go in order to have a workplan and discussion at the next April full committee meeting. So that's kind of the timeframe we're looking at after we get through the original review.

Before we go through the scoping document, Val, I know I went through this quickly. Is there anything I missed or anything that you want to pull out?

Valerie Watzlaf: No, I don't have anything to add. You're doing great. Just to say thank you, too, because I know you initiated this and I know our whole subcommittee, the PCS Subcommittee, is very pleased to be able to be doing this together with standards. So thank you for that, Tammy.

Tammy Feenstra Banks: That's one thing, though, the Standards Subcommittee was very vocal on, was as we went through looking at it from a Standards Subcommittee, as we looked at the changes that have occurred since HIPAA, you just can't look at privacy and security and standards alone on some of these topics. So it just totally made sense. So really appreciate your collaboration and partnership on this.

What was hopeful was that we could actually go through this document. And I know you guys have reviewed this multiple times, but if we could just go through paragraph by paragraph, see if there's anything there that needs refinement or other kind of conversation, let's just start with the first paragraph. Does anybody see anything that needs to be refined, or are they comfortable with that? Nothing has been changed since the review that went out with the briefing materials.

Valerie Watzlaf: We do have a comment in the chat from Maya that she just said, a reminder that administrative simplification refers both to the transaction code set standards and to privacy and security standards.

Tammy Feenstra Banks: Is there a change that you would recommend?

Maya Bernstein: It seems like it's talking about the Standards Subcommittee side of things, even though it's using that term, so I just wanted to make sure that you intended to include, when you talk about administrative simplification section, that encompasses all the standards including the privacy and security standards.

Tammy Feenstra Banks: Is there anything that needs to be more clear? Vision for harmonized federal electronic information and technology standards --

Maya Bernstein: I guess it struck me that the examples were on the standards side. We talk about prior authorization, we talk about -- I didn't know if your intention was to start with that. But that may be where the document originally started, and then since privacy and security were added later and combined later --

Tammy Feenstra Banks: Maya, would it be okay to keep going through the document? And then come back and see if we should revisit that?

Rebecca Hines: Maya, if you want to send specific suggestions -- you'll see there are places where it's much more clear. But this is definitely, this opening is an opportunity, I think, to add what you're saying, but it would be great to have a specific suggestion for how to do that.

Tammy Feenstra Banks: And something may pop up as we're going through this. So let's not lose that thought.

Valerie Watzlaf: Rich has a comment to put in -- 25-plus years. In the third paragraph.

Rebecca Hines: Yes, indeed.

So this is another place where privacy or security could probably be --

Tammy Feenstra Banks: The movement of the information requires the security of that information, and I know that we have put language further down. So I'm wondering if we have to move it up to the first paragraph just to clarify that.

Valerie Watzlaf: And then Lorraine has a comment, too, about how to specifically write out the HIPAA transaction standards so they're clear and differentiating between TCS and privacy and security.

Participant: Yeah, just how we've been given guidance in some of our rulemaking from the Office for Civil Rights, that we specify the transaction standards, which are the HIPAA transaction standards, like a claim or a remittance advice or any of those, to clarify as Maya is suggesting, that those are different than the privacy and security standards, because those are standards as well.

Tammy Feenstra Banks: Do you have language that you want to put in there?

Participant: I said the HIPAA transaction standards, in the comment. So we can provide that if you like. We can provide that where you might need it, just for that -- a minor differentiation that they've given us.

Rebecca Hines: That's great, Lorraine. Just send that where you want that added.

Tammy Feenstra Banks: Can we move on? Anybody have any revision?

Rebecca Hines: I'm wondering whether we could come up with, since the committee has been using the term since 2016, 2017, Beyond HIPAA, maybe weave that into this bullet point? Since this really is just sort of outside the scope of HIPAA, but it's still really important and really captures -- it's dealing with the spirit of HIPAA, that HIPAA was written before anyone conceived of apps on phones that would access your data without your knowledge unless you were really up to speed.

Tammy Feenstra Banks: So we have new actors have emerged since the passage of HIPAA -- would you rephrase that sentence?

Rebecca Hines: I would say here, put in something like NCVHS has coined this -- this is very off-the-cuff, sorry.

Valerie Watzlaf: Reference or cite the Beyond HIPAA report.

Rebecca Hines: Yeah, exactly.

Maya Bernstein: I wouldn't say that we coined it.

Rebecca Hines: Okay. So I don't know the right way to say it, because it's late in the day, but has I guess studied this and -- did we issue? We sort of had a -- I know we had --

Valerie Watzlaf: Environmental scan was done and then also there was something written for policymakers.

Rebecca Hines: And commissioned an environmental scan, that's right. There we go. Something like that. We can clean it up.

And per the comment we received this morning, it's that kind of a thing where smartphones didn't exist in anyone's consciousness 25 years ago, or wearables.

Tammy Feenstra Banks: Any aversion to the addition? It highlights our work, so I think it's good.

So now the increased -- the last three bullets there.

Maya Bernstein: Can you say what you mean by a noncovered disclosure of PHI? If it's PHI, there's permissible disclosures and non-permissible, right? And other disclosures. But once it's not, once it's outside of HIPAA, it's no longer PHI. That's just a little bit confusing, that phrase.

Rebecca Hines: Well, except I think the next sentence pretty much explains it. People sell your grocery store, drugstore, all kinds of purchase data, en masse from the credit card companies, and then --

Maya Bernstein: But it's not PHI. It's PII. But PHI is a term of art in HIPAA that means it's a covered entity, it's individually identifiable information held by a covered entity.

Rebecca Hines: So is this PII? Is that what you all mean, PII?

Valerie Watzlaf: I think we do, yeah. I think it might be more PII than PHI. I see what Maya is saying.

Maya Bernstein: And then we should expand what that is, since I don't think we used that term before.

Valerie Watzlaf: Good point.

Maya Bernstein: But personally identifiable information, but it's not under HIPAA. So that's what I'm saying. Noncovered disclosure of it under HIPAA, it just means it's not covered by HIPAA. Is that what you mean?

Valerie Watzlaf: I think that's what we meant.

Maya Bernstein: It's not covered by HIPAA.

Tammy Feenstra Banks: It was not intended. This was not happening when HIPAA occurred. It's just one example of all this information that's flowing.

Maya Bernstein: I am sorry, I haven't looked at this in a while, but if it's protected health information, it's inside a covered entity. It's possible that you could disclose to an entity that's not a covered entity. But once they have it, it's no longer covered by HIPAA. It's not PHI anymore. So it's a little bit awkward just to say that it can be accessed and used by entities that are not covered, because once they have it, it's not covered anymore. Do you see what I'm saying? They can obtain it under a proper disclosure. But if you are talking about pre-HIPAA, then PHI doesn't come into it.

Valerie Watzlaf: But isn't that what this is saying? That they can then access and use it outside of the protections of HIPAA, because they wouldn't fall under it?

Maya Bernstein: You're talking about not at all.

Valerie Watzlaf: It's not protected.

Maya Bernstein: What is the it you're talking about? So are you talking about data that derives from a covered entity that was once PHI and is now no longer PHI? Or stuff that's commercially generated, like Fitbit data?

Participant: I wouldn't say Fitbit is commercially generated.

Tammy Feenstra Banks: This example is great, right? You can go to the drugstore and you buy something, you don't think about anything, right? You just bought it and leave, and then all of a sudden that data is mined and used for purposes that it wasn't intended.

Maya Bernstein: Okay, that's not PHI.

Denise Chrysler: It is PHI if it's the pharmacy portion of the drug store, and that's why I was getting confused is my guess is most drugstores form as hybrids so that they have all their over-the-counter sales and then they have their pharmaceutical sales, because for filling prescriptions and then electronically billing third party payers, the drugstore is going to be a covered entity, but if they've segregated, they've separated out their over-the-counter work, then that portion wouldn't be covered by HIPAA. So anyway, not quite sure how that all fits together.

Valerie Watzlaf: Where would their purchase history I guess be?

Rebecca Hines: Well, if you're buying a medication --

Valerie Watzlaf: It depends.

Rebecca Hines: Contraceptives are going to be available -- I think they are available -- over the counter now. I mean, that's PHI, folks.

Denise Chrysler: So that's not right.

Participant: Morning after.

(Crosstalk.)

Maya Bernstein: It's PII. It's not PHI.

Valerie Watzlaf: Some parts are, they're saying. Go ahead, Cathy.

Catherine Donald: I would argue the different approach. I mean, I think just because it's PHI and it leaves a covered entity, there's still health information in there. You buy condoms, I don't think they log your name and your date of birth and all that. That's completely different than birth control pills or something like that, but I think part of what we're trying to say is when the PHI leaves a covered entity, we still want it to be protected. Now maybe there's another term, but I think it's way more than personally identifiable information once it leaves. I think there's some aspect of health in there that I think we need to consider and discuss somehow. I don't know what the term is yet. I haven't come up with it. But they're still health information in there that I think needs to be protected.

Tammy Feenstra Banks: Well, Jamie is going to solve it, Catherine.

Jamie Ferguson: But I'm going to solve it in a way different from Cathy. What I would suggest is that we don't use PHI or PII, just talk about personal data, and -- because we're talking about protecting personal data outside of HIPAA, and I would just leave it there at this point.

Catherine Donald: Is that strong enough?

Valerie Watzlaf: Yeah, because you could say personal health data.

Tammy Feenstra Banks: Can we go personal data, i.e. PHI, PII?

Maya Bernstein: PHI is a problem.

Tammy Feenstra Banks: Personal health data isn't necessarily PHI then. It is not.

Jamie Ferguson: Once it's outside of the HIPAA entity, as Maya said, it's not PHI. It's just personal data, and that's what I would call it.

Participant: It's personal data that can include health data as well as personal identifiable data.

Jamie Ferguson: Well, is your financial transaction record about your over-the-counter pharmacy purchases, is that health data or is it financial data? Or is it personal data?

Rebecca Hines: I think yes. I mean, if I buy Benadryl or Zyrtec or whatever and that information gets sold to somebody, that's health-related information. Somebody now who has no HIPAA-covered anywhere requirements knows that I'm taking some drug that I didn't necessarily agree to them knowing.

Participant: I mean, the more cogent example is the example of over-the-counter birth control. That's clearly health data, and it opens up a can of worms when it comes to reproductive health privacy.

Jamie Ferguson: So the fact that we can't call it PHI because PHI is a defined term within HIPAA covered entities doesn't mean it's not health data, doesn't mean it doesn't include personally-identifiable information.

Rebecca Hines: So what we need to --

Participant: I think personal data, including personal identifiable data and health data, might be comprehensive.

Valerie Watzlaf: What did you say, Michael?

Michael Hodgkins: I was saying personal data, including personal health data and personal identifiable data or something to that effect, because that's the equivalent of PHI. All we're saying, I think, is that while we can't really call it PHI because PHI is defined within HIPAA covered entities.

Rebecca Hines: So I think what we need to do is go through this first, this opening, and clean it up to get it clear, because those are specific terms, PHI and PII, and we don't want to misuse them. So it sounds like we have an alternative term for the data when it's outside of the technical use under HIPAA, and we need to go and clean that up. Is that a reasonable sort of next step after today?

Participant: Yep.

Tammy Feenstra Banks: Well, and the question is do you want identifiable, right? It's including identifiable --

Valerie Watzlaf: I think both are in there, with including.

Rebecca Hines: But you just can't use those terms unless you actually are talking about HIPAA, being covered under HIPAA. So we'll have to go get this cleaned up, and I'm going to leave that to the lawyers. Denise Chrysler, you've got a job.

Participant: My comment is on the next line. I'm assuming we're done with PII. So on the SDOH, just slight tweaks on the turning, because it talks about addressing healthcare equity, it's usually addressing health equity and when we're talking about the disparities, it's reducing disparities and then you're improving community health. So collect SDOH data to address health equity, reduce disparities, and improve community health would better align to how we talk about it at the SDOH gravity project.

I'm just saying that when we talk, that's kind of how I've seen it done. Welcome input from others, but that is what I immediately noticed as some minor tweaks that would make it better. Any other suggestions or edits besides that for this particular line?

Tammy Feenstra Banks: All right, moving onto transaction processing and then one, two, three, four more bullets.

Maya Bernstein: I think we established earlier that it's application programming interface.

Tammy Feenstra Banks: Interface singular?

Maya Bernstein: We can talk about them in the plural.

Valerie Watzlaf: Yeah, because we do say APIs there. So should it be plural?

Participant: That's fine.

Participant: I have a question about the generative AI. It says in the middle, this tool will help facilitate the exchange of clinical data. Is it for sure? I think it does, but it seems like we say the tool -- it seems like we should say the tool may help, because it's definitely not always going to help. But I'll yield to any AI expert on the call who differs, but I think it's a may instead of a will.

Participant: I might say can instead of may. I agree with that. Can instead of may.

Rebecca Hines: Mike Kavounis, can you open up the Q&A so that if people who are listening from the outside have suggestions, we can capture those, please? Thank you.

Participant: Can we make it can?

Maya Bernstein: A little nit, but you've expanded health level 7 a couple of times. You don't need it the second time in the bullet that we're in, because you did it above in the prior bullet.

I think that what we want to say about generative -- what I hear you saying about generative AI is that it has the potential to facilitate exchange, doesn't mean it will always be facilitated, but if used properly with the proper controls and so forth, then it has promise or --

Participant: Maybe six months ago, Maya, I would agree with you, but how fast things are moving, no. It's going to do it. It's just a matter of can we control it before it gets out of hand.

Maya Bernstein: Well, that's what I'm saying. It's not -- if it gets out of hand, its promise isn't realized in the way that we intended, right?

Valerie Watzlaf: Do you want to just say this tool has the potential to facilitate?

Rebecca Hines: Somebody give me the right answer here.

Tammy Feenstra Banks: It has to be may, can, or will.

Participant: Let's leave it simple, because we're getting more into the weeds of how AI really works.

Catherine Donald: I think may. Let's go ahead and use the word may.

Rebecca Hines: I think that's reasonable. I think we know it's happening, but we don't want to oversell at this date.

Tammy Feenstra Banks: May works for me, but it may not work for you.

Rebecca Hines: We will keep track of what's in the Q&A, which I think only the members and staff can see. We will keep track of that and revisit it. We'll get that file from Mike Kavounis afterwards and we can add those suggestions, if it makes sense to. Thank you to the members of the public. Keep it coming. We'll take your ideas and we'll look at them.

Tammy Feenstra Banks: Anything on the consumer-focused price transparency?

Dobbs world? That could be a movie.

Rebecca Hines: I'm sure it will be.

Tammy Feenstra Banks: ICD-11?

Maya Bernstein: There's a suggestion in the Q&A that we talk about generative AI as a technology rather than a tool, if that resonates with any of you.

Rebecca Hines: I was thinking what we would do with the Q&A is get the file afterwards, Maya, and just go through it, rather than trying to do that and the members input today, but whatever you all want to do.

Maya Bernstein: Well, I don't want to change things if the members have already agreed on while we're discussing the very topics.

Participant: What was that suggestion again?

Rebecca Hines: It says recommend that we refer to generative AI as a technology rather than as a tool.

Participant: That's a tough one. Yeah, let's talk about that later. That can kick up a whole discussion.

Rebecca Hines: This is a living document, and it sounds like it's going to need another round before we post it on the web, but today the main idea is to get everybody on board with it, with obviously any refinements we can do today.

I think we can go to the next one?

Jamie, we need to toss in, find a citation about the post-coordination. So we can cite, footnote, the ICD-11 syntax and structure, because we know it's going to -- we already know that it needs a new standard, but not everybody does. So we just need to put the right cite for that bullet point.

Jamie Ferguson: Well, that could be the WHO overview that we cite elsewhere.

Tammy Feenstra Banks: The technical specs, the implementation specs, the presentation one has everything on it.

Maya Bernstein: That last line in the last bullet there, it's not clear that data flow is among other federal agencies; for sure FTC, but it's not confined to those. It could be states. It could be not regulated. There are data flows that are not regulated and there are some under FTC, but not all of its federal agencies.

Tammy Feenstra Banks: So are you suggesting it's under the FTC, comma, other federal agencies --

Participant: Why not just put the period after safeguards in HIPAA?

Rebecca Hines: You want to do that and not go into states?

Maya Bernstein: Agreed.

Rebecca Hines: You want to delete this.

Participant: I think the point, the critical point we're making, that things are well beyond HIPAA.

Valerie Watzlaf: That's right.

Maya Bernstein: I wouldn't put it there. Just say it's outside the safeguards of HIPAA.

Tammy Feenstra Banks: Are you ready for the problem statement?

Rebecca Hines: And thank you to the four commenters in the Q&A. Keep it coming, and we will review all of your suggestions next week.

Maya Bernstein: Can I ask a question? In the bold type where it says there's a broad industry requirement to modernize the standards adoption framework, I think of that and maybe wrongly, I think of that as the transactional standards and not the privacy and security standards.

Tammy Feenstra Banks: It is, and Michael Cimmino actually mentioned that in his remarks earlier.

Maya Bernstein: Okay. So maybe this needs a little adjustment, because it looks like where it's followed by including enhancing privacy and security that there's something wrong with the framework for how we adopt those.

Jamie Ferguson: Should that say modernize the HIPAA transaction standards adoption framework?

Maya Bernstein: I think it's the including that's throwing me off, but yes, also. I think Lorraine's comments make sense there. Those seem like separate tasks and maybe it wants to be enhanced. So modernize HIPAA transactions, enhance privacy and security, harmonize clinical, public health, administrative, you know. I think enhancing should be enhance. If you meant -- intend to make a list of things that need to be updated, I don't have a problem with the content. It just seemed like they weren't -- they didn't mean to be part of one another.

Rebecca Hines: That's nice. It's much clearer.

Maya Bernstein: So again, I think in the next sentence you mean the transaction standards. So maybe we just go through and review when we mean the transaction standards and when we mean the --

Participant: We would update all that language accordingly.

Maya Bernstein: We would figure that out a little bit more precisely.

Tammy Feenstra Banks: Is that something, Lorraine and Maya, that you guys can work through?

Maya Bernstein: Yes, for sure. Persnickety staff at your service.

Valerie Watzlaf: We don't always know the right terminology I think in separating them.

Jamie Ferguson: If I can circle back to one of the previous questions, there was a question about the citation for ICD-11 and post-coordination requiring new standards. Actually, we just had testimony on that today. So both the HL7 and NCPDP presentations specifically addressed what they were doing and how they were developing new standards to accommodate that.

So I don't know if we can just cite that here, because it's directly applicable.

Valerie Watzlaf: And very current, right? Good idea.

Tammy Feenstra Banks: Okay, how are we with the problem statement, with the corrections that would be made or the clarifications.

Rebecca Hines: Refinements. My favorite word, refinements.

Tammy Feenstra Banks: Okay, let's go on to challenges.

Rebecca Hines: All right. Challenges are -- I am going to hit page break here just to help.

Maya Bernstein: I might ask about one of my pet peeves, which is the word balance.

Tammy Feenstra Banks: Denise, I know we put -- this is a really good point that you had raised. Is there another way that you would phrase this? I mean, I get the balance. I don't know what would be a better word.

Maya Bernstein: We always get more of one and less of the other, if we get less of the other, and vice versa. Is that always true? I just --

Participant: I would just change it to address.

Jamie Ferguson: We need both. Balance is sort of an either or. We need both, right?

Valerie Watzlaf: Would that work for you?

Rebecca Hines: You want to change balance to address?

Jamie Ferguson: That sounds good.

Maya Bernstein: Or address, yeah. Instead of while.

Valerie Watzlaf: Denise has a thumbs up.

Tamma Feenstra Banks: This is a collection of everybody's thoughts. I just want to make sure we don't change something that that causes hell. I should say knowledge, not thoughts.

Rebecca Hines: Did you see Maya's and/or comment? I don't know what that's --

Tammy Feenstra Banks: Some of them are necessary, so we're going to have to do that later.

Maya Bernstein: Or means and or or. And means and. In some cases, it makes a difference and makes it ambiguous in a way that you don't want.

Tammy Feenstra Banks: It depends on who, right? It could be and for me but or for you.

Maya Bernstein: But that means you want --

Participant: Or subsumes and.

Maya Bernstein: Or means inclusive or.

Tammy Feenstra Banks: One or the other.

Maya Bernstein: No, it means one or the other or both. Unless you specify otherwise.

Tammy Feenstra Banks: I always read it as one or the other. Learned something new.

Maya Bernstein: That would be exclusive or.

Tammy Feenstra Banks: Do you want to get the rest of that bullet if that's not it? I think it is. There we go.

Any comments, or can we move on?

Okay, project scope. I think this is the last.

Jamie Ferguson: I have a problem with the specific mechanism for testing standards. Lack of an agreed upon mechanism. I would say it's lack of an agreed upon set of criteria, not a specific mechanism or a specific --

Participant: That's a nice change.

Jamie Ferguson: And then these criteria could be implemented in testbeds.

Rebecca Hines: Testbeds, or neutral testbeds, Jamie?

Jamie Ferguson: I would say testbeds. And then a set of criteria could be established by the federal government. To me that is better than seeking to specify a mechanism.

Participant: The other thing, Jamie, the way you made that change, because set of mechanisms implied they were building something, whereas a criteria would allow the industry to build it or an entrepreneur vendor to build it in terms of how you would have something that allows this test.

Maya Bernstein: Testbeds prior to, without the that could be used. Is that an important -- these criteria could be implemented in testbeds prior to final balloting. Is that allowed; does that say the same thing?

Jamie Ferguson: Yep.

Maya Bernstein: And here in this last paragraph, are we talking about one standard, one consensus-based standard? It does say it will result in a consensus-based standard.

Participant: Resulting consensus-based standards and get rid of the a?

Maya Bernstein: Is that right? Not my area. But it just --

Rebecca Hines: Well, right now we're talking about having more than one standard going at the same time.

Jamie Ferguson: Right. So this will result in consensus-based standards, plural, that are available.

Rebecca Hines: And Jamie, do you want to change mechanisms to criteria?

Jamie Ferguson: Yep.

Maya Bernstein: Are in place.

Tammy Feenstra Banks: On to project scope.

Maya Bernstein: This refers to the PCS Subcommittee guidance. I don't think that's appropriate, because the committee issues these recommendation letters, not the subcommittee. Everything you do is a committee product.

Rebecca Hines: Where are we on that?

Maya Bernstein: Second to last or third to last line. After Convergence 1.0, 2.0, and PCS Subcommittee guidance.

(Crosstalk.)

Jamie Ferguson: And other committee products, yeah.

Maya Bernstein: Those are committee products, and there are, contained. Other committee recommendation letters. It's okay. Just to be clear that subcommittees can't act without the committee.

Valerie Watzlaf: Do we want to add the Beyond HIPAA in there as well? I just realized we don't have it there. It might be good to add that one as well.

Participant: Is Beyond HIPAA a letter?

Valerie Watzlaf: It's a letter and an environmental scan.

Jamie Ferguson: But also it's not only those things that are contained within cybersecurity, public health emergencies, and those particular letters, right?

Rebecca Hines: Would you want to make it more inclusive, Jamie? Can you help out here?

Jamie Ferguson: Let me read this over again.

Maya Bernstein: Just take out are contained within.

Jamie Ferguson: Exactly and put in a comma instead. Okay, good. Thank you.

Rebecca Hines: Denise Chrysler, can you take what you put in the chat and send it by email as well so we can make sure? We'll get the chat file, but if you can do that, that would be great.

Tammy Feenstra Banks: Anything on the project scope statement? Otherwise, we'll move to goals. Just trying to get our time going here.

Participant: Explore ways to strengthen HIPAA, including entities outside of HIPAA. We're trying to strengthen entities outside of HIPAA?

Rebecca Hines: Do you mean data protections? You're saying including identifying approaches to increasing data protections outside HIPAA?

Jamie Ferguson: Yeah, that can't be including because they're by definition outside HIPAA. So we want to strengthen HIPAA and data protections outside HIPAA.

Participant: Is it really data protections outside HIPAA or are we trying to make sure that these, all of these things, are covered in HIPAA?

Jamie Ferguson: I don't think we're rewriting HIPAA.

Tammy Feenstra Banks: Yeah, it's just a goal. And so then the action would be to decide if you want to put them --

Participant: Wouldn't it be as well as protecting data currently outside HIPAA?

Jamie Ferguson: I like that articulation. That's good.

Rebecca Hines: So what did you say, Michael?

Michael: As well as protecting data currently outside HIPAA. Outside of HIPAA.

Jamie Ferguson: Great, that's what we meant. Those are the right words.

Rebecca Hines: That is exactly what we meant.

Tammy Feenstra Banks: That's why we look at it again and again.

Participant: Currently outside of HIPAA.

Valerie Watzlaf: And you're okay with the beginning that says explore ways to strengthen HIPAA, since we really can't change it.

Rebecca Hines: Well, I think the HIPAA security rule that you approved this morning is an example of that, right?

Jamie Ferguson: Both concepts are viable.

Tammy Feenstra Banks: Okay, number three bullet.

Michael: Project timeline, the next decade, right?

Tammy Feenstra Banks: Five years is usually 10, or 20.

Michael Hodgkins: Just kidding. Just leave it as workplan proposal is under development.

Rebecca Hines: Late afternoon smiley face.

So the product is recommendations that you believe will be actionable targeted towards HHS. You obviously only have purview over HHS, but you can certainly suggest other actions that you --

Jamie Ferguson: Does health data application need to be capitalized?

Rebecca Hines: I don't know. That's your neighborhood.

Jamie Ferguson: It should not be.

Maya Bernstein: Just a reminder that we can only make recommendations to the Secretary.

Rebecca Hines: That's right, but if you look at our charter, it's not like we can't talk about other aspects of the environment.

Maya Bernstein: No, but this at the beginning says actionable recommendations for specific federal agencies, states, localities, vendors. We cannot make actionable recommendations for any of those.

Tammy Feenstra Banks: Except for the Secretary. I know Lorraine was going to give us some language for this.

Participant: What you're saying, the HHS just be recommendations, not actionable?

Maya Bernstein: You can make actionable recommendations but only to the Secretary, not to states, not to localities, not to developers.

Tammy Feenstra Banks: Just send them to HHS and if they're about any of them, then they would forward if appropriate or if not.

Rebecca Hines: It does say in our charter to work with other organizations. So we just need to get -- we definitely need to refine this language.

Maya Bernstein: But you have a huge amount of influence over those other entities.

Rebecca Hines: No, but people do -- and I'm always -- I never cease to be amazed at how much our letters are cited by other people and I randomly find out about it.

Maya Bernstein: This is what I'm saying. I'm saying you have a huge influence over those other entities, but technically you can only make recommendations to the Secretary.

Rebecca Hines: And so really the question, I don't know if you want to go back to the slide deck, Tammy, because this is really the concept part of --

Tammy Feenstra Banks: Yeah, the rest is just BP.

Rebecca Hines: Whether we want to just have general discussion for a couple of minutes. Is everybody directionally, okay? Is everyone directionally, are we in the right lake? Is everybody on board with this? We don't need to take a vote, per se, because it's really to say we will move forward as a committee with refinement, as discussed today, and take into account; I see some thumbs up.

But I really want to make sure everybody is on board as a full committee before we get into details. Are we directionally --

Participant: I'm liking what I'm seeing. I have to admit, I didn't review much of it until on this call. I love what I saw. Wish I'd seen it five days ago.

Tammy Feenstra Banks: The other question is is there anything missing or you felt wasn't representative of what you want to see there? That isn't Rebecca's minor refinement, sorry.

Participant: Not so much missing. I'm just wondering when we look at it I guess again tomorrow morning, whether there might be places we might want to beef up. I was just happy with the content, not necessarily seeing if there's someplace where it could be more elaborated, but then if we elaborate more, then there's more discussion on the words. It may be fine.

Tammy Feenstra Banks: Well, and the point is how much do you want in this document and how much do you elaborate on the workplan and the work product? This isn't a masterpiece. It's a guidance document that we're going to continue to go back and refine as things change.

Jacki Monson: Yeah, I think my only comment is that it's really, really heavy standards, which I know is where it came from, and so I think we should take a hard look at it and see if there's more that can be incorporated for PCS, because there's a lot of synergies and I'm not sure how deep we'll have the time to go, because we're working on the security letter, but just from my

read of it, it's super heavy standards.

Valerie Watzlaf: And we can look at it again, because we didn't; I know the subcommittee I think maybe looked at it once or twice. It wasn't a lot of time, because we were so focused on the security letter. But so I looked at it, but we can certainly do that again. You know, it is a working document, right? So we could look at it again and add.

Rebecca Hines: Absolutely, yes. And we don't need to post it on the website until we've done another couple of weeks of sending it around and getting these little things refined.

I see Steve's hand up.

Steve Wagner: So are we saying there are no, in HIPAA at this point, there are no security standards referenced? I seem to remember putting some in there way back when we developed HIPAA.

Tammy Feenstra Banks: No, I think what they're referring to is the standards subcommittee refined this document and then privacy and security reviewed it. So they weren't able to incorporate reference to privacy and security in all the places that they would like to have reference, because it's strong, from a standards perspective, and so they just want to revisit it in that light to make it as collaborative and cohesive as possible.

Steve Wagner: Okay, I thought one of the changes for that was stay in HIPAA transaction standards or something.

Tammy Feenstra Banks: Yeah, that's what Maya and Lorraine are going to look at it from how to reference both and then I believe Maya and Val and subcommittee will review just to see if there's any other areas that the reference to privacy and security is not there or should be in order to make it a more cohesive document.

Rebecca Hines: Yes, and Jacki, we'd love if once we go through if you could also let us know.

Valerie Watzlaf: I mean, it's natural it's going to lean more towards standards since it started there. So we do appreciate being a part of it, and we need to focus on it, I think, a little more, and we'll be happy to do that.

Tammy Feenstra Banks: We look at standards whenever you talk about standards, you're also talking about privacy and security elements in it, and you want it expressed, not just so how do you set it up so that that's how it's viewed.

If there are no more questions, we can go through the first topics.

Rebecca Hines: Tammy, did you want to talk about the joint topic? So Mike, can you pull up slide deck K?

Tammy Feenstra Banks: We're going to need more time with the joint topic though.

Jacki Monson: My thought, Tammy, is we're at a good stopping point now and I think we should go to public comment and adjourn for the day and pick this back up during your time tomorrow.

Tammy Feenstra Banks: Okay.

Rebecca Hines: All right, so Mike, you can take those down, and so for tomorrow, we'll actually get into the what are the projects that you'll start now and then report back at the next committee meeting in the spring, probably April. What are the actual projects you'd like to work on.

So any other discussion? I get the sense there's general agreement, it's fine to move forward on this, and tomorrow we'll get into the details on for projects. Is that right? Okay.

Public Comment

Rebecca Hines: We're a little ahead of schedule. Let me just check. I don't think -- we've received one letter, which is quite lengthy, which I forwarded to all of you, and I'm not sure that person is on. She actually let me know that her internet went down, and she'll try to call in tomorrow. So let's go ahead and move to public comment.

For the members of the public, I see there's 32 of you here at this point. If you'd like to make a public comment, please raise your hand to have your audio unmuted. I don't see anyone who is on the phone right now. If there is someone and I'm not seeing it, press star-9 to request unmuting of your phone, and of course you can always send us comment by email, and I did forward one comment we got today. It's lengthy, and we will append it to the meeting summary so that members of the public can see that comment. It was from a state Medicaid.

I see we have a former member, Vickie Mays.

Vickie Mays: Thank you, Rebecca. I just wanted to comment, because I've gone through the slides for the last presentation on the joint work between standards and PCS. I just wanted to say I think it's very smart work, because I think the thing that Tammy said at the end was this issue of some of what you see in standards impacts PCS as well, and I think that the complexity of what we're dealing with these days really puts us in a position of not just can PCS comment about a problem, but can standards help with a recommendation that would really change the nature. We're not waiting for someone to discover it, but instead, within NCVHS that you're actually coming up with recommendations, because then the industry gets to be a part of it. So I just wanted to offer that I think this is very smart work.

Rebecca Hines: Thank you. Anyone on the public side have anything? I don't see anything in the email box. I apologize we're not right at 5:15, which was when the agenda said there was public comment. We also have public comment tomorrow scheduled for 4:45, which may end up coming sooner than 4:45. We don't know. So just make sure you stay tuned.

So with that, public comment period is closed.

Jacki Monson: Thanks, Rebecca. Thanks everybody for such a great day today, and we will see you all tomorrow bright and early for us Californians.

Rebecca Hines: See you at 9:50 a.m. Have a good evening, everybody.

(Whereupon the meeting was adjourned at 5:00 p.m.)