National Committee on Vital and Health Statistics

Transcript
March 30, 2022 11:00 a.m. – 2:05 p.m. ET
Virtual Meeting

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Jacki Monson	**Sutter Health**	**Chair**
Sharon Arnold	**DHHS**	**Executive Staff Director**
Rebecca Hines	**NCHS**	**Executive Secretary/DFO**
Debra Strickland	Conduent	Member
Denise Chrysler	University of Michigan School of Public Health	Member
Denise E. Love	Individual	Member
Jamie Ferguson	Kaiser Permanente	Member
Margaret A. Skurka	Indiana University Northwest and Principal, MAS, Inc	Member
Melissa M. Goldstein	The George Washington University	Member
Richard W. Landen	Individual	Member
Tammy Banks	Individual	Member
Valerie Watzlaf	University of Pittsburgh	Member
Vickie M. Mays	UCLA	Member
Wu Xu	University of Utah	Member
NCVHS Staff		
Name	**Organization**	**Role**
Maya Bernstein	ASPE/OSDP	Staff
Lorraine Doo	CMS	Staff
Natalie Gonzales	CDC	Staff
Marietta Squire	NCHS	Staff
Nate Kim	ASPE	Staff
Ryan Mintz	ASPE	Staff

Welcome and Workshop Overview

Rebecca Hines: It is 11 a.m. eastern. Good morning and a warm welcome to the National Committee on Vital and Health Statistics, to our members and committee staff and members of the public in attendance with us today. My name is Rebecca Hines and I serve as executive secretary and designated federal officer for the Committee.

Today, the committee is holding an abbreviated meeting for the purpose of bringing two sets of recommendations to HHS for final discussion and vote. Our next regular full committee meeting is now scheduled for mid-July, the 20th and 21st. Our chair, Jacki Monson, will review the agenda in detail. Let us take care of roll call now, starting off with our chair. Jacki, do you want to start us off?

Jacki Monson: Sure. Good morning, everyone. Good morning on the West Coast. Jacki Monson, Sutter Health, chair of NCVHS and no conflicts.

Rebecca Hines: Thank you. Denise Chrysler.

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

Rebecca Hines: Denise Love.

Denise Love. Denise Love, member of the Full Committee, co-chair of the Standards Subcommittee, no conflicts.

Rebecca Hines: Jamie Ferguson.

Jamie Ferguson: Good morning. I am Jamie Ferguson with Kaiser Permanente, member of the Full Committee, a member of the Subcommittee on Standards and I have no conflicts.

Rebecca Hines: Margaret Skurka.

Margaret Skurka: Hi. I am Margaret Skurka. I am a member of the Full Committee. I am a member of the Standards Subcommittee and I also have no conflicts.

Rebecca Hines: Melissa Goldstein.

Melissa Goldstein. Good morning. I am Melissa Goldstein. I am a professor at George Washington University. I am a member of the Full Committee, co-chair of the Committee on Privacy, Confidentiality, and Security and I have no conflicts.

Rebecca Hines: Rich Landen.

Rich Landen: Good morning. Rich Landen, a member of the Full Committee, co-chair of the Standards Subcommittee, no conflicts.

Rebecca Hines: Tammy Banks.

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

Rebecca Hines: Val Watzlaf.

Valerie Watzlaf: Good morning. I am Val Watzlaf. I am associate professor emeritus University of Pittsburgh. I am a member of the Full Committee and also co-chair of the PCS Committee and I Have no conflicts.

Rebecca Hines: Vickie Mays.

Vickie Mays: Good morning. I am professor at the University of California, Los Angeles. I am a member of the Full Committee, the Privacy, Confidentiality, and Security Committee and I co-chair the Workgroup on SDOH/SOGI.

Rebecca Hines: Thank you, Vickie. Wu Xu.

Wu Xu: Good morning. I am Wu Xu. I am adjunct faculty with the University of Utah, a member of the Full Committee. I have no conflicts.

Vickie Mays: I have to say. I have no conflicts, Rebecca.

Rebecca Hines: Yes. And we do have a quorum. Thank you all very much.

Moving over to our executive director, Sharon Arnold. Good morning.

Sharon Arnold: Good morning. Happy to be here.

Rebecca Hines: Thank you, Sharon. For lead staff, Lorraine Doo.

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

Rebecca Hines: Thank you. And Natalie Gonzales.

Natalie Gonzales: Hi. I am Natalie Gonzales. I am lead staff of the Privacy and Security Subcommittee. I am at CDC in the Privacy and Confidentiality Unit.

Rebecca Hines: Thank you, Natalie. And Maya Bernstein also in Sharon Arnold's office. Good morning.

Maya Bernstein: Good morning. I am Maya Bernstein. I am the senior advisor for Privacy Policy in Sharon's Office at ASPE. I am also the lead staff to Sharon as the executive director of the committee and staff to the Subcommittee on Privacy, Confidentiality, and Security.

Rebecca Hines: Thank you, Maya. Before moving on, I just want to note for the members of the public on today's agenda with two sets of recommendations being discussed and deliberated. We are including two public comment periods, one tentatively scheduled for 12:15 p.m. eastern on the topic of privacy, confidentiality, and security considerations for data collection and use during a public health emergency. And a second public comment period we are estimating around 2 p.m. eastern for the Standards modernization topic. For members of the public, you are welcome to make a comment orally. We will

provide instructions. And just to get a sense of them, the instructions are up on the screen. You can also send a written comment to the NCVHS mailbox or by using the Q&A function during the public comment period.

And I just want to note. It is possible that the timing on the agenda may shift. The times listed are our best estimate. The public comment periods may fall earlier or later than the times noted on the agenda. If you are planning to make a comment orally, please monitor the proceedings closely or feel free to email us at ncvhsmail@cdc.gov and we will read your comment aloud for consideration.

Maya, you have your hand up. Okay. Over to our chair, Jacki Monson.

Agenda Review

Jacki Monson: Can we call up the agenda for review? We just finished roll call. We will at 11:10 start the Subcommittee on Privacy, Confidentiality and Security. The plan is to discuss the recommendations that we have related to data collection use during a public health emergency, led by Melissa and Val. We will break for public comment specific to that particular letter. And then we will move back into the letter for hopefully the action to approve the letter. And once that is completed, we will take a break at 1 o'clock. At 1:15, we will move into the Subcommittee on Standards with Rich and Denise, and we will be discussing the recommendations to Modernize Aspects of HIPAA and other HIT Standards to improve patient care and achieve provider burden reduction.

After we review that letter, we will break for public comment. Once we have heard public comment, we will back into the Subcommittee on Standards and the plan will be to take action on that letter and hopefully obtain approval from the committee.

And then we will have next steps and adjournment at around 2:55. That is our robust agenda for the day. Let us go ahead and get started.

Melissa and Val, do you want to kick us off?

Subcommittee on Privacy, Confidentiality and Security

Melissa Goldstein: Hi everyone. We are really glad that you could join us today. We are looking forward to going through what we believe is a much-improved letter. The version that we are going to show on the screen has comments from the members, I believe four members, that we have assembled since we sent out the latest draft to you all. The comments themselves are in the margins and reflected in track changes in the actual document.

The areas that we will be going through the document paragraph by paragraph to see if there are other comments from the group to discuss issues that are still remaining if any of you have any issues.

Thank you to Val for incorporating everybody's comments into the version that we are going to show on the screen. We will be discussing some of them. We may want to author some of them. But as we go through, hopefully after the public comment, we will have a chance to actually vote on a product that substantially reflects the content that we really want with the understanding that after the vote, we will probably fix typos, things like that, typos, references, things like that, the smaller issues. That is my plan for today. Val, do you want to say hello? Introduce yourself – first full meeting as a co-chair of the Subcommittee.

Valerie Watzlaf: Yes. It is my first full meeting as co-chair of our Subcommittee. I also just want to thank everyone who really – it was a true team effort of the whole team that really put the letter together. Just thank you to all of the staff as well as our PCS Subcommittee for this. I guess we could put up the letter and go through it and feel free to provide your comments as we move forward.

Melissa Goldstein: Yes. Thank you. I second Val's thank you to the staff and everybody who helped assemble really the members of the Subcommittee and thank you to all of the comments that you sent in so far of members of the committee. It is kind of like Oscar speeches where you learn from the – of other people. I have learned from the thank yous.

Maya Bernstein: Can I just interject very quickly. We just inadvertently skipped over Nate Kim, who has also worked very hard on this letter and can – subcommittee. Do you want to introduce yourself?

Nate Kim: It is all okay. I am Nate. I am also staff to the PCS Subcommittee. Thank you, Maya.

Rebecca Hines: Apologies for that, Nate. Welcome. You are now a full-fledged member of this wonderful group.

Valerie Watzlaf: And he helped us a great deal also. Thank you.

Rebecca Hines: Thank you, Nate.

Melissa Goldstein: Let us pull up the letter. Natalie, are you going to be up? There is Natalie. Thank you, Natalie. Can everybody see it okay? Should we make it a little bigger?

The first part of the letter that you see here is essentially a cover letter summarizing the recommendations. You will see that we added thanks to Rich. We changed the word from secretary to secretaries, reflecting that there were many over the past I think we say decades maybe or a couple of decades with HIPAA. Thanks, Natalie.

We will go down to the next paragraph where we reflect the paragraph that starts with the purpose of this letter. It is an essential summary of our goal with the letter, and you will see that we just made minor edits to disclosing. Instead of disclosure, we put disclosing information to make it parallel. That is really just a minor edit.

Let us move down to the next page. Here we summarize the objectives of the meeting that was held on September 20, 2022. These were the objectives of the meeting. This all comes straight from the meeting itself.

This is how we approach the hearing. This is what we did in preparation for the hearing, the following. And then we get into the recommendations themselves. We have changed the language a little bit, mostly to make it parallel but also to reflect our – you can see where Val thankfully put into the comments where the language has been changed, where the ideas came from. Rich, Denise, make sure that we have reflected accurately what you suggest.

Recommendation 1. We will be going over these all in more detail along with the justifications in the next part of the letter when we get past the cover letter. This is a summary of the recommendations.

Rebecca Hines: Melissa, we might want to scroll back up like a half an inch so people can see the lead-in to the recommendations. They make sense grammatically.

Melissa Goldstein: This is the lead in. This is the in preparation for, the hearing itself. We asked panelists several questions ahead of the time. Yes, Rich. I see your hand up.

Rich Landen: You got my comment on the screen, but I do not see that you have accepted or rejected the comment. I am okay --

Maya Bernstein: We did that on purpose so that everyone could see – find it easily.

Valerie Watzlaf: I just put the comments in and then we can discuss if you – but I did not accept them yet. None of us did that part yet.

Melissa Goldstein: We left them in because they are changes from the version that we sent out to the Full Committee. We wanted everybody in the Full Committee to see what has been changed since that version.

Rich Landen: My apologies. The earlier ones you had actually inserted edits in the text like you have here with Denise's comments. I just did not see that – to know which way you are leaning.

Melissa Goldstein: Got it. Thank you, Rich.

Okay, so I think you can see the summary of the recommendations here and the language. The language here I believe, Val, should be exactly the same as the language in the full letter with the appendix and the justification. Why don't we move forward? Instead of going over the recommendations now, we can move forward to where they are in the justifications. They are summarized here and then we say you will find detailed justifications for each and then this is a summary paragraph at the end here so we can stop here for a minute.

Denise Chrysler has helped us add in tribes and territorial levels of government as well. You will see throughout the letter where sometimes we have added the whole list, local, state, federal, tribes, territories, and some other times, we have used the language at all levels of government. And then you can see Rich has some concerns.

Rich Landen: Do you want to address the first one? Scroll up a couple of lines please. See if we can get the full recommendation on the screen. See if we can see all of Recommendation 5 language. Good.

My concern is we start off the recommendations – address inequities in collection and reporting. But at the end, we are only talking about reporting. To me, that is kind of a little bit of the disconnect. Are we still talking about both or are we only talking about both meaning collection and reporting or are we just talking about reporting here in the second half of the sentence?

Melissa Goldstein: I think it has to be both. The assumption is you cannot report data you have not collected. It would be both. We can put that in or we could just --

Rich Landen: Take out the second reference.

Melissa Goldstein: Just put a period after local levels.

Maya Bernstein: That works.

Valerie Watzlaf: Good catch.

Rich Landen: If you are ready to scroll down to the next one after the period gets inserted. Good. In the very last sentence of the letter, we use the term look forward to working with the department to "help carry them out". I understand the intent and I am fine with that. To me, carry out raises the concern is we are an advisory group. We are not an operations group. I am little unclear as to what we mean by carry out. To me, that implies some sort of active role in the roll out distribution of whatever the secretary chooses to do with the recommendation.

Melissa Goldstein: I think that the paragraph is just supposed to mean continue to give you advice, which I think we can probably end the sentence and put a period after the word department. I think that works.

Rich Landen: That resolves mine.

Melissa Goldstein: Thank you, Rich.

Valerie Watzlaf: There is question in our Q&A. I do not know if we want to do that now or later.

Melissa Goldstein: Rebecca, do we want to look at the Q&A question?

Rebecca Hines: It is fine. It is totally optional since we are not in a formal public comment period. But since we are on Zoom and it is here, it is completely optional. But if it is helpful, feel free to.

Melissa Goldstein: The question is were non-health or non-government entities such as community-based organizations considered within recommendations. Our recommendations are to the secretary, the Secretary of Health and Human Services. But I guess the question is intended to mean were we thinking about implementation within the industry. I think we have used that term throughout the letter, which we would consider those types of – I can consider that part of the ecosystem of the industry as well.

Vickie, go ahead. I see you have your hand up.

Vickie Mays: Yes. I would say that as we did our work, we thought about groups. In terms of addressing what to do, the what to do is actually addressed to the secretary. But in terms of things that we recommended, I think we did have a broad hat.

Melissa Goldstein: I agree. Thank you, Vickie.

Val, do you want to add?

Valerie Watzlaf: I agree also.

Melissa Goldstein: Let us move forward. Thank you, Natalie. Here, you can see we have the appendix. We have added this language at the beginning. These are the recommendations. March 2022, soon to be April. Based on lessons learned from the hearing as well as consideration of reports developed on this topic by a variety of other organizations, other, meaning other than us, NCVHS makes the following

recommendations to HHS. Here, we have the first. We have made the recommendations parallel. You will see instead of the language in each one that says NCVHS recommends, it is in the predecessor paragraph here thanks to Rich.

Rich, have we addressed your comment? I guess it the following paragraph, beginning with data governance. The first recommendation is developing a national governance strategy specific to public health emergencies in collaboration with federal, tribal, state, territorial, and local partners that increases the trustworthiness in data collectors, data stewards, and those who share the data collected in and after the PHE.

Rich Landen: Melissa, if I am reading this correctly, it looks like you have accepted and put in the edits to actually quote the language from the report that is footnoted. And yes, that resolves my issues.

Melissa Goldstein: Thank you. That is great.

Natalie, let us resolve – I guess we could have in the previous pages resolved the comments as well. But let us hit that we resolved that comment in there. Great. Thank you.

Maya Bernstein: This one here.

Melissa Goldstein: Yes. I do not know how to get – that one.

Maya Bernstein: If we are settled on the language, we should accept it so we know what happened at the meeting, what you agreed on.

Melissa Goldstein: Maya, can you say that again? I did not hear you.

Maya Bernstein: It is also if you are accepting the edits, it would be good to actually accept them in the language – so that we have a record of what was agreed to during the meeting. Does that make sense? Natalie, if we agree on the language – the issues, you can select that language and just hit accept in the review button and it will show that that is now the language accepted in the letter by the committee.

Valerie Watzlaf: Do you mean in the edits? Is that what you are saying, Maya?

Maya Bernstein: Yes. Also then people can see what is now look like and be sure that that is what they intended.

Natalie Gonzales: -- accepting it --

Maya Bernstein: The red lines. Select the red lines. Collect them as a group and just hit the accept button and it will go away. All of them that you want to accept together, you can select together.

Tammy Banks: Highlight the paragraph and accept and you will be good.

Maya Bernstein: Exactly.

Melissa Goldstein: We need to do all of the language before this point as well or we could just write ourselves a note.

Rebecca Hines: For the sake of time, I suggest we just make a note of that and keep moving.

Melissa Goldstein: That sounds great. Natalie, do you want to stick a comment in the margin that says accept all edits prior to this point?

Maya Bernstein: I am also tracking.

Melissa Goldstein: Let us move onto the paragraph that starts with trustworthiness, which is very important to the Subcommittee, the idea of trustworthiness.

Denise Love: I have a question on that.

Melissa Goldstein: On this paragraph, Denise, or do you want us to go to the previous one?

Denise Love: On the one we were just on, the one with the data assets.

Melissa Goldstein: I did not catch this and I apologize. Could we go to where we just were on the data assets and the transparency? I can see it. The data assets. Do you see on the righthand --

Denise Love: Do we mean that the data assets are accessible as well? That is a data steward that kind of gives me pause. There are certain things – I just want to be sure we are understanding what is accessible. The policies are accessible.

Melissa Goldstein: It is not access. It is a data asset. I am a little confused by the question.

Rich Landen: Melissa, if I might jump in. This was my concern as well. But since we made the change, this whole sentence is now a verbatim quote from another organization.

Denise Love: Okay.

Rich Landen: If I were writing it, I would not write it this way. I agree with your assumption. I do not know what – talking about data assets and assets transparence. To me, it is more the process and the input that has to be transparent. But rather than arguing with the definition and rewriting it, I think if we are quoting it, it is sufficiently – it is good. It is not perfect.

Melissa Goldstein: The citation is to the GAO. Let us put it up. And we paid a note in there.

Denise Love. Okay. I just want to be sure we all understood that.

Melissa Goldstein: Let us put a note in there that it may need direct quotations so that we can check the actual source.

Natalie Gonzales: This whole paragraph or a specific part?

Melissa Goldstein: To citation 5, to reference 5 that we need to make – if it is a direct quote then we need to have it in quotations.

Rich Landen: Yes, it is a direct quote.

Melissa Goldstein: Thanks, Rich. We need to make sure we do that. As a law professor, I am very upset by that there are no quotations there.

Rich Landen: That thought did occur to me, Melissa.

Melissa Goldstein: Sorry about that. I did not catch that one. It is all about human failure. Fallibility.

Now, we will move on to trustworthiness. Thank you, Denise Love, for helping us with that. Here, we are also citing the Belmont Report, which is a fundamental document about human subjects' research dated 1979, developed as required by the National Commission on Bioethics, established by Congress. I see Rich has made a comment here. I guess, Rich, we should check with you to make sure that we want a footnote. That is a good point.

Rich Landen: This is outside my expertise field. My ignorance is showing. When I first read Belmont Report, the first thought that popped into my mind was something about horse racing. The footnote would help people like me.

Melissa Goldstein: That is a great point. Thank you. Any other comments on this paragraph? Should we move forward? It looks good.

The following paragraph. NCVHS recommends that HHS develop a national data governance strategy. This is the main import of this particular recommendation. Overarching integrated across data platforms and agencies while resource socially interoperable at all levels of government and then we define what we mean by that. Let us keep going down. The strategy should recognize. And then some language changes at the end of the paragraph and then the paragraph starting with we have learned from. The point that we have learned from other public health emergencies, specifically infectious disease outbreaks.

Natalie, if you hover over the comments on the side, you will be able to put – you can show the full comment so that everybody gets to see if people are interested. Thank you. That is Denise's edits about the importance of including tribal governments and then Rich's edits.

Allocation. Rich, for this comment, did you recommend particular language?

Rich Landen: No, I did not. I just simply ran out of time. But the point is that one of the real values coming from the data is the ability to inform actions taken by the various state, local, tribal, et cetera governments. And that whole aspect of this informs the choices of actions to take to maximize the benefit that public was missing from the list. I am sorry. But I do not have language to suggest here.

Melissa Goldstein: Okay. The verb is need easy and rapid access to public health data to support public health surveillance, research policymaking, and public communication. How about based thereon and allocation of resources by governmental agencies --

Rich Landen: Decisions about allocation of resources.

Melissa Goldstein: Okay.

Natalie Gonzales: And decisions?

Melissa Goldstein: And decisions. We are just adding to the list. Yes.

Natalie Gonzales: This is about allocation --

Rich Landen: Correct. Then you will need take out the previous "and", the one in front of public communications. That is it. That has got it. Thank you.

Melissa Goldstein: Thanks to you both. Great. We may want to leave in the -- I think it is okay to accept what is in red and leave what is in green. That is what I would do. We will need to rename this version of the document to make sure we know what we did.

While Natalie is doing that, we can move forward to the next paragraph. NCVHS also recognizes the need for improved information system capabilities and public health agencies. Natalie, if you can hover over Denise Chrysler's addition here. This first issue is relying on what one of the panelists said, an actual panelist comment. And then the next comment is Denise Love's.

Denise Love, this comment – this statement is also reliant on what a panelist emphasized.

Denise Love: Right and I realized that through our back and forth and so I do not know if this is relevant. I do not disagree with the comment of the panelists. But my opinion is not that the policies are not embedded into local and public health, it is that they vary so much that is stalls exchange. I do not know if it is relevant to clarify that or add that or let it stand. I would just ask the group because in my opinion, that is more of a problem than not having the public health policies and practices because I would argue they do.

Melissa Goldstein: I would say it varies widely. Some of the states do and the laws have them embedded. Some of them do not. I think we do in the letter refer at various points to the variety in state laws and paying attention to how they vary and to what extent they vary.

We may want to – I do not have a problem with adding that again here, that state laws vary if that is what --

Denise Love: I would defer to Denise Chrysler who is more in tune with this. It is just that when I read that not understanding it was from the panelists. It raised my attention because I disagreed with the statement. Because a panelist said that, I totally understand why it is in there and it is cited. How we deal with the variation, I would defer to Denise Chrysler.

Denise Chrysler: Denise, I was okay with just deferring to what folks said. Are you thinking we should expand based on our viewpoint?

Denise Love: I do not know how to deal with it but that has been my observation and frustration over the years is the variation, which makes data exchange extremely difficult.

Melissa Goldstein: There is a comment in the Q&A that I would like to point out. Lisa McCain has stated, they generally do not have, and I am assuming she is referring to states, they generally do not have a standardized guideline. Each silo may apply differently.

Denise Chrysler: Yes. I agree with that.

Melissa Goldstein: As do I, but that is not what the panelist was talking about.

Denise Love: Okay. I just wanted to point that out.

Melissa Goldstein: Thank you. It is important.

Wu, I see your hand is up.

Wu Xu: I am thinking this belongs to the governance structure issue. Could we address that? This governance needs to address the state and local variation.

Melisa Goldstein: I view that as actually, Wu, as legal advice because of the role of the federal government versus the role – and later on, and I believe maybe in Recommendation 4, I cannot remember. Do you remember, Val, Recommendation 4? We do talk about the varieties of state and local when we are talking about the notices of enforcement discretion. Can we put a ticker on that, Wu, and see if --

Wu Xu: That would be good. Because as a state, we like a common law model so we can standardize. That is a problem. Not standardized. We need some variation, but we need some common policies.

Melissa Goldstein: Okay. We will put a ticker to revisit that when we get to Recommendation 4. Maya, will you keep us honest on that? Maya and Natalie? Thanks.

Natalie Gonzales: Do you want me to resolve this or keep it?

Melissa Goldstein: I would leave it for now. I think you can resolve the previous one though. Denise Chrysler, I think we – yes. And leave Denise Love's at the moment.

The next paragraph. Additionally, to help support clarity of roles in data sharing and reduce duplication of data collection efforts, NCVHS recommends that HHS provide guidance on the role of business associates during future PHEs. Natalie, that was great. Hovering over Rich Landen's comments.

Rich, do you want to help describe to the group what you were thinking here?

Rich Landen: Yes. This usage of business associate really had me scratching my head. There are all sorts of business associates. There are let us call them lower-case business associates or lower-case BAs. The upper-case BAs are specifically the business associates of HIPAA-covered entity for whom by statute and regulation certain obligations fall on them directly and not simply – and not exclusively through the covered entity who is their business associate. I really did not understand the committee's intent here. I think that is pretty critical because if we are just talking about uppercase business associate, meaning specifically those covered as business associates of HIPAA-covered entities, it is a very different scope.

But my reading of the intent of the recommendation to me says we are really talking about business associates' lower case especially when you think of a state or a tribal or governmental authority in their data flows for public health and health provision of health care. They will also business associates. Although for the non-health care purposes, non-direct health care purposes, those business associates are not covered as business associates under HIPAA.

Then reading down through the rest of the text in the paragraph, all the conversation, all the examples are about HIPAA-covered entities. My conclusion is that if we – we need to state whether or not we are restricting the scope to uppercase business associates, those affected by HIPAA or not. And if we are, we need to say that very precisely. If we want the lowercase, the wide or the broader spectrum of business associates then we should probably besides making that clear as well, we should also throw in a few

examples of those types of non-HIPAA business associate relationships and implications for the downside of not following the recommendation. I hope that is clear.

Melissa Goldstein: It is. I appreciate that. In this particular paragraph, we are talking about capital B, capital A business associates because we are talking about enforcement by the government and notices of enforcement discretion by the Office of Civil Rights. We are talking about the role and governance and honestly enforcement of the roles of HIPAA business associates.

We could capitalize the term there and drop a footnote explaining with a citation to what a business associate is. We could also say NCHVS recommends that HHS provide guidance on the role of business associates with regard to their duties to covered entities or something like that.

Rich Landen: That would clarify it. But I guess still in the back of my mind is this is all explanation of the Recommendation Number 1 about developing a national government strategy.

Melissa Goldstein: Right. We put that here because of the fact that the example later in the paragraph about the actions of business associates once these notices of enforcement discretion. We have given an example here of a particular issue, which we have – if you look down, this starts – you do not have to scroll down yet, Natalie. About halfway down the paragraph, we start and we talk about one example. This notification was issued quickly to allow data to be disclosed during PHE. The next sentence. At the time, at least one electronic health record organization --

Rich Landen: She froze.

Melissa Goldstein: -- that it would pull the data to which it had access and send it to various agencies and organizations. We have a citation there to an interview. The message was not a request to health care providers. We have this example later in the paragraph that we want to highlight of an official business associate taking actions without necessarily getting consent from its covered entity. It is a contractual arrangement between a covered entity and a business associate.

The reason this paragraph is here in Recommendation 1 is because of that general data governance milieu. I know others may want to add to. We do have a more detailed description of these notices of enforcement discretion in Recommendation 1. We could consider moving this down there, which might solve a little bit of the problem. I would like to hear what other people think.

Maya Bernstein: Do you mean Recommendation 1 or a different one?

Melissa Goldstein: This is now in Recommendation 1. But if we moved it, it would go into Recommendation 4. Was that your question? Yes.

Rich Landen: I guess I am still scratching my head because the introductory sentence to the paragraph talks about supporting clarify of roles in data sharing and reduced duplication. But the explanation I just heard is that it is really about NEDs. I think to clarify that if we just change that first sentence to talk about NEDs rather than the more general data sharing and reduce duplication.

Melissa Goldstein: I think it is clarity of roles. It is not necessarily NEDs. It is clarity of roles between a BA and a covered entity.

Rich Landen: Then if it is clarity of roles, in my mind, that still takes us back outside of HIPAA.

Maya Bernstein: The way I read it is if it is helpful if I may is just the example of where the roles are not clear. Particular example between – major relationship in the whole health eco structure.

Melissa Goldstein: We could take out the language and reduce replication of data collection efforts. And at the beginning of the next sentence before an early 2020, we could put for example.

Tammy has put in the chat – Tammy, do you want to describe what – do you want me to read it?

Tammy Banks: No. I was just saying that his point is a really good one. I understand that you are looking at the HIPAA definition. But maybe at the end of the paragraph, we can be clear that under a national framework, we are going to need to take a look at the extension of the definition of the covered entities or of the business associates. I was trying to figure out how to do that in a short sentence.

Melissa Goldstein: We are not suggesting that we change the definition. We are saying that the definition should be followed. Natalie, can you scroll down to the end of the paragraph? The next paragraph is what we want to get. The one that says the NED potentially sets a – this paragraph. Potentially setting a precedent that could create conflicts between covered entities and the business associates, which you do not want to do. Covered entities rely on business associate agreements, which are contracts, to manage their data. Some more even during PHEs. NCVHS recommends that HHS provide guidance that clearly outlines the roles of business associates during PHEs specifically, including requiring permission from a covered entity to – on its behalf. That clearly outlines the roles of business associates during future public health emergencies, including requiring permission from a covered entity to release information on its behalf if that release of information will help rapidly address data needs. The guidance should also consider the varying nature of local and global PHEs and methods to avoid duplication of effort.

Denise Love has commented also, which I think is part of this discussion along with Tammy and Rich. Permission or notice. I worry about opt out in a PHE. What I would say to Denise's comment is that this is contractually based. The business associate's power, if you will, depends entirely on the covered entity. That is how it works. I think that is the idea of clarifying the roles.

I see Rich has raised his hand again.

Rich Landen: Thank you. As I hear the conversation about this, it seems pretty clear. The intent here is only within the HIPAA-covered entities. I would suggest we need to add -- in both of those paragraphs, add the term covered entity as the term of art, meaning capitalize CE. And then in the very first sentence of the previous paragraph, NCVHS recommends that HHS provide guidance on the role of HIPAA businesses, HIPAA covered entity business associates.

Melissa Goldstein: At the very beginning of this? Okay. Good.

Rich Landen: Right before the business that is highlighted for the comment of HIPAA covered entities business associates.

Natalie Gonzales: Is business associates capitalized too? Are we doing that?

Melissa Goldstein: We can fix that later, I think – and the dropping footnotes and giving definitions and citations and that sort of thing.

Valerie Watzlaf: There is also a comment in the Q&A. Maybe third-party entities as subcontractors.

Maya Bernstein: They are included in the definition of BAs – the ones we defined --

Melissa Goldstein: Rich, do you think we have resolved your initial comment?

Rich Landen: Yes, I do. I would like to get some distance and time and re-read it to make sure. But from everything I can see now, yes. It addresses my comment, and it clarifies the intent of the Subcommittee.

Melissa Goldstein: Okay. That is good. We can resolve that comment that you have the pointer on, Natalie. And then my question would be we want to make sure that we resolve Tammy and Denise Love's comments as well. And then we have a couple of other comments about that paragraph as well.

This is mine. There is a phrase in here and I wanted to ask your advice. At the time, at least one electronic health record organization provided notice to the covered entities with whom it had business associate agreements that it would pull the data to which it had access and send it to various agencies and organizations. My question to the group is would we like to include more specific language there of various agencies and organizations or are we happy with it like it is. Does it need to be more specific?

Denise Love: I am wondering if agencies and organizations -- what I am struggling with is if the covered entity, I am trying to think this through, is operating for a public health entity that has a mandated reporting, do we need to specify or – this is so complex. I have to leave it to the legal people. I will retract that. I was trying to clarify agencies and organizations reporting under a mandate or of some clarification. I am not sure that helps.

Melissa Goldstein: Okay. And Rich's comment here is that it is hard to be more specific without access to that cited interview. Here are a couple of thoughts. Thanks, Rich. Modify the language and send the data to which it was obligated to provide reports that might help. Examples from the interviews possibly. Multiple county health departments, multiple state health departments. I see, Vickie, you have your hand up too.

Vickie Mays: It is really in relationship to Rich's comment. I just did not understand send the data to various agencies and organizations to which it was obligated to provide reports. I just did not know. Is that just typical or would that be a burden? I just wanted to make sure we are not suggesting something that then groups experience as a burden unless it is really necessary. I think Rich would have to help me understand what he was thinking.

Rich Landen: I think, Vickie, one of my challenges – I am not sure what that – we cite as a source for this, an interview. I do not know what the subject is. In my mind what I think about when I read the scenario is like with the COVID pandemic, hospitals in the State of California had to report similar data in different formats to multiple counties. Solving that with a more universal template that meets the needs of all the individual counties but only that would – there is still a reporting obligation in each county. But the burden on that hospital if I am guessing is the right example then the burden on the hospital is still there. But it is much reduced because we have one set of data and one format to go to each county.

Vickie Mays: Can I just comment, Rich, because – actually, we are right in the middle of writing a paper similar to this. But the issue then is the extent to which when you report it to different groups that you have to worry about – particularly if we want disaggregated data. There are a lot of rules that then say how many cells can be available and all that. It is kind of like there is a dual problem there that you have

to worry about. You can report it to some groups that way because the privacy law allows you to do it and in other groups, you cannot. As we push for disaggregated data, we also have to think about what that means. This is really complicated, I think.

Melissa Goldstein: I agree. I want to get others' comments in here. I saw Denise.

Denise Chrysler: Have we considered – as Vickie said, it is very complicated, and I thought I understood and had a comment. Now, I am reconsidering to make sure I understand the issue.

Melissa Goldstein: Okay. We would like to specify the language a little bit more. I see Denise – do you have another comment, Denise? No. Okay.

Maya, we do want to move on. Do you have a suggestion for how to specify the language?

Maya Bernstein: I was just going to give a quick explanation of what actually happened here because Rich is correct. The hospitals had the obligation. But the business associates went out on their own and reported data without permission of the hospitals. That was awkward for the hospitals in this particular case. The committee here is trying to formalize I think that relationship under what circumstances it is appropriate for a business associate to go off on their own without coordinating with their hospital from which they have the authority without which they would not have the data in the first place.

Melissa Goldstein: I do want to check in with Tammy and with Denise Love about their comments as well and if we need to add something else.

Tammy Banks: No, that is fine. I was just adding that the question about the HIPAA business associate definition and covered entity and where the advance in technology that there are other types of entities that are exchanging data. But I think that may be irrelevant to the point that you are trying to make, maybe an expansion that you do not need.

Melissa Goldstein: Thank you, Tammy. I would say that unfortunately Vickie Mays has to leave us so that she can fulfill her obligations to her students, which we understand. Thank you, Vickie. We are sorry we will not have you for the rest of the afternoon, but we certainly understand. Thanks.

Let us move forward. Denise Love.

Denise Love: I think this discussion helped me. I have no more comment. Thank you.

Melissa Goldstein: Thank you very much.

Natalie, let us move forward. Recommendation is a big one so it is okay that we spend a lot of time on it. We went through this discussion a little bit. Natalie, I think we can resolve Denise Love's comment on the right.

Rich, do you think we can use data governance in this paragraph? I see your point.

Rich Landen: I would hope so. I do not see any reason why not. But I was not on the Subcommittee. Unless there is a reason not to use data governance, I would suggest we use data governance.

Melissa Goldstein: That is a great point. I think you are absolutely right.

Valerie Watzlaf: I should have made that change. Sorry about that.

Participant: I am just trying to track. As opposed to strategies? What is the alternate?

Valerie Watzlaf: Governance instead of governing.

Rich Landen: It is just the term governance versus governing.

Melissa Goldstein: Perfect. Now we are up to Recommendation 2. As part of this data governance strategy, develop data stewardship responsibilities based on fair information principles for all entities collecting, using, and sharing data during a public health emergency.

NCVHS encourages HHS to define and employ data stewardship responsibilities for public health and clinical entities. And Rich in the comment in the margin has asked why are we limiting our discussion to these particular two entities, meaning for public health and clinical context. How do we define clinical entity? Three, paragraphs up, we talked about an EHR developer with this neither of public health nor clinical entities suggest leading the content in the parentheses. I am trying to remember now why we included that parenthetical.

Rich Landen: I note that in the recommendation itself, we very clearly state all entities and yet in the first sentence, we limit it to two and we delete the all farther on based on fair information principles for entities, not all entities. We seem to be vacillating between all and a target group or a subgroup.

Melissa Goldstein: The only thing I can imagine is that we were thinking about HIPAA covered entities and that we do not have direct control over all other entities. Maya, do you remember?

Maya Bernstein: I do not remember but of course you can make recommendations that the department look at all entities or expanded scope. That is up to the committee. You could, for example, to make it match Recommendation 2, take the parenthetical and just say all entities.

Melissa Goldstein: I am okay with that.

Valerie Watzlaf: I am okay with deleting, as Rich recommended.

Rich Landen: NCVHS has previous letters to the secretary that talk about data stewardship and did not circumscribe the recommendation for public health and clinical entities. Thank you.

Melissa Goldstein: Do we have that cited? I think it is somewhere in the letter that we have the data stewardship, the previous data stewardship material cited. We also have cited the non-covered entities Recommendation 2 report.

Natalie Gonzales: -- deleting --

Melissa Goldstein: We are deleting the parenthetical and we are resolving the comment.

Maya Bernstein: And adding the term “all entities” in there instead.

Valerie Watzlaf: You can put for all entities there.

Maya Bernstein: As a regular part of the sentence I think is what I was proposing. I do not know if Rich was saying that that works for him or for --

Rich Landen: That works for me.

Maya Bernstein: You are right that in the past, NCVHS has in some of its recommendation letters been quite broad about what it recommends.

Rich Landen: I would suggest, however, instead of the four all edit that you have there, just put an "all" in front of in line two right before the word entities. That way you do not have to repeat the word entities twice in the same sentence. Delete "for all". Delete "entities" in the parens. And then go to the right six words and add all before entities.

Melissa Goldstein: Okay. Let us go to the next paragraph. NCVHS has also discussed the need for revisiting the HIPAA de-identification standard and then a comment from Rich strikes me as a mentioning in passing paragraph. The letter does not say anything about how de-identification is specifically problematic. The reference to the recommendations from 2017 clearly pre-pandemic. It does not seem much of a value if we cannot add some specific applicability. I think our main point here, Rich, was that this was something that was actually mentioned by the panelists quite a bit in the hearing itself, which is why we felt that we should include it.

Val, do you want to say a little bit more about our reasoning?

Valerie Watzlaf: Sure. It was discussed a great deal in the meeting, in the hearing. And then I think why we want it in the quote that we put I think from one of the panelists was how relying on the de-identification methods alone can really risk public trust. Because we were talking about that, the trustworthiness and so forth, we wanted to bring it up here again. I know the 2017 letter is pre-pandemic. But it really does have a lot of good recommendations that I think we all thought could be used now and nothing has been done I do not believe on those recommendations either.

Rich Landen: The reason I raise the issue is because the recommendation is about data governance strategy specifically for PHE and there is nothing in the de-identification discussion that really talks about data governance or PHE. I understand the issue and I am very much in favor of we need to – the country needs to revisit the de-identification standard. My concern was just it just does not seem to fit in to the context here. That being said, I do not have any objection in including it. I just wanted to point out that it seems to be not tied to anything.

Valerie Watzlaf: We did discuss that. I think we did move it around a few times, didn't we, Melissa, as far as where it would go.

Melissa Goldstein: We moved this up from the discussion about the notices of enforcement discretion to this area so that we would – because we thought it seemed to be a part of a general governance strategy. That was the thought.

It is a bit of a tangent, but we thought out of respect for the panelists that we should include it. The question is where does it best fit.

Rich Landen: As I said, I have no objection including it. You might want to just throw in something in the first line about this did originate at the panelist. Maybe based on panelist input, NCHS has also discussed.

Melissa Goldstein: I think that is great. I like that solution. Thank you.

Wu, I saw you had your hand up.

Wu Xu: Yes. I think we need to keep that in. It belongs to the data stewardship responsibilities. Now that it is in I am fine.

Melissa Goldstein: Let us put at the hearing. Natalie, that is fine. Based on panelist input at the hearing comma. And here, I have just noted – and then we can resolve the comment on the side, Rich's comment on the side. Great. Thanks.

I have just noted that we move this paragraph up from the Recommendation 4 on NEDs to remind myself to tell you guys that that is what I had done was moved it up. Apparently, I knew myself.

The next paragraph. There should also be a focus on uses of data that go beyond their original purpose. Rich has noted, clearer might be that go beyond the original purposes for which they were collected. I think that is great actually. I think that is great.

Denise Love: This is to clarify. All data sources beyond their original purpose, not just genomic.

Melissa Goldstein: Yes. The genomic is only an example of that. Do you think we should add language there, Denise?

Denise Love: No. It is a big job because I just think of mortality data, which is used widely beyond the original purpose. It is irrelevant for this.

Melissa Goldstein: Thanks.

Denise Chrysler, I see your hand.

Denise Chrysler: I think we may have some reasonable minds that would disagree or agree about what the original purpose is when I think of public health agencies collecting data. I think of them collecting it for broad purposes. Data are of course related to the public's health. But I did not see needing to get into that because I saw that more is drilling down beyond the intent here, part of the discussion.

Denise Love: Thank you, Denise. I think that was my thought too. Most of the data are used beyond the original purpose.

Melissa Goldstein: Natalie, I think you can resolve that comment and the comment above by me. Collecting data for public health purposes is different than collecting something like genomic data for a particular purpose, which is why we highlighted it as an example. There are other examples. I think that this includes the idea of collecting mortality data for general public health reasons.

We do need to break for public – Denise, do you still have a question.

Denise Chrysler: I was just going to comment. Whenever collection of data is authorized such as mortality data, it then has provisions in law and policy that says when it can be shared or used for – actually, it is more the disclosure issues than the use issues. I guess I am not adding anything more. I agree. Let us move on.

Melissa Goldstein: Okay. Thanks. Rebecca, let us pause here. Natalie, let us make sure we save this with another name so that we do not forget, I guess. Let us move to public comment now.

Public Comment

Rebecca Hines: Natalie, when you are done saving, we can stop sharing your screen. Wonderful. Thank you. Kim, can we have the public comment slide. We are pausing while the Subcommittee is in progress, discussing these five recommendations. We have seen some questions in the Q&A. If anyone in the public attending today would like to make a comment, please click raise your hand to have your audio unmuted or you can use the Q&A to request an open line. We do have a couple of people on the phone. If you are on the phone, you can press *9 to request unmuting of your phone. As I mention earlier, you can always email to the NCVHS mailbox. Let us open it up. Do we have any comments? I am checking the box.

Melissa Goldstein: I know we want to do this one in the Q&A so we can start with that.

Rebecca Hines: Let us read for the record. Rita Torkzadeh has put in the record regarding vendors, non-EHR apps may be relevant such as those developed for COVID-19 notification and reporting related question and comment. Do public health emergency innovations involving individuals and patients such as using COVID-19 notification apps and sharing test results collected at home fit in this letter and discussion focused on technology and consent? Rita, would you do us a favor and add to the Q&A where you work and your title with that organization, please? Thank you.

Melissa Goldstein: Rita, I would say that we do address those issues later on in the letter.

Rebecca Hines: For the second comment, can the public get a copy of the letter when it is final? All committee letters are on our website. But because this is a work product, we are just working our way through it. It will be posted once it has finished.

What else do we have? Rita is currently unaffiliated. Thank you, Rita.

Any other comments on this particular letter? I think we can close this public comment. If you have missed for some reason, just email me at NCVHSmail@cdc.gov.

Do we want to go back to the letter? Natalie, would you like to take a break and let Maya take a spell at this. I know it is a lot to have to be on.

Subcommittee on Privacy, Confidentiality and Security

Maya Bernstein: I am very happy to do that. Thanks very much to you both. I think it is best to take turns on this kind of thing.

Rebecca Hines: Just as a time check for members, ideally, we would be ready to take a vote by 1 o'clock. You have just under 40 minutes to finish the remaining recommendations.

Maya Bernstein: Can folks see my screen okay?

Rebecca Hines: You could make it a tad bigger, maybe 10 percent.

Melissa Goldstein: This first sentence is indeed long and complex, as Rich notes. Either break it into two or begin the sentence with applause in order to promote greater understanding, trustworthiness, and transparency. I think that is fine and we can do that probably later. Just leave the comment there I would say and then we can adjust the language afterwards. Rich, I agree. That is what happens is they get long.

Recommendation 3. Support the development of accelerated interoperable information sharing for PHEs that prioritizes privacy and security. Wu has noted for this first paragraph, a question about the phrasing around real-time data, which we had worked on a little bit before. The language now says real-time data is data that is collected, processed, and analyzed on a continual basis. It is information that is available for use immediately after being generated near real-time data. It is a snapshot of historical data so teams are left viewing a situation as it existed in the recent past rather than it is now.

Wu, do you want to tell us a little bit about what you were thinking in this comment?

Wu Xu: Basic I was thinking the common practice daily data process practice for almost all the public health agencies. So follow the daily process data is by this definition is near real time data. But actually, for public health is latest most recently available data. I think for the current definition, the historical – this term is throwing me off. For public health, that is the most recent data or most latest available data is not historical data. It is the first time a report to the CDC to the public. That is my concerns on this definition.

Melissa Goldstein: Rich, do you have a solution for us? I know we have talked about this before. It is a finessing it.

Rich Landen: I think the objective of the recommendation is very clearly and well stated in the sentence right before the one that is highlighted and that is data should reach its users as close to real time as feasible, given the systems involved and the specific use case for that data transfer. If we talk in the letter about definitions of real time and near real time and the one we have in the draft is batch processing. We go down a rabbit hole.

I would strongly recommend that we just delete those two or three sentences that talk about what real time data and near real time data is and just stick with the language that data should reach its users as close as to real time as feasible. That would be as I mentioned in the sentence right before what is highlighted.

And then down in the next paragraph we use similar language. Just use the exact same language in both paragraphs because I think we clearly state the objective. We leave the how up to the people who implement and understand that implementation will be depending again on the system, on the setting and where in the chain of data flow it is. Solutions can be either real time or near real time or batched, depending on how much the data needs to be massaged on the complexity of the transmission. All sorts of things. We should just stay out of the definition area here. Leave the system design to others and just state our objective as we want the data to get to the end users quickly as we possibly can. By the way, that does not happen well now.

Wu Xu: I agree. That is good.

Denise Love: I would concur.

Melissa Goldstein: I am okay with that. Val, Jackie, do you have ideas on that particular – on the real time, getting rid of these last two sentences?

Valerie Watzlaf: I agree also because I think we added them based on the discussion that we had previously to make it a little more clearer on the definitions. But I am fine. I agree with Rich.

Melissa Goldstein: Okay. A lot of teamwork.

Tammy said something in the – agree with deletions; otherwise, use the standardized definitions for transactions. But you are okay with the deletion. Right?

Tammy Banks: I think that is the best method.

Rebecca Hines: I just want to note. There is a comment in the Q&A that says real time data is current as data is being processed. I do not know if that that adds anything to the discussion, but just FYI.

Melissa Goldstein: Thank you. That is a bunch. Then we go to the next paragraph, which is interoperability includes health data exchange architecture and standards, which enable data to be accessed and shared appropriately and securely across the spectrum of care. Then the next sentence is about the pandemic has made it clear that health care providers and public health agencies alike must be more effective in managing data and ensuring that it is as close to real time as feasible to better understand.

And then I am looking for the language. Rich has pointed out language modernized to using sounds awkward. It is in the next sentence.

Public health official at the hearing mentioned the limited interoperability between states and insufficient state funding to modernize to using new standards, and Rich has pointed out that it does sound awkward. I do not recall whether that was a direct quotation or not. Nate, do you remember whether that is a direct quotation? If not, we can change the language.

Nate Chen: I am not 100 percent sure. Sorry.

Melissa Goldstein: Okay. Maybe we can put a ticker in there, Maya, that will make that sound better. Adjust the language according to what – we will need to look back and make sure that we are reflecting the panelist's discussion.

Denise Love: If not a direct quote, you could say to modernize to accommodate new standards. But I do not know if this is a direct quote.

Melissa Goldstein: Thank you. That is a great point.

Need for an interoperable health care system that effectively integrates public health information is evidence, promoting its use and then Rich has made a comment. It is not what the recommendation is

about. Suggest changing to accelerating the development of an interoperable system. I am fine with that.

Valerie Watzlaf: I agree.

Melissa Goldstein: Rich, we really appreciate your close read because you have a little bit – it is the distance is extremely useful. Because when you read something a million times over and over again, you skip over things.

The next paragraph has a few edits from Denise Chrysler. And then we have the bulleted list of following practices may support more efficient and effective information sharing during a PHE while respecting the privacy of the patients whose personally identifiable data are the basis of any successful strategy. And then the bullets are strengthening the IIS, developing a standardized use agreement within the ideas of TEFCA, creating data commons platforms and we added some citations here at the end of the paragraph about what that means. Sharing data within communities, providing effective privacy and security guidelines, collecting and sharing of complete demographic data.

We have a note. Recommendation 4 is focused on the notices of enforcement discretion, the public health emergency waivers and sub-regulatory guidance. Review the current process is what we thought would be a good idea. Rich has noted, we need to immediately and explicitly state review the current process to what end.

Rich has also noted, it is pretty much a non-statement. All the specific outcomes we want, realized, or buried in tons and tons of tech. Need to gather those desired outcomes and list them in the very first paragraph under Recommendation 4 so not within the recommendation itself. That is helpful.

Maya, there is a comment about pick up discussion with Denise L. and Wu about standards for state/local data sharing. Does that relate to Recommendation 4 or Recommendation 3?

Maya Bernstein: That was from our discussion during Recommendation 1, I believe. Do you want me to make a note? I made a note.

Melissa Goldstein: I knew you would remember.

Maya Bernstein: I do not remember. I put it in a note.

Melissa Goldstein: Rich, do you think that we should add in the first paragraph of Recommendation 4, a list of what we think should be done?

Rich Landen: Yes. When I read through this – I understand we need a review but I think we need to be very clear what we are reviewing for. You do not do a review just to do a review. We have a lot of stuff buried in the narrative under here. But I think we just need to extract the nuggets and then list those nuggets immediately as a new first paragraph under the recommendation. Answer the question, why should we review the current process.

Valerie Watzlaf: I think what we did was in relation to one another comment where we wanted to provide a little more background information on the waivers and the NEDs for a better understanding and then lead into, I believe. Is that correct, Melissa?

Melissa Goldstein: It is. We needed to add more details (inaudible) all of this law is that happened. It makes sense that it is long. I think that is a good point, Rich. I am wondering if we need to wordsmith that now or if – no, not necessarily. We can do that. Maybe just put a ticker Maya, that says just add language – go ahead, Denise.

Denise Love: What I think it is really trying to say is NCVHS recommends that HHS review the current process version for clarity in the issuance of the following. That is how I see the paragraphs that follow. Adding clarity or specificity. I will leave it to – you guys know the letter better.

Rich Landen: Clarity is one thing but there are also the issues of advance notice instead of just making the decision at the eleventh hour. There are a number of things in there that make a lot of sense. There are two pages of detail. I think all that detail is important. But you just need to summarize that early.

Melissa Goldstein: Some of it is clarification. Denise, I agree. Some of it is actually – when you have a notice of enforcement discretion, it should have – currently, they do not. That is the idea that we need to – that some of it needs to be changed because the notices of enforcement discretion were actually used differently during this ongoing pandemic than they had been used in the past. And of course, we had a crazy public health emergency where we just had to move, which is understandable. But what do we do in the future? When and if we have some time to think about it, but we should make a plan for what happens next time. It is reviewing. Like Rich said, there are some issues that need to be thought through in advance of the next PHE whatever it is.

Rich Landen: To be clear, I am not suggesting adding or changing anything, just summarizing what is already there.

Maya Bernstein: That is what I was going to ask. Are you suggesting, Rich, that we summarize maybe with bullets in the recommendation what we actually recommended in the text? Do you want to move it up? I think it is important for the committee to agree on the language of the recommendation at least and get a sense of the exposition.

Rich Landen: My sense of the recommendation is fine and I am comfortable with everything that is in the detail. What my struggle was is in order to really understand the purpose of the review, I had to wade through two pages of text. I would like to see – I do not want to usurp the prerogative of the drafter. You do not want Franken(?) letter here. Yes, start out with bullets and then reformat it into whatever makes sense to fit in with your flow of the letter.

Rebecca Hines: I will say if you do want to change the actual wording of the recommendation like adding specificity, you need to do that for the vote purposes. You all need to agree on the exact wording of the five recommendations. If you are going to change adding the words for specificity, please make sure you do that because we do not want to do that outside of the Full Committee venue.

Melissa Goldstein: You mean the bolded part, the actual recommendation.

Rebecca Hines: The actual recommendation. Rich and Denise, based on your input, do you want to add word specificity? Maybe we need to stop and take three minutes to figure out what that little tweak might look like.

Rich Landen: I do not. Denise?

Denise Love: What you are reviewing it for is opportunities to improve but you do not need to necessarily say that in this. I see Rich's comments. I did not read it that way. I defer to the drafters because I do not have – other than specificity or a wording that may or may not capture the next two pages. I do not have anything intelligent to say.

Maya Bernstein: One thing I could do – I do not know if you really want to do this but I would -- while you are working on the other – go pick out what the exact things are, put them in bullets and show you what that looks like before you vote on both --

Melissa Goldstein: I think that complicates the vote, doesn't it, Rebecca?

Rebecca Hines: You can vote on both of them at the end of the meeting.

Melissa Goldstein: I was just thinking. When I think about Congress reviewing a statute after a sunset provision, I think about reviewing it. I use the word review but that includes improve. I think that is what I was thinking here. If you would prefer for us to be explicit about that, I think we can. My understanding was that you are not just reviewing it to reviewing it. You are reviewing it because you want to improve it.

Rebecca Hines: Can you just say to improve what specifically and then I think you might have it?

Melissa Goldstein: I think we get into – that is going to get complicated because there are too many things that are --

Denise Love: The problem with – I thought it was for improvement, but the problem is with the review. Maybe there is no fix. I do not want to make an assumption.

Melissa Goldstein: That is a good point, Denise. They may decide that this is the way that they are going to do it. Okay.

Rebecca Hines: If all the members are okay with this, knowing that there will be a summary in the first paragraph or so, then I think it sounds like there is agreement that the wording of the actual recommendation proper is acceptable.

Melissa Goldstein: Thank you, Rebecca.

Let us move on to – good. Thank you. Thank you, Maya. We are scrolling down. We give an example of what happens under Medicare and Medicaid and CHIP, which is where NED is temporarily – eliminate or change things. We talk about a lot of law.

Go ahead, Maya.

Maya Bernstein: I just want to know where you want to be looking because there are no comments on a bunch of this. I heard Rich say that he did not have any objection to the exposition. I do not know if anyone else. But there are no comments on whole pages you could skip.

Melissa Goldstein: Okay. I just want to give people a chance if they have comments on any of this text within Recommendation 4. Hearing none, we can keep going. There is a lot of stuff on that, Rich. You are absolutely right.

Recommendation 5. Address inequities in the collection and timely reporting of datapoints on disaggregated race, ethnicity, geography, and age in use now and in the future at the federal, tribal, state, territorial, and local levels for PHE reporting. Rich did some edits in the text and then said without granular individual level data, inequities will continue to remain unaddressed. Confusing. Recommendation 5 specifies disaggregated but here, we assert the necessity of granular individual-level data. One precludes the other. Need to resolve the dichotomy. I wish Vickie were still with us.

Maya Bernstein: Isn't disaggregated the same as granular individual?

Denise Love: It can be. Yes.

Rich Landen: I have a hard – if it is individual data, that about an individual, how can that be disaggregated?

Maya Bernstein: It is not aggregated.

Melissa Goldstein: We do not want aggregated data. That is where we said disaggregated.

Rich Landen: Okay. I think I am just -- I was thinking aggregated in the recommendation rather than disaggregated. I withdraw my comment. Sorry about that.

Melissa Goldstein: No. It is a good question. It makes me think. Valerie has noted that we should in the recommendation after local levels. Good point. Put a period there.

Then we move on and we talk about the data. CDC reports the race and ethnicity. Here, we are talking about a little bit of a variance, how data is reported. Rich has added some language, thank you, into the text. In the absence of CDC reporting, Kaiser Family Foundation has taken over.

NCVHS recommends that HHS accelerate work to assist the development of standardized state-based reporting. Denise Chrysler has added some edits into the next paragraph about OMB standards, which are also slightly different.

The next paragraph highlights our concern about standards that support the reporting of cases by age, which differs. A panelist. Here, we are talking about the January 25 panel, race and ethnicity data. And then this paragraph gives the details about it, how state dashboards can be different, different ages. Some of them highlight ages 0 through 17. Some of them highlight 0 through 19.

And the next paragraph that is in pink highlighted NCHS also recommends that HHS continue to develop solutions to the monitoring the evolution of intrastate policy across states as well as explore new ways to bridge any differences in data sharing and use between HIPAA and non-HIPAA compliant organizations in a way that is private and secure. Rich has noted that this is way too convoluted to grasp too many related but different concepts. This is actually a comment, Maya, you made earlier that they are completed accepted concepts. Recommends continue to develop solutions to the challenge, monitoring the evolution, policies across states, new ways to bridge. You mean separating these all into separate sentences, Rich?

Rich Landen: Yes. Having all those concepts in one sentence is just – could not parse it.

Melissa Goldstein: Do you suggest bullets or do you want separate sentences? What do you think is – we only use bullets in one other area.

Maya Bernstein: Two now because we are going to have them at the beginning of the other recommendations.

Melissa Goldstein: I agree with you. Val, I think we can wordsmith this later if you are okay with that, Rich.

Valerie Watzlaf: I agree too. I was not sure with this comment, Rich, if you wanted to put more in. But I certainly understand it now. Thank you.

Rich Landen: Just want to unpack it a little bit.

Melissa Goldstein: And then we have a finally. Finally, NCVHS notes that in the focus on developing technology, we did want to point out here. For exposure notification and vaccine scheduling, many people can be left behind, including those who cannot use the technology because of lack of access, broadband, or due to geographic and financial reasons. We also point out that individuals with disabilities and limited English proficiency – we could even put language proficiency I guess there – have been disproportionately impacted during the pandemic as many technologies have failed to ensure effective communication.

Rich has noted. It sounds like we are blaming the technologies themselves rather than the humans who chose those technologies. Perhaps this language as many of the notification and scheduling technology were ill suited for the capabilities of those. I like that. I like that language, Rich.

Valerie Watzlaf: I agree. Very nice.

Melissa Goldstein: They were thinking way beyond what we actually could do. Good idea.

Then I think we conclude. That is our conclusion.

Maya Bernstein: The conclusion is in the cover letter –

Participant: That is right.

Melissa Goldstein: It is even more exciting. We are done. We have made it through the entire letter. Thank you, guys. This is an amazing job – letter, which we have been working on for a very long time. I think we have covered some very important points and I think it really has been a collective effort not only among the Subcommittee and the staff but also all of the Committee members trying to make this the best it can possibly be. I really think that this is – I think this is a big --

Denise Love: Thank you, Subcommittee.

Valerie Watzlaf: Thank you. Your comments I think have really helped us a great deal. As Melissa said, we were so close to it, so we needed some fresh eyes. Thank you, all.

Melissa Goldstein: Yes. We needed fresh eyes. We needed other perspectives. It has been a little tiring but I think we have come up with a great process.

Jackie, should I turn it over to you for the next little bit?

Jacki Monson: Yes. The question is are we ready to take a vote.

Melissa Goldstein: With the understanding that we are going to add --

Jacki Monson: With the modifications we discussed today.

Rebecca Hines: I would say if there were interest because I know, Rich, you made a comment that it is distributed to the Executive Subcommittee to make sure all of the edits are as intended and discussed today. I think that would be a fine thing and we have done that in the past.

Jacki Monson: Absolutely.

Melissa Goldstein: I think that is fine.

Rebecca Hines: Would someone like to make a motion?

Rich Landen: I will move to approve the letter with the changes discussed.

Jacki Monson: Do we have a second?

Denise Love: I will second.

Jacki Monson: All in favor? If you would like to raise your hand, it is probably the best way we can get the total count.

Rebecca Hines: I see nine hands raised. Do we have – ten hands raised. Thank you all.

Maya Bernstein: Is that unanimous or are there opposition?

Rebecca Hines: That is all ten members. That is our quorum. Jacki, the letter is approved.

Jacki Monson: We will consider the letter approved. Because we did such a fabulous job at getting through this, let us break until I believe, Rebecca, 1:15 is when we will be back.

Rebecca Hines: Exactly. Thank you, all.

(Break)

Jacki Monson: Welcome, everyone. In the interest of time because we may lose our quorum at 3 o'clock, we are going to go ahead and get started. The focus of this afternoon is going to be on recommendations for modernizing aspects of HIPAA and other HIT standards. Rich and Denise, I am going to turn it over to you to get started.

Subcommittee on Standards

Rich Landen: Thank you, Jacki. For those of you on the webinar, this is Rich Landen. Denise Love and I are co-chairs of the Standards Subcommittee. The Standards Subcommittee is bringing this letter to the

Full Committee for review and hopefully action to approve as a letter of recommendation to the Secretary of Health and Human Services.

What we will be doing in this presentation will be to review the background on what this letter is and why it is. We will then review the draft letter. We will entertain questions and comments from the committee and then the letter will be up for voting and approval just like we did for the PCS letter earlier.

The title of the letter is recommendations to modernized aspects of HIPAA and other HIT standards to improve patient care and achieve burden reduction. The Subcommittee on Standards has been deliberating industry comments from our August of last year listening session, which was part of a landscaping exercise for the Convergence 2.0 projects first phase.

The findings from that listening session indicated several sticking points around certain standards related industry needs. Those needs are well known to industry and also to CMS regulators. They have not yet been acted upon and there is a sense of urgency from the industry spokespeople with which the Subcommittee concurs.

The purpose of the letter is to advise HHS specifically and then by delegation down to CMS to take action. It is needed we think to meet some critical immediate needs. It is clearly a very limited scope. We did not want this to be a general letter. This is not part of the Convergence 2.0 project, which the Subcommittee is still working on and we hope to have specific recommendations of a longer-term nature coming to NCVHS for the summer meeting. But that is not what we are doing today. As I said, it is for immediate needs. The Subcommittee agrees that there is perceived value if HHS would adopt the recommendations that we are proposing here. We also concur – the Subcommittee concurs that if action is not taken, there is a negative effect and down sides to industry.

The recommendations I mentioned are for short-term actions. They are compatible with and do not preclude the longer-term strategies that we are reviewing as part of the Convergence 2.0 project. The four recommendations at issue today are consistent with the areas for which the Subcommittee has already achieved consensus on the Convergence 2.0 project. If you recall, we did a presentation of those consensus areas at our January Full NCVHS Meeting.

The content of the letter adheres to the ICAD report viewpoint of structuring short-term actions that build toward a more comprehensive and more integrated future vision. That is the framework for it. There are four recommendations. The first is – and this verbatim recommendation. Publish the CMS interoperability and prior authorization proposed rule, which includes the HL7 FHIR Standard to support APIs, application program interfaces, to automate payer/provider prior authorization workflows.

I want to point out that prior authorization is a high priority area, not only to NCVHS, but also to HITAC. It was one of the – not certainly an inclusive focus but one of the significant focuses of the ICAD final report. More recently, the HITAC Task Force responding to the ONC request for comment on electronic prior authorization that our own Tammy Banks co-chaired. This was a very high-priority item for industry and for ONC as well as for us.

The recommendation goes to electronic prior authorization. We have identified it as a critical need for industry. The standards that are available to support an electronic prior authorization rule are good enough to begin national roll out, not perfect, for all potential use cases. But they work well enough for

the majority of uses. In other words, they are not totally mature but they are sufficiently mature to bring to a national scale.

The CMS had actually published a final rule, adopting electronic prior authorization back in January of last year. But that rule was subsequently pulled back. It is also in that rule – this is the first time that the HL7 FHIR standards have been named as standard as CMS. But I need to point out that these were standards for adoption, not part of HIPAA. They are not mandates on the covered entities. They were requirements of certain federal programs rather than a blanket HIPAA mandate.

The FHIR standards that support electronic prior authorization have been tested by many large stakeholders. The issue of testing is, we believe, fairly well in hand.

Second recommendation is to adopt a standard for electronic attachments as soon as possible to meet today's business needs. The rationale for that is standards allow industry to exchange attachments as necessary. Attachments contain additional information not contained in the standard transaction itself or in the code sets supported within the standard transaction.

Information and attachments can be in many forms, including codified data, free text, images, waveforms and the like. Attachments provide information needed for clinical decision making, for instance, lab reports, MRIs, specialist reports, patient history op notes, rehab notes, consents, et cetera. Attachments are very necessary to the prior authorization workflow that we talked about in the – not the workflow, but the prior authorization that we are advocating in the first recommendation. Attachments are useful for other transactions, including claims, referrals, and some on the all-claims audit side. Without an industry consensus, meaning a common standard for attachment, a prior authorization cannot be successfully automated. This is a prerequisite if we are going to adopt regulations around electronic prior authorization.

If we fail to adopt prior authorization regulations or standards, there would be adverse impact on the patient that has been identified in some of the HITAC and ICAD testimony by individuals and organizations. And the prior authorization burden would not be reduced, which is a high priority of the current administration and the industry.

Recommendation number three is talking to regulatory flexibilities. This gets into the HIPAA/non-HIPAA thing that I mentioned briefly before. The language of the recommendation is HIPAA transaction rules notwithstanding, evaluate and adopt regulatory flexibility strategies to permit HIPAA-covered entities to implement new technologies such as FHIR standards.

Rationale. Electronic prior authorization rule would be the first adoption of an API-based standard and specifically we are using the HL7 FHIR in the regulation. API is a different technology from what X12 uses under HIPAA and although I believe NCP is making progress toward development of API standards, those adopted under HIPAA are still the electronic data interchange.

FHIR standards are designed to work both in conjunction with the X12 standards and independent of the X12 standards. Again, this is important because the X12 standards are mandated for use by HIPAA-covered entities. FHIR can utilize the X12 278 transaction implementation guide that is health care services review, which encompasses prior authorization.

It can also use the X12 275, which is a patient information transaction, formerly called the claim attachment. This is an attachment standard that we talked about. The 275 has not been adopted under

HIPAA. Because it has not been adopted, there is no mandate to use it but there is also no prohibition against using it.

The Subcommittee on Standards consensus is implementers should be allowed to use FHIR without being mandated to use the X12 278 when the business use case does not require use of the X12 278. And then irrespective of whether the use without the 278 is allowed or not, federal guidance must be clear on that point. For members of the committee who are not on the Standard Subcommittee, the situation right now is because the X12 278 is adopted as a standard transaction under HIPAA, it must be used. HL7 has new technology, which does not per se require the use of it. But because it is a mandate, industry would still have to take the HL7 FHIR standards but use it in conjunction with an X12 278 and that is not always – sometimes that is workable. Other times, it is just very inefficient. What we are doing here with this piece of the recommendation is setting the stage and bringing to CMS' attention that there needs to be an accommodation to the evolving technology that the HIPAA mandates right now do not allow. It is calling that to the forefront of their attention.

Recommendation 4. The wording is streamlined. The process for adopting HIPAA transaction standards so that it is reliable, efficient, and timely. And the rationale is that industry has long and we use the term vociferously complained that HIPAA rulemaking process does not deliver necessary and timely updates to the adopted standards. There is lack of certainly if or when an item – a potential rule that is listed on the HHS unified agenda will be acted upon and without a reliable system for rule promulgation, industry cannot budget or cannot plan its implementation.

Industry develops then work arounds because of the lack of approved methodologies within the standard transactions and those work arounds are inefficient, which is – and inefficiency is contrary to the intent of the HIPAA legislation.

This recommendation number four urges HHS and CMS to continue to consider how its HIPAA rulemaking can be modernized to better meet industry needs. It is something we know CMS has been looking at all along. This is essentially just an affirmation that this needs to be a high priority.

This recommendation reiterates the findings that we came to under the Predictability Roadmap process and the ICAD recommendation. There is consistency here. And this also helps set the stage for our forthcoming Convergence 2.0 project recommendations.

From here, we will take a look at the letter itself. We will walk through it. We have had several rounds of commenting, not only from Subcommittee, but also from the Full Committee and the Executive Subcommittee. We are hoping that all of the comments that we – we have looked at all the comments and probably over half of them we accepted and put into the current draft. Others we accepted with modification and very few did we actually not – did we decide not to incorporate into a re-draft. With that, if we could go to the letter itself and then we will open it up for committee discussion as we walk through. Again, the intent is after we do the walkthrough and get all the questions on the table and discuss like we did with the PCS letter. We will move this to a vote for approval to send to HHS.

Denise Love: Do we want to address Q&A now or later?

Rebecca Hines: I suggest holding off. You are welcome to address it in your discussion. But in terms of public comment, that is coming up in less than 30 minutes.

Rich Landen: We have got this up on the screen. We will walk through it paragraph by paragraph like we did this morning. Lorraine will be capturing the comments and the edits. Let us take a minute to look at the first paragraph. This first section is fairly boiler plate.

The second paragraph just talks about the NCVHS analyzes and deliberating the input that we got.

The third paragraph then states a finding that HIPAA's regulatory structure for adopting national standards for transactions and code sets is out of date. Major remediation is needed to reflect the convergence of administrative and clinical data flows that have occurred over the past decade.

Seeing no hands raised, the Subcommittee on Standards developing recommendations for a broader framework that will include much more than the original HIPAA, including the convergence with clinical, some of the public health, wellness, SDOH, SOGI. And then the sentence, in the near term before those structural types of changes are made, updates to HIPAA given the current structure for rule promulgation. That is still needed and required. We have to continue doing business under the current rules as well as then look forward and plan ahead.

Here, we spell out the recommendations, the same four that I just read to you. Focus on recommendation number one. Recommendation number one is to encourage CMS to publish a final rule on interoperability and prior authorization as soon as feasible.

Let us go to the second paragraph. If we are going too fast, raise your hand and we can slow down or pause. Key in this paragraph. There is a lot of prior auth currently is performed manually and we see a lot of value into moving the whole prior auth workflow to a more automated system that requires a lot of development and on the payer side. It also requires some development, new software on the provider side. But it focuses on reducing – once implementation is done, it reduces – we think there is a lot of value in reducing burden on providers and eliminating the adverse effects about delays and treatment for the patient.

The standards. This last line on this page here above the footnote. The standards, we think, are available. We know are available from the designated standards development organizations.

Final paragraph – under recommendation one. Acknowledging that the CMS rule, as we understand it, is outside the scope of HIPAA. In other words, it is not adopted under the HIPAA legislation. It is adopted under other legislative authority. But the rule is built to utilize the same definitions and code that are in the HIPAA adopted transactions. It includes, as I mentioned before, the adopted 278.

Questions there? Seeing none, Recommendation 2, adopt the standards for electronic attachments as soon as possible to make today's business needs. As I mentioned, there is multiple need for an attachment standard. CMS has not adopted one. We understand there are issues around adopting an attachment standard. There is a large unresolved conversation in the industry of whether a document approach to attachments is the best way or is it a more discrete data approach rather than a document approach.

Our conclusion of the Subcommittee is that irrespective of which is "better", there is substantial demand and good value right now for a document-based approach. We are recommending that this document-based approach be adopted now. We also point out that this does not preclude also adopting in the future a data-based approach.

Either eyes are glazed over or everybody is in agreement. I am not seeing hands raised. Let is move on to number three. HIPAA notwithstanding evaluate and adopt regulatory flexibility strategies. As I talked about briefly, HIPAA is a very rigid structure. It is a mandate. It is one size fits all. A single version at any one time. A single version of the standard at any one time. The new API of which FHIR is one manifestation, one type of API, has a lot of promise. It has been well tested in large organizations. Let me stress large organizations. We think it is good enough to begin a national roll out. This would support a lot of the objectives of the administration, a lot of the objectives that the Standard Subcommittee sees as being good for the industry.

We see the current HIPAA structure is a bit stifling toward innovation and letting the industry take advantage of the efficiencies of the newer technologies.

Any questions or comments on Recommendation 3?

Recommendation 4. Streamline the process for adopting HIPAA transaction standards. Again, this is not the first time we brought this up. We need a reliable thing. This is to start the process of thinking forward toward the future. What are the options to start the process? How do we achieve a better way of adopting standards in the future? Specifically, we are bringing this up now so that by the time later this year the Subcommittee bring forward its report and recommendations coming out of Convergence 2.0. We will already have – we will be able to have conversations with CMS and others and HHS about the future design of a potential fairly major changes to the HIPAA regulatory structure.

Rebecca Hines: Rich, I have a question. The second to the last paragraph, given where it is now, to be clear, wouldn't it be Recommendations 1, 2, and 3 outline actions intended to address industry's immediate needs while four is the longer term. That paragraph got edited so many times. I think we have changed it. But I think it actually now makes sense to say one, two, and three.

Denise Love: Do you mean here where it says to be clear. Recommendations 1, 2, and 3.

Rebecca Hines: Yes.

Rich Landen: I agree with you. Two alone does not make any sense.

Rebecca Hines: Not anymore. It did on the previous version but not in this one. And then outline would be –

Rich Landen: That looks good to me. Any other reactions to the Subcommittee members.

Denise Love: I think that is fine. I know one and two clearly. I think it is fine. Three is somewhere between one and two and four. The immediate three is maybe a little intermediate and four is longer to me.

Rich Landen: Three essentially sets out – we have these FHIR – the FHIR technology coming at us quickly and yet we are kind of locked into it. We have to jump through hoops to use the exception process if we want to actually – we, being providers and payers obviously, and clearinghouses. We want to jump and actually start processing live transactions without going through the convergent in the nanosecond convergent into and then back out of an X12 transaction. It is near term but it is not a long-term fix.

Denise Love: But I see one and two is urgently needed now. Three goes along with it. I am fine with the edits.

Rebecca Hines: And a previous co-chair of the Subcommittee noted that number three needs to start right away if you read the Q&A. I think we are good.

And that begs the question for us – Rich and Denise, would you like to go to public comment? Would you like to have the comments from stakeholders that we are familiar with? Matt Reid and Amber Thomas read into the record for discussion. How do you want to proceed?

Rich Landen: If we are done, if there are no questions from the committee members then yes. Let us read into the record the comments we have on the Q&A.

Rebecca Hines: Very good. Starting off with Matt Reid, he has written, standards might have been tested by large health systems but not small medical practices or solo clinics, also not by the EHR vendors that supply health IT to medical specialties. There is a massive gap between the resourcing capabilities of independent medical practices and large health systems. Testing must occur within and among small rural solo medical practices.

The second, he follows up. The statement about testing large organizations is sufficient does not align with the HITAC Electronic Prior Authorization Task Force report to ONC that states "testing is crucial especially across physician practices of all sizes and specialties to make sure the technology functions well across practice setting and in production."

Third comment is from Amber Thomas. She has written, we appreciate the committee's recommendations as it relates to prior authorization and health care attachment standards in part because of the challenges with payer portals to conduct this task. Did the committee evaluate based on January's committee meeting whether to take up a recommendation specific to amending the direct data entry DDE exemption, i.e., payer web portals, to be more user friendly and less burdensome to providers?

While the recommendations set forth in this letter are helpful in reducing provider burden, not addressing payer portals simultaneously is like mopping the floor when the sink is overflowing. Thank you for the continued dedication to this important work.

Fourth from Alix Goss, we need Recommendation 3 to get underway.

Denise Love: Thank you.

Rich Landen: I think to acknowledge the comments, the testing has been reported and this is primarily through the recent work of the HITAC Electronic Prior Authorization Task Force, which those conversations were communicated to the Subcommittee on Standards. One of the emphases on testing has been among the larger organizations. Small organizations have not been excluded. I will invite members of the Subcommittee to speak for themselves if I misstate what their thoughts are.

We believe that between the level of testing that has been done by different types of organizations, even acknowledging that it is not extensive in smaller or specialty organizations. It has been done and the EHR vendors and a lot of the other IT developers had been participating with the various initiatives associated with FHIR and HL7, Da Vinci Project, and others, that it meets the criteria for sufficient for

CMS to begin the rulemaking process or to make its decision on whether or not to promulgate a rule. Again, a recommendation is for CMS.

There are safeguards built in within the CMS rule promulgation system for public comments, for publication of federal register. There are implementation periods between the time a final rule is published and when that rule would go into effect for compliance. We think enough testing has been done to begin this process. And we think there are sufficient checks and balances in the system. We certainly understand that the smaller entities at this point just do not have the resources to participate regularly in national standards development that they will be concerned, which is fine.

And those concerns then need to be addressed but our thinking is that there is sufficient evidence for us to recommend to CMS to launch the project and then let the CMS process react to the comments about the different providers and whether the testing has been sufficient.

I think I need to go back and look at that other question.

Denise Love: The portal question, which is on the – for the longer term for us.

Rich Landen: Exactly. The portal question is a structural change to the HIPAA regulations. That is on the Subcommittee's discussion list and I assume will be part of the Subcommittee's recommendations that come back to the summer meeting of that. That is not something that the Subcommittee thought could be separated out and addressed as part of these more short-term focus since it is structural and is -- I am not saying it is important to the stakeholders and it is certainly something. Workflows need to address. It is not something that is per se an impediment to the adoption of the FHIR-based EPA standards.

Comments from other Subcommittee members?

Public Comment

Rebecca Hines: I think with that, we are ready for public comment, unless there is anything else to discuss.

Lorraine, you can stop sharing your screen and we can have the public comment slide posted. We are now in the public comment period for this letter. On Zoom, you can click raise your hand to have your audio unmuted or just use the Q&A. Mike, we have Margaret Weiker. Margaret, do you want to introduce yourself when you are unmuted? Let us know where you are.

Margaret Weiker: Thank you, Rebecca and thank you, Standards Subcommittee, for a great report and letter. I am the vice president of Standards Development for the National Council for Prescription Drug Programs or NCPDP, which is an ANSI-accredited SDO. And our standards have been named under HIPAA as well as MMA and in ONC certification criteria.

In Recommendation 1, I am assuming you all are referring to medical prior authorizations and not pharmacy prior authorizations. I do not know if you need to perhaps clarify that that you are just referring to medical prior authorizations.

Recommendation 3. I want to ensure it does not preclude the use of NCPDP's standards that maybe used as an API as Rich mentioned during his PowerPoint presentation. NCPDP is in the process of

migrating its telecommunication standard format from an EDI format into a JSON format, which obviously can be used for API. I just want to ensure that Recommendation 3 does not preclude that NCPDP could use that recommendation.

Recommendation 4. I wholeheartedly support, as I can imagine you all know that. I have been one of those people complaining about this process for several years now. And just remind the committee that NCPDP started in August of 2017 to have our standards updated under HIPAA. It is now March 2022, and we have no NPRM. In the unified agenda, the date has been changed three times and still no NPRM. I do not know if perhaps you would want to use that as an example or even perhaps a recommendation number five would be to issue the NPRM for the pharmacy standards that have been recommended by this committee.

Thank you for the opportunity to comment.

Rebecca Hines: Thank you, Margaret. I very much appreciate adding those refinements. I am sure the committee can continue discussing those when we get to the end of public comment period.

Does anyone else in the attendee side of this meeting have a question? I did see a hand and then it disappeared. Let me check the email box just to make sure. Nothing there. I will wait a few more seconds. Anyone else?

Rich and Denise, I think we can close the public comment period. Back over to you to complete the discussion.

Subcommittee on Standards

Rich Landen: Margaret raised some good points. National Council, prescription drug programs. I believe that the CMS Final Rule that was published in January of ’21 did specifically talk about medical prior authorization. I think that addresses Margaret’s first concern there.

The second concern in Recommendation 3. We are specific about new technologies, API-type technologies such as FHIR. We did not exclusively restrict our recommendation to FHIR. The NCPDP JSON technology would be accomplished in that recommendation. I hope that does not present issues for NCPDP because it is clearly not our intent to preclude them or preclude the use of their standards.

Rebecca Hines: Just for your awareness, two more comments did come in over the Q&A. I will read one from Lisa McKeen. The attachments in the X12 275 would be greatly helpful for clearinghouse, et cetera. Kathy Sykes(ph.) asks, is there an attachment standard recommendation. And also note the chat, please.

Rich Landen: The attachment recommendation. The NCVHS had already sent several recommendations. The latest recommendation – I am losing my historic perspective here. About a year ago. We did not specify a version since we have not held hearings on any of the current versions available. Again, without holding a hearing to get input on the pros and cons of a specific version, we are essentially punting the version decision over to CMS. We are just saying that standards should be adopted and we will have – it is our belief that we will have ongoing conversations with CMS about versioning.

Rebecca Hines: There are no more comments in the Q&A.

Rich Landen: Are we ready to give it back to the chair for the vote?

Jacki Monson: I will happily take reigns again. Are there any final comments before we take a vote? Hearing none, look for movement.

Tammy Banks: Tammy will forward a motion to approve the document as written.

Jacki Monson: Can I get a second?

Valerie Watzlaf: This is Val. Second.

Jacki Monson: All in favor, please raise your virtual hand.

Rebecca Hines: We have one, two, three, four, five, six, seven, eight, nine, ten members. Thank you very much. We have a quorum and the letter is approved.

Jacki Monson: Awesome. Congratulations to Rich and Denise and the Subcommittee and thank you for all your hard work on it. I am so proud of us today in all that we have achieved getting two letters approved in a really short period of time. I want to thank the PSC Subcommittee, Melissa, Val, and staff for all of their work. I know that that one had a lot of blood and sweat from my own personal experience as the co-chair. I really appreciate us getting that across the finish line.

Rebecca, anything else before we get ready to adjourn?

Rebecca Hines: For members of the public, once these letters are – the typos are smoothed out and Jacki signs and they go to HHS, they will be posted on our website. For those who have asked, all the final letters are posted as well as any responses on the website.

Thanks to the committee staff. Maya, Nate, Natalie, Rachael Seeger, who is no longer with us, and Lorraine Doo. Wow. You all are a stellar team and none of this would be possible without you. Thank you all very much. You make this committee hum.

Next Steps & Adjourn

Jacki Monson: I want to thank everybody, and we know that a lot of work goes into from Rebecca and others and planning for these meetings and facilitating the meetings. I want to thank them for that.

And then I want to give a special thank you to Natalie Gonzales. This is her last official meeting with us. She has been staff to the PSC Subcommittee for several years, and most recently was the lead staff, and she is leaving CDC to go to the Department of Homeland Security in an assistant role as a senior policy analyst. I just want to thank her for all of her work and support over the years. We will certainly miss her. But we will watch her work from afar in the privacy office at CISA. Thank you, Natalie, for all of your work and support to us.

Debra Strickland: This is Deb Strickland. I just wanted to check with you --

Rebecca Hines: Thank you, Debra. We did want to read Debra Strickland into the record – she arrived to the meeting late today. Debra, do you want to introduce yourself, where your work, and any conflicts please?

Debra Strickland: Sure. Debra Strickland. I am on the Standards Subcommittee and I have no conflicts.

Jacki Monson: With that, thanks everybody again. We are officially adjourned.

(Whereupon, the meeting adjourned at 2:05 p.m.)