Health Information Technology Advisory Committee

Transcript
July 11, 2019
Virtual Meeting

SPEAKERS

HITAC Members		
Name	**Organization**	**Role**
Carolyn Petersen	**Individual**	**Chair**
Robert Wah	**Individual**	**Chair**
Michael Adcock	Individual	Member
Christina Caraballo	Audacious Inquiry	Member
Tina Esposito	Advocate Aurora Health	Member
Cynthia Fisher	WaterRev, LLC	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil Jain	IBM Watson Health	Member
John Kansky	Indiana Health Information Exchange	Member
Ken Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Arien Malec	Change Healthcare	Member
Denni McColm	Citizens Memorial Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Aaron Miri	The University of Texas at Austin Dell Medical School and UT Health Austin	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
Raj Ratwani	MedStar Health	Member
Steve Ready	Norton Healthcare	Member

Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member

Federal Representatives		
Name	**Organization**	**Role**
Terry Adirim	Department of Defense	Member
Laura Conn	Centers for Disease Control and Prevention	Member
Kate Goodrich	Centers for Medicare and Medicaid Services	Member
Jonathan Nebeker	Department of Veterans Affairs	Member
Ram Sriram	National Institute of Standards and Technology	Member

ONC Speakers		
Name	**Organization**	**Role**
Lauren Richie	ONC	Designated Federal Officer
Donald Rucker	ONC	National Coordinator
Elise Sweeney Anthony	ONC	Executive Director, Office of Policy
Cassandra Hadley	ONC	HITAC Support
Steve Posnack	ONC	Executive Director, Office of Technology
Zoe Barner	ONC	Staff Lead
Seth Pazinski	ONC	Director, Strategic Planning & Coordination Division

Operator
Thank you. All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning, everyone. Welcome to the Health Information Technology Advisory Committee meeting. We have an exciting agenda today looking at our final recommendations from the Trusted Exchange Framework and Common Agreement, as well as a couple of other updates from our USCDI and ISP task forces. So, with that, I will do a brief roll call before we get started. Carolyn Petersen?

Carolyn Petersen – Individual – Co-Chair
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Robert Wah? I do believe he's on. Michael Adcock?

Michael Adcock – Individual - Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Christina Caraballo.

Christina Caraballo – Audacious Inquiry – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Tina Esposito? Not yet? Cynthia Fisher?

Cynthia Fisher – WaterRev LLC – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Valery Grey?

Valerie Grey – New York eHealth Collaborative – Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Anil Jain?

Anil Jain – IBM Watson Health – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
John Kansky?

John Kansky – Indiana Health Information Exchange – Member
I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Ken Kawamoto?

Ken Kawamoto – University of Utah Health – Member
I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Steven Lane?

Steven Lane – Sutter Health – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Leslie Lenert? Not yet? Okay. Arien Malec?

Arien Malec – Change Healthcare – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denni McColm?

Denni McColm – Citizens Memorial Healthcare – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Clem McDonald. Not yet? Okay, Aaron Miri? Brett Oliver?

Brett Oliver – Baptist Health – Member
Morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Terry O'Malley?

Terrence O'Malley – Massachusetts General Hospital – Member

Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Raj Ratwani?

Raj Ratwani – MedStar Health – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Steve Ready?

Steve Ready – Norton Healthcare – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sasha TerMaat?

Sasha TerMaat – Epic – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Andrew Truscott? Not yet? Okay, Sheryl Turney?

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denise Webb? Not yet? Okay. Laura Conn. Kate Goodrich? Terry Adirim? Ram Sriram?

Ram Sriram – National Institute of Standards and Technology – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Johnathan Nebeker? Okay. We'll circle back and hopefully the others will join. With us from ONC we also have Dr. Rucker, Elise Sweeney Anthony, Steve Posnack and Seth Pazinski. At this point I will turn it over to our national coordinator Dr. Rucker for a few remarks.

Donald Rucker – Office of the National Coordinator for Health Information Technology – National Coordinator
Yeah. Hi, everyone. I hope everybody has recovered from their July Fourth activities. I want to thank folks for getting to the final set of draft recommendations on the Trusted Exchange Framework. A

concept in particular I want to thank John Kansky and Arien Malec for leading the TEFCA task force, and I look forward to getting your thoughts there. Also, I would like to welcome Dr. Jonathan Nebeker to the HITAC. Jonathan's currently the acting CMIO for the VA and has been working in healthcare I.T. for a long time. So, I look forward to getting to his contributions.

A general reminder, we have our third annual interoperability forum August 20th-22nd, and I know some of you will be there. For folks, the basic of this concept of this forum is to try to address and get further insight on what are the hardest issues in interoperability. I think everybody knows – or I think many people know – certainly from a public point of view, it's good. But obviously, there are a bunch of challenges. So, dissecting those out is really what the interoperability forums are all about. So, anyway, that's it on my end. I'll turn it over to Carolyn and Robert, though I think Robert may be having audio difficulty, so I will turn it over to Carolyn.

Carolyn Petersen – Individual – Co-Chair
All right. Thank you, Dr. Rucker. Welcome everyone and good morning. Let us all share our appreciation for your dialing in on summer vacation. We normally try to take a break so everyone can get out and do some fun things. We really appreciate your coming back to go through the TEFCA recommendations this morning and look at a little bit of other business. So, I'll start by reviewing the agenda briefly. We will begin with our Trusted Exchange Framework and Common Agreement draft recommendations, and we do need to vote on those today. John Kansky and Arien Malec and the task force have done a tremendous amount of work, and we have really good presentation and I think an opportunity for excellent discussion this morning.

We will also have a couple of updates. First from Christina and Terry. The U.S. Core Data for Interoperability Phase 2 Task Force. And then from Ken and Steven with the Interoperability Standards Priorities Task Force update. So, with that, I will ask for a vote on the meeting minutes from the June 19 meeting. All those in favor of approving those minutes, please state aye.

Group
Aye.

Carolyn Petersen – Individual – Co-Chair
Are there any opposed to approving the minutes? Are there any abstentions? All right. The meeting minutes from the June 19 meeting have been approved. I will now pass the mic to Robert.

Robert Wah – Individual – Co-Chair
Thank you, Carolyn, and good morning everyone. Again, thanks for using part of your summer for this important work. We appreciate everyone's engagement. We assume everyone got the batches of materials again and has had a chance to read them, the things that we are going to go over today. I think we'll go straight into the TEFCA draft recommendations. As we all know, these are due soon. So, we want to go ahead as a committee to review and approve the committee's hard work that has been led by John and Arien. So, with that, I'm going to turn it over to John and Arien to go through the brief that has been sent out already.

Arien Malec – Change Healthcare – Member
Good morning. So, the way we're doing this this morning is I'm going to be doing the play-by-play and John is doing the color commentary. We've got our recommendations organized by sections. So, I think Carolyn and Robert, I think the plan for us is to pause at each section, get feedback, and go to formal voting. Is that right?

Robert Wah – Individual – Co-Chair
Yeah, I think that's the best way to organize this. This been successful in the past, and we'll keep with that.

Arien Malec – Change Healthcare – Member
Excellent. Good, okay. So, this is our overall agenda. Just to remind everybody about the membership, the overall charge, and then dive into the final recommendations. So, let's keep going. Just as a reminder, these were the members of the TEFCA task force. We've been very fortunate in having consistent and active membership. From the first TEFCA task force to the same group that has been reviewing TEFCA 2. We really thank them for their work, their incredible recommendations, and the engagement that they showed through a little bit of a death march to get to this final set of recommendations. So, for anybody who is listening, as well as for posterity, just profound thanks for this group. Going to the next slide.

All right. So, our charge was to review the TEFCA Draft 2 and to make recommendations in the following areas. We will go through these areas section by section. If we go to the next slide, our first goal was to make overall recommendations, overarching recommendations. So, Recommendation 1 is just to look at what is the TEFCA and what is it designed to do? There's a specific charge that Congress gave in the CURES act relative to ensuring cross-network exchange. We felt it was important to balance or to express the broader policies of better treatment, quality of care, and a more efficient health system. And we felt that it was important for that to be the policy goal and success criteria for that TEFCA.

And then, we really looked at the value proposition for QHINS and participant members joining overall over the umbrella of common framework and common agreement, and felt it was important to balance adoption of new requirements with existing frameworks and networks to make sure that the TEFCA is appropriately adopted. And then, ONC establish both carrots and sticks, so that there's appropriate incentive for participant members and QHINs that can include fully pulpit tools like education, outreach, coordination within existing frameworks, any funding opportunities. And then, in particular, making sure that there's appropriate incentive for participants and participant members to participate in the TEFCA. You'll see in our later comments that we believe that addressing 21st-Century Cures information blocking mandates and requirements appropriately should be the easiest to most direct value proposition. There could be additional value propositions. That's recommendation No. 1. If we go to the next slide.

So, with respect to the interoperability rule, and in particular, the information blocking requirements, we are asking ONC to align the TEFCA with the rule. That goes to key definitions like HIE, HIN, EHI. So, just kind of a block and tackle perspective. And then, we discussed the relationship between the TEFCA and forms of exchange that the TEFCA permits or enables, and information blocking. We

recognize that there is much more to appropriately accessing, exchanging, and using electronic health information than the cross-network exchange facilitated by the TEFCA. We do believe that that kind of cross network exchange is an important way that information will be exchanged. We believe that active, good-faith participation in exchange should address and be evidence for compliance with the relevant information blocking requirements. We don't believe, from the same perspective, that it's only a portion of information exchange activities. We don't believe that TEFCA participation alone should be a formal exception or create a safe harbor.

We also don't believe it should be a condition of maintenance and certification requirements for the information blocking condition, but it should be the easiest and most direct path to address those relevant requirements. So, that's Recommendation 2, which is really about alignment to the information blocking requirements. We also looked at the notion that information blocking requires and Congress in 21st Century Cures requires all information to be exchanged, accessed, and used. The TEFCA mandates that the USCDI be the target of exchange. I know there are many comments out there relative to aligning the USCDI with information blocking.

With respect to the TEFCA, we believe it's appropriate for ONC to set a floor with the USCDI, and that may mean that in some cases, there are some paths of exchange that won't be addressed through the cross-network exchange facilitated by the TEFCA and that organizations may need to do other activities if they need access to information that is not addressed in the USCDI. As we expand the USCDI, we believe that this issue will get better but there is substantial value for making sure that the USCDI is addressable through cross-network exchange. And the next slide.

Robert Wah – Individual – Co-Chair
Hey, while we're switching slides, because you're going through quite a bit of play-by-play here as you say. I'll just remind everybody that as you want to join the conversation, please use the raised hand function. If you're not on the app, then we'll have to hear you on audio.

Arien Malec – Change Healthcare – Member
Okay, let's go back one slide, and that is the overarching recommendations section. So, it's a good time to pause, collect feedback, and go to a formal vote. Now John, anything you want to add that I didn't cover in the detail play-by-play?

John Kansky – Indiana Health Information Exchange – Member
No. Let's see if there are questions.

Robert Wah – Individual – Co-Chair
Any questions on the first three recommendations? Comments? All right. Christina, I can see your hand up?

Christina Caraballo – Audacious Inquiry – Member
Yeah, I'm trying to just look at this last bullet in Recommendation 2, and I'm formulating my question. But I just wanted to get some clarity on this one. If it's not required as a condition of the e-certification to participate in the TEFCA, I just have some concerns there. I think we discussed this at the last call, and they brought this up. I do not think that it should be required for vendors to participate,

necessarily, but I do think that that path for participation and that crossover with live and active sites in participation in the TEFCA should be a requirement. So this one's just kind of a sticking point for me. I guess I'd like some more clarity, because I believe that everybody does need to participate, and I want that to be clear. Any live active site and certified technology that's being used in the industry should connect to TEFCA.

Arien Malec – Change Healthcare – Member
If it helps, we definitely discussed this in the task force, and our basic belief is that the information blocking rule should be the horse and TEFCA participation should be the cart. Rather than create a ton of programmatics around TEFCA participation, we should focus on making it easy to participate, and a natural way to address information blocking. To some extent, it creates a presumption that if you're exchanging data with the TEFCA for those relevant portions of exchange, you are addressing the information blocking requirements. If you are not, then I think that regulators and other actors would want to look to see if you are not participating in TEFCA how else you're addressing these forms of exchange, and how you're making your data accessible for access, exchange, and use. So again, the basic thought was let's make sure that information blocking is in the driver seat and that the TEFCA is an appropriate and easy way or means to achieve these requirements. Does that help?

Christina Caraballo – Audacious Inquiry – Member
Yes, and I agree with the third bullet that TEFCA shouldn't be a safe harbor, but I guess I would like a little stronger language that even though it is not a safe harbor and you have to show that you are not information blocking in many ways, participation in the TEFCA, I think, is still a fundamental piece of achieving interoperability. So, I do think that you have to have a line to it, even if it's that floor. I am concerned at the way the final bullet in Recommendation 2 is almost saying that it's not necessarily required.

Arien Malec – Change Healthcare – Member
Okay. So, just as a reminder –

Christina Caraballo – Audacious Inquiry – Member
I think we are thinking the same.

Arien Malec – Change Healthcare – Member
Yeah, I think just in Recommendation 1, we do note that it is appropriate to include TEFCA in federal contracts as well as CMS programs. Maybe it's appropriate to say, "Participation in TEFCA is an important building block for nationwide interoperability, information blocking – I'm trying to formulate an amendment as we talk. But it might just be better to frame this recommendation with some of the notions that you're talking about in terms of the TEFCA being an important building block for interoperability. John, can you frame, maybe, mentally an amendment here that addresses their concerns?

John Kansky – Indiana Health Information Exchange – Member
Actually, I'm going to the transmittal letter and seeing if any of the introductory comments seem to speak to what Christina is saying. The other thing, and it's not pushing back against a proposed

amendment, but as those on the task force know, there was a lot of balancing of perspectives in the language that we settled on, is probably a good way to say it.

Arien Malec – Change Healthcare – Member
Yes. But I don't think there would be any objection for saying that the TEFCA is an important pillar of nationwide interoperability.

John Kansky – Indiana Health Information Exchange – Member
Should that go in the words of the recommendation or the words before the recommendation, I guess is what I'm saying? Are we editing the recommendation or the transmittal letter?

Christina Caraballo – Audacious Inquiry – Member
What are your thoughts on striking the "should not be a condition for maintenance and certification?"

John Kansky – Indiana Health Information Exchange – Member
Given the amount of discussion on the task force regarding that and trying to balance the different perspectives on this one, I think that's a fairly significant change. I don't know what Arien thinks.

Arien Malec – Change Healthcare – Member
Yeah, we had a substantial amount of discussion about this point early on. Basically, the thought process here – and I actually think from the regulatory perspective – ONC couldn't make it a condition of maintenance and certification. Because TEFCA by nature is sub-regulatory other than regulatory, and conditions of maintenance and certification probably need to get done through rulemaking. So, I don't actually think this changes the real rule that much. I mean, A), it's just a recommendation to ONC, and B) I don't believe it actually changes anything in respect to the voluntary participation in the TEFCA.

Christina Caraballo – Audacious Inquiry – Member
Understood. Apologies, I tried to join your task force calls but wasn't able to. What about just putting in here that if you have – I think you kind of alluded to it, it should however be an easy task. What about having something that, "As part of certification, a clear path to connect to the TEFCA must be established." And what I'm getting at here is that every certified product has a clear way for their client to be able to see how they can connect to the TEFCA, and that is documented and very clear and transparent to where are those connections happening. Does that make sense?

Arien Malec – Change Healthcare – Member
Yeah, so just to frame up how ONC was thinking about the TEFCA. The TEFCA is primarily a QHIN to QHIN set of exchange standards in how participants and participant members connect to the QHINs themselves is sort of outside of the technical framework. But you're right, we probably shouldn't be saying that relevant standards are outside of certification. So, don't want to imply that. So, John, what would you think about adding the comment that irrelevant standards may be appropriate for certification?

John Kansky – Indiana Health Information Exchange – Member
Sure. I don't think people would have issue with that. If that helps.

Arien Malec – Change Healthcare – Member
Yes. Christina, would that address your overall desire for clarification?

Christina Caraballo – Audacious Inquiry – Member
Yeah, I think so. I just want there to be a clear path and it not to be hidden. Easy to be able to kind of connect where needed.

Arien Malec – Change Healthcare – Member
Okay, so how about we add at the end of this recommendation that relevant interoperability requirements and standards should be considered for future certification?

Robert Wah – Individual – Co-Chair
So, Arien, I think I hear an amendment to your Recommendation 2 forming here?

Arien Malec – Change Healthcare – Member
That's right.

John Kansky – Indiana Health Information Exchange – Member
Is that specifically at the end of bullet four?

Arien Malec – Change Healthcare – Member
At the end of bullet four, correct.

Robert Wah – Individual – Co-Chair
At the end of bullet four, you want to add the words – and I don't think I've got them down.

Arien Malec – Change Healthcare – Member
Yeah, so the words would be "Relevant standards should be considered for future certification programs including QHINs as well as participants and participant members." Again, the point just being that we want to align standards like enabling standards for the USCDI as well as QTF standards as appropriate to certification programs.

Robert Wah – Individual – Co-Chair
Okay, those last words you weren't planning to put in, right? You're planning to put it in –

Arien Malec – Change Healthcare – Member
Correct.

Robert Wah – Individual – Co-Chair
After the last bullet on Recommendation 2. I'm not sure we can edit this on the fly.

Arien Malec – Change Healthcare – Member
No.

Robert Wah – Individual – Co-Chair
And display it. But I want to make sure everybody understands what you're proposing. You're going to add the words "Relevant standards should be considered by QHINs and participant members?"

Arien Malec – Change Healthcare – Member
Yeah, relevant standards. Let me do another mental editing pass at this. So, "Standards relevant for participants, participant members, and QHINs should be considered for future rounds of certification."

Robert Wah – Individual – Co-Chair
Okay, you flipped it. Okay.

John Kansky – Indiana Health Information Exchange – Member
That's your best version yet.

Arien Malec – Change Healthcare – Member
That's my best version. We're sticking with it.

Robert Wah – Individual – Co-Chair
You started us out on SportsCenter; I don't know what we're doing. Okay. Is everyone clear on the proposed amendment? And Arien, if I can ask you to repeat it at least one more time to make sure everyone's got it?

Arien Malec – Change Healthcare – Member
I probably should write it down.

Robert Wah – Individual – Co-Chair
So, we're talking about on the slide of the **[inaudible] [00:25:45]**.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
I'm going to email this to myself. We could try to get that displayed quickly or just circle back to that one so everyone can see it.

Arien Malec – Change Healthcare – Member
Yeah, why don't we circle back? I like that proposal. Why don't we circle back to this issue? And then, just presuming that we will get agreement on that particular amendment, it might be worthwhile to look at support for these three recommendations.

Robert Wah – Individual – Co-Chair
All right so let me just entertain any other comments or discussion on these first three recommendations, understanding that we're working on displaying the amendment to Recommendation 2. Steven?

Steven Lane – Sutter Health – Member

I just wanted to say I think these are well thought out, intuitive, and I support them. And I thank the committee for coming to this point.

Arien Malec – Change Healthcare – Member
Thank you.

Robert Wah – Individual – Co-Chair
Other comments or questions or suggestions for the first three recommendations? Okay. It looks like we are trying to change the presenters to maybe make it possible for Arien to type in. So, Arien, you're on the presenter chat.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yeah, it may take us a couple minutes to get that displayed.

Arien Malec – Change Healthcare – Member
Why don't I send you the draft text, and then we circle back to this rather than trying to do it on the fly.

John Kansky – Indiana Health Information Exchange – Member
Is it helpful if I type what I heard Arien say in the public chat?

Arien Malec – Change Healthcare – Member
Sure, yeah. Yeah, that's really useful. If you could do that, we could move on with – maybe we could get some consensus on these three recommendations and then move on.

Robert Wah – Individual – Co-Chair
What I'd like to do is let's vote on these first three.

Arien Malec – Change Healthcare – Member
John is working on the…

Robert Wah – Individual – Co-Chair
Yeah, yeah, yeah. That's okay. I think it's fine. We'll come back to these three. If you guys look at your app in the lower right corner there is a presenters' chat. You can do it in there, because there are only seven of us in there right now.

Arien Malec – Change Healthcare – Member
Yeah, so John is putting it in the public chat right now. "Standards relevant for QHIN-"

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yeah, they don't have access to the presenters' box.

John Kansky – Indiana Health Information Exchange – Member

That's what I heard. That may be a little bit off.

Arien Malec – Change Healthcare – Member
That's completely appropriate. Yep. That's exactly it.

Robert Wah – Individual – Co-Chair
Okay. All right. Well, then I'm assuming everyone can see the presenters' chat. I'm sorry, the public comment chat where John has just typed the proposed amendment that would go at the end of the fourth bullet of Recommendation 2 that's on the slide that is currently being displayed. Okay, Sasha you have your hand up?

Sasha TerMaat – Epic – Member
This is nitpicky, but we do we really need "QHINs, participants or participant members?" The standard could be relevant for one of those groups, not all.

Arien Malec – Change Healthcare – Member
Absolutely fair. And it is nitpicky.

Robert Wah – Individual – Co-Chair
That second order amendment, let's change the word "and" to "or," is that what I'm hearing?

Arien Malec – Change Healthcare – Member
Yes.

Robert Wah – Individual – Co-Chair
Okay. All right. Other comments about this amendment? So, I think now, what I see on my app is a little box that says, "Notes 11." It lists the proposed amendment with the second order amended change as well. Which I guess we'll just take it as a regular amendment. That would go at the end of the fourth bullet for Recommendation 2 that you see displayed on the screen. Other comments or questions about this amendment? All right. Hearing none, let's vote as a committee on amending Recommendation 2 with the addition of language that is viewed in Notes 11 at the end of the fourth bullet. Is everyone clear on that? Okay. All those in favor of this amendment please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Co-Chair
All those supposed to say no. Any abstentions? Okay, so Recommendation 2 is now amended. Let's take a vote on these first three recommendations as amended and I will ask for any final comments on Recommendations 1, 2, or 3, understanding that we have now amended Recommendation 2. Seeing no other comments on Recommendations 1, 2, and 3. Let's take a vote. All those in favor of Recommendations 1, 2, and 3 as amended please signify by saying aye.

Group

Aye.

Robert Wah – Individual – Co-Chair
All those supposed to say no. Any abstentions? All right great, good.

Arien Malec – Change Healthcare – Member
All right. Let's go on to the next cluster that relates to applicable law. So, a little bit of background here, there are a set of requirements in the so-called MRTCs, the Mandatory Required Terms – I forget what MRTC stands for, but it's the terms and conditions that are required for all QHINs as well as appropriate pass-throughs to participant members. And these are really the foundational rules that are laid down by ONC as opposed to any additional terms that get added by the RC and QHINs. And in those MRTCs, ONC basically has recapitulated HIPAA to make sure that there is appropriate coverage for noncovered entities and nonexisting BAs, to make sure that we apply the key and relevant HIPAA terms. So, given all that, the task force felt it was very important to make it clear that there are some of the terms and conditions in the MRTCs that are repeats of HIPAA obligations extended to cover Participants and Participant Members who are not covered entities or BAs.

And then, some are new privacy and security obligations that go beyond HIPAA and cover all Participants and Participants Members. And so, some of those examples are some of the specificity around meaningful choice, the use of EHI outside the U.S., and specific identity-proofing and authentication policies. So, basically, just wanted to make sure that we clarified what's a repeat of HIPAA, and what are additional terms and conditions. That flows through with some of our other recommendations as we go on with the next page.

We noted that most HINs, HIE's in some cases will need to amend terms and conditions within their participation agreements with their participants and participant members, and that that work – and anybody who has been involved in negotiating terms knows that many lawyers are involved and the experience is somewhat less than pleasant. With no disrespect to the legal profession. And that it would be desirable to limit or to address these additional terms through amendments and attachments rather than through trying to renegotiate wholesale words that have been lovingly negotiated. So, we recommend that the MRTCs be addressable through terms and conditions in existing agreements whenever possible, and we provide a suggested set of means that are intended to be illustrative but not constraining.

So, those means include allowing the RCE to evaluate and approve existing participant agreement or relative terms of that agreement and allowing QHINs with the support of the RCE should do the same thing relative to producing better agreements with participants. Potential designate terms and conditions as "required" versus "addressable," so taking that little page from the way that HIPAA is set up. And then, in cases where there are changes to existing agreements, basically allowing a grace period where TEFCA-based exchange can continue to occur while the QHINs are renegotiating their agreements with existing participants. There are already two forms of cross-network exchange. We believe it's important to bring this into the fold of the TEFCA, but also recognize that there is going to be a period of renegotiation. That's Recommendation No. 5. If we go on to the next page. That's it. So

that is the addressable law, applicable law set of recommendations. Let's pause here for comment and for potential approval.

Robert Wah – Individual – Co-Chair
Okay, thank you. Comments, questions, suggestions for Recommendations 4 and 5? All right, I don't see any hands up. Don't hear any additional comments. So, let's go ahead and vote on approving Recommendations 4 and 5. All those in favor of approving Recommendations 4 and 5, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Co-Chair
All those opposed say no. Any abstentions? All right, great. To you, Arien.

Arien Malec – Change Healthcare – Member
Thank you. And Zoe reminds us it is Minimum Required Terms and Conditions, that's what MRTC stands toward. Thank you. Thank you, Zoe. Okay. Now onto a nice and meaty cluster topic relative to the QTF, which is the QHIN technical framework. And then, exchange modalities and exchange purposes. So, Recommendation 6 is in many ways a repeat of our recommendations from our last round in the TEFCA Task Force. Really asking that ONC be specific primarily about how – sorry, about "what" and leave room for flexibility and innovation on "how." So, the TEFCA should outline functional requirements sufficient to meet the policy goals and avoid whenever possible identifying technical solutions. There is a little bit of a gloss to this. The task force, I think, did realize eventually that the MRTCs outline functional requirements, but they got confused with the very specific nature of the QTF.

It was sort of easier to read the QTF than to read the terms and conditions that are buried in the MRTCs and so we felt it was appropriate for ONC to remove the QTF, because that's really RCE and a QHIN, that discussion with their familiar exchange standards and approaches. And secondly, clearly separate and document the functional requirements. And we sort of jokingly referred to this as the QFF, the QHIN Functional Framework, because there has to be an acronym for everything. Again, these requirements actually are documented in the MRTCs. They're just not – from a user perspective, they're not clearly called out as the functional requirements applicable to the QHINs. And so, the nature of this recommendation was to make the document and the terms and conditions more user-friendly so that people know exactly what the functional requirements are and then, to the extent that there's any suggested enablement, separate those two. And then, relevant to our recommendation that we are moving the QTF, since there was a QTF in draft 2, and since the QTF was created and intended as the initial guidance, we recommend that the RCE be provided the comments and feedback that ONC received. It's already is clear, but just double down on the clarity that the RCE's free to choose any technical enablement of the functional requirements. So, that's Recommendation 6. It's sort of a meaty one.

Recommendation 7, we got confused as a task force on the term "Targeted and Broadcast Query," Because the way that it's defined in the MRTCs is actually not aligned with what we call the common

language view of broadcast query but the accepted meaning that exchange aficionados would think when they think about the words "targeted query" and "broadcast query." So, we recommend that ONC avoid using those terms and focus primarily on the functional requirements for the QHIN query response. And if we can go on to the next recommendation.

We had a substantial amount of discussion about this notion of specialty QHINs that sort of morphed to fit the exchange purposes and modalities well as for participants and participant members. The TEFCA MRTCs already carve out an exception for participants and participant members that primarily focus on individual access services. We also make recommendations relative to public health and there may be additional participants or participant members, so we discussed briefly during the task force the notion of SSA and disability determination that may use the TEFCA modalities and exchange purposes somewhat differently from more general actors like providers. We believed as a task force that it is appropriate for QHIN to serve a floor set functional requirements. We also believe that they need the appropriate participants and participant members to serve and respond to a subset of exchange purposes and modalities that are appropriate to their scenario of usage.

And then, in the comments of the recommendations, we also note some of the elements that might be part of that floor and also note that there will be evolution off the floor, and in those areas where there is evolution off the floor there may be a role for some specialized QHINs.

Recommendation 9 is the recommendation relative to the notion that there should be a single on-ramp. We believe that there are multiple exchanges already operating across the country and that – again, this is consistent with the recommendations the first time around – that really the TEFCA is intending to address a subset of nationwide exchange requirements. And the ONC should clarify the role of the TEFCO relative to parallel trust frameworks. In particular, we focused on message delivery and the intended uses of message delivery relative to other uses of network activities that send messages, including DirectTrust and also including local exchange of EDT messaging. So, let's just make sure that we are clear about what message delivery is intended for and what forms of exchange it tends to supplant, and what forms of exchange are intended to be parallel to the TEFCA. I think that's it. What does the next page look like?

Robert Wah – Individual – Co-Chair
I think this is a good group.

Arien Malec – Change Healthcare – Member
Yeah, so let's take this one as a group and get comments, and potentially approve it.

Robert Wah – Individual – Co-Chair
All right, great. So, we have before you Recommendations 6, 7, 8, and 9. Any comments or suggestions for this group of four recommendations? Christina?

Christina Caraballo – Audacious Inquiry – Member
Thanks. So, just a quick question. If you go back one slide, slide 11 I think – yeah, that one. Just the comment that the RCE should be able to choose the technology and standards, and ONC should take

away from this. I'm a little concerned about that. I understand that the current models exist, and we need to have a balance, but I just would like some more clarity and discussion on where you see that kind of floor for standards that need to be in place in order for interoperability to work. Because if you're looking at just functional requirements, a functional requirement can use multiple standards and approaches. Is that going to be a barrier to interoperability?

Arien Malec – Change Healthcare – Member
No, thank you for that. Good opportunity for clarification here. So definitely, the RCE is establishing the QHIN Technical Framework and establishing a floor set of technical framework elements. This really is already enshrined in TEFCA Draft 2, that the QTF that was in Draft 2 is what intended as helpful starting point. Our feedback as a task force is that it's actually less helpful than you think because in some ways it sort of limits the discourse that the RCEs and the QHINs are likely to engage in, No. 1, and No. 2, there are areas where there is existing exchange that uses some of those standards, and there's existing exchange that doesn't. And we believe it's appropriate for the RCE and QHIN just to be really clear about the functional requirements as they're choosing the technical specifications.

So again, the notion in the TEFCA is that the RCE does establish the QHIN Technical Framework, and that without variation, that's sufficient for achieving the policy goals. Really, the intent of this is to say, "Let's make it really clear what the functional requirements behind these technical specifications are," so that we don't have the technical specifications driving the show. Then secondly, really double down on the notion that's already in the TEFCA Draft 2 that the QTF is a real helpful starting point but should not constrain the selection effort that the RCE will go into when it negotiates exchange standards. So, as an example, there's a seed change that we're going through here between SOAP-based transaction standards and FHIR-based transaction standards. The RCE and QHINs may feel it's appropriate to kinda go with the existing standards for a little while we make a transition to FHIR, and we also believe that it's more appropriate to make a more rapid transition to FHIR, and we don't want to overly constrain that discussion by saying, "Hey, ONC says this is the initial set of standards." Does that help?

Christina Caraballo – Audacious Inquiry – Member
Yes, thank you. I'm trying to find a balance of where I want us to be and kind of the reality to get by and make this work.

Arien Malec – Change Healthcare – Member
Yeah. No, our comment as a task force was that the RCE is presumed to be familiar and comfortable with exchange standards. There are any number of nationwide networks that are already using exchange standards across network to exchange data, so we already have an emerging body of work here, and it'd be probably more appropriate for the RCE to take that emerging body of work and see where we need to go.

John Kansky – Indiana Health Information Exchange – Member
And Arien, I would add that not to minimize what this recommendation is saying, I actually think it's not that big of a change in that we're saying our understanding is that the RCE is given the QTF as a starting point anyway. So, what we're sort of saying is "Oh, okay. While the RCE is going to make sure

that TEFCA is implemented in a standard way, we want to sort of underline that the QTF is the starting point since it is already out there, but we also want the RCEs to have the benefit of the comments that are ultimately approved by HITAC.

Arien Malec – Change Healthcare – Member
Exactly. Thanks for that.

Robert Wah – Individual – Co-Chair
Christina, did you have other comments or questions, then?

Christina Caraballo – Audacious Inquiry – Member
No, I really appreciate the clarity and the thought that went into this. So, thank you.

Arien Malec – Change Healthcare – Member
Thank you.

Robert Wah – Individual – Co-Chair
Good. Other questions, comments, suggestions for Recommendations 6, 7, 8, or 9? All right, I don't see any additional hands up. Let's go ahead and vote on approval of Recommendations 6, 7, 8, and 9. All those in favor of those four recommendations, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Co-Chair
All those opposed say no. Any abstentions? All right, great. Arien, on to 10.

Arien Malec – Change Healthcare – Member
All right. This is a weighty set of topics relative to individual access services. I will give a little bit of gloss for 10, 10a, and 10b. We had a pretty split discussion in the task force relative to the initial floor of individual access capabilities. There was strong agreement in the task force that read-only access is only one of the individual access needs. That there are multiple, and we enumerated such activities as correction and amendment, patient-generated health data, data donation for research as key individual exchange use cases. So, we wanted to start off our recommendations, No. 1 saying that the needs of individuals should be front and center in the TEFCA and that those needs certainly will be broader in exercising the read-only right to access as established under HIPAA.

The second part of this recommendation is noting that the access patterns the patients have or that we as individuals have are somewhat different from the access patterns that providers have. So, as an example, where it would be appropriate to provide a clinical document formatted for clinical interpretation to clinicians, patients are much more likely to access via APIs. And so, as we considered the standards, and particularly the USCDI enabling standards, we should be thoughtful about how we align the exchange modalities with API-based access so that the patients can actually achieve the benefits of TEFCA on their, for example, smartphones.

And then, the second part of this represents a real split in the task force, and I will frame up a and b saying that there is a split between folks who want the TEFCA initially to go farther and are prepared to force a little bit new use cases into the TEFCA before it starts, and a group represented by Alternative Recommendation 10b that believes that achieving nationwide access is a significant step forward for individuals and that we should certainly not stop there. So, the sense of the task force was split between those people who say, "Look, if you do not force a high bar right now then we are just going to keep kicking the can down the road," versus those who say, "Hey, if you get substantial amounts of individual access today that are cross-network that is actually a huge step forward and we should continue to work on it. So, that's what framed up in 10a and 10b.

10a says ONC should expand it immediately, including a minimum right to amendment and additional use cases including shared care planning, patient-generated health data, and data donation for research. And then, 10b says let's establish a policy framework to get to broader individual access to individual services including the ones listed above. That the services should be rolled out when available and ready for large-scale adoption, and that the exchange purposes described in Draft 2 should start immediately because this is a significant step forward. So, that's where we got to. A little bit of a split decision here. We wanted to fairly represent both sides of that decision. Going to the next slide.

There was a little bit of a technical issue with respect to the term "Direct Participant," so we wanted ONC to clarify the Direct Relationship, and we wanted ONC to clarify the meaning of the term "Direct Relationship" with respect to response, as it sometimes says versus with respect to kinda where the home participant is relative to query and access. Recommendation 12 is more specific about making it clear that there is an intent to distinguish between the home participant member for an individual relative to which participant members are allowed to respond to query, that ONC probably shouldn't use the same term in both places. And then, we should align the term "Direct Relationship" with the applicable law. And we have a little bit more on the next slide with respect to this. No, we don't actually. Sorry.

Recommendation 13, relative to individual access services notes that there are public health agencies whose mission is primarily to collect data for disease surveillance. They do not maintain any longitudinal patient record that is formatted and applicable for individual access, and the data that they get is really copies of data that is already held by the data source that generally is a covered entity. So, we felt it was in those cases, it was going beyond the mission of public health to require them to respond to individual access queries unless required by applicable law. And just note that research, this is highly variable state-by-state. Again, just the notion that we don't want TEFCA to change the mission of public health relative to surveillance. There is some commentary relative to immunization registries that if you're interested you can read. There's a little more nuance here, but this is the gist of recommendation the task force agreed to. So, this is the cluster relating to individual access services, I believe. I don't think there is anything more on the next slide.

Robert Wah – Individual – Co-Chair
No.

Arien Malec – Change Healthcare – Member
No, good.

Robert Wah – Individual – Co-Chair
So, let's go back. First, let's ask for comments, questions, or suggestions on the entire bundle here. I'd like to go back to Recommendation 10, with its modification and alternative recommendations 10a and 10b. Let me just make sure I am understanding. You have a common Recommendation 10 at the opening of this slide and then the two alternatives. Is it the feeling of the task force that these two alternative recommendations are not in conflict with each other and could be adjusted as additional supplemental recommendations?

Arien Malec – Change Healthcare – Member
Absolutely not. No, these are alternative recommendations that are inconsistent with each other. Because A says we should hold off until we address a larger subset of needs, and B says we should get going with individual access as quickly as possible.

John Kansky – Indiana Health Information Exchange – Member
It's actually the reverse of what you just said.

Arien Malec – Change Healthcare – Member
Sorry. Thank you. Sorry for confusing you. They are inconsistent and not mutually adoptable. So, they're really alternatives that express the profound split in the task force.

Robert Wah – Individual – Co-Chair
So it is that the desire of the task force then to have the committee choose one of these two?

Arien Malec – Change Healthcare – Member
No. I suspect that the committee is going to be in the same position as the task force. In fact, there were multiple committee members who were on the task force, and so our recommendation is just to pass these alternatives onto ONC and essentially kick the problem upstairs.

Robert Wah – Individual – Co-Chair
So, as a committee, if we approve two alternative recommendations that are not compatible, you can't get both, right? So, we are putting forward these two alternative recommendations for consideration by ONC as background for them making a decision on where to fall on this.

Arien Malec – Change Healthcare – Member
Right. That's right.

John Kansky – Indiana Health Information Exchange – Member
Or are we choosing one?

Robert Wah – Individual – Co-Chair
That's the point.

Arien Malec – Change Healthcare – Member
I'm sorry. I would believe that the sense of the committee would be equally as split as the sense of the task force, because as I said there were many committee members who were on the task force. And so, it is our recommendation as a task force that we pass these alternatives onto ONC representing the sense of the task force and the profound split. That's why we really tried to frame around Recommendation 10, which is the real recommendation, the consensus recommendation here which is intending to focus on ensuring that ONC and TEFCA address the needs of individuals first and foremost as exchange participants in the TEFCA, and that also that they set an expansive – a common recommendation here is that ONC set an expansive policy goal with respect to individual participation. Then really note the difference of opinion relative to 10a and 10b.

Robert Wah – Individual – Co-Chair
Okay. With that as clarification, comments, questions, suggestions for – let's start with Recommendation 10 with its two alternative recommendations. I would like to know if there is anyone on the committee that has comments, questions, or suggestions on this slide that you see displayed and these alternative recommendations? What I'm hearing from the task force is their recommendation is that we as a committee put forward both Alternative Recommendation 10a and 10b without showing preference for one or the other, but they be used as background for the Office of the National Coordinator to then formulate their positions. I see a couple of hands. I think I saw Les come up first?

Leslie Lenert – Medical University of South Carolina – Member
Hi. So, I have two comments. One, if we send up these alternative recommendations, we really are endorsing Recommendation 10, which covers a broad scope and makes this very clear. I believe that substantial effort is needed in this area, I'm just not quite sure that it's the first step that should be taken in an incremental world. Secondly, I would like to say that Alternative 10a, which again, I would support conceptually, I'd like to see a little different language on the Precision Medicine Initiative saying that a patient should be able to download for the purposes of the Precision Medicine Initiative and upload their clinical data, and that this should be supported. I can give some specific language if we decide to adopt 10a to make this more precise, but I have concerns that if we try to force it as something that is not ready, we are going to wind up in kind of an early meaningful use a situation where the rules are clearly ahead of our capability.

John Kansky – Indiana Health Information Exchange – Member
So, Les, I take it you're a 10b-er. And I just want to reflect that there are 10b-ers and there are 10a-ers.

Leslie Lenert – Medical University of South Carolina – Member
I certainly like the content of 10a, but I just don't know whether we're ready.

John Kansky – Indiana Health Information Exchange – Member
Yeah. And then, with respect to your concern about the specific wording on PMI, the recommendation here is to address the use cases and try to get into detail about how to address these cases. But I think it's an appropriate to note the need to address these use cases which might include the capabilities that you described.

Leslie Lenert – Medical University of South Carolina – Member
Yeah. I mean you could just say the Precision Medicine Initiative to allow it. The first might be enough. It may be better not to go into the details of the protocols used within that.

John Kansky – Indiana Health Information Exchange – Member
Yes.

Leslie Lenert – Medical University of South Carolina – Member
Thank you.

Robert Wah – Individual – Co-Chair
So, Les, I hear you considering an amendment to the third bullet of Recommendation 10a. I'll let you ponder that for a moment, and I will go on to the other folks with their hands up.

Arien Malec – Change Healthcare – Member
Yeah, I think if you look at the bullet, I think it actually does address the concern that Les is raising, but it really is focused on the policy and not on the specific standards of enablement. If Les, on rereading and further consideration, wants to propose an amendment obviously we would support that.

Robert Wah – Individual – Co-Chair
Like I said, it sounded like he was thinking about maybe deleting all the words after "access to health information" but I am not sure. So, let's maybe consider that, Les, and let us know if that is something you want to propose, and I will go on to Christina?

Leslie Lenert – Medical University of South Carolina – Member
Okay.

Christina Caraballo – Audacious Inquiry – Member
Yeah, so it actually is in line with what Les was talking about. For the Precision Medicine one, I think that the Precision Medicine isn't allowing patients necessarily to access their information. It's dependent on them accessing and contributing it to all the research programs. So, maybe a slight amendment that is dependent on enabling… Let me think about that.

Arien Malec – Change Healthcare – Member
Yeah, I think Les's proposal here is that we delete everything after "NIH)."

Leslie Lenert – Medical University of South Carolina – Member
Yes. That would be pretty close, yeah. If you wanted to just say, "additional use cases to incorporate may include the Precision Medicine Initiative. Otherwise we are getting into the details.

Arien Malec – Change Healthcare – Member
Yeah. Totally fair. I would support that amendment. John, I think that actually makes it clearer.

John Kansky – Indiana Health Information Exchange – Member
Yeah, it's simpler.

Arien Malec – Change Healthcare – Member
Yes. So, let's, let's frame that amendment. The amendment is to delete the words in 10a sub-bullet three starting at the word, "that allows," all the way to the end of the sentence.

Robert Wah – Individual – Co-Chair
All right. So, we have a proposed amendment. By deletion, we have a proposed amendment in second order to delete all the words following the parentheses (NIH). Any questions, comments about the proposed amendment? Steven, I know you have your hand up, but I believe your hand was up before the amendment was made. I'm happy to entertain comments, but what I'm looking for right now are comments about the amendment. So, Steven, if you have comment about the amendment please.

Steven Lane – Sutter Health – Member
I mean, it's not a comment about the amendment per se but it's sort of an important comment that we may want to consider prior to finalizing the amendment.

Robert Wah – Individual – Co-Chair
Okay. Go ahead.

Steven Lane – Sutter Health – Member
If I may. I'm trying to get clarity on what we are talking about with regard to the additional access services. To me, access implies access. Patient access or individuals accessing data. It seems to me that in 10a, we are talking about individuals contributing data, and I don't see that specifically spelled out. I mean, we're talking about requesting an amendment. I mean, that's not really contributing data to their record, it's simply sending a message. You know, it sends to an HIN saying, "I'd like to request an amendment."

When we're talking about participating in shared care planning, I mean, you participate by simply accessing the shared care plan and maybe commenting on it, or you can actually contribute data to it. You know, when we're talking about patient-generated health data, are we talking about the patients simply being able to access the data that the healthcare system has collected from them? Or are we actually talking about a bidirectional flow here? And if we are talking about bidirectional, which I think we are by implication, we should really state that explicitly.

Arien Malec – Change Healthcare – Member
Yeah, so maybe this could be a second amendment. The TEFCA was framed in terms of individual access services, or IAS. I think the intent of Recommendation 10 is that we should set policy goals relative to individual services that include both access and data contribution. So, I think your understanding is exactly correct. And some of the ambiguity here is that we're moving from language that ONC is using relative to individual access to a more generic set of individual services. But I think to Robert's point, I think the amendment is being suggested is separable from that point, so I might suggest that we address the amendment first to clarify that bullet, and then come back to this issue of individual services and clarify the intent of 10 is to be more expansive in access.

Robert Wah – Individual – Co-Chair

Yeah, thanks Arien. So, yeah, I agree. Steven, I think your comment is more directed at the entire issue. I want to finish off our discussion on the proposed amendment to the third bullet of Recommendation 10a. So, other comments or questions about the proposed amendment of deleting those words in the third bullet of Recommendation 10a? See no other comments or questions. Let's go ahead and vote on the proposed amendment. Again, the proposed amendment is to delete all the words after that (NIH) to the end of the sentence. Oh, there, somebody just put that in the middle. Okay. So, this language that you see in Notes 12 would be what's remaining after the deletion of the third bullet of Recommendation 10a. So, one last time, any comments or questions about this amendment? Seeing none, all those in favor of this amendment, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Co-Chair
All those opposed say no. Any abstentions? All right. The proposed amendment then passes so we will delete that language. Now to Steven's point, let's go back to the entire set of Common Recommendation 10, Alternative Recommendation 10a as amended, and Alternative Recommendation 10b. Other comments, questions or suggestions? Steven, back to you.

Steven Lane – Sutter Health – Member
Yeah. So, you were talking about whether we can more clearly define individual services. And clearly, other parts – we used the term "Access, exchange, and use." I wonder if those same terms could be utilized here in referring to what we are offering to individuals. Certainly, 'exchange' captures the idea that they will go bidirectionally between the two parties. And we certainly want the individuals to view their data, so that would be one potential terminology to incorporate.

Arien Malec – Change Healthcare – Member
Can I propose an amendment here is that we propose that after the words "access over time," we insert, ", to include full access, exchange, and use?"

Robert Wah – Individual – Co-Chair
So, you're looking at Common Recommendation 10. At the end of the first sentence in Common Recommendation 10?

Arien Malec – Change Healthcare – Member
Correct.

Robert Wah – Individual – Co-Chair
Adding those words.

Arien Malec – Change Healthcare – Member
So, the first sentence in Recommendation 10 would then read, "those needs will certainly be broader than exercising the HIPAA right to access over time, to include full access, exchange, and use."

Robert Wah – Individual – Co-Chair
Okay. I think that is being displayed in the public comment chatline. And the words you want to propose to add are "to include full access, exchange, and use." Do you have that right?

Arien Malec – Change Healthcare – Member
Yes.

Robert Wah – Individual – Co-Chair
Okay. So now, Notes 13 as displayed here shows the proposed amendment – I don't know if we can highlight that or not. So, that language that's highlighted is the proposed additional words that would be added in the amendment. Okay. So, let's take some comments about the proposed amendment. Steven, did you have additional comments? Or otherwise I'll go to Cynthia.

Steven Lane – Sutter Health – Member
No, I think that is fine, thanks.

Robert Wah – Individual – Co-Chair
Okay. Cynthia, you have your hand up?

Cynthia Fisher – WaterRev LLC – Member
Yes, hi. I'm trying to pull up – if the note could just get a little bit lower then I can see both the Common Recommendation 10 and the amended note. Could you just clarify this? Because it just seems a bit obscure, a little vague. Could you just clarify tightly what you are saying here, or what you're trying to say here in Recommendation 10 for the individual?

Arien Malec – Change Healthcare – Member
Yes, thank you. So, the existing TEFCA focuses on individual access. So, that would be the right of an individual to access their data using the means established through the TEFCA for cross-exchange access, so functionally that would be the ability of the patient to pull down their record regardless of where it exists. The amendment here suggests that while that's – I don't even want to get into that, because that's the difference between 10a and 10b. The amendment here wants to clarify that the end-stage of ONC policy should be to enable individual access, exchange, and use which could include the use cases that are discussed below that involve not just access but also exchange that is supplying information and use. That we establish a broader set of individual services that are relevant for the variety of needs that individuals have to participate in their care.

Cynthia Fisher – WaterRev LLC – Member
In all due respect. I'm just commenting back. Is that okay?

Robert Wah – Individual – Co-Chair
Yeah, yeah. No, go ahead.

Cynthia Fisher – WaterRev LLC – Member

In all due respect, so is it just that the individual can readily access and they push their information to, say, an open standard API tool of use and be able to also exchange, or edit, or correct, or are you looking to add even deleting correct information, that the patient is empowered to control that access? But to make it very usable so that the patient can also – let's take a circumstance where you have one surgeon needing to get what the critical care plan is of a patient, and the patient wants that authority, and they're stopped because they can't get it out of the institution. It's in there somewhere in their data world but how does, with banking as that, as a patient goes across providers or across specialists that they are able to readily exchange and use that. Is that what you're saying here concretely? And are they readily able to **[inaudible] [01:17:37]**

Arien Malec – Change Healthcare – Member
Yeah. So –

Cynthia Fisher – WaterRev LLC – Member
If the care plan is wrong. Like, for instance, on my medications in my database right now in a major institution are so incorrect, from 15 years ago. Because they don't apply. Antibiotics from 10 years ago. So, how do you correct to say, "No, I haven't been taking that antibiotic for 15 years."

Arien Malec – Change Healthcare – Member
So, I think you're exactly on the intent here. The TEFCA Draft 2 establishes the notion of cross-exchange access that would address some of the needs that you are describing. Your ability to get access to your information regardless of where it was stored, regardless of what exchange serves that particular participant. That you're going to lock into one network where you can exchange data but then somebody else uses a different network, you can't. I think you understand better than anybody that that's the real world, the patient's experience. I can access data through this app but not through that app, from this institution but not from that institution. So, the intent of TEFCA Draft 2 as stated is to broaden access services. And then, you are exactly correct. The intent of this amendment is to say for this – sorry, the intent of Recommendation 10 is to ask ONC to broaden the individual services beyond access to incorporate broader services.

We use the technical language that Congress used in Cures in this amendment that Stephen suggested to incorporate exchange and use. And then, we highlight in 10a and 10b some of the use cases that include, as you know, the ability to request amendments to existing records as well as participate in shared care planning. So, that would be contributing your goals and your status toward your goals as well as other use cases including data donation for research, participating research activities, and submitting patient-generated health data for example from an attached glucometer, etcetera. So really, the intent is encompassing the scenarios that you described. And the broad intent is to open from access-only to a broader range of individual services.

Cynthia Fisher – WaterRev LLC – Member
So, Arien, that's great. And I think that the thing that would be really helpful for the world in which we live is for control and management of the patient, that it's not that they need to go back into a system and put in a request. To say "Okay, now will you update this blah, blah, blah," and it takes multiple steps and individual human resources to do that. So, I think to be able to give more empowerment

and control to the patient in their health information and where their health information can and cannot go. It would be great, as we move to the world in which we live in other capacities of our lives.

Arien Malec – Change Healthcare – Member
That's right. And that's the intent of the second sentence in Recommendation 10, which really calls on ONC to note that the access patterns for individuals are different from the access patterns for providers, and in particular, that individuals are more likely to access the app of their choice. And so, the capabilities that are established in TEFCA should be aligned with those usage patterns.

Cynthia Fisher – WaterRev LLC – Member
Well, I guess this is about giving the patient empowerment and control of their information. That they can actually change their information where it's not correct or provide that exchange. I think you had, Steven, or you guys had put exchange in, which is great. I would just push one more level to say to the empowerment of control.

Arien Malec – Change Healthcare – Member
Yeah, I think if you look in Recommendations 10a and 10b, you'll see all of those use cases that you're looking for. Sometimes I think we use technical language rather than patient-friendly language, so we talk about HIPAA right to modification or amendment which encompasses a correction and the like. Maybe it's just a question of terminology, but I think we're all aligned with exactly what you're talking about.

Cynthia Fisher – WaterRev LLC – Member
Yeah, it's who has that right? Right? So, if it's modification, that it's not the EHR vendor, it's not the provider, it's the patient is empowered with that modification or change in exchange. Right? So, somehow, it's just looking for more in control in the patient's hands.

Arien Malec – Change Healthcare – Member
Yes, so if you go to propose an amendment, I think we'd be happy to consider it.

Cynthia Fisher – WaterRev LLC – Member
Could we add that? Could we add the words empowerment and control, or that the two-way in the exchange that there is a readily, easily, available control for the patient or empowerment with their information.

Robert Wah – Individual – Co-Chair
The opening of the recommendation does put the individual front and center. I don't know if that helps you at all, Cynthia. Let me just see if there's other comments. Yeah. I understand. I want to focus on this amendment that you see displayed on the screen in blue, those additional words. Cynthia, if you could just hold on just a second, I want to see if there are additional comments as well. Steven?

Steven Lane – Sutter Health – Member
Yeah, I just wanted to respond to Cynthia. I think actually access, exchange, and use are things that we're all pretty comfortable with. Control, I think, really goes to a new level, and suggests to me what I think what you're getting at, Cynthia, is data that was collected by a provider is maintained by the

provider in their system, but the patient could directly modify that. I will just say as a clinician that that's uncomfortable to me. I think the idea that patient can addend it, that they can request amendments to it as they can now under HIPAA is awesome. But the idea that a patient could go into a record that I created and actually strike data from it and modify data from within it and without my review, consent, etcetera. I think that really crosses into a whole new realm that we haven't really discussed. So, I'm comfortable with access, exchange, and use. I think when we talk about direct control, I'm not ready to go there quite yet. I think we have to lay a foundation for that.

Robert Wah – Individual – Co-Chair
Carolyn, do you have a comment?

Carolyn Petersen – Individual – Co-Chair
I did, thanks. I just wanted to commend Stephen on the framing of that perspective and to note my agreement with it. As all of you know, I have worked pretty directly and pretty tightly on patient empowerment and engagement in facilitating access of all sorts for patients and the expanded use of patient-generated data, patient-reported outcomes and other things. But I think Stephen is spot on with the way that's framed. I think that's a perspective we should seriously consider. Thanks.

Robert Wah – Individual – Co-Chair
Thanks. Other comments or questions about the proposed amendment which is now visible under Notes 13 highlighted in blue? Okay. Let's proceed with voting on this amendment. All those in favor of this amendment to add the words that we see in blue, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Co-Chair
All those opposed say no. Any abstentions? All right. The amendment has been passed. So, we now have our amended Recommendation 10 and Alternative Recommendations 10a and 10b which, at the recommendation of the task force, is we submit both alternative recommendations 10a and 10b for additional background for the ONC. Let's go ahead and vote on just this slide. Common 10 as amended, Alternative Recommendation 10a and 10b to be submitted for ONC's consideration. Any other comments about Common Recommendation 10, the two alternative recommendations and the process of proceeding forward with both Recommendation 10a and 10b? Seeing no other comments, let's go ahead and vote. Let's take a vote for approval of Common Recommendation 10 submitting alternative recommendation 10a and 10b. All those in favor of this please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Co-Chair
All those opposed say no. Any abstentions? Okay, great. Now, if we can remove Notes 13 from the screen. Let's finish off on the additional recommendations that were here as well. I think we have 11, 12, and 13. Let me just make sure, did we have any comments about Recommendation 11, 12 or 13 as presented in the play-by-play by Arien? All right. Hearing

none, let's go ahead and vote on approving Recommendations 11, 12 and 13. All those in favor of approving Recommendations 11, 12, and 13 please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Co-Chair
All those opposed say no. Any abstentions? All right, great. Arien, back to you.

Arien Malec – Change Healthcare – Member
Yes. John, could I ask you to take over for a second? I'm in the unique position of being locked out of my computer for a second, so if you can take over, and then I'll get back in and get control back.

John Kansky – Indiana Health Information Exchange – Member
Sure. No worries.

Arien Malec – Change Healthcare – Member
Thank you.

John Kansky – Indiana Health Information Exchange – Member
So, we're on the privacy section beginning with Recommendation 14. This is related to meaningful choice, and the recommendation that we leave granular requirements to the RCE. There was significant conversation about the definition of meaningful choice and its intent, and we are reloading this in RAM.

Arien Malec – Change Healthcare – Member
Okay, I'm back if you want me to…

John Kansky – Indiana Health Information Exchange – Member
Yeah.

Arien Malec – Change Healthcare – Member
Yeah, okay. Perfect. Okay, so the notion of meaningful choice, this is a term that was originally established by the Privacy and Security Tiger Team of the policy committee many, many years ago. The notion here is that individuals be fully explained the choice that they are making. And then, with respect to the TEFCA, that choice is to participate or not participate in TEFCA-mediated exchange that is cross-network exchange. The task force discussed a couple of things. No. 1 is that it's a little confusing what choice they're exercising, and we want to make it clear that they're exercising the choice to participate in TEFCA-mediated cross-exchange. But there may be other choices that they need to make with respect to local exchange and their EHI.

And the second is really just to establish what we mean by meaningful choice, that it's not purely an opt-out. It is a meaningful choice that incorporates the sub-bullets below that allows people time to make a decision, not compelled, nondiscriminatory, full transparency in education, commensurate with circumstances, consistent with expectations, and revocable. So, we really wanted to clarify what

meaningful choice is and both where it applies and also how it's presented to the individual. If we could go on to the second page.

Cynthia Fisher – WaterRev LLC – Member
Excuse me Arien, I have my hand up just to ask a question – it's Cynthia.

Robert Wah – Individual – Co-Chair
Cynthia, is this about the first recommendation in meaningful choice?

Cynthia Fisher – WaterRev LLC – Member
It's a question that I have about privacy and meaningful choice, yes, and it's about an application of it, please.

Robert Wah – Individual – Co-Chair
Sure, go ahead.

Cynthia Fisher – WaterRev LLC – Member
Thank you. So, I have a question and that is a real-world example of a question. I can give you an exact example in the Boston area of an urgent care that is hospital-owned by a major hospital, that in their installation of their EHR vendor on privacy – and I've brought this up in a HITAC meeting previously. But when you go to sign in and they ask you to sign digitally in there is nothing to read. You are just given a signature line to sign your HIPAA release of privacy on how your data is used. So, you're just given an iPad with a blank screen. And then, even having someone be a 20-year-old who would be now an adult, even though they're insurance card is provided and their information is provided, being a parent of a young adult, the next field that is required by this major hospital system and their EHR vendor is both parents' names, a credit card number, and the parents Social Security numbers. You cannot go to the next screen or get urgent care unless the credit card and Social Security numbers are entered.

Now, if we're sharing all this data and information across systems, for one, I question and challenge why a 20-year-old person who is insured needs both parents' names and Social Security numbers as part of a field that needs to go in, even when those Social Security numbers I thought were something that the industry got away from requiring as an identifier because of possible identity leaks. But this is real world. This is here in Boston. And how, when we're sharing patient information, when that hospital system now has both parents and their credit card and their socials to that link to that child as an adult, how does that get shared and how is that privacy maintained? And is that even legit? And how is it, when I went to talk on the last note about control, how does the patient say, "I don't want that in my record, and I don't want that shared across the TEFCA system?"

So, this is my question to you all in a practical sense about how I think there's some overreach being done. How we think as an organization we think that there is overreach being done on the privacy of information and the ask for information, and even the providing of what that signature line is really signing for. Could you please all help me with how this would be handled?

Arien Malec – Change Healthcare – Member

So, thank you very much for that comment, and I think that's exactly what we are saying here. That was the recommendation as far back as I want to say 2011 from the Privacy and Security Tiger Team. This notion of meaningful choice, the focus is not just on the choice that patients are making, but also the conditions for making that choice meaningful. And so, if you look at the sub-bullets, the six sub-bullets here, for example, to address some of the concerns that you just raised relating to your real-world experience. No. 2, the notion that the choice "Is not compelled and not used for discriminatory purposes." So, you can't force an individual to – "Yeah, you can opt out, but if you opt out, I won't provide you care." It would be prohibited here.

Second is full transparency in education. What actually are you consenting or not making a choice about? And the revocability of that choice, so the ability to change your mind. I think all of those are certainly in line with what we're recommending here and in fact what's already enshrined in the TEFCA, and we're just seeking greater clarification. So, I believe that everybody here agrees with that point and the intent here is to make that point even stronger and clarify obligations relative to providing appropriate choice to patients and individuals.

Cynthia Fisher – WaterRev LLC – Member
Yeah, I think, Arien, the challenge is that patients – this is a real-world situation. Unfortunately, I experienced it firsthand. That's how I'm speaking, you are hearing it from the horse's mouth, where the patient was refused care without those fields being completed.

Arien Malec – Change Healthcare – Member
Yep.

Robert Wah – Individual – Co-Chair
Cynthia, I think that's what they are trying to address here in the first six bullets after Recommendation 14.

Cynthia Fisher – WaterRev LLC – Member
And then, the question that I have is how does the hospital have a right to ask for an adult person's parents' credit card and Social Security number? How does the patient have recourse to argue that that's built into their system and they don't want that shared as part of their personal health information or not their personal, but their electronic health information? So, you are saying it nicely here but is it strong enough for what is happening out there and this financial information that's affecting many people. Not just that patient, but that financial information – that to me is overreaching and how does that patient even know that is overreaching? Because most people won't even know. What do we do to protect here? It's a question I have because there is a big power in these organizations. And there's a lot of information gathering that may not be appropriate and how does the patient have recourse when they are denied care?

Robert Wah – Individual – Co-Chair
So Cynthia, let me propose that we let Arien finish off the presenting of the Privacy: Meaningful Choice of recommendations and see if that doesn't – obviously you have some strong experiences in this area, so I would like to let him finish his task force recommendations to the committee in this area of meaningful choice and privacy. And let's see if that doesn't help, I guess, for where you want to be.

Cynthia Fisher – WaterRev LLC – Member
Thank you. I guess the thing is that if you all can just tell me if this information that a certain oligopoly in the Boston market is collecting today would be shared now across TEFCA. In today's world as we have defined TEFCA, would those fields be shared?

Arien Malec – Change Healthcare – Member
The intent of these recommendations is to require participants and participant members, including the organization to which you refer, to provide non-compelled, clear choice to the patient, to the individual, about how they wish to participate. So, the answer is no. Now, clearly the policy tools in TEFCA have a certain set of applicabilities. So, this tool alone is not going to compel organizations always to do the right thing, but the intent is to make a clear set of obligations for participants and participant members that are exactly what you're looking for.

Cynthia Fisher – WaterRev LLC – Member
So, do we need a privacy to present to patients their Bill of Rights? This is sort of why, and I understand where everybody went on not putting control in there. But as a patient, if I don't want my parents' or my daughter's parents' financial, Social Security numbers, and credit card information to be shared across TEFCA, I should know that as a right. That I could disentangle identity and financial information if I chose to. And be in control of that.

Arien Malec – Change Healthcare – Member
Cynthia, the answer is yes. I think if you look at the sub-bullets here, I think you'll find that we are reiterating exactly what you are asking for. Robert, I'm going to propose as you say that we continue with the other set of recommendations relative to privacy.

Robert Wah – Individual – Co-Chair
Yep. Please do.

Arien Malec – Change Healthcare – Member
So, if we can go on to the next page, 15. So, again, just a little bit of background here. The TEFCA Draft 2 notes that when a patient changes or revokes their choice to participate and says, "Hey, I don't want to participate," there's some information that's already been shared, that has been incorporated into the charts, may have been made for medical decision-making, and we're not asking that that information we'll maintain in the chart. There was a discussion by the task force as to whether there should be some segregation of that data that had been previously shared. I think the consensus of the task force is that that was not practical, and that where the TEFCA Draft 2 lines up is correct. There was a strongly held minority opinion that there should be additional segregation of that data, so this is just a note to the ONC to note those strong opinions in that regard.

Recommendation 16 is a very technical issue that the way that the MRTCs were defined, they referred to a specific section, and we believe that where it refers to Exchange Purposes, we believe it should actually refer back to Section 2.2.2 of the MRTCs, which is a broader set of constraints and definitions relative to disclosure. Now, I'm seeing the screen move all around, so maybe somebody's scrolling?

And when you're scrolling, you're scrolling for everybody. Thank you. Okay. Sorry. Can we go to Recommendation 17?

Robert Wah – Individual – Co-Chair
Thank you. Cynthia, let me just hold off for a second, Cynthia, because you've had a chance to comment. I want to make sure we allow others to have comments on the suite of recommendations under the heading of Meaningful Choice. So, any other comments, questions or suggestions for this group of recommendations on Privacy: Meaningful Choice? Les?

Leslie Lenert – Medical University of South Carolina – Member
Thanks, yeah. As an operator of the health information exchange, this is a very high bar. While it's extremely important that patients have the right to choose about where their health information goes, we're going to have to look at the costs and the benefit, and whether you will exacerbate health disparities by placing the very high bar that Meaningful Choice has for patients to understand and to decide to contribute their activity. This sort of opt-in approach is likely to result in much less uptake of HIE by people, supposedly consistent with their preferences but mostly because there are no micro economic incentives for them to do this until they actually need care.

Arien Malec – Change Healthcare – Member
Les, just to clarify – and we're trying to stay away from the words "opt in" or "opt out," but the intent of the TEFCA exercise of choice is the default to participate with the ability to not participate. We're really focusing on the obligations that participant and participant members have to explain what's going on to patients in practice.

Leslie Lenert – Medical University of South Carolina – Member
I am not exactly sure that that is clear based on my reading of this, that it's favoring an opt-out framework. My feeling is it feels much more opt-in than opt-out.

Arien Malec – Change Healthcare – Member
So, I apologize for that. We're going off the TEFCA and making recommendations in areas where we seek greater clarity in the TEFCA. And the TEFCA makes it very clear that the choice that's exercised is a choice to not participate with the default to participate.

Leslie Lenert – Medical University of South Carolina – Member
Okay, that sounds great. I'm sorry if I have distracted us, then. But the key point here is that an opt-in choice with a Meaningful Choice system would be extremely onerous.

Cynthia Fisher – WaterRev LLC – Member
This is Cynthia, as I had my hand raised. Thank you. I agree with Les and would look to see perhaps in this Recommendation 17 if it could just be more clear, and maybe to restate that it is really an opt-out rather than an opt-in as a stated in TEFCA. And I do think that I would like to add that however anything is communicated, that it's communicated very clearly in sort of Strunk and White English to the patients, or in what language the Strunk and White would have simply stated to patients so it's very clear. And then, finally, I guess I'm still confused about how, if there's information like the requirement by the EHR vendor in the hospital provider system to have perhaps overreach with

linkage to parents and financial information, or another situation where a patient could correct and require that that information not be shared across all networks through TEFCA. In fact, we should empower patients to be able to…

I guess, the question I would ask for the task force, how would you address the question I asked earlier, where if it didn't automatically default that you're in unless you opt out, how would the patient be able to say, "Hey, I'm happy to be opt-in, but this is not appropriate to share across systems?" Because AI and big data and go delve into information that they shouldn't be. Could you guys please help on how we address that type of problem, and how we address that information being shared that shouldn't?

Arien Malec – Change Healthcare – Member
Yeah, can we go back up to Recommendation 14, which I think is two pages up? Yep. So, No. 1, I believe Recommendation 14 already expresses the intent here is that the choice that the patient's exercising, or the individual is exercising, is to disallow further prospective Use and Disclosure. So again, we kind of avoid "opt-in/opt-out," because it's a shorthand. It's not terribly helpful sometimes. But that clearly is an opt out consideration that's very clear in the TEFCA and also clear under Recommendation 14. Secondly, again, just look at the six bullets below. I think we had a discussion about more granular choices that that patient or the individual would exercise, and in the language surrounding this recommendation, we very clearly note that over time, we support this big floor and that we would expect, given some NRCEs to establish additional requirements to provide more choice than is the floor that's mandated by the TEFCA. So, Robert, I think maybe we should just go up to this group as a block and see if we have agreement on these recommendations relative to Meaningful Choice.

Robert Wah – Individual – Co-Chair
Yep. Any further comments, questions, or suggestions or recommendations under Privacy: Meaningful Choice, which is Recommendations 14-17, I believe?

Arien Malec – Change Healthcare – Member
That's right, 14-17.

Cynthia Fisher – WaterRev LLC – Member
So, Arien, just to get clarity, if I'm a patient, the only choice I have today is to totally opt out of my entire record being shared. So, that's what the answer is to my direct question?

Arien Malec – Change Healthcare – Member
Yeah. With respect to the TEFCA and cross-exchange activities, the floor that the TEFCA proposes is to opt out of full exchange. The task force supports that that be a floor, and that additional means – and we had a substantive discussion about this in the task force – additional means for additional control be added, and that this be clearly a floor.

Cynthia Fisher – WaterRev LLC – Member
So, there's no redaction ability at all? In today's world, redacting certain private information, financial or private, it all goes right now? All or nothing? That's it, there's no ability, and so we're just saying in

that other recommendation from last week or something, you're saying that future recommendations are the only things that are going to handle this problem?

Arien Malec – Change Healthcare – Member
Yes, that's right.

Cynthia Fisher – WaterRev LLC – Member
I'm just trying to understand if anybody of your sharp mind has a way that it could be done today other than that.

Arien Malec – Change Healthcare – Member
No, I think you're right in understanding the current situation and the current set of recommendations.

Robert Wah – Individual – Co-Chair
Sasha, do you have a comment?

Cynthia Fisher – WaterRev LLC – Member
I would just like the task force to add that we add a line clearly to communicate that to patients, then. That patients know that all that information including their financial and social, all that information would go. That somehow in the privacy portion that they know in today's world, this is how it is going to work. And perhaps in the future they will be able to redact certain information. But today it is that. Can we put that in the recommendation somewhere, that we're clearly communicated?

Arien Malec – Change Healthcare – Member
I do think that's already expressed. And again, maybe the language is not as clear as you are hoping, but I do think the intent is to clearly explain in plain English to patients and individuals what's actually happening.

Cynthia Fisher – WaterRev LLC – Member
Okay, thank you. I just have trouble reading this language, so God bless them for being able to get there. But thank you very much.

Robert Wah – Individual – Co-Chair
Sasha, you have your hand up?

Sasha TerMaat – Epic – Member
I was just going to add that there may be a way to help with the question, briefly. There are current credit card processing guidelines about how credit card information can be used and stored to protect the consumer's privacy. So, while not part of TEFCA directly, it is something that is presently available today. It's just sort of tangential to the discussion that we're having about that health data under TEFCA.

Arien Malec – Change Healthcare – Member
Thanks for that clarification.

Robert Wah – Individual – Co-Chair
Other comments or questions about Recommendations 14 through 17? Seeing none, let's go ahead and vote. All those in favor of approving Recommendations 14 through 17, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Co-Chair
All those opposed say no. Any abstentions? Seeing none. Arien, do you want to proceed? Also, to the group, we are approaching our sort of pre-assumed time frames. Our priority with this call is to complete the HITAC approval, or modification and then approval, of the recommendations from the TEFCA task force. And so, we're going to proceed with that. We have two updates from two other groups that we have scheduled, and we'll get to those after we finish our first priority, which is to deal with these TEFCA recommendations. So Arien?

Arien Malec – Change Healthcare – Member
Thank you. I will refrain from saying we are through the hard bits and should be on the downslope, because saying that always leads to trouble. So, we are now at the set of recommendations relating to the Summary of Disclosures and Auditable Events. The MRTCs in the TEFCA address those Auditable Events and Summary of Disclosures. We are requesting that we combine and align those recommendations, so that what's audited is also feeding the Summary of Disclosures. That there's a little terministic around retention being focused on audit, as opposed to on Summary of Disclosures. We want to clarify where the Summary of Disclosures takes place. So, it's going to be entered in with a Direct Relationship to the requesting individual. And disclosures when data has been pulled from the associated QHIN and when requested by the associated QHIN. So, it's really a set of disclosures with respect to the entity the individual has a relationship with.

On the next page… What do we have on the next page? Yep, good. Okay, so those are our recommendations

Robert Wah – Individual – Co-Chair
[Inaudible] [01:56:46] your privacy ones.

Arien Malec – Change Healthcare – Member
Yeah. Those are our recommendations relative to Summary of Disclosure, not of Auditable Events.

Robert Wah – Individual – Co-Chair
Great. Other questions, comments, suggestions for Recommendations 18 or 19 on the Disclosures and Auditable Events? All right, seeing none. Let's go ahead and vote on Recommendations 18 and 19. All those in favor of Recommendations 18 and 19, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Co-Chair
All those opposed say no. I'm sorry? I heard a comment.

Clem McDonald – National Library of Medicine – Member
Yeah. This is Clem, I just wanted to let you know I'm late, but I voted in that last round.

Robert Wah – Individual – Co-Chair
Okay Clem. Great to have you, thanks. Okay. I think I stopped at any abstentions on voting for Recommendations 18 and 19. Hearing none. Arien, move on.

Arien Malec – Change Healthcare – Member
Excellent. Okay, now for security. So, there were some specific recommendations related to EHIs outside of the U.S. Our Recommendation No. 20 is that ONC should focus on the need for risk-based security assessment and remediation for QHINs, and not make "where the data resides" – that should be "where the data resides," we have to have a typo. So, first of all, I request an amendment to add an 's' to "where the data resides." As "the central criterion for security." And then, we had a whole bunch a discussion relative to data at rest. the TEFCA draft makes reference to cloud services. We think it's better to talk about data at rest in the U.S. That's really to make sure that we got clarity on governing law.

And then, Recommendation No. 22 recognizes that individuals do leave the United States. In particular, DOD, State Department members, and then all of us as individuals may leave national boundaries and still wish to get access to our information. So, we believe it's appropriate not to restrict data access to U.S. national boundaries and instead let the data follow the patient. So, that's a set of recommendations relating to EHI outside the U.S.

Robert Wah – Individual – Co-Chair
Why don't we pause here, because I think even though these are all under the umbrella of security, there are some very discrete segmentations to them.

Arien Malec – Change Healthcare – Member
I agree. I think this is a nice little block to vote on. And so first, I'll just request amendment.

Robert Wah – Individual – Co-Chair
And so, any comments? I'm sorry. Obviously, I think just sort of a typo thing, that adding the 's' to reside.

Clem McDonald – National Library of Medicine – Member
Question about Recommendation 22. This is Clem. And that's regarding I think it's appropriate and necessary for sort of extensions of U.S. healthcare systems like the Department of Defense to be able to get at the data where they exist. But I think it might get tricky to say just anybody can get it and the patient can get at it, anybody else can get at it from other countries. Because it would get tangled in with some of the laws of the other countries where the Department of Defense might be contained. There are embassies or things like that we would be safe. So, help me with that.

Arien Malec – Change Healthcare – Member
Yeah. So, the clarity here is that the data needs to reside and be protected within U.S. national boundaries to make sure that we have U.S. national laws applied. Our recommendation is that that restriction does not restrict where data may be accessed. And again, as a reference, I think a number of us do support actors including DOD, State Department members and others who do need to access their information outside national boundaries.

Clem McDonald – National Library of Medicine – Member
Are there more than those groups? Are you saying anybody can add – a doctor in Germany who's taking care of them can look it up? And would that then entangle us into the German law?

Arien Malec – Change Healthcare – Member
No, I do not believe that a doctor in Germany could access it, but we are stating that there are cases when an individual might be outside national boundaries using their mobile phone and wishing to access information and that we permit that.

Clem McDonald – National Library of Medicine – Member
Okay, good. Nice distinctions.

Robert Wah – Individual – Co-Chair
Okay, other comments or questions on Recommendations 20, 21, and 22? Okay. Seeing none, let's go ahead and vote. All those in favor of Recommendations 20, 21 and 22, please signify by saying aye.

Group
Aye

Robert Wah – Individual – Co-Chair
All those opposed say no. Any abstentions? All right. Arien, do you want to do the next group?

Arien Malec – Change Healthcare – Member
Let's go. All right. Controlled Unclassified Information, there were some very clear and specific requirements related to Controlled Unclassified Information, a definition enshrined in guidance about certain classes of information where PHIs often considered Controlled Unclassified. And we recommend striking the section that creates obligations broadly for QHINs to address Controlled Unclassified Information. And instead, we recommend that ONC make it clear that additional obligations on data handling or any other specific requirements will be borne by Federal partners. And as Federal partners onboard, ONC should work to make sure additional security requirements don't impede the principle of reciprocity.

And just a little gloss here is that a number of us have experience with Federal partners joining exchange, and then passing very high-bar, over-usual practice for health data enshrine by HIPAA onto other actors, and while we feel it's appropriate for Federal partners to join and participate, we also feel that the additional complexity should be borne by those Federal partners. And maybe that's a logical grouping as well, because we're sort of into a whole lot of detail here.

Robert Wah – Individual – Co-Chair
Okay. All right. Let's go ahead and take comments, questions, or suggestions on Recommendations 23 and 24. Again, seeing none, let's go ahead and vote on Recommendations 23 and 24. All those in favor of Recommendation 23 and 24 please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Co-Chair
All those opposed say no. Any abstentions? Great. Next grouping.

Arien Malec – Change Healthcare – Member
All right. Privacy/Security Labeling. I think we had 27 recommendations, so maybe I would propose we just take 25 to 27 as our next cluster. Privacy/Security Labeling, there was some discussion related to tagging. We believe "data labeling" is the appropriate term. And we recommend aligning any Privacy/Security Labeling requirements to common national standards and policy framework that's implemented in provider workflow systems. We noted that this committee previously recommended to ONC that there would be value in privacy labeling, but more work is required to make labeling implementable. In particular, there should be accompanying policy guidance that addresses when labeled data can and can't be used, and how duplicative data, both labelled and unlabeled, should be handled. So, this is again consistent with our previous recommendations in this area.

Now, let's go to Recommendation No. 26. Sorry. I think 28 is our last recommendation. And this is sort of a grab-bag. So, Certificate Authority, there was a specific set of requirements for Certificate Authority. These were organizations such as identity assurance and an issue, for example, enabling X.509 certificates. We believe that the requirements to be a good CA – that is Certificate Authority – go far beyond what is proposed in the MRTC terms, and should be out of scope for TEFCA, and we recommend deleting the provision.

With regard to Identity Proofing and Authentication, we recommend that ONC make it clear that QHINs can accept identity proofing that's done by Participants and Participant Members on the basis of flow-down terms, and that we agree on ONC's inclusion of AAL2 and IAL2. These were specific requirements relating to identity assurance and authentication that set a somewhat higher bar than one that's actually in alignment with current norms, including the use of two factors. And we recommend that ONC allow appropriate time for the industry to accommodate these requirements. So, that's 24, 25, 26, 27, and 28 at a group. A grab-bag group of fairly detailed recommendations.

Robert Wah – Individual – Co-Chair
All right. Not to diminish the importance of any of them. So, let's take comments about these last four recommendations in the grab-bag of 24, 25, 26, 27, and 28. Any comments, suggestions, or changes?

Clem McDonald – National Library of Medicine – Member
This is Clem. I have a question. I guess a question and a comment. First, I've got to compliment the explicit and exquisite kind of thinking that went into all these things. It's really very, very nice and

good. The question was about the first recommendation – I think it's 25. How does that relate to segmented privacy?

Arien Malec – Change Healthcare – Member
Yeah, thank you Clem. I appreciate the thought there. Segmented privacy is exactly what we are talking about in terms of labeling. What we are recommending here is that rather than create additional TEFCA-specific labeling, tagging, segmentation requirements, that we align any requirements in the TEFCA with a national standard of certification and policy. And again, the key point that we keep coming back to on both this task force and we addressed as a committee is that the policy standards need to go hand-in-hand and I think that is consistent with the committee's broader recommendations. Again, just to be super clear, this is exactly the same topic. Data segmentation, labeling, or tagging are all exactly the same thing.

Clem McDonald – National Library of Medicine – Member
Okay. I brought it up specifically because the committee discussion was sort of – it wasn't definitive on how fast we need to proceed with segmented data, segmented privacy.

Arien Malec – Change Healthcare – Member
Clem, I think this recommendation is – that's not how I characterize the position, but I think this recommendation is consistent with the committee's previous recommendations in the area. Which are to say that we have standards but not enabling policy, and that the standards aren't actionable in practice. And so, our recommendation generally is to firm out the policy and make sure that standards are applicable in practice.

Clem McDonald – National Library of Medicine – Member
Okay thanks. That's good.

Robert Wah – Individual – Co-Chair
Okay. Other comments, questions, suggestions for Recommendations 25, 26, 27 and 28? All right. Seeing none, let's go ahead and vote on these last four recommendations. All those in favor of Recommendation 25 through 28, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Co-Chair
All those opposed say no. Any abstentions? All right. So, let me thank Arien and John and their entire task force with what has been a monumental task to get through all of these recommendations. Thank you for formulating them and thank you for presenting them. And I think at this point, we will move on to our updates. Our first update will come from the USCDI interoperability task force. Christina and Terry.?

Christina Caraballo – Audacious Inquiry – Member
Great, thanks. Robert, I know we're little bit behind on time. I don't know how much time we need to leave for the ISP task force but feel free to move me along if we need to. If we could go on to the next

slide? So, today we are going to go through our draft recommendations of where we are with the task force and give an update to the group. Just in general, we are very pleased with the draft that ONC has put forward. As we are going through our recommendations, we started generating a lot of questions and we have gotten guidance from ONC that we should start to try to answer those questions instead just, say, providing more clarity. So, we would like HITAC to look at areas that we have provided recommendations on where we want more clarity to start thinking through that. So, just keep that in mind as we go through.

Another overarching thing is we have identified that we really don't want to just create a model in the USCDI that simply classifies Data Elements, but really look at creating a model that facilitates the progression of the Data Elements through the process.

So, with that, we are going to go through the Promotion Model Guidelines first. And then move on to the Lifecycle and Submission Information. So, with the guidelines here on the screen, what you'll see are the actual USCDI guidelines that are actual text in the draft. We thought it was worth going through this just as a kind of an introduction to HIPAA group thinking. So, just at the beginning, any individual or entity may submit a Data Element into the process or contribute to a Data Element. Stakeholders will submit Data Elements for consideration as part of the USCDI Promotional Model. Under that, a Data Element with multiple Data Elements may be submitted, but constituent Data Elements will be individually evaluated for placement and advancement. Data classes may have Data Elements at different levels of classification. A single Data Element may be a Data Class in name as well. So, the Data Element information submitted for entry in the USCDI Promotion Process will determine whether the Data Element is classified as Level 1 or Level 2. We are recommending putting a new classification, and this is later on in our recommendations, as well. As I go through this, anything in red is additional language from the task force. So, we are proposing that different comments that are submitted but not reviewed are labelled as "unclassified," and then once they are reviewed by ONC and do not go into Level 1 or Level 2, they are classified as "Proposed." Moving on to the next slide. No Data Element can proceed directly into the USCDI. This is for transparency purposes, and the USCDI Promotion guidelines and criteria will be transparent to the public. If we could move on to the next slide.

On this, we're moving to the Promotion Model Lifecycle. So, for the guidelines, we do plan to go back and provide more recommendations at the end, but where we are now is that submission model lifecycle. So, just to review, the edits that we've made are in red. We'll try to go through this relatively quickly, but the submission cycle begins when ONC announces a new version of the USCDI. A submission cycles end at the end of the calendar year. Submitted Data Elements exist as comments. Kinda getting through this. Proposed Data Elements will be removed if not classified into Level 1 or Level 2. Once classified into Level 1 or Level 2 by ONC, a Data Element has up to three submission cycles. We can go on to the next slide.

If a Data Element is removed due to lack of progress, it will be archived, and after a Data Element's level of classification has been published, a submitter may request information. So, if we go on to the next slide, and let's do that quickly. And the next slide. Because in our recommendations, we pulled the language again, so we'll be able to reference it through our recommendations. And that's just the

overview we went through just now. So, for the submission cycle and entering as comments, this is our formal recommendation as it stands: "The task force supports the concept that anyone can submit a data element via an open comment process. The task force suggests that Data Elements submitted for review, currently labelled as "Comments," become "Proposed" Data Elements once reviewed, until classified as Level 1 or Level 2.

Robert Wah – Individual – Co-Chair
And Christina, just let me interrupt for just a minute. So, just to be clear, what we are doing here is updating the committee on your taskforce's work. Your task force has formulated some initial recommendations here, but at this time we are not voting on any specific actions. We are not taking any specific actions as a committee. We are taking these proposed recommendations as an update of your task force's work. Just to be clear.

Christina Caraballo – Audacious Inquiry – Member
That is correct. With the two areas that we have provided recommendations in this presentation are around the lifecycle and the data element submission information. I think we're at a point now where we have contributed as a task force and the recommendations are as they stand. And we're ready to move on to the next section. So, we would really like feedback from the full committee today on these first two sections, because we are planning to move forward and we'll revisit them at the end but are kind of putting them on the shelf for a little bit right now.

Robert Wah – Individual – Co-Chair
Yep. Great Yeah, so we will be looking for input from the entire committee on your task force's work here.

Clem McDonald – National Library of Medicine – Member
This is Clem. I don't really have specific comments on this, but it is sort of the question to ask. So, will there be some kind of notes to what is already in the guidance on levels? What I'm worried about is laboratories are already in there. And so, then I'm going to get peppered by individual lab test requests from companies, and did they want us to be specifically cited in the USCDI, or will there be something that is already covered? Maybe that is too big a question.

Robert Wah – Individual – Co-Chair
Clem, it sounds like you are asking the question specifically of the Office of the National Coordinator.

Clem McDonald – National Library of Medicine – Member
Well, how are they going to keep from getting barraged by stuff that – yes, maybe it's not appropriate for now.

Robert Wah – Individual – Co-Chair
No, it's fine. I guess what I'll do is I'll allow them to formulate their response, but let's move on with the discussion and presentation of Promotion Model Lifecycle, and then I will allow ONC to come back in.

Clem McDonald – National Library of Medicine – Member

Okay.

Robert Wah – Individual – Co-Chair
Christina, you want to proceed?

Christina Caraballo – Audacious Inquiry – Member
Yes. I think we can move to the next slide. Okay, so this is around the Data Elements that are not classified as Level 1 or Level 2. They have three submission cycles from the ONC final decision period to remain at the comment level before they are removed. And then, we just want some clarity on how proposals should be modified, updated, or resubmitted. We got some later comments in here around the recommendations around the Data Elements being removed or whether they should be archived, and what that looks like. If you do not mind, I would like to go through the four slides and then come back to this. So, next slide please.

Robert Wah – Individual – Co-Chair
Sure.

Christina Caraballo – Audacious Inquiry – Member
Okay. So, our next recommendation is to put a process in place as a group/merge related Data Elements, and when possible, tag Data Elements as belonging to a data class that already exists in the USCDI and/or as part of the newly proposed data class. One thing that we wanted to note is that the USCDI process operates at the level of the Data Element and not the data class, but data classes may advance to incorporate more Data Elements and new data classes can emerge through this practice.

Our next recommendation – if we could go back one more slide – is around the actual removal process and this was what I was alluding to before in this recommendation. So, our recommendation here is that the Data Elements are listed as "proposed" when ONC determines that they are not Level 1 or Level 2, but Data Elements may be marked or tagged as inactive after a five-year period. I put a question mark beside it. But should remain in the proposed category. We are kind of looking for a balance here on what becomes too cluttered in that "proposed" and when it should be archived. And then, when it it's archived, we don't just want Data Elements to get lost in a bucket of cobwebs. So, Clem, this kind of goes in line with what you were asking, your question to ONC on how much should be in there or not. It would be great to get some feedback on this.

Our next recommendation is that Data elements in the "proposed" category should be grouped into data classes when possible. We want transparency on where they live the data class ecosystem. Moving on to next slide. Final recommendation in the lifecycle is that this should be public so that all interested stakeholders understand the classification decision and include those kinds of grading criteria that led to that decision, as well as justification and exchanges that happen between the submitter and ONC. I will pause there.

Clem McDonald – National Library of Medicine – Member
This is Clem again. I do not disagree with anything, but I worry about having to deal with the element level always. And I worry about then if the people who submit need to get debriefed per element, because there are possibly tens of thousands of elements people could – this could be like a denial of

access and Internet if they throw in that stuff or not. I just think we've got to be careful about having such broad requirements on ONC when we can get down to these tenty little pieces that could be part of any particular category of testing.

Carolyn Petersen – Individual – Co-Chair
Clem, do you think that the recommendation to the group that ties into the data classes helps with that at work?

Clem McDonald – National Library of Medicine – Member
I mean, the wording says that the decision made at the element rather than the class is a little bit of worry. It's a challenge. I don't know. I don't have good counter suggestions, but I just worry about the ability to absorb, especially if an industry wants to get busy. You can make up hundreds of elements or thousands of elements, and there are at least 40,000 lab tests already. And now, are they going to have to deal with every lab test that a new vendor comes up with a new product, or will that be consumed on their labs?

Robert Wah – Individual – Co-Chair
So, just to keep the discussion moving, I think the way I would like to propose we do this is that the task force on USCDI take the comments from the committee and not necessarily feel like they have to address them as they come up, but take them as input for their ongoing discussions of these issues. Also, I got a note back from ONC that particularly in this area that Clem is bringing up, that this bombardment risk which would lead to a denial of service is something that they will get back to Clem about rather than try to do it on this call. I think what we are trying to do is gather information from the entire committee on the task forces' work to then inform the ongoing discussions of the task force. Does that seem reasonable to everybody, I hope?

Group
Yes.

Robert Wah – Individual – Co-Chair
Okay. Other comments for the task force on these Promotion Lifecycle slides that Christina has just presented? Okay. Want to go to the next section, Christina?

Christina Caraballo – Audacious Inquiry – Member
Yeah, that sounds great. So, I'm not going to read through these, because each of the areas is highlighted in each, but these are the fields for when a data element is submitted. These are the fields that are required for the submission process. So, if we could go to the next slide, we'll start with the Data Element name and description. We recommended putting "proposed" in here. Recommendation 1 under this field is that we think that ONC should review and name the description of the Data Elements that are submitted. This includes a review of all submitted Data Elements to group similar submissions and refine them as necessary prior to assigning a level. This may include refining the name and/or description before a Data Element is assigned to a level. This is where we were hoping to kind of consolidate a lot of similar submissions and streamline the process as much as we can.

Our next recommendation is to add an additional requirement for the submitter to identify related Data Elements already submitted, whether "proposed," a Level 1, or a Level 2. And then, in our recommendation under this section is an optional field should be included to indicate any existing or propose a new data class for the Data Element. Robert, I think maybe we can keep moving along unless you see a hand up.

Robert Wah – Individual – Co-Chair
Yeah. Let's go ahead and do all the data element submission ones you have here.

Christina Caraballo – Audacious Inquiry – Member
Okay. So, moving on to the next slide. We already did. The next criteria to be filled in the submission form is why should this Data Element be captured and available for nationwide exchange? We have added a few more examples of use cases. **[Inaudible] [02:27:45]** promises to provide applicable use cases, and our first recommendation here is to expand that list and include all stakeholders needed to achieve the quadruple aim. As an example: public health, research, and population health. And then, we are recommending expanding upon the criteria and guidelines for a submitter to provide adequate information to support the Data Element. Moving on to the next slide.

When asked if systems currently capture the submitted Data Element, we are recommending to also include details of the structured capture of data that exists. When asked if standards exist to represent the Data Element, we are recommending that any standards that exist be pointed to in ISA. No recommendations under the description of any connect-a-thons, pilots or production use of the Data Element. And then, for any additional information, we are recommending that a field also be included to include letters of support and/or a method to endorse Data Elements that have already been submitted. Can we move onto the next slide?

Robert Wah – Individual – Co-Chair
So, I think this is a good place just to take a pause to see if there are any comments or suggestions or input to the task force on the topic of Data Element Submission Information.

Clem McDonald – National Library of Medicine – Member
I'll just repeat my worry about the elemental size. There are 14,000 drugs. You could take any areas, you get lots of devices, there's probably a million. So, at the element level, I think we've got to worry. I think we've got to find a way to lump them up a little bit.

Robert Wah – Individual – Co-Chair
Other comments or questions for the task force? All right. Christina, do you want to go on to the next section?

Christina Caraballo – Audacious Inquiry – Member
Great, thanks. I'm going to pass it to Terry.

Terrence O'Malley – Massachusetts General Hospital – Member
Okay, thanks. There are really two issues that have been raised within the task force but not really widely discussed, so we want to bring them up today to put them in front of the committee for any

additional thoughts or input. It's really sort of what, how, and why we're raising this. So, the first issue is around sort of a national health information strategy. So, we're thinking USCDI looks a lot like a market-driven process right now, where Data Elements are proposed and then advanced. Much is driven by those with most experience in moving Data Elements through standardization and testing. And the concern is that there may be Data Elements and data classes that aren't really amenable to that process. So, we will be discussing this issue further in the task force, but have the question for the committee to consider, and there's one more slide on this. So, is this an issue that's worth pursuing? Has it already been solved, and we don't know about it? So, that would be one set of questions.

If we go on to the next slide, please. Let's break it down a little bit more. We were trying to think of sort of functions in the process of advancing Data Elements through USCDI. We're not proposing a mechanism, and we're not proposing a structure. But the thought – and these have been raised in the committee – is how do we get these sort of functions into the process in a way that first of all, doesn't clutter it up and make it more onerous, but also helps us meet the strategic needs that data and specific Data Elements are going to play in getting to the quadruple aim. So, I'm going to let you guys read the slide rather than me. I think that the overriding concern is that we think that you need both a strategic approach to identifying data elements, as well as a market approach. They're both important, they both contribute significant values, but I'm not sure that either one is sufficient by itself. So, those are the questions, and we just ask for some comments or observations or anything at this point.

Robert Wah – Individual – Co-Chair
Sure, yeah. So, we're taking input now to these two areas that Terry just covered. Actually, Terry, you have one last one, right?

Terrence O'Malley – Massachusetts General Hospital – Member
Yes, that is the data promotion model itself. It's just around the model.

Robert Wah – Individual – Co-Chair
Okay. All right. So, let's talk about these gaps and these missing functions that Terry has proposed. Any input for the task force from the committee?

Clem McDonald – National Library of Medicine – Member
This is Clem again. I think market may be too narrow, at least market in the public. I mean, it's wide open, and I think if we describe some other force as strategic, who really controls that? Is that going to be a secret hand? I just worry about special categories. How would we choose that? It's as open as it can be now isn't it? Or not?

Terrence O'Malley – Massachusetts General Hospital – Member
Clem, thanks for the comments. You're absolutely right. I think it is a balance. The question is, is the process sufficiently open now to make sure that Data Elements that will help us get to the quadruple aim but maybe, as we put in the last bullet, may be orphaned in the sense that there is not enough of a market uptake to push them forward. But if they have been identified as part of a broader strategy, then you need a strategy to move them forward in addition to supplement what the market is doing.

Clem McDonald – National Library of Medicine – Member

I've got to add one more thing. Who is supposed to collect it and put it in? Is it for one group to say, "You work for me," by another group.

Terrence O'Malley – Massachusetts General Hospital – Member
I guess the question I turn back is there a national data strategy? Is there a group that has looked at the data needs across a government privately?

Clem McDonald – National Library of Medicine – Member
As I mentioned previously, there is. In fact, it met coincidentally with this meeting, so I couldn't be on it today. So, there is a Federal task force information system task force – I.T. task force – that is trying to orchestrate a strategic plan. But it's very, very early.

Robert Wah – Individual – Co-Chair
Are there other…? I think it's good to take this input not necessarily to address it here today because I don't know that we've got enough time to address every comment. But I want to make sure that we get maximal opportunity for the committee to give input via task force, Christina and Terry. Other comments from the committee to help the discussions of the task force? All right, seeing none. Terry, why don't you wrap up with your last section.

Terrence O'Malley – Massachusetts General Hospital – Member
Sure. So, the meat of the work that we are going to have to do going forward is to figure out what the promotion criteria are, and ONC has provided a really nice outline. And again, like all of this, to Clem's point, it's a balance between making sure that the Data Elements have gotten the technical specificity that they need to actually be interoperable and broadly deployed, and on the other hand not making the process so onerous that it gets in the way of moving them forward. I think this is a comment made last year about "Well, there too many stages." So now, there are fewer stages. But, I kind of think that the criteria are going to be quite similar. You are still going to have to go through a series of gates and the question is how we make those gates efficient and not obstructive. This is where the task force is going in the next couple months. That's it, Robert. Thank you.

Robert Wah – Individual – Co-Chair
Thanks for the update. So, before I recognize Steve, any other comments or input for the task force from the HITAC? They are telling you where they plan to go next and they are looking for input. This is an opportunity for the committee to give input today. At the current time I don't see anybody from the committee with their hand up. I recognize Steve from ONC.

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology
Thanks, Robert. I just wanted to express our thanks to Terry and Christina for tackling what they have thus far, and I think you've all been exposed today to some of the broader, let's say, next-decade challenges as we look against the USCDI. It's interesting, the juxtapose of the challenges that they have raised through their initial presentation here with recommendation three from the TEFCA work to focus on the rapid expansion of the USCDI. So, a lot of work that they are doing right now in wrestling with the promotion model is to figure out how to address the recommendation three from the other task force and the struggles that are involved in making sure that there is an open delivery

process that leads to greater transparency for all the stakeholders, but is something reasonably everybody can participate in, which is part of those last couple slides. I just wanted to express our thanks. You know, they have really taken it to the next level in terms of moving the draft forward that we have provided.

Robert Wah – Individual – Co-Chair
Great, thanks. Other comments from the committee for the USCDI task force? All right. So, as you all have noted in the agenda, we do have a commitment to the public to allow them to have their public comment period at 12:15 which is in five minutes. What I would like to do is start on the next section, to provide an overview of their work and then we will solicit input on the interoperability standards priority task force. And if the public comment period allows us enough time, we'll come back to that. Ken and Steven, if you can go ahead and get started on your section, and we will take a hard break at 12:15 to allow public comment.

Steven Lane – Sutter Health – Member
Sure. We can certainly we can get started. Thank you so much, Robert. Thank you for the opportunity to provide an update on the work of the Interoperability Standards Priorities Task Force. Our task force took a bit of a hiatus during the period of time that we were all focusing on the proposed rules but have been back at work for the last month or so. You will recall that our charge is to make recommendations on priority uses of HIT and associated standards and implementation specifications that support such uses, and we are nearing the end of our term of service and are getting ready to work on finalizing our recommendations and preparing a report that we hope to bring back to all of you in the fall. The next slide shows the task force members, just as a reminder. We want to thank both the HITAC members and members of the public who have been participating in this. It's really been a great process.

On the next slide, we'll first have a reminder that our task force has already brought back to the HITAC prior recommendations related to orders and results, as well as referrals and care coordination. Our third major topic area was to dive into the data standards and implementations related to medications and pharmacy data. We have had a number of meetings; we have invited a number of subject matter experts both of industry and the not-for-profit world and we have identified really the Core subdomains where we feel that we have the opportunity to provide specific recommendations. So today, we are not going to be going through the recommendations in detail because don't think that we're quite ready for that. Rather just identifying the subdomains that we are digging into. So, we will take these last couple of minutes before the public comment to just cover what those subdomains are, and then we are hoping again to highlight some particular ones where we want to get input from the committee.

Essentially, we broke the subdomains related to medication data into priority one and priority two items. These are in no particular order, though we have discussed the importance of being able, for prescribers and others including individuals to get data about dispensing of medications and administration, for the importance of being able to get information about eligibility for payment and formulary checking, accessing information about alternative therapies, both pharmaceutical and nonpharmaceutical, the critical importance of real price data transparency as it relates to medications.

With regard to this, the importance of Electronic Prior Authorization transactions for medications covered under the prescription benefit. We have had some specific recommendations that we are going to be offering specific to electronic prescribing controlled substances which is now live in production but has not been fully embraced across the care spectrum.

We have spent some significant time talking about the value of discrete/structured medication sigs and we will have some specific recommendations about the support for those as well is the challenges of medication reconciliation. On the next slide just very briefly. I just want to display this.

Robert Wah – Individual – Co-Chair
Steven, why don't we just take a break here.

Steven Lane – Sutter Health – Member
All I'm going to do is just display this, that's all. Just 30 seconds to see the list, and then we'll go to **[inaudible] [02:43:48]**

Robert Wah – Individual – Co-Chair
Yeah, they're going to override this slide with the public comment slide.

Steven Lane – Sutter Health – Member
That is fine. Go right ahead.

Robert Wah – Individual – Co-Chair
Thank you for that. We are not stopping here; we are just taking a pause. So, let's go ahead, and I'm going to turn it back over to Lauren to run the public comment process and allow her appropriate time to allow public comments.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Operator, can we open the line please?

Operator
Yes. If you would like to make a public comment, please press star one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star two if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
And do we have any comments in the queue?

Operator
There are no comments in the queue.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Okay Robert, we may just circle back if folks are taking a couple minutes to dial-in. But if we take get any comments on the phone, I will let you know.

Robert Wah – Individual – Co-Chair
Great, thank you. So yeah, the comment period will open so people can go ahead and dial-in. If we can put the slides back to – yes exactly. So, Steven, why don't you go ahead and continue on your discussion?

Steven Lane – Sutter Health – Member
Actually, I'll let Ken take it from here.

Ken Kawamoto – University of Utah Health – Member
Sure. So, what we have here are some of our other what we consider priority two recommendations and then we have some specific issues we want to get feedback on. With regard to our secondary priorities, the primary ones included things like price transparency and such. These include the ability to transfer prescriptions across pharmacies, etcetera, having standard ways to access a PDMP prescription drug monitoring program data, issues with costs associated with accessing PDMP data and taking advantage of things like – go ahead. Okay.

Issues with costs to access PDMP data and bringing that down. Perhaps leveraging some ongoing work that ONC is working on. More standard ways of detecting and reporting adverse drug events through available data, RxNorm code availability and use – so, this includes some minor things including API availability of past archived RxNorm codes which currently is not available through API, and also through the National Library of Medicine resource there that they are aware of and I think we'll be able to fix. And use of RxNorm codes particularly where MVC codes are more prevalent with regard to dispense medication. There are a number of issues there, for example, for estimating price when those transactions tend to be done at a level of MVC. Another issue is with regard to electronic prior authorizations where prescriptions that are considered a medical rather than pharmacy benefit have much less infrastructure and standards around it.

Also arising from acknowledgment that NCPDP standards are not publicly available, this turns into a larger issue of should there be public access to standards required by federal programs? And we believe they should be available. If we are going to require them, they should not be behind the table. Also related to that, we shouldn't create perverse incentives by penalizing groups that have decided to make their standards open such as HL-7, and broadly support the developers of standards that are required by federal programs. Next slide please. Maybe Steven, you can walk folks through this.

Steven Lane – Sutter Health – Member
Sure. So, we wanted to pull out a few of the key recommendations that we are looking at and just highlight them to take the opportunity for the input from the committee. Really, on the whole, our interest is in getting your input as to whether the items that we have identified are appropriate for the input of the task force or whether there are some key ones that we feel are missing or some that we have waded into that perhaps people have concerns about. But these are some that we thought we were getting ready to bring forward. Specifically, the concept of incentivizing and requiring payors and PDMs to make real-time prescription benefit information available so that the system can calculate

and present the true out-of-pocket cost data both to prescribers and patients in real-time. This has been identified by a number of commenters as a real opportunity.

Clearly, some payors and PDMs make this data available, not all do. The data is not fully integrated into workflows today. It seems there is an opportunity to really incentivize this and add value to the patient prescribing process. Similarly, the notion of freely sharing prior authorization requirements, again from the payors incentivizing the free sharing of that data, making it available both to providers and to our patients, individuals, so that they can then utilize apps to prepare for and manage through the prior authorization process. Just want to make this data available. The third one here encouraging or incentivizing or acquiring potentially prescriber adoptions of EPCS for all controlled substance prescriptions. Clearly, this is a key component in our efforts to quell the opioid crisis and it has been shown clearly that using e-prescribing is very valuable, and there are number opportunities for us to close the gap so that nearly all controlled substances are e-prescribed.

And then, as Ken mentioned, this notion of the public availability of standards that are required by certification criteria and other federal programs. This is a gap that has been identified in terms of standards and made public only during public comment period, and then they go back on the table, and that just did not make sense to our task force. So, these are some key issues we would love to hear comments on from the committee or others that we have mentioned as priority one and priority two.

Robert Wah – Individual – Co-Chair
Good. Thanks to both you and Steven. Let's go ahead and take any time for the committee to give comments and input to the task force. Any questions for them as well?

Clem McDonald – National Library of Medicine – Member
If no one else does, I have a comment, but I'll wait a bit more.

Robert Wah – Individual – Co-Chair
Sure, go ahead Clem. There is no one raising her hand.

Clem McDonald – National Library of Medicine – Member
It's a well thought through and very meticulously specified set of suggestions which I think are almost all excellent. The one I do not agree with, as it's stated anyway, is the one about the structured sigs. I don't think it's given enough thought. Firstly, we didn't have access to the NCPDP proposal for that to know what we're really talking about. Secondly, from my experience working with physicians in order entry, having to click through, these are only relevant to the competent prescriptions which represent 2% or 3% of all the prescriptions written. They are very hard to enter in a structured format. It's a lot of clicks for physicians. It's quite easy for the hospital to set up templated text that explains it all, and that doesn't make more work for physicians, it does make more work for pharmacies to translate it into their internal system. So, I think we should give it more thought and not make it a first priority.

Robert Wah – Individual – Co-Chair
Thank you, Clem. Ken, I'd like to get as much input as we can from the committee to the task force. I don't want to cut them short. So, I don't think we have time to address each comment. Let's just take

it as input for right now. If you have a clarifying question for the comment then we can do that, but I don't want to try to get back-and-forth where we're trying to address each comment.

Ken Kawamoto – University of Utah Health – Member
Sure. Just to be very quick. Clem, if you look at the detailed recommendations, what you mentioned is all captured and addressed.

Robert Wah – Individual – Co-Chair
Okay. Good. Carolyn, I'd like to recognize you now.

Carolyn Petersen – Individual – Co-Chair
Thanks, Robert. If we can see the previous slide again, please. Thank you. On that fourth bullet point, "Support public availability of health IT standards required by EHR certification criteria and other federal programs." I think that is a great path to go down and look at fleshing that out and getting more around that. Just in our own deliberations, a number of times we have had discussion points come up where there is the issue of standards versus policy and how they fit together and our inability to address things that are of interest and importance to the HITAC because one or the other is not in place.

I know certainly in some work I have done with the group looking at university and health literacy of information that patients and consumers get from the EHR as delivered under regulation, it's difficult for people to understand how to improve the quality of that information so that it is more useful and more usable. I mean, it is great to get that health information, but if it's not in a manner that you can understand it, it's not helpful to you. I think if we can clarify for the public and make it more relevant, health IT standards that the health groups that are interested in and enhancements and improvements to patient and health information. Thanks.

Robert Wah – Individual – Co-Chair
Other comments from the committee to provide input to the task force as well? Okay. I believe there are no public comments in the queue.

Steven Lane – Sutter Health – Member
Just one other comment, Robert, from the task force. That is as we formulate our final recommendations in this area for medications and pharmacy data, that we want to be sure that we get broad input. I do not know that we're going to have another chance to bring the detailed recommendations back to HITAC for consideration. We may yet. But if there are individuals on the committee who are not actively involved in the task force and feel that you have thoughts or domain expertise in any of this area and would like us to include you in the review of the detailed recommendations, please just reach out to Ken or myself and we will do that.

Robert Wah – Individual – Co-Chair
All right. Okay. Ken, any other comments from you?

Ken Kawamoto – University of Utah Health – Member
No, thank you.

Robert Wah – Individual – Co-Chair
Lauren, I am just verifying that there are no public comments.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Nope. There are no comments in the queue.

Robert Wah – Individual – Co-Chair
Okay. Well, folks, we are approaching the end of our allotted time for the meeting. Let me just certainly thank all of our co-chairs. As we heard before, John and Arien ran through a very detailed set of recommendations from the TEFCA and thank you to your task force. Christina and Terry, thank you for your work on the USCDI Interoperability Task Force, and your task force as well. And Ken and Steven, thank you for wrapping us up with your presentation on the Interoperability Standards Priority Task Force, and thank you to both you and your task force for all the hard work you are doing.

As my final comments, I will just say thank you to the HITAC. Again, as we said earlier, this is a summer intervention that we had to have because of our need to get back to the ONC with our HITAC comments which we have done today in approving the TEFCA recommendations. A transmittal letter will be formulated, and Carolyn and I will send that transmittal letter to ONC on behalf of the entire committee as we did in the other proposed rule for interoperability. We are looking forward to our next meeting which is in person and so we will be sending out some notes for that. Please be looking for batches before that happens. With that, I will turn it over to Carolyn and wish you all a great rest of the summer and we will see you in the fall. Carolyn.

Carolyn Petersen – Individual – Co-Chair
Thanks Robert. And again, my thanks to everyone for making time in your summer schedule to attend the meeting, to my co-members on the TEFCA task force for all the work that we did in being able to bring these recommendations moving forward and for Robert and I to be able transmit those to ONC. I really look forward to seeing everyone in September. Then I will now pass the mic to Lauren.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Thanks, everyone. So, just as a reminder, September 17th, that's actually in person here in DC. Just a couple of other reminders. Our next USCDI call is tomorrow July 12th, next week our annual report work group is meeting on the 19th, and also the ISP task force is meeting again on the 23rd. Again, everything is also on healthit.gov, including the materials for today's call. So, with that, we will adjourn. Thanks again, everyone.

Group
Bye.