Health Information Technology Advisory Committee

Transcript
April 25, 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 Care	Member
Cynthia Fisher	WaterRev	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	Member
Brett Oliver	Baptist Health	Member

Terrence O'Malley	Massachusetts General Hospital	Member
Raj Ratwani	MedStar Health	Member
Steve Ready	Norton Healthcare	Member
Patrick Soon-Shiong	NantHealth	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member
IB TF Speakers		
Name	**Organization**	**Role**
Michael Adcock	Individual	Chair
CMC TF Speakers		
Name	**Organization**	**Role**
Raj Ratwani	MedStar Health	Chair
Denise Webb	Individual	Chair
USCDI TF Speakers		
Name	**Organization**	**Role**
Christina Caraballo	Audacious Inquiry	Chair
Terrence O'Malley	Massachusetts General Hospital	Chair
HITCC TF Speakers		
Name	**Organization**	**Role**
Carolyn Petersen	Individual	Chair
Aaron Miri	The University of Texas at Austin	Member
ONC/ CMS Speakers		
Name	**Organization**	**Role**
Lauren Richie	ONC	Designated Federal Officer
Donald Rucker	ONC	National Coordinator
Elise Sweeney Anthony	ONC	Executive Director, Office of Policy

Steve Posnack	ONC	Executive Director, Office of Technology
Thomas Mason	ONC	Chief Medical Officer
Zoe Barber	ONC	Senior Policy Advisor, Office of Policy
Mark Knee	ONC	IB TF Staff Lead

Operator
All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning, everyone. Welcome back again here so quickly. We have a jam-packed agenda today, so we're going to go ahead and jump right into the roll call. Carolyn Petersen?

Carolyn Petersen – Individual – Chair
Good morning.

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

Robert Wah – Individual – Chair
Good morning. Present.

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

Tina Esposito – Advocate Aurora Healthcare – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Cynthia Fisher? Okay, maybe not yet. Valerie Grey?

Valerie Grey – New York eHealth Collaborative – Member
Present **[Inaudible] [00:00:41]**

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. 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? I know he said he may be dialing in late. Ken Kawamoto?

Ken Kawamoto – University of Utah Health – Member
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.

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

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
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? I thought we had Denni on the phone. Clem McDonald?

Denni McColm – Citizens Memorial Healthcare – Member
I'm present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you, Denni. Clem? Maybe not yet. Aaron Miri?

Aaron Miri – The University of Texas at Austin – Member
Good morning.

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

Brett Oliver – Baptist Health – Member
Good 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
Morning.

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

Sasha TerMaat – Epic – Member

Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Andy Truscott? Maybe not yet. Sheryl Turney? I thought I heard Sheryl. Denise Webb? I thought I heard Denise as well. Okay –

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
Sorry, this is Sheryl. I said I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Got it.

Denise Webb – Individual – Member
And this is Denise. I'm present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Do we have Kate Goodrich or Mark Roche from CMS? Chesley Richards? Ram Shuran? Laura Conn? Okay. All right. And then from the ONC side, we have Elise Sweeney Anthony, Executive Director of Policy; Steve Posnack; Executive Director of Office of Technology at ONC; our National Coordinator, Dr. Rucker; Seth Pazinski; and myself. With that, I will turn it over to our National Coordinator for opening remarks.

Cynthia Fisher – WaterRev LLC – Member
Lauren, this is Cynthia Fisher. I am present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you, Cynthia.

Donald Rucker – ONC – National Coordinator
Okay. Hi, everybody. Thanks for – I know we've had a large amount of work here in the last couple weeks. So, apologies for that. We sort of have a lot of stuff that came together. As you may have seen, we've been busy with various things as well. For the ONC and CMS rules, we've extended the public comment period by 30 days. They are both due June 3rd now. So, heads up on that. I think Lauren will talk. But we're gonna use, I think, the May 13th meeting to finalize recommendations on the proposed rule.

Part of the reason we extended the comment period was so that commenters could also be aware of what's in the TEF framework. I don't think they're really strictly related, but just, they're obviously side-by-side in the underlying CURES law and deal with interoperability, so we wanted to have that. The other thing we had heard in our earlier – in the earlier public dialogue was concern – and we've met with a number of folks on concern that providers and the EMR vendors might bear liability if patients download their data under their HIPAA right of access. And a number of people believe that that might be the case. We wanted to clarify and

have it as a formal FAQ from the Office of Civil Rights on the part of HHS that in fact, once the patient downloads their data, it is their data and their responsibility. And they are responsible if they download it to an evil app or whatever. And they need to sort out whatever secondary use issues. But the liability for stewardship of the data ends once the patient has downloaded it. And to make that clear in the HIPAA right of access. So, that's out there.

I do want to say the TEFCA comment closes June 17th. So, that has a little bit different timeline. And when you read the TEFCA stuff, obviously because of the way Congress wrote it, we had to come up with a series of terminology. But at the very top level, the qualified HINS, the QHINS, if you will – think of those as the HINS that take the responsibility to do national search for the records at the top level. And then the regular HINS are the HINS of today with the new minimum required terms and conditions over time, as opposed to some other thing that allows a lot of what is going on to be as little disrupted as possible. So, just keep the fact – there is actually – and there's simplicity there. We have to drill into some verbal detail on some of the participants and stuff. But the goal is to minimize any disruption to the current HIEs. And then the ones who want to sort of go to a national scope and scale in terms of providing search and coordinating can do so.

Two roster updates. So, Chesley Richards from the CDC will be stepping down temporarily. So, we'll be represented by Laura Conn, who's the Director of Health Information Strategy, the Center for Surveillance at CDC; and Lauren Thompson, our federal representative for both agencies, will be stepping down as well. So, we want to thank Lauren as well as Chesley. And let me give it to Elise.

Elise Sweeney Anthony – ONC – Executive Director, Office of Policy
No, thank you so much, Don. I just want to reiterate my appreciation to the members of the task forces and to the full committee for the work that they've been doing over the last several weeks. We hope that the extension provides some additional time for the HITAC to really kind of think through and move forward with these components. And as always, the staff leads are here to assist and to help with the process. I always say it, but you guys definitely have day jobs, and we appreciate that. So, whatever we can do to support you throughout this process, we 're here to do.

Other than that, I'm looking forward to the full agenda today. And you'll note that we do have a presentation on TEFCA to provide some background, even though the task force will start up a little bit later. But we wanted to provide background on what's in there, and particularly on some of the updates we've made since draft one. And I think that's all I have now. I think we're turning it over to Carolyn and Robert.

Carolyn Petersen – Individual – Chair
Great. Thanks, Elise.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thanks, Elise. So, I also just wanted to acknowledge, we are also joined by Dr. John White, our Deputy National Coordinator at ONC.

Carolyn Petersen – Individual – Chair
Thanks, Lauren. Good morning, everyone, and let me add my thanks to you for coming to our meeting today, for all of the work you've put in on the task force meetings. I know for some of the task forces, that has been quite a lot. We have a really packed meeting today, so I will move right into the agenda and review our work ahead. We will start this morning with an Information Blocking Task Force update from Mike Adcock and Andy Truscott. Then we'll move into a Conditions and Maintenance of Certification Requirements Task Force draft recommendations and vote with Raj Ratwani and Denise Webb. We'll have a public comment period and then a break, and when we come back from the break, Zoe Barber and Alex Kontur of ONC will give us an overview of the Trusted Exchange Framework and Common Agreement draft two.

We'll then move into direct recommendations and vote from the U.S. Core Data for Interoperability Task Force with Christina Caraballo and Terry O'Malley. That will be followed by an update on the work of the Health IT for the Care Continuum Task Force. We'll have another public comment period, and then we'll have our closing remarks and adjournment. And with that, I'll pass the mic to Robert for his thoughts.

Robert Wah – Individual – Chair
Thanks, Carolyn. Good morning, everyone, and appreciation for everyone joining in, and recognize we're across multiple time zones. So, those of you on the West Coast, appreciate you really getting up super early. As well as just to note that the batches have been coming out fast and furious. Yesterday, there was an invitation sent out with I think about nine attachments that tried to summarize all the batches. If you're using the Adobe Connect app on the far left side of the screen just below the HHS logo, all the downloads are there also in case you missed a batch somewhere in the emails. Since we're all producing for the batches, you know the tight timeframes that have been occurring to get these things out. And the bakers and the ovens are moving as fast as they can. So, we appreciate everyone's patience with that.

And I think the next order of business is to review the meeting notes from the 10 April meeting that we just had. So, does anybody have any comments, suggestions, edits, or corrections to meeting notes of 10 April? Hearing none, we'll just vote to approve those. All those in favor approving the meeting notes from 10 April, please say aye?

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay? All right. Thank you; they are approved. I think with that, our next order of business then is to move to the Information Blocking Task Force update. Is Andy on? I don't see him.

Michael Adcock – Individual – Member
Andy's traveling. Michael's on.

Robert Wah – Individual – Chair

Okay. All right, thanks. So, I'll turn it over to Michael to start the review of the Information Blocking Task Force update.

Michael Adcock – Individual – Member

Very good. Thank you, Robert, and thanks, everyone. Good morning. We're going to have – if you've noticed, our time is short and the agenda is packed. We've got about 30 minutes. I'm gonna go over, briefly, the task force charge. We won't spend a lot of time on that. Go over status updates for each of the workgroups. And then want to have some discussion around price information and price transparency as we move forward. Next slide, please.

And Andy sends his regrets. He is traveling right now internationally, so he was unable to join us on the phone. So, here's the charge. I won't read it to you. I will remind you, however, that we broke our work from the Information Blocking Task Force – we broke our work down into three workgroups. Workgroup One was around definitions, Workgroup Two was around exceptions, and Workgroup Three was around conditions and maintenance of certification. So, what we'll do – you can see there's lots of different work there under specific charges. But I will talk about these in relation to the three individual workgroups. We will not be having a vote. We do not have material to present for a vote today. We will continue to discuss these as individual workgroups and task force as a whole to send recommendation to the entire committee before the next meeting. Okay, next slide, please. Next slide.

Okay. So, Workgroup One, again, was the definitions. We discussed this pretty much in depth at the last – on the April 10th meeting, but we have discussed definitions of EHI, including inclusion of price information, **[audio cuts out] [00:13:41]** exchanges, health information networks, health IT developers of certified health IT. One thing that I do want to point out is the workgroup voted internally to expand the breadth of the definition of health IT developer of certified health IT so that it is not anchored to certification. Due to the changing market and things that are going on out there, anchoring it to certification, we felt, would be problematic and not cover entities that are gonna have a significant role as we move forward. We did discuss potential enforcement issues, given that the language in the CURES Act regarding OIG's enforcement authority is actually tied to certified health IT. And we will be finalizing the recommendations for the HITAC vote at the 5/13 meeting.

One thing I did want to point out, and it's not in the slide, that we're gonna have a discussion afterwards, is that we have a majority agreement around the definition of EHI. We felt we had a very strong definition of EHI, and we added a little bit of language in there that'll be sent out. We actually discussed it at the last meeting. But we also have potentially a minority opinion that I'll open up for discussion when we get to the questions portion after Workgroup Three. But I just wanted to prep everyone for that. Again, we're finalizing these recommendations. We will send them out prior to the vote at the 5/13 meeting. Next slide, please.

So, Workgroup Two, again, was exceptions. We discussed the exceptions for recovering costs reasonably incurred and licensing of interoperability elements on reasonable and nondiscriminatory terms. So, we discussed the rand portion of that. You can see the references to that respectively. We have a lot of very lengthy, great work that's been done on recommendations for exceptions. And I'll open that up. If we have time after we discuss price

transparency, I'll open it up to areas to discuss some of the stuff that we talked about relating to the fees and recovering of costs reasonably incurred in combining two elements after we discuss price transparency. We're going to revisit the request for information regarding possible information blocking exception for complying with TEFCA, obviously after we hear some more of the update around TEFCA version two. And this, again, will be finalizing recommendations for HITAC vote on the 5/13 meeting. The information will go out prior to that so that everyone has a chance to review. I will say that, again, there's been a lot of work that's going on here. There are a lot of recommendations that have been written up, or not a lot of recommendations – but the recommendations that have been written up are very solid and cover a lot of great detail. Next workgroup, please. Next slide.

So, Conditions and Maintenance of Certification, again, this is just a brief update from the April 10th meeting. We're gonna revisit the request for information in the assurances section regarding TEFCA, again. And we have some solid recommendations from Workgroup Three. That workgroup had its work pretty much completed, other than looking at the assurances, again, under TEFCA – had its work done prior to this. We again wanted to look back over this waiting on TEFCA version two. And again, all of this will be sent out prior to the 5/13 meeting, and we anticipate a vote at that HITAC meeting on the 13th. Next slide, please.

So, there's error – there's room here for discussion. Again, the three areas that I was hoping to discuss – price transparency is one of them. I was hoping that we might get a chance for Cynthia, if she's able to join – I know she was able to join the call, to discuss her opinion around the definition of EHI and then maybe move into price transparency. One of the things we wanted to talk about in price information and transparency – price information, within the definition of EHI, we do feel that it's there and that it should be addressed. Price transparency for ONC in this rule and HHS moving forward, we just want to have some discussion around that, want to get some feedback from the entire group.

And again, then If we have time, I would love to have Arien discuss the fee section of the exceptions. But I wanted to give Cynthia an opportunity to talk about her proposal around the definition of EHI, if she has a chance. I'm putting her on the spot, and I apologize for that. But I know that there was a lot of discussion around EHI and the definition. So, Cynthia, if you have a moment or are able – I'm sorry again for putting you on the spot – but if you wanted to discuss your proposal around EHI, that'd be great.

Cynthia Fisher – WaterRev LLC – Member
Thank you, Michael. Yeah, I'm just pulling up my background materials now because I didn't know I was gonna be talking.

Michael Adcock – Individual – Member
Yeah, I'm sorry to **[crosstalk] [00:18:40]**.

Cynthia Fisher – WaterRev LLC – Member
So, let me just pull that in front of me. So, I think just as it looks at price transparency and the ability to look at the electronic health information definition, is as we looked at referring back to the health information definition in the 1996 HIPAA Act, there were three levels of

definition in HIPAA. So, what the recommendation was is looking at real price transparency, and really in order for the patients to be able to look across the board, across the spectrum at what the best price at the best quality would be able to be in time to have a broader perspective at seeing prices, and have them be readily searchable. That could even be compared to their own specific health plan negotiated rate as it pertains to the individual.

So, for instance, there may be, in the competitive marketplace, a cash price, or there may be a lower negotiated price or another provider that would take a lower price than even the negotiator grade of the patient, the consumer's plan. And so, being able to see a broader spectrum, we look at the health information definition as any information that relates to the health information and the care that is transmitted through electronic media per 45 CFR 160.103. And that's where it says that just it relates to the past, present, and future health or condition of the individual, the provision of healthcare to the individual, or the past, present, and future payment for the provision of healthcare to an individual.

So, what the recommendation was is that you have a broader definition for electronic health information that takes out or strikes out where it identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. So, that language restrictively could only present the specific health plan or the contract negotiated rate cost, out of pocket cost, if that's the lower plan rate, as it pertains to the individual. If you strike that, as it pertains to the broader information, you're still in the bucket of providing health information related to healthcare in the form of the individual. But it will enable the patient to have a broader view at access to prices.

And so, there's a one-pager that I submitted to the task force that explains this well, and, that is, explains it to be consistent with the three levels of definition that are in the Portability Act of 1996 for the definition of health information as HIPAA defines it. So, let me see. One last thing . . . that the electronic health information here that is identifiable information is different than what Congress had in CURES Act. And in the CURES Act, the statute had referred to phrases that had already had authoritative construction by Congress. So, to make other changes or limit it to identifiable information, which is a separate and distinct defined term under the U.S. code and federal regulations, would be a conflict with the proper reading of the statute.

And then, just finally, there were some concerns that were brought up that the revision to go to the broader definition consistent with CURES Act, consistent with HIPAA – this information would not bring in information that is unrelated to the care or the payment for the individual. While the definition does not require information to be identifiable, it must be related to the health, healthcare, or payment for the provision of healthcare to the individual. So therefore, aggregated or anonymized data would likely not be EHI. Also, there's a concern that specific types of data should not be included, such as certain research data, this is better addressed by narrowly tailored exceptions rather than overbroad carving out of other types of data, including the broader price information.

So, that is the inputs that I just wanted to provide you all that I think really, as we look at how transparency can work for individuals, is that it should be easily searchable. And at the point of

care, having that dialogue with the physician, who many today have no idea what the prices are or where to go get an MRI that's most feasible even within their own plan. It will open up the opportunity to still be specific to care with the individual but to allow for a broader search on relevant information for good decision-making at an affordable price.

Michael Adcock – Individual – Member

Cynthia, thank you very much. And again, I apologize for putting you on the spot there. But you did provide some detailed information and a very valid point, and I wanted to make sure that you had the opportunity to discuss that within the broader HITAC committee. So, thank you very much for that.

Cynthia Fisher – WaterRev LLC – Member

Thanks, Michael.

Michael Adcock – Individual – Member

Yeah. Thank you, Cynthia. Mark, was there anything that I missed when I went through that section? Because we went through it kind of quickly, and then I think we've still got about 15 minutes. We'll open it up for discussion about what other members of the committee would like to see as we look at the RFI for price transparency.

Mark Knee – ONC – IB TF Staff Lead

No, I mean, I think the discussion about electronic health information definition and price transparency ties together. And just to be clear, in our proposed rule like we talked about, we say specifically in the preamble that price information is included in the definition of EHI. And I think what we talked about within the group is do we want to expand what -- do you want your recommendation that ONC expand kind of our understanding of what price information would entail in our rule, or also, just there's also list of questions that were included in the proposed rule that get into more specificity about what price information and price transparency would entail.

So, I think maybe just the discussion, if others have thoughts. And just to be clear, I think what Cynthia was discussing will likely be conveyed as a minority opinion, because I think others in the group felt that maybe eliminating the tie-in to the individual would overly broaden the definition of EHI. So, if others have thoughts on that discussion as well, I think that would be good to talk about now.

Michael Adcock – Individual – Member

Thank you, Mark. And just for the group, I don't have the – I'm assuming that someone has the view where they can see whose hand's up. I do not have that view, so I will lean on either the committee chairs or ONC if anyone has that view to be able to say who has their hands up so we can go through some discussion. But I'd be very interested in hearing the opinions of the group.

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

Thanks, Michael. Yes, we do have Terry O'Malley with his hand up first, and then Cynthia.

Terrence O'Malley – Massachusetts General Hospital – Member

Great, thanks. This is Terry. And part of the question is for Cynthia as well, so good timing. I guess I'd be interested to know if you have any thoughts or a model about how the pricing information is going to be shared as one. And then secondly, whether there are specific data needs, thinking from the USCDI, that need to be considered to facilitate the exchange of or sharing pricing information. Those are my two questions. Thank you.

Michael Adcock – Individual – Member

Cynthia?

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

Cynthia, are you muted?

Cynthia Fisher – WaterRev LLC – Member

Yes, sorry about that. I was muted. It's a new phone. Yes, thank you, Terry. I think what might be helpful for the group is if I could submit the one-pager that I had submitted to the task force subcommittee that I was on, so at least the rest of the HITAC could have that in writing on the revised definition of electronic health information.

And then, Terry, getting to your question, regarding on how things can – well, how the data sets would be – needed to be posted. I think what we can look at, and speaking with several tech companies, I think part of it is putting the contract negotiated terms, putting the rates posted in a transparent way of what those prices are that would be acceptable between provider and consumers. And I think what one could look at is the potential for a third party to, as long as they're in machine-readable form and quantified, bundled or unbundled, a third party could easily harmonize, in relatively reasonable time, data across the spectrum. And I just think what we want to avoid is, we want to deliver interoperability across the spectrum on the clinical ,and on the payment, and on price, as is defined in the definition in near-term, as we see with many other facets of our lives -- Venmo or other opportunities. We used Uber as examples. But I think one of the concerns is to not get bogged down with a decade of defining standards of how that gets presented, where we can present it and look to innovators to harmonize.

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

Thank you. And Michael, I don't see any other hands up at this time.

Michael Adcock – Individual – Member

Wow. I thought there'd be a lot of discussion around price transparency, honestly. But we will continue to discuss this in our group. I do appreciate the extension of time so that we have time to discuss this in detail. It is a very important topic, obviously. It's also a very complex topic, as you talk about pricing, and cost, and payment, and different issues. There are lots of

pieces there that need to be discussed. Is Arien on? I don't remember.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sorry, Michael, I do see a hand.

Arien Malec – Change Healthcare – Member
I'm here.

Michael Adcock – Individual – Member
Okay. You have hands?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yeah. So, maybe we should go to Steven and then Arien.

Michael Adcock – Individual – Member
Okay.

Steven Lane – Sutter Health – Member
Thank you. I just wanted to comment that Cynthia, I really appreciate your input. Cynthia also sits on our Interoperability Standards Priorities Task Force, which is currently on hiatus. But we fully intend to take up again the question of price transparency and looking at it from the standards perspective. So, I think in the same way that Terry mentioned, we need to think about this from the data elements perspective, that having the standards clear will also be important. I think that the points that Cynthia is making are really quite relevant. I think it is hard for us to fulfill the goals that have been stated by ONC and CMS to support patients being able to identify the most high-value care available to them. So, I think continuing this discussion of how to bring forward price transparency data in a way that is both meaningful and functional is really gonna be important.

Michael Adcock – Individual – Member
Agree completely. Thank you, Steven. Arien?

Arien Malec – Change Healthcare – Member
So, you wanted me to address the pricing section?

Michael Adcock – Individual – Member
If you have discussion on the pricing section, yes. And then I really wanted to go through the work – unless somebody else had discussion on pricing, I really wanted to go through the work in your actual workgroup where we discussed combining the exceptions around fees.

Arien Malec – Change Healthcare – Member
Yeah, so – but that's on the pricing fees. Sorry, a little confusion in terminology. So, yeah, happy to discuss the fee section. Again, just as a refresher and background for the full

committee that hasn't been deep in the weeds in the way that we have, there are seven permitted exceptions to information blocking. And so, the way the information blocking rule works is that information for permissible uses must flow unless the restriction is covered by one of the exceptions. There is a perspective that attaching any fees to access, exchange, or use constitutes blocking unless permissible. And then there's a framework in the – under two exceptions, 171204 and 171206, that subdivide two types of allowable fees. So, sometimes the double negatives and triple negatives get a little confusing. But the best way to think about these sections, fees are not allowable unless they are allowable under 171204 and 206. 204 covers cost recovery, and 206 covers licensing of interoperable elements.

The task force, as we were trying to figure out 171204 and 171206, had a hard time figuring out and understanding when 204 and when 206 would apply. I think by the end of our deliberations, we finally got some of the intent, that 171206 was really intended for licensing of intellectual property rights that affect access, exchange, or use; and that 204 covers all other situations. But because of the issues that we had in parsing through 171204 and 206, we made a recommendation to ONC that ONC combine 171204 and 206 into a single exception that covers permitted fees. That section would be larger and more complicated, but least you'd have all of the information on what fees are and aren't allowable in one section, and it would be easier to adjudicate whether a particular prospective fee that you were charging or a fee that you were being charged did or didn't meet the exception criteria under the exceptions, or was permissible under the exceptions. Again, the double negatives here sometimes get a little hard to move their way through.

So, that was discussion point number one. Discussion point number two was based on the broad definition of electronic health information, as we just went over, which, as Cynthia notes, does come from a combination of the HIPAA regulation under, oddly, the Social Security Act, as well as the Public Health Service Act. And that definition's sort of broadly pulled through into CURES. And it is very expansive and very broad. And then the set of actors that are prospective information blocking or blockers under CURES, and in particular, the definition of developer certified health information technology, health information exchange, health information network. All three of those are fairly broad terms, and provider has a very broad set of applicability.

And so, when you think about pricing and what allowable fees – or what fees are allowable to charge and not charge, the task force had a concern and formalized the concern in a set of requirements or sort of recommendations, rather, about the attachment of all kinds of access, exchange, or use activities under the fee section, including access exchange and use activities that are value-added. Things like, for example, building an AI-based risk model for a patient would fall under access, exchange, or use. And the task force believed that that framework, combined with the breadth of actors and the breadth of health information exchange, was too broad to attach restrictive pricing fees.

The task force did believe and did acknowledge that fees are often used as a way to disincent or place gates, whether intended or unintended, behind access, and that intellectual property can be a deterrent to downstream access and use. And so, accordingly, the task force put together a framework by which certain kinds of activities attract additional scrutiny in terms of pricing, and additional requirements in terms of pricing to mitigate the concerns of

information blocking. In particular, we defined a category called basic access. Basic access is intended to cover access to what some people call the legal medical record. Other people pointed to the definition of data under the designated record set. And then there's also a notion of the non-IPR-able facts of the record. So, if I take a blood pressure reading, I can't patent or copyright that blood pressure reading, and it's a fact. And we shouldn't be putting gates or gatekeeping functions around those facts.

In addition, the task force discussed certified standards and reasonable mapping of certified standards when certified health information technology accords to a standard – again, a principle – that there shouldn't be additional fees on top of the health information technology that's already purchased relative to enabling that standards-based access. So, the specific recommendations there are that the cost-oriented fee restrictions should apply to that category of access, particularly basic access, that enables information to flow. And with regard to the definition of EHI of all types that are covered by and under CURES.

And then, we discussed intellectual property rights. And again, same distinction. There are intellectual property rights that are value-added, for which a free and open marketplace should be the appropriate mechanism for setting and establishing prices. And then other intellectual property rights that are necessary for access, exchange, or use. In the standards world, this concept is called standards essential. And so, we defined a category of access, exchange, or use essential, intellectual property rights. An example of such an intellectual property right might well be a terminology set that is necessary to read or interpret the record.

So, as an example, somebody might have a procedural terminology set that is not licensed – I give this for background for the committee. Many of the terminologies that fit under use and are defined by federal actors are also licensed by ILM on behalf of – NLM, rather, the National Library of Medicine – not the special effects company – are licensed by NLM on behalf of the nation. There are some terminology sets, for example, procedural codes, that don't have that broad licensing. And there are actors that license the intellectual property rights. And so, you can't actually use or interpret the procedural codes unless you have the decoder ring. And the decoder ring is covered under copyright law. So, that would be an example of an access, exchange, or use essential IPR. And again, the task force believed that the reasonable and nondiscriminatory pricing structure that's well under use for standards essential intellectual property rights was appropriate to apply for access exchange and use essential intellectual property rights.

We had some discussion about proprietary coding and what the obligations of an organization that used proprietary coding would be. So, would they be required to make that code available as a standard code through some kind of translation layer at their own cost, or would they also be required to license the proprietary code set on IPR or on Rand IPR basis, as we were discussing.

Michael Adcock – Individual – Member

Thanks, Arien.

Arien Malec – Change Healthcare – Member
And so, I think we have a little more discussion to go there. But that's the broad framework that we've established for the fee section.

Michael Adcock – Individual – Member
Arien, thank you very much. And I know we're running right up on time. If anyone has any thoughts, comments, questions, concerns, please make sure that you send them out to me and Andrew, and we'll make sure that the task force and the workgroups get them. But I wanted to take just the last minute before I hand it back to the chairs to thank everyone that's on the Information Blocking Task Force for a tremendous amount of very hard work, and lots of calls, and lots of time spent on this. We're getting close to the end. Again, we will send out stuff from all of our workgroups into the task force and then to the larger HITAC committee for discussion before a vote on the May 13th meeting. So, thank you all very much, and I will turn it back over to the chairs.

Carolyn Petersen – Individual – Chair
Thanks, Michael. We really appreciate the update you've given us and all the good discussion and commentary about the work of the task force, as well, of course, as the work of the members on their individual subcommittees.

So, let's shift now to the Conditions and Maintenance of Certification Requirements Task Force draft recommendations and vote. I'll hand the mike to Denise and Raj Ratwani.

Denise Webb – Individual – Member
Good morning. This is Denise Webb. I believe Raj is on as well, but he may have to step out. And so, I'm going to be conducting the presentation. And if Raj is on throughout, if you could jump in, Raj, that'd be great.

Raj Ratwani – MedStar Health – Member
Yes, Denise, I'm here. I'm here, and I'll try and jump in when I can.

Denise Webb – Individual – Member
Okay, great. So, this morning, we want to quickly review who our members are, what our charge was, and our recommendations around conditions and maintenance of certification, updates to the 2015 edition certification criteria, and then our recommendations on deregulatory action. The way we're going to proceed through those recommendations is to do them in those groups. And we are going to be stopping after each recommendation to call for a vote. Our recommendations are final and ready for a vote, except one of the recommendations. And one recommendation, we voted on at our last meeting. And we will also request some discussion on a draft recommendation that we have not come to consensus on if time permits at the end. And if not, we're going to ask that the members provide any input or what their perspectives are via email to Raj and I. Next slide, please.

This is our task force roster. We had a fairly small task force. And I want to thank our task force members for the time committed to getting us to this point. Next slide, please.

This was our overarching charge to address recommendations around three of the conditions and maintenance of certification, being APIs, real-world testing, and attestation; updates to the 2015 edition health IT certification criteria, and then changes to the criteria or the certification program; and finally, deregulatory actions. I will note that we had no recommendations on changes to the certification program. Next slide, please.

This is a just to remind the committee that we all discussed maintaining the clarity on – providing clarity on the rationale for maintaining the 2015 edition, and recommended that ONC introduce a new edition, and this was approved by this HITAC. Next slide, please.

Now, we'll go into our recommendations on the conditions and maintenance of certification for those three areas, starting with real-world testing. The recommendation two – we're recommending that instead of requiring submission of an annual real-world testing plan to the ONC ACB no later than December 15th of each year, to require the submission no later than the latest certification anniversary date of each health IT developer's applicable certified 2015 edition health IT modules. And really, this was to avoid holidays and avoid overloading the ONC ACBs and federal government all at once, given the number of participants.

So, I would ask if there's any discussion, and if not, call for a vote. Okay. So, all those in favor of this recommendation, indicate so by saying aye.

Group
Aye.

Denise Webb – Individual – Member
Any abstentions? Any objections? Okay, we'll move on to recommendation three. Recommendation three is recommending that ONC provide more clarity around the care settings and venues the test plan must cover, with the goal of making minimum expectations clear.

I'll call for a vote. Or any discussion? No vote? All right. Hearing no discussion, all those in favor, indicate by saying aye.

Group
Aye.

Denise Webb – Individual – Member
Okay. Any abstentions? Any objections? All right. Recommendation four. We are recommending the ONC provide guidelines for a test plan. We also are endorsing the idea of a proposed pilot year and recommend that this be in the final rule. And we are suggesting that after the pilot year and some data is collected, that ONC create a standardized template to incorporate the elements of an acceptable test plan.

Any discussion? I see no hands, so, a vote. Those in favor, indicate by saying aye.

Group
Aye.

Denise Webb – Individual – Member
Any abstentions? Any objections? All right. Recommendation five. We're recommending that ONC provide clarity on how successful real-world testing is met for the following areas listed here on the slide. One around continued compliance with the criteria. Number two, around exchange and intended use settings, and number three on real-world testing related to receipt and use of electronic health information and the certified EHR.

Any discussion? All those in favor of this recommendation, indicate so by saying aye.

Group
Aye.

Denise Webb – Individual – Member
Any abstentions? Any objections? Okay. Moving right along. We've 35 to get through here, or 34, excuse me. Now moving into the area of scenario and use-based, case-focused testing, with recommendation six. We are recommending that ONC clarify and define the terms "scenario" and "use case-based testing," as well as the term "workflow." All three of these are used, and there is some question about whether "scenario" and "use case" are the same thing, so we are seeking that clarification in the final rule in the preamble as well as the regulatory text, and further recommend that the final rule preamble be clearer and reasonable with what is intended where the preamble states that developers can and should design scenario-based test cases and incorporate multiple functionality as appropriate for the real-world workflow and settings.

Any discussion on this? Oh, excuse me, before we head to a vote, we also are asking ONC to clarify where existing interoperability testing, such as that performed by the Sequoia Project or other existing networks, can satisfy expectations for real-world testing. That wasn't absolutely clear in the preamble. Any discussion? All right. I see no hands, so I'll call for a vote. All those in favor?

Group
Aye.

Denise Webb – Individual – Member
Any abstentions? Any objections? Okay. On to recommendation seven. This is just asking – we're recommending that ONC modify the regulatory text to include as permissible testing approaches automated testing and regression testing. And we show here on the slide the current proposed regulatory text with those two types of testing added.

Any discussion? Okay, a vote. All those in favor, say aye.

Group
Aye.

Denise Webb – Individual – Member
Any abstentions?

Clem McDonald – National Library of Medicine – Member
Yeah. This is Clem. I think I'll abstain just because I don't understand how this is done. But I'm not against it.

Denise Webb – Individual – Member
Okay. Thank you, Clem. And any objections –

Cynthia Fisher – WaterRev LLC – Member
I join Clem – this is Cynthia – on the abstention as well, for the same reasons.

Denise Webb – Individual – Member
Thank you, Cynthia. Any objections? Okay. And I assume ONC are capturing accounts here, right?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yes, we're capturing.

Denise Webb – Individual – Member
All right. Thank you very much. Okay, we're on to recommendation eight. We are recommending that ONC provide clarification around testing the use of the information we see through exchange versus the testing of the exchange of information, i.e., the sending a receiving. And note that obviously, where there's no end users of a health IT product, that there would not be any use-based testing. We are recommending that ONC expect that if health IT developers are testing the use of data received through exchange that they would have intended users involved in the usability testing. And further, we note that users were not considered in the cost estimates for real-world testing, and so therefore, we are recommending ONC revise the estimates. And then finally, we're recommending, to reduce cost, that ONC prioritize real-world testing criteria based on risk.

Any discussion? And I will note that if you look in the memo, the transmittal memo, we have the CMC task force's discussion around this recommendation that I can refer you to.

Clem McDonald – National Library of Medicine – Member
So, I'm just not clear on what is meant. If it's usability testing, we should say that the use of information – how do you test the use? I mean, the sentence doesn't tell me what it really is asking, except it goes on about usability. That, I get.

Denise Webb – Individual – Member

Clem, in the second portion of this, you'll note it says that health IT vendors should have intended users involved in usability testing.

Clem McDonald – National Library of Medicine – Member

No, I get it. But testing uses – I mean, is it being used? Is it used well? I think it's ill-stated.

Raj Ratwani – MedStar Health – Member

Clem, this is Raj. I made be able to provide a little bit of clarification. So, the term "use" is coming from the proposed rules. That's how we have that kind of word in there. And what we're trying to say is we want to look at how that information is being used from a usability perspective. So, as it's presented to our clinicians or whoever the intended users are, when they're trying to use it, is that information presented in a way that actually matches their capabilities and meets their needs. So, I get that there's a little – "use" there is not the greatest term, I think, but we're trying to match within the proposed rule language.

Clem McDonald – National Library of Medicine – Member

Well, it would work if you said "examine the use" or "witness" or "watch the use," or something like that. Or "study the use."

Denise Webb – Individual – Member

Clem?

Raj Ratwani – MedStar Health – Member

But, so we're saying testing the use. So, help me with the difference between study the use versus testing the use.

Clem McDonald – National Library of Medicine – Member

I don't know what it means when you say testing. And when you say study, someone's gonna watch to see what they're doing, and if they use it, and if they can use it. I don't know. If no one else –

Raj Ratwani – MedStar Health – Member

That's certainly what's intended. So, when we say testing the use –

Clem McDonald – National Library of Medicine – Member

Studying the use, study how it's used or whether it's used. But I may be a Lone Ranger on this, and I don't want to hold it up if I am.

Denise Webb – Individual – Member

Mm-hmm. So, Clem, just to sort of help out, when we're getting that testing use – so when a health IT product receives data from the outside, so what we've heard from user feedback is they want that data to be viewable, actionable, and reportable alongside their native data - to be useful and to reduce burdens on providers. So, right now, the present rule as proposed is

pretty quiet on what is expected in real-world testing around testing the use. And they didn't even include estimates of involving users in the cost estimates. So, we are recommending to ONC that they need to put more meat on the bones here around what this looks like.

Clem McDonald – National Library of Medicine – Member
Well, I agree, and I'd love to – there was a specific proposal in an earlier meeting that the data should be able to be presented and displayed in concert with the other data that exists from outside. Is that somewhere else stated still, or is that just –

Denise Webb – Individual – Member
It's in the discussion that went forth in the transmittal letter. And as a task force, we discussed this, and there was concern about being prescriptive on the design and architecture of a vendor's product. We don't intend to prescribe how they design their product or how they architect it, but rather that when they go to do real-world testing, that they are able to demonstrate that the way they did design it is usable and useful and doesn't present burden on the **[crosstalk] [00:59:48]**.

Clem McDonald – National Library of Medicine – Member
But there's nothing in here about test the ability for users to absorb data that comes from outside systems. That seems to be the point of what was an earlier discussion. It's not coming across.

Denise Webb – Individual – Member
Well, we're trying to capture that in the second point, where we say "testing the use of data received through exchange." So, when it's received by the provider. We weren't the vendors to do usability testing on that data that's received with the users and its purview.

Clem McDonald – National Library of Medicine – Member
Well, if no one else hears the words funny, I will back away. I know your intentions are good. I'm just not sure if it'll come across through these words.

Denise Webb – Individual – Member
Steven Lane also has his hand up. Maybe he can bring in **[crosstalk] [01:00:39]**.

Steven Lane – Sutter Health – Member
Yeah, thank you. So, as a clinician at an organization that has really put a lot of effort into just this, receiving, integrating, and utilizing discrete external data, I can tell you, it's really hard. And I think that perhaps, the introduction of an additional word, to test the integration and usability or use of external data, might help clarify what Clem is getting at. Because I think that's what we're all talking about, is integrating the data into workflows. Perhaps if you say integration and use, that could clarify it.

Clem McDonald – National Library of Medicine – Member
That helps me.

Denise Webb – Individual – Member
So, the friendly amendment is to take the second line and say the task force recommends – or actually, once we vote, the committee recommends ONC expect that if health IT developers are testing the integration and use of data received through exchange, the health IT vendors should have intended users involved in usability testing. That would be one change. And maybe on the top around testing the integration and use of information in that second line. So, Stephen, where are we? Or do we just need to put it in the first part of this recommendation on the second line around the testing of integration and use.

Steven Lane – Sutter Health – Member
Yeah, I think that might be more efficient, to just put it in your top bullet there.

Denise Webb – Individual – Member
Okay. So –

Clem McDonald – National Library of Medicine – Member
Well, you know there's slight, subtle differences. You're saying "exchange," and he said "external data." And I think there's a different semantic.

Denise Webb – Individual – Member
No, around the testing, the integration, and use of information received through exchange. Because this is focusing on testing of the interoperability requirements. So, can the module exchange data? And can the provider take the data that they've received and integrate it and use it? Sasha, your hand is up.

Sasha TerMaat – Epic – Member
Yeah. I was just thinking through Stephen's suggestion about adding the word "integration." And I think the task force would want to think about that in conjunction with all of the criteria that real-world testing is proposed for, because while I can certainly see that in some of the criteria, some products might find it desirable to integrate the data, other of the criteria that this is proposed for would not necessarily have the same need. And I, again, fear being overly prescriptive in regulatory guidance in a way that would jeopardize the ability to design in conjunction with users.

Denise Webb – Individual – Member
Thank you, Sasha. That is a valid point. And as I'm thinking about this, the word "integration" is not used in the real-world testing preamble. It's testing use of the data received, which – "use" could include integration if it's appropriate to the product. So, we're sort of at a standstill on this one.

Raj Ratwani – MedStar Health – Member
Well, so, this is Raj. I would just add to your last point, Denise, when we think about the term "usability," as this gets exercised and as vendors and provider organizations test this, they would then further define what they mean by usability, which I think to your point would include things like the integration of information, if that's appropriate for that intended end

user. So, I think there's a need to stay pretty general at this level, knowing that if this were to roll out and one was to actually test the usability of that information, it would the be further defined to include things like, well, should it be integrated? That would be a usability criteria that would be part of that testing. There would be several others as well, and that would provide more of the contextualization there.

Denise Webb – Individual – Member
So, co-chairs –

Steven Lane – Sutter Health – Member
Yeah. I just wanted to agree with that concept. I think saying that we're testing the integration and use doesn't imply that we are requiring the integration in every case; just that we're looking at it.

Robert Wah – Individual – Chair
Denise, this is Robert.

Denise Webb – Individual – Member
Go ahead, Robert.

Robert Wah – Individual – Chair
Clearly, there's a lot of, I think, additional discussion needed on recommendation eight. It may be necessary to table consideration of eight right now. And it might be useful for your task force to review the comments that have been made and perhaps solicit other input. Fortunately, we've been given a little extra time here, so maybe we can use it for recommendation eight a little bit more.

Denise Webb – Individual – Member
Okay, yeah. We can do that, certainly, Robert. All right.

Robert Wah – Individual – Chair
And maybe just to – yeah. So, if you don't mind, maybe we'll have you present the recommendations, and then Carolyn and I can go ahead and call for the votes to move this along.

Denise Webb – Individual – Member
All right. That would be great. Thank you.

Robert Wah – Individual – Chair
I just want to take the burden off of you to have to keep notes and follow all this as well, so.

Denise Webb – Individual – Member
Okay, thank you. So, if we can move on to recommendation nine. We are recommending that ONC clarify the expected involvement of providers and third parties to support the real-world nature of the testing, and this is within the rule preamble. And we're also recommending that

ONC, related to this, provide guidance on testing options that address the use of simulated data and address requirements for unidirectional versus bidirectional test cases.

Robert Wah – Individual – Chair
Other comments or questions on recommendation number nine? I don't see any hands raised. So, if there are no comments or questions, all those in favor of recommendation nine, please say aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions? All right, thanks. Denise?

Denise Webb – Individual – Member
All right. Recommendation 10. This addresses methodology of testing. We are recommending that ONC allow for flexibility for vendors with regard to real-world testing where there is no difference in the testing approach, result, or capability in their various settings and venues. So, that includes the idea of common capability testing once across all settings and test cases. In the case of an unchanged capability, allowing a vendor to attest to the capabilities that remain unchanged, rather than retesting. Common requirements, test one, and then if the requirement doesn't vary across settings, it would only have to test one production experience, clarifying whether real-world testing is required for what already has long-standing evidence and history of operating in the real-world production environment. And then clarifying applicability requirements for various practice and care settings. And then finally, to explicitly allow for attestation instead of retesting. So, to address all of this in more detail in the preamble of the proposed rule.

Robert Wah – Individual – Chair
All right. Comments or questions about recommendation number 10? Hearing none and seeing none, all those in favor of recommendation 10, please say aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions? Hearing none, back to Denise.

Denise Webb – Individual – Member
All right. Recommendation 11 addresses measurement and metrics in real-world testing. We're recommending ONC include a description of measurement and provide clarity on the role of measurement and specificity for what kinds and for what purposes or proof points within the preamble. We're also recommending that ONC consider including updated metric expectations after the real-world testing pilot year that we endorsed. So, where real-world testing is for both interoperability, the sending and receiving of data, and the use of received

data, we are recommending ONC consider specifying that there be at least one metric of interoperability and one metric of use, which might correspond to metrics of use and safety-enhanced design testing.

Robert Wah – Individual – Chair
All right. Comments or questions about recommendation 11? And seeing none and hearing none, all those in favor of recommendation 11, please say aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed say, nay. Any abstentions? All right, thanks. 12?

Denise Webb – Individual – Member
All right. The next recommendation, 12, addresses the standards version advancement process as related to real-world testing. And we're recommending ONC elaborate and provide more clarity on the standards version advancement process when a version of standards is available, but does not yet have testing tools available to determine conformance. So, we are recommending the final rule preamble clarify how health IT developers are to address new versions for which tooling does not exist yet, but they have attested to support, and how this will be judged or determined for conformance. And then finally, we are recommending ONC clarify whether testing will be required in the subsequent year's real-world testing plan once tooling is available, or whether the previous attestation is sufficient.

Robert Wah – Individual – Chair
Great, thanks. Questions or comments about recommendation 12?

Clem McDonald – National Library of Medicine – Member
This is Clem. I didn't put my hand up, though.

Robert Wah – Individual – Chair
That's okay. Go ahead.

Clem McDonald – National Library of Medicine – Member
Okay. So, the thing here is, let's take a case now. The ONC asked which version of FHIR should be supported in the current NPRM. So, I worry that this is kind of confusing that issue. So, is the idea they'll have to test and support all versions, or just the most recent version? And if there are no tools that exist to test conformance, that's stronger – then it seems like it's too early, or something seems to be wrong. Because the FHIR conformance is autotested. So, I'm not sure exactly, when I put it against some real-world case, what this is saying.

Denise Webb – Individual – Member
So –

Clem McDonald – National Library of Medicine – Member
It's saying they must test all real-world versions. I don't think that's necessarily ideal.

Denise Webb – Individual – Member
No, the health IT developer has to test for what they're certified to in their product. If they decide to have their product support one, two, or three versions, the current version plus one that's in the standard advancement. So, let's say ONC specifies in the final rule that it's going to be FHIR release Two, then if FHIR release Four is acceptable under the standards advancement process, yet there hasn't been a full suite of test tools developed to determine conformance with the ACBs, because obviously, they have done testing to get to the point where FHIR Four is acceptable under the standard advancement process. It's just the availability of the tools widely for conformance testing by the ACBs.

So, the proposed rule says that they can attest that they meet because they did the testing of their product to meet the requirements of that particular standard. So, this is more about – the rule says this can be done through attestation. And really, what we're recommending, that there be clarification on when those conformance tools do become available for the ACBs, will they need to retest? And Raj, jump in if I missed anything on this, or Sasha, or any of the others on the task force.

Robert Wah – Individual – Chair
So, Clem, does that help answer your question? Did we lose Clem?

Denise Webb – Individual – Member
Is he on mute?

Robert Wah – Individual – Chair
Yeah, he might be on mute. I don't know. Well, we have several hands up, or actually, we have mics on, not hands up. Sorry. Clem, are you still on?

Clem McDonald – National Library of Medicine – Member
I got pulled away. So, I am now. I mean, the conformance thing, my understanding is FHIR has built-in conformance testing, and it's not a matter of you have to make a test. Am I wrong on that? It's part of the spec. It's part of how it works.

Denise Webb – Individual – Member
Well, I don't know if ONC can jump in here and help out. My understanding under the standards advancement process, they may endorse a standard that's gone through all of the testing amongst the community but has not yet established a conformance testing tool that can be used so that the ONC ACB can prove that they conform when they go in for certification – that the product conforms.

Clem McDonald – National Library of Medicine – Member
Well, I don't know about that. So, if they could clarify, that would be helpful.

Denise Webb – Individual – Member
Lauren, is anyone able to clarify that from ONC?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Is Kate on, by chance? Tipping? Okay. All right. We may have to come back to that, Denise.

Denise Webb – Individual – Member
Okay. So, are we tabling this for a vote? I mean, are there any other hands up, Robert?

Robert Wah – Individual – Chair
I don't see any other hands. Other comments or questions on recommendation 12? Again, it might be necessary to get clarification on this. But again, we'll take –

Denise Webb – Individual – Member
Well, I would ask, though . . . Can't we still take a vote? I mean, this is consensus voting, right? I mean, we could have every recommendation –

Robert Wah – Individual – Chair
Yes, we have – right, but if we have a sort of unanswered question that perhaps could be answered with a little bit more time, then I'm not sure we have consensus to vote on it.

Denise Webb – Individual – Member
Okay.

Robert Wah – Individual – Chair
I mean, fortunately, with the extension, we have a little bit more time, and that may require another call of your task force, which is unfortunate, but you're already gonna probably do it for eight.

Denise Webb – Individual – Member
Yes. Thank you. Let's continue.

Robert Wah – Individual – Chair
Go ahead.

Denise Webb – Individual – Member
All right. Recommendation 13. We're recommending that ONC clarify the role and expectations of third parties over which health IT developers have no control or authority over. We further recommend that ONC clarify whether declining to purchase the paid and real-world testing is considered to be information blocking. Let's see. And that ONC consider and clarify in the final rule how reasonable protections can be provided both to those who have limited resources and therefore are unable to participate in an unlimited set of tests.

Robert Wah – Individual – Chair
All right. Questions or comments about recommendation 13? It looks like Terry, you have your hand up?

Terrence O'Malley – Massachusetts General Hospital – Member
Yeah. I guess it comes to the definition of how good does something need to be to be put into production. And I'm a little concerned about the phrasing here, which seems to me to imply that if you can't – if you don't have the resources to do the testing, then you're absolved from that responsibility, or am I misreading that?

Denise Webb – Individual – Member
They are not absolved from testing. What this is addressing is – so, for instance, if I'm a provider ,and I'm a very small provider organization, and I am not able to participate in my vendor's real-world testing, I wouldn't be considered to be information blocking by declining to participate in real-world testing, because I have limited resources. This is not about the vendors conducting the testing. It's about those who do not have control over . . . **[Crosstalk] [01:21:19]**

Clem McDonald – National Library of Medicine – Member
In that sentence, if one specified, instead of saying "those," say "third parties." The TF recommends providing for those who have limited resources. I think if you clarify what that's a reference to, that would help Terry and me, because I think it could be taken to be those vendors, those manufacturers of the systems.

Denise Webb – Individual – Member
Okay. So, we can amend "those" to "third party".

Clem McDonald – National Library of Medicine – Member
Period. Well, just –

Denise Webb – Individual – Member
Third party. Yeah, because we're talking about third party.

Sasha TerMaat – Epic – Member
Well, I actually think we don't want to say third parties, because health IT developers could also be the recipients of requests to test. And if one health IT developer received 50 requested test from other health IT developers, they may only be able to accommodate five of the requests, for example. So, I think what we want to change it to is instead of "third party," something like "recipients of requests to test."

Clem McDonald – National Library of Medicine – Member
Well, I think it's – they're third parties with respect to the other vendor. I think it still comes out something – maybe they're second parties. But they're not – isn't that right?

Sasha TerMaat – Epic – Member
I just think it would be more clear to say "recipients of testing requests," because that is more specific to the intent.

Clem McDonald – National Library of Medicine – Member
But that may absolve the vendors again. Because if they're saying it to the doctors, and the hospital that is the one they run, that's a recipient.

Arien Malec – Change Healthcare – Member
No one's talking about absolving anybody in this recommendation. I think what we're talking about is ONC clarifying the obligations. And I think the concern is if any decline to participate in real-world testing, it's ipso facto considered to be information blocking, that creates a strange situation, where you may have agreed to 50 real-world testing requests and then earn information blocker on your 51st. So, maybe as a recommendation, we tighten the language. But I think the intent is pretty clear, and so – unless I'm missing what the actual objection to this is, we're asking ONC to clarify the conditions under which somebody can or cannot decline to participate.

Cynthia Fisher – WaterRev LLC – Member
Hi, this is Cynthia.

Robert Wah – Individual – Chair
Go ahead, Cynthia. Go ahead, Cynthia.

Cynthia Fisher – WaterRev LLC – Member
I'm just concerned about, if using Sasha's recommendation of looking at this, is there might be 50 requests and only time for five, a concern is, as innovators look to get into the field, is to not have de facto information blocking because a vendor says, "I only have time for five," when there are 50 requests to come through and have access to the information, and do a readily available test. So, I guess my concern is just that it not be so prescriptive that we're actually blocking innovation and blocking information from free-flowing to be able to allow for open APIs and mobile apps to change the game. So, how do we look at this as a committee that we're reasonably making practices not be protectionary or selective?

Denise Webb – Individual – Member
All right. So, it sounds like we're gonna have to table this recommendation to revise the language.

Robert Wah – Individual – Chair
Yeah. If there was a simple word change that could clarify this, I think it would be appropriate to go ahead and do it now. I'm not sure we're hearing that. Somebody has the magic word combination. And again, I think the goal is to convey to the ONC what the issues are that the committee and the task force has found here, and what's the best way to convey that to the ONCs, what you're seeking to do, at least.

Denise Webb – Individual – Member

So, are we permitted to vote on agreement with the intent of this recommendation with the request to tighten up the language? Or do we just table it? **[Crosstalk] [01:26:24]**

Robert Wah – Individual – Chair

It'd be my observation that the net effect would be the same. So, the task force – you've heard the input from the committee, and before the committee votes on the recommendation, you'll come back with maybe a different set of words here that will convey all the input that you've had. So, whether we vote on the intent right now or the specific wording, I'm not sure it's gonna change.

Denise Webb – Individual – Member

All right. Well, we have a lot to get through, so why don't we just table it and move on. All right. Recommendation –

Robert Wah – Individual – Chair

I just want to make sure we – have we had all the comments and input we want on recommendation 13 before we close it out? All right. Hearing none, why don't we go to 14.

Denise Webb – Individual – Member

Okay. 14, we're recommending that ONC review and revise the regulatory impact analysis time estimates so that they accurately reflect and align with what all they except here or don't accept, and change in the final rule. It's probably a given, but we wanted to make sure that we're expecting that.

Robert Wah – Individual – Chair

Comments or questions on recommendation 14? Hearing and seeing none, all those in favor of recommendations 14, please say aye.

Group

Aye.

Robert Wah – Individual – Chair

All opposed?

Denise Webb – Individual – Member

Great.

Robert Wah – Individual – Chair

Any abstentions? Okay. Let's move on to 15.

Denise Webb – Individual – Member

Great. Recommendation 15, we're moving into attestation. And we have on recommendation. And this really is around the deadlines that the rule specifies for these attestations. They're

rather prescriptive and have a predefined 14-day window. And we're suggesting that ONC include a specific deadline at the middle of the year and the end of the year, or the beginning, and consider, for example, setting the deadline for the health IT developers to submit their semiannual attestations to the ONC ACB the last Friday of January and July. Really, this is to get around the conundrum we've had in the past around holidays, and when does the 14-day start and end, and that they specify a specific time period or date, that this would avoid this.

Robert Wah – Individual – Chair

Great. Questions or comments on recommendation 15? Hearing and seeing none, all those in favor of recommendation 15, please say aye.

Group

Aye.

Robert Wah – Individual – Chair

Any opposed? All right. Any abstentions? All right, thanks. Denise?

Denise Webb – Individual – Member

All right. Now we're moving to application and programming interfaces. Recommendation 16. In the current proposed rule, there is little discussion on the relationship between an API technology supplier and the API user, whereas the other relationships are discussed more extensively. So, we're recommending ONC clarify what is considered an acceptable relationship in this realm between an API technology supplier and the API user, or clarify what activities are expected or permitted to occur between those two groups of actors. And in particular, this relationship, as I mentioned, was not sufficiently addressed in the preamble.

Clem McDonald – National Library of Medicine – Member

Could you just clarify what the issues are that might be problematic? I mean, I'm not against this. I just don't picture what the model is here that people are worried about.

Denise Webb – Individual – Member

So, the proposed role doesn't contemplate or address the fact that it's not as sequential, where the API technology provider provides technology to the API data users, or the data providers, or the users. There are these third party application developers that are actually working with the technology supplier to test their third-party apps, like a lot of consumer apps. But none of that – without having to pull up the rule, and I would refer you to the section in the rule – there's quite a bit of discussion about what API technology suppliers can or cannot do or expect with API data providers and users – I mean, excuse me, and API data providers.

There is a huge discussion and detailed discussion on the relationship between an API technology supplier and an API provider. And it infers that there's only a relationship between the data provider and the actual users, and that's not true in the case of these third party app developers who are engaged in a relationship with the technology suppliers. So, this is more to provide clarification around the expectations of what that relationship looks like, just as they describe what the relationship looks like between the API technology supplier and the API data

provider.

Clem McDonald – National Library of Medicine – Member
But I assume there are some relationships you'd like to prevent by that statement. Is that correct?

Denise Webb – Individual – Member
Not necessarily. We think that it just needs to be addressed.

Clem McDonald – National Library of Medicine – Member
Okay.

Robert Wah – Individual – Chair
Other questions or comments on recommendation 16? Hearing and seeing none, all those in favor of recommendation 16, please say aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions? Great. 17?

Denise Webb – Individual – Member
Great. Recommendation 17. ONC was seeking our input on which FHIR release should be in the final rule. And we're recommending ONC solely adopt FHIR release Four or a subsequent 4.X version if one is created through errata in the final rule. And that would affect the regulatory text and the preamble sections noted here.

Clem McDonald – National Library of Medicine – Member
I like it.

Robert Wah – Individual – Chair
Steven, you have your hand up?

Steven Lane – Sutter Health – Member
Yeah. I agree that we should support the use of this latest version of FHIR, but I think if we write into regulation release four that when release five subsequently comes along, we're gonna need new regulation to adopt that. So, I think if we could phrase it in such a way that, as you say, 4.X, but it could be "or any subsequent valid version," perhaps through the standard advancement process, that would give us more flexibility going forward.

Denise Webb – Individual – Member
Stephen, I'm just curious, do you think that that's not already provided for through the standards advancement process? Because I think the way ONC described it, they have to be

definitive in what standard they're specifying in the regulatory text and wouldn't be able to refer to a version that doesn't exist yet.

Steven Lane – Sutter Health – Member
That may well be. Perhaps ONC or Steve could best comment on that.

Clem McDonald – National Library of Medicine – Member
That's been true in the past.

Denise Webb – Individual – Member
And what we're suggesting here is sometimes there are corrections to a release, like four, and it creates a dot X, an errata, and that that would be expected, versus a new release, which would **[crosstalk] [01:35:35]** advancement process.

Steven Lane – Sutter Health – Member
If we feel that that's covered through the standards advancement, then I think we're fine.

Robert Wah – Individual – Chair
Other questions or comments about 17? All right. Hearing and seeing none, all those in favor of recommendation 17, please say aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed? Any abstentions? Great. Denise?

Denise Webb – Individual – Member
All right. So, recommendation 18 is recommending that ONC go ahead and move forward in the final rule with implementation specifications and implementation guides to ensure everybody's working off the same set of specifications, because this would definitely enhance interoperability and reduce complexity and cost. And we see value in the developers harmonizing to a specified version and release of these guides, specifications and guides.

Robert Wah – Individual – Chair
Questions or comments about recommendation 18? Hearing and seeing none, all those in favor of recommendation 18, please say aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions? Denise?

Denise Webb – Individual – Member

All right. Thank you. Recommendation 19, we have noted, Raj and I, that this was a new recommendation from the task force, because when we first presented our recommendations, we had 33. We now have – well, 35, and soon to be 36. So, recommendation 19 was in the presentation at the last HITAC. And we have revised it slightly based on the feedback we heard. And we are recommending ONC require compliance with HL7 U.S. Core FHIR implementation guide, rather than specifying the Argonaut implementation guides in the final rule and preamble. And then where HL7 IGs are not available for the corresponding and required Argonaut functionality, we're recommending ONC assist in facilitating their inclusion in the HL7 U.S. Core FHIR IGs.

Robert Wah – Individual – Chair

Questions or comments about recommendation 19?

Clem McDonald – National Library of Medicine – Member

This is Clem. I have two ambitious questions. Is it possible for them – well, there's been so much assumed in a lot of the other discussion and the regulation about Argonaut. I'd at least like to hear input from ANC whether this is gonna be a problem. But the other thing, can it still get done if we still have to get other stuff into the U.S. Core FHIR IGs? I mean, is that doable? Does anyone know what's missing in the Core versus the Argonaut? **[Crosstalk] [01:39:02]**

Ken Kawamoto – University of Utah Health – Member

As far as I know, a lot of things that are needed are in there. I did talk to Micky Tripathi, the project lead or project manager for Argonaut. He thought this sort of direction was fine. But if Steve Posnack is aware of any particular gaps, yeah, that would be good to know.

Denise Webb – Individual – Member

Would that change our recommendation, though?

Clem McDonald – National Library of Medicine – Member

Well, and one other conundrum is what the current NPR recommends is 15 resources. And how does that align with what's in here? Does it collide with it, or is it gonna create additional problems? Are those all Argonaut, and they're not in the Core? Or are they in the Core now? I just don't know that detail. Does anybody?

Ken Kawamoto – University of Utah Health – Member

You're talking about the data elements, Clem, or what are you talking about?

Clem McDonald – National Library of Medicine – Member

The NPRM recommends 15 distinct resources be supported by every – medical record vendors. Things like patient and order, etc. And I don't know how that relates to Argonaut or how this would change anything, or whether it could collide with it. We're saying that how does those 15 line up with the FHIR implementation guides? Because the guides were very true, specific resources.

Ken Kawamoto – University of Utah Health – Member
I think, except for the new ones that got tacked on in the regulations, it's there, right? Because the Argonaut resources and search parameters have been just going to U.S. court regularly. So, I don't think there's an issue. But again, I'd lean on Steve or the ONC leaders in the details to identify if there's any issue.

Clem McDonald – National Library of Medicine – Member
Could we then accept this, conditional –

Arien Malec – Change Healthcare – Member
I don't understand why this recommendation has any bearing on which profiles are or aren't included in an HL7 IG. This is really a process question, not a – I'm confused as to the issue here.

Denise Webb – Individual – Member
And Arien, I'd also state that our last sentence in there is really getting at if there's something that needs to get moving that has not landed in U.S. Core FHIR implementation guide, that ONC has a role in facilitating and providing some levers to get it in there, I think. And if anybody else from our task force wants to chime in, such as Ken, on what we intended with that statement? Because really, our concern here is having regulatory text referencing a body that is not a standard voluntary body consensus. So, that's what we're trying to get at here, but we're also saying where the guides of HL7 U.S. Core are missing something, and it's because of a process problem, that ONC could facilitate getting that going or done.

Robert Wah – Individual – Chair
Clem, does that help clarify it for you?

Clem McDonald – National Library of Medicine – Member
Yeah. And I mean, I understood that the motive for the whole thing is to get it into a full standard consensus process, rather than a group. It's not quite open to everybody. But I just hope we could get ANC to warn us if there's some "gotcha" that we didn't recognize.

Robert Wah – Individual – Chair
Arien, were you raising your hand to comment again on this, or do you have something new?

Arien Malec – Change Healthcare – Member
Yeah, I was originally raising my hand to comment on this. So, again, as Micky noted, or as Ken noted, as Micky noted – so, Micky's the program coordinator for Argonaut. The Argonaut process is tightly linked and coupled with HL7. And the goal is to take any of the testing output and the profiles that are developed through testing, I think. The function of Argonaut is to do real-world testing with a variety of EHRs and app developers. And as Micky notes, or as Ken notes as Micky notes, I think this recommendation is just fine. This is the normal process that Argonaut follows. I think the notion that at some point, we might have timing issues is a valid one, but that's really – I think this recommendation addresses that by acknowledging that ONC

has a role to play to make sure that HL7 and any testing organization, including Argonaut, coordinate their calendars to make sure that we have finalized implementation guides for the community.

Robert Wah – Individual – Chair
Right. Other questions or comments about recommendation 19? All right. Denise, I think we can take a vote on this. All those in favor of recommendation 19, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions?

Arien Malec – Change Healthcare – Member
This is Arien. I'll abstain.

Robert Wah – Individual – Chair
Okay. Denise, do you want to go to 20?

Denise Webb – Individual – Member
Okay. Recommendation 20 recommends that ONC address the legitimate and expected activity for smart guide to protect patient data with respect to providing persistent tokens to applications, and the application's ability to keep the token confidential. So, we're recommending that ONC clarify who is responsible for determining that API users developing products that are provided a persistent token are keeping the token confidential, and how is this determination made. So, we're just looking for some clarity around this in the preamble.

Robert Wah – Individual – Chair
All right. Arien, you have your hand up?

Arien Malec – Change Healthcare – Member
Yeah. I guess my perspective here is this is something that should be addressed in the implementation guide and not addressed in regulatory text or – and preamble would be nonbinding. But this is a classic example of something that you just don't want to put in regulation; you'd rather put in an implementation guide so that it can be tested, revised, etc. There's security considerations for almost all implementation guides and guidance, and I think if there's a particular concern here, it should get addressed either through the testing process or through the HL7 process to make sure that this is properly addressed in the security consideration section.

Denise Webb – Individual – Member
So, Arien, what we found in the proposed rule, it wasn't clear on who's responsible for determining whether an app meets this or not. It's more about assigning responsibility. And I guess maybe that might – and when we say how the determination is made, maybe that

portion of this needs to be removed, because if that has to be covered in the implementation guide, that's already a standard process.

Arien Malec – Change Healthcare – Member
Yeah. I mean, I consider the use of persistent tokens to be something covered by an implementation guide and addressed through the security considerations of that implementation guide, as opposed to something that you probably – that you want to address through regulation.

Sasha TerMaat – Epic – Member
I think the challenging part, Arien, is that the implementation guide says that the expected practice is to provide a persistent token only if the application – it's a confidential client. But ONC, in their guidance, specifically overrules the implementation guide, and instead of having that be an optional component, says it's required to offer a persistent token, leaving the interrelationship unclear.

Arien Malec – Change Healthcare – Member
Got it. Yeah.

Sasha TerMaat – Epic – Member
Is it still just for confidential clients? And if so, how are those determined, given the other restrictions on app vetting? Or is it actually overriding and saying provide a token even to nonconfidential clients, which seems to actually be in conflict with the implementation guide?

Arien Malec – Change Healthcare – Member
Yeah.

Sasha TerMaat – Epic – Member
So, I agree with you. If it completely deferred to the implementation guide, that would be preferable, but ONC is already calling this out as a special case.

Arien Malec – Change Healthcare – Member
Yeah. I think I would double down on the same requirement, that this is something that probably shouldn't be addressed through regulation – it should be addressed through the implementation guide. And if ONC feels like the implementation guide doesn't set – or sets things in ways that are contrary to public policy, that they probably should work with HL7 to make sure that that's reflected. And then with respect to all of that, I agree that if ONC wants to overrule the implementation guide and create, effectively, an additional implementation guide through regulation, then that regulation needs to have the same effect as an implementation guide and clarify rules and responsibilities. So, I think I'm conditionally agreeing with this recommendation. But my general recommendation would be this is something classically that should be punted to an implementation guide. **[Crosstalk] [01:49:14]**

Denise Webb – Individual – Member

Go ahead.

Steve Posnack – ONC – Executive Director, Office of Technology
This is Steve from ONC, if I may just jump in for a second. Because I think what's been proposed is slightly misrepresented, as far as I can understand. In large part, we've proposed to adopt what was included in the smart app launch framework implementation guide, which references two types of tokens – an access token and a refresh token. We have not required what's been referred to in the cases and has been discussed as persistent tokens. And in fact, we've just proposed to follow what the implementation guide lays out. However, requiring that refresh tokens be provided, which is not a requirement in the implementation guide. And so, that's the only thing that we've proposed to require in terms of the pattern of interaction using the OAuth2 standard that refresh tokens must be provided as a part of providing access via the APIs. Otherwise, the proposal as a whole defers to the implementation guide itself. **[Crosstalk] [01:50:20]**

Denise Webb – Individual – Member
What was that, Clem?

Clem McDonald – National Library of Medicine – Member
Can we clarify this particular recommendation, then, given this additional information?

Denise Webb – Individual – Member
Well, we may not need the recommendation. So, what I was gonna ask Sasha is based on that clarification from Steve. Is this recommendation really necessary for the committee to put forth?

Sasha TerMaat – Epic – Member
Yes. I think we just used the wrong word in recommendation 20, and we mean refresh token where we said persistent token. Refresh token still has the discussion about offering it to confidential versus public clients.

Denise Webb – Individual – Member
Okay. Terry's got his hand up.

Terrence O'Malley – Massachusetts General Hospital – Member
Sorry, I don't think I lowered it.

Denise Webb – Individual – Member
Oh. Okay. So, if we changed this to "refresh tokens," Arien, would that still – would your comment still stand? Are you recommending that we remove this and just write a recommendation that they follow the IG? But it sounds like Steve says they are following the IG, with the exception that they're requiring refresh tokens.

Arien Malec – Change Healthcare – Member
Yeah. My general preference would be that the IG – that there be a particular IG that is refresh

token only. But I guess with Steve's clarification, I don't have as much of an issue with the need for this recommendation. I just generally feel like ONC should not be providing implementation guidance through regulation; that the implementation guide should be clear, and ONC should be able to point to a subset of the implementation guide that's relevant for the particular certification criteria, so.

Denise Webb – Individual – Member
Okay. So, Robert, can I ask that we take a vote, that you conduct a vote with the change of "persistent" to "refresh?" And if the majority of the committee agrees this isn't needed, then they would vote nay. I mean, excuse me, if the majority of the committee votes nay, then we know this recommendation won't go forth and isn't needed.

Steve Posnack – ONC – Executive Director, Office of Technology
I stopped paying attention. Say that again.

Robert Wah – Individual – Chair
Steve, was that you? Okay. So, Denise, I'm fine with doing that. I think it's putting a lot of – you're making a change in the wording, so we're sort of amending recommendation 20 to change "persistent" to "refresh," I think is what I heard. And then you're also –

Denise Webb – Individual – Member
Right. Because we used the wrong word.

Robert Wah – Individual – Chair
Yeah, yeah, no, I got it. And then you're also asking the question, is this recommendation needed at all? And I'm a little concerned we're putting too much into one vote, but . . .

Denise Webb – Individual – Member
Well, no. What I'm suggesting is if the majority of the committee does not agree with this recommendation, then it doesn't go forth. I know that the task force voted on this recommendation, and the entire task force agreed we needed this recommendation. And apparently, we used "persistent" – we used the wrong word when we were capturing the text on this.

Robert Wah – Individual – Chair
Right. I understand. So –

Denise Webb – Individual – Member
So, I'll take your direction. Whatever you think we should do.

Robert Wah – Individual – Chair
All right. So, I think everybody's clear. I want to make sure, any other comments or questions about recommendation 20? So, the task force has recommended changing the word "persistent" to "refresh." With that change, it's still the recommendation of the task force that recommendation 20 be accepted by the committee. Given the discussion we've had, I think we've aired that completely, let's go ahead and vote on the amended recommendation

20. And I'll ask one more time, is everybody clear on where we are? All right, seeing no other comments or hands, all those in favor of the amended recommendation 20, please say aye.

Group
Aye.

Robert Wah – Individual – Chair
Great. All those opposed, say nay. Any abstentions?

Arien Malec – Change Healthcare – Member
This is Arien. I abstain.

Clem McDonald – National Library of Medicine – Member
Clem. I'll abstain too.

Leslie Lenert – Medical University of South Carolina – Member
Les. I abstain.

Robert Wah – Individual – Chair
Yeah. I heard three abstentions. Okay. All right. Denise, why don't we go ahead and try to get through recommendation 21?

Denise Webb – Individual – Member
Okay.

Robert Wah – Individual – Chair
We have public commentary scheduled at 11:30 in just a couple minutes.

Denise Webb – Individual – Member
Okay. So, recommendation 21 was a new recommendation that we had a bit of discussion on in the last HITAC meeting. And we took the input from the committee – excuse me – yeah, the committee members and revised this. And now, we are recommending that ONC work with OCR and other responsible agencies to provide formal guidance on current uses of FHIR APIs, such as in smart on FHIR applications or CDS Hooks services with respect to compliance with relevant privacy and security relations such as HIPAA, with the concern here being the inappropriate sending of full patient demographic details or the inappropriate use of broadly scoped data access tokens. And we're suggesting that this deliberation can leverage the work and recommendations of the prior policy and standards committee's joint API task force as a starting point.

Robert Wah – Individual – Chair
Questions or comments about recommendation 21?

Clem McDonald – National Library of Medicine – Member

Yeah, a comment. I think this and maybe more is important. So, to use Hooks, because Hooks doesn't have much smarts at the medical records side. So, say if a drug study wanted to use Hooks, they'd have to get, say, everybody who got admitted – just the ID – and then decide which ones they need to respond to. So, I think this also suggests that HL7 should figure out some logic on the medical records side to filter. But I think this is a good suggestion as it stands.

Ken Kawamoto – University of Utah Health – Member
This is Ken. I'll just address that point. In practice, the standard isn't discuss it, but all real implementations of CDS Hooks I'm aware of use something called trigger cards, which is just a fancy way of saying the EHR's native rules engine to restrict when things are sent. But I think that raises the good point that the standards themselves oftentimes don't speak to this. And there's probably expectations of what happened outside of it. But that still needs to be worked out. **[Crosstalk] [01:57:50]**

Denise Webb – Individual – Member
That's a request for formal guidance.

Clem McDonald – National Library of Medicine – Member
Yes. Ken, is there some movement to formalize the logic on the medical records side to make it more easy to use or more general?

Ken Kawamoto – University of Utah Health – Member
There is discussion in CDS Hooks specifically and for FHIR, these kind of things. I did touch base with **[Inaudible] [01:58:13]**, the FHIR project manager, and he did acknowledge that the standards themselves didn't really address this. And they are looking to see if they can address it in the standards, but at this point, probably need things outside the standards in terms of policy and processes to address.

Clem McDonald – National Library of Medicine – Member
Okay. And is Hooks actually a formal HL7 standard or is it sort of a **[Inaudible] [01:58:30]** standard?

Ken Kawamoto – University of Utah Health – Member
CDS Hooks has been balloted, and it's currently in the process of being published as a 1.0 spec.

Clem McDonald – National Library of Medicine – Member
Oh, okay.

Robert Wah – Individual – Chair
Other comments or questions about recommendation 21? All right, hearing none and seeing none, all those in favor of recommendation 21, please say aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions? All right. With that, we're gonna just pause this discussion and allow the public to comment as per scheduled on the predistributed agenda. I'll turn it back to Lauren to run that.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sure. Thanks, Robert. Operator, can we please open the public line at this time?

Operator
Certainly. If you'd like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. And you may press *2 if you'd 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 * keys.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. And just as a reminder to members of the public, the comment phone number is always in the lower left-hand corner, so feel free to dial in, even shortly before the official public comment period starts. Operator, do we have any comments in the queue at this time?

Operator
Yes, we have comments from the line of Adrian Gropper with Patient Privacy Rights.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Please go ahead with your comment.

Adrian Gropper – Patient Privacy Rights
Hi. I want to urge the committee to seek guidance or make recommendations around – clarity around dynamic client registration, as mentioned in the draft, and the importance of dynamic client registration to satisfying the "without special effort" requirement. In particular, to note that dynamic client registration doesn't mean consent for actual information exchange. And so, not offering dynamic client registration is simply a barrier to use in a wider and more interoperable ecosystem. Thank you.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you for your comment. Operator, do we have any additional comments in the queue?

Operator
Not at this time.

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

Okay. So, then I think that leaves us with just about 10 minutes or so before our virtual break here. So, Robert and Denise, if it's okay with you, we can use the last 10 minutes to resume the recommendations.

Robert Wah – Individual – Chair

Great.

Denise Webb – Individual – Member

Sure.

Robert Wah – Individual – Chair

Denise, recommendation 22?

Denise Webb – Individual – Member

All right. We're on 22. We have some concerns over ONC not proposing a standard way for a request for multiple patients' data, and recommends ONC specify a standard approach that will be available in FHIR R4, which we had recommended in one of the previous recommendations, that that be the release that is specified in the final rule. And so, if ONC identifies FHIR R4 for implementation in the final rule, this standard could be used for bulk queries, but we're suggesting on a different timeline than implementation of more established R4 implementation guides that support search for a single patient's data. We'd like to see successful implementations of the products that search for multiple patients using the standard prior to adopting across the industry.

Robert Wah – Individual – Chair

Arien, you have your hand up?

Arien Malec – Change Healthcare – Member

Yeah. So, I just want to remind the committee that the successful transition to FHIR -based API access for patients was done in much the same grounds as, I think, ONC's proposing for bulk data export; that ONC is proposing functional specification at first, with a registered intent in the preamble to switch to a standard, and that just given where we are, it's appropriate to let the community test bulk data export and make sure it's fit for purpose, make sure it addresses the portability requirements as well as the, for example, some of the needed requirements relative to risk adjustment or quality measurement – the other sorts of things for which bulk data access is typically performed.

So, I think actually, ONC's gotten the policy framework right. And it may just be that we want to recommend additional preamble clarifying ONC's intent. I can't wrap my head around a rule where ONC would say, we intend – where in the rule, ONC would name a standard that isn't yet established. But I think the only appropriate way to address this is either not include it as a requirement, or include it as a functional requirements with preamble text that explains kind of what this recommendation is addressing. So, I don't know if Steve has any comment here in

terms of regulatory jujitsu. But that's the way it would seem to work in my head, is either ONC does not establish certification criteria, or ONC establishes functional certification criteria with a preamble intent to switch at some future time to a FHIR -based implementation guide.

Clem McDonald – National Library of Medicine – Member
So, this is Clem. I'd just like to add or chime in that I would not like this thing to block or stop going forward. And as it's stated now, I could imagine it would, with the other parts of R4.

Robert Wah – Individual – Chair
Other comments or questions about recommendation 22? And Denise, I don't know if you want to try to respond, or you want to try to have **[crosstalk] [02:05:34]** at this point?

Denise Webb – Individual – Member
Well, I think if – I guess what we're suggesting is if the regulatory text specifics FHIR R4, and it specifies for the bulk data, a different implementation timeline than the 24 months, 25 months that's being proposed for the other criteria, again, ONC would have to comment, as Arien mentioned, what's permitted to put in regulatory text. Is it just a functional certification criteria in the rule text, and then in the preamble, their intent to expect it to be R4? So, I'm not exactly sure where we go from here on this. And I would welcome others to comment.

Robert Wah – Individual – Chair
So, Clem and Arien, if you could just clarify your position on this recommendation. Are you recommending changing, modifying, or deleting this recommendation?

Arien Malec – Change Healthcare – Member
Yeah. From my perspective, I believe, if I understand ONC's proposed approach, that ONC's following the same API certification approach that was successful in enabling a transition to standard FHIR-based APIs. And I suspect that when you look at the actual rule, the enablement of this recommendation will amount to effectively the same thing, that we do a functional specification first and then transition to a FHIR-based specification at a later date. I think it's completely appropriate for ONC to clarify its intent in preamble. But I would be opposed generally to naming an implementation guide in regulation that hasn't gone through appropriate pilot testing and has been established as fit for use . . . and believe that the regulatory approach that ONC's proposing is exactly the right one.

Clem McDonald – National Library of Medicine – Member
So, my word is, I think this makes sense, the proposal. But I wouldn't want it to then lock up the progress on FHIR. So, if we could find a pathway to do what Arien said, I think that would be good.

Denise Webb – Individual – Member
Mm-hmm. Arien, can I ask – this is Denise. And what in the current proposed rule would prevent each developer from implementing this differently?

Arien Malec – Change Healthcare – Member
Yeah. This is exactly what happened with the patient API regulatory framework, where ONC

established a functional specification for access to APIs. And at the same time, many of the EHR vendors collaborated around a transition to FHIR-based APIs. So, it provided flexibility for EHR vendors to be certified to – and effect a proprietary method for addressing the functional requirement, the provided incentive for the community to transition to a standards-based way of doing this. And I think what we've seen in the real world is a rather rapid transition to API-based access, both from a data supplier and EHR perspective and from an app perspective. And I suspect that the same regulatory framework will play its way out in bulk data access.

Denise Webb – Individual – Member
So, I'm thinking that this is sounding like probably I should take this back to the task force to discuss further.

Robert Wah – Individual – Chair
It sounds like perhaps, a couple of additions would make this more useful, is what I'm hearing.

Denise Webb – Individual – Member
Mm-hmm. Okay. Thank you.

Robert Wah – Individual – Chair
All right. So, let's table 22 and see if we can do 23.

Denise Webb – Individual – Member
This one's a simple one, and it's just a minor addition of a couple words in the preamble text, because we were not clear on what happens at six months and what happens at 24 months concerning the publication of API documentation. And you'll see here the three words we add. We just wanted to make it absolutely clear that the publication and documentation is for sub-7, 8, 9 of 170.315G, and not 10 and 11, which get – 10 and 11 are new, and they have 25 months to complete development, so we – that's it. Nothing more.

Robert Wah – Individual – Chair
Comments or questions about recommendation 23? Seeing none and hearing none, all those in favor of recommendation 23, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions? Let's try to do one more.

Denise Webb – Individual – Member
Okay. The next one has to do with the app registration portion of the condition of certification requirements. And we are recommending ONC provide further clarification on the requirements and expectations around the app registration condition of certification. And we just identified a number of issues. And so, the areas that we're concerned about are providing clarification on what the practice of registration consists of or does not; what verifying the

identity of an API user consists of and does not; vetting an app in contrast to verifying identity of a user consists of, and what falls out of the definition of that; and identifying any tasks that fall outside of registration, identity verification, and vetting. And this would be within the preamble.

Robert Wah – Individual – Chair
Okay. Questions or comments about recommendations 24? Hearing and seeing none, all those in favor of recommendation 24, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions? All right. All right. So, we are at our scheduled break. And we have – what do we have, 10, 12 more to go, Denise?

Denise Webb – Individual – Member
Not quite. 25 is a placeholder. So, I think we have nine more to go.

Robert Wah – Individual – Chair
Anyway, we have nine more to go. So –

Denise Webb – Individual – Member
Actually, we have 11 to go.

Robert Wah – Individual – Chair
Yeah, okay. So, yeah, as your chairs, it's always a challenge for us to predict how much time these are gonna take. And we never want to limit discussion or make people feel like they don't have an opportunity to voice their concerns. So, I've been trying to balance this through this discussion. We have a presentation scheduled right after the break with a person who has a very tight timeframe. Give us the break to think about whether or not we'll continue this task force recommendations, or we'll go straight to that presentation that's scheduled after the break. But recognize that we're trying to strike that balance where we're getting through as much material as we can as efficiently as we can, but never want to step on or inhibit anybody from bringing up a point for discussion. We do have a little bit of extra time given us by this extension of the comment period for the rule-making, so we could bring this back at the 5/13 meeting as well. But with that, why don't we take a break? Please be back online promptly at 12:15. And we will pick up the committee's work at that time. Thank you all for your attention, and have a good break. We'll see you at 12:15. Thanks.

Denise Webb – Individual – Member
And Robert, quick question. If we have time at the end, can we circle back and try to finish some more of these?

Robert Wah – Individual – Chair

Yeah.

Denise Webb – Individual – Member
Thank you.

Robert Wah – Individual – Chair
Like I said, we're gonna spend a couple minutes here. I just didn't have it ready to go, so.

Denise Webb – Individual – Member
Okay, thank you.

Robert Wah – Individual – Chair
Yup. [Music plays until 02:41:50]

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Okay, welcome back, everyone. Hope you were able to take a quick break there. We are now joined by Zoe Barber, our Senior Policy Advisor here at ONC in the Office of Policy. She will do an overview of the very recent draft two of Trusted Exchange Framework and Common Agreement. Again, this is really just meant to be an overview, because we have two other task forces to get to today. But of course, we will continue to hear from the Trusted Exchange Framework Task Force and the full committee moving forward. So, with that, I will turn it over to Zoe.

Zoe Barber – ONC – Senior Policy Advisor, Office of Policy
Hi, everybody. Thank you so much, Lauren. As Lauren said, my name is Zoe Barber, and I'm a senior policy advisor here in the Office of Policy at ONC. I'm so excited to be presenting on a TEFCA draft two for you all today. I know that you guys have a lot of work that you need to get through today, so I will try to keep this as brief of an overview as possible. And then we will be diving into the TEFCA and doing more detailed presentations in the coming weeks.

So, last year, we convened the first Trusted Exchange Framework Task Force, and the recommendations that came out of that task force were extremely valuable and helpful in developing the second draft. So, I'm really looking forward to the new task force. And before I begin, I would also like to introduce my colleague, Alex Contour, who's also on the line. And he works side by side with me in the Office of Technology. He is our subject matter expert on everything QHIN technical framework, and he will be working alongside me on the task force as a subject matter expert, and will be available to help answer questions today.

All right. So, the first slide we have here, this is the CURES Act language. I hope that you are all familiar at this point with the CURES Act. I think if we're not, then we have some bigger issues to resolve, so I think we can move to the next slide.

So, our primary goals in designing the Trusted Exchange Framework and Common Agreement were threefold. First, we were aiming to provide a dual on ramp to nationwide connectivity.

That means enabling all types of healthcare stakeholders to participate in nationwide exchange regardless of who they are, where they're located, or which health information network, if any, they participate in. We also wanted to ease the flow of electronic health information to allow patients to securely access it when and where it is needed most, and to allow patients and their caregivers to better manage their data and have greater control in managing their care.

And then, third, we wanted to support nationwide scalability. So, the primary focus of the Common Agreement is on exchange among health information networks. And we understand that there are varying rules and regulations that govern different entities and states, and we are aiming to establish a baseline set of protections to enable all of these different actors to come together and access exchange and use relevant electronic health information across disparate networks. In order for this to happen, all health information networks must agree on this minimum set of principles, terms, and conditions to enable trust. Next slide, please.

Okay. What are the Trusted Exchange Framework and the Common Agreement? Next slide. So, by now, I'm guessing all of you have already read through the entire TEFCA and have noticed that we've separated it into three appendices. The first is the Trusted Exchange Framework, which is a set of common principles that are designed to facilitate trust among health information networks. These principles are guiding principles. They're rules of the road. But they're not binding legal terms and conditions, and you won't necessarily see in the text some of the same vocabulary or terminology that you'll find in the MRTC, like QHINS or RCE. But the Trusted Exchange Framework is the foundational element upon which the MRTCs and later the Common Agreement will be built. And these principles include things like standardization, transparency, cooperation, and nondiscrimination, privacy, security, and safety, patient access, and population-level data. Next slide.

Okay. Next, we have the Common Agreement, which is the actual legal agreement that health information networks will sign in order to access, exchange, and use health information over the network. And the Common Agreement will include three parts, the first of which are your minimum required terms and conditions. And that's what you will find in Appendix Two of the TEFCA. ONC developed these mandatory minimum required terms and conditions, and we did so keeping in mind the areas of major variation that we found between trust agreement out there today that are currently inhibiting health information from flowing as it should.

We will then be working – in the upcoming months, we'll be working with an industry-based, recognized coordinating entity that will help us to develop additional required terms and conditions in addition to the MRTC. And these ARTCs, if you will, will include anything that the RCE and ONC deem necessary in order to fully support an operational and an effective data use agreement. So, this can include things like further details on fee schedules, or governance and compliance processes between the RCE and the QHINs. The RCE will be the primary writers of the ARTC, but ONC does have final approval on the ARTCs and the full Common Agreement.

And then next, we have the QHIN Technical Framework, which is a new addition to the package this time around. And so, if you go to the next slide . . . The QHIN Technical

Framework will be incorporated by reference into the Common Agreement. And it specifies the functional and technical requirements for exchange among QHINs. It contains proposed specifications for things like certificate policies, authentication, and authorization, record location, error handling, and more. And our goal in separating the technical specifications from the legal requirements, which we did in large part from feedback that we received from this group specifically, is to allow us to stay on pace with the industry as standards evolve, without having to constantly revise the Common Agreement and come out with a new edition every single time a new standard enters the market.

The purpose of this first draft that we put out for public comment is really to key up to technical issues and the discussions that are going to be happening between the RCE, and the QHINs, and in the task force. We will be spending a lot of time in the task force talking about the QHIN Technical Framework. And this is an area where we will really be relying on the task force and their expertise to help us and to provide us with good feedback so that we can move this forward. Next slide?

Okay. We're gonna go through some of the major updates to draft two of the TEF and the MRTCs. Next slide. So, this is not an exhaustive list of the updates that were made. But these are some of the key changes that we received feedback on. The first, we've updated the exchange purposes that are included in the Common Agreement and adopted a subset of the payment and healthcare operations purposes as they are defined in HIPAA. We've also added an exchange modality for a QHIN message delivery. This is a push through the network to allow for sending of a patient's electronic health information to a specific qualified HIN for delivery, or one or more qualified HINs for delivery. We've added the QHIN Technical Framework, as I just discussed. And we've broadened the definition of a QHIN to allow for a broader set of health information networks to apply and to be eligible. But we've also added lengthy application process that will include rigorous testing and surveillance to ensure that the QHINs are successful and secure before they start actively exchanging data on the network.

And then, finally, we've extended some of the timelines that were included in the Common Agreement for updating legal and technical health **[audio distorts] [02:52:06]** specifications. So, to begin, there is no specified timeline for the initial onboarding of qualified health information networks. That is something that may be left up to the RCE to help define through the ARTCs. But we have said that once you have signed on to one of the framework agreements, when a new version of the common agreement is published, entities that have signed a framework agreement would have 18 months to implement any updates to their technical and legal standards. Next slide.

Okay. What is the structure of the Common Agreement? Next slide. So, here you can see many of the stakeholders that would be included or could be included in the TEFCA network. The TEFCA is designed to be inclusive of many different types of stakeholders with varying requirements and regulations that govern them. So, first we have health information networks, of course. And we do use the definition of health information network that you guys have been reviewing as part of the NPRM task force. So, we will be discussing that definition as well in the TEFCA task force. We also included public health agencies, payers, technology developers, government agencies, and of course, providers, and all different types of

healthcare providers across the country and on the care continuum.

And then, most importantly, we have here individuals. And our definition of individual includes both the patient who is the subject of the information being accessed, exchanged, used, or disclosed. And it can also include a personal or legal representative of the patient or any other person having authority to act on behalf of that patient. So, that's another definition that we'll be looking at as part of the task force. Next slide.

Great. So, this slide illustrates a holistic view of the common agreement – all of the different pieces and actors within the Common Agreement and how they interact with each other. So, we're gonna break each of these down. So, if you go to the next slide.

So, one of our major goals in designing the Common Agreement is to collaborate with the industry and to build a public/private partnership to implement and sustain the Common Agreement. So, we wanted to work with an industry-based entity called a recognized coordinating entity to help us implement and monitor compliance with the common agreement. And the RCE will be selected through an open and competitive notice of funding opportunity, or a NOFO, which we've also released alongside the release of the TEFCA. And they will be awarded for a period of four years and will be helping us develop, update, implement, and maintain the Common Agreement; identify, designate, and monitor QHINs; modify and update the QHIN Technical Framework; virtually convene public listening sessions; develop and maintain a process for adjudicating QHIN noncompliance; and proposing strategies to sustain the Common Agreement at a national level after the initial cooperative agreement period. Next slide.

All right. Next, we're gonna talk a little bit about the structure of a qualified health information network. So, in short, a QHIN is an entity with the technical capabilities to connect health information networks on a nationwide scale. They are the gatekeepers of all of the electronic health information that will be flowing through the network, and thus, they have additional responsibilities that allow them to securely exchange large volumes of data across the country on a daily basis. So, as you can see here, QHINs will connect directly to participants, who can be any person or entity that enters into an agreement to participate with a QHIN. Participants then correct directly down to participant members, who can be any person or entity that has entered into an agreement to use the services of a participant.

And then we have individual users, who are individuals who make requests for individual access services, which we'll go over in a few minutes, using the services of a QHIN participant or a participant member. So, individual users can connect directly to anyone on the network, any of these three actors on the network, as long as they are providing individual access services. And the consumer has the flexibility to choose who they would like to receive their individual access services from.

Also, notably, we recognize that every health information network serves unique purposes and unique constituencies with different needs. And so, we've designed the Common Agreement in such a way as to not dictate the internal requirements or business structures of the QHINs. And not all QHINs must be composed of the same types of participants. And the participant

members and individual users can also vary between the health information networks. So, depending on its internal structure, there could be several different amalgamations of participants and participant members within and across QHINs. So, if you go to the next slide . . .

Here we have an example of a network of health IT developers. So, many of the participants in this network are health IT developers, including analytics products, EHRs, and consumer apps. And those that use the services of participants are the participant members, so it also has a consumer app down here at the participant member level – a provider, pharmacy, and anybody else that would be using the services of a health IT developer. Next slide.

How do you become a QHIN? Next slide. So, as I mentioned earlier, we've expanded the definition of who can apply to be a QHIN to allow for a broader set of entities to apply. But we've added this lengthy and rigorous application process to ensure that QHINs are secure and successful before they start exchanging data on the network. And we are trying to protect against failure of a QHIN once it's already been onboarded and has participants and participant members who are exchanging data and using their services, because at that point, failure could result in significant disruption to the network. And so, QHINs should go into the application process with an understanding of the breadth and scope of their responsibilities before they are applying.

So, in order to apply to be a QHIN, you first have to be a health information network. Again, that's the definition that we've been looking at through the MPRN task forces. You must operate an existing network with participants that are already exchanging data in a live clinical environment; that a network must meet all applicable federal and state laws; and you must submit a plan to the RCE on how you will meet all of the QHIN requirements. Next slide.

So, once a HIN submits the QHIN application to the RCE, the RCE will then approve or reject the application. And if approved, the health information network will be designated as a provisional QHIN. At that time, both the provisional QHIN and the RCE will sign the Common Agreement, and then the provisional QHIN will be put into a cohort where they'll work to implement all of the requirements of the Common Agreement. And during that cohort period, the RCE will be assisting and providing technical assistance, guidance, and surveillance of the QHINs and any other QHINs that are within the cohort to ensure that they are successful at the end of that period. And then at the end of the cohort period, the RCE will test to ensure compliance and will provide written notice of the QHIN designation, if that QHIN passes, to both the health information network and to ONC. Next slide.

All right. Now we're gonna go through a couple of the exchange purposes and modalities that the Common Agreement can be used for. So, go to the next slide. So, as we mentioned before, we updated the exchange **[audio distorts] [03:02:07]** in the first draft to include a subset of the healthcare operations and payment purposes as defined in HIPAA. So, the **[audio distorts] [03:02:18]**. Sorry. So, the seven purposes that are proposed in this draft include treatment, public health, utilization review, business planning and development, quality assessment and improvement, benefits determination, and individual access services. And we should note that treatment and public health utilization review, business planning and development, and

quality assessment and improvement, are defined as per their HIPAA definitions. And so, they are limited to covered entities and business associates.

Benefits determination and individual access services are exceptions to that. And individual access services specifically supports two use cases. One is the ability of a patient to request access to all of their electronic health information from all the places that they've been seen. And two, to request that that electronic health information be sent to a third party of their choosing. So, it's important to note that individual access services, as we've defined it, applies to certain pieces of the HIPAA right of access in 42 CFR 164524 to apply to all electronic health information and to apply to all actors that are participating in the Common Agreement, whether or not they are covered entities or business associates.

Another thing to note about the individual access services is that it requires that a response be sent back whether or not the request was made directly by the individual or by a third party app that's acting on the individual's behalf. And we're gonna dive a little bit deeper into the individual access services exchange purpose specifically as we get into the task force meetings in the next few weeks.

One more thing to note on the exchange purposes is that actors within the Common Agreement have a duty to respond for all of the exchange purposes. The only exception to that is, if you are an entity that is only providing individual access services, then you are only required to respond for requests for individual access services. Next slide.

And then here, we have three exchange modalities that we are proposing in this draft of the TEFCA. So, first, we have QHIN broad task query and QHIN targeted query, which were included last time. And then notably, we've added QHIN message delivery, which will be extremely helpful in supporting many of the public health and care coordination type use cases. And then in this draft, we've also removed the population-level query at this moment in time. And we anticipate working with the industry and working with the RCE to potentially phase that use case in as it becomes more mature on a network scale. Okay, next slide.

Okay, great. So, almost finished up here. Next steps, if you go to the next slide, we have a timeline of the next steps for the TEFCA. So, as I mentioned, we released the TEFCA package and the RCE notice of funding opportunity on April 19th. The public comment period closes for that on June 17th, and the RCE applications will also be due on June 17th. We then plan to award the RCE around the August/September timeframe and immediately begin working with them to develop the ARTCs and to update the QHIN Technical Framework. And then we will release a draft one of the Common Agreement, the full common Agreement, for public comment. And then subsequently, we will release a Common Agreement version one for protections. Next slide.

So, in the next few weeks, we're very excited. We are gonna be reconvening the task force, and we'll be diving into some specific details of the MRTCs, and going through all of that fun legal language. So, the overarching charge for the task force is to develop and advance recommendations on the TEFCA draft two to inform the development of the final Common Agreement. Specifically, we will be making recommendations on the minimum required terms

and conditions, and the QTS, including things like the definition, structure, and application process for qualified HINs, the exchange purposes and modalities, privacy and security. We're gonna be going into a lot more detail on all of the privacy and security elements in the MRTCs and specifically looking at some of the areas where we align HIPAA provisions to apply to non-HIPAA entities that are participating in the Common Agreement. And then finally, we will be taking a deep look at the QHIN Technical Framework and making recommendations on the technical and functional specifications for exchange among QHINs.

So, thank you so much, everyone. I really look forward to engaging with you all again on this process. I think we have a few more minutes for questions. And I'll turn things back over to Lauren Richie.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay, thanks so much, Zoe. Yes, we do have time for maybe just a couple of quick questions. And again, we'll have additional time to dive into some of the details, particularly at the first TEF task force meeting.

John Kansky - Indiana Health Information Exchange – Member
Lauren, this is John Kansky. Can I sneak in a question?

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

John Kansky - Indiana Health Information Exchange – Member
Can Zoe comment on whether with the new QHIN eligibility rules, whether it's clearer that EHR vendors will or will not be eligible to be QHINs?

Zoe Barber – ONC – Senior Policy Advisor, Office of Policy
Sure. Hey, John. So, as long as the entity that is applying meets the definition of the health information network and they are operating an existing network in a live clinical environment with participants that are currently exchanging data in that environment that meets all applicable and federal state law, they should be eligible to apply to be a QHIN. The RCE will be reviewing the application for those entities that are applying. And so, the RCE will be making determinations on whether or not entities are eligible to apply.

John Kansky - Indiana Health Information Exchange – Member
Thank you.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Last call for questions before we move on? Seeing none, Zoe, again, I want to thank you for your time in joining us today. At this point, we will transition to Christina and Terry to present on the USCDI's final draft recommendations. Terry or Christina?

Christina Caraballo – Audacious Inquiry – Member
Great. Thanks, Lauren. I guess we can go ahead to the first slide. Just as a review, our charge was to review the newly specified data elements proposed in the USCDI V1 and provide recommendations on those data elements. Today, we are gonna go through all of the task force's recommendations and vote on each. We have a total of 18, so we will be pausing after each recommendation that's presented and take a vote. So, next slide?

Robert Wah – Individual – Chair
Christina?

Christina Caraballo – Audacious Inquiry – Member
Yes.

Robert Wah – Individual – Chair
This is Robert. Looking at this, maybe the best thing to do would be to follow your – here on this slide, you've got five specific charges, and you've got recommendations under each one of them. So, maybe as we finish one group of charges, it might be three things, we'll vote on that. So, I think there'll be five areas to vote on rather than 18.

Christina Caraballo – Audacious Inquiry – Member
That's fine. Under each, we have recommendations that are kind of in three buckets. Okay.

Robert Wah – Individual – Chair
I think the way it's laid out –

Christina Caraballo – Audacious Inquiry – Member
Yup, that works.

Robert Wah – Individual – Chair
You'll do new patient demographics; we'll vote on that. You'll do provenance; we'll do that, and then so on.

Christina Caraballo – Audacious Inquiry – Member
Perfect. That works for us.

Robert Wah – Individual – Chair
Thanks.

Christina Caraballo – Audacious Inquiry – Member
So, if we could move to the next slide. Terry and I just wanted to take a moment and say that we've been really grateful to the task force for all their hard work and lively discussions, and wanted to send a special thank you to our awesome ONC staff leads, Stacy, Adam, and Johnny. So, thanks, guys. It's been great putting these together with you. All right, so moving on. Next slide.

As we went through each of these newly proposed data elements, we had a set of guiding principles. Throughout our deliberations, we constantly thought about identifying the key data elements which were needed to build a foundation for interoperability. And our goal was to avoid data elements that seemed too granular for version one and really try to strike a balance between the overall burden and benefit. So, as we went through these recommendations, we looked at whether we would include the proposed data elements as is, revise them, omit then altogether, and then also looked at additional data elements towards the end.

So, moving right into patient demographics. For each of these, we also looked at different use cases that the data elements would support. Highlighted in the patient demographics use cases, we were thinking about patient matching, identity verification, and clinical care. Moving on to the next slide.

The data elements in the proposed V1 of the USCDI were address and phone number. Our task force did recommend including both address and phone number, with some subrecommendations. So, for the subrecommendations under the address, we said that you should use both current and previous addresses. We recommend that we require addresses to be entered using standardized formats and content, because both have been shown to improve patient matching and reduce data entry errors. We recommend including destinations for individuals experiencing homelessness, including displaced persons and refugees. This will help identify populations at high risk for adverse health outcomes and addresses persons displaced by natural disasters and others who possess data matching challenges. And then finally, on this recommendation, we said to explore the feasibility of using and/or supporting an international address standard.

So, we're gonna go ahead and move on to recommendation two, which is the next slide.

Clem McDonald – National Library of Medicine – Member
Are you taking questions as you go?

Christina Caraballo – Audacious Inquiry – Member
Well, I think Robert just said he wanted us to move through each of the sections and then take a vote, and discussion at the end of the each of the sections, as opposed to each of the recommendations.

Robert Wah – Individual – Chair
Yeah. Well, we can discuss it however we want, but I thought we'd vote on them as a block. Sasha's got a comment on recommendation one. Maybe we'll just do that at this point.

Sasha TerMaat – Epic – Member
Sure. So, I had a question, really. It seems like the subbullets of recommendations one have different actors, and I might suggest that it would be clearer for our voting if those were made clear. So, for example, in D, I assume you're tasking ONC with exploring the feasibility of supporting an international address standard. But in A and B, using both current and previous addresses, requiring addresses to be entered in a standardized format, is that an expectation that a system that supports USCDI, like a software system, would support a standardized

address format, or a policy expectation that some mechanism would require clerks who enter addresses to populate them in a standard format, or a software expectation that software would reject addresses not entered in a standard format? I guess I'm trying to understand sort of when you're saying do these items, which are the actors who this obligation would be falling on?

Clem McDonald – National Library of Medicine – Member
I think those are good points. But also, to the international address, if the other people who were on this morning are still on, we may have a group that understands what currently is there as a standard address, which is in all of the standards, and how does it differ from international, and do we really want to change to the international format? And I don't know if – Arien, are you still on? Is someone else on who has more – deeper experience? I'm not hearing . . . Or Ken, do you know?

Ken Kawamoto – University of Utah Health – Member
I do not have any experience in this.

Clem McDonald – National Library of Medicine – Member
I mean, what I worry is that it's a null errand – that is, it's settle for the same, or the differences wouldn't be acceptable. And I think probably somebody knows.

Robert Wah – Individual – Chair
The recommendation is to explore to feasibility on the area of international. I don't think we're making a recommendation to do one or the other.

Clem McDonald – National Library of Medicine – Member
Well, I'm just thinking someone knows the answer, and we may be wasting time. But I don't know the answer, so I guess we're not wasting time.

Christina Caraballo – Audacious Inquiry – Member
We didn't know the answer in our task force discussions, but it came up that supporting an international standard for address should be considered before we implement and require systems to default support the U.S. Postal Service. It could be that in conjunction with an international standard. We weren't really sure. So, we kind of had tapped ONC in these recommendations to say, as we lay this foundation in USCDI V1, let's make sure we're really looking at the right standards to support addresses. So, our recommendation is to standardize it.

Clem McDonald – National Library of Medicine – Member
Yeah, address standards have been standardized for 20 years in messages. So, this is not a green field. It was standardized in FHIR. It was standardized in V2. I don't know where the idea is coming from that it's sort of a new thing. I think we should then **[inaudible] [03:19:16]** and explore the feasibilities, explore the benefits and the pros and cons of using it, because I'm not sure there's any reason to upheave what's been working for decades.

Terrence O'Malley – Massachusetts General Hospital – Member
Clem, this is Terry. I think one of the issues that we tried to address was, although there might be a standardized way of expressing an address, that often was not translated in how the addresses were entered, or a common format. And the result, there was an AHIMA paper that pointed out as a result, there are increased data entry errors as a result of not using standardized format. So, we were trying to push the industry, to Sasha's point, to adopt a format and a content standard in their systems, so that, again, it's interchangeable, interoperable, and it's a common format.

Clem McDonald – National Library of Medicine – Member
No, I understand it's the entry side that's the problem, but it's hard to control. But the format, there is a standard format that exists. Whether it's used properly is another question. And so, opening up two other new standards – I think we should say pros and cons about the international, not to say feasibility, because it could be feasible and still a bad idea.

Robert Wah – Individual – Chair
So, maybe we can also go back and address Sasha's question about the first – I think it was two and three. Well, two, I think, is the one that she was asking about.

Clem McDonald – National Library of Medicine – Member
Well, that's a good point.

Sasha TerMaat – Epic – Member
I think it would be helpful to identify the actor for each of the subrecommendations, or actors, if there are multiple entities that would be expected to cooperate to achieve the recommendation.

Clem McDonald – National Library of Medicine – Member
Yeah. And apropos of that, the current and previous, I think what you're really saying is keep the previous ones. I don't think you're asking people to record all their addresses when they register, or are you?

Terrence O'Malley – Massachusetts General Hospital – Member
I think we're recommending that we include a field for previous addresses as a way to assist patient matching.

Clem McDonald – National Library of Medicine – Member
Good idea.

Sasha TerMaat – Epic – Member
And then the second bullet would be read as that systems would support entering standardized addresses, or is this an obligation on the users who actually put the address into the system?

Robert Wah – Individual – Chair

Christina or Terry?

Terrence O'Malley – Massachusetts General Hospital – Member
Yeah, it's a good question. I'm not sure.

Christina Caraballo – Audacious Inquiry – Member
I'm thinking through it, and I think the actors is catching me off-guard a little bit, because I was just thinking it's pretty much whoever is using USCDI would be expected to send the data in the standardized format.

Sasha TerMaat – Epic – Member
I guess my question, Christina, and this is maybe getting into the nuance, which is usually probably Arien's territory, but I don't know that the USCDI proposal in certification has the possibility to obligate how users enter data into an EHR. As I understand the authority here, USCDI incorporated into certification only controls sort of what the software permits. And so, I get worried about things that, say, require addresses to be entered in standardized format, because does that mean that somehow a certified EHR has to tell a clerk or a patient, I reject your address because it's not standardized? Or is this really going into a different set of authority and suggesting a policy to ONC outside of certification that says, look, we also recommend that you encourage standardized use of how addresses are captured or standardized formatting of them through an address verification service outside of the scope of certification because we think that's a desirable factor to the industry? But I feel like it's important as we vote on this recommendation to be able to assess what of those it is.

Clem McDonald – National Library of Medicine – Member
Well, I would suggest that the system would support to entry of a standardized address. And a lot of systems now do go out and look at the Postal Service and come back with recommendations and forces it to be standardized. I don't know how well medical record systems do that. And I don't know whether we can impose that.

Terrence O'Malley – Massachusetts General Hospital – Member
Yeah. Sasha, is your concern mainly around the "require?"

Sasha TerMaat – Epic – Member
It's a clarity concern. I guess I would feel better voting on this if I understood who was expected to do each of the bullets on the recommendation.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
And just a note, we also have Steven in the queue.

Terrence O'Malley – Massachusetts General Hospital – Member
Steven, is your comment on this particular topic, or did you have a new one?

Steven Lane – Sutter Health – Member

Absolutely, yeah. I just wanted to point out that in general, our thinking for the USCDI Task Force has been that it's focusing on the data itself – which data, characteristics of the data fields, etc., as opposed to the workflows that are used to populate those fields or whose responsibility it is to populate them. But I think if we keep our focus on the data, agreeing that addresses should be standardized, that there should be current and previous, that we should explore international standards – I think those are all really good ideas. But I think when we get into whether or not a particular user is required to enter the data or what the workflow is, I think that's sort of going beyond what USCDI should focus on.

Christina Caraballo – Audacious Inquiry – Member
Yeah, and I think that's a really good point.

Clem McDonald – National Library of Medicine – Member
Okay. To get it off the dime, could we say in that first one, not use both, but provide fields for past addresses, as well as the current address? And in the second one, I think it's that the system would – I'm not sure what to do with that, after Steve's comment.

Christina Caraballo – Audacious Inquiry – Member
I think the first one, changing it to provide fields to support current and previous addresses works. And that was really the intent, so that's a good change in the wording.

Terrence O'Malley – Massachusetts General Hospital – Member
And then the next one may be that the address fields are in a standardized format.

Sasha TerMaat – Epic – Member
I don't know what that means.

Clem McDonald – National Library of Medicine – Member
Yeah, I agree.

Robert Wah – Individual – Chair
Okay, so we're off to a flying start on recommendation one.

Clem McDonald – National Library of Medicine – Member
Well, the third one, I think we could turn it into – we could have a field specifying the special categories of homelessness as having a field.

Robert Wah – Individual – Chair
This is a question for the chairs of the task force, both Terry and Christina. Perhaps it is necessary to take this recommendation back to your committee and finish it.

Terrence O'Malley – Massachusetts General Hospital – Member
Sounds fine.

Robert Wah – Individual – Chair
With this input. I just want to move on to the next . . .

Terrence O'Malley – Massachusetts General Hospital – Member
Yup.

Robert Wah – Individual – Chair
And while I thought we could do these as a group, that may not be possible. But let's go on to recommendation two and see how we're doing. Well, let me ask, are there any other comments or questions about recommendation one? I don't want to skip over without **[inaudible] [03:28:02]**. All right, seeing none, let's go to recommendation two.

Christina Caraballo – Audacious Inquiry – Member
Okay. Recommendation two was including phone number, which we supported. We recommended the use of the mobile phone number as primary and the landline as secondary. We also recommended that when entering a phone number in a child's record, to make a clear distinction between whether the number is that of a parent or guardian, or whether it belongs exclusively to the child.

Clem McDonald – National Library of Medicine – Member
Sorry, I don't mean to be picky, but why is it important to say which one's primary if you have separate fields for each of them?

Christina Caraballo – Audacious Inquiry – Member
Because we found that the mobile number seems to rise above the landline as better for patient matching and identity verification, so we're just kind of highlighting that. I do think that you make a good point, Clem, though, because it's more about supporting the fields in the USCDI – maybe encouraging the mobile but making sure both are supported, as opposed to just default phone number.

Clem McDonald – National Library of Medicine – Member
Yeah. That's what I would do. And then the child rec, I think what we need is a field not when entering the number, because that's back to the operators. We need a field that distinguishes whether it's the number of the parent/guardian or the child, not when entering. We're putting that on the clerk, and they can't change the software.

Christina Caraballo – Audacious Inquiry – Member
Okay, so we can change the second to include a field to make the distinction.

Clem McDonald – National Library of Medicine – Member
I think that's the way – go on, yeah.

Christina Caraballo – Audacious Inquiry – Member
So, with those two changes, do we have any other changes on this? So basically, on the first one? Robert, was that you?

Robert Wah – Individual – Chair
Yeah. Well, Sasha typed in a thing on the comments, but I think she also had her hand up.

Sasha TerMaat – Epic – Member
Oh. I agree with the clarifications Clem suggested. But if we're making them now on the fly, I was gonna listen to Christina's edits to see if that resolved my question.

Robert Wah – Individual – Chair
Okay. Christina, I'm sorry, I interrupted you.

Christina Caraballo – Audacious Inquiry – Member
No, you're fine. For the first one, we were going to change it to say provide a field for both mobile phone number and a field for landline. And I think we wanted to encourage the use of mobile phone number, but I don't see how that can be a requirement of USCDI. It's only providing the two fields with the distinction if it's mobile or landline, for the purposes of the USCDI. And then, for the – go ahead, Clem.

Clem McDonald – National Library of Medicine – Member
I just said, I have not seen an input form recently that didn't have both, in lots and lots of places.

Christina Caraballo – Audacious Inquiry – Member
Great. Then it'll be easy. So, for recommendation two, we're going to make it a field to distinguish that it is the number of a parent or guardian and does not belong exclusively to the child.

Clem McDonald – National Library of Medicine – Member
Well, I think you've got multiple cases. You should keep them all, whether it's a parent/guardian, or that it belongs to the child exclusively. I wouldn't suggest –

Terrence O'Malley – Massachusetts General Hospital – Member
Yeah, that was the point.

Christina Caraballo – Audacious Inquiry – Member
Primary owner of phone number.

Clem McDonald – National Library of Medicine – Member
Well, I think the way it stands, it's pretty good. You just have a set of choice selection, a menu.

Denni McColm – Citizens Memorial Healthcare – Member
So, this is Denni. As just an implementation question, I guess. So, what's the process, since we don't have that field commonly now? Would there be some timeframe that the EHR vendor, we're supposed to put that field and make it available?

Clem McDonald – National Library of Medicine – Member
Yeah, yeah. That's a point for a lot of these things. Yeah.

Terrence O'Malley – Massachusetts General Hospital – Member
And that kind of gets to the issue of certification, and at what point do you need to be implementing USCDI V1.

Clem McDonald – National Library of Medicine – Member
Well, that's a big issue, because FHIR's already in there, and it's got specified fields. So, we need help from the ONC people about how one could encourage this. This is maybe for the next path generation or something instead of the one that's coming out that we're – one that's bound to the NPRM. Can someone from ONC help us?

Steve Posnack – ONC – Executive Director, Office of Technology
This is Steve, your phone a friend, Clem. That's only a generational reference now, I suppose. So, there are really two pieces which I think the committee is discussing. One is the phone number as a data element in general, and then the type of phone number. And to some of the earlier conversation that Sasha and others brought up, we can – and I'm gonna say this from a hypothetical standpoint. We could include specific types of phone numbers in the USCDI. And then if the data is available, presuming that it's recorded in those fields, then the obligations on those software developers who'd be able to transmit that information in accordance with whatever content standard that data needs – in which it needs to go. Pushing that upstream is not necessarily something that we have the compulsory ability to impose on the healthcare provider community.

Clem McDonald – National Library of Medicine – Member
Well, so the question is, if we define new fields, does that stop the current proposal for FHIR? Or if not, how do we encourage that – when would that happen, or would it happen?

Steve Posnack – ONC – Executive Director, Office of Technology
Well, I mean, I think for new fields, it would be something that this task force is gonna take on related to the kind of expansion model that we've talked about for the USCDI over time. And if there was something unique for this particular rule-making, I'm sure in addition to what we may get out of the HITAC itself, we'll also get recommendations from other stakeholders about data they believe should be included in the USCDI that was not necessarily an explicit proposal. And we'll have to wade through those things, both in terms of the substantive nature of the proposals as we've made, as well as whether or not standards are available today to support them.

Clem McDonald – National Library of Medicine – Member
Okay. So, we should still do what we think is right, and then it'll happen the way it might happen with whatever can happen. Can I interpret it that way?

Steve Posnack – ONC – Executive Director, Office of Technology
Yeah. I mean, with the dual hat here of many different roles, I don't want to bias the committee's recommendations one way or the other to say that things do or don't work. A lot

of this is gonna get mixed in with the public comment as well, and then we'll have to evaluate all of the responses that we get in their kind of totality.

Clem McDonald – National Library of Medicine – Member
Okay. We shouldn't worry about those fine details, I will say. We'll just put in what we think is right and then see what happens.

Robert Wah – Individual – Chair
Okay. Other comments or questions about recommendation two as it's been modified? Christina, do you want to go to three?

Christina Caraballo – Audacious Inquiry – Member
Okay. We can move on to recommendation three. These were the additional patient demographic data elements. So, the first one was destinations for electronic communication. We identified a need to capture a field for electronic addresses to enable the exchange of electronic information. This could include a personal email address, director address, or other URL, such as a personal health record. The second is a preferred method or methods and destination of communication. This is basically a field to capture the patient's preferences for electronic communication. The third is the individual with authority to consent to treatment and use data, we recommend adding the identity of the individual with consent authority. I believe it's essential for care of minors and for individuals with guardians or activated healthcare proxies.

The next one is to include the last four digits of the Social Security number. And next is an optional identifier to include fields that capture state and federal IDs. These can include driver's license, state-issued IDs, passports, military service numbers. And we believe that this really support our use cases of patient matching and identity verification, again, as additional optional fields that are supported. And the last is to include self-reported gender identity as well. So, I will stop there and open it up for discussion.

Robert Wah – Individual – Chair
Questions or comments about recommendation three?

Clem McDonald – National Library of Medicine – Member
The different bullets are –

Denise Webb – Individual – Member
Hi, this is Denise. I think this screen to raise hands has gone away. I don't see it anymore on my Adobe. But on the optional identifiers concerning IDs issued by state and federal governments, how would one know for those optional fields when a number's put in a field whether it's a driver's license, or whether it's a Medicare ID, or how is that distinguished?

Christina Caraballo – Audacious Inquiry – Member
Yeah. I think what we did was we recommended fields supporting those additional IDs. And again, it's for when data is available, it is collected. And when the patient wants to give that

information, then it can be collected. And it was a way to help improve patient matching and identity verification. But we did believe that it was just important to start capturing this as we can.

Denise Webb – Individual – Member
Oh, I agree. But what I'm asking is, when you enter a number in a field, how does somebody know what that number represents, whether it's a driver's license number, or a Medicare ID? Or does it not matter for matching purposes if that number appears somewhere?

Clem McDonald – National Library of Medicine – Member
What was implicit in this recommendation is that they would have that stuff somehow. We didn't try to write the program.

Christina Caraballo – Audacious Inquiry – Member
Yeah.

Denise Webb – Individual – Member
Okay.

Christina Caraballo – Audacious Inquiry – Member
They would be labeled.

Robert Wah – Individual – Chair
Other comments or questions about recommendation three?

Clem McDonald – National Library of Medicine – Member
Well, I think it might be helpful to add to – let's see, the last fourth and fifth bullets that this is to assist matching, just to make it clear to readers. And then the other ones have their own purposes, but.

Christina Caraballo – Audacious Inquiry – Member
Yup. And in the transmittal letter, we did put the use cases that each support. And if you recall, the first slide on this was the put the use cases that we believe, which are the patient matching, identity verification, and clinical care. So, that has been addressed.

Clem McDonald – National Library of Medicine – Member
The second bullet was intended for a way to deliver the patient's medical record data to wherever they want it, because that's one of the key issues in the 21st Century CURES Act. And I don't think it quite comes across the way it says.

Sasha TerMaat – Epic – Member
And to Clem's point – this is Sasha – I saw there were different types of addresses that were envisioned for A and B. Some email addresses, some that might be direct addresses, and then it also mentions a URL. From a technical perspective, you wouldn't want to comingle some of those things. So, I just want to make sure that the recommendation permits flexibility so that

those can be stored in a way that makes sense so that they can be used then for whatever communication mechanism would be pertinent.

Terrence O'Malley – Massachusetts General Hospital – Member
Yeah. And Sasha, this is Terry. Your points are well taken. I think that we may be getting a little bit more detailed than we need, to go back to Steven's comment about focusing on the data elements themselves, and how they are actually displayed and being completed is sort of a separate – important but separate issue. So, it's really whether these data elements are reasonable and useful.

Sasha TerMaat – Epic – Member
I think that would be – if that's the overriding principle, in that the task force is focused on the data elements and not on the design of how they're implemented, an overarching clarification of that would be helpful to take all of the recommendations in that context and ensure it's not later misunderstood.

Clem McDonald – National Library of Medicine – Member
I agree. And I don't think it would be bad to say, such as a URL and a direct and – because this can tell me I want to use the telephone or texting. That's all I'm gonna get out of this one.

Terrence O'Malley – Massachusetts General Hospital – Member
Yeah. We can certainly add the new overarching principle if it'll help clarify this.

Steven Lane – Sutter Health – Member
Can I jump in with a comment? This is Steven Lane. Someone made a comment a little earlier about whether these recommendations apply to this generation or half a generation forward. My understanding is that the specific charge to this iteration of the USCDI task force was to provide feedback on USCDI version 1 as specified in the NCRM, that the task force considered a number of ideas that we felt were really more appropriate to hold for USCDI version two. But everything that we're bringing forward today, and please feel free to correct me if you feel differently, Christina or Terry, is really recommendations for version one as referenced in the NPRM. I just want to make that clear.

Christina Caraballo – Audacious Inquiry – Member
Thanks, Steven. Yes, these are all recommendations for version one unless noted.

Robert Wah – Individual – Chair
Other comments about recommendation three?

Denni McColm – Citizens Memorial Healthcare – Member
So, this is Denni. So, that's back to my question, meaning what, that as a provider, I'm now required to provide all these fields which I don't currently have in my EHR system? At what point, I guess?

Clem McDonald – National Library of Medicine – Member

Yeah. It'll take six months or so to get them into FHIR, and maybe longer.

Steven Lane – Sutter Health – Member
My recollection is that the NPRM has a two-year time horizon for implementation of these changes, but we can go back and check that.

Clem McDonald – National Library of Medicine – Member
Yeah, but I assumed that that meant from the time things were fixed or settled. I don't know.

Steven Lane – Sutter Health – Member
Right. I think what we're saying is whatever is specified in the final rule, that will specify the timeline for any and all changes in USCDI version one.

Robert Wah – Individual – Chair
So, hearing no additional comments on recommendation three, Christina, why don't we see if we can move on to the next group?

Christina Caraballo – Audacious Inquiry – Member
Okay.

Robert Wah – Individual – Chair
I think this group, you've had a lot of input on, and I think you have some clarity about how the committee would like to proceed with the recommendation. Is that right?

Christina Caraballo – Audacious Inquiry – Member
That sounds good. So, I guess we're not ready for a vote on patient demographics. But we can go ahead and move to provenance?

Robert Wah – Individual – Chair
I mean, what I heard was there's gonna be an overarching comment about how these are being put forward, and then there are some specific comments within each of the three recommendations.

Christina Caraballo – Audacious Inquiry – Member
Yes. So, can we go ahead and move to the next slide?

Robert Wah – Individual – Chair
Yup.

Terrence O'Malley – Massachusetts General Hospital – Member
So, that was easy. So, now we get to provenance. So, again, just thinking about provenance and the use cases that it supports, obviously trusting the data source. And then some really important processes that are difficult currently – de-duplication and data element versioning. So, we kept those in mind as we thought about what it is provenance should entail. So, next slide, please.

So, ONC proposed the following three items. First, organization author and author's time stamp. And what the task force recommended was changing "author" to "author's organization," with the realization that it's been extremely difficult to unambiguously and consistently identify who a particular author might be. So, as an example, if you had a lab test, is the author the equipment, the tech, the lab director? How would we label that? And how would you label that consistently across all entities that produce lab results? And I think that was one of Sasha's comments last time. And so, the feeling was that using author's organization was simpler and less ambiguous than trying to identify a particular author. So, that's the rationale behind that.

But the second piece, if we're gonna use author's organization, is we really need a nomenclature that uniquely identifies that organization. It's got to be something that can live with the organization, so whether that's, as we noted before, whether that's an NPI number or something else – NPI is useful for some organizations but not for others. But the importance for identifying the author's organization really requires some sort of unique identity. And that same thing applies when you think about a patient as an organization and author. So, they're one and the same thing. But in that same construct, you need a unique patient identity as well for patient-generated data. So, that was our first recommendation, was change "author" to the less granular but more easily defined "author's organization." Next slide, please.

All right. And so, the using author – there are some important uses for "author," but the use should be restricted, and restricted to situations where the author is unambiguously established. So, for example, you know who wrote the progress note or wrote the prescription, or the patient who provided the data. So, in those situation, using "author" is really helpful, and it does add to provenance. And it's easy. But this should only be used, I think – we proposed that "author" only gets used for those situations where it's really unambiguous. And otherwise, "author's organization" is the primary level of identity. And later versions of USCDI, if there's a need for it, can look for ways to define "author" more clearly, more granularity to "author," and assign permitted authors to different data types. But that's work later on. So, that's recommendation five.

And related to that, since we want to – or since we don't want "author" anymore, we really want "author's organization timestamp." And what that means – what we took that to mean is that the time at which a particular data element is available within the source system, within the source organization's system for use by someone other than the other. So, it's really sort of the release time of the data element. And those are our – let's see, next, we have several –

Robert Wah – Individual – Chair
Those are the three for provenance?

Terrence O'Malley – Massachusetts General Hospital – Member
Yeah. So, we have six. And we have a seventh recommendation under provenance. Next slide, please. So, this is actually one of our bigger recommendations, and it was the need to create an identity, a unique persistent identity for each data element. And we thought that there were really four components to this initially, and perhaps with provenance, if it's more

sophisticated, others will be added. But it's really the source organization, with its unique identifier; the author's organization timestamp; that each organization also creates currently in their own system a unique local identification code; and finally, the data type. And these four elements, we thought, would allow you to uniquely identify each data element.

And then the important part is what happens with this data element as it's exchanged. And the exchange, there has to be a governance structure that says when you exchange data, if you leave the original provenance associated with the data element intact and unchanged, then you're attesting that the data element is unchanged. If, however, you change the data element and add a new identity based on some modification at a different time by another agent, then you're attesting that you have altered the data on it.

Clem McDonald – National Library of Medicine – Member
I think we're outside of our expertise on it, and I don't think we should do it, although I was involved and made some of these proposals. The unique identifier is in the resource record, not in the provenance. It's there already. But there are lots of problems with picking the right one, and I think it needs much more discussion. So, if you get a result that comes from a laboratory, LabCorp, and they don't have a patient ID, they just have an accession number, they send it to the hospital that connects it to the patient. Which is the original result? It's not approved by the hospital until it gets there and they look at it. I think this is beyond what we can do. It'll happen, but I don't think we've got the horsepower to do it in this committee. There is a unique identifier in the resource record. The provenance record is a separate critter that is packaged with it that kind of piggybacks with it.

Terrence O'Malley – Massachusetts General Hospital – Member
Yeah. And we're proposing to use the elements of provenance, which have been proposed in USCDI, with two other currently existing data elements, the data type and the source code with the identity of the organization, which we are able –

Steven Lane – Sutter Health – Member
I think we may be confusing two things here. One is, again, USCDI is about the data elements. It's independent of the standard that is being used to transport that. So, I think, Clem, some of your comments have to do with the structure of FHIR resources, which is awesome. It's awesome that they've got this unique identifier in one place versus another place. But USCDI is agnostic to that. It applies to CCDA, to V2, to FHIR. The point here is that we want that unique identifier that's generated by the source system to travel with the data.

Clem McDonald – National Library of Medicine – Member
I get it, but I don't think it belongs in provenance. It isn't specific to FHIR, but it isn't part of provenance in the discussions that I've gotten into after we had the discussion. You're gonna end up with things doubly defined, and it's gonna be a quagmire for the developers if we don't get it straight.

Steven Lane – Sutter Health – Member
Well, again, as someone from an organization that's trying to do this exchange today using CCDA because FHIR isn't there yet. This thing is missing. This component of provenance data

that would allow us to de-duplicate and to version doesn't come consistently So, I don't know – in our other task force, the ISPTF task force, this was also proposed as a key element of provenance data. So, I don't know if we need to call it something different, but it's critical data that needs to move with the record.

Clem McDonald – National Library of Medicine – Member
I think it would be good to insist on a unique identifier, but don't say where it goes.

Terrence O'Malley – Massachusetts General Hospital – Member
Well, okay. It can go wherever it wants, as long as it's associated with the data. Anyway, those are the seven recommendations – well, the four recommendations.

Robert Wah – Individual – Chair
Those are four for provenance, right?

Terrence O'Malley – Massachusetts General Hospital – Member
Right.

Robert Wah – Individual – Chair
Again, this is a good discussion, and as I said before, I value a good open discussion about the topics. That's our goal here, is to provide our opinions and perspectives and expertise on these recommendations that we're planning to forward to the ONC on the proposed rule. So, with that as our primary goal, I think we are accomplishing that in this discussion. We are running out of time for it right now. Terry, I guess for you and Christina, it looks like both the first two groupings have had enough input that may require some rediscussion at your task force and reconsideration of them? Is that –

Terrence O'Malley – Massachusetts General Hospital – Member
Agreed. Yup.

Robert Wah – Individual – Chair
– fair to say?

Terrence O'Malley – Massachusetts General Hospital – Member
Yup. Not a problem.

Robert Wah – Individual – Chair
But I want to make sure people have had an opportunity to provide that input, both now and in the future, by email or however you wish to do it. But I think for the purposes of keeping somewhat to the schedule – and I'm not one to be always a slave to the schedule. Like I said, m primary goal is to make sure we have an open and good discussion and get to the best outcome on this – why don't we stop at this point? You can take the input you've heard on these first two sections, and then what our plan is, is to move to the next topic. And if we end up with time at the end of this meeting, we're gonna bring back those things that we haven't been able to accomplish. And then if we can't get it done in that time, we have another

meeting scheduled on the 13th of May where we can catch some of this up as well. And we'll be thinking about whether or not we need to actually have either an extension of that meeting or an additional meeting. And we'll be bringing you more information about that as we get it. But I think just – I would prefer to move on to the next topic at this point and allow your task force to take this input on these first two sections.

Terrence O'Malley – Massachusetts General Hospital – Member
So moved.

Christina Caraballo – Audacious Inquiry – Member
Sounds great.

Robert Wah – Individual – Chair
Okay. Thank you very much for your time. And at this point, our next topic is to look at the Care Continuum Task Force. And for that, I'm gonna turn it over to Carolyn, and I don't know if Chris is on the phone or not.

Carolyn Petersen – Individual – Chair
Thanks, Robert. Yes, this is Carolyn. I will be presenting the whole presentation myself today. Dr. Lehmann had a prior commitment and was not able to attend. So, with that, if we could have the next slide, please.

This presentation will be an update of the activities of the Care Continuum Task Force so far. We are not asking anyone to vote on anything today. We wanted to let you know kind of where we landed with the pediatric recommendations and also some additional considerations, those being the opioid use disorder, request for information, the data segmentation for privacy, and consent management for API certification criteria; and also to kind of let you know the discussions we've been having about the feedback you gave us at the April 10th meeting a couple of weeks ago. If we could have the next slide, please.

So, this is our membership, myself and Aaron Miri from HITAC. We have three physicians on the team – Dr. Lehmann, Dr. Steve Waldren, and Susan Kressly. And we also have a member from the developer community, although Dr. Kressly is working in that area as well. We had hoped we could have a physician member of the task force to be on call today to answer any questions that are best answered by users of pediatric software and pediatric considerations in EHRs. We were not able to make that happen. So, Aaron and I will be taking any questions and feedback back to the task force meeting tomorrow morning at 9:00 Eastern, and also next Friday, and any other meetings that we need to have prior to bringing forward something that the task force here can look at and vote on. And we do encourage you to come to our meetings if you are interested in hearing our discussions and providing comment through the public feedback mechanism. Could we have the next slide, please?

So, again, real quick, here is our overarching charge. We're looking at recommendations on ONC's approach, recommendations and the identified 2015 edition certification criteria to support pediatric care and practice settings, some related criteria to support multiple care and practice settings, and requests for information on how health IT can support the treatment

and prevention of opioid use disorder. Specifically, we're looking to provide recommendations on the 10 ONC pediatric recommendations to support voluntary certification of health IT for pediatric care, the identified 2015 edition certification criteria for supporting the certification of health IT for pediatric care in practice settings, the 10 pediatric technical worksheets that we've previously mentioned and shown you at the March 20th and April 10th HITAC meetings, the 2015 edition DS4P and consent management for APIs certification criteria, and generally how health IT can support the treatment and prevention of opioid use disorder in alignment with the HH strategy around these issues. Next slide, please.

So, we wanted to do some clarifications and summary of the ONC pediatric recommendations. We recommend that HITAC recommends to retain the 10 ONC pediatric health IT recommendations for voluntary certification and to affirm the proposed rule, identified existing and proposed certification criteria as relevant for the voluntary certification of health IT for pediatric care. This task force also provides recommendations for the development of nonregulatory informational resources that can provide additional tech support for pediatric health IT implementation that are focused on those 10 ONC pediatric health IT recommendations, and that this resource may be informed by implementation considerations as identified by our task force. Next slide, please.

At our last meeting a couple of weeks ago, it became clear that it was not really clear to HITAC members exactly how we were approaching these criteria that ONC has charged us with reviewing. And so, we've come up with a crosswalk approach for these 10 recommendations that we hope will help clarify for HITAC exactly what we're asking and what we're proposing, and what we're asking you to vote on. So, on this one, I'll go through it in more detail, and then we can hit the relevant points on the following recommendation. So, for recommendation one, that was, use biometric-specific norms for growth curves and support growth charts for children. There was also a supplemental children's format requirement for this recommendation that would be to allow unknown patient sex, record gestational age assessment and persist in the EHR, and support growth charts for children. The second column here shows how this aligns with the 2015 edition certification criteria. And the third column shows how that aligns with the proposed new or updated certification criteria. In the fourth column, we have our task force draft recommendations and some implementation considerations to inform future potential nonregulatory informational resources.

So, our recommendation as a task force that we bring forward to you is that all functional criteria under the alignment with 2015 edition certification criteria and the alignment with proposed new or updated certification should be retained as listed. We're not asking that anything be dropped. Additional implementation considerations would be that we should include a visual display to serve as an alert, and the displayed value must be able to reference correct datasets, limiting to data that are in the public domain and evidence-based. A recommendation for supplemental requirements would be to retain all supplemental requirements as is for recommendation number one. If we could go to the next slide, please.

So, this brings us to recommendation two, and that was to compute weight-based drug dosage. This one also has a supplemental children's format requirement. And that would be rounding for administrable doses and an alert based on age-specific norms. And moving to the far column, the task force's recommendation is that all functional criteria under the alignment

with the 2015 edition and with the proposed new or updated certification should be retained as listed. Some additional implementation considerations are that it should be limited to liquid medication. It should be displayed in milliliters. Calculators should not be able to round more than what is humanly measurable. And prescription final dose should be transmitted with metadata – that's additional information in text on how that dose was derived. And also, to include original weight for calculation.

The recommendation related to that supplemental requirement would be that we retain the rounding for administrable doses and remove alerts based on age-specific norms. These pertain to medication dosing only, due to the lack of availability of age-specific dose ranges for pediatric medication in the public domain. Could we have the next slide, please?

So, let's come to recommendation three. That's the ability to document all guardians and caregiver. And with this one also, there's the supplemental children's format requirements. That would be the ability to document parental or guardian notification or permission, the ability to record parental notification of newborn screening diagnosis; authorize nonclinician viewers of the EHR data, and to document decision-making authority of the patient representative. Moving to the far column, our recommendation as a task force to you is that all functional criteria under the alignment and the alignment with proposed new should be retained as listed.

We have some additional implementation considerations. That would be that the guardian and caregiver information should be documented in a structured way, including their role. We encourage nomenclature development in the future to reference to. We should have the infinite ability to add lists for all relevant contacts of the family, rather than a limited fixed number, recognizing that sometimes families are blended or include people who are not biologically related, but function as important caregivers. And finally, the ability to manage a list of active and historical participants, including remove, archive, or start or end dates, that provides more flexibility to accommodate very flexible and changing caregiver and guardian requirements.

Finally, we have a recommendation around the supplemental requirement. That would be to retain all supplemental requirements for recommendations three, with additional implementation considerations that the authorized nonclinician viewers for the EHR data should not be provided as free text. It needs to be something that is usable and manageable. The next slide, please.

Recommendation four. This is a segmented access to information, and the supplemental requirements that goes with that, the problem-specific age of consent. And moving to the far right column, our recommendation as a task force is that all functional criteria under the alignment with 2015 edition and the proposed new should be retained as listed. Some additional implementation considerations include that we're going to prevent what information gets sent out relevant to dependents on family-based insurance. Okay, that would be things like billing information. We wanted to allow the EHR to grant user access level to tag and to provide protection when the user adds data. We want to prevent tagged data from showing in CDA's portal or exist note given to another provider.

A future work consideration would be improvement in the transmission and sharing of data, and the level of granularity involved with tagging. That's not something we want to request a vote on today, but we think that that may be something to look at in the future. And also, a recommendation for the supplemental requirement. That would be to remove problem-specific age of consent requirements due to challenges of varying state and local laws. Could we have the next slide, please?

I'm sorry, I'm still seeing the same slide. Was that slide advanced? Okay, number five. This is to synchronize immunization history with registries. And here, that would include the supplemental children's format requirement to produce completed forms from EHR data. In our far column, what the task force is recommending is that all functional criteria under the alignment with 2015 edition and the proposed new certification should be retained as listed. Some additional implementation considerations: Any future work into consolidating state immunization forecasting models into a single resource. We need to reduce the amount of time needed to update forecasting. We need to look into onboarding practices for immunization forecasting. And clinicians should be able to verify source origin. And the recommendation along with the supplemental requirement is to retain them as recommendation five. Next slide, please.

So, for recommendation six, this is the age and weight-specific single dose range checking. The task force's recommendation is that all the functional criteria with the 2015 edition and the proposed new should be retained as listed. Some additional considerations would be to look at similar limitations on dose calculation that we see in recommendation two. That's the weight-based drug dosage. Existing sources for dose range recommendations should be integrated into workflow. Allow user access to best practices or standards. That would be demonstrating correct information source and element of shown work for the clinician to verify, the ability to test EHR accuracy, and to include in the QA and QI testing process. Next slide, please.

Recommendation seven. This is transferrable access authority. And for the supplemental, this includes the age of emancipation. So, moving to our far right column, the task force's recommendation is that all the functional criteria in the 2015 edition and proposed new should be retained as listed. The additional considerations here are more control to be – for example, we want to be able to mark individuals with specific privileges until standard nomenclature can be developed. We note that it's important to distinguish access versus legal decision authority. We recommend an ad hoc limited standard or best practice paper to be developed in the meantime. We recognize the need for nomenclature to be developed based on state and local laws. And consideration around contradictory access. At the moment, this is broad and vague. The EHR should be able to document this via a text field. And then with regard to the supplemental requirement, the task force is recommending that HITAC retain that as is. Next slide, please.

So, recommendation eight. That was to associate maternal health information and demographics with the newborn. Coming over to the far column for the task force's recommendation, task force recommends that all the 2015 and proposed new criteria are retained as listed. The additional considerations include information should be available in a format that can be exported and easily digested by a pediatric EHR that would further

integrate records between maternal and child. For example, a capability exists, but mainly as text info now, to include some family health history. And also, that further research is needed on existing transmission of this type of data. Next slide, please.

Recommendation nine is that we track and complete preventative care opportunities. Coming to the far right column, the task force's recommendation is that all the criteria around the 2015 edition and the proposed new are retained as listed. The additional considerations here, that we need to generate lists for recall purposes, and we need to be able to flag patients to create an alert for when a patient falls outside the expected values. And next slide.

Finally, coming to recommendation number 10, to flag special healthcare needs. The recommendation of the task force is that all the functional criteria from the 2015 edition and the proposed new are retained as listed, with the following additional considerations: the ability to determine generic flags; the ability to transmit in a coded way from system to system; the ability to track mental health for children; and the option to incorporate into SNOMED or ICD.

So, those are the 10 recommendations and our recommendations to the HITAC about what to do with these. If we could have the next slide, please. So, now we'll move to the request for information on health IT and opioid use disorder prevention and treatment. In this part of the work we're doing, ONC had requested information. However, we have been asked to provide that in the form of recommendations.

Robert Wah – Individual – Chair
Carolyn?

Carolyn Petersen – Individual – Chair
Yes.

Robert Wah – Individual – Chair
Sorry to interrupt. I was on mute. There were a number of comments typed into the public comment area by our committee members on your pediatric recommendations. Maybe we can just go back real quick and capture those. I think they're made by Sasha and Steven, if they want to articulate those.

Sasha TerMaat – Epic – Member
Sure. This is Sasha. I can start. I had three questions. I guess first of all, Carolyn, did I hear you correctly that the additional implementation considerations are not currently proposed as part of the certification criteria, but are just guidance for the future?

Carolyn Petersen – Individual – Chair
They are things that have come out of our discussion. If you look back in the slides, they are framed as considerations. The recommendations that we are asked to go back and **[inaudible] [04:20:52]** the documentation from ONC, there were four questions. Part of that requests that the task force say, yes, we should retain the original 10 recommendations, or no, we should not, and then to bring out, highlight some other considerations for implementation. What are

the issues?

Aaron Miri – The University of Texas at Austin – Member
Yeah. And Sasha, this is Aaron. To give you a little more context, like the one about the liquid medication versus pills and whatnot, obviously divide or subdivide a pill because of weight-based or pediatrics, there was a bunch of discussion about examples of such. So, it was start with liquids because that's easier to get it right, and then work towards the other versus trying to boil the ocean. It was that sort of thing. So, yes, they were observations based on what it would take in the real world to get some of this done.

Sasha TerMaat – Epic – Member
That's helpful, thanks. And I think if the intent is just to capture some of the themes of the discussion of the task force, I think that makes sense. If there was a certification obligation associated with those themes, I had the same, I guess, question that I had back with the previous task force, which is that there seem to be different expectations associated with different bullets. Some of them are sort of directives to ONC or the standards community about work that ought to happen. Some of them seem to be implications about things that should be considered during software design. And I think if we were using them as more than just the notes of the discussion, it would be important to clarify who the intended actors were for each of those.

Aaron Miri – The University of Texas at Austin – Member
That's a great point.

Carolyn Petersen – Individual – Chair
Yup, and I'm taking notes.

Sasha TerMaat – Epic – Member
Then I had two more specific questions. The task force said that it should not be tasked, the format for authorized nonclinician viewers of the EHR. But I wasn't clear what format was anticipated. It would be names of people, right?

Carolyn Petersen – Individual – Chair
Which recommendation does this relate to?

Sasha TerMaat – Epic – Member
I didn't write that down at the time. It was the one that included authorized nonclinician viewers of EHR data, which is . . . I'm scrolling. Three.

Carolyn Petersen – Individual – Chair
Okay, I'm pulling up my notes from the discussions too.

Sasha TerMaat – Epic – Member
Okay.

Carolyn Petersen – Individual – Chair
The concern was that the information needs to be documented in a structured way, and at some point in the future, there would be a nomenclature for this. I'm looking to find additional feedback. I'm not seeing –

Sasha TerMaat – Epic – Member
So, the idea would be that if a patient said, I want to authorize a parent, that then the parental relationship would be standardized nomenclature, or just that there would be some way to recognize that when the name Bob Smith is entered, that that's somehow recognizable, or there would be an identifier for Bob Smith? I guess I was just trying to follow what the recommendation was.

Carolyn Petersen – Individual – Chair
Yup. And that's a great question, and I will take that back to the discussion with the task force tomorrow.

Sasha TerMaat – Epic – Member
Okay.

Carolyn Petersen – Individual – Chair
I'm sitting here with my discussion notes from all our meetings, and I don't see that called out. And I think I should probably not speak for physicians. But we will get an answer on that and bring it forward back to HITAC.

Sasha TerMaat – Epic – Member
And then on four, I had a question. What does it mean, allow EHR to grant user access level to tag?

Carolyn Petersen – Individual – Chair
With this particular recommendation, we were looking as well at some of the data segmentation for privacy, the DS4P standard. DSFP standard is a tagging mechanism and a protocol that allows metadata tagging within the system. A FHIR-based solution is also in the rule. One of the physicians felt that it's important that EHRs allow user-level to tag individual items, like problems, notes, medications that the user can protect in some way. At the same time, another individual noted that it's a good suggestion, but it's important to try to avoid solving this issue in a way that could become an implementation or a workflow challenge. I think that gets at your point.

There was some discussion around the standard nomenclature to notify that this kind of information may be missing. So, for example, if something's been tagged and a receiving entity of the health data couldn't see it, there would at least be some note that something was not there. Of course, that brings up the point that if it's known that something is missing, that could be a breach of privacy. So, it is certainly a discussion that was quite full and involved a lot of different perspectives as we tried to work out how to address that. And that's why it's brought forward as something to consider, but not something that we've laid out in a recommendation that we asked HITAC to vote on or adopt, because it still is something to

think about and not resolved.

Sasha TerMaat – Epic – Member
Thanks for the clarification. I think that it might be helpful if there's more helpful from the task force's conversation for consideration to flesh that bullet point out a bit more, because I wasn't sure exactly what type of EHR functionality was intended by that bullet point, and other developers might benefit from more context in their understanding of it as well.

Aaron Miri – The University of Texas at Austin – Member
Yeah, and I think that's a good point, Sasha. This is Aaron. We could call out some of the privacy-specific concerns and items that needs to be worked through, as well as – I recall this conversation pretty vividly now. It was about also the patchwork of privacy laws as it varies by state and the difficulty it would take to implement some of those, particularly with pediatric considerations, and how would we get to a baseline that if that was acceptable across the whole country. So, I remember this conversation. You're right; we should give some of those callouts. You're right.

Clem McDonald – National Library of Medicine – Member
This is Clem. Can I comment on some of this at this time?

Aaron Miri – The University of Texas at Austin – Member
Please, sir.

Clem McDonald – National Library of Medicine – Member
Well, first, I think some of these things apply to adults as well about this tagging and the big problem with hidden information. I mean, that's a big deal. It's not gonna be handled by a standard. I mean, if you can't know the certain results, you're gonna kill them by mistake. So, it's really bad that they can hide – and that's the implication, they can hide data from the provider?

Steven Lane – Sutter Health – Member
Can I chime in here? This is Steven. I've got my hand up.

Clem McDonald – National Library of Medicine – Member
Yeah, please.

Steven Lane – Sutter Health – Member
Yeah. I think these are really interesting implementation considerations that have been raised, and I agree with you, Clem, they don't apply only to pediatrics. But I think it's important that we not overstep, either as we explore this brave new world – the way that the implementation considerations are phrased in recommendations four, it says prevent what information gets sent out or prevent tagged data from showing. I think that the system should provide the ability to prevent that, but that it's really a judgment call based on clinical and privacy and workflow considerations as to what data should be sent or not sent. I think asking developers to develop tools that would support that is a good idea. But I don't think at this point in the game, we should be specifying what is or isn't sent in what settings.

The other question that I had, kind of tagging on to Sasha's, about recommendation four, is I didn't fully understand what was meant by provide protection when user adds data. I don't know what protection you're providing. Is it to the user, or to the data? I didn't know what that meant.

Carolyn Petersen – Individual – Chair
Yup, and I am looking at the notes from that discussion right now to see if I can . . . So, there was a comment that the task force should not get stuck in the perfect end goal. The right answer is to start to lead EHRs to protect granular elements. For example, don't hide the problem list; hide the problem. Don't hide the medication list; hide the appropriate medication. And this led us to our discussion about whether the data segmentation has the standard nomenclature that helps let people know that something has been withheld. At this point, we also dug into a discussion about legal issues, and the fact that you have all these different regulations in different states. For example, in the state of New York, the diagnosis has to be on the bill.

There's a need to understand the lack of legal standards, sometimes for different things, beyond just the fact that there are differences among states. We have to be careful about putting a burden on clinicians in making them the gatekeepers of a lot of this knowledge, and a lot of the understanding and decision-making that result from this highly patchworked field. It's going to be a struggle without some of these legal standards and a clinical understanding of what's appropriate. Is that helpful, Steve?

Clem McDonald – National Library of Medicine – Member
So, just to clarify, people are suggesting that one might, in the practice setting, hide a given drug or hide a given diagnosis, or is this just for sending out to people who aren't providers or aren't taking care of the patient, that these things are there for?

Carolyn Petersen – Individual – Chair
It is really a very variable situation. And some of it has to do, I think, with the age of the individuals we're talking about. For example, if a child has spent early years in an unstable home situation, it may be that people around the child have observed atypical behavior, and the child was then given medications to treat mental health conditions that may be very difficult to diagnose in, say, a three or four-year-old. And there is some thought that as that child gets older, the child could carry diagnoses that might not be accurate, in fact. And this may be compounded by the fact that when the child has become placed in a different home environment, some of those behavioral issues are resolved. The child is older and can learn different coping skills and different ways of engaging.

Children are entities that are still in formation, and in formation for many years. And while there is a great concern about ensuring that they get the care they need, there is also a concern about not burdening them with labels or other kinds of labels that can influence the care they receive, and the way that they are treated and moved through the healthcare system and other systems in their community in the future. I know that that sounds really vague, but there's a real need to ensure that kids are not improperly labeled and thereby

tracked in ways that are not helpful for them or not correct for the rest of their life.

Steven Lane – Sutter Health – Member
I think another really important use case, Clem, is the whole area of adolescent confidentiality, and the fact that there's some data in the charts and medications and diagnoses, and even potentially some immunizations that the adolescent themselves can consent to treatment and then have the legal right to keep that data private from their parents/guardians. And then it gets tricky when data regarding that care gets shared between organizations, because the receiving organization might not have the same standards for protecting the adolescent confidential data, and it could sneak out to parents or guardians even in a way that would endanger the safety of the child or the adolescent. So, I think there's a lot of work to be done on this yet. So, I think it's good it's being called out, but it's certainly not fully fleshed out.

Carolyn Petersen – Individual – Chair
And that's why we put it into the category of implementation considerations and things to think about for the future, as opposed to specific recommendations that HITAC should adopt.

Aaron Miri – The University of Texas at Austin – Member
Yeah, and this is Aaron. And as I'm sure all of you are aware of, there are a lot of states and even at a national level thinking of how do we fix some of this data segmentation concern? Because it is impacting real-world clinical care, and I can even see Brett Oliver's comments in the box about this agreement, that data segmentation – I'm sure he can give us an example or two of where this has really impacted care. But as to the degree of where the laws state and where things are supposed to be done, particularly for covered entities, it puts folks in a precarious situation that do have to work this out. Brett, I don't know if you want to add any coloring, like with an example or two.

Brett Oliver – Baptist Health – Member
Well, I'm just concerned about where this stops. State laws not withstanding, where does this data segmentation stop? We're talking about pediatrics. I hope that I'm mature and wise enough as a provider to know that the patient may have been in a bad home situation "labeled" with something. That's still an important part of their past history to deliver the proper future care for a child. I mean, does an adult then get mislabeled? If I don't like a diagnosis that was given to me, then I can hide it somehow or segment it from future providers? I mean, there should be a way to correct a chart, and we have that. To start segmenting data further – I mean, the whole point – one of the whole points of this task force, and I mean, of our committee, is interoperability and exchange of information. And this seems counterintuitive to that.

Clem McDonald – National Library of Medicine – Member
Well, I agree 100%. And I don't know if it's really gonna be workable, because you still have free text all over the place. And it's not gonna be possible to screen it except by keeping free text all hidden. Now, the first round of segmentation was just, you could do all or none for a whole record and never used, never used. That's why they're going to this next stage.

Carolyn Petersen – Individual – Chair

Okay, thank you.

Clem McDonald – National Library of Medicine – Member
Yeah. I took care of drug abuse patients, and they would tell me what they wanted to tell me. And we didn't put some of it in the chart. We didn't write it down if they didn't want it said. Anyway, this is gonna be a – I think it's gonna be a mess. And we're gonna have doctors being sued or refusing to see patients who are gonna hide part of their data.

Robert Wah – Individual – Chair
Other comments on the pediatric recommendations? Carolyn, you want to wrap up with the opioid?

Carolyn Petersen – Individual – Chair
Okay. If we could go forward with the slides, please, back to the opioid section. Thank you. So, again, this is a request for information. And ONC has asked us to provide that in the form of recommendations. But we are not bringing specific recommendations forward to the group today, just sharing our discussion so we can get HITAC perspective on this.

So, the task force has identified and explored some promising tools – for example, CDS Hooks – and some practices of health IT for opioid use disorder prevention and treatment. And we're offering our collective input so HITAC may vote to affirm the value of health IT for opioid use disorder prevention and treatment, and to convey any information as discussed by our members to the national coordinator. So, again, we're being asked to affirm the value of health IT for opioid use. We're not being asked to provide solutions.

So, the task force has discussed some topics around how health IT can support the treatment and prevention of opioid use disorder that aligns with the human health and human strategy – the HHS strategy to address the opioid crisis. And so, we've got some feedback here for consideration. Task force supports that health IT can further clinical priorities, as well as public health goals, while offering more systematic coordinated approaches for UOD prevention and treatment. We believe that health IT can support a clinician's ability to access and use community resource information and to make referrals for individuals with or at risk of opioid use disorder. And we recommend that the medication history in the prescription drug monitoring programs should be available as a single point of entry for clinicians to access without the burden of having to log in and use multiple portals. If we could move to the next slide, please.

In terms of a general sense and value, existing and new criteria can support clinical priorities and advance interoperability for OUD. Specifically, the successful implementation of health IT can help support OUD and aid in achievement of national and programmatic goals, especially where they align with initiatives across the Department of Health and Human Services and with stakeholder and industry-led efforts. Our task force also discussed topics around health IT solutions and effective approaches to improve opioid prescription practices and clinical decision support for this condition. We looked at issues of burden, usability, and the trigger for CDS Hook from the clinician's perspective as that pertains to workflow, and acknowledging the value of CDS tools, including CDS Hooks for opioid use disorder use care.

And we recognized the importance of having underlying data available and in the USCDI. We feel that implementation should be made as simple as possible, ideally one click, to ease tracking and monitoring of the desired outcome. We should be functional at the point of care, particularly for rural areas, where Internet connections can be unreliable. We recommend the creation of a standardization order set to more effectively and quickly bring decision support to the treatment of the disorder. Next slide, please.

And then finally, with regard to health IT and neonatal abstinence syndrome, the task force supports the idea of health IT policies, functionalities, and standards to support providers engaged in the treatment and the prevention of OUD. Specifically for the NAS use case, the task force is recommending that we explore roader ways to begin standardizing definitions with order sets. The order sets need to be computable and to identify specific language for EHR to be able to implement more accurately. And we recommend that when such data sets are created, these data sets not be used for punitive measures in ways that discourage patients from seeking care when they need it. For example, creating the potential for the loss of children from the home or prosecution by law enforcement, or other things that can incentivize people to avoid getting the car that they need and the care that we want to ensure that they all have.

So, I think that's the last slide we have on this part of the discussion. Are there any comments from HITAC members? Robert, if you can call any raised hands, that would be helpful.

Robert Wah – Individual – Chair
I don't see any at the current time. Other comments about the opioid use disorder part of this discussion?

Clem McDonald – National Library of Medicine – Member
Well, that can be one of the primary things hidden in the record.

Robert Wah – Individual – Chair
Yeah. Per our other discussion, yup. Other comments or questions for Carolyn? Carolyn, does that wrap up your presentation, I think?

Carolyn Petersen – Individual – Chair
We have one slide left, the data segmentation aspect of our task.

Robert Wah – Individual – Chair
Oh, that's right. Sorry.

Carolyn Petersen – Individual – Chair
Yup. But we're almost there. And if we could have the next slide, please. So, part of our charge was also to look at this data segmentation for privacy and consent management for APIs certification criteria. You may have encountered this in other parts of the NPRM in shorthand as the DS4P. So, ONC proposes to remove the current 2015 edition DS4P send and receive

certification criteria and replace them with three new criteria, two that relate to the CDA and one for FHIR. Based on the discussion that we've had so far, the task force supports this proposal, and it acknowledges that the DS4P would help for opioid management and provide greater confidence in sharing information that's related to opioid use disorder. We also recognize that the consent management for APIs proposal would aid in furthering the exchange of information.

So, we recommend that users should have the ability to tag at the user level; acknowledgement of the need for the development of a minimum dataset description to represent stakeholder consensus on what data is considered private; and see that further work is needed to develop patient privacy best practices for universal adoption. This last point gets to some of the discussion we've had this afternoon about differences and differing needs. For example, the patient's perception of privacy, that is important for him or her to move on with his or her life, versus the clinician's concern about having all the information and being able to understand all the things going on in the patient's life. We do recognize that there's a lot there to unpack, and we fully support and recommend that HITAC supports this push for best practices around privacy. So, I'm happy to take any questions about this part of the work we're doing now.

Robert Wah – Individual – Chair
Right. Sasha?

Sasha TerMaat – Epic – Member
Thanks. One thing that I noted in reading the Trusted Exchange Framework draft two, which of course, Zoe told us about earlier today, was that there was a specific data segmentation for privacy proposal in there that would be interesting for the task force to consider in this light also. That proposal identified certain use cases for privacy, which could include, for example, opioid and substance use privacy restrictions, and suggested implementing maybe more narrowly or along certain identified prioritized use cases. Given sort of the questions that are raised about governance and how this would be implemented, I think that focusing on a specific use case, for example, opioids, would make sense for DS4P implementation, and I think it would be worth the task force considering that now that we have the TEFCA draft to see that proposal.

Carolyn Petersen – Individual – Chair
Great. Thank you. That's a great point. And if I may ask our ONC partners to send, this afternoon or this evening, to the Care Continuum Task Force, that part of the TEFCA two part that relates specifically to data segmentation? I don't know that we can get to it tomorrow in our discussion, but certainly, Chris and I can present that to the task force and alert them as something they should take a look at so that we can, perhaps next week, discuss that and see if we have any at least initial thoughts around how to frame our recommendations for this piece related to the NPRM. Thanks, Sasha.

Clem McDonald – National Library of Medicine – Member
So, I think I support – this is Clem – sort of a narrower look at it. And there's three or four things that nobody's talking about. One of them, someone has to mark these things as being

protected in various ways. And in the full blossom of the DSP4, it allows patients to take every result at every date and specify who can see it, when, and where. I don't know if that's in the current proposal. But this is gonna be an office practice responsibility, I suspect. The patient's not gonna be able to mark it. And I think it was also in the original one that the clinical office should explain to the patient all the things they can control and how to do it. How is there gonna be time for that? That's one question.

So, we should do some usability testing on this for sure. And the other thing is the question about narrative. How are you gonna keep that secret? You said the first round – you said, oh, the narrative goes into the whole report gets hidden. Is anybody talking about that or thinking about that? Industry people I've talked to say it's not implementable.

Carolyn Petersen – Individual – Chair
To date, the task force has not considered the specifics around office practices, per se, in the sense of how you would keep a secret about a narrative. In the real world, that is going to be a consideration. But it's not something that ONC has specifically asked us to address. And I think that's reasonable, because there are so many different kinds of office settings and health institution settings, it would be difficult, because we would just be kind of guessing at what we're guessing at. We have tried to focus our discussion so far on the more nuts and bolts and specifics of our charge. But I will certainly note it as something to consider going forward with our discussions.

Clem McDonald – National Library of Medicine – Member
There should be some usability testing, or we're gonna shut down practices – or they're gonna have everybody fleeing even more than they are now from taking care of patients.

Carolyn Petersen – Individual – Chair
And I've made a note of that.

Robert Wah – Individual – Chair
Other comments or questions about the presentation? Great. Thank you, Carolyn, to you and your committee. If we could get –

Carolyn Petersen – Individual – Chair
Thank you so much for the opportunity to update. And let me reiterate again that Aaron and I have been taking copious notes during this discussion, and we will send these notes out to the task force tonight, because they can be a part of our deliberations tomorrow and next week, and at whatever other future meetings we have. Thank you very much for the rich engagement. We really appreciate your help.

Robert Wah – Individual – Chair
Okay. Let's see if we can back to the CMC. Denise, are you available to restart the discussion? We've got a few minutes before our public comment period starts. And let's see if we can get through a few more of the recommendations.

Denise Webb – Individual – Member
Hi! Okay, I'm here.

Robert Wah – Individual – Chair
Great.

Denise Webb – Individual – Member
I think we left off on recommendation 25.

Robert Wah – Individual – Chair
Yeah, I think we finished 24, right?

Denise Webb – Individual – Member
We did. We took a vote.

Robert Wah – Individual – Chair
Yeah. I think we're now at 25.

Denise Webb – Individual – Member
Okay. We were asked to look at the applicability of the three conditions and maintenance of certification requirements that our task force addressed. And that was around real-world testing, APIs, and attestations. And if you'll go to the next slide, please. We have a placeholder here, because we have not finished deliberating on this recommendation and have not come to consensus yet. And if we have some time at the end, we have a slide at the end where we would like to get some of the broader perspective of the full committee for us to continue our deliberation on so we can come to consensus, particularly around real-world testing. So, that's all I have to say on this. So, if we can move to recommendation 26.

All right. So, we're gonna look at the updates to the 2015 edition certification criteria recommendations, starting with recommendation 26. We are recommending that ONC provide clarity around the scope of the EHI export that's expected in the 2015 edition certification criteria, or specified, I should say. And we are recommending that it be limited to EHI collected and retained by the certified EHR technology and apply only to the EHI that is commonly understood to be part of the legal medical record. Further, we recommend that health IT developers be required to provide a plain language definition of EHI typically included in the legal medical record held by their certified health IT module as part of their export documentation.

Robert Wah – Individual – Chair
All right. Questions or comments about recommendation 26?

Denise Webb – Individual – Member
Before we go to comments, there's a little bit of discussion that might help the task force if they didn't happen to look at this in the transmittal memo. But we think that narrowing the EHI export scope and certification criteria to the legal medical record is important in a lot of

respects, such as for research data that's stored in the EHR. And we discussed some of the other challenges with exporting data outside of the legal medical record, including incomplete information, such as a half-finished note. And we as a task force also acknowledged in our discussion that non-certified health IT of course might need similar EHI export capability so as to not be information blocking, because we acknowledged that there are systems that are not certified that a vendor may provide that hold patients' EHI, and that there would be an export capability needed to support patient access and to support a provider's transition of this information and data to another health IT system.

But we really concluded that the information blocking provisions were sufficient to ensure that health IT developers met the export needs of patients and users in these places where the technology is not certified, yet they are subject to providing the information, avoiding to be information blockers.

Robert Wah – Individual – Chair
Okay. Other comments, questions? Seeing none, we can then proceed to a vote on recommendation 26. All those in favor of recommendation 26, please signal by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions? Okay. 27?

Denise Webb – Individual – Member
In 27, we're recommending that ONC clarify that the export process must accommodate manual review by the API data provider to comply with state and local laws prior to being released. We recognize that a state may have laws prohibiting the release of certain EHI. So, to some extent, this can't just be an automatic release of information via the export process, and that this would need to be accommodated to assure compliance.

Robert Wah – Individual – Chair
Great. Any comments, questions about recommendation 27? Seeing none, all those in favor of recommendation 27, please signal by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions? Okay. 28?

Denise Webb – Individual – Member
Okay. 28, we are recommending that ONC include audit log data for the EHI export transition between the health IT system transition use case, but not for the EHI export patient use case, due to privacy concerns for health system staff. And this is in the preamble. No change to the

regulatory text.

Robert Wah – Individual – Chair
Very good. Questions or comments about recommendation 28? Seeing none, all those in favor of recommendation 28, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions? Okay. Denise, next?

Denise Webb – Individual – Member
All right. On to 29. In this recommendation, we are recommending ONC not require that the EHI export criterion include capabilities to prevent healthcare providers to set date range or specific time periods for the EHI exports due to the complexity experienced by health IT developers in complying with the same requirements and flexibility in the view/download/transmit certification criterion. And additionally, patients should have access to all of their data, regardless of time period.

Robert Wah – Individual – Chair Okay. Questions or comments about recommendation 29? Hearing and seeing none, all those in favor of recommendation 29, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions? Okay. Denise?

Denise Webb – Individual – Member
All right. So, on recommendation 30, this concerns the CMC criteria around – or, excuse me, the 2015 edition criteria around electronic prescribing. And we're recommending that ONC change the final rule regulatory text and preamble section so that EHR ePrescribing transition – I can't talk today – transactions make some of these optional that are not applicable to all settings or that may need piloting as well. If all transactions would be required, this could jeopardize the timeline to meet right now for availability and production use.

So, you see here on the slide, the first Grouping shows those parts of this standard that apply to the prescriber. And then optional prescriber parts of this. And then on the next slide, we show the ones that we are recommending apply only to long-term care and pharmacy only. And then one item that's not applicable, as it's an obsolete method of message retrieval that's essentially unused.

Robert Wah – Individual – Chair

All right. Comments or questions on this recommendation? Seeing and hearing none, all those in favor of recommendation 30, please signify by saying aye. I'm sorry, Terry, did you have a comment? I missed it.

Terrence O'Malley – Massachusetts General Hospital – Member
I did, and just a clarification. This is really sort of the process and the message types that are going, but is not specifying any of the message content. Is that correct?

Denise Webb – Individual – Member
Sasha, do you want to help out and jump in on this one?

Sasha TerMaat – Epic – Member
Sure. So, Terry, the script standard specifies different what are called transactions. And each transaction has a format which would, I guess, include the content. But then each transaction also has intended purposes. And what we're identifying in this recommendation is that some of these, like a pharmacy to pharmacy message, would not be applicable for requiring and certification of an ambulatory EHR product. So, it would potentially have content implications as defined by the script standards.

Terrence O'Malley – Massachusetts General Hospital – Member
Yeah, that's helpful. I mean, the reason I raised this is that there are some data elements missing from these transaction types that are extremely valuable. And we identified one in the USCDI, and that was indication, or associated diagnosis for a particular medication. And my question is, should that rest in USCDI, or is there a nook into which we can place it in electronic prescribing?

Sasha TerMaat – Epic – Member
I think it's actually already accommodated in ONC's proposal. And we didn't comment on it here because the task force thought what ONC had proposed was reasonable. But they include putting an indication in when the transaction accommodates that.

Terrence O'Malley – Massachusetts General Hospital – Member
Okay, thank you.

Robert Wah – Individual – Chair
Other questions or comments about recommendation 30?

Denise Webb – Individual – Member
Thank you, Sasha.

Robert Wah – Individual – Chair
Okay. So, again, I'm sorry to hesitate, but I want to make sure that we get comments in. All those in favor of recommendation 30, please signify by saying aye.

Group

Aye.

Robert Wah – Individual – Chair
All those opposed, say no. Any abstentions? Right, Denise, 31?

Denise Webb – Individual – Member
All right. The next area of certification is around clinical quality measures. And we are recommending ONC update the proposal and final rule text and preamble for the table that is shown below. The first table shows what is currently proposed, and then the second table shows what we are recommending be the adoption requirements. What ONC has proposed, that all products adopt both the CMC ambulatory IG for QRD83 and CMS inpatient IG for QRD81. If this change we're asking for isn't made, developers will not know how to comply with requirements for QRD8 that are not relative to the care setting supported by their product. So, we gave an example with the inpatient implementation guide.

Robert Wah – Individual – Chair
Okay. Questions or comments about recommendation 31? Hearing and seeing none, all those in favor of recommendation 31, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say no. Any abstentions? Okay. 32.

Denise Webb – Individual – Member
All right. Recommendation 32. ONC asked about applying FHIR -enabled APIs to quality reporting. And while we agree quality reporting using FHIR -enabled APIs is a good aspirational direction for ONC to take, but include in future rule-making. We don't think it's ready today to replace or complement QRDA reports for quality reporting and improvement.

Robert Wah – Individual – Chair
All right. Questions or comments about recommendation 32? Sorry, go ahead.

Denise Webb – Individual – Member
Yeah. And just to help folks out, for some reason, the exact text from our transmittal menu didn't make it onto this slide, and we do have – the CMCTF recommends ONC – no, I apologize. I'm getting ahead of myself. We're good.

Robert Wah – Individual – Chair
Yeah, I think. Okay. Seeing no comments or questions, we'll go to a vote. All those in favor of recommendation 32, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say no. Any abstentions? Okay, let's go to 33.

Denise Webb – Individual – Member
All right, 33. And this concerns the privacy and security transparency attestation criteria. And we're recommending ONC apply the privacy and security attestations only to new certifications and new products after this rule is finalized, and not to products already in widespread use, where the widespread publication of the attestation on these criteria might create a vulnerability and unintended consequences if we had malicious actors out there that had this information about existing production systems.

Robert Wah – Individual – Chair
Why don't you go on to recommendation 34, then, because it's pretty similar, and just wrap these two up together?

Denise Webb – Individual – Member
Oh, okay. Now the two together?

Robert Wah – Individual – Chair
Yeah.

Denise Webb – Individual – Member
On recommendation 34, this is an attestation criteria, a yes/no, but we are recommending that ONC add a text box where the developers would describe their yes/no attestation. And this would require a modification to the regulatory text and preamble. This would help with clarity for use cases such as log in and sign, APCS, etc. And it would allow developers to provide clarity to stakeholders as to what use cases and third party considerations and so forth that they considered when attesting yes or no, as well as be useful to ONC.

Robert Wah – Individual – Chair
Right. Questions or comments about recommendations 33 and 34? Seeing and hearing none, let's vote on them together. All those in favor of recommendation 33 and 34, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say no. Any abstentions? Okay, homestretch. Denise?

Denise Webb – Individual – Member
One more to go! All right. We have two recommendations around deregulatory actions. One of these deregulatory actions is to remove randomized surveillance requirements. And we're recommending that ONC not remove the prohibition on consecutive selection of one health IT

module in the final rule text and preamble. The goal is that if the proposed deregulation is implemented, to remove this requirement to conduct random surveillance. The ONC ACD could still randomly surveil, but cannot consecutively select the same health IT module for random surveillance more than once in a 12-month period. And obviously, if they discover some nonconformance in the random surveillance, they would still be allowed to follow up within the 12-month period through its reactive surveillance authority. So, that's 35.

Robert Wah – Individual – Chair
Why don't we do 36 too?

Denise Webb – Individual – Member
Okay. And then on 36, this has to do with removal of certain 2015 edition certification criteria that's part of deregulatory actions. And we are recommending that ONC adopt a general principle and a final rule of not duplicating data-capture criteria within the certification criteria. And we used an example such as demographics for data classes included in USCDI. And then based on this principle, we're recommending ONC consider other criteria such as demographics be removed under the deregulatory actions in the final rule.

Robert Wah – Individual – Chair
All right. Questions or comments about recommendations 35 and 36? Hearing and seeing no comments or questions, let's go ahead and vote on both of these together. All those in favor of recommendation 35 and 36, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say no. And any abstentions? And back to Denise to wrap up.

Denise Webb – Individual – Member
All right. And then I believe we have one more slide. I said we would come back to 25. As noted earlier, we're still working on the recommendations around self-developers. And so, we did want to hear the perspective of the broader committee on the appropriateness of requiring self-developers of health IT to meet all of the real-time testing requirements proposed in the rule, and particularly with regard to maintenance of certification for their certified health IT modules that are not offered for commercial resale, but must be certified in order for providers using these modules to participate in certain federal programs. So, if anyone has any perspective they'd like to share that we can deliberate on tomorrow when we meet, that would be very helpful. And if you don't have something at this moment and would email either – well, both Raj and I, then we can take that up with the task force tomorrow when we meet.

Robert Wah – Individual – Chair
So, what I'm gonna do, Denise, is we're gonna break for the public comment, because we're schedule to do that, but we may have some time after that. So, that gives people a little bit of time to think about their feedback for you. So, I'll open it back up after we've finished the

public comment period to see if there's committee feedback on that particular topic.

Denise Webb – Individual – Member
Great. Thank you.

Robert Wah – Individual – Chair
And with that, I'll turn it over to Lauren to get on with the public comment period.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thanks so much. And Operator, can we open the line?

Operator
If you'd like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue, and you may press *2 if you'd 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 * 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
Not at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. I will turn it back to Denise and/or Robert. I don't know if there's anything else that we wanted to wrap up around the self-developers.

Robert Wah – Individual – Chair
Sure. So, if somebody comes on the public line, just please interrupt and let us know. Denise has just laid out for you the interest of her task force to get feedback from the greater committee on the self-developers. Any comments for her or her committee, the task force? Any other wrap-up comments you want to make, Denise?

Denise Webb – Individual – Member
Well, I would be generally interested to know if the rest of my fellow committee members are in favor of requiring self-developers to meet the real-world testing requirements or have any concerns with that. **[Crosstalk] [05:14:50]**

Steven Lane – Sutter Health – Member
This is Steven. I think this has come up in a number of our task force discussions. Whether somebody is certified or not, whether they're self-developing or not, I think the standards that we have as developers and apps should be standard across the board, and that there shouldn't

be loopholes that allow people to bring things to market and into our ecosystem without appropriate review and oversight. And I think real-world testing is part of that. So, I think the direction you're going in makes sense.

Aaron Miri – The University of Texas at Austin – Member
This is Aaron. I agree. And we build a lot of homegrown apps here at the University of Texas, as well as a lot of commercial products. And it would be quite the difficult step if suddenly there were two different standards held. And there'd be a lot of issues, I think, if we don't try to encourage harmonization of both sides of the coin.

Denise Webb – Individual – Member
So, just to share with the full committee, we did have some members of our task force that were greatly concerned, particularly around the maintenance of certification. Not the first year of real-world testing, but maintaining and satisfying the requirements each year. And there were also a few thoughts that in general, applying the conditions of maintenance and certification around real-world testing would stifle innovation. So, we had quite a bit of debate about that. And the issue is, self-developers, which are generally considered under information blocking definitions to be providers, provider organizations – they are subject to information blocking, regardless of whether they decide to go certify their product or not, or need to because of programs they participate in.

And I know a few of us across the board have some experience, like you mentioned, Aaron, with self-development around the certified technology. And there's nothing that, unless your program participation at a federal level requires it, that says you have to get it certified. But it doesn't preclude that you would still be subject to information blocking, whether you self-develop or buy a commercial product.

Aaron Miri – The University of Texas at Austin – Member
This is true. I'll give you a real-world example. One of the things about being the CIO is almost everything rolls up to you at some point, and you see just about every system being built or installed. And so, I was speaking to one of our self-developers, bright developer who did not consider the privacy and security ramifications. And it's like, no, you must meet the rigor as if this was being used for patient care. I know it's research, but it's for patient care. And so, to the degree of it, we can all do our own part internally at our organizations, but we're gonna have a hodgepodge in the environment if not everybody has the same level of rigor. So, there may be some arduous needs to self-attest and others. But applications, no matter what, if they are gonna be out there for public use or for patient care of any sort, in my personal opinion, need to be held to a higher standard.

Denise Webb – Individual – Member
The patient safety aspect of all of this –

Aaron Miri – The University of Texas at Austin – Member
That's exactly right.

Denise Webb – Individual – Member

– might have a greater weight, obviously, than someone perceiving their innovation as being stifled.

Aaron Miri – The University of Texas at Austin – Member
You can never be too careful when it comes to patient information.

Denise Webb – Individual – Member
And I can't see, Robert, is there anyone else with their hand raised?

Robert Wah – Individual – Chair
No, there's no other hands raised. So, I'm just asking, are there comments or . . .

Denise Webb – Individual – Member
Well, if anyone else has any other thoughts on this before our meeting at 3:00 Eastern tomorrow, certainly shoot us an email. I'd appreciate it. Thank you.

Robert Wah – Individual – Chair
All right, Denise, thank you and your task force for all their work, and thank you for coming back at a moment's notice and getting this done. So, as we're starting to wrap up, let me just say that, again, it's been the goal of your chairs to make sure we have a robust and open discussion here. I know I sound like I'm a bit of a slave to the schedule, but I really am a slave to making sure that we as a committee produce the best possible product. And so, we've had to make some adjustments, and I appreciate everybody's indulgence as we did that, and patience. But I think we had a good discussion today. We are looking at an extended deadline for comments here. And so, that's given us a little bit of freedom. But I don't want to use that freedom to get us jammed up at the end of the month of May.

So, we have a meeting scheduled for 13 May right now. And right now, our plan is to put the remaining task force recommendations on for that day. If we don't complete that, I think we're going to put a backup day after 13 May on the schedule so that we have something on the books. To have a meeting of the committee, we need at least 15 days' notice in the federal register, so we can't put it on at the last minute. So, you'll most likely be seeing a request for an additional meeting. If we don't need that meeting, it's a lot easier to cancel it because we already put it on than try to put it on later if we need it. So, please understand, and we appreciate your patience on that as well.

I think we've given some feedback to the two task forces that presented today. They'll go back to their committees and work on their recommendation again. The other two task forces that you heard from today also had comments that they will feed into their discussions and bring us back their final, final recommendations. But we do have a deadline here, and nothing focuses the mind like a deadline. So, ONC, even though they've extended the comment period on this rule-making, we do have to comply with that new deadline. And so, we don't have unlimited time to discuss this.

Again, I hope you all understand where we are, and I appreciate your indulgence and patience

as we try to be flexible with the meeting today. Terry, I see your hand up.

Terrence O'Malley – Massachusetts General Hospital – Member
Yeah. And just a comment on sort of the HITAC process. What was striking today to me was the extent to which each of the task forces, although focused on sort of the warp of the issues, have overlapped, and they're just crosscutting issues that apply to several task forces at once. So, it's sort of the warp and woof of getting through task force buckets and crosscutting issues. I'm just wondering if there's a structure that's been thought about to bring that together so that somehow, we can inform each other – each task force can inform other task forces about issues that are shared in different ways, but allow us to have a little richer discussion and thought around how best to make recommendations.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Terry, this is Lauren. I can take the first stab at that. So, a little bit of that is already occurring internally within ONC. We have each of the task forces meeting on a weekly basis just for that exact reason, for areas of overlap and synergy between the task forces. But we can certainly perhaps maybe think about a meeting of the task force co-chairs to do that outside of ONC, like with the committee members. We're certainly open to additional suggestions.

Terrence O'Malley – Massachusetts General Hospital – Member
Great. Thanks. And I'm not looking for more work for the co-chairs. But that may be the process that works best.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yup, absolutely. Well, we'll work on that, Terry, and we'll recap to the various co-chairs.

Robert Wah – Individual – Chair
Other comments about the day or where we are and where we're heading?

Carolyn Petersen – Individual – Chair
This is Carolyn. I just wanted to again reiterate my thanks for all the hard work that has occurred at the task forces, and to thank everyone for hanging in with a long, mentally taxing day. We processed and discussed an amazing amount of information this morning, and I really appreciate your hanging in with us and continuing to contribute, even when it becomes a bit intense and overwhelming.

Robert Wah – Individual – Chair
Just to say, there's more to come.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yeah. And this is Lauren again. Just as a reminder, as I mentioned, the TEF Task Force will be resuming again here shortly. For those members that are on that task force, you should have received an invitation already for the ninth of May. We haven't yet established the full

cadence of meetings, but when we do, we'll share that with the full committee.

Robert Wah – Individual – Chair
So, Lauren, you want to walk us through the logistics of the next steps, the next meeting?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sure. So, I mean, clearly we still have to hear from all four of the task forces, whether – kind of in various stages of the final recommendations. So, we will certainly have a little bit of a repeat of the meeting today, minus the Trusted Exchange Framework. We'll have to kind of play it by ear and see how much we're able to get through on the 13th. And as Robert mentioned, if we need to put an additional meeting on the books for perhaps later in May, we will get at least a tentative hold put on your calendars for that meeting. Otherwise, that is all I have for today, Carolyn and Robert, unless you have anything else?

Robert Wah – Individual – Chair
Nope.

Carolyn Petersen – Individual – Chair
I don't.

Robert Wah – Individual – Chair
Again, thanks to the committee. As Carolyn said, we recognize this is a tremendous amount of work. We'll try to get those batches out to you as soon as we can before the next meeting. Clearly, it's important that everybody review the materials before the meeting. There's a lot of meat in these recommendations. And so, we appreciate all of the work you do to prepare for the final votes on them. Lauren, did you have to adjourn this? I think you do, right?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yes. I think that is enough for today. I want to thank everyone for your time and especially for the extended virtual meeting and being with us pretty much all day. So, thank you, everyone. We will adjourn, and we'll talk again in a few weeks.

Carolyn Petersen – Individual – Chair
Thank you.

Robert Wah – Individual – Chair
Thanks, everyone.

Male Speaker
Thank you.

Female Speaker
Thanks