National Committee on Vital and Health Statistics

Transcript
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Virtual

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Jacki Monson	**Sutter Health**	**Chair**
Sharon Arnold	**DHHS**	**Executive Staff Director**
Rebecca Hines	**NCHS**	**Executive Secretary**
Cathy Donald	Alabama Department of Public Health	Member
Debra Strickland	Conduent	Member
Denise Chrysler	University of Michigan	Member
Tammy Feenstra Banks	Individual	Member
Jamie Ferguson	Kaiser Permanente	Member
Margaret A. Skurka	Indiana University Northwest (retired) and Principal, MAS, Inc	Member
Melissa M. Goldstein	The George Washington University	Member
Michael Hodgkins	Healthcare Consultant	Member
Richard W. Landen	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
Donna Pickett	NCHS	Staff
Marietta Squire	NCHS	Staff
Grace Singson	ASPE	Staff

Call to Order/Roll Call

Rebecca Hines: Good morning, everyone, members of the public and members and staff of the National Committee on Vital and Health Statistics, NCVHS, a warm welcome to everyone joining us here today. Once again, we are meeting virtually and I hope everyone is keeping well. My name is Rebecca Hines and I serve as Executive Secretary and Designated Federal Officer for the committee.

Today, the Full Committee is meeting for the specific purpose of deliberating two sets of draft recommendations and one set of draft comments. We will get to those specifics in a few minutes.

But first, just for everyone, I want to make sure you have access to the agenda so I am putting that here in the link in the chat. I will put the link to that in the chat when the chat is open to everyone.

I do want to take a minute to emphasize that the committee will be meeting in person next month, July 19 and 20, at the Humphrey Building here in Washington, DC. The format will be hybrid and you can attend either in person or by Zoom. The agenda for that meeting will look more typical of a meeting of the Full Committee than today's agenda.

I would also like to pause and point out to members of the public, of a request for information, RFI, and a meeting announcement that was published yesterday in the Federal Register. We are seeking input on the potential use of ICD-11 for morbidity coding in the US. We welcome your responses from industry stakeholders, interested individuals, and your organizations, really any member of the public in advance of the August 3, 2023, expert roundtable meeting being organized by the committee's workgroup on timely and strategic action to inform ICD policy. I would like to put a link to that but for some reason, the chat is not letting me send to everyone. The option is not there. But I will definitely put a link to that at some point during today's meeting or you can just Google it.

One other note. We are delighted that two new members recently were appointed by the Secretary to serve on the committee. Onboarding for two of them is complete and they will be with us today. During the July meeting I just referenced, we will have time for full introductions. For now, you can visit the NCVHS website for details on the committee's membership.

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

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

Rebecca Hines: Thanks, Jacki.

Cathy Donald. Cathy might be on mute.

Catherine Donald: My name is Cathy Donald. I am a member of the Alabama Department of Public Health. I am the Chief Financial Officer and the Chief Operations Officer. I am in Montgomery, Alabama. I am a member of the Full Committee and I am on ICD-11 and the Privacy and Confidentiality Subcommittees and I have no conflicts.

Rebecca Hines: Thank you and welcome Cathy. We look forward to meeting you in person next month.

Deb Strickland.

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

Rebecca Hines: Thanks, Deb.

Denise Chrysler.

Denise Chrysler: Hi. Denise Chrysler. I am with the Network for Public Health Law. I am on the Full Committee and the Privacy, Confidentiality, and Security Subcommittee and I have no conflicts.

Rebecca Hines: Tammy Feenstra Banks.

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

Rebecca Hines: Rich Landen.

Rich Landen: Good morning. I am Rich Landen. I am member of the Full Committee. I am Co-Chair of the Subcommittee on Standards, member of the Executive Committee or Executive Subcommittee and no conflicts.

Rebecca Hines: Jamie Ferguson.

Jamie Ferguson: Good morning. Jamie Ferguson, Kaiser Permanente, member of the Full Committee, Co-Chair of the ICD-11 Work Group, member of the Subcommittee on Standards and Privacy, Confidentiality, and Security and no conflicts.

Rebecca Hines. Thank you, Jamie.

Margaret Skurka.

Margaret Skurka: Hi. My name is Margaret Skurka. I am a member of the Full Committee. I am a member of the Standards Subcommittee. I am a retired professor from Indiana University Northwest Campus. I currently manage a consulting business and I have no conflicts.

Rebecca Hines. Michael Hodgkins.

Michael Hodgkins: Good morning. Michael Hodgkins. I am an independent consultant, a member of the Full Committee and the Subcommittee on Standards. I have no conflicts.

Rebecca Hines: Welcome to the committee, Michael.

Melissa Goldstein.

Melissa Goldstein: Good morning. Welcome to the new members. My name is Melissa Goldstein. I am on the faculty of George Washington University. I am on the Full Committee. I am the co-chair of the Privacy, Confidentiality, and Security Subcommittee and I have no conflicts.

Rebecca Hines: Valeria Watzlaf.

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

Rebecca Hines: Wu Xu.

Wu Xu: Good morning. My name is Wu Xu. I am a retired state health informatic director and also the adjunct faculty with the University of Utah. I am a member of the Full Committee and the ICD-11 Work Group. I have no conflicts.

Rebecca Hines: Thank you and we have one more member we are expecting today. And when she is able to join us, we will read her into the record. That is Vickie Mays.

Moving over to the staff with the Office of the Assistant Secretary for Planning and Evaluation, Sharon Arnold.

Sharon Arnold. Good morning and welcome everybody. This is Sharon Arnold from the Office of the Assistant Secretary for Health. Thank you.

Rebecca Hines: Thank you, Sharon. We are expecting lead staff to one of the subcommittees. We will get back to her. Maya Bernstein.

Lorraine Doo.

Lorraine Doo: Good morning. Lorraine Doo with the Centers for Medicare and Medicaid Services, Health Informatics and Interoperability Group under the Office of Burden Reduction and Health Informatics and staff to the Subcommittee on Standards.

Rebecca Hines: The lead staff to the Subcommittee on Standards. We are very grateful for your incredible commitment and dedication, Lorraine.

Grace Singson.

Grace Singson: Good morning. My name is Grace Singson. I am an ORISE Fellow from ASPE and Office of Science and Data Policy.

Rebecca Hines: Great. Thank you. And just to say hello to Marietta Squire who is our behind-the-scenes everything committee management specialist. Thank you, Marietta. Have I forgotten any members or staff? Very good.

I wanted to make one comment about public comment on today's agenda. There is a public comment period. It is scheduled for 11:30 a.m. Eastern. But depending on how the morning's agenda flows, the timing for the public comment may shift somewhat earlier or even later but we would pause for it. Please stay tuned and you will see there is a slide here. We will bring that up to give you all the instructions so that you can request an open audio line. Participants in the public comment, you will have three minutes. I think that is all the preliminaries.

Jacki, I am delighted to turn it over to you.

Jacki Monson: Rebecca, before we do that, it looks like Maya joined if you want to get her to read into the record.

Rebecca Hines: Beautiful. Good morning, Maya. Would you like to say good morning and introduce yourself?

Maya Bernstein: Good morning. Thank you. I am sorry I am late. I am Maya Bernstein. I am the Senior Advisor for Privacy Policy in the Office of the Assistant Secretary for Planning and Evaluation at HHS. I am the lead staff to the Executive Director of this committee and lead staff to the Subcommittee on Privacy, Confidentiality, and Security. Good morning, everyone.

Rebecca Hines: Good morning. Glad you can be with us.

Agenda Item: Agenda Review

Jacki Monson: I first just want to give our new members a warm welcome. Two of them are on today. We have others who are listening with us and we will obviously give them a more larger warm welcome in July during our Full Committee meeting. Today, the plan of the agenda is we are going to review the three letters for discussion and action. We have two standard letters and one privacy letter in response to the request for comments on the NPRM.

We then will go to public comment. We will take a break after public comment. Then we are going to go back to the Subcommittee on Standards, specifically to review the final recommendation and we will do that first on the CORE Operating Rules. The second will be on X12 Standards. And then we are going to take a break. And then we will move to the Subcommittee on Privacy, Confidentiality, and Security, specifically as I mentioned, the comments on NPRM HIPAA Privacy Rule to Support Reproductive Health and Health Care Policy. We will review that and request a vote for that. And then we will wrap up and adjourn. We have a very full agenda today.

Rebecca, let us go ahead and get started.

Rebecca Hines: Beautiful. Thank you. You can pull up the slides for the CAQH CORE proposed recommendations please.

Agenda Item: Review of Three Letters for Discussion and Action

Tammy Banks: Excellent. Thank you. If you want to go to the next slide. Basically what we are going to do for both letters, we are going to really mirror is just describe the proposal that we received, explain the review process followed by the subcommittee, review the recommendation, and then this afternoon, we will pull up the letter and then we will also go through the initial letter and finalize the recommendations for the submission to the secretary.

As you know, the role of NCVHS as it relates to Operating Rules is to receive the requests either new or updated from the Operating Authoring Entities. In this case, it was CAQH CORE. We then go out and solicit industry and public input. We did that with the request for comment as well as held an industry forum and then determined whether the requested updates meet the requirements for Administrative Simplification as amended for efficiency, effectiveness, cost/value, et cetera. And then we make the recommendations to the Secretary of HHS.

The updates that we received were for both new and updated Operating Rules. One was the Eligibility and Benefits 270/271 Data Content Rule, Claim Status, which is the 276/277 Infrastructure Rule, which have updates and reference to the Connectivity Rule, Payment and Remittance Advice or the 835 Infrastructure Rule, and then Eligibility and Benefits Infrastructure Rule.

In addition, the Connectivity Rule Version C4 would replace existing connectivity requirements in infrastructure components of the operating rules mandated under HIPAA and add new requirements to these rules.

Eligibility and Benefits Single Patient Attribution Data Content was a new operating rule that was proposed, utilizing the 270/271. And then there were four rules regarding attachments, which will encompass in one bundle.

August 2022. We received presentations from CAQH/CORE to better understand the new and updated rules. We really appreciate – again, I have to echo this from our previous presentations, our collaboration with WEDI. WEDI did an excellent job reaching out to their members, performing surveys and Member Position Advisory Groups and other ways to reach out and pull additional information to supplement our request for comment as well as our hearing.

We also on an ongoing basis not just for CAQH/CORE have consulted conversations with the Office of Burden Reduction and Health Informatics, the National Standards Group, and the ONC on all these issues of interoperability.

Our hearing, you may remember, was on January 19. It was virtual. And after that, the subcommittee reviewed all the information we received from the comments, the hearing, and written comments and came up with this recommendation based on your feedback on these Operating Rules that were presented.

As we review this, these are the thought processes that we went through. Was there industry consensus around the need for the changes? Was there sufficient cost and value data, along with identification of the burden, opportunity, and efficiency for the proposed operating rules? Again, this is not the ROI like they do in the Federal Register. This is just basically the additional information. Is it going to bring value to your constituents or to you. And if so, what value? Just to understand what is the benefit and the use cases that would be enabled through an updated or new operating rule.

How do these requests address industry concerns expressed to NCVHS as we look at the Predictability Roadmap and the Convergence 2.0?

And then the other is the main one. Does these Operating Rules further the objective of HIPAA and ACA?

We came up with five recommendations. The first one is to conduct rulemaking to adopt the infrastructure and data content updates for Eligibility and Benefits and Claim Status Operating Rules.

The second is to conduct rulemaking to adopt the new patient attribution content in the Eligibility and Benefits Operating Rule.

The third is to conduct rulemaking to incorporate the updates to the CAQH CORE Connectivity Rule as it applies to the adopted X12 HIPAA standards in the adopted operating rules. We specifically noted the

need for consistency with the NIST cybersecurity guidance and so highlighted the need to ensure that those rules were consistent in the proposed rule that will move forward.

Recommendation 4. Not adopt the CAQH CORE new proposed operating rules for attachment standards for claims and prior authorization. Testimony was very clear that the need for these operating rules should be considered only after publication of a Final Rule adopting a health care attachment transaction standard under HIPAA just to ensure that it does complement whatever rules or standards that are adopted pending the proposed rules that are out there.

And Recommendation 5 is just a reminder. If the Secretary chooses to move forward with these operating rules to exclude the CORE Certification requirement language included in these proposed operating rules since the certification is not a requirement of HIPAA and the verbiage that we reviewed did include it and I believe in the past proposed rules of this nature, this was removed as well so just a reminder.

In the letter, we have Appendix A, which includes the rationale for recommendations. We pulled actual testimony that was given as well as comments in regard to the debate in regard to these operating rules and also provide a little bit more detailed rationale for each recommendation that we made.

Appendix B includes the copy of the CAQH CORE Request Letter to NCVHS.

This was really a fun experience. We were able to get this letter done early. We were able to circulate it across the Full Committee. I just want to thank all the members of the Full Committee as well as the new members for taking time to review it. Many of you provided additional revisions for clarity so that we were able to incorporate those and obviously we can never do these letters without staff so Lorraine, Rebecca, and other staff that support this effort. We really appreciate that again. Hopefully, we will be able to expedite the review of this letter in the second half.

Are there any questions in regard to these recommendations? Rich, if you have anything to add, I would love to have you add it as well.

Rich Landen: I have nothing to add. I think you did an excellent summary. Thanks Tammy.

Tammy Banks: Thank you, Rich.

Any questions, otherwise, we will move on to X12?

One more. This slide is also on the other deck as well. Please go to the NCVHS website. Record this website to get any of the letters to the Secretary, any of the work products or summaries, recordings, and transcripts.

Should we move to X12?

Rebecca Hines: Let us open it up just for a moment so all members can pause to see if anyone has any questions, anything that needs to be discussed. You all have copies of the letter.

Tammy, I think we are ready to move to the second one.

Tammy Banks: Excellent. Thank you, Rebecca.

Recommendation for the recent X12 recommendations. Same thing. Objective for this session – describe the proposal, explain the review process, review the recommendation to HHS, and then in the afternoon, we will review the actual language. Much of the language is in this presentation as well and go for a vote to move this letter forward.

We received requests. Obviously, any rule related to HIPAA standards. We receive requests for new or updated standards from the development organizations. We receive input from the Designated Standards Maintenance Organizations that make up the DSMO committee, which includes the ADA, HL7, NCPDP – I know it is an alphabet soup but many of you have been in this industry long enough to know what these acronyms are but many important committees that provide feedback into the next steps in regard to HIPAA standards. Obtain industry and public input, determine whether the requested updates meet the requirements of the Administrative Simplification, again, for efficiency, effectiveness, cost/value with the same caveats I made with the CAQH CORE bullet point, and make recommendations to the Secretary of HHS.

X12 requested NCVHS review four updated transaction implementations. Three of them fall under the claims or the 837 for the professional, institutional, and dental. The 2022 CAQH Index adoption rates indicated 97 percent of the claims transactions are being used for medical while only 86 for dental. It is a high usage transaction. The Payment/Remittance Advice or the 835, the adoption rates are 83 percent for medical, 36 percent for dental. And X12 asked to move from Version 5010, which is the current standard mandated today to Version 8020. And all other adopted transactions would again remain on Version 5010.

NCVHS evaluated Version 8020 of the implementation guides. And X12 also requested that NCVHS recommend the upgraded versions for adoptions. And X12 also asks that HHS use the 8020 version for the initial steps of the federal rulemaking process.

And they also suggested that when HHS is ready to issue a Notice of Proposed Rulemaking to gather public feedback, X12 will identify the most recently published version of the implementation guides and list any substantive revisions, additional functionality that had been added between 8020 in the future guide.

And then X12 suggested that HHS would include the latest versions of the standards in the NPRM to ensure that these versions named in the NPRM and Final Rule processes reflect the most up-to-date requirements.

NCVHS reviewed that, did our due diligence, and attempted to find out if this could be a process to expedite and make sure that we have the most current X12 standard placed in a proposed rule and we were informed that CMS is held to the Administrative Procedure Act requirement, which would not allow this above process to be implemented unfortunately.

August 2022. We also had presentations from X12 going through the updated standards, collaborated with WEDI and again, the same wonderful response in regard to gathering additional information above and beyond our request for comments and our testimony.

We again discussed the conversation and our recommendations with OBRHI, NSG, and ONC. The hearing was also held on January 18. Afterwards, we reviewed all the comments, hearing testimony, and written comments as we deliberated on where to go with the recommendation for X12.

As we looked at these X12 transactions, we really tried to understand was there industry consensus around the need for proposed changes and updates. We found a very broad range of views. There really was no consensus either way. Was there sufficient cost and value data in applicable use cases? Again, I want to reiterate. This is not ROI data. This is additional data. This is what this calls for this use case. This is why we can auto post more. This is the efficiency we can have. The simple, basic way that an updated standard can enhance the business processes is the information that we are trying to get from the industry. Was there availability of the information to confirm the background capability since we are looking at 8020 transactions for only four transactions versus the entire 8020 suite? The next subset proposed, again, is 8030 for three transactions. And then we also see Version 6020 for select transactions in the attachment NPRM.

How does the proposal address industry concerns that were expressed to NCVHS during again our efforts with the Predictability Roadmap and the Convergence? Is there pre-adoption testing, consideration of burden on all stakeholders, the timing of the implementation in relationship to other NPRMs and other standards and operating rules that will be moved forward?

NCVHS recommends that HHS not adopt Version 8020 update to the four specified transactions, the health care claim and the claim remittance advice at this time.

There is really three reasons that we want to raise to the attention of HHS and X12. We really reviewed the versioning and the multiple versions of different transactions in the industry. Because if we adopt a subset of 8020 – because remember in the past, it was all 5010 put in as a suite. These issues were not as relevant. Adopting a subset of 8020 transaction versus the entire 8020 suite would result in multiple transactions versions, some 5010 and others 8020, with unknown compatibility issues, possibly causing disruption across industry trading partners. Evidence of the 8020's backward compatibility to existing 5010 transactions is needed.

This chart really lays out exactly what we were trying to share. As you can see, we have two standards for four transactions that would move to 8020 with a recommendation to move forward.

We then have three more transactions that are coming forward that would be 8030 version. And then we have one transaction and two proposed new transactions under the HIPAA umbrella that would be 6020. And then actually, there is another transaction that would be 6020. And then we have two other – the last two remaining of the HIPAA mandated transactions. We are not sure if a new version will come forward or not. This is the chart that really provided the compelling conversation about what do we need to think about now so we can move forward and ensure limited disruption in the industry as we move forward to a newer and updated standard.

The second point that we really debated was the idea of cost and value as we talked about somewhat this morning. We really rely on industry value to provide sufficient cost and value data, the indicated use cases, the burden, opportunity, and efficiency for the proposed standard upgrades.

While we appreciate X12 providing preliminary implementation and value data, the depth of that information and the information we gleaned from the comments and the testifiers in both the written and oral testimony was really inadequate to make a determination. There were no stakeholders that said we needed this information. This is the efficiency it is going to give and why. I think we heard more. We just need to get to the next version, not why.

And that conversation within the testimony and comments really highlighted a previous recommendation that we made to the Secretary and that there really is a need, a quick need for a guidance framework for standard development organizations and other industry stakeholders how to develop and report measures for new and revised standards readiness, costs, overall adoption value to really support these standards in its development, testing, evaluation, and adoption phases.

The last reason that we really came to the recommendation that we did is that Version 8020 lacks accommodation for impending updates to two or three – or actually two HIPAA medical code sets. This version does not accommodate ICD-11, which is expected to replace ICD-10. It is not currently an adopted code set. However, it is under study and is being used for non-payment issues. An updated version of these transaction standards will be needed to accommodate ICD-11's variable-length cluster codes for current and future industry use cases. If these transactions would move forward, another version would be needed to accommodate ICD-11.

Also, the FDA has published a proposed rule. This is not an eminent need. But they are also going to be modifying the format of the National Drug Code. There is NPRM currently.

As a committee, this was very difficult to write because we know there is a need for an updated standard. However, the concerns that kept coming over and were quite compelling were the multiple versions across transactions, accommodating changes in the code sets, and the long lead time for regulatory processes that we really felt that needs to be addressed now. The committee urges X12 in conjunction with industry and regulators to speedily address the needs and submit a new version for adoption under HIPAA as soon as possible.

We do comment X12 and the participating stakeholders in its proof of concept and look forward to these results. We feel that they may shed more light on backward and cross standard capability and that the proof of concept could provide supplemental value data to support X12's future proposal to move to the next version to actually get these standards to move forward.

Again, really encourage all stakeholders to really think about and submit benefit and return on investment data to NCVHS or CMS upon request to assist in the review and again, not the ROI, not the data that is needed for the proposed rule. Simply, what does it mean to you and your constituents? Getting an extra data field can do what? How can it impact you? We did get quite a bit of it from the dental industry. That is something that we really hope that you think about as well moving forward.

We had two issues that came up. To be responsive to these stakeholder input, the committee offers these additional comments for HHS' consideration. The committee finds that both important concerns are HHS implementation guidance issues rather than issues with the implementation guide themselves. However, we just are bringing all the comments and testimony that we received to the attention of the owners of these issues.

The Virtual Credit Cards. I just also want to refer that we did do a paper or recommendations in regard to Virtual Credit Cards. We are encouraging HHS to develop and publish additional Virtual Credit Card guidance and education and really think about increasing the enforcement effort when it investigates complaints of inappropriate or involuntary use of Virtual Credit Cards.

And the other is the Device Identifier portion of the UDI in claims. We received a lot of comments in regard to the use or questions in regard to that field choice. The committee encourages the FDA to

review these stakeholder comments and testimonies to identify the concerns to NCVHS regarding the collection of the UDI codes. They may find this helpful in their conversations moving forward.

In addition to the letter, the overall letter, we do have Appendix A, which includes the rationale for recommendations. We have selected experts from the comments that we received from the request for comments, oral testimony, and also more detailed rationale for each recommendation.

Appendix B. We did expand out the comments we received in regard to those two topics that we just discussed. And then Appendix C will have the copy of X12 Request Letter to NCVHS.

Again, same thing with the X12 letter. This was a shortened turnaround time. Again, the Full Committee delivered as well as the staff, Lorraine, Rebecca, Maya. All gave excellent recommendations and comments to incorporate as well as many of the Full Committee. Again, I cannot thank you enough for taking the time to do this work before the Full Committee meeting. Again, hopefully, we will be able to expedite the review and approval.

These again are our resources. Please use it. And you will be able to get a summary of this recording, transcripts, and additional information as we move forward.

Are there any questions or comments at this time?

Rebecca Hines: As a reminder, after the public comment and break, we will go through each letter for a final deliberation and action. Now is a good time if there is any information that Tammy summarized this morning that you have any points of clarification or questions.

Tammy Banks: And again Rich, if I missed anything or you want to add, I did not mean to leave that out.

Rich Landen: No need. You covered it well. I thank you very much. I just might like to double down on what you have already very clearly stated and that is that the Subcommittee and hopefully the Full Committee agrees that the 5010 is in need of updating but the package as submitted did not demonstrate sufficient value to warrant a national implementation. There are just too many loose ends, which we have identified in the comments. Job well done. Thanks Tammy.

Tammy Banks: Thank you, Rich.

Rebecca Hines: Vickie Mays has joined us. Before we move on to the comment letter, Vickie, good morning. Would you like to read yourself into the record.

Vickie Mays: Good morning. Thank you, Rebecca. Vickie Mays, University of California Los Angeles. I am a member of the Full Committee and I am a member of the Privacy, Confidentiality, and Security and a member of the Work Group and I have no conflicts.

Rebecca Hines: Thank you, Vickie. I am glad the link situation got worked out.

I believe, Jacki, we are ready to move over to the third item for action today. Is that right?

Jacki Monson: Yes. I think so. I think we are ready to turn it over to Val.

Valerie Watzlaf: Thank you. We are going to be providing an introduction, an overview of the NPRM on the HIPAA Privacy Rule to Support Reproductive Health Care Privacy. And then we will summarize the focus areas that are included in our draft letter of comments.

Before we do that, I know that my Co-Chair Melissa and I want to thank everyone for all the feedback, the comments, and discussion over the last few months. We greatly appreciate the timeliness of your review and feedback so very much.

A special thanks to those on the Privacy, Confidentiality, and Security Subcommittee and also to the entire committee for providing much comment and discussion on the many issues in this proposed rule, sometimes on the weekends and the evening. We definitely appreciate your time. And a special thanks to our staff, Maya, Grace, and Rebecca for all their work on this over the past few months. We could not have done any of this without your hard work and support. Thank you.

This is just an introduction that on April 12 of this year, the Office for Civil Rights at the US Department of Health and Human Services issued a notice of proposed rulemaking to modify the HIPAA Privacy Rule to strengthen reproductive health care privacy. The proposed rulemaking is one of many actions that were taken by HHS to support President Biden's two executive orders that were issued in the weeks after the Supreme Court's decision in Dobbs v. Jackson Women's Health Organization to protect access to reproductive care.

And under one of those executive orders, President Biden did direct HHS to consider taking additional action, including under HIPAA to better protect sensitive information related to reproductive health care and also to bolster patient-provider confidentiality.

In the NPRM, HHS specifically invited NCVHS to provide comments and it also cited much of NCVHS' past work, which is shown on our next slide here.

Before I just briefly summarize this, we do want to congratulate the department for the foundational work that is done in drafting the proposed rule. We are particularly pleased that much of the committee's past work regarding particularly sensitive health information found in medical records including, among other categories, reproductive health information has been cited in the proposed rule. And this slide just shows some of the past work that actually extends from 1997 up to 2010.

For example, in the June 1997 letter, it states that the committee holds to the principle that has been at the core of our work for over 25 years. That medical records should not used for purposes outside of the health care setting that could harm the subject of the records, particularly for law enforcement or other governmental purposes. In particular, medical records should not be used against a patient, a provider, or any third party for merely seeking, obtaining, providing, or facilitating health care. That was in a June 1997 letter.

And then from 2005 to 2010, NCVHS held nine hearings that addressed questions about sensitive information and medical records and it identified additional categories of sensitive information beyond those addressed in federal and state law, including sexuality and reproductive health information, which NCVHS did elaborate on in a 2010 letter that is listed at the righthand side of this slide entitled Recommendations Regarding Sensitive Health Information. That was November 10 of 2010. We just want to point that out because this was cited in the NPRM all of the past work of NCVHS.

We wanted to provide you with just a brief overview. There is a lot in this proposed rule but this is just a brief overview of the key provisions that the NRPM includes. One of those areas is a new category of prohibitive uses and disclosures. This proposes to strengthen privacy protections by prohibiting the use of disclosure of PHI by a regulated entity, which included covered entities or their business associates collectively. They do this for either a criminal, civil, or administrative investigation against any person for seeking, obtaining, providing, or facilitating reproductive health care where such health care is lawful or also in prohibiting the identification of any person to initiate an investigation.

For this proposed prohibition to apply, the relevant criminal, civil, or administrative investigation must be in connection with one of the following. Such disclosures of PHI would be prohibited when the reproductive health care is provided outside of the state where the investigation is authorized and where such health care is lawfully provided.

For example, if a resident of one state traveled to another state to receive reproductive health care such as an abortion that is lawful in a state where such health care was provided.

Also, such disclosures of PHI would be prohibited when the reproductive health care is protected, required, or authorized by federal law regardless of the state in which such health care is provided.

An example here is if the reproductive health care such as miscarriage management is required under EMTALA, which is the Emergency Medical Treatment and Labor Act, to stabilize the health of the pregnant individual or such disclosures of PHI would be prohibited when the reproductive health care is provided in the state in which the investigation is authorized and that is permitted by the law of that state.

For example, if a resident of a state receives reproductive health care such as a pregnancy test or treatment for an ectopic pregnancy in a state where they reside and that reproductive health care is lawful in that state.

In these circumstances, the department felt that the state lacks really any substantial interest in seeking the disclosure and that protecting against disclosures of PHI in these circumstances directly advances the purposes of the HIPAA privacy and protections without interfering with state prerogatives.

Now the Proposed Rule would continue to allow a regulated entity to use or disclose PHI for purposes otherwise permitted under the Privacy Rule where the request for PHI is not made primarily for the purpose of investigating or imposing any liability on a person just for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. Some examples are listed here.

For example, a covered health care provider could continue to use or disclose PHI to defend themselves in an investigation related to, for example, professional misconduct or negligence, which involves reproductive health care. Or they could use it to defend any person in a criminal, civil, or administrative proceeding. Reliability would be carried out on that person for providing reproductive health care. Or a covered entity could continue to use or disclose PHI to the inspector general where the PHI is sought to conduct an audit for health oversight purposes.

To help with compliance, the Proposed Rule would require a covered entity or a business associate to get a signed attestation that includes that the use or disclosure is not for one of those prohibited purposes that we discussed earlier.

The attestation requirement would reply in any of the circumstances listed. They are on the slide. Heath oversight, judicial and administrative proceedings, law enforcement, or disclosures to coroners.

It provides covered entities in a way of confirming in writing the request for a PHI are not then for a prohibitive purpose.

The Proposed Rule does go on also to discuss whether it would be beneficial if a model attestation was developed and what would that look like.

These are just some other key provisions in the NPRM. They did add and define a new term of reproductive health care that they said is a subcategory of the existing term of health care. They did state that they wanted to keep this definition of reproductive health care very – to be interpreted very broadly and inclusive of all types of health care related to an individual's reproductive system. It does go on and give the specific definition of what that would include.

Also in their request for comment under the definition of reproductive health care, they did ask whether it was necessary to define reproductive health, whether examples are needed for reproductive health care, and whether it would be helpful to define any additional terms and to provide those if we felt that was needed.

They also go on to define public health surveillance, investigation, or intervention to mean population-based activities to prevent disease and promote health of populations. They also go in and clarify the definition of person and then they do talk about updating the Notice of Privacy Practices to include more detail to understand the prohibition and also to include the proposed attestation requirement.

They did encourage – HHS encourages everyone to submit comments. As I mentioned before, NCVHS was specifically asked to respond. And those public comments are due this Friday actually, June 16.

These are some of the main focus areas in our letter of comment that we have. We have a lot in there. But these are just to summarize some of the major issues. The first one there is to reduce burden and uncertainty for covered entities and to make the rule more feasible to implement. We are asking that the department reconsider the rule's provisions that distinguish between care that is illegal in the state provided versus care that is legal.

The second one is to reduce uncertainty and burden among covered entities and to make the rule more feasible to implement. We are asking that HHS should consider requiring attestations for all requests for PHI rather than limiting the requirement to requests that are potentially related to reproductive health care.

However, if the final rule continues to require attestations only for requests that are potentially related to reproductive health care, then we are asking that they consider defining reproductive health care in a very clear and a very specific manner.

If the Final Rule continues to prohibit use and disclosure of records based primarily on the provision of reproductive health care, then the prohibition would also benefit from a more specific and clear definition of reproductive health care as well.

And the second bullet there. If the department continues to include a definition of reproductive health care in the rule, we recommend that the department include clear and specific terms in the regulatory text when providing the examples of such care.

And then to develop protections for access to reproductive and other health care as they consider use of all available authorities at its disposal, not just using – have a privacy rule but other governmental authorities that could assist.

We recommend that the department clarify the new definition of public health in the rule to ensure it does not produce unintended consequences on public health investigations or individual-level activities.

We also recommend further clarification on what constitutes de-identified data as construed by the role. In this regard, NCVHS did make specific recommendations earlier in a 2017 letter regarding an update to better defining de-identified data. But that definition has not been updated.

We also recommend that the department consider adding a requirement in the rule that an attestation include a statement that the recipient of medical records pledges not to redisclose the data to another party for any prohibited purposes that are named in the attestation.

And then we are recommending that specific updated to the Notice of Privacy Practices should be considered that include language that is very clear and not misleading to patients.

And we also recommended that the department consider addressing other areas of health information exchange that were not specifically addressed in the rule such as the rule's relationship to telehealth and also interoperability and information blocking.

If we go to the next slide, I think that is it. I do not know if anyone from our Privacy, Confidentiality, and Security Subcommittee has any additional comments but please feel free. Anything I missed?

Melissa Goldstein: Thank you so much, Val. I think that was a wonderful and comprehensive presentation. I do want to underscore that we very much appreciate the administration's effort in this regard and understand how complex an effort it is to address this very sensitive information and sensitive issue in general.

My colleagues have raised a few implementation challenges, which we will discuss later today. And what we are asking really is presenting these challenges to the department for consideration in addressing them. We do appreciate the effort of the department. We just have a few things that we would like further clarification on and more information and consideration of an implementation because it might prove difficult for covered entities and others to understand exactly.

Valerie Watzlaf: Thank you, Melissa.

Anyone else from – anybody on the committee or anyone have any questions, comments, anything to add?

I know we are going to later on this afternoon, we will also go over some of the major comments and so forth. We will discuss that a little bit later.

If no other questions, do I turn it back over to Jacki?

Jacki Monson: Yes. Rebecca, I think we are way ahead of schedule here. Do we want to go to public comment?

Rebecca Hines: We have two options. We can actually pull up the comment letter that Val just talked about, and use the next half hour to start going through it and then open public comment at 11:30 because we may have people who were not here at the beginning and did not hear my caution or we can do public comment early. I prefer to keep it a little closer to the posted time on the website. But what do you think, Jacki?

Jacki Monson: I think we can start going through the letter. The conversation that we were having earlier is that fundamentally, I think, most of us are aligned on the major themes of the memo but not all of the language is going to be completely crisp and clear today and we will work on that after. We just ran out of time to incorporate everybody's edits.

With that said, Maya, I am actually thinking we should start with the Standards letters and then do the Privacy one this afternoon. Do you have any thoughts on that given the exchange offline?

Maya Bernstein: Thank you. I think that is fine. I think there will be less to discuss. It seems like there will be less to discuss in this case for the Standards letters. And I think if you want to get that out of the way and focus your attention on Privacy this afternoon, that might be a good way to use your time now.

Jacki Monson: I think we should do that.

Rebecca Hines: Rich and Tammy, are you ready to pivot and Lorraine, do you have the CAQH CORE final draft letter available to share on your screen? Okay. It seems like everybody is ready to pivot to Standards. Why don't we go ahead and take this afternoon's 12:30 agenda item and move it up to right now.

Subcommittee on Standards

Tammy Banks: As Lorraine is bringing it up, the actual language of the recommendation was included in the slides that I presented earlier. We are going to go just paragraph by paragraph. First, the letter will set up what was presented, the recommendation language again, and then the closing. We will scroll through it and then ask for approval, pending no additional edits.

Lorraine Doo: I am sorry and just to be clear. You want to do the CAQH CORE letter – pull up the screen now before public comment. I will share my screen.

Tammy Banks: Lorraine, you will just show as much paragraphs as you can and review, see if there are any comments, and then move forward just to the letter. You have been through this drill.

Lorraine Doo: Is that large enough because I have made it 115? Rebecca is my test.

Rebecca Hines: Fifteen percent larger.

Lorraine Doo: I usually give it 130 or 150.

Rebecca Hines: Thank you, Lorraine.

I see, Rich, your hand is up.

Rich Landen: I would just like to make mention to those listening in today that we will take into consideration any comments on these letters we hear during the public comment period before we bring this to a final, final vote.

Rebecca Hines: Thank you, Rich.

Tammy Banks: Rich, you reminded me of one thing I forgot. I am hoping Denise Love is listening from across the waters, but she was instrumental in creating these letters and spent a lot of time crafting and making these easy and concise to read. I just want to thank her, number one, for her work on these letters, as well as her time as co-chair. I really appreciate her service. Thank you, Denise.

Rebecca Hines: Denise is here and available during the public comment period, Tammy. For those in the public, Denise Love's term on the committee and as co-chair of the Subcommittee on Standards wrapped up. It ended last week. But as Tammy said, she had an instrumental role and she is welcome to provide comment when we get to the public comment period.

Tammy Banks: In that case, if there is anything you do not like, it was Denise's. Just kidding, Denise.

Denise Love: That is okay, Tammy.

Tammy Banks: Alright. First three paragraphs. Any comments, revisions, suggestions. It basically just sets up what was asked. No comments is acceptance. If you want to go to the next three paragraphs.

This is just a listing of what we reviewed in the slide of what was proposed.

Lorraine Doo: I see a typo here. This K, Tammy, right here.

Tammy Banks: Excellent. Correct it. Never have enough eyes on this stuff.

Lorraine Doo: I probably put it there by mistake.

Tammy Banks: Do you want to go to the recommendations? Any comments or questions?

Let us move on. If we are going too fast, please raise your hand as well. That was all on the slide language.

Lorraine Doo: I am assuming people are able to read the paragraphs. Just let me know because this ends the body of the letter. No comments on the letter?

Tammy Banks: Jacki, is it appropriate for me to request a vote to approve the letter to the Secretary for the CAQH CORE requirements?

Jacki Monson: I think we are going to pend the vote until after public comment. I think from the committee's perspective, we are ready to vote. It sounds like there is no feedback. Let us pend final vote until after public comment. Let us go through the next letter.

Lorraine Doo: Excellent. Thank you. We do not need to look at the rationale?

PARTICIPANT: No. Then we can go to the X12 letter.

Rebecca Hines: We are sticking with the main body of the letter.

Tammy Banks: I have looked at this letter so long, Jacki, that I forgot we did not have the public comment.

Jacki Monson: Oh good. That is what I am here for.

Lorraine Doo: Is that large enough, test committee?

Rebecca Hines: Yes, ma'am. Thank you.

Tammy Banks: The first four just relays what NCVHS is and what we are doing.

Lorraine Doo: I will go to the main body. If someone could just wave their hand or go ahead and move forward, that would be great.

Tammy Banks: And the tables and Appendix A that we showed in the slide deck.

Lorraine Doo: Yes.

Tammy Banks: This is one, Lorraine, the second bullet, and Lenel, jump in here if I get this wrong. NCVHS relies on industry input to provide sufficient cost and value data, indicated use cases along with –

Lorraine Doo: That is here. Do you want that up here? That should be here – let me put it in red line.

Rebecca Hines: Tammy, Rich has his hand up.

Rich Landen: I just want to point out the backup in the recommendation itself and then description under that we very intentionally and consciously used the language not recommend at this time. As Tammy presented earlier, we understand that an update is needed. We are being very, I think, transparent in saying that we are not rejecting the concept of updates. We are saying that they are just not quite ready for prime time as packaged and presented.

Tammy Banks: Good call out, Rich. Thank you.

Lorraine Doo: Tammy, I am sorry. Let me show – let me do this first.

Tammy Banks: What you got is perfect. Lenel, let me if it – you made that great edit.

Lorraine Doo: I put it in the wrong place. Sorry.

Tammy Banks: No worries. There has to be a reason to go through it so we have to have at least one change.

Lorraine Doo: I thought I put it in the right place.

Tammy Banks: No worries.

Lorraine Doo: Do you want me to go to the next page?

Tammy Banks: Go for it.

Rebecca Hines: Tammy and Rich, you might want to point out for our public attendees this section here on additional comments specific to Virtual Credit Cards and the UDI.

Tammy Banks: Definitely yes. As we said in the presentation and Rich, jump in, these were two key topics that were brought up while they are not related to the implementation guide review itself. They are HHS operational issues in the use of the field. Because of the great comments that we have received, we wanted to make sure that the right groups had access to these comments. Hence the inclusion of Virtual Credit Cards and the referral to our previous testimony and recommendations and the referral to the FDA who also provided comments just to review the additional comments that may be helpful as we move forward.

Lorraine Doo: And all the letters are on the website so if anyone wanted to review them, they would be able to.

Tammy Banks: Yes definitely. Please go to the NCVHS website and you can access all of those comments on these topics and more.

Vickie Mays: Can I ask you to go back up? There is a question I do not understand. It is where you wanted comments to go to NCVHS for someone else.

Tammy Banks: For CMS upon request to assist in the review of all future proposals.

Vickie Mays: Should that be “and” CMS? Would it be appropriate for comments only to come to us and then not to CMS or should it be “and”? Should it be “and”? I do not know if we are the official body. Shouldn’t it go to also CMS?

Rich Landen: Let me respond to that, Vickie. We are talking about future actions here and the choice of “or” was deliberate because we do not know what the mechanics will be in the future. It is possible that we, NCVHS, could make a request in which case they would come to us. It is possible that CMS would issue a request in which case comments would go just to CMS or it is possible we could do something jointly and they would come to both of us. The “or” I think covers both all three of those contingencies a little bit more accurately than an “and”.

Vickie Mays: Okay. I understand.

Rich Landen: If we could go back to the Virtual Credit Card, I just would like to point out particularly for members of the public that are listening in, the letter from September 23, 2014, from NCVHS to the Secretary. That contains a lot of the detailed rationale around the issues that so many of you were very keen on while you were providing your comments both oral and written to us in our January hearing. I would encourage you to go back and look at that letter and see all the thinking that the NCVHS did back nine years ago because the Virtual Credit Cards and the potential abuse was well identified back then and we had already gone on record with the Secretary on many of the issues that you asked us to take some action on just this past January.

Rebecca Hines: I am putting the link to that letter in the chat. If you want a shortcut to reviewing the letter that Rich just outlined, it is available under the product section of the web page.

Lorraine Doo: Tammy or Rich, do you want me to move down? This is the last part of that paragraph. And then these are your appendices and a similar ending.

Any other comments or concerns?

Tammy Banks: Thank you for the extra set of eyes and we will look forward to bringing it up this afternoon.

Rich, anything to add?

Rich Landen: No, in the absence of any questions or comments from the committee members, maybe we are close enough to the appointed hour to go to public comment.

Public Comment

Rebecca Hines: You read my mind, Rich. I think we are only nine minutes ahead of that posted time. If you could bring up the slide with the instructions, we can now begin the period of public comment.

For those of you who are attending today, you can click raise your hand to have your audio unmuted or use the Q&A to request an open audio line. There are a couple of you on the phone. Press *9 to request unmuting of your phone. You are always welcome to send comments to NCVHSmail@CDC.gov, which we would either read into the record if they phone now or we would include in the meeting summary.

Mike, I see we have two commenters to start us off, starting with Dr. Alex Shteynshlyuger.

Alex Shteynshlyuger: Hello dear committee members, thank you for the opportunity to comment. First, CAQH CORE rules do not provide a legitimate opportunity to file complaints of violations of the CAQH rules to small medical practices, which CAQH according to CMS is in charge of enforcement. The threshold to follow CAQH complaint is impossible to meet for practice with less than dozens of hundreds of physicians. Corporate entities are afraid to file complaints due to the concern about health and retribution. This has to be addressed. The system needs to work for everyone not just big corporate entities. That is number one.

Number two, all the standards under discussion today, including the CAQH and X12 standards are adopted under the HIPAA Act of 1996 Section 1172B a reduction of costs. The currently adopted rules 45 CFR 163.12 secretarial action regarding complaint of the compliance reviews, refer to informal means of complaint resolution. That is a failed approach as evidenced by rampant non-compliance and thousands of complaints.

Currently, the adopted standards to not being enforced by CMS Office of Burden Reduction, the Division of National Standards, and one of the problems is, what they call, informal means of complaint resolution. It does not work. It failed.

No standard that is not enforced can be shown to lower costs. CMS cost saving calculations depend on near universal adoption and near universal compliance. Without these two critical elements, the standards cannot lower the cost and invalid. As a result, the current rules regarding complaints CFR

163.12 cannot withstand the legal scrutiny. They are illegal according to the governing HIPAA. They cannot be shown to lower the costs and they could not have been adopted. At this point, they should be withdrawn, and a legitimate enforcement mechanism put in place with their required APA notice and comment period. Thank you.

Rebecca Hines: Thank you very much.

Next person up is Erin Weber. Mike, can you open her line?

Erin Weber: Thank you. Hi everyone. This is Erin Weber, vice president of CAQH CORE. I wanted to comment on one sentence in the draft letter related to the development of operating rules by standard setting organizations. The Affordable Care Act defines operating rules as the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specification. Therefore, additional operating rules cannot be developed if they are already addressed by the standards and their implementation guides. This statement is really unnecessary. A broad statement on standards that have not been fully implemented or reviewed by industry could restrict future need for operating rules as standards evolve and may need to interact.

For example, CORE and NCPDP right now are working collaboratively to develop operating rules for how medical pharmacy – to address medical pharmacy needs by the industry. We request that that sentence be removed as it is not specifically related to these CORE operating rule recommendations and could negatively impact future industry need for interoperability.

Thank you all to the committee for your hard work and effort in developing this letter. Please do feel free to reach out to us if you have any questions or need any additional clarifications.

Rebecca Hines: Thank you so much, Erin.

Next, we have – and I apologize if I am mispronouncing your name, Niraj Acharya. It looks like your line is open. Please identify yourself and your title and organization please.

Mike, it looks like their line is open.

Staff: Yes. All I can do is request that they unmute – they actually unmuted themselves. I think there may just be a problem with their microphone if you want to come back to them later.

Rebecca Hines: Do you want to try again, Niraj? There is something happening with the audio there. I apologize. We are not able to hear you.

Let us move to Denise Love. Denise, please unmute yourself.

Denise Love: Thank you. I am going to stay off video because of my jet lag here. I do not really have anything to add except kudos to Tammy's excellent presentation.

I just wanted to affirm that the subcommittee did their intense diligence of these proposals and in collaboration with industry and CMS. I think we heard that these proposals highlighted many issues that we have an opportunity to address now to improve the standards process going forward because we expect cadence to increase and these reviews will continue more regularly to improve and respond to the changing health information needs going forward. I just wanted to acknowledge that the Standards

Subcommittee is in good hands and the depth of expertise and knowledge on the subcommittee is impressive and I will miss working with you all. Thank you.

Rebecca Hines: Thank you so much, Denise. We will miss working with you as well.

Niraj Acharya, do you want to try to open your line again to unmute yourself? You are unmuted. There is an issue with the audio probably on your end. I am not sure.

Let us move to Heather McComas. Mike, can you open Heather's line please?

Heather McComas: Hi there. Can you hear me okay?

Rebecca Hines: Perfectly. Just remember to let everyone know your organization and title, Heather.

Heather McComas. Absolutely. Thank you so much, Rebecca. This is Heather McComas from the American Medical Association. I am director of Administrative Simplification Initiatives. I wanted to just really express my appreciation for the committee's work on these letters. I think this is very much in line with Amy's comments.

I do want to second Erin Weber's request to remove the – I think it is just one sentence, kind of limiting the future scope of operating rules. I think, as Erin noted, it does not really relate to the operating rules that are being recommended. This NCVHS recommendation said, and also it could hamper future operating rule development to meet future needs for standards. I just would request along the lines she did a removal of that particular sentence. Thank you.

Rebecca Hines: Thank you. I am sending a note to Niraj. We are unable to hear you but you are unmuted. Can you try again, Mike, please? Niraj, your audio line is open. You might try calling in by phone. I do not know, Mike or Ella, if you can put in the chat a phone number to call in. That might be the fastest way to get this person a live audio open line.

Can we open the line for Rebekah Fiehn please? Your line is open. Please introduce yourself.

Rebekah Fiehn: This is Rebekah Fiehn. I am the director for Coding and Dental Data Exchange here at the American Dental Association and would like to go ahead and just echo the comments about removing the line about the future operating rules. The American Dental Association is actively working on pursuing some operating rules for dental business operations and would hate to see anything that would hinder that. We would just like to go ahead and echo what the individuals from CORE and the AMA have said.

Rebecca Hines: Thank you for your comment.

Lorraine Doo: Rebecca, this is Lorraine. I just want to confirm so when the committee has their discussion that this is for Heather or Erin or Rebekah. Hello everybody. This is the line on the last page where it talks about operating rules being developed for standards, which need them. It is on the fifth line. I can confirm. I can send it out when we look at it. It just says that standards have their own operating rules embedded within their implementation specifications. That is the one you are talking about.

Erin Weber: Lorraine, this is Erin. That is the one.

Lorraine Doo: Okay. Thank you. I just wanted to clarify.

Rebecca Hines: That is helpful.

Niraj, there are instructions to dial in the chat to get an open line. Let us wait one minute. And also, Mike, if you can unmute their line just to see what is happening.

Niraj Acharya: Can you hear me now? Thank you so much for trying so hard to let me speak. I really appreciate that. I am Dr. Niraj Acharya. I am a solo practitioner from Kings County Brooklyn, New York. Virtual Credit Cards are really problematic for small practices. I see, as I follow, that it seems the committee is recommending further study. I strongly believe that anything that you do – if there is not any effective enforcement mechanism, a solo practice like me going against a 400-billion, 500-billion-dollar a year revenue corporation. There is no chance. My government needs to work for me as much as for somebody who owns half of the country.

It is really important that you take into consideration what happens to – right now, I am speaking from my practice in an inner-city area that is two or three percent extra charges that comes with Virtual Credit Card is a very significant hardship and things that the Federal Government, Congress did not put it in HIPAA, the industry should not get some back door entry.

They can very well send all the lobbyists to Congress and go and get it changed. But even in that process, I do hope that the people will pay attention to what happens to the smallest person. I am one person. That is all that is there. I do not even have much ability to keep on being on the phone in trying to fight with all the plans who try to force it upon me this Virtual Credit Card that I never consent, and somehow end up paying me with that. Thank you very much and I really appreciate you trying so hard to give me the opportunity to talk.

Rebecca Hines: Thank you, Dr. Acharya. We appreciate your comments.

Mike, I see Terrence Cunningham. His hand is up. Hello Terry. If you could please introduce yourself and your line is open.

Terrence Cunningham: Hi. Thanks. I do not want to belabor the point because my colleagues have already made it. I am Terry Cunningham. I am the director of the Administrative Simplification policy with the AHA. I share the comments made by Heather and Erin concerning that one sentence. I would recommend its removal. Thank you.

Rebecca Hines: Thank you, Terry.

And former member and co-chair of the Subcommittee on Standards, Alix Goss. Her hand is up. Alix, your line is open.

Alix Goss: Thank you so very much. I am Alix Goss. I am weighing in here on behalf of the HL7 community in regards to that sentence that is perceived as being limited or limiting to future efforts. I am not quite tracking with the concern of the sentence that says standards such as those created by HL7 and NCPDP have their own operating rules embedded within their own implementation specifications or implementation guides.

This is a valid sentence. It reflects testimony and the longstanding positioning of HL7 and NCPDP as encompassing providing all of the rules soup to nuts, that are needed by the community. That I do not think precludes any collaboration as the innovative work going on related to medical pharmacy between NCPDP and CORE.

Part of it is a question back to those who are seeing that as a limiting statement, and would suggest that it is an affirming statement to the current regulatory landscape in recognizing that CORE has an authority related to operating rules to be mandated in regard to X12. I would suggest that it be kept and if there was some level of future consideration that has been brought up that we need to account for, I would add another sentence that would say to the akin of that this does preclude the ability of CORE and standard setting organizations to collaborate in meeting industry need.

Rebecca Hines: Thank you for your comment, Alix.

I see another hand has just shown up. Lisa McKeen. Mike, can you open her line please? Please introduce yourself, Lisa.

Lisa McKeen: Hi. I am Lisa McKeen. I am with GDIT HIPAA Privacy and Security Officer. I would like to comment on the comment that Alix just made regarding the HL7 comment. And maybe with a comment that she just made, it might actually explain and justify the sentence that was in that statement. I think it would clarify even more for those that understand the collaboration between the HL7 and the CORE committee because otherwise it sounds like it is actually precluding other entities from participating in the collaboration. That is all I wanted to say.

Rebecca Hines: Thank you for your comment, Lisa.

I will pause here. I see nothing in the NCVHS mailbox. I do not see any more hands up. Stanley Nachimson. Stanley, please introduce yourself and your line is open.

Stanley Nachimson: Thank you very much. I appreciate the opportunity to talk. I am Stanley Nachimson, an independent consultant and a member of a number of standards organizations and other industry organizations.

I am a little concerned about the recommendation to not move ahead. I have several issues with it. Some of the rationale seems somewhat off in the future. ICD-11, for example, is years and years away from adoption. I do not understand why that is an issue right now and it is a relatively easy change for X12 to make that.

Secondly, it sounds to me like you may be holding X12 to a little higher standard than other standards that have been recommended in proposed rules. I would prefer to see the committee's recommendations say that you have some concerns with these recommendations and the standards and CMS should consider whether they can meet ICD-11 or whether or not there is the backwards compatibility rather than putting up a stop right now and having things roll back. I would hate to see this process of moving ahead with more up-to-date standards held up while people are figuring out whether they want to send things to NCVHS or to CMS or what the process is. Again, I would suggest sending a recommendation to CMS saying take a look at these issues but move ahead with sending these out and certainly asking in the proposed rule for specific comments on those issues. Thank you very much.

Rebecca Hines: Thank you for your comments, Stanley. I also want to note. Donna, thank you for editing your written comment in the Q&A. Since we are on Zoom, I will go ahead and read this. Donna Campbell from Provider Portal Connectivity product owner, HCSC. She writes, I would request the decision be reconsidered with respect to not supporting the operating rules regarding the attachments. It would be helpful to require instead that these trading partners are already exchanging the X12 275 that they must adhere to the requirements for the attachment operating rules. At a minimum, that allows for standardization amongst the trading partners who already support this transaction and moves us closer to making sure they are used and exchanged with the intention the TR3s and operating rules bring. Thank you for your comment.

Anyone else on the attendee side this morning? With that, I believe the public comment period is complete. Jacki, I just want to check in. We are not back on track with the agenda to come back at 12:30 to handle final discussion on the two standards recommendations letters and potentially, hopefully vote on those.

Jacki Monson: Yes, on track so let us break now.

Rebecca Hines: Very good. We will reconvene at 12:30. You are welcome, and I encourage members especially to keep your Zoom link live and mute your camera and sound.

(Break)

Jacki Monson: Rebecca, I also see that we got a late public comment. I do not know if we want to address that.

Rebecca Hines: I think I will read it into the record and for the purposes of the meeting summary, you can just add this to the public comment part of the report. This is Diana Fuller from the State of Michigan Medicaid. Sorry for the late reply. I am having computer issues. I support NCVHS' recommendation in this letter. The State of Michigan would only support moving the industry to one standard for the whole suite of transactions. Providers have one EHR system.

The brunt of the costs of implementation and maintenance for allowing multiple standards will fall on the clearinghouses, vendors, and payers. Allowing multiple standards in the industry will have clearinghouses, vendors, and payers dealing with the same issues as they do today. Maintenance, down time, standard changes, emergency patches, and costs. But when you allow multiple standards, these issues will multiply. Allowing multiple standards at the same time at length not just overlapping for new standard implementation is a recipe for trouble for all payers, vendors, and clearinghouses in the industry. Thank you very much, Diana, for your comments. It is now read into the record and it will be noted in the meeting summary.

Jacki Monson: Thank you, Rebecca.

I think what I want the game plan to be for this afternoon is let us take a vote on the two standards letters and then we will move into the privacy letter, go through the general themes again, make sure everybody is good with them. If we need to have a conversation, we do. And then we can reference specifically the comments or the actual letter for areas where we might have concern or need to have further discussion.

Michael, it looks like you have your hand up. Do you have a comment?

Michael Hodgkins: I just was curious what the procedure is, given that there seemed to be conflicting comments with respect to one sentence in the letter.

Jacki Monson: A really good question. Our co-chairs, I know, have been conversing offline and going through and making decisions on whether they want to revise or not. When we go through the letter and get to the approval conversation, they will specifically talk about whether we would like to incorporate it or not and then obviously, we have an opportunity to have a discussion about it and then we will take a vote after.

Rebecca Hines: Everything is up for discussion, Michael.

And I also just want to ask all of our members. I know everybody's computer is different. Make sure you can find your raise hand button if at all possible. That really helps us when it comes time to counting votes. Please look for that. I do not think if we were to tell you how it looks on my screen or on someone else's screen, it would necessarily be the same on yours. Just see if you can find that.

But for our two new members who are here today, the process is to now bring up the letter, go through it, and ask if there are any areas that need further deliberation whether of your own or because of some public comment that was suggested, have a discussion. When you get to the point where you are comfortable calling for a vote, a member can call the question. And once that is seconded, we can take a vote. Members are permitted to abstain, or it is fine if you do not approve. We do not need consensus. We need a majority. With 13 members here today, we need 7 approvals. Then the vote is what would be to approve the letter for our chair's signature and submission to HHS.

Jacki Monson: If no other question, go ahead and take it away Tammy.

Subcommittee on Standards

Tammy Banks: Number one, we really appreciate the public comment. It is always helpful, and that is why I was hopeful that we review the letter after, but this works as well.

Rich and I reviewed the public comment points that were made. I just want to reiterate to the Full Committee that HIPAA and ACA regulations are very specific on what we can and cannot do. I know there was mention in regard to attachment rules. Why not approve them so they can be used by those who are already using the standard? I just want to inform the subcommittee that according to ACA, we cannot adopt an operating rule for a non-HIPAA standard. That is not an option for us at this time.

However, we did include in the letter because we do think those operating rules are important and need to be considered When and if that NPR becomes a final rule and does name a HIPAA standard.

And the reason it was written the way it was in response to testimony, which clearly indicated that they did want to these to be revisited but the NPRM need to come first. That was in response to one comment.

Does anybody have any questions on that?

The second issue is in regard to revising the language. Lorraine, I do not know if you want to –

Lorraine Doo: Do you want me to pull up that letter?

Tammy Banks: You can, but I can speak to it – revising the letter – in regard to operating rules can only be brought forward by a standard operating rule entity. And standard designated organizations can put operating rules within their implementation guides. And the language – the way we said it is very thoughtful and represents the subcommittee's position and the industry testimony that we heard. It does not preclude any collaboration. It does not – it basically reflects the language within the Affordable Care Act and recognizes that standards can be created by the SDO, which HL7 and NCPDP has indicated that they do have operating rules in their implementation specifications if they choose to collaborate with the CORE in order developing operating rules begin. Nothing precludes that from happening. Rich and I have discussed, and we feel the language does represent the subcommittee deliberation and that it should remain as is.

Rich, would you like to add any comments that I may not have made as clear as I should have?

Rich Landen: I think for the benefit of the committee members that less into the weeds as the Subcommittee on Standards is, a standard is something like how the patient name, last name, first name, middle initial is transmitted and if that is defined by the standards development organization, which it is and adopted under HIPAA, there cannot be any operating rules that alter what the standards organization has included in their standard and specifically in their implementation guide or implementation specification, whatever the SDO calls their particular work product.

But an operating rule is something that is not addressed by the standard and to cite one relatively simple example of an operating rule from the CORE connectivity is that the CORE operating rules and CORE is designated by HHS as an operating rule authoring entity or ORAE to add to your acronym pile. CORE specifies that system availability in this version is more hours per week. I will not cite the specific because it is not germane to the point. But these operating rules include a requirement for systems to be available to exchange the transactions more hours per week or per month or per year than the previous version. The number of hours that a payer system must be available for providers to submit the transactions be it eligibility or claim for prior auth is something that is covered by the operating rules.

And the regulations, as Tammy said, are pretty clear. If there is an issue, then it is up to industry. The industry can take it either to the operating rule authoring entity or to the SDO and either get it embedded in the next version of the SDO's implementation guide or implementation specification or they can do it as an operating rule.

I am really glad to hear during the public comment that there is collaboration going on in the industry to address these issues. The gist of the matter is there is an identified issue. It needs to be resolved and there are two mechanisms to do that, depending on the nature of the problem and the resolution is either the implementation specification or an operating rule.

We think the language in the letter, which was very deliberate and is predicated on similar statements we made in earlier recommendations around operating rules and standards, is pretty clear. It does not preclude any of the industry members from doing anything that the public commenters today said they want and need to be able to do. But it also makes – it kind of reiterates that there is a distinction between an operating rule and an implementation guide that is adopted as a standard under HIPAA. I hope that is helpful to the members.

Tammy Banks: Michael.

Michael Hodgkins: I guess I should take myself off mute. That is very helpful. I guess I do not understand given the comments, why it would not be appropriate to add something following the last sentence, to the effect that this does not preclude collaboration between entities to develop additional operating rules as needed.

What you said is that this language does not preclude that. So what is wrong with the statement to that effect?

Rebecca Hines: Basically, you are asking for reassurance. Just a sentence of reassurance, Michael.

Michael Hodgkins: Yes. I am just begging the question. What I have heard from the co-chairs is that this language does not preclude such collaboration. If that is the intent that it not precludes such collaboration, what is wrong with adding a brief statement at the end that says that?

Rich Landen: I guess my reaction to that, Michael, is it is a really good question and it gets to kind of the art of drafting. I am generally reluctant to make last-minute changes because we have not had the opportunity to review them and really think about are there implications of language changes. Offhand, I would – I can't come up with a definitive reason why that would not work. However, I do not think it is necessary.

I am hesitant about changing due to the what I perceive as a risk of unintended consequences down the road without having to have the ability to go back to the subcommittee for discussion of are there any implications.

The bottom line is I do not see that adding – again, my opinion and you are welcome to disagree. This is not trying to pontificate or anything. I do not see that adding that sentence adds any value or changes anything that is not already in existence.

Do other members of the subcommittee want to chime in?

Rebecca Hines: Please feel free to discuss. It is an important question. Rich, this is a perfectly fine time to discuss unintended consequences. Obviously, it is not ideal, given that four months of thinking went into this already. However, I think it is worth taking a minute just given that it has been raised just to deliberate the pros and the cons.

Lorraine Doo: Michael, could you just repeat what the sentence would be? I just want to put it here just for visibility.

Michael Hodgkins: I was not trying to wordsmith, but just something to the effect that this does not preclude collaboration between entities to develop additional operating rules.

Lorraine Doo: Okay.

Michael Hodgkins: I would stop at operating rules, and not use if needed. I understand the points that are being made. Really, this is not something that I am going to – which would cause me to vote against the letter by any means. Given the objections that were raised in the public comments, it seems to me that this is not a substantive change where unintended consequences might arise. That is just my opinion. Again, this is not a hill I am prepared to die on.

Tammy Banks: We do not want you to do that, Michael.

Deb.

Debra Strickland: I agree with Rich. I think we – honestly, we have deliberated over this so much. We did belabor the review to make sure that we were trying to cover all these things. I would like to just leave it the way that it is.

Rich Landen: Michael and any other member of the committee, your comments are always welcome. If you would like to make a motion that would be very appropriate. We will make the motion. Let us see if it gets a second and we will follow due process. If the group agrees, we can make that change. We can always change the letters.

Jacki Monson: I think it is really important to just note that. That is the purpose of these meetings and have it in front of the public and the opportunity for discussion. We can always modify based on either feedback from the public or feedback from the members before we get the opportunity to vote. I just want to be clear that we should be contemplating whether we change it or not.

Michael Hodgkins: Since I was the one that raised it, since there have not been comments from either other members of the Full Committee or the Subcommittee save one, I think that silence supports leaving the language as is.

Rich Landen: Okay. Again, I just want to reiterate that every member of the committee has a voice here. If you have a concern, you are welcome to pursue it. This is a collegial approach. It is not top-down. Discussions are important. It is really good to hear recognition of the public comment. It is always an interesting journey and a burden and task to come with a consensus outcome. Michael, very much appreciate your input.

Jamie.

Jamie Ferguson: Hi. Thank you. I am fine with the language of the letter as is. At the same time, I would not object to Michael's proposed addition but I would leave the last two words in if needed because I think that is the whole point is that we would only want new operating rules when they are needed. I think where Lorraine has that highlighted – if you could highlight the last two words then I would certainly agree to that addition. I think it is not a bad change. I would vote for it either way.

Rich Landen: Okay. Anyone else with comments? Melissa.

Melissa Goldstein: I would only say that I am not sure that we would want to – and you guys know this much more than I do – call out certain entities to the exclusion of others. Maybe just collaboration between entities. Does that make any sense if we add language? I am just thinking along your lines, Rich, about unintended consequences. That is really where I am going. It is hard to think about it all now all at once.

Rich Landen: I think that is a good point, Melissa. I know we did not hear in the public comment today but the subcommittee is aware that X12 and CAQH CORE have an ongoing collaboration.

I am trying to think through it here. If we take out the example HL7 and National Council for Prescription Drug Programs that leaves it pretty vague if we leave entities undefined. Again, what would be the value add there?

Melissa Goldstein: Can you say standards development? Can you specify with an adjective or two? I understand the problem. I am just trying to think what might be an effect of the language?

Rich Landen: Let us just think about that. Michael, do you want to add something?

Michael Hodgkins: I was just going to say that I agreed with the comment to remove the reference to HL7 and NCPDP if we are going to add this language. I don't think it is necessary to include specific reference to HL7 and NCPDP in this additional sentence if it is to be added.

Rich Landen: Okay.

I see Catherine Donald. You are on mute.

Catherine Donald: Sorry. Apparently, I have a problem with my mute button. I am reading the sentence that has highlighted now the addition of the other one that does not preclude. In a way, to me, they are almost saying the same thing and I know less than it changes really you feel rushed. But I am wondering if the first sentence could be changed a little just to make clearer the meaning that it does not preclude because it is almost like we are saying the same thing twice but in two different ways because you are saying however operating rules should only be developed and are adopted for standards, which need them. Is that not the same thing as collaboration between professional organizations to develop additional operating rules if needed or operating rules if needed?

Lorraine Doo: That is why I put it in there so you could see that I think you were saying the same thing and I was wondering the same thing myself, which is why I put it in the paragraph.

Catherine Donald: It was very helpful. Thank you.

Rich Landen: Tammy.

Tammy Banks: I was going to reiterate. I think the comments that we have going around is why, Rich, you stated this was thoughtfully considered and is this – are we adding anything to what was already said? I do not think we are adding anything, and we can wordsmith this all afternoon. But if we are not adding a thought that is not already captured, why are we going to go through this exercise? I question the need. I heard what the public comment said. I hear the comments that are being stated now. Again, I just do not hear a difference with the addition except to just add it. Not being thoughtful about it considering the regulation that is backing what is being said, I do not feel comfortable adding it at this juncture.

Rich Landen: Okay. That brings us around again to the proponents of possibly making the change. Michael or Jamie, would you like to make a motion? I think what we have on the table here is this would not preclude collaboration. I suggest we change that to, among organizations to develop additional operating rules if needed.

Lorraine Doo: I think Catherine is saying that you have a redundancy now in the paragraph.

Rebecca Hines: Right. We need to ask the two people who are in favor of where they are right now.

Michael Hodgkins: Again, I said I was not prepared to die on this hill. For procedural purposes perhaps -- I will make a motion that we amend the language in this paragraph to add the final sentence, but replace the word between with among. Let's vote on it and get it done so that we do not have to discuss it anymore.

Jamie Ferguson: I will second that.

Rich Landen: We have a motion. We have a second. The motion would be to add a sentence as you see on the screen. This would not preclude collaboration among professional organizations to develop additional operating rules if needed.

Jacki Monson: Is there any discussion?

Rebecca Hines: I just want to say you can vote for this and if it does not pass, you can vote the other way as well. It is not like you get one vote.

Jacki Monson: Any discussion? Rich, I see your hand is up.

Rich Landen: I would question the inclusion of the limiter to professional organizations. Those are generally seen as a subset of all organizations that might be stakeholders in operating rules.

Jacki Monson: Standard development.

Rich Landen: No, not standards development because that again gets into the technical term SDOs and what we are trying to do is encouraging a broad range of stakeholders, be they individual companies or be they professional societies or be they industry organizations to name one just as an example, for WEDI.

Michael Hodgkins: As the maker of the motion, I accept that amendment.

Rich Landen: Jamie, do you accept?

Lorraine Doo: Is entities right, Rich?

Rich Landen: Yes.

Jamie, do you accept the change – friendly amendment?

Jamie Ferguson: Yes.

Jacki Monson: Any other discussion?

If you support the motion, please raise your virtual hand.

Rebecca Hines: Right now, we have – let us count. Michael, Wu, Vickie, Valerie, Jamie, Melissa, Denise Chrysler, Deb Strickland, and Jacki Monson. That is a majority. Margaret just added her vote. We have nine in favor, and please clear your hands. Do we have any not in favor? We have Rich, Tammy, and Cathy. Margaret, you voted for it. Margaret, which is your vote? For or against?

Margaret Skurka: For.

Rebecca Hines: Can you take your hand down? Not in favor, we have Rich, Tammy, and Catherine Donald. The motion to –

Maya Bernstein: Abstentions.

Rebecca Hines: Oh, are we missing anybody?

Maya Bernstein: I don't know. I wasn't counting.

Rebecca Hines: We are missing one person's or either I did not count correctly.

Jacki Monson: I do not think we got a vote from Melissa.

Melissa Goldstein: I voted.

Rebecca Hines: Okay. Ten in favor and three not in favor to pass the motion to approve with this addition. Therefore, the motion is passed, and the letter is approved as with amendment.

Jacki Monson: Great.

Rich Landen: Wait a minute. We are just talking on building on the amendment, not the whole letter.

Rebecca Hines: Okay. I misunderstood the motion. Thank you.

Michael Hodgkins: The motion was just for the amended language, not the letter. I would be prepared to make a motion to adopt the letter as amended.

Tammy Banks: Let us hold it here.

Jacki Monson: Vickie, I think has her hand up.

Vickie Mays: I am just a little concerned and I just want to hear from Rich and Tammy because they are the co-chairs. They did not vote for the amendment. Can you tell me if there is something that is of serious concern that you think is going to go awry based on what is there? Why didn't you vote for the amendment? Can I ask that or I am not supposed to ask that?

Tammy Banks: Definitely. We carefully crafted it based on the ACA and based on testimony. Without being able to go back to the ACA, make sure we reference, and then we are talking about taking out names of entities. Now, we are talking about – it is the whole paragraph and figuring out how to change it instead of we had a paragraph that accurately reflected what the subcommittee came up with based on review of regulation, based on the review of the testimony, but now we are adding. It is just it is bigger than it appears, is my concern. It does not add value because it already says it. That is the challenge. We are trying to make one change that seems simple, but as you see, it is not simple and the implication is not simple. That is my concern.

Rich Landen: And mine is – okay, just look at the sentence here. This would not preclude collaboration among entities to develop additional operating rules as needed. Can that be construed as us encouraging more organizations to develop rules or existing organizations to develop more rules. It does

not add anything. If someone reads this and wants to develop operating rules, they need to be aware that the operating – in order to have an operating rule considered for adoption under HIPAA, the submitting organization must have the HHS designation as an operating rule authoring entity, which only CAQH CORE. and I am not quite sure about the NACCHO, whether they are designated or not. It seems to be setting up a mechanism that is not necessarily tied to the existing regulations for how operating rules are brought forward for adoption.

Vickie Mays: Thank you. I think I heard you all say those things, but I understand better the meaningfulness of what you said. Thank you.

Jacki Monson: Are we ready for a motion for the entire letter?

Rich Landen: Let me ask Tammy. Have you done – are you finished with your comments on what we heard from the public comment?

Tammy Banks: No. I am concerned with the change in the language and would love time to go through the ACA and figure out are we doing some unintended consequences. A lot of people voted for this, so maybe they know more than I and there are no unintended consequences. I just would like to make sure.

Jacki Monson: Tammy, are you proposing that we give you some time to do that?

Tammy Banks: That would be great. But before we do that, what are the other changes to this paragraph that the Full Committee wishes to make, so we can look at them in the entirety?

Lorraine Doo: I do not think there are any other changes to this paragraph, Tammy. I do not think there were other changes to the letter. Let me go to the top quickly. We had a typo, which we corrected.

Tammy Banks: It is just that paragraph. Someone wanted to strike some stuff and there was other comment on that. I am just wondering what is the --

Maya Bernstein: You always have time after the approval of a letter to perfect the specific language, as long as you are not deviating from the recommendations.

Jacki Monson: With that advice from Maya, would you still like time?

Tammy Banks: Let us go ahead.

Rebecca Hines: Go ahead and what?

Tammy Banks: Go ahead and vote.

Maya Bernstein: Let me make a caveat. This is not my area of expertise just in terms of process. Tammy, you want to be sure that this actually is not contrary to what the – to say this would not preclude that language there. That the added language, this would not preclude collaboration. That sentence. Are you going to look to see if in fact the law would preclude it and therefore it would not be appropriate to say that?

Tammy Banks: Exactly.

Rebecca Hines: I just want to remind members. If somebody wants to call the question to vote on the letter without the amendment, you are welcome to do that right now as well.

Tammy Banks: Let me call that to question. Val, you go first.

Valerie Watzlaf: That is what I was going to do because I do not think that I realized, Tammy, until you explained, that this could go against a rule that you have not been able to really look into it. I would, if I could call the question. I do not know then. Could we vote on the letter without it?

Maya Bernstein: There is a suggestion in the Q&A that might be helpful to you in figuring out what to do here from Ms. Campbell.

Valerie Watzlaf: It says can you add something like where regulation does not conflict - this does not preclude.

Maya Bernstein: That would maybe take care of Tammy's concerns that there might be something in the law. You could make it --

Rebecca Hines: It does not address Rich's concern, however, on some unintended communication.

Tammy Banks: We have to explain entities.

Rich Landen: The added language has been voted upon and approved and incorporated in the letter. The question has been called, and I believe that question is called for the approval of the whole letter, which would include this new language, this one sentence that we just added.

Rebecca Hines: No, just the opposite. Val was calling the question given the comments, to put to a vote the full letter. This would be the final vote. So be careful if this is what you are ready to do without any revisions.

Melissa Goldstein: I do not think you can do that. I think the language has already been amended. We would have to re-amend it separately, then call the question on a vote.

Maya Bernstein: You could vote against this version and then vote to vote on one without the language. Melissa is correct.

Melissa Goldstein: Or we could add an additional amendment that says, within the constraints of the law. But you cannot call the question on a previous version.

Rich Landen: The question has been called so that is an up or down vote on the entire letter, including the amendment that we just approved. If the vote is yay, then the letter is in front of us with the amendment becomes final. If it is no, then we can reopen the discussion.

Rebecca Hines: Is someone going to second the motion?

Catherine Donald: I will second the motion.

Jacki Monson: What motion are we seconding here? What is the motion?

Rich Landen: The motion before us is to approve the entire letter, including the additional sentence that we just added with our previous vote.

Rebecca Hines: Because it has already been voted on. Lorraine, could you stop sharing so I can see everyone and their hands. That would be helpful.

Lorraine Doo: I just wanted to capture that narrative.

Rebecca Hines: Again, if you are voting in favor for this vote, you are voting for the letter with including the amendment that was just approved.

Jacki Monson: Who is motioning that first?

Rebecca Hines: That was Val.

Jacki Monson: Is there a second?

Rich Landen: Val called the question. Tammy seconded it.

Jacki Monson: All in favor, raise your hand.

Rebecca Hines: We have one member in favor of this version of the letter. All those not in favor? Sorry, Jacki. That is your role.

Jacki Monson: All those not in favor, please raise your hand.

Rebecca Hines: We have 1,2,3,4,5,6,7,8,9,10. So we have 10.

Vickie Mays: 11.

Margaret Skurka: I couldn't find my hand.

Rebecca Hines: Margaret is 11. So we 11 and 1, and we are missing one person.

Maya Bernstein: I see 12 hands.

Rebecca Hines: You see 12 hands. Thank you. We are 12 and 1. Then the motion is not approved to – is voted down to approve the letter with the amendment.

Jacki Monson: Where are we going?

Maya Bernstein: Jacki, you may wish to entertain a motion to approve the letter without the amendment.

Jacki Monson: Anybody want to move that motion?

Valerie Watzlaf: I will. This is Val.

Jacki Monson: Is there a second?

Debra Strickland: Second.

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

Rich Landen. Discussion, Madam Chairman.

Jacki Monson: Discussion. I have never taken these many votes in one committee. Discussion. Seeing none, if you approve, please raise your virtual hand.

Rebecca Hines: Again, this is to approve the letter without the amendment. One, 2,3,4,5,6,7,8,9,10. Margaret is 11. Am I counting correctly?

Jacki Monson: Yes, you are. Anybody dissenting?

Michael Hodgkins: Did you ask for abstentions?

Jacki Monson: Abstentions?

Rebecca Hines: Wait a minute. Can everyone take their hands down please? Take your hand down. Please unraise yourself. Go ahead, Jacki.

Jacki Monson: Does anybody not approve?

Rebecca Hines: Wu does not approve.

Jacki Monson: Any abstentions? We have one abstention.

Rebecca Hines: We have Michael abstaining. With that, it is approved. The motion is approved.

Jacki Monson: Congratulations on having your letter approved. Let us move to the next letter.

Lorraine Doo: To confirm, that is the letter with the revised language?

Jacki Monson: Without the amendment of the revised language.

Rebecca Hines: No edits other than typos.

Tammy Banks: Just the K, the letter K. And then X12 will be brought up. I do not know if we need to bring it up because we just looked at it.

Lorraine Doo: I am happy to bring it up. Let me just grab it. X12.

Tammy Banks: Michael, did you have comments on the X12 letter?

Rebecca Hines: He just unraised his hand.

Lorraine Doo: You can see the X12 letter, folks?

Tammy Banks: Anybody have any last-minute comments or questions before we call it to vote?

Lorraine Doo: Let me just confirm that there were no typos on this one that we did from – this is one.

Rebecca Hines: Tammy, you just want to remind people that you just moved the phrase, use cases, in this one sentence. No material changes. Is that a fair assessment?

Lorraine Doo: Yes. Let me just confirm. That was the only one.

Tammy Banks: Okay. Jacki, hearing no questions or comments, can we make a motion to approve as is?

Jacki Monson: Yes. Does anybody have a motion?

Debra Strickland: I make a motion to approve the letter as written as revised.

Jacki Monson: Is there a second?

Michael Hodgkins: I will second. This is Michael.

Rebecca Hines: Lorraine, can you unshare your screen and then all those in favor, implement the virtual hand. One, 2,3,4,5,6,7,8,9,10,11,12 – there we go, 13. It is a unanimous approval.

Jacki Monson: Any discussion? It is considered approved. Let us move on. Congratulations.

Valerie, take it away.

Subcommittee on Privacy, Confidentiality and Security

Valerie Watzlaf: Okay. I think we have – I will just ask Maya. Do we have a letter or themes or both to go through?

Jacki Monson: I think we should go through themes first and then go to the letter if we have conversation based on the themes. Maya, do you have any friendly amendments to that?

Maya Bernstein: No. I have a file here listing the major themes of our discussion. Some of them you will see. If I can share my screen. I am on my little screen here. I usually have two. But where I am now in New Mexico, I do not. I do not know if I can see all of you while this is going on. Jacki, Val, Melissa, I will defer to you to call on people as their hands are raised. I cannot see it. I am just going to try to take notes here for you in public. We also Grace Singson, who is also going to help us take notes.

I will say this – we have not had a chance to reconcile all the comments together that have been submitted on the letters that we are doing. It might be a little awkward truthfully. We are going to do the best we can today to get through and make sure – if I can add to what the committee members want to say about these topics and gauge your level of agreement and whatever discussion you would like to have, and we are going to make sure that the letter properly reflects those views by doing a reconciliation of just things that came in at a different time. We have some time to do that tomorrow as Val said in her very eloquent presentation this morning. We have to turn them in by Friday. We have a little bit of time to reconcile and make sure we have the language right before we submit them.

Valerie Watzlaf: And we definitely do want to hear from anyone else, too. We certainly want to hear your comments today. Please feel free.

Melissa Goldstein: And the public comments as well.

Maya Bernstein: I was surprised truthfully, we did not have any public comment. Do we have another public comment session on this?

Rebecca Hines: We do not.

Jacki Monson: We took all public comment at the same time.

Maya Bernstein: I was surprised we see anything on this particular thing, but also other people unlike the standards letters, other people have an opportunity to weigh in on their own.

I put together – no one has seen this really. I just put together this list of the major topics. I hope I got them all. Feel free to add one that I did not capture. I will defer to the co-chairs or Jacki on how you want to run this meeting. I am just here to support that. But this is the – is it big enough for people to see first of all?

Valerie Watzlaf: Yes. I think it is fine. I think we can go through and then maybe --

Maya Bernstein: You can see. There is quite a list of topics here. I tried to put the major ones at the top. There are quite a number of them, as Val pointed out this morning.

Valerie Watzlaf: And Maya, these are the same – similar ones that we did call out in the beginning of the letter that deals with the summary?

Maya Bernstein: Yes. That is right. There are some other – the summary, as we have been talking about, is going to have to be produced after we figure out exactly which points we are going to keep. Some we may decide not to – you may decide not to keep in the letter either if there is no consensus or you just are not ready to comment on this for whatever reason. They are listed here. Why don't we just try to plow through as much as we can and see where we are?

Valerie Watzlaf: We could start right at the beginning, I think, and just look at the structure where it says we do endorse the structural approach of the rule that requires attestations for certain requests of records for records. And then I think – I guess that would separate in relation to the tone. I think that is another --

Maya Bernstein: Each of these bold ones are intended to be a different topic.

Valerie Watzlaf: Any comment on the first one there about the structure?

Melissa Goldstein: Val, are you talking about the structure of the rule or the structure of the letter?

Maya Bernstein: The structure of the rule.

Valerie Watzlaf: This deals with the rule that requires the attestations.

Melissa Goldstein: And essentially, we are asking committee members if everyone is happy with the structure of the rule as described in the letter.

Maya Bernstein: No. That is not what I intended.

Melissa Goldstein: We have to reconcile our views as reflected in the letter. These are major themes in the rule itself, that you want to discuss instead?

Maya Bernstein: Not instead. What I was trying to do was say, to talk about the topics in the rule and whether there is something about the rule that you want to comment on, positively, negatively, and so forth. The very most high-level thing is the rule itself has this structure. It sets up an attestation for certain parties that are required. I have not heard truthfully, any particular comment or objection to that in the discussion that we have had leading up to it. People are pretty much satisfied it seems or have not taken an issue with the idea of having an attestation and so forth.

We have not commented on that except at the very beginning of the letter that says we generally agree with your approach.

Melissa Goldstein: That is helpful because some of these themes are themes that we have been discussing that are already in the letter like tone of letter. Legal versus illegal care. Structure is different. You want us to comment on the structure on the rule and if we have any issues about it.

Maya Bernstein: Right but each of these is sort of what comments you might make about what the rule is. That is what you are commenting on. If you want --

Melissa Goldstein: Specific to what is written in the letter.

Maya Bernstein: Yes. If you have particular ideas about what is written in the letter, we now have two versions. I can call both of them up so you can look at what we said, and we will have to find some language between those two, or going with one or the other or however to reconcile the language, which we just have not had time to do. It is very complicated. There are a lot of topics, and it is very complicated.

We are not as far along in the development of a letter as we have been with the standards. But I thought it would be helpful to just gauge to see where people are with these topics, some of which are not particularly controversial like the structure of the rule making –

Valerie Watzlaf: I don't think we really received comment on that.

Maya Bernstein: But we affirmed that this structure is okay with us. We endorse the work that – in all the draft, it says we endorse the work of the department. We endorse this approach as appropriate, that kind of thing.

I just wanted to ask if there is any further issue or comment or objection we hadn't heard about that. If not, we can just move on. The tone maybe is something we want to take up later after we talk about the particular topics. I may have gotten the order wrong here.

Melissa Goldstein: Val, do you want to walk through them?

Valerie Watzlaf: The first one there – because we can come back to the tone of the letter – was really dealing with the third bullet or the third bold there whether – distinguishing between care that is legal versus illegal. Which I think I did bring up a lot of these earlier this morning.

I do not think anyone has an issue with that. I think everyone has seen many drafts of the letter too. But if you do, please bring that forward.

Maya Bernstein: I can call up what it looks like in that discussion if you want.

Melissa Goldstein: I think let us just go through this first. What I would say is that as written here that the department should consider not distinguishing, is a good way to phrase it. Tone is my – I would say, my largest concern about the letter as written. As long as we say the department should consider not distinguishing, I think it is fine. That there are suggestions for the department.

Valerie Watzlaf: Is there any other comment regarding this area? Okay.

Hearing none, let us move on to the next section, which is looking at the difference between – if you are going to consider requiring attestations that is just specific to reproductive health information or potentially related to reproductive health care, because that can be so broad, would it just be better to require those attestations for all requests and would include all records? Is there any concern about this area? Questions, concerns?

Melissa Goldstein: Again, we have first noted in the letter as written, that several of my colleagues have brought up issues that could arise in terms of implementation of the current requirements as written in the NPRM and that one of the possibilities of alleviating these concerns and issues with implementation, could possibly be extending the requirement for attestations to all PHI as opposed to limited to particular types, meaning reproductive health care. And again, I say my point is that it is an idea for the department to consider, but not necessarily – well, essentially that it is an idea for the department to consider period.

Valerie Watzlaf: Which we do have there.

Maya Bernstein: We tried to capture that kind of tone.

Valerie Watzlaf: I know in the letter it does go into the burden this would place on covered entities, which you just stated.

Melissa Goldstein: That our colleagues have their raised their hands in response here. That is why I wanted to bring u that particular issue so that they would –

Valerie Watzlaf: There is Michael. Go ahead. And then Vickie.

Michael Hodgkins: I was just going to say that I think this is a particularly important recommendation for the department to consider. In the letter, it is made in tandem with the thought that if they only want to consider attestation in the cases where reproductive health care information is being solicited that they need to define reproductive health care better than they have. I just wanted to point out that those things are in tandem in the letter.

Valerie Watzlaf: And we do have that I think in the next bolded there. Right underneath it does say that. Thank you though. I appreciate that comment.

Go ahead, Vickie.

Vickie Mays: I agree with what Michael was saying in the sense of how important I think that particular issue is.

The only thing I am going to differ on with Melissa is kind of the tone and the strength by which we say what we say. I think if we were writing a letter that is a letter of recommendation that was just us, I might be kind of a little more on the side of modulating our tone. But I like that our opinion – and this is an opinion we have been asked for, that in the opinion that we qualify it by the strength of our belief about that opinion.

I am a little less – when I read the letter, I thought it kind of took some of the oomph out of it. But in general, I think what we are saying is fine. I just have a different sense of the tone by which we convey the importance of these things to us.

Melissa Goldstein: I would just respond to Vickie there by saying I think I take the exact opposite on a comment on a rule, a notice of proposed rulemaking, an actual regulation, and a committee's discussion and bringing up ideas on our own in a letter like we have done with the standards letters.

I would also remind everyone that we do have hearings planned on July 19th and 20th, and that we are planning to discuss the general issues, not the particular NPRM necessarily, because the deadline for comments is Friday, like Maya have said. Actually, I guess Thursday midnight. I am not entirely sure about the exact timing.

Maya Bernstein: 11:59 p.m. Friday.

Melissa Goldstein: As a lawyer and law professor, maybe that is where I am coming from here. But I do have a different perspective of that, which it is fine that we have different perspectives of course always. I do believe that it is something that the department should consider. I would not say we strongly recommend. I would not say we strongly urge, things like that in terms of tone of the letter. But obviously, people have different opinions about that.

Valerie Watzlaf: Thank you.

Rich.

Rich Landen: I guess it is the question for the subcommittee members who have been looking into this. The concept of requiring an attestation for pretty much everything has the beauty of simplicity. On the other hand in thinking it through from a burden perspective if 99.9 percent of the attestations are just simply pushing paper, then there is value added and indeed we add to the cost and burden to the system. My question is do we have any concept about the two approaches, how will – what will the volume look like with one approach versus the other? In other words, if we can reduce the volume significantly, then adding the complexity of going to a targeted attestation around reproductive health and giving the previous comments about better defining that might be the way to go.

If there is not much difference in volume, then the simpler approach as just getting attestation for everything would make more sense from a systems perspective. Any idea by any other member what the difference in volumes would be under the two approaches?

Valerie Watzlaf: I think what we heard from our colleagues that it would be much more difficult to parse out information where it is specific to reproductive health care and that that would become more

burdensome. I am not sure that we know about the true volume of that. But I know that was brought up before by several others.

Michael has a comment. He may be able to add more.

Michael Hodgkins: I have no idea about the volume. I think the implementation issue was the one that really came to the forefront because reproductive health care information can be in many different places in electronic records. It creates the opportunity to inadvertently share such information when a request for PHI is being made on another subject.

I think the other point where I think that this suggestion about attestation for all PHI – it is linked to when that – I believe it is linked. The members of the subcommittee would be able to weigh in on this. I thought the attestation was specifically tied to requests dealing with criminal administrative, blah, blah, blah.

Maya Bernstein: That is correct. There are four places, four kinds of requesters. It is not all requests.

Michael Hodgkins: We are not talking about attestation for any request of PHI. We are talking about attestation linked to those four areas. While reproductive health care, obviously is the issue that has come to the fore given the recent Dobbs' decision. There are other aspects of health care that are coming under legislative attack, for instance, gender-related care. I think requesting attestation when it is linked to those four things for any health care information also then provides privacy protections for individuals seeking gender-related care.

Valerie Watzlaf: Thank you.

Go ahead, Vickie.

Vickie Mays: I just want to respond to Melissa just to be on the record here because I agree with Melissa that we can agree to disagree. I do think there is a difference between where we are operating alone writing a letter from hearings and stuff like that. And maybe I have a really big bias because this secretary used to be my attorney general. I know how he considers information and that when he hears from people, he weighs it based on credibility, authority, et cetera.

I do think for this we ask for opinions. I think opinions can be given with weight that differentiates the extent to which you support or believe a particular issue, not that we threw out this whole thing – advocates and just anything for the issue. We are just on top of it and say do it, do it, do it. We are very measured in what we do.

I do think that if we are of an opinion about something that we think is a central data – and we come from our expertise in that, we should say it because I think that helps him and whoever is working with him in their decision making rather than everything is conditional. Maybe things should be conditional and there should be things that the strength of the weight of our opinions. I am just going to leave it at that. He is an attorney and he is pretty good. That is my bias.

Valerie Watzlaf: We appreciate it. Thank you, Vickie.

Jamie.

Jamie Ferguson: I wanted to respond to I think Rich's concern about the volume of attestations on all requests for PHI versus those that may potentially be related to reproductive care.

In the first place, even a narrow definition of reproductive care – that kind of information will be found in all kinds of different record systems, all kinds of different specialties and so forth and different parts of the EMR and many other systems.

When you talk about information that is related to reproductive health care, it broadens it further. When you then talk about information that may potentially be related to reproductive health care, that broadens it to practically if not truly all systems, all databases, all records and all record types. I do not think it is a material difference in volume or for all PHI versus request that may potentially be related to some kind of reproductive health care. That is the first point.

And then the other is that if you are aiming for administrative simplicity and efficiency, it is far more efficient to require the attestations for all versus something that is extremely and I would say unduly burdensome to try to segment or identify under a broader definition.

Valerie Watzlaf: Thank you, Jamie.

Melissa.

Melissa Goldstein: I cannot claim to know the secretary or the secretary's points on this. Vickie has that California thing going. But I would say that this is a notice of proposed rulemaking that has followed the Administrative Procedures Act that has come out of the agency, HHS, that no doubt these issues were debated quite completely at the agency level, that it went through OMB as well before being released. I do respect the decisions and the pluses and minuses, benefits and burdens that were weighed at the agency level, which is essentially what I am trying to respect here.

I absolutely agree that we should say what our opinions are. I think the crux of the nub here is that we have different opinions on what we might want to say and my effort is really to reconcile that by instead of having – by using what Vickie might have said and maybe like water-down language like consider this because I think we all do want them to reconsider the decision to think about the issue and to raise the issue for the department to think about. I do not know that we all would want them to make one decision versus the other and I am not sure that we can say that in one letter, but we can all say that we want you to think about it again. Go back to the drawing table and think about the difference in light of all of the concerns that have been expressed by Michael, Vickie, Jamie so far, and everybody else during our discussions.

Margaret, I am sorry – you may not be on mute but I do not know if you were trying to say something to me. No. Okay. I just wanted to answer Margaret if there was a question for me.

Valerie Watzlaf: Thank you, Melissa.

I do not know if Margaret knows, maybe she is not on mute. She may want to mute her --

Rebecca Hines: Mike, could you mute Margaret Skurka's line please. Thank you.

Valerie Watzlaf: Anything else on this? Thank you. Thank you so much, Maya. My goodness. You are great in taking notes. You are so quick.

Maya Bernstein: I type quickly but it is mostly for me to go back and remember where the conversation was. We do have a summary made of these meetings, but it takes a couple of weeks to get. It is not going to help us tomorrow when we need to put this together.

Is there any feeling or reconciliation about the discussion that we have just heard? For example, I would like to know when drafting, because we have the different opinions that have been expressed here, are both now – I am trying to figure out when I am drafting for you, what is the thing that is going to be in the committee's voice so I can capture that.

Is it worth calling up the letter as an example while we are at this discussion, and then moving on to the next one? How do you want to proceed here?

Valerie Watzlaf: I think there are some because we are hearing that sometimes I think from Vickie that the letter should be stronger and then I think from Melissa that it should be more of consideration.

Maya Bernstein: Conciliatory. One thing I heard from Vickie is there are places where she might want to be stronger and places where she – and I do not know if she can identify those now the certain things. I heard Val, for example, during the conversations that you felt strongly about certain pieces of the comments and less strong about our other pieces.

Valerie Watzlaf: Right. I did say that particularly –

Vickie Mays: I am happy to do that –

Valerie Watzlaf: Good. That would be very helpful, I think.

Vickie Mays: You got it.

Valerie Watzlaf: Thank you. That is great. Because I think in the next part, we do say – which we are giving consideration to a lot of things. We do provide options. In the next part, it does say that if the department does want to continue to use the definition of reproductive health care then to define it specifically particularly for the – and we provide ways to – we keep saying if you are going to go back to that. It is not like we are saying they have to do this or anything. There are options that are provided and that is what the next part says. I think that is in relation to the attestations.

Maya Bernstein: I am looking at this and realizing I was not very clear here of something that we -- I realized in the drafting that we did last week was that the term reproductive health care and this is a new definition in the rule is used in two different ways. We have a section of the draft that addresses each way separately. One is that it defines as we were just talking about which records. When a request comes from one of those four entities that would be required to make attestation if the rule was made final. Judicial – tribunals. Various kinds of tribunals, different kinds of law enforcement, health oversight and coroners, essentially, investigative types of entities.

The attestation applies to when records that are reproductive health records would be caught up in the request. That is one way it is used and that is what we have been talking about.

The other way that it is used is that the attestation itself says you may not – we agree. Those of us who are signing an attestation, we agree that we will not use or disclose whatever those records are that we got for the purpose of I am going to paraphrase informally but targeting a patient or a provider or a third

party for seeking, obtaining, providing, or facilitating health care. It is used in the prohibition on use in the second case. It is used to define the group of records that might be caught up in the first case. There are two different ways it might be used.

I think we are saying that in either case it is useful to understand and for various reasons, there are reasons to expand to all records but different reasons for both of those two cases. Does that make sense?

Valerie Watzlaf: Yes. Thank you for that.

Maya Bernstein: Here, I only use the – potentially related to – that language comes up in the request for records. We were looking for any records that are potentially related to reproductive health care. It does not have to do with the text of an attestation itself.

Valerie Watzlaf: And as you said, maybe doing away with potentially related to because that just broadens it even more.

Vickie, go ahead.

Vickie Mays: Maya, I am not sure I will know in the document when it is the one meaning or the other meaning. Can you go through and make sure that the statement is aligned with the two different kinds of meanings?

Maya Bernstein: In the last draft that you saw, I did that. It may not have been clear that that is what I was doing because they – but I did try to do that to make clear that the arguments about potentially related to reproductive health care relating to which records are caught up. Those are the kind of discussion, the colloquy that just happened between Rich and Jamie and Melissa and so forth. The idea of burden, what kinds of burden. It is not really about volume but more about can you actually separate things out whether segmentation is possible, available – the cost of that. That discussion as opposed to should we expand the prohibition in the attestation, saying I will not use the records against a patient. And there are different policy reasons why you might want to do that to protect the trust in the system, the patient and the provider not being – not second guessing when care is legal or not. It is not second guessing which care counts as reproductive health care or not if it is not well defined. That sort of thing.

And maybe even avoiding some of this --

Melissa Goldstein: Are we talking about the definition here, Maya? Is that what you are talking about here or are you going back --

Maya Bernstein: It is related. It is the idea here – I did sort of started talking about the definition itself. Sorry about that.

Melissa Goldstein: I do not think we can know whether there is a volume issue at this point or not. We would be asking for something that is not currently included. I do not think we have evidence. I think all of that is really speculation on our part. I think we really just do not have any evidence. Of course, it is informed speculation, but it is still speculation. I do not think we can really answer that question 100 percent. I think Rich's question was actually quite valid about volume.

I think there is the extension issue, which I would separate from – the next bullet is if you decide not to extend it after you revisit it – the definition, then we recommend we agree – we recommend that you consider. We believe you should consider a different – an easier definition to implement possibly more specific. Here is when I think the language that is included in the current draft about the current definition being quite broad – I think one version used the word swallow, the distinction, eliminate the distinction like what is it.

Maya Bernstein: My point when I originally looked at the structure or this piece of the rule, they are not really using the term reproductive health care just as they defined it, which is already broad. They are saying related to and then potentially related to. And somebody earlier said that was starting to expand to be almost everything anyway.

But I also think that there is another issue besides Rich's that someone, Jamie or Michael perhaps, stated about that the issue is not necessarily the volume. It is more about how complicated it is to find the stuff.

Valerie Watzlaf: Michael has his hand up again – he wants to elaborate and then Jacki as well. Go ahead, Michael.

Michael Hodgkins: I wanted to reiterate and I think Jamie actually captured this better than I did initially. The question is not volume. The question is where is this information? It is in so many different places. And the risk of exposing this information is too high.

Related to that and I do not know if Vickie will note this as an area where she believes we should be stronger but I would say that if we are going to be stronger somewhere, I would certainly vote for placing more emphasis on the recommendation or whatever we are going to call it that that attestation be required for all PHIs when it is related to the four areas that are mentioned in the letter. It has to do with this issue of implementation. Again, the potential for reproductive health care related information to be located in so many different areas and so many different databases I think the risk is too high if we do not require attestation for PHI whenever it is tied to those four areas and by also requiring PHI or rather attestation for all PHI when it is tied to those four areas, we are now also providing protection for other areas such as gender-related care and so forth. Who knows where these state legislatures are going to go in the future in trying to interfere with the doctor-patient relationship around such private matters?

Valerie Watzlaf: Wonderful. Thank you, Michael.

Jacki.

Jacki Monson: Michael, I agree with your comments generally and many of you know that I am in the health care provider space and I think we are going to defer to the physicians if the definition is not clear or it is too broad because I am not, as a layperson, going to decide what is reproductive health and what is not. But I can tell you that in preparation for our own comments to the rule, the NPRM, we pulled a couple of records and in those records, reproductive health in some way, shape, or form was mentioned thousands of times. We know for public health, for COVID, all the things, those records went everywhere. There is just no way to put the protections in place so we would want to, as Michael commented, without having the ability to do that. I think we underestimate every time it comes up.

It could come up in an ED visit with respect to them wanting to give you medication. You might have to get a urine test if you are of child-bearing years. There are just so many ways with such a broad definition of reproductive health that it can come up that it would be very burdensome to the health care provider and although, Melissa, you are right. We cannot put a number on it today. I could put a pretty close number to that by just pulling those two records and commenting how many times reproductive health was mentioned. I would always defer to the provider if there were not a clear definition and a regulation to tell me whether it is or not. I think that impacts the time with the patient. It means less time with a patient potentially or it means to have these conversations upfront.

In some cases, when you are developing the trust of your provider and you are talking about very sensitive topics, it might actually impact your comfort in dialoguing. We really do not want to implicate the physician-patient relationship in this area and I do not believe that was the intent of the proposed rulemaking. It is an unintended consequence in the way that is currently drafted.

I think to Vickie's point, some of these things we should be commenting pretty direct on because I think our opinions are valued. We were specifically asked to comment, and I think that is part of our job with NCVHS is to be direct where we have strong opinions and feel like it should be absolutely considered.

Michael Hodgkins: Just to pile on, as a primary care internist when I was practicing, as part of the review system with any woman of childbearing years, the question is always asked, how many times have you been pregnant, how many times have you carried to term, and have you had any abortions. That is in a routine new patient visit record.

Valerie Watzlaf: Thank you, Michael.

Melissa has her hand up.

Melissa Goldstein: Thank you guys for voicing all of these issues. It is exactly the – I think it is important for the public to hear all of the issues that people are no doubt struggling with and wondering how to implement this rule.

I do think, however, that our role is to suggest, it is a reply to a notice of proposed rulemaking, and to suggest that the department consider what we think they should suggest. I agree with you that these issues should be considered. I think the differences, how strongly when you state them, whether you direct them to (inaudible) something. We are not a law-setting body. We want them to consider all of these issues that you were raising. That is what we want them to do. That is all I would say.

Valerie Watzlaf: Vickie. Thanks Melissa.

Vickie Mays: I just want to pick up on something that was somewhat implied in what Jacki was saying that I think should be kind of raised up in this. We have been clearly talking about protecting their providers. We have also been talking about protecting the patients in the sense of commenting in a way in which where we have the expertise to know that something could go awry, and they do not and it is an unintended consequence that what we are then doing is impacting the fact that they will not trust a health care system. They will not come back to the health care system.

I just want to say that there are layers in which it helps us to define how strongly we are saying something and I think the subtleness of those layers are sometimes not known to people who are either not providers or not working at different places in the system.

At one point in this letter, we are worried about people who are helping people, people who are the pharmacists, people who are driving people. I think that there is a complexity that I want the public and others to recognize of what went into this and the strengths sometimes of what we are seeing really is a function of there is an attempt to protect more than just the identified provider or the identified patient.

Valerie Watzlaf: Thanks, Vickie.

Melissa, did you have another comment or was your hand – Michael.

Michael Hodgkins: I am not sure what the best language is here and I understand the point that is being raised about our role. There is a place in the letter and as I recall, it is actually somewhat disconnected from this question about attestation that had to do with unintended consequences for the health care system in terms of residencies and other training programs for physicians.

Maybe one way to handle this is to use some language when we are talking about the suggestion of attestation for all PHI to referencing unintended consequences because I will note that there is a lot of rumbling in the medical community about people now making different choices about where they want to go to medical school because of these laws and certainly where they intend to do their residencies because of these laws. This whole area could be enormously disruptive to the health care system and access to health care.

Maya Bernstein: -- find a couple of articles just about that because people are asking about citations and stuff. I think it was in a Post article about – or maybe it came from – and I do not remember what the citation is but specifically saying that we can already see the changes in people's preferences for residencies or areas of practice, places to practice in terms of states. That obviously has other cascade of other possible consequences to access and disparities and so forth.

Michael Hodgkins: It has consequences for the patient as well. I am sure we have all heard stories or seen stories in the news about people considering moving out of their state because of these laws.

Valerie Watzlaf: I just wanted to mention too that I think a lot of these things that you are bringing up today are in the letter. Do you agree, Maya? I think the tone issue is still not addressed. That is probably the biggest thing. But many of these things – I do not know that we have elaborated or it has been elaborated as much. But I know that a lot of these issues have been included. I do not know to the extent.

Melissa Goldstein: I do not think anyone disagrees about the importance of addressing these issues. I do not think the department – I cannot imagine that is the reason for putting out the NPRM to begin with. In response to Michael, I think that you are absolutely right and I think everybody agrees on the importance of addressing the issues. I think the job here is to address the NPRM and the language in it and how would we like it to be different. How would we suggest that they revisit the language? I do not think anyone disagrees with the issues and I think it is important to bring up the mechanics that might cause the issues that you all have spoken to about implementation and where it would go and how it would go.

Maya Bernstein: Can I just make a time check? I love this discussion and the richness of this discussion. I want to make sure that the committee has an opportunity to talk about some of the other things that are in here. I see that there are things going on in the chat, which I cannot follow while I am doing this. If

people have strong feelings about it or if the co-chairs want to follow that and bring up any issues or invite them to speak out loud about something that might be in the chat, that would be great.

I did capture the idea of swallowing --

Valerie Watzlaf: We can keep going.

Maya Bernstein: We do not seem to have a disagreement about saying -- let me ask this to clarify. Does anyone object the idea of saying we should suggest or recommend that the department consider language like that, expanding to all – I am going to be precise – the records that may be an issue in an attestation to all records and in the alternative if they do not do that to define reproductive health records more specifically. Are there any strong objections to that approach to this comment?

Valerie Watzlaf: Are we looking at a particular bullet here?

Michael Hodgkins: Instead of records though, wouldn't it just be --

Maya Bernstein: It is PHI. I am trying to be precise but I am not being – that two-part approach and then we are going to have to talk about the tone of how we say that.

Melissa Goldstein: We are still back at the top. You did not move down to further additional themes.

Maya Bernstein: I just have a lot of stuff in here that I try to get it all in my one little screen. The second theme is about the definition – to define the definition very specifically to make it implementable in the alternative.

If you want to see what that language looks like now, I can call up the letters and we can look at what that language looks like, or we can move on to other things just to gauge where people are in terms of their thinking about that. I see Jamie has a hand up.

Valerie Watzlaf: Go ahead, Jamie. I think we might want to go through the rest but go ahead, Jamie.

Jamie Ferguson: I was going to suggest that we move on. I think that we have a lot of input on that and we will have opportunities to refine the language.

Valerie Watzlaf: Thank you.

The next section was clarifying the definition of person, I think. We just put --

Maya Bernstein: I think Jamie raised a comment about that in his more recent comments. I do not have a description there because I was not quite sure. The definition of person says that the definition – a person includes both a natural human person and also corporate persons and organizations. But in terms of the definition of human natural person, it refers to an existing definition in the US code. It says a person is someone born.

There must be a place where that is used, Jamie, that was important to something you said and I did not quite capture what that was. I am not being that helpful. Is that enough – talking about? No.

Jamie Ferguson: Let us come back to that.

Valerie Watzlaf: Just looking at available authorities, other authorities.

Maya Bernstein: The department has other authorities obviously. They are not in HIPAA. We have, for example, Medicare results of participation. We put rules on any time someone gets money, grants, contracts, other kinds of things, any federally funded programs, what happens in our community health centers, for example, that are funded by HRSA. All those things have rules associated with them because we are giving money. And if you want the money, you have to comply. Those are authorities that could be used to protect reproductive health information. That even could be used to – not all regulations are focused on one single authority. Many of them use multiple authorities to affect the policy that they are trying to affect. That could be the same in this rule. It just has not traditionally. The department has not traditionally done that for this rule but could.

Valerie Watzlaf: We do have in the chat that Jamie said he think his intent was to recommend that HHS affirm that providers or other CEs engage in providing or facilitating reproductive health care on an individual basis are excluded from the definition of public health activities because such activities such activities are better defined as being diagnosis or treatment related.

Maya Bernstein: We are going to have a section on public health activities. Let us move that to there.

I put this on this list toward the top because it is not something that we discussed a whole lot but it is in the draft of the letter. I do not know. People have not been talking about it so I cannot gauge the attractiveness or not of this kind of idea among members of the committee. There is a very short paragraph there that says something like that.

Vickie Mays: I think we talked around it sometimes but, for example, the role of the FDA in this process was – we thought was pretty important. It is not like at times where we have talked about is this the I do not know Federal Trade Commission or something. The FDA plays a very central role. I thought at one point – we even had a recommendation for HHS or we talked about HHS reaching out to the FDA. I do think this is one that we should keep because of the importance of the FDA in this process.

Maya Bernstein: Just to be clear, we do not call out any particular agency. We just say use other authorities available to the department.

Vickie Mays: Right. That is what I am saying. Because we are not doing what we have talked about at times, which is to bring up names, I think it is important that we at least say this as we may want to think about whether to mention the FDA because of the critical role that FDA plays in drugs and then we would be talking about pharmacists, et cetera. Yes, let us keep this and this is one where I would say do we want to be a little stronger than we have been in terms of talking about the FDA in particular.

Maya Bernstein: -- willing to draft up a sentence or two in the background because I do not think we have a sentence on that right now that would capture your idea there?

Vickie Mays: Yes.

Maya Bernstein: Thank you.

Michael Hodgkins: I was going to say I would not limit it to FDA. Actually, the FTC has been much more active in this area with respect to telehealth relying on the HBNR, the Health Breach Notification Rule.

Valerie Watzlaf: I thought we did mention FTC but maybe not under this section.

Michael Hodgkins: I guess what I would suggest is rather than naming names, just encourage them to coordinate with other agencies who have an interest in privacy that is not covered under HIPAA.

Maya Bernstein: Melissa, I see your hand up.

Melissa Goldstein: I think that we have bright language in many of our other letters about coordinating with others. I think the language that we have used all authorities within HHS because obviously HHS has no power over the FTC. All of the authorities within HHS, which includes FDA and all of the agencies because FDA is part of HHS and work with all of the agencies outside, which I believe is already happening across the administration. I think that we have some standard language like that in other letters that might be easy, Vickie, if you want to include.

I do not know that calling out the FDA necessarily makes sense because then we are leaving out CMS, all of the other areas, HRSA. We could. It is just that runs into a little bit of the problem that we ran into with the first letter today where you call out a few. That does not mean we are excluding others. We have to add just more language about that.

Maya Bernstein: Right. With CDC and Indian Health. There are a bunch of different agencies that would have authorities in this area that we have not had time really to --

Valerie Watzlaf: We could list it as examples rather than –

Jamie.

Jamie Ferguson: I do not because I cannot see the rest of these bolded subject areas. It is maybe covered later. But I would say in terms of authorities, of course, HHS has a lot of contracting authority, most notably the 21st Century Cures Act, TSCA, the extension of HIPAA as contract provisions in the common agreement and enforcement of that is an authority that we should mention in the letter and also it needs to go here. HHS has used the contracting authority in other cases in conjunction with OPM and other parts of government that are maybe additional ways of ending the reach of this rule beyond HIPAA covered entities.

Valerie Watzlaf: Great. I believe that is also in the letter but I am not sure if we wanted to move it into another section. But that is in the letter, I think, as well. We talked about should it be later or keeping it where it is. Thank you, Jamie.

Maya Bernstein: Anything else on other authorities?

Valerie Watzlaf: The next area I think would be under the redisclosure. I do not believe we had any comment on that either in the past. That has been in there. Or was that something new that you might have added or expanded?

Maya Bernstein: I think there has been a sentence or two in there and then we just –

PARTICIPANT: -- in the current summary at the beginning.

Maya Bernstein: But is there a discussion in the letter about it? I am not sure that there is a discussion in the letter about it because we had focused on the other more overarching --

Melissa Goldstein: I think it is a short paragraph. I do not think we go into detail but it is mentioned because you also mentioned in the letter that CFR that Part 2 exists and its current iteration. It is mentioned. It is quite a long letter. But it is definitely mentioned.

Valerie Watzlaf: I do not know. Would you like me to read a comment that came from Lisa McKeen in the chat about – it was about the FTC, I believe. It says to comply with the FTC Act in HIPAA, you must confirm that all required privacy rule statements are made in your HIPAA authorization and per the FTC Act, ensure that taken together, these statements do not give a deceptive or misleading impression.

Maya Bernstein: She is talking about the notice of privacy practices? That kind of statement that a covered entity might make? Require privacy rule statements.

Melissa Goldstein: And there is a section of the letter devoted to updating the notice of privacy practices.

Maya Bernstein: We are getting to that.

Valerie Watzlaf: We are still on re-disclosure. Anything more on re-disclosure or the attestation?

Maya Bernstein: Telehealth. Michael.

Michael Hodgkins: This is where I start to nerd out.

Maya Bernstein: On telehealth?

Michael Hodgkins: The definitions here are a mess. I am not sure what you had in mind. Some people tend to limit telehealth to audio and/or video interactions between clinicians and patients. That would be covered under HIPAA because that is no different than an in-person encounter. Other people then use the definition of telemedicine, which is more encompassing and includes the use of digital apps. And of course, as we all know, unfortunately, health apps are not covered under HIPAA. That is where FTC has been taking enforcement actions. In fact, one of those enforcement actions was against an app company whose app specifically deals with reproductive health care. The FTC (inaudible) for violating patient privacy. When you use telehealth, I was not sure what your intention was.

Valerie Watzlaf: I think what we were trying to do here was really talk about when telehealth is used by a provider across states and where the provider may be in a state where the reproductive health care would be considered legal but then providing that care to a patient who is in a state where that reproductive health care is illegal.

Michael Hodgkins: That is a fair distinction.

Maya Bernstein: Or the opposite.

Valerie Watzlaf: Or the opposite. And there was no discussion. There was nothing in there about that.

Michael Hodgkins: I recall that now. I think that that is an important point. Perhaps you could consider expanding the discussion to include the use of health care apps that are not specifically covered under HIPAA.

Maya Bernstein: See next topic. Interoperability.

Michael Hodgkins: Interoperability is not quite the same thing.

Maya Bernstein: The reason I called it that here or it was called that here is because the interoperability rule of CMS and the rule from ONC on information blocking that were issued on the same day – I think it was May 1, 2020 – together encouraged the use of APIs for the ability to provide apps and also for patients to be able to download their personal health information onto their own – you cannot see my little device that I am holding up here because – on their own device. Privacy was not – the privacy, as you were talking about, was not addressed in those rules. This is something that I brought in truthfully to the discussion and there has been some disagreement about but the idea is that the rule in May 2020 did not address privacy. Some commenters did comment that they should have done so including the AMA. In a post-Dobbs environment, the risk might be much greater.

Lorraine Doo: I was going to say, May, they do address privacy. They refer to the privacy rule. ONC worked very carefully with the Office for Civil Rights. But it is how they pertained to them in terms of those uses and disclosures because apps are under the FTC I think as someone was intimating. Apps are – because they are separate devices, they are not covered by the HIPAA rule because those entities are not HIPAA-covered entities. It is a very – complications related to that --

Maya Bernstein: It is true. They address it in the following way and to be more precise than I have been. An app could be covered by the HIPAA privacy rule if it were offered by a covered entity and if that – provided like your personal health record. It could be but most of the time, it may not be.

A lot of the question is here is a case where the department may have some authority. Yes, FTC is now covering it because it is just not covered anywhere else. As a consumer app or whatever, something available to consumers, FTC can cover it as much as their authority will allow. I know that other people have comments on this so I will be quiet now.

Valerie Watzlaf: Vickie has her hand up and then Melissa.

Vickie Mays: Maya actually started what I was going to raise because there are, at least in our health care system, wearables that are covered under HIPAA. Some of them have even been designed by the UC system or what have on.

But here is where I think we did have discussions that brought up the FTC. I want to ask Michael a question, which is – Michael, do you think that it is important for us to make some kind of definition or explicate better when we are talking about telehealth versus telemedicine? I know there are some of us that are really clear about those differences and it is when we do telemedicine that you think much more about some of these apps and what have you.

Can you just kind of continue what your thinking was about the telehealth versus telemedicine?

Michael Hodgkins: I am sorry who made the point. But the specific reference to telehealth in the draft letter had to do with telehealth across state borders, I believe. It is a unique situation where a physician

in one state where reproductive health care is in all aspects is legal is communicating across state borders into a state where it is not. I do think that needs to be addressed and it is addressed in the letter.

My only suggestion was perhaps also including a reference to telemedicine, which encompasses the use of various digital health tools that may or may not be prescribed by clinicians or providers or may or may not be offered through the health system such as your portal. That is where the FTC has been asserting itself in these independent apps that are not covered by HIPAA.

Vickie Mays: Thank you.

Melissa Goldstein: I would like to read into the record two Q&As that we received from Lisa McKeen. I also know that there is a third one from an anonymous attendee. If you could rewrite it with your affiliation, your name at least, that would be helpful and then we can read it in as well.

Lisa's first comment at 218 was they are currently working on that now. I am assuming you mean the administration or HHS. Telehealth API apps have to have associated agreements now. That is separate.

And then the second comment is the person is giving their own consent. I am assuming you mean with the interoperability rules that Lorraine and Maya were talking about. Unless the person is giving this information to a health organization or to their physician, there does not need to be a BAA or a DUA.

I would just note that I think it is fine to raise issues that are not covered in the rule now, including telehealth and telemedicine. I generally use telehealth to be the broader term of the two to include telemedicine. I am certainly not the authority on that issue. And the interoperability issues that the department could consider. We suggest the department consider. But I would note that there was a very extensive notice and comment period on the interoperability rules. These issues are not new and they have been debated. It is not the current NPRM. I think considering it is appropriate, suggesting that it is considered appropriate. But there was an independent notice and comment period on that.

Valerie Watzlaf: Thank you.

Jamie.

Jamie Ferguson: Thank you. I also wanted to have the committee consider adding some of the other kinds of systems in addition to the certified EHR technology and the systems noted in the CMS rules.

There are many other kinds of systems regulated by HHS that do contain reproductive health information. Certainly, they also contain many other records potentially related to reproductive health. I am thinking of things like the CLIA-certified lab systems that make lab results under the CLIA rules, that make lab results accessible by both the patients and the ordering providers. I am thinking of FDA-regulated laboratory systems, the LISs, the FDA radiological devices, imaging devices. And then there is an area that frankly I have not thought through as a potential impact on FDA-regulated software devices. There are these many other kinds of systems that are regulated by the department that also should be considered.

Valerie Watzlaf: Thank you. Are we getting to the bottom?

Maya Bernstein: This is the end. I have no idea – I am in the wrong time zone.

Valerie Watzlaf: I do not know how much time we do have. I do not know if someone can give us –

Maya Bernstein: Until four or something.

Valerie Watzlaf: We do? Okay.

Rebecca Hines: Jacki and I decided to blow through the break, which was at two because we were in the middle of a conversation and the thinking was when you are ready to pivot from the themes to the letter, we would take a break then.

Maya Bernstein: Good idea. We are almost there.

Valerie Watzlaf: I guess the next one is the public --

Maya Bernstein: These are the last ones. Public health. That was an issue. I do not think there was particular controversy about that. That is why I put it at the end. Does one of you who originally made the comment, Denise, want to explain what this issue was or Melissa, you have your hand up. Or I can describe what I meant here.

Melissa Goldstein: I can read the additional comment from the public that the person that I asked to identify themselves has identified themselves. It is Janice Karin of the Massachusetts Health Data Consortium. I think that there are – the ONC-CMS rules did address privacy. It just said it was under FTC for third-party apps. Also please note the FTC has no oversight over non-profit workers. Thank you for that. I appreciate it. That is helpful.

Maya Bernstein: Public health.

Valerie Watzlaf: Did we get all of the comments then, Melissa, from the Q&A?

Melissa Goldstein: I believe so. I just thought it was especially important since we are not going to have a separate public comment period.

Valerie Watzlaf: I agree.

Jamie, go ahead. And then there is Denise also.

Jamie Ferguson: If I could just add, in addition to the limitation of regulation of not-for-profit entities, their authority really is to bring cases against individual infractions that maybe decided up or down and then hope that others would get in line. But they do not really have the same kind of broad regulatory authority even in the Health Breach Notification Rule that we are talking about here. I just wanted to note that difference in authority to bring individual cases versus the broad regulatory authority of HIPAA.

Valerie Watzlaf: Good point. Thank you.

Okay. Now, Denise. I think you wanted to discuss a little bit more about the public health clarification.

Denise Chrysler: Sure. The current rules do not contain a definition of public health and this was added in the proposed rules. The concern is no attestation is required for public health activities but then

public health is defined in a way that is a concern because it talks just about population-level activities of surveillance intervention and investigation. And public health activities can, especially in communicable disease context, involve civil administrative actions, involving individuals such as contact tracing. Then if an individual is acting in a way that jeopardizes the public, it may lead into an administrative action or an injunctive action to – so that the person ceases the activity that is endangering the public. The whole purpose was just broad in the definition of public health so that it does not sound like or could be misconstrued as population not to include individual where it is traditional public health functions.

Valerie Watzlaf: Thank you for that.

Maya Bernstein: If other people have comments about it, I was just going to explain. I think what the issue there just to put a point in it, I guess, is those individual actions that Denise described, those individual-level activities of public health do not fall into the disclosure exception. Right now, you can disclose PHI in identifiable form to public health for public health purposes, if you need to or want to.

If that disclosure provision no longer includes those individual-level things, then it might move those individual-level things into law enforcement where it would require an attestation because those are authorized investigative demands in the language of the law. Is that what was intended?

I think the language here in the letter just asks for clarification to make sure that that is not what was intended or to clarify – indeed what was intended to make sure that it is clear. We think that that was probably an unintended consequence or that they did not expect people to read it that way for some reason. It asks for clarification on that.

Denise, I want to ask you because you said – I think what you said is we should define it differently. There was a reason why they defined it in the way that they did so that – I am just guessing – there is a reason why they did that because they thought it would be more protective of reproductive health to ensure that we are only talking about population-level stuff so not individual-level stuff where a particular individual might be at risk of having their reproductive health information sort of become public somehow. I think it looks to me like an unintended consequence, but I am not sure that the fix would be to go back to the way it was. They still need to fix their problem that they are trying to fix but they may need to do it in a different way. I think we are just trying to highlight that. Does that meet with what you understand too?

PARTICIPANT: Correct.

Valerie Watzlaf: Any other comments on the public health clarification?

Wu Xu: Denise and Maya explained it well.

Valerie Watzlaf: Thank you, Wu.

And then the next two are just dealing with recommendations on de-identification, something that we brought up I think before too but bringing up our 2017 NCVHS letter to really clarify in more detail what de-identified data would include. And then the other was the notice of privacy practices and the language that we were recommending to include in there.

Were we going to include specific language or was that taken out, the model language?

Maya Bernstein: We had not ever settled on specific language. I took it out because I thought we were going to have time to really hammer out exactly some sentence we would want to say. But I think there is a suggestion that they provide specific language.

The discussion among committee members might be – the reasoning there suggests that in a state where care is not legal, the state might pass something like a gag rule or something like don't say gay we are calling it in Florida, those kinds of rules that talk about what you can and cannot say. There have been in the past even before the overturning of Roe. Michael or clinicians may know better than I do. Provisions that require a physician to say or not to say a particular kind of thing.

The suggestion is that we say in the letter that the department provides specific language or model language anyway. Right now, they do not. They do not say what you should say. They say you must say something about this and you must use at least one example to show what kind of circumstances and attestation would be required in. They do not give specific language.

I am imagining a state could require language that would be inappropriate somehow either confusing or misleading because there have been examples of those kinds of laws in the past.

There is a short paragraph that suggests letting us put something more specific about the notice of privacy practices so that the information unit does not end up being confusing or misleading to patients.

Valerie Watzlaf: Okay. We are at the bottom, I think, of our major themes here. Correct? That is it. I do not know – did we want to break now and then go to the letter or go to the letter? I did not know what our timing was.

Jacki Monson: I think we should take a break. I propose we take the 15-minute break now and then we come back to the letter.

Rebecca Hines: If we made it a 17-minute break, we would be back at 5 minutes to the hour, which would be 2:55. The agenda has us wrapping up at 4:30 Eastern. That would give us a solid hour and a half.

Jacki Monson: That sounds good.

Rebecca Hines: Okay. We will see you all. Make sure you turn off your video and sound.

(Break)

Rebecca Hines: Do you want to lay out what the plan is for the next hour and a half?

Jacki Monson: Yes. I think the plan and Val and Maya and Melissa, you are welcome to chime in but I think what we would like to do is pull up the drafts, starting with Vickie's draft, because we have multiple versions and I think what happened about 14 hours before this hearing today is we had some additional comments and changes that we were unable to incorporate in time for the meeting. I think we will start with Vickie's draft first and go through her comments. And Melissa, we just ask that you chime in particularly with your concerns with respect to softening the language. And then I think we will go from there.

Val, Maya, anything to add?

Valeria Watzlaf: That sounds good.

Melissa Goldstein: I had responded to the draft that Maya sent out late one evening, and Vickie had not had a chance to respond to that. But I responded to Maya's latest draft.

My understanding was that Vickie's was not as extensive as but we had had a meeting at 6 this evening. We had gotten off at 7:30 and then Maya had sent out that version at about 11:30 or midnight. I am not sure, Maya. But before she was traveling, getting ready to travel. She was not able to send it out. And then I responded to that one when I got up on Tuesday, as quickly as I could during a workday. And Vickie had responded the night before.

I am not sure which are more extensive but we definitely want to reconcile the two. I am not sure which makes sense. Vickie, if you want to comment on my language. But re-doing all of my comments verbally. I had commented in writing, and some of it with flow and language actually and understandability of the letter, not just my own concerns. I don't know if you want me to replicate the process in a public meeting but I do want my – my edits were meant to be edits.

Maya Bernstein: I understand. My plan is to try to reconcile those two documents tomorrow after we decide on what the content is supposed to be.

Vickie Mays: Most of my comments were edits and I did not think they were major. They could be taken or left. I think there may have been only one place where I might have had something. For the most part, I think I am okay.

Maya Bernstein: So maybe we can go through those and make sure that we are okay because some of the – the same. Melissa also made extensive edits. You made some edits. Some of them conflict on the same paragraphs because those were the ones we are most churning on. It has just been challenging to do that. Some of this language has been available for some weeks, the same kinds of paragraphs. We have been moving them around. But I tried to do as much as I could when I had it.

Melissa Goldstein: But the wordsmithing obviously – I think what we have done earlier today with the themes is most important because the wordsmithing will be hard. We were wordsmithing one line earlier with the standards letter and it took 45 minutes.

Maya Bernstein: We are going to try not to do that. Let me do both.

Valeria Watzlaf: Can I ask a clarifying question then? If we get to a vote, are we then going to be voting on those major themes? Can we do that or do we have to have the letter and vote on that?

Jacki Monson: Maya and I talked about this last night, and I think again this morning, exchanged some messages. Rebecca so let me take a stab at this and then you two can correct me if I am off. We can vote on the major themes. We can finesse and have – as long as we have the spirit and intent of what the committee wants to say, we can vote on it and then we can wordsmith over the next day or so until we are ready to submit it on Friday. And the co-chairs along with me along with Maya and Rebecca will get on the same page about – make sure that we are in sync before I put my signature on the letter. I think that is what our plan is for today.

I do not think we are going to go – it is 20 plus pages. There is no way if we go line by line that we are going to finish it in time for this meeting to end. I think, Melissa and Val, you guys were comfortable

with that this morning. I would like that to be our approach and that is why we started and have really been focusing on the major themes. But I think any and the comment discrepancies that change the intent, we need to get to today. That is what I think we want to focus on first with Vickie's comments and then Melissa, we will be incorporating yours too. But I do not even think there is a way for us to get through all of your comments in the next hour and a half.

Valerie Watzlaf: We would be focusing when we pull up the letter on people's comments, not on the actual what is written in that letter. I just do not want people to think we are going to go through line by line.

Maya Bernstein: I think what I would like people to focus on is whether, as I show you the sections, they meet with the discussion we just had. That is why we had that discussion so we sort of know – I wanted to gauge where everybody is so that you as a whole group, which none of us have been able to meet together all together at once on this letter up until today. There was no meeting at which everyone was present, and you all had an idea of everybody else's comments at the same time. That has been a frustration I know for the committee members and for myself as well.

What I can do is – let me share my screen. I have both letters up here. You are going to see one at a time. It might not be big enough for you to see at the moment so let me fix that.

Rebecca Hines: It is good. It is quite readable. It is bigger than it was this morning.

Maya Bernstein: Let me get to the top. This is the beginning of the letter. It is dated today because that is when the vote is being taken. We can date it tomorrow or whatever as long as it is dated before Friday. There is some nice introductory language and so forth. There are some small changes here. We can see if I hover who made them. Those were based on somebody else's comments. What I did was I put in the comments that Vickie said from another draft so into this draft that other people had already worked on. Here, at the end of last week is where I added the short summary that we are going to complete after we have the language for everything else when we decide what is in and what is out. We are going to make bullets that represent the major topics that are in the letter, anything we are recommending consideration of. You see there is this first draft with these comments here.

Here, Vickie had a comment and I tried to respond to it. She said I do not understand the difference between this one and that one. It was an important comment because this is where I started to realize reproductive health care is used in two different ways. Here, I responded to her concern. We talked about that already today. If there are more questions about those two things, we should get them nailed down. But I separated the two comments as a result.

Rich Landen: Maya, while you are on the topic of the two definitions of reproductive health care, the NPRM contains a definition of reproductive health care but does not really address either one of those. In fact, the definition is entirely circular. We might want to consider a comment on the definition of reproductive health care as it is in the NPRM. Essentially, it says reproductive health care is care services for reproductive health.

Maya Bernstein: That is right. I think that is why that first major topic was this is not very useful and it is going to be so broad or so vague that it is going to end up being all health care anyway. Maybe it would be easier in application if you just did away with this definition and said all health care. That is what that discussion was about. Or in the alternative, we need a better definition than this, which is what you were saying and that is in the letter --

Rich Landen: I am saying two things. One is a circular definition. I do not know how it passed muster to get published. And second is you are saying that it is used two different ways and the definition does not allow for two different ways to define it.

Maya Bernstein: No. No. It is the same definition. Sorry. I was unclear. The same words, the same definition is used in two different ways. It is not two different definitions.

Rich Landen: Okay. Sorry I misunderstood.

Maya Bernstein: That is the only definition but it is used both in describing which records are going to be subject to an attestation and then it is used in an attestation to say what uses and disclosures you can make. Those are two different uses of the same term. It gets a little bit confusing, but I am trying to get more clear every time I try to explain that.We used the word circular. I like that word. I do not know if other people like that word.

Rich Landen: Just in case I am not clear, circular is when you use the same – whatever the term is, you use those exact same words to define the term.

Maya Bernstein: I will read it to you. It says reproductive health care means care, services, or supplies related to the reproductive health of the individual.

Now, there is a discussion in the preamble to the rule about what they mean by that.

Valerie Watzlaf: There is more detail.

Maya Bernstein: There is plenty of discussion about what they mean by that in the preamble but of course, the preamble is not rule. It is not the law. It could be looked at but to understand what the department meant. It is still not in the actual text of the rule.

Would it be helpful to read the one little paragraph about what they said about that?

Rich Landen: No. I just want to make the point that it is circular.

Melissa Goldstein: I think we just want clarification.

Maya Bernstein: There is a discussion – remember, this is just the summary. It is probably best if we skip over the summary language. I am just trying to call out Vickie's comments in particular here. I added the citation in response to this comment and she asked us to add an explanation. I added some language here. I do not know if that is helpful. But we are going to get back to the summary and exactly what we say in the summary based on where we come out on the actual discussion.

Vickie, maybe you can look at this language that I added in response to your comment.

Vickie Mays: I think it – it needed to be to complete the thought.

Maya Bernstein: Again, Vickie has some very good comments on areas that was not really good enough like what do you mean. Say something here about what this means. We did that. You see in some places we have changed – consider we are trying to change the tone also at the time based on comments that

Melissa had made in earlier meetings. Even before we had a draft, we were trying to soften the tone there.

One thing I did not talk about in the comments was that Denise Chrysler had made a comment that she particularly preferred that the signature – we had drafted a thing – we made this in the form of a shorter letter with an attachment. And Denise Chrysler – do you want to say something about your preference that the signature just be at the end of all the comments together? We can do it either way. It is a stylistic thing.

Denise Chrysler: I am okay either way. I just did not want our comments to be an appendix. That was the reason for the comment.

Maya Bernstein: I mean they sort of are at the moment. Here is Jacki's signature if it stays here and then underneath her signature is a document that says – I did not call it an appendix. I just said comments.

Denise Chrysler: I defer to Jacki. She is the one signing the letter. It was simply because of the concern about comments being an appendix. We have a summary and then we have all the detail and it is all our comments.

Maya Bernstein: I do not want the two things to get separated from each other so that it would not clear that it is all of one piece. This is mostly stylistic on the part of the committee of whatever you like.

Vickie Mays: I just wanted to comment. I do not want them to think the appendix is something that explains the other things because it really is that these are comments that support – usually what we put in the appendix, we put old letters. We put things you have seen before or the justification. I think it is a little different. Again, we are offering opinions here. It is not about the specific thing that we are recommending.

Maya Bernstein: I think this wants to say attached as opposed to following. The comments are attached in full. In the letter is a summary of those comments but the real comments are in the attachment or the next document all together. Is that what you meant?

Vickie Mays: Don't call it an appendix.

Maya Bernstein: It says our comments. We provide the following comments for your consideration. Here is a summary of our comments. And then at the top of this document it says these are the comments.

Valerie Watzlaf: I think someone did put a question in the Q&A or do you want to wait?

Maya Bernstein: You are the co-chair. It is up to you.

Valeria Watzlaf: It was about the attestation. It says – it is from Janice Karin. Has there been discussion of the impact of requiring attestation for all PHI requests on FHIR APIs, both those currently mandated by regulation meant to be a floor and additional exchanges optionally implemented that go beyond those minimums.

Maya Bernstein: Rebecca, I have a note here that says you would like to answer but I can – does one of the committee members want to – It looks like this commenter is confusing – we are not asking for

attestations to be required for all requests for PHI. We are asking it to be – there are only four kinds of requests that require an attestation. In the case of a request from health oversight, a court or a tribunal, law enforcement, or a coroner. No other requests require an attestation. The question is what records are subject to an attestation like if an attestation from any one of those groups contains reproductive health information or potentially related to reproductive health information, then an attestation is required. There has to be a determination by the covered entity that the records requested might include reproductive health information. I think that is the discussion that we were having earlier about how difficult it is to make that determination on the part of a provider and also does that significantly increase the number of times a provider would have to make that determination or not.

This looks like it might mean all – suggesting that all requests for PHI and that is not what is happening. Thank you, Janice. There is an assumption in the conversation about this. But you will see in the letter --

Valerie Watzlaf: She does follow up and say your language both this morning --

Maya Bernstein: I am going to show her why that – I think there was an assumption in our language – attestations under D, E, F, and G. Each time we say D, E, F, and G –

Valeria Watzlaf: I may not have said that when I presented it. It is in there.

Maya Bernstein: I try to be precise. And if you find a place where I was not precise about that, that limitation that we are all assuming then I will try to be more precise about that.

Valerie Watzlaf: She said thank you for clarifying. Thank you, Janice, for your comment.

Maya Bernstein: We were talking about lawful and unlawful and here, I dug up a particular example. I am not sure whether it helps. I was asked for some evidence about some of the things we were saying. There is a report, for example, that pre-eclampsia is pretty common. It is like 5 percent of cases. They are not all emergent necessarily. But when it is an emergency, it is a bad emergency and it only comes after 20 weeks, which is after most states who are making limitations on reproductive health care would allow an abortion, for example. The point was it comes up often. I think there was a comment made about how do we really know if it comes up often. I went off to see if I could identify some examples.

Someone with more clinical background than myself can tell me whether this makes sense or not to – I was thinking maybe you drop a footnote as an example or something like that if you wanted to keep this kind of language.

Valerie Watzlaf: I do think the more examples you can provide the better because I think they do ask for that.

Maya Bernstein: It is just hard with the time that we have to be able to – try to find one or two places where I thought it was critical.

There are some things that we combine in this draft. Here are the changes that Vickie made. Obtaining health care or health information, which I thought was useful like not just obtaining health care but also important to have truthful trustworthy information.

She made a comment here and I just thought it was a little awkward. This sentence says as with any prosecution in which some types of evidence are not available to the prosecution, state investigations

could proceed by other paths using whatever other resources or evidence may be available to support their cases. Vickie adds nothing that is derived from the medical record.

The point here is that we understand that states are entitled to pass laws and to prosecute things that they think are worth prosecuting. It is more like we just are not going to help you by giving you the medical records to do it if you are going after the patient, the provider, or any other third party specifically for seeking, obtaining, providing, or facilitating health care.

Vickie Mays: Maya, if you think that protects that third party, that was why I put that in. Again, you read the medical record to find out the sister went and picked up the prescription and therefore, you want to prosecute the sister. I just was not sure that that third party element is understood.

Maya Bernstein: That is fair. It is in other places. We say patient provider or third party. We do not say it here. I think in this case, we were talking particularly about the patient for seeking or obtaining care. I think one of the things we say somewhere in this letter is that the original HIPAA privacy rule only protects patients. It is clear the current rule only protects patients. It does not protect the privacy of providers or anyone else. But the NPRM – there is a lot of discussion in the preamble that the changes here are intended to protect not just the patient but the provider who is providing this kind of care and other third parties who may facilitate that care by driving, by educating, by other things that are associated with reproductive health care. That is a change. I think a significant change in the purpose of the rule making that we have not had before.

In the past and Val spoke about this morning about in 1997 and in other places across letters that this committee in its history has sent to the secretary – has made clear that it is important – that the medical records should not be used against the patient for – should not be used against the patient.

We do allow some you might call patient harm or things that are not health care. If you are involved in a crime of some kind – we can respond to requests from law enforcement with certain limitations to allow them to prosecute if you are involved in a fraud for other reasons that might affect the patient and cause the patient harm but not for the obtaining or seeking of health care itself. That is what we are talking about here after Dobbs. I tried to make that point that merely for seeking or obtaining health care and then in other places we add – we could add here too if it is important if the committee wishes. Also, against a provider for providing that care or for any third party for facilitating that care.

Vickie Mays: Maya, I think because that is the new part, it should get – I was told to speak up when I think something should be emphasized. This is the kind of emphasis that I think drives home that it is not business as usual because I think it is a really big change from us and everyone else just kind of focusing around HIPAA. We have been doing Beyond HIPAA for some time. I think this is an instance we are raising it up to the extent that we can when – I do not want to wreck our writing here but at the same time, that is what is new that we are bringing forth. That is the nuance that we are raising.

Maya Bernstein: I cannot see if other people have their hands up but I think I remember now why I did not put it here and that is because when I got to the provider part, it is pretty easy to say the patient for seeking or obtaining health care. A provider and providing care – you still want – in order to uphold the integrity of the health care to be able to go after a provider who is committing fraud or who is providing care that I would say does not fall into the standard of care, a provider who is providing substandard or inappropriate care even if you call it care. How do you distinguish between care that is I guess within the standard of care that is not incompetent, that is not malicious even or some other word that means the care is somehow inappropriate even just because the provider is unlicensed. They are providing care,

but they are doing it while unlicensed. You can separate out unlicensed because being unlicensed is not – it is connected to the provision of care. They are providing care while unlicensed. I think we would say it was okay for them to have an action against them for that.

But dividing between the provision of care that is appropriate and care that is still care but not appropriate is difficult to parse out here. I was struggling with how to do that sort of efficiently.

Valerie Watzlaf: I do have a comment. Lisa McKeen says it should be added. We will add the trust with the patient and provider, and for transparency for care.

Maya Bernstein: I do not think anyone disagrees that it is in there and it is in there in other places. There is even a discussion where someone on the committee suggested and I thought it was a good suggestion or maybe it was Grace, in fact, my colleague, who suggested that. The problem is using the term standard of care.

Melissa, you were going to remind me what I learned in law school about standard of care and health law. My understanding is that there is a local standard. It is in the community.

Melissa Goldstein: The regional, local. It is people like you.

Maya Bernstein: Right. In a state where the care itself is illegal, how could you possibly be operating under the standard of care if you were providing that care. In a case where you have one those edge cases where the care is legal or not legal.

It was suggested that maybe we make an appeal to a standard that is a more national standard like the standard of care that is endorsed by the board certification or authority. Maybe that is ACOG. I do not know who it is for OB/GYN. So that it would be a more national standard of care for this purpose. But this is all getting into stuff – it is explaining why I did not – I probably did not use it here because it was – there is a lot to – I do not disagree that it is important.

Vickie Mays: Again, what I love about Maya's writing is it is very tight. I can understand that what this is doing is wrecking your writing. I just love it when attorneys are like no, we need this precision. I am more than willing to say let us move it from here. But is there some place where we can call out that distinction a little more clearly? Because I think what we have done is we have added it in various places, but to me, it is really important. It is like if we were to say what is new about what we are saying, that is a new thing and it is a big hill. Counselor, I withdraw.

Maya Bernstein: No. Do not withdraw. But I was in fact trying to capture that.

Vickie Mays: -- it sounds like in terms – I do not want to mess up the logic that you have before this. If moving it is easier then I say let us move it. But it is just important, I think.

Maya Bernstein: Let us make a note about that because I was truthfully trying to capture that and then I was struggling for the reasons I just explained. But there is a discussion, and you see that I can find where we talked about standard of care, trying to respond to that issue in other places in the letter.

Valerie Watzlaf: Just for time, it is about 3:30. Are there other comments that you need to discuss with Vickie that she has not seen your response?

Maya Bernstein: Vickie had a question about whether – when I said medical professions, I could say clinicians. She wanted to make sure we included midwives. I consider them medical professionals, but I do not know if that is a term that is somehow --

Melissa Goldstein: Can we use providers? Providers is generally thought to be a nice broad term. A midwife is a provider.

Valerie Watzlaf: Vickie is nodding so that is good.

Maya Bernstein: Only because it includes entities that are institutions as opposed to clinicians, which I was trying to get at.

Melissa Goldstein: Clinicians might be thought to be more narrow typically.

Maya Bernstein: This is the discussion on authorities. Apparently, that is okay. Did I miss anything important here?

Jamie probably did not see this note somewhere about TEFCA but we are going to talk about that.

This is what I was trying to figure out. Here is the language that you added about person, Jamie, since I have it here. You said that in the context of exclusion from public health activities.

Jamie Ferguson: Actually, I think that was misplaced and I replied to that in the chat a while ago. Roll back up to that. It really belongs about the public health and it is really about covered entities and providing reproductive health care on an individual basis should be excluded from the definition of public health activities because they are really better defined as being diagnosis or treatment related.

Maya Bernstein: Okay. I will go move that up to public health.

Valerie Watzlaf: That is in the chat if we do --

Maya Bernstein: Rebecca, you can get the chat for me. Right?

Rebecca Hines: Absolutely.

Maya Bernstein: Other people – I do not know if this was Vickie. Somebody who likes to use the passive voice. It drives me crazy. When we say the preamble – something may need to be provided. I am like who do you want to provide that thing. It might have been clear here. I suggested here when you are talking about examples that when we put examples, I suggest we could be either in the rule itself, in the preamble, or in subsequent guidance for some things. We can decide where we say we need examples. I think this is the discussion of NPPs, the notice of privacy practices.

Here, someone asked me whether there was language in here, which is towards the bottom here – you can see it is towards the bottom of the letter that if we end up asking the department to make more precise the definition of reproductive health care that it – we start by saying that the definition is broad and it might be construed. I think that was the language that Melissa suggested, which I like, and I think people agreed on but it could be construed to include all these other things. Either say so definitely or leave it to all health care, which would include those things sort of by not specifying them. Does that make sense?

Vickie Mays: Do not leave that yet. But I do not think we are saying what we want them to do. Therefore, it may be important to make explicit what the department intends in plain language. We say that. We read the definition even though these things are not explicitly identified. We do not go the next step and say that we think this is important to make explicit. Being like you, the sentence before, we are not clear as exactly what we want to be explicit. We just say the language is not explicit. Can we not say that those things we think are important to explicitly include?

Valerie Watzlaf: I think that is explained later, isn't it, in the second paragraph?

Maya Bernstein: These parts, right? We were talking about this kind of language.

Vickie Mays: I am.

Maya Bernstein: Okay.

Valerie Watzlaf: I think in the second paragraph, isn't that explained a little bit more where you do say examples should be provided?

Vickie Mays: Yes, but it is almost like to me it is too low key. You are saying if you do this, here is a way to do it. We do not ask that they do. We just say if you do it – to me, that is how I read it. If you do it, here is some language. Rather than we are asking you to do it and here is some language. To me, that is the difference.

Valerie Watzlaf: -- stronger. This is another place you would like it to be stronger.

Vickie Mays: The committee is on solid ground – and all this other stuff to actually ask for it. We have an expertise by which we are asking. We are not advocates on this.

Maya Bernstein: I think it is in the context of saying we actually suggest first that you include all health care, which would include these things and then this is the alternative and explaining how the alternative would be most helpful.

Valerie Watzlaf: Jamie has his hand up.

Jamie Ferguson: I put a little something in the chat. I do not know if you can see it. It is a potential language. If they want to be specific, use your own adopted standards to tell us what it is basically. Which things are included? That could be in value sets, provided through the value set authority, an NLM, for example, used by ONC. There are many different ways to do it. If you want to make it easily implementable, you will actually tell us very specifically what it is.

Maya Bernstein: Because then they are marked already or they are identified in the record.

Jamie Ferguson: Exactly. Then that would make it identifiable, therefore more easily segmented or sequestered as needed.

Maya Bernstein: I know you put that comment in the other version that we are about to go over. In the subsequent version. In the other one that has – and together with Melissa's comments where we are talking about.

Valerie Watzlaf: We have had many versions. Right? We have had many versions.

Vickie Mays: Can I ask Jamie a question?

Valerie Watzlaf: Michael does say something in the chat too --

Michael Hodgkins: Jamie, I just would caution that that would be a voluminous list of conditions, procedures, medications.

Jamie Ferguson: I do not disagree that that could be voluminous but that would be something that could be automated is what I am thinking. If you look at the value sets for quality measures, that is voluminous. And yet they are in there because it makes the eCQMs implementable. This makes it implementable. It is a potential way to consider doing it.

Valeria Watzlaf: Go ahead, Vickie. I am sorry. I think I interrupted you.

Vickie Mays: In terms of what Jamie is saying, now that he is saying it could be automated, and I kind of go huh. But at the same time, I want to make sure we call these other things out because what we then are dependent upon is whatever they have been doing in the past is what gets called out, as opposed to making sure given that we know what is being – where the rights are being pulled back that we call out to say we want to make sure that these things are included as well. I am not against what Jamie is saying but I do not want it to also cover this because I do not know that they thought this through. This is why they were asking us to do all the SOGI stuff because we may be –

Maya Bernstein: Are there codes for this even yet?

Vickie Mays: It is interesting. There are codes in there not used and we do not know in the ICD, why the codes are not being used well enough. This is part of what UCLA – they are exploring. What is the problem? That is what I am saying. Jamie, I am fine with what you say. It is a real challenge to them. But I think if you are going to say that, we should say using automation so that they do not get overwhelmed by it.

Valerie Watzlaf: I do think Tammy might have brought that up in her comment previously. I think we thought some of about that. But she also puts in the chat non-complexity can be programmed and automated but ambiguity can't. I am just reading these because I think, Maya, you cannot see them. Is that true?

Maya Bernstein: I can call it up and look at it but it blocks my screen. I am trying to – I only have my little laptop and not my two big screens that I have at home.

Valeria Watzlaf: That is why I was reading them.

Maya Bernstein: It is a nice point. It might be a long implementation to get to that point but then once you have the definition from the standards, it is a lot of them but you can at least mark them.

I think I captured that idea. When we get to that point in the other letter where Jamie had added some language there and it is nice. We will all look at it. The one last thing I think here is about talking about how we talk about the definition of public health. It might not be clear. This caused me to realize it might not be clear. We sort of offhand talk about the definition of public health. There is not one in the

current rule. Even though the term is used, it is sort of defined kind of in the context of saying, you can disclose to a public health entity. That is one of the uses and disclosures you can make without an authorization. And then it sort of says, and by public health entity we mean. It is embedded in the use or disclosure exception.

This new definition of public health really truly is new. And part of the problem that we are identifying here is that it is not just used in that one place. It appears in other places and we actually went to look. Do they use the term public health (inaudible), public health investigation? Where is that used in the rule? And figured out that this could be a problem that we have identified here. I think that was not something that was particularly controversial but just to understand that this is a totally new thing for them to be doing to actually define public health.

Let us look at the other one. Back to the top, this is – I made for myself a very short title up here so that I could tell which letter was which while I was looking at it on the screen. If I go through the changes, I can – this version does not include Vickie's comments that we just talked about. It includes other comments that came before. You will see that Cathy Donald made some comments that were helpful to the organization – pointing out where things were duplicative and stuff. We have fixed a lot of that and that is why this is deleted. Paragraphs have been moved around because of those kinds of comments.

Rebecca Hines: Maya, I think the answer to Michael's question in the chat is where there will be a second bite of the apple before the proposed rule is finalized because it is unlikely given the timeframe they are on. Correct?

Maya Bernstein: That is unlikely. I do not know what I want to promise. I have blocked off all tomorrow to work on this. I traveled on the day I did so that I would be in a stable place on Monday and on Wednesday and Thursday when I needed to work on this.

Valerie Watzlaf: Is that what you mean or do you mean – by the agency.

Maya Bernstein: By the agency, not by us.

Valerie Watzlaf: He said before it is finalized.

Maya Bernstein: I think the answer is very unlikely. It is possible. In the administrative procedural process, sometimes agencies will go out with another proposal. That happens. But my best guess is that that will not happen in this case because – and other people can chime in with what they are feeling. This is my personal opinion. I do not have any intelligence about this. Just looking at the circumstances that we find ourselves in with this administration, the administration is likely to have the goal of finalizing this rule before the end of this administration and before there is a potential change in administration where this kind of rule could be pulled back and also before the possibility of having it overturned by the Congressional Review Act. All regulations – once they are published, Congress has an opportunity for so many legislation days. Do not ask me. But certain period of time to pass a law that would undue the rulemaking. That is not likely to happen in the current makeup of the Congress. But after 2024-2025, anything can happen. I am expecting a lot of comments on this regulation.

It is going to be a lot of work for the department to cull through those, figure out what they are going to do in response to those to those comments or what they are going to do with the rulemaking in its final form based on the information it learns from the comments is a better way to put it. My guess is they are going to want to have a final rule by April.

Rebecca Hines: Well, in time to avoid any possibility that it is overturned.

Melissa Goldstein: We have to make clear that this really is just speculation by us and we do not have any control over that. It is speculation by all of us because not even Maya is included in the writing of the rule. Just focus us a little bit. I am not sure which version this is. This is not the version that I saw.

Maya Bernstein: Yes, it is. It is your version plus some comments.

Valerie Watzlaf: I think that what we are seeing is – oh, I thought this looked like the same one that you were just going through.

Melissa Goldstein: Does this include my edits or is this the one you sent last night Val, or this morning? Did we include my edits or this is one -

Maya Bernstein: Hang on a second and I will tell you.

Melissa Goldstein: There was one you did on the plane – that you did not circulate to us.

Maya Bernstein: Let me talk, please. That is correct. That is the one you just saw, the one where I responded to Vickie's comments. That is the one you just saw, the one I did on the plane.

Melissa commented on an earlier document that it did not include Vickie's comments. That is this document plus Jamie also weighed in on it. I circulated this to everybody during the meeting. Melissa, when you sent your comments, I did not realize that they were not – when you sent them last night, they were not circulated to the whole committee.

Since I know that there were certain members of the committee that had concerns about the same sections as you – you did send it to Vickie but not to Jamie, for example. I wanted to make sure that everybody had it. Jamie had an opportunity – I do not know how managed to weigh in on a few things during the meeting today. That is this version. It has both your comments and those of Jamie, plus all these other ones that were added earlier that were in existence in the version that you had when you read it.

I can make some of this go away. I can, for example, hide these so that we are only seeing your comments and Jamie's comments if that would be helpful because others of these, for example, Val's comments were in both drafts, as Cathy's were. Does that make sense? These are all the people that have marked on this draft, including yourself. That is Melissa up here. MMG, myself, Cathy, two versions of Jamie at different times.

Melissa Goldstein: You sent this earlier today so I could pull it up and follow.

Maya Bernstein: Yes.

Valerie Watzlaf: Do you want to go through those? I do not know that I am seeing Melissa's comments though.

Maya Bernstein: Just a minute. You are not seeing them on this particular piece of the document. That is all.

Valerie Watzlaf: Okay. I thought you were on them.

Maya Bernstein: We are toward the end of the document here.

Valerie Watzlaf: We have 13 minutes.

Maya Bernstein: Here are all of Melissa's comments. You can see that some of them are quite extensive.

I just want to answer quickly Michael's comment. We can continue to comment both on the rulemaking and on anything else related to things that you want to advise the Secretary because we are the Secretary's advisory committee kind of at any time. If we got them to the department timely enough for them to look at them before the final rulemaking, they probably will. That is a more complete answer to your question. And that is why we are having – part of the reason why we are having the hearing on July – the panels on July 19 that we are planning to talk more about reproductive health care, protection of reproductive health care in a broader context.

Some of these are – I want to see where Melissa's – these are too far down. Melissa did not get all the way through the letter. This is the beginning part of the letter. I think all of these are just editorial in that part.

Melissa Goldstein: My screen is not changing.

Maya Bernstein: Really. I am going to go out and come back in.

Jacki Monson: While you do that, we actually have more than 13 minutes. We end at 4:30 Eastern. We have about 40 minutes.

Valerie Watzlaf: Great. Thank you.

Maya Bernstein: Just what everyone wanted to hear at the end of a long day.

Valeria Watzlaf: But even in 40 minutes – we can go through and Melissa, if you want to comment on the major items I think of your concerns, that might help.

Melissa Goldstein: -- that there is anything different. I pretty much accept them today. If we look at the very beginning of the document --

Maya Bernstein: Red is Melissa. This red-pink color is Melissa on my screen. Can you see that now?

Melissa Goldstein: It is a little bit of a professional problem of the teacher. Sorry about that. The comments at the very beginning, the bullet is summarizing. I used language that – not everyone was on the call last night at 6 o'clock, but many people were and we talked about the language. Vickie, you were not. Jamie, you were not. You two have both been very vocal about areas that you care a lot about. Maybe we should focus on the summaries, the bulleted part that you had at the very beginning, Maya, and that might make it easier to use or not use the language depending on how you reconcile. This is a little bit of a redo of the thematic issues that we had this morning or this afternoon. Now, I cannot remember. It has been a long day.

Maya Bernstein: MMG is Melissa and the red is her. The blue here is me. But some of those are responding to other people's comments where I edited it in response to comments and some are maybe my own that I noticed as we went through. This is the very beginning of the section with the bullets.

Melissa Goldstein: Vickie and Jamie, if you look at the first bullet about the distinction between law and not law so this included Wu's suggestions last night. I do not remember who else said but we reworked it together.

Maya Bernstein: When you say reconsider here --

Jamie Ferguson: If this is the last one that I sent back to you a couple of hours, then this includes my comments on top of Melissa's and yours and Vickie's.

Maya Bernstein: Did you comment – you did not comment on the bullets themselves, only on the later discussion, as I recall.

Jamie Ferguson: I commented where I thought it was important to comment.

Maya Bernstein: Okay. Would it be helpful to go look at those things? I can go through just your comments and see where you commented on Melissa's, for example, I can --

Jamie Ferguson: Maybe starting at the bottom of page 7. But I do not know if you want to skip all the way to there.

Melissa Goldstein: I only made it through with the - I assumed that the language at the top that we worked through would be taken through the whole document. I sent it back to Maya last night only through page 10. I thought it would be easier to align language farther down the document after the language at the beginning was set. I would recommend focusing on the language at the beginning and then taking that type of language all the way through the document if we agree on the language at the beginning.

Maya Bernstein: What Jamie is saying is he commented where he thought it was important to comment on it.

Melissa Goldstein: -- right now up at the top what I have said, then it means we agreed on it.

Valerie Watzlaf: Vickie has her hand up.

Vickie Mays: Go to the top because there is a sentence that seems to be missing something. But Melissa, it is kind of like I am not sure that I would say there can be blanket find and replace kind of thing because in different sections --

Melissa Goldstein: Oh no. It would have to be done with care. It absolutely cannot be a blanket find and replace. It just gives the tenor. The beginning part will give the tenor, the tone. If we agree on that, then that can be --

Maya Bernstein: When you say the beginning part, you mean the first ten pages --

Melissa Goldstein: -- which is essentially thematic. The summary includes the big point. There certainly cannot be a find and replace. It would have to be done carefully.

Vickie Mays: Can I just ask about the bullet, bullet 3? If the final rule continues to require attestation only for requests that are potentially related to reproductive health care, then HHS should what? Something is missing.

Valerie Watzlaf: - define reproductive health care.

Maya Bernstein: You took out the word here consider. I do not think you intended to, Melissa.

Melissa Goldstein: Yes, I did. I said should define the words, the definitions.

Maya Bernstein: But you did not take out this part so that is why she thinks it does not – you have to take out –

Melissa Goldstein: There are so many drafts now. Who knows? It should say – in a very clear and specific manner.

Maya Bernstein: It says should the definition be fine is what is the problem here.

Vickie Mays: If there are attestations, then you want the – what health care is defined. Is that what you are saying?

Melissa Goldstein: If they decide to keep it as it is, if they do not extend it –

Vickie Mays: I see what you are saying.

Melissa Goldstein: If they do not extend it, then at least be very clear what goes into it.

Maya Bernstein: This is why when I started looking at it, it was taking me a long time because you added things but did not take out what needed to be taken out, so it was not readable.

Vickie Mays: Melissa, the only thing I would say is I still think we have said things that they should consider in that specific – how do you say – in that clear and specific manner. I would want to say I am fine with that, but also include thinking that it occurs in this letter. I do not want them to go off and just do it by themselves. I want them to go off and do it also informed by what we are saying or we are suggesting.

Melissa Goldstein: I think the second folder is an alternative.

Maya Bernstein: This is in the alternative. What Melissa's suggestion – it should say if the final rule continues to require attestations only for requests that are potentially related to reproductive health care, then HHS should define reproductive health care in a clear and specific manner. Quite definitive.

Vickie Mays: No, but suppose they are thinking about gender-affirming care? We do not know that.

Maya Bernstein: They could include it in being specific and clear. We have not said that explicitly here.

Vickie Mays: No. We do not say it here, but we say it later. The only thing I am saying is this is do what you usually do in terms of your definition. I want to make sure that we are coming up with some things that we want them to consider. In their definition if they are not going to say all health care, then I want them in their definition to include the things that we said. If we just say do it and do not think about what we said, then they might just – their default is they will just do what they usually do.

Maya Bernstein: And you mean by those things, gender-affirming care? What else?

Vickie Mays: That stuff. Whatever that is. We want to make sure they include that in their definition. That is why I would not just give them – with our blessing, whatever blanket thing they want to do, because we have written throughout this letter rationales for why things should be broader than they normally are.

Maya Bernstein: Can I ask you about the drafting, Vickie? You and I had a conversation in which – in fact, I think you talked about this in some meeting we were in about the strategy for how to do this. You suggested that – this is the front of the letter that maybe we do not include that language in the very front of the letter but we make clear that that is what we meant at the end sort of strategically so we do not throw people off at the beginning of reading.

Vickie Mays: I am not saying here to put those words. I am suggesting that what they say and considering the things that we have discussed. You are saying to them if you have a definition, do whatever the definition is but be informed also by our document. I agree with you 100 percent. I would not want to put those words in the very beginning.

Maya Bernstein: What words would you put here in addition?

Vickie Mays: I would say – HHS should define reproductive health care in a clear and specific manner informed by this whatever we call it, letter, opinion piece. It is just that simple – read this letter and also think about what we are asking for --

Melissa Goldstein: If we put a page number – what if we say with consideration of the other elements of this letter or the other points we have made or something like that? In consideration of, while considering, in addition to considering. What could we add there? We want you to rethink – we want you to give a very clear and specific definition. But while you are thinking of that definition, think about what we have said. Do not forget what we mean.

Maya Bernstein: In the whole context of this letter is what --

Melissa Goldstein: That is good. In the context -- consider the rest of this letter when you are doing it. Something like that.

Valerie Watzlaf: Is that like saying do not just read these and stop. Keep reading. We could put that in.

Vickie Mays: What I am trying to say is do not do business as usual. We are not giving you just carte blanche to come up with a definition because it sounds like that is what you are saying. Just define it. But what I am saying is define it being informed by reading this letter. It is a little different. I am not going to die on this hill or something. I do not go to war so I might have the analogy wrong. Again, it is like do what you do but it is kind of the — it is like there was a lot of thought that went into this.

Melissa Goldstein: How about the principles of this letter? The principles that we have –

Vickie Mays: The way people interpret principles – I want them to interpret the words that we say. But principles allow you to put your own ethical sets. Two different people can interpret the same principle. I really want them to use the words of the letter. But again, I am willing to compromise on this but it is just important they not do it what they usually do.

Maya Bernstein: I am scanning around for words.

Melissa Goldstein: We can do that. Is everybody okay with that? And then Maya implement with her magic wand.

Maya Bernstein: We have not asked. Just in the back of your mind before the end of the meeting, consider how you are going to answer my question. How many of you are going to be available for random questions during the day tomorrow?

Valerie Watzlaf: We do have a comment in the chat. Lisa McKeen. We are seeking an informed definition as to the inclusion of what is considered to be reproductive health care.

Vickie Mays: I think we have given them the informed.

Maya Bernstein: -- later discussion. When we get down there, you will see this.

Vickie Mays: I want to use ours.

Maya Bernstein: I think I have enough and I will try very hard to represent what you guys are trying to do here. That is the point.

Rebecca Hines: Are we getting close to being able to synthesize for a vote?

Valerie Watzlaf: Can we go to other major areas maybe so we just make sure everybody is in agreement? Anything other major ones? These are Melissa's. Right?

Maya Bernstein: Right. Remember, these are the two different uses of reproductive health care. One having to do with records and one having to do with the attestation.

Melissa Goldstein: That second bullet was my question about do we need to add those words without an attestation if that was an accurate – is that accurate? If the final rule continues to prohibit use and disclosure – that was my question.

Maya Bernstein: That is right.

Melissa Goldstein: I thought it was a clarifying point.

Maya Bernstein: Wait a minute.

Melissa Goldstein: These three bullets all talk about giving a clear definition, Vickie. All three of those bullets.

Maya Bernstein: This is the language that is in an attestation. The prohibition is the language in the attestation that says I will not use or disclose this to take action against a patient, provider, facilitator, or whatever for provision of reproductive health care. This is the prohibition part. I have to clarify this.

Melissa Goldstein: Beginning of the sentence a little bit. That is where I was getting --

Vickie Mays: I don't know how I feel about the last bullet – should consider and available.

Maya Bernstein: I am just going to remind myself that it means prohibition on use and disclosure by one of those parties that is requesting.

Vickie Mays: The last one is a very strong request. I am not sure about consider? I am sorry. I thought it was the last one and it is not.

Maya Bernstein: There is more of them. A lot of them.

Vickie Mays: For access to reproductive – the department should consider use of all available authorities at its disposal. What it was should use all available authorities at its disposal. I feel like we are speaking on behalf of – I do not know. I guess I am okay.

Maya Bernstein: I do not know. I do not like the way I drafted this here but something like that.

Can I just skip over the one –

Vickie Mays: I like that one better. I will reconsider it when you put applying because it means going through a process of consideration for each thing and to use it. You are telling them still to do something. But I am good there.

Maya Bernstein: Melissa, are you okay with that?

On the previous bullet right here, I noticed that – there are these two bullets about how the definition of reproductive health care is used, not to belabor this point. The third one is about the definition itself and maybe that is the place where this language that Vickie is talking about, the specific language where we ask for more extensive examples. It is not just the definition should be – we will have to make these work together but use similar language but clear, precise, specific terms in the text. This discussion that you were having about using the standards, all that stuff, is here about this definition.

Melissa Goldstein: I would just say if you did that, then say, for example, including but not limited to, because we are not the – there could be all kinds of stuff we are not thinking of that we would want protected. Just think about these as examples. For instance, if you did put gender-affirming care, which we have talked about several times today, that is not the only kind. You would want to put and others, et cetera, that kind of stuff.

Valerie Watzlaf: Jamie has his hand up. I do not know if you wanted to talk about that, Jamie.

Jamie Ferguson: I am back on the extending use of other authorities. I do not know if you want to go back to that or not.

Maya Bernstein: What was that language that I – including but not limited to. It is a pet peeve.

Jamie Ferguson: Just further down in the letter, maybe halfway through just before the definition section. You had asked me to explain why the use of TEFCA was important. I drafted a couple of –

Maya Bernstein: Do you want to go look at that? We can look at that.

Jamie Ferguson: It is immediately before the definition section – explanation.

Maya Bernstein: That is not it. We are still in the bullets. That is right. Here it is.

Jamie Ferguson: This is it. This is just thinking to explain why considering – extending the provisions of the HIPAA rule through contractual enforcement is important.

Vickie Mays: Jamie, does this apply to public health?

Jamie Ferguson: It could apply to public health. In fact, in the CDC data modernization and public health information strategy that they published a couple of months ago, they included the use of TEFCA pilot programs I think next calendar year for public health reporting purposes. It could apply potentially there.

Rebecca Hines: Jamie, is there an SOR missing? No sharing of PHI for individuals.

Jamie Ferguson: After PHI, I think it should say among.

Melissa Goldstein: In my day job, I actually work with CDC the Data Modernization Initiative. TEFCA is – like Jamie said, it is a strategy guideline but I hesitate to put into this – if you want to talk about contractual, I just think – I would need some more time to look at this and compare it with the actual documents. I would hesitate to put this in right now. It is a little bit bigger than this.

Jamie Ferguson: The common agreement clearly extends provisions of the HIPAA privacy rule to also signatories of the agreement.

Melissa Goldstein: It has not been adopted yet though. And there are no citations. I think this is a big thing. Do we want to say – you can say BAAs. You can say things that are actually in use now. I just think it is a larger section that I would want to actually throw in now and then vote on.

Jamie Ferguson: Are you saying don't mention TEFCA?

Melissa Goldstein: I think we have to add that somewhere else.

Vickie Mays: I was asking about its relation to public health because I am trying to make sure - and I hope Denise is looking at this as well that we – there is something that tells me that this may change some or I am not sure. Melissa, can you send the URL for the – you said they just published something or – just so that we can look at it.

Melissa Goldstein: The USCDI actually has the latest version. It has a couple of elements that are public health related. TEFCA. The plan is to include some public health. TEFCA does not exist yet. They are starting to get the common agreement. They are starting to get people to sign on. This is all future and not included now. This is all a future thing, assuming that people will sign on and that it will be used in the future.

The problem with it is that I would need to analyze this separately in a way that I am too tired actually to do now. It is a little bit like the amendment this morning. This language actually raises bigger issues. I believe that TEFCA is mentioned somewhere else, Maya. I can't do a search and replace. Maybe you can. We really only have 16 minutes. Michael reminded us.

Jamie Ferguson: We may end up potentially disagreeing on that. I think the comment –

Maya Bernstein: This is the only place TEFCA is discussed in this paragraph.

Melissa Goldstein: -- also has a very good comment in the chat that the common agreement will depend on use cases so it depends on public health use cases. There are only a few elements now that are included in the USCDI. It is all uncertain at this point. It is a goal. It is absolutely a goal.

Jamie Ferguson: That is true for the public health use of it. I was not referring to that. I was referring to its broad use by covered entities and non-covered entities and individuals who are expected to hold through the TEFCA network uses, information related to reproductive health this calendar year. It had public announcements. It has been processed. There is a lot of public information about this. It is not indefinite in the future.

Maya Bernstein: The purpose of this discussion was as an example of a kind of a contractual agreement that could be an additional authority that the department might look to for where it could protect reproductive health. This is the section saying the department has a bunch of different kinds of authorities. This was an example of one of those authorities. Could we couch this discussion in a way that limits it to the example Jamie just gave. It does not include public health.

Melissa Goldstein: My question is are you going to – are you and Grace and Jamie going to be able to do the research and verify --

Maya Bernstein: Jamie just wrote this here because he intends to make it not apply to –

Melissa Goldstein: There are no citations.

Maya Bernstein: There were no citations throughout the entire letter, which is one of the – there are some but we are going to have to go through and do these citations all tomorrow.

Melissa Goldstein: I am sorry. It is too last minute. It really is just too last minute for me to digest this now. There are other people that do not even know anything about TEFCA in the committee.

Rebecca Hines: This is where you have to decide whether you trust a member who has the expertise or you prefer not to.

Melissa Goldstein: Of course, I trust a member but I have a different perspective on TEFCA and I work with them every day. This is a little bit --

Maya Bernstein: I think what he was saying is he is talking about the parts that do not affect what you are working on with CDC that in other places, it is already about to be in place this year and we could maybe excise the language so that it does not affect those parts that you are concerned about.

Valerie Watzlaf: I was just going to say can we assign Jamie to review this section and then just move on to where the majority of the membership can make comments and provide feedback because going back and forth on individual opinions is not moving us to meet that deadline that Michael keeps reminding us of.

Tammy Banks: I agree that it should be included in some way if at a minimum to say to make sure that they review TEFCA to ensure it is consistent and that it is enforceable, depending on whatever comes out of the NPRM because it has to be in concert.

Valerie Watzlaf: -- he will provide TEFCA citations.

Vickie, you have your hand up.

Vickie Mays: Tammy at the very end said what I was going to say. I think we contextualize it. It is a future activity. We want to make sure that they are on top of it and that in particular, we want to make sure that there are not any conflicts in terms of – any unintended consequences for public health. Jamie is very clear about outside of public health. I can see us supporting that but in public health, we do not know. I think Denise Chrysler also – I do not know if we can ask Denise Love, but Denise Chrysler can look at it and make sure it has that protection there. I think we should then consider it and consider whether to --

Melissa Goldstein: I would be happy to look at the final language tomorrow.

Maya Bernstein: I am going to go back up to the top.

Valerie Watzlaf: Because I think now, we do need to vote on the major areas, which are in the top. If we can all agree on those.

Maya Bernstein: Have we gotten through all the --

Valerie Watzlaf: This looks different than the other one, I believe. Or do you want to pull up the letter or the themes or what do we --

Maya Bernstein: We had started working on – we were working through the bullets at the top of the letter at Melissa's suggestion. We went to look at the specific language about TEFCA in order to decide about the bullet at the top of the letter and the tone of what the top of the letter says. Now, we are going back to the next bullet at the top of the letter.

Valerie Watzlaf: We did the authority. I guess we did not do public health and the other ones that deal with --

Maya Bernstein: These are definitions. Here is where we came to the definitions. We were talking about the authorities and then here is public health. I did not hear a lot of disagreement about --

Valerie Watzlaf: Those last two there were removed. I do not know that this is – anyway. I do not know --

Maya Bernstein: Melissa, you started to say something about it in particular here but did not finish your thought related to public health definition. Is it okay if I just excise this?

Melissa Goldstein: I believe those two bullets had been combined in an earlier version that we recommend in the final rule should revisit. That is what the in particular was. We also fixed that last night so I am not sure what happened in between. Wu also fixed it last night. Something got --

Valerie Watzlaf: We are missing some here.

Melissa Goldstein: The last two bullets were combined – we looked at yesterday together.

Wu Xu: We should agree that in particular the department should revisit. Delete the --

Maya Bernstein: Why isn't this showing up?

Tammy Banks: Maya, do you have all the edits clicked or you just have Jamie's and Melissa's?

Maya Bernstein: Just Jamie's and Melissa's. That might be it.

Valerie Watzlaf: I think the previous version you had up might have the better language.

Melissa Goldstein: It had been combined before we looked at it and then we fixed it last night.

Valerie Watzlaf: Vickie, do you have a comment or is your hand up from before?

Vickie Mays: I was just going to say we only have eight minutes left. I just want to make sure we do not hit 1:30. I am sorry. 1:30 my time. 4:30 your time.

Rebecca Hines: Val, did you want to suggest how we can move forward on summarizing the themes? We have been going back and forth between the letter and the themes that we did before the break. And I am wondering whether it would be safer to go to the themes before the break since there was --

Valerie Watzlaf: I agree. I think we could vote. If we are able to do that, I think those are clear enough. And if we can vote on those and approve those, then --

Jacki Monson: Let us just get a pulse on where everyone is at. That is what I would like to do. And then if everybody is at a comfortable level, then I think perhaps we ask for approval of the major themes. We reviewed quite a bit, so you are understanding where Melissa is coming from and her perspective to soften the language. We have heard from Vickie and Jamie. Where is everybody at? Are we thinking that we are comfortable enough with what we have discussed that we can trust the experts to carry this through to the end? What does everybody think? I heard from two. Wu also. That is three. Denise, you have been quiet for a little bit. Are you good? Alright. Michael is ready to go. He is like let us finish this. I have other things to get to. Deb, Tammy, Rich.

Debra Strickland: Yes. I am good to let the experts go ahead and take care of it.

Maya Bernstein: Thanks you guys for your support. What my plan would be for tomorrow, just so you know what the procedure is from here, is to take the two documents that we talked about plus the discussion we are going to have about the themes and reconcile them with the language that we talked about. And in the places where I thought there was particular disagreement of active discussion, however you want to call it, I think what I would like to do is send those paragraphs to you individually in an email and say could you just check this and see whether this is okay with you kind of thing. That

may happen throughout the day in order for us to get a signature by the end. The goal is to have Jacki be able to sign this by the end of the day.

Rebecca Hines: I think that is a good approach.

Maya Bernstein: By Friday at the latest.

Melissa Goldstein: That is the question. End of which day and what time?

Maya Bernstein: We will work that out.

Melissa Goldstein: Some people have later days and time zones than others. That is the question.

Rebecca Hines: Ideally, we would have this done COB tomorrow Pacific. If not, we can go into Friday. Myself, and Marietta, will do what you need to do to get this submitted before midnight Eastern on Friday, but we would prefer not to get to the end.

I like Maya's proposition to put it all together and wherever there is seemingly not total consensus to send an email with – let us say there are four areas. I am making that up. Send four separate emails. Get those separate threads all dealt with and then put the whole thing together. If we can do that by tomorrow evening, that would be ideal so that Jacki can look at the final product before we apply her signature and upload it.

Vickie Mays: Can I just suggest an amendment to that, which is, Maya, if you know who it is that had disagreements, can you send it to the small group and let us try and work among ourselves to help get – so there are not so many separate things. Let us talk to each other and agree. We work together well. We can agree to disagree. I just think it will be easier on drafts if you let us try and work out among ourselves too.

Maya Bernstein: I would be delighted if you would pick up the phone and call one another and send me a note.

Vickie Mays: We will do it by email. I am not promising by phone yet.

Maya Bernstein: It is going to take me most of the day to get through all this. When I get to your section – I forgot. You are going to Iceland.

Melissa Goldstein: I am a privacy expert and I may not have told that to the entire world but that is okay.

PARTICIPANT: You told that to a whole bunch of us.

Melissa Goldstein: I am going to be on a glacier. Who knows? It will be cold.

Maya Bernstein: I will pledge to you that we are going to do our best to represent everything that you have talked to us about in meetings or in your draft so that it properly reflects –

Melissa Goldstein: I would say that if Vickie, Jamie, any, I would like to iron that out on email early tomorrow and then you can implement if you would like.

Rebecca Hines: Maya, if you can instead of getting the whole letter since you know where there is agreement, maybe leave that to the end and go to the four, pulling that number out of the air, the four areas where there is some --

Melissa Goldstein: I do not need the whole letter, Rebecca. I think we need the beginning parts that we already talked through a lot. Vickie, what do you think? I do not think we can wordsmith the four of us the whole letter but I think – again, I think if we get the tone down and the words down that it can be pulled through the whole letter.

Maya Bernstein: I am on mountain time over here. I got some time this afternoon. Although my mother is expecting me but anyway. In theory, I am here visiting my family. I will try to do some of that this afternoon because if I – by tomorrow morning, it is going to be not early tomorrow for you.

Debra Strickland: Maya, weren't you going to do the citations as well tomorrow? That is a lot.

Maya Bernstein: It is a lot. A lot of the citations I put in there – I have some help from staff. If somebody had a grad student that wants to help, I would love to do that. You do not have lawyers with you but anyway.

Rebecca Hines: It sounds like we have a general direction on how this is going to go. Maya, you are going to try to work on especially the areas where there is some more working out the particulars of the language today, try to get the full thing out as early tomorrow as possible. With that in mind, is the thinking that we could go through the themes that were agreed to and have a vote on are they the appropriate themes?

Maya Bernstein: Grace and I are going to be doing this together.

Valerie Watzlaf: We need to vote on those.

Maya Bernstein: This part let me share with you because the themes page that we talked about before – it does not have the precise language that you guys have been talking about.

Valerie Watzlaf: That is right though. It does not have to be exactly – we do not have exact language.

Rebecca Hines: Correct.

Maya Bernstein: This particular version has now all the discussion and the notes that I took. I could just take one minute and excise it. Do you want to vote on them?

Vickie Mays: We are voting on – not the explanation. We went through the themes and you had notes to collect it. Our understanding should still be with us from earlier. We should vote on --

Jacki Monson: Vickie, I am ready for your motion.

Vickie Mays: I move that we vote on the themes that have been discussed in the meeting today. What else do I say, Jacki?

Jacki Monson: For the privacy NPRM and that we are going to carry through the spirit and intent and the rest of the written document.

Vickie Mays: What she said. That is what I say. That is my motion.

Jacki Monson: Is there a second?

Michael Hodgkins: Second.

Rebecca Hines: For the record, that was Tammy and Michael seconding it. Maya, can you stop sharing so that I can see the vote please?

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

Melissa Goldstein: Can you repeat what we are voting on?

Rebecca Hines: Jacki, you said it beautifully. The spirit and the intent to reflect it in the discussion in the themes.

Maya Bernstein: With an understanding that the document will reflect those accurately.

Rebecca Hines: We have ten votes so far and we – what am I missing?

Melissa Goldstein: Are we going to have discussion on the motion?

Rebecca Hines: I see 11. I am missing a 12th member.

Maya Bernstein: Wait a second. There is a motion. There is a second. Discussion before you vote.

Melissa Goldstein: I do not believe that we have the common understanding and intent. That is the problem there. I think that is what we are looking for now. On many of them, we do. I think on a few of them, we do not. I am not sure what you want us to do with that. But I do not think we are there quite yet. We can vote on the rest of them and then work out the others tomorrow.

Rebecca Hines: You cannot vote tomorrow.

Vickie Mays: Since I made the motion, such an eloquent motion I made, can I also comment? Melissa, I agree with you. But the very important word there was the spirit and we came up with a process in which to reach that spirit, which is the disagreement will be resolved. We are agreeing that. If I disagree with something, we are going to resolve it and then agree. It will reach the spirit. And that is what we are agreeing to do in the next day.

Melissa Goldstein: I am agreeing to agree on something later.

Vickie Mays: No, you are agreeing to agree that the spirit of this work going forward is we will reach an agreement. You are trusting that we will reach an agreement that we can say if I disagree, I am going to give you my vote anyway.

Jacki Monson: Can I ask that people put their hands down for a minute so that we can have this little discussion?

Vickie Mays: I think that is what it means by the spirit is that we have experts sitting here. We have had difficult times in the past where we can come together to agree. In this vote, I think that is what we are

saying. That is my sense of what in the spirit means. But we also can vote and the majority will rule on – say that as well.

PARTICIPANT: -- indulgence, can I ask a question?

Jacki Monson: You can if I can just finish a thought real quick. I think what we are voting on is that we generally agree to the major themes. We do not agree necessarily on the language and incorporating what you want to be softer. That is where we get to the spirit and intent where we are going to carry through what we did in the first introductory conversations today through the rest of the letter. If there is no consensus or there is still concern about whether we have met the spirit and intent, that is where we will have the offline conversations with the relevant individuals to get alignment.

Melissa Goldstein: And Vickie and Jamie, do you think that we have agreement on the spirit and intent in the beginning? I thought there was still some substantial disagreement.

Jamie Ferguson: I do not see any substantial disagreements. I thought that we were pretty darn close.

Vickie Mays: I was going to say I am of the belief that we will reach it. I have worked with everybody long enough that I really believe we can. I do not say that in every committee meeting but I do think we will.

Maya Bernstein: My question was whether -- I believe that it is pretty close too. Since Melissa is expressing a concern, can you – are there some of them that we do not have to worry about? Can you identify those that you are particularly concerned about and then I will focus on those this afternoon so that we have a maximum time for you to talk with those members where you thought you had a disagreement?

Melissa Goldstein: It is essentially the softening of the language – the language to suggesting that HHS consider the various options.

Maya Bernstein: As I recall, Vickie said most of the time she is okay with that and there are certain places where she was not. Some others agreed with that as well. If we can identify those places where she wants to be stronger, will that help you to talk with her about that?

Jamie Ferguson: We offered to indicate what those places were.

Vickie Mays: I would do just the opposite because we are faster. If Melissa can say which ones are her – it is difficult to move for her at all, then let me work on that. I think it is faster to do what --

Melissa Goldstein: Essentially, it is the extension of the attestation requirement. I do not want that to be strongly worded. And it is the difference between where treatment is legal and illegal. I would also not be strongly there. The rest of them are essentially okay.

Vickie Mays: Maya, if you can do those, I am happy to give those attention first. Melissa, I always enjoy talking with you. I have no problems with us having --

Melissa Goldstein: Absolutely not but it is very difficult to agree to something that does not exist yet.

Maya Bernstein: Val is going to be in this too because I know she feels strongly about the legal versus not legal thing. I see there are a couple of hands up.

Melissa Goldstein: I thought Val was okay with softening the language as we had done last night.

Valerie Watzlaf: I did not know it was around the illegal versus legal, I do not believe. And another thing is --

Melissa Goldstein: I have the language in there.

Valerie Watzlaf: I am sorry. I am going ahead of Tammy. But another thing is if we do not vote on this then that means that this cannot go forward.

Rebecca Hines: Correct.

Valerie Watzlaf: And is that what we would want to have happen. I do not think so. But because if we do not vote now, is that correct, it will not move ahead.

Rebecca Hines: Correct. And what I would suggest you then do – I do not even want to say that yet or maybe not at all. I am going to pause there. Tammy, you are on mute.

Tammy Banks: Can we limit the comments to a motion and then take a vote? People can say yes, no, or abstain. But can we just take the vote?

Jacki Monson: We had a conversation. Is there any other discussion?

Rebecca Hines: I just want to note that Cathy Donald is in an area where there is a tornado or a tornado watch and is not with us so we are now down to 12 people. We would need 7 votes to approve this.

Jacki Monson: All in favor, please raise your hand virtually or on the screen, whichever is easier.

Rebecca Hines: Ten. Tammy, are you in favor or not in favor?

Tammy Banks: Yes. I thought I had mine up.

Melissa Goldstein: And this is in favor of continuing the conversation in the spirit of – got it.

Rebecca Hines: By email or phone tonight and tomorrow. It appears that we have all 12 present members approving finalization in the spirit and intent of today's discussion. There are no abstentions and no disapproves. We have everybody. It is unanimous with 12.

Jacki Monson: Okay. Fantastic. Maya and – others, thank you so much. I know you are going to be putting in probably a long night. Let us know how we can support you in getting this across the finish line. Thank you, everybody, for your time today. I want to especially thank the staff, Rebecca, Maya, others and those behind the scenes who were helping us with Zoom. I know that there is a ton of work that goes into that so just deeply appreciate it. To my fellow members, thank you for your candor and great conversation today. I hope you have a great rest of your day, at least for those of you that are on the West Coast where the day is still very young. Thank you so much.

Maya Bernstein: If any of you have a preferred way I should communicate with you, email, text, phone, please send me an email.

Rebecca Hines: Very good. Bless you, Maya. Thank you for pulling all of this together. This meeting is adjourned. 4:42 for the record.

(Whereupon the meeting was adjourned at 4:42 p.m.)