Health Information Technology Advisory Committee

Transcript
May 13, 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
Andrew Truscott	Accenture	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
Christoph Lehmann	Vanderbilt University Medical Center	SME
ONC Speakers		
Name	**Organization**	**Role**
Lauren Richie	ONC	Designated Federal Officer
Jon White	ONC	Deputy National Coordinator

Mark Knee	ONC	IB TF Staff Lead
Mike Lipinski	ONC	Director of the Regulatory Affairs Division

Operator
All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning, everyone. Happy Monday. Welcome to the HITAC meeting. We have a full agenda today so I will get started immediately with a roll call. I did just want to know that a revised agenda went out today with just a slight change in the order for the information blocking and the Care Continuum task force. So, I just wanted to note that change if you have noticed from the prior version that went out earlier last week. With that, we'll get started with 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
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? Cynthia Fisher? Valerie Grey.

Valerie Grey – New York eHealth Collaborative - Member
Here.

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

Anil Jain – IBM Watson Health - Member

Present.

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

John Kansky?

John Kansky – Indiana Health Information Exchange - Member

Here.

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

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

Les Lenert? Arien Malec? Sorry, was that Arien? Okay, maybe not. Denni McColm?

Denni McColm – Citizens Memorial Hospital - Member

Present.

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

Clem McDonald? 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

I'm here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Terry O'Malley? I do believe we have Terry. Raj Ratwani?

Raj Ratwani – MedStar Health - Member
Good morning.

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

Steve Ready – Norton Healthcare - Member
Present.

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

Sasha TerMaat – Epic - Member
Here.

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

Andrew Truscott – Accenture - Member
Present.

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

Sheryl Turney – Anthem Blue Cross Blue Shield - Member
Here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denise Webb? I believe we have Denise on the line.

Denise Webb – Individual - Member
Present.

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

From CMS, do we have either Kate Goodrich or Mark Roche? Laura Conn from CDC?

Laura Conn - CDC

Present.

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

Ram Sriram from NIST? Terry Adirim from DoD? Okay. And with us, we have our Deputy National Coordinator, Dr. Jon White who will be providing opening remarks today. Jon?

Jon White – Office of the National Coordinator for Health Information Technology – Deputy National Coordinator

Thank you so much. Good morning, everybody. Welcome. I want to thank you all for agreeing to meet again in such a short amount of time. My colleagues and I are definitely looking forward to the continued discussions on your recommendations so far on the ONC proposed rule. Two or three announcements to make. The TEFCA task force began their work last week. We're expecting their final recommendations next month. So, thank you to the members of that task force. Member updates. Hello to an old friend, Laura Conn, from the CDC. Good to hear your voice. In addition to the member update that Dr. Rutger announced at our last HITAC meeting, I would like to formally introduce and welcome to the committee Terry Adam. Terry is the deputy assistant secretary of defense for Health Services Policy and Oversight at the Department of Defense and will be serving as a federal representative.

And now, I'll turn it over to our co-chairs, Carolyn and Robert for a review of today's agenda. Thank you.

Carolyn Petersen – Individual – Chair

Thank you. Good morning. It's great to see everyone here bright and early on a Monday. We have a lot of good work ahead of us today. And I will get right into it by going through the agenda. We will be looking at several transmittal letters today and, hopefully, we win some votes. We'll start with the Conditions and Maintenance of Certification Requirements task force draft recommendations and vote followed by the US Core Data for Interoperability task force draft recommendations and vote. And then, they Health IT for the Care Continuum Update and hopefully a vote. We'll have a public comment period and a break. And then, we'll go to the Information Blocking task force draft recommendations and vote. Another public comment period and then, our closing remarks and adjournment. We had sent out minutes for the April 25 meeting. I'm wondering if we are ready to approve those meeting minutes. May I have a motion, please?

Unknown

Motion.

Carolyn Petersen – Individual – Chair

All right. Will those in favor of approving the minutes from the April 25 meeting please signify by saying aye?

All

Aye.

Carolyn Petersen – Individual – Chair

Would all of those opposed say nay? And do we have any abstentions? All right. The minutes from the meeting of April 25 are now approved. And I will hand the mic to Robert for his comments.

Robert Wah – Individual – Chair

Thanks, Carolyn. And good morning and good Monday, everyone. I hope everyone had a great Mother's Day weekend. And it's great to be back. We have a lot of material to review and approve today. We'll probably keep the same methodology we used at the last meeting where we would go through and vote. In some committees, we'll vote individually on each recommendation and others we'll probably block them or group them together for more efficient movement through the materials this morning. But without further ado, I'll turn it over to Denise and Raj to take us through the first task force set of draft recommendations and vote. Do we have Raj and Denise on?

Raj Ratwani – MedStar Health - Member

Yeah, good morning. This is Raj. I'm on. Denise, are you on as well?

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

You may be on mute.

Robert Wah – Individual – Chair

I thought I heard her.

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

Yeah, she was on earlier. Okay. Raj, can you go ahead and get started until we can get Denise back on audio?

Raj Ratwani – MedStar Health - Member

Yes, I can. Just one second. I'm going to get the chart. Okay, great. Thanks, all. So, quickly jump in here. So, we had a lot of progress on the last meeting going through several recommendations. And then, during that time, there were a few that needed some revisiting by the committee, which we have done. So, we thought we could review the work that's already been done and then, quickly jump into some of the modifications. So, I'm going to jump to Slide 3. I'm sorry. I'm still getting the Adobe Connect launched over here.

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

So, Raj, the numbering may be a little bit different but you can just say advance the next slide and then –

Raj Ratwani – MedStar Health - Member

There we go. I'm all set. Thanks. So, to review the overarching charge, we focused on providing recommendations on the application programming interfaces, real world testing, and attestation. As I mentioned, we've made it through several of these recommendations and we're going to focus on the few now that needed some modification. Next slide, please. So, a summary of the ones that were approved from the last meeting, Recommendation 1, clarity on rationale, was covered. Real world testing through several of these recommendations. I'm not going to review which one. I'm hoping that people had time to look at this. Next slide. The same with attestations. And then, APIs, we made it through a lot of this content. All of these, again, were approved. Next slide. The same with EHI, electronic prescribing, and clinical quality measures. Next slide, please. Okay.

So, jumping into the ones where there was a fair amount of discussion at the previous full HITAC meeting and needed some revision on our side, the first had to do with real world testing. And I think much of the conversation at the last meeting was around how we were describing the receipt and use of information and the kinds of usability testing that could be required. And I know Steve Lane and Clem had some really great comments here. So, we took it back to the task force and had a lot of discussion on this. And you can see the proposed changes here. So, the strikethrough is what we were cutting from the last recommendation. And the red is showing some of the enhanced modifications to this. So, Recommendation 8 revised now reads, "ONC states that successful rule of testing means electronic health information is received by and used in the certified health IT.

And the CMCTF recommends ONC provide clarification in the final rule preamble around testing, the receipt and use of information received through exchange versus testing the exchange of information, just sending and receiving. When the health IT being tested does to receive data and the criterion being tested, use based testing would not be pertinent. The task force recommends the ONC expects that if health IT developers are testing the use of data received through exchange, the health IT vendors should have intended users involved in usability testing. Users and providers were not considered in the cost estimates for the rule of testing in the proposed rule preamble. Therefore, the task force recommends ONC revised the rule of testing cost estimates in the final rule preamble section."

So, the really big change was rethinking the way we were describing the need for usability testing, trying to make this general enough so we're not being overly prescriptive about the processes that should be used and balancing the different opinions that were coming from the overall committee. Comments on the content here.

Steven Lane – Sutter Health - Member

Raj, I've got my hand up. This is Steven Lane, if I may.

Raj Ratwani – MedStar Health - Member

Yes, please. Go ahead, Steve.

Steven Lane – Sutter Health - Member

I think in your second to the last paragraph, users I would insert the word including in the parentheses. Users including providers because, of course, nurses and other users of EHR technology, health IT, financial folks, etc., folks beyond providers may be required. And none of those costs were included. So, I would just say users including providers.

Raj Ratwani – MedStar Health - Member

That's a great point. Thank you.

Andrew Truscott – Accenture - Member

Raj, it's Andy here. I've got my hand raised.

Robert Wah – Individual – Chair

Yes, Andy. Andy, can you hold just a second? So, I think what we're going to do here is given that this is a recommendation from the task force and it's now being presented to the committee, obviously, we want to hear from the committee and make any amendments as needed. But I think to keep this clean and allow us to go ahead and approve each recommendation with or without the amendments, we'll take these as amendments to the recommendation from the task force as we hear them. And that, hopefully, will get us to a product that we can all approve as a committee. I hope that makes sense to everybody. So, for Steven's comment, Steven, if you could once again articulate the change that you recommend as an amendment to this Recommendation 8.

Steven Lane – Sutter Health - Member

Sure. I recommend an amendment inserting the word including in the parentheses regarding providers.

Robert Wah – Individual – Chair

Okay. I think that's, obviously, pretty clear. I don't know that we need to project that. So, let's allow a discussion of that amendment first. And then, after that discussion, we'll vote on amending this recommendation with that change. And then, we'll proceed to the next comment. So, I'd like to have a discussion about the change that Steven is recommending in the parentheses. Any comments about that? Okay. Hearing no comments, all of those in favor of amending Recommendation 8 with the additional words in the parentheses, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Okay. So, now we have amended this recommendation with the small word change. Let's go on to the further discussion of the overall recommendation. Andy?

Andrew Truscott – Accenture - Member

Thanks, Rob. A quick question. Where you've got the strikethrough, you've stricken through when there are no end users of the health IT product being tested. And then, you say use base testing would not be pertinent. The word use in use based was, obviously, germane to end users in the bit that's been stricken through in that sentence. And the word use is used earlier in that sentence when we talk about receipt end use. So, has the context of use based testing been changed by that strikethrough?

Raj Ratwani – MedStar Health - Member

I'm just rereading with your lens here.

Denise Webb – Individual - Member

And Raj, this is Denise. I'm on. So, Andy, we were trying to clarify that. We realized that there is data that can be received and used by a machine where there is no user involved. It's machine to machine. There's receipt and use by the machine. So, we were trying to clarify that when health IT being tested does not receive data in the criterion being tested. So, the criteria of a user receiving and using the data, use based testing by users would not be pertinent.

Andrew Truscott – Accenture - Member

Okay. So, my recommendation would be to modify that last line. So, instead of saying use based testing it should say end user based testing. That would be a recommendation from me to your task force.

Denise Webb – Individual - Member

That sounds good.

Robert Wah – Individual – Chair

So, we'll take that again as an amendment to this recommendation that we've already previously amended. I want to make sure we have comments about the change we're talking about and if everybody is clear on this. Again, it's fairly small change. The top paragraph, last line where it says use-based testing, we would modify that word to be end user based testing. Andy, tell me of that's correct.

Andrew Truscott – Accenture - Member

That's correct, yeah.

Robert Wah – Individual – Chair

So, as I said, it's a fairly small change but I want to make sure everyone is clear on that. And I'll take any comments on that amendment. Hearing no comments, all of those in favor of the amendment to Recommendation 8, please signify by saying aye.

All
Aye.

Robert Wah – Individual – Chair
All of those opposed say no. Any abstentions? All right. Hearing none, now we've made two amendments to Recommendation 8. Other comments about Recommendation 8 overall? Hearing none, all of those in favor of the now amended Recommendation 8, please signify by saying aye.

All
Aye.

Robert Wah – Individual – Chair
All of those opposed say no. Any abstentions? Okay. Raj and Denise, move on to the next one.

Raj Ratwani – MedStar Health - Member
Great. Thank you. Denise, I'm going to turn over to you if that's okay. You certainly have a lot more context around this than I do.

Denise Webb – Individual - Member
Okay.

Raj Ratwani – MedStar Health - Member
But we can go to the next slide. Here's another recommendation, Recommendation 12 that there was a lot of discussion on in the overall committee meeting and also in the task force. So, at this point, we want to withdraw this recommendation all together.

Denise Webb – Individual - Member
Yeah. And I can clarify. We did talk about this in the transmittal memo. We revisited what was in the proposed rule and we thought that the proposed rule sufficiently addressed this area where we would not need this recommendation. And, therefore, we're withdrawing it. There were some things that we did not see in the proposed rule that ONC pointed out to us. And that's noted in the transmittal. So, there's no vote. It's withdrawn.

Robert Wah – Individual – Chair
Yeah. There's no action that's needed here. It's really a recommendation but I just want to make sure the committee has an opportunity to ask any clarifying questions about the background for the withdrawal if anybody has such a question. Now would be the time to have that discussion. So, any comments or questions about the withdrawal of Recommendation 12? Andy, you have your hand up.

Andrew Truscott – Accenture - Member
Yeah. Guys, you, obviously, felt strong enough that you put this in in the first place. So, what

happened?

Denise Webb – Individual - Member

So, Andy, that's what we were just saying. There was a section of the preamble that talked about the testing infrastructure and the lag times that may occur with updated test tools. And we as a group thought that this sufficiently addressed how the process should work such that we did not need to advance this.

Andrew Truscott – Accenture - Member

Oh, no, I got that. Thanks for that, Denise. I understand and that's good. But at some point in time, someone must have felt that it didn't so it was suggested. Did you just go back and reread it and say oh, yeah, it is really?

Denise Webb – Individual - Member

Well, actually, we had one task force member that had put this forth originally as a concern that what were health IT developers to do once the testing tools were available because they're going to be doing an attestation that had conformed with the criteria for that approved version update from the ONC. And that's a relationship between the health IT vendor and the ONC ACB. And the task force member that originally raised this and we had looked through it had felt comfortable that once this was put forth what was in the proposed rule, this area that was pointed out that they didn't think this recommendation was necessary and that they felt comfortable.

Andrew Truscott – Accenture - Member

Okay. Thank you.

Denise Webb – Individual - Member

Yeah.

Robert Wah – Individual – Chair

Great. So, again, we don't need to take a vote on this but we just wanted to make sure that we had an opportunity to discuss it. Other comments or questions about the withdrawal of Recommendation 12? All right. Hearing none, before we move on in case anybody is just on audio only, Arien, Cynthia, Les Lenert, and Clem McDonald have also joined on the call so welcome. And with that, Denise, we'll move on to the next recommendation.

Denise Webb – Individual - Member

All right. Do you want me to take this, Raj?

Raj Ratwani – MedStar Health - Member

Please.

Denise Webb – Individual - Member

Okay. So, on Recommendation 13, there was a lot of concern about the use of the term third party. And so, to be absolutely clear who is being referred to here in third party, we as a task

force came to an agreement that we're really talking about testing partners. That could be any number of entities because third parties a lot of times is referred to as like a third party developer. But testing partners could be public health with the immunization registry and so forth. So, that is the major change that we made to this recommendation to provide that clarity. And you'll see in red there all of the places where we clarified we're talking about a testing partner.

Robert Wah – Individual – Chair

Great. Questions or comments about the revised Recommendation 13 from the task force? Andy, it looks like your hand is up.

Andrew Truscott – Accenture - Member

I'm sorry, guys. I don't want to be commenting on every single one. But partners would infer a partnerial relationship. Is that the intention? Or is the intention to say actually there might not be a direct relationship, we might not have control?

Denise Webb – Individual - Member

Well, I think it's both. When we think about – I guess each person has a different perspective on who a partner is. But when a healthcare provider organization is working with the state immunization registry, they are partnering with them. They're working in a partnerial relationship. But I think that's the word we came up with. If you have a friendly amendment on a different word, we'd be happy to entertain that.

Andrew Truscott – Accenture - Member

I would suggest inserting after the first word use the word partner in parentheses who may or may not be subject to formal contracts or something like that, closed bracket. And then, each time you use partner the first time in that paragraph, I would just put that in because then, that way, you've kind of covered all bases.

Denise Webb – Individual - Member

I think that's good clarification. Yeah. That's good clarification because that's one of the dilemmas. If you have a contractual relationship then, there are contractual requirements to be met. If you don't, it sort of – and I go to public health as an example because they have very limited resources and sometimes are operating on a shoestring. And they may not be able to test for every request that's made of them. And then, the developer shouldn't be penalized because they didn't get a commitment for testing from a particular partner where there is no contractual relationship. So, the amendment that you're suggesting is on the first testing partners to add in parentheses –

Andrew Truscott – Accenture - Member

Who may or may not be contracted or subject to contract.

Denise Webb – Individual - Member

Subject to contract.

Andrew Truscott – Accenture - Member

Who may or may not be subject to contract, closed bracket. And then, in the second bullet point as well just again after the first time you use the word partner. And that's for you to consider.

Robert Wah – Individual – Chair

Okay. So, what I've heard is an amendment to the recommendation. In the first block of texts, after the first time, it says testing partners there would be a bracket with the words, and I'm not sure I have this right because I didn't write it down, testing partners who may or may not be subject to contract. Is that what I heard?

Andrew Truscott – Accenture - Member

Yeah. In brackets, who may or may not be subject to contract or contractual revisions. I wouldn't mind an ONC person just chipping in with a suggestion around how to correctly word that.

Denise Webb – Individual - Member

I'm actually in the Power Point, not the one online but capturing some notes here. So, I put in parentheses who may or may not be subject to contractual requirements.

Andrew Truscott – Accenture - Member

Yeah.

Denise Webb – Individual - Member

I think that captures it.

Robert Wah – Individual – Chair

And then, that same bracket verbiage would be on the second block of text after the first time it says partner as well. Is that what I also heard?

Denise Webb – Individual - Member

Right. I got that, too.

Robert Wah – Individual – Chair

Okay. All right. So, why don't we read that text one more time because we're not able to project it on the Adobe Connect, unfortunately?

Denise Webb – Individual - Member

So, the CMC task force recommends ONC clarifying the final rule preamble, the role and expectations of testing partners who may or may not be subject to contractual requirements or which the health IT developers have no control or authority over. And we were really talking about the partners where there are no contractual requirements. And then, the same change in the first sentence on the next block.

Robert Wah – Individual – Chair

Okay. So, let's have a discussion about this proposed amendment. Comments or questions?

Arien Malec - Change Healthcare - Member

I apologize for process issues. But one additional sort of blanket item is that anywhere where it says CMC task force or TF, we should substitute the HIT Advisory Committee because that's the final recommendation. This is the final recommendations letter.

Denise Webb – Individual - Member

Actually, Arien, this is our final recommendation to the full committee and then, these will be revised once they're voted on.

Arien Malec - Change Healthcare - Member

If that's the process then, I'm good with that.

Denise Webb – Individual - Member

Yeah, that is. That's what Lauren Richie had explained to all of us.

Robert Wah – Individual – Chair

The final product will be actually the transmittal letter, which we will modify to come from the actual committee.

Arien Malec - Change Healthcare - Member

Okay. So, we just all understand that we're not making recommendations on behalf of the task force. We're making recommendations on behalf of the committee.

Robert Wah – Individual – Chair

Right. Well, the task force is making recommendations and then, the committee is accepting those recommendations as coming from the entire committee, yes. That's the process. Thank you for that clarification though. Okay. Other comments about the proposed amendment concerning the contractual coverage or lack thereof after the words testing partners? Hearing no additional comments or questions, let's go ahead and vote on the proposed amendment. So, again, the words would be in brackets after the words testing partners on the first and second blocks of text. All of those in favor of the amendment, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Okay. So, we're now discussing the revised Recommendation 13 with the amendment that we just made concerning the contractual coverage. Other comments or questions about the revised and amended Recommendation 13? Okay. So, all of those in favor of the revised Recommendation 13 with the amendment concerning contractual coverage, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Okay. Denise, next one.

Denise Webb – Individual - Member

Great. This Recommendation 22 concerned the API use case around bulk query for multiple patients' data. And there was a lot of concern about the process and how this works when a particular standard wasn't quite ready for when the rule was going to be published. And so, concluded on the final one sentence here that the CMC task force recognizes additional standards and piloting work of bulk API queries is important and to allow for that work. I think what we were really concerned about was the timeline and that for this particular use case in the proposed rule, we're recommending on the required functionality 12 months after other API updates are expected because we do believe that the standards are ready for the use case for the individual patient data request but not for the multiple patients' data and it's going to need more time. So, that's our revised recommendation.

Robert Wah – Individual – Chair

Okay. Additional comments or questions from the committee about Recommendation 22?

Denise Webb – Individual - Member

Oh, and I'll add this, generally, also aligns now that the test version 2 is out. Many of you might realize or remember that they have delayed the purpose around bulk data queries.

Robert Wah – Individual – Chair

Okay. Other questions or comments about Recommendation 22? All right. Hearing none, all of those in favor of Recommendation 22, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Great. Denise, next one.

Denise Webb – Individual - Member

All right. I think this is our last recommendation. This was a new recommendation and it has not been advanced yet to the full committee from our task force. We did finalize this in our last few meetings. And this is a recommendation around the applicability of the conditions and maintenance of certification requirements to self-developers. And what we're recommending is that ONC evaluate the appropriateness of requiring self-developers that are seeking to maintain certification to meet all of the requirements as proposed in the rule for real world testing APIs and attestations to conditions of maintenance and certification for certified health IT modules, in particular that are not offered for commercial resale but must be certified in order for these providers using these modules to participate in certain federal programs. So, we're more

specifically recommending the following in ONC's evaluation around real world testing and APIs.

We had no specifics around attestation. That was not a large concern. But, generally, from our task force, the largest concern was around real world testing and permitting self-developers that are seeking and maintaining certification to use the actual production experience for the venues where they have deployed their software and their actual trading partner experience to meet the real world testing requirements. That's assuming that they otherwise meet the capabilities that are required for certification. We think that the maintenance of certification could be rather onerous for a number of these self-developers in subsequent years and it would be appropriate for ONC to consider allowing the results of the initial real world testing if nothing has changed in a way that their product functions or operates to allow them to attest to that rather than have to conduct real world testing in subsequent years.

That's on real world testing. And then, on APIs, we reviewed the regulatory text around the applicability of fees, the requirements around fees. And some of those may not apply to self-developers that seek and maintain certification. It would only really apply to self-developers if they're actually selling their API technology or charging for its use. So, we wanted to have that clarified that those self-developers seeking and maintaining certification to their API technology would only be subject to the API requirements concerning fees if they were actually selling their API technology or charging others to use it. So, that is our recommendation.

Robert Wah – Individual – Chair

Great. It looks like, Arien, you have your hand up.

Arien Malec - Change Healthcare - Member

I do. So, with regard to the API fee issue, I don't see how that's different from any other developer who doesn't charge fees for their APIs. It seems like it's a more general concern than something that's related to self-developers. And then, with regard to real world testing, I, generally, appreciate the sentiment here. There are some cases and, again, API for consumer applications and others, where the bounds of the universe aren't simply regular trading partners and where issues might come up where a limited subset of trading partners that had been endorsed by the self-developer have no problem but a new app developer who has been doing real world testing with other EHRs has their patient seek to connect to that system. So, I think this may be a little more nuanced in practice. And I would recommend that – I think we're actually recommending that ONC evaluate the appropriateness of requiring self-developers.

I would not look at the real world testing recommendations as always allowing trading partners to meet the real world testing requirements. I think there's a subset of requirements where trading partners would be appropriate. I'd recommend amending to say permitting self-developers seeking and maintaining certification to use production experience for venues where they deploy the software and the actual trading partner experience to meet the real world testing requirements applicable to trading partners only.

Denise Webb – Individual - Member

I think our group included patients. I did. I consider a patient a trading partner.

Arien Malec - Change Healthcare - Member

Yeah. So, the concern here is I have five patient apps that are connecting but the sixth one comes along and you haven't had the same experience that an EHR developer has in certifying or in testing the range of patient applications. And so, that patient can't connect their app to the self-developed application. So, I think that's probably the area where real world testing is the most applicable for self-developers. As I said, I generally agree with the recommendations here.

Robert Wah – Individual – Chair

If you could restate the amendment that you're proposing.

Arien Malec - Change Healthcare - Member

Yeah. So, to meet the real world testing requirements for capabilities that are relevant, particularly to trading partners.

Robert Wah – Individual – Chair

Okay. Denise, you said you're maintaining a copy of your Power Point, is that correct?

Denise Webb – Individual - Member

I am. I'm trying to type this in. So, can this go in parentheses after to meet the real world testing requirements and in parentheses for capabilities relevant –

Arien Malec - Change Healthcare - Member

To trading partners, yeah. Or relevant to a limited set of trading partners.

Denise Webb – Individual - Member

Oh, okay.

Robert Wah – Individual – Chair

And, actually, to the team that's supporting us, is there a way that Denise can share a screen? Does she have to be listed as a presenter to do that?

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

Unfortunately, we can't live edit right now because it's a large PDF file.

Robert Wah – Individual – Chair

Right. Lauren, I know we can't do that. But if we list Denise as a presenter and she uses the Share My Screen functionality, will that work?

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

Oh, yeah, we can do that. Sure.

Robert Wah – Individual – Chair
That's what I'm thinking. Sorry. So, Denise, do you have that proposed amendment typed onto your Power Point?

Denise Webb – Individual - Member
I do and I just have to find out where – I'm on the Adobe.

Robert Wah – Individual – Chair
Yeah. And so, on the far right side, it says screen share.

Denise Webb – Individual - Member
Okay, let's see. Oh, yeah. It says I'm sharing right now. So, let me open. Can you all see that? No?

Andrew Truscott – Accenture - Member
Yeah, Denise. The administrators need to move it across. It takes them a couple of minutes.

Denise Webb – Individual - Member
All I did was go to my Power Point.

Robert Wah – Individual – Chair
So, did you hit Share My Screen?

Denise Webb – Individual - Member
Let me go back to – right now, the only button I see is Stop Sharing.

Robert Wah – Individual – Chair
I can't see your screens.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denise, is there an option to – oh, sorry. At the top, click applications tab and then, click Power Point.

Denise Webb – Individual - Member
I'm not seeing it. All I'm seeing is I'm making a presentation. I see your text.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Try to click again on Share My Screen.

Denise Webb – Individual - Member
Oh, Share My Screen. Okay, I'm in the wrong box. Share My Screen. All right. Now, can you see it?

Robert Wah – Individual – Chair
It's coming.

Denise Webb – Individual - Member
There are so many boxes in that Adobe Connect. I was not looking in the right place.

Robert Wah – Individual – Chair
In the drop down, it asks –

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yeah, there should be an application tab and then, you can –

Denise Webb – Individual - Member
Okay. Let me go back because I just thought I had to go to my – okay. Oh, yes. I was just going too fast. Sorry about that.

Robert Wah – Individual – Chair
Thank you, everyone, for your patience for trying to use the technology to make this more clear about what we're trying to do.

Denise Webb – Individual - Member
Here we go.

Robert Wah – Individual – Chair
Okay. There we go. This is looking promising.

Denise Webb – Individual - Member
Good. This is the first time I've ever done this so now I know how.

Robert Wah – Individual – Chair
All right. So, do you have a text – oh, there it is. Can you make your screen full screen at the bottom?

Denise Webb – Individual - Member
Yeah. Hold on a sec.

Robert Wah – Individual – Chair
It's no longer highlighted but, hopefully, everyone can see the new parentheses there.

Denise Webb – Individual - Member
It starts at the end of the third line of real world testing.

Robert Wah – Individual – Chair
Great.

Denise Webb – Individual - Member
I was just going to say to realize this is recommending that ONC evaluate this to make sure that they've looked at all aspects of this when it comes to self-developers. And we otherwise believe that self-developers should meet the other requirements of real world testing APIs and attestations. We're just calling out these specific areas that they really need to take a look at.

Robert Wah – Individual – Chair
Okay. Great. Andy, I see your hand up. Is your comment specifically about this amendment or do you have additional comments?

Andrew Truscott – Accenture - Member
It's specific about this amendment.

Robert Wah – Individual – Chair
Okay. Great.

Andrew Truscott – Accenture - Member
No, sorry. I spoke incorrectly. It's not about this amendment. It's about this recommendation. Ignore me.

Robert Wah – Individual – Chair
Standby. We'll get back to you in a minute. So, what we'd like to do now is entertain comments or questions about the proposed amendment that you see on your screen with the addition of the parentheses, the language. So, any additional comments or questions about this proposed amendment? Okay. Hearing none, and Denise, did you have any other comments on behalf of the task force on this amendment?

Denise Webb – Individual - Member
No, I don't unless Raj has something to add.

Raj Ratwani – MedStar Health - Member
I don't have anything else to add.

Robert Wah – Individual – Chair
Okay, great. All of those in favor of the proposed amendment you see on the screen in the language in the parentheses there, please signify by saying aye.

All
Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Okay. So, that is now amended. Andy, I think you have your hand up for another comment about the overall recommendation.

Andrew Truscott – Accenture - Member

I did, sir. Thank you. This is all around particular conditions and maintenance of certification. So, this will only apply to self-developers of certified health IT, correct?

Denise Webb – Individual - Member

Correct. So, if they don't seek certification, none of this applies.

Andrew Truscott – Accenture - Member

And that fields a second path. If you don't have to be certified then, none of this applies by definition.

Denise Webb – Individual - Member

That's right because it's conditions of certification and maintenance. So, you have to be seeking certification. And the point here is in the proposed rule, self-developers, and this is in the information blocking section, are generally considered to be healthcare providers. These are the self-developers they're speaking of because a lot of other self-developers aren't out seeking certification. I think, generally, they say a self-developer is a healthcare provider because otherwise, it's a commercial developer, right. So, our task force is very concerned that – a few members were very concerned that self-developers being healthcare providers may have to get their products certified or their API technology because, if they don't, they can't participate in certain federal programs.

And so, there were concerns around particularly the real world testing and the fact that they actually have real production experience with their self-developed product more so than in some cases that commercial developers would. And that's where the conversation went.

Andrew Truscott – Accenture - Member

As you know, we've discussed this one in some length in information blocking as well. It feels like we do have multiple different tracks for applicability of the regulations depending on who you are in terms of are you a self-developer or not, are you certified or not. And do we want to discuss that here or do we want to discuss it at some other point? Is it something, Robert, Carolyn, something that we should be discussing in committee? Or is it a task force discussion point or what?

Robert Wah – Individual – Chair

Andy, if I understand your comment, you're talking about any developer, let's just say any developer, that may not be seeking certification.

Andrew Truscott – Accenture - Member

Well, what I'm talking about is let's talk about **[Inaudible] [00:50:58]**. They can fall into one of at least four camps right now. They can either be a developer for commercial reasons or a self-developer. And then, each of those can either be seeking certification or not. And if you're not seeking certification as either a commercial or a self-developer, none of the regulations apply to you.

Denise Webb – Individual - Member
Andy, let me jump in there for just a minute.

Andrew Truscott – Accenture - Member
Please do.

Denise Webb – Individual - Member
Because it says in information blocking that ONC proposes that a self-developer is a healthcare provider and I don't know the exact page but what we discussed in our task force is if they decide not to certify their products and it has EHI and they don't share it when requested to share it like if the patient wants all of their data then, they would be subject to the information blocking because they are healthcare providers.

Andrew Truscott – Accenture - Member
And that's fine in their role as a healthcare provider. But if I were to say, for example, a healthcare insurer who is also a self-developer then, they wouldn't come under the provider actor definition. So, they would be a self-developer of noncertified health IT.

Arien Malec - Change Healthcare - Member
Andy, I propose that we address that in maybe one of our broader comments relating to health information technology, generally, and the applicability of Cures. In this case, as Denise says, because we're talking about providers who are self-developers, in almost all cases, the risk of poor interoperability based on their self-developed EHR falls entirely on them. And so, the rationale here is that unlike cases where a developer is broadly selling and the risk of certification that doesn't work out in practice falls on the range of actors who have purchased the technology, we're really subsetting the recommendations for real world testing in cases where the risk is primarily born by the developer itself. I think it's a much narrower issue and I think we should address the larger issue in the context of information blocking.

Andrew Truscott – Accenture - Member
So, Arien, my point was not to litigate it here. My point was purely to say to the chairs where should we discuss this as an entire committee.

Arien Malec - Change Healthcare - Member
Got it.

Michael Lipinski - Office of the National Coordinator – Director of the Regulatory Affairs Division

This is Mike Lipinksi at ONC. I just want to make clear for context that we give a definition of what a self-developer is. So, we base that on the ONC's permanent certification. So, the starting point is somebody getting certified under the program. So, it's not anybody, a plan, somebody else getting a product certified or not getting a product certified I should say in that case. It's somebody who is getting something certified. So, that's the first step. And so, that's the context of our definition of self-developer. So, I just want to be clear that's where we're starting **[Inaudible] [00:54:28]** working from. And then, making the connection who gets certified under the program, who are the actors covered under info blocking. And then, we say in info blocking they're not going to be considered a developer of certified health IT if they don't sell it. They're going to be a self-developer. And I think that's just the connections that are taking place for clarity here.

Andrew Truscott – Accenture - Member

Thank you, Mike.

Robert Wah – Individual – Chair

So, Andrew, in terms of where you want this discussed, I think this has been a reasonable discussion here unless you think there is more to be done or said here. And, Arien, maybe you can –

Andrew Truscott – Accenture - Member

To Arien's point, there is a bigger issue space. I think it would warrant the entire committee discussing. And at some point, we need to make time to have that discussion.

Robert Wah – Individual – Chair

So, I'll propose this then because I think we're nearly finished with this Recommendation 25. Let's complete this and then, that will allow us some time to sort of formulate a place and a plan for this broader discussion that I think I hear you guys bringing up.

Andrew Truscott – Accenture - Member

It works for me.

Robert Wah – Individual – Chair

Okay. So, Denise, further comments about Recommendation 25.

Denise Webb – Individual - Member

I have none. If the committee has no further then, maybe you could call for a vote.

Robert Wah – Individual – Chair

That was my next step. So, to the entire committee, other comments or questions about our amended Recommendation 25 we have before us? Hearing none, all of those in favor of the amended Recommendation 25, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Okay. Final comments, Denise or Raj.

Denise Webb – Individual - Member

I think that was our last slide, right, Raj?

Raj Ratwani – MedStar Health - Member

I believe that's it.

Robert Wah – Individual – Chair

Excellent. So, thank you to your task force. Thank you both as chairs and thank you to your task force. Let's move on to the next group. That's USCDI, Christina and Terry. And thank you, again, to the entire committee. I know this is a challenging process to go through in a virtual way. Go ahead.

Christina Caraballo – Audacious Inquiry – Member

Great. I think we can go ahead and jump to the fourth slide. So, today, we're going to be going over the USCDI's recommendations. Could we go back one more slide? Sorry. It's passing for the task force numbers. We've seen it quite a few times and I want to keep moving along. I know we're a little behind. So, if it's okay with the chairs, Terry and I had discussed taking votes based on the data classes. So, we'll go through demographics, take a vote, go through the clump on provenance and then, clinical notes and then, the others if that's okay.

Robert Wah – Individual – Chair

Sounds perfect.

Christina Caraballo – Audacious Inquiry – Member

Great. So, jumping right in, I do want to go through these guiding principles and scopes just so that as you guys hear our recommendations again, you're reminded of just some basic principles that we followed. So, first, our primary focus is on Phase 1 regarding the proposed or missing data elements in USCDI Version 1. We did not consider how the proposed data elements could be incorporated into future or current systems or provide recommendations on how that might occur. Unless otherwise indicated, each of our recommendations applies to USCDI Version 1. We do cite different transport standards as examples. However, recommendations are agnostic regarding transport. That said, our task force does assume that all USCDI data elements will be tightly specified and semantically interoperable.

So, moving on to the next slide, we're going to start with demographics. We identified some use cases as prior to going into our recommendations that demographics support the big one for patient matching, identity verification, and clinical care. Moving on to the next slide, we have seven main recommendations under demographics. The two data elements that were proposed by ONC included address and phone number. For address, we accept address but we had some recommendations and additions under address. So, Recommendation 1A is to include both the

current and previous address. And 1B is to encourage the use of the United States Postal Service standard addresses. And we recommend that ONC request excess for healthcare organizations to be able to use the USPS standardized address to capture in clinical systems via API. We found that this is extremely helpful for improving interoperability and patient matching but did recognize that it is not easily accessible in a standardized way from USPS.

So, we've asked ONC to look into that further. And 1C is to explore the feasibility of using and/or supporting international address standards. So, this is simply a recommendation to start looking at it and see if there is potential to support this in future versions. Next slide. Our second recommendation group is to accept the phone number with a few changes. So, 2A is to include destinations for both mobile and land line. We are recommending that the software support multiple phone numbers and, specifically, identify the mobile. Recommendation 2B is to include a destination indicating whether the phone number is associated with the patient or another party. This helps capture if the phone number is private or shared supporting adolescent confidentiality and also showing when it's shared with a patient, spouse, guardian, etc. And 2C is to have a designation for each number as to whether the patient has approved leaving a confidential message on the associated number.

Moving on to Recommendations 3 to 4, these are our bonus recommendations. So, Recommendation 3 is to include a destination for electronic communication such as an email. We recommend that the software support collection of email and for ONC to consider requiring collection in future versions to support now. Recommendation 4 is to include contact information for individuals with authority to consent to treatment and data use. If we can move to the next slide. Recommendation 5 is to include the last four digits of the social security number. This is to require systems support this, not necessarily to get in. The task force did recognize that the value of this data is extremely important for patient matching but noted associated privacy concerns. So, again, this is for systems to support it. Recommendation 6 is to include optional identifiers such as state or federal government IDs.

And Recommendation 7 is to include self-reported gender identity. And we noted that systems should continue to record this as well. So, at that, I will pass it over to Robert for a vote or discussion. Or I guess we can open it for discussion first.

Robert Wah – Individual – Chair

First, let's discuss this. Thank you for that. So, you now have before you what we'll call the demographic recommendations from the task force. Let's go ahead and open up the discussion of all of those recommendations that fall under patient demographics. I see a number of hands raised here. Let's start with Steven.

Steven Lane – Sutter Health - Member

Hi, thank you. And, Christina, I apologize because I know we were on the task force and we should have taken care of all of this. But every time you see this, it's sort of fresh. We call out the previous address and I don't know if we specifically kept that singular as opposed to saying previous addresses. It seems to me that if systems have more than one previous address that there's no harm and perhaps some benefit in exposing and exchanging those. So, I was just curious whether you and Terry specifically wanted that to be singular or whether plural would be acceptable as

an amendment. My other question was I know at one point, we talked about alternate addresses such as school or work as another beneficial piece of subtlety to the address recommendation. And I just wanted to be sure that we had intentionally dropped that for simplicity sake.

Christina Caraballo – Audacious Inquiry – Member

So, Steven, for the first point with addresses, I'm pulling up the letter and that's a typo in the slide. It says to include the current and previous addresses in the letter.

Clem McDonald - National Library of Medicine - Member

This is Clem. Could I just interject on that one? I think we should distinguish between having the ability to hold multiple addresses versus a requirement to backload. That would take patient registration time and it could be burdensome and there could be a lot of old addresses. So, it comes across kind of as saying you've got to go pull them in and store them. But it's different to have a place and then, keep them once you've got a change in address. I don't know if you think that's important. But I think you could put a lot of burden on the places if they've got to drag out 20 years of addresses.

Terrence O'Malley – Massachusetts General Hospital - Member

Clem, this is Terry. I think that gets handled by just saying the system should be able to store this, have a place to designate current and previous addresses. But, again, we're not advocating any particular workflow or how that information gets in when it gets in.

Steven Lane – Sutter Health - Member

Well, I think the other piece of that, Terry, is store it and to have the ability to exchange them if you have them. But we're not demanding that you store them. Just that you have the capability to and that you then can exchange them.

Clem McDonald - National Library of Medicine - Member

Okay. As long as I'm clear on those modifications, I'm happy with it. Not modifications, those intentions.

Christina Caraballo – Audacious Inquiry – Member

Okay. So, are we okay with the language in the letter?

Andrew Truscott – Accenture - Member

Yeah. I thought that was around addresses, too.

Steven Lane – Sutter Health - Member

Wait, Christina, I don't think you responded to my alternate work/school address question. I just wanted to be clear what our intention was on that.

Christina Caraballo – Audacious Inquiry – Member

We do not have that in these recommendations.

Steven Lane – Sutter Health - Member
So, it was in an earlier recommendation. I gather we intentionally dropped that.

Christina Caraballo – Audacious Inquiry – Member
We did at one point. We can bring it back up for discussion.

Terrence O'Malley – Massachusetts General Hospital - Member
Steven, I think it was for simplification as you pointed out.

Steven Lane – Sutter Health - Member
Yes. I don't object. Thanks. I just wanted to be clear.

Robert Wah – Individual – Chair
I see Andrew and Carolyn's hands up as well. Do you have a comment on this particular area of the recommendations or on another area of the demographic set?

Andrew Truscott – Accenture - Member
No, particular to this one.

Robert Wah – Individual – Chair
Okay. Go ahead, Andy.

Andrew Truscott – Accenture - Member
So, an individual can have multiple addresses, which are currently associated with them as well. You have a principal address, potentially, and secondary addresses. But it's very, very easy and straightforward for an individual to have more than one. So, the singular current address as well as the singular nature of the previous address, which I think is a missed typo. I would suggest an update to this to allow for a plurality of current addresses as well as prior addresses to distinguish the fact that a prior address is a place you used to live. Whereas a previous address is different addressing for the same place because addresses do also change over time.

Clem McDonald - National Library of Medicine - Member
I have to say I don't get that distinction.

Andrew Truscott – Accenture - Member
It's a nuance that's embedded in some of the PAC type functionality, which postal services use whereas if I live at 123 This Street then, actually, every now and then, things happen like renumbering, etc., and that's now 123B or something This Street. I haven't moved. It's just a subtlety. My point would be that we should be able to cater for having multiple current addresses as well as prior addresses.

Christina Caraballo – Audacious Inquiry – Member
I think that might be getting complicated based on the discussions and feedback that we got in

our task force, especially by just the vendor capabilities. The recommendation or the proposal from ONC was address. And I think here we're recognizing that address alone isn't enough. So, multiple addresses that are kind of, as you said, plural addresses I think I would propose just going for a primary and supporting the multiple addresses to capture multiple addresses. But two primary addresses seems a little complicated at this stage based on the discussions we've had.

Andrew Truscott – Accenture - Member

Okay. Let's see what your recommendation would be then and we'll look at it then because I'm not quite sure what your suggestion is on the reword if at all.

Clem McDonald - National Library of Medicine - Member

I think that you'd have trouble getting clerks to get it right with a big line of people checking in to register. I mean, those distinctions that you've mentioned, not having multiple addresses.

Andrew Truscott – Accenture - Member

I see. That's why I'd leave it as purely multiple addresses because there are many different reasons for different addresses.

Christina Caraballo – Audacious Inquiry – Member

Yes. So, our recommendation is current and previous addresses. So, this slide was a typo and the recommendation do say both current and previous plural.

Andrew Truscott – Accenture - Member

If you reword to say current and previous addresses then, that would be fine. But that's not what the slide says right now.

Robert Wah – Individual – Chair

And I think what they've said is in the transmittal letter, it does say plural and the slide it does not, correct?

Andrew Truscott – Accenture - Member

No. I believe I said in the transmittal letter, the previous addresses were pluralized but the current address was singular.

Christina Caraballo – Audacious Inquiry – Member

I don't know that we have an agreement to do plural current addresses.

Clem McDonald - National Library of Medicine - Member

I think that we had a lot more rustling and figuring out. I still wonder how you go to a clerk who has got six people in the line that are going to get that right.

Andrew Truscott – Accenture - Member

I'm not disagreeing, Clem.

Christina Caraballo – Audacious Inquiry – Member

We could do the primary address. Put primary and previous addresses.

Andrew Truscott – Accenture - Member

Actually, my suggestion would be for you to consider just simply changing it to current and previous addresses.

Steven Lane – Sutter Health - Member

It seems like a pretty simple change. And to Clem's point, more and more people are entering their addresses online rather than with a clerk with six people in front of them.

Clem McDonald - National Library of Medicine - Member

I like that new phrasing.

Terrence O'Malley – Massachusetts General Hospital - Member

This is Terry. The transmittal letter says include both current and previous addresses.

Andrew Truscott – Accenture - Member

That's fine then. Perfect.

Robert Wah – Individual – Chair

All right. Andy, are you comfortable? Okay. So, Carolyn, did you have a comment about this specifically or on the larger set of demographic recommendations?

Carolyn Petersen – Individual – Chair

I have a question about Recommendation 4.

Robert Wah – Individual – Chair

Okay. Let's just complete this then, in terms of this address question. I think we're complete on that discussion unless there are other comments from the committee on this Recommendation 1. Hearing none, Carolyn, why don't you discuss Recommendation 4 that you want to discuss.

Carolyn Petersen – Individual – Chair

Thanks, Robert. Thanks, Christina and Terry. I just had a quick question about No. 4. This is the recommendation that ONC includes the individual with authority to consent to treatment and data use. In looking at the language in the transmittal letter, I note that it seems to address treatment and data use. But it occurs to me that in practice, people sometimes have someone that consents to day to day issues about treatment and data use by different individuals in their advance directive for larger issues like being removed from life support. I'm wondering if the task force has considered additional language noting that there should be the ability to include all of these different contacts for different purposes, healthcare related purposes.

Robert Wah – Individual – Chair

Terry or Christina?

Christina Caraballo – Audacious Inquiry – Member

Yeah. I think that's an excellent recommendation. And I think we can include it in the example. Right now, we just have the care for minors. We put care for minors and for individuals who cannot give consent. So, that was implied. I know we had discussions around this. But if we'd like to change the language to explicitly state that, I think that can be done.

Terrence O'Malley – Massachusetts General Hospital - Member

This is Terry. We were a little bit more general in the lead in because we said to include the individuals with authority to consent to treatment and data use. So, we kind of left it pretty broad. And multiple individuals could certainly be included. I don't know if that fully addresses, Carolyn, your concerns.

Carolyn Petersen – Individual – Chair

I'm thinking it could be helpful perhaps if there was, in addition to the field for the individual and the contact information, also a notation as to whether this is someone to contact for day to day treatment versus advanced directive types of decisions. For example, if I have day surgery and the physician is concerned that my vital signs aren't where they'd like them to be and they would like consent for me to remain in the hospital overnight for observation that could be a decision that I would be fine with a friend making. Whereas if something happens to me and I am no longer conscious and there is no brain activity, I'm really concerned more that family members who live in other parts of the country and might not even have been aware that I was having a day surgery be contacted for that decision. I think healthcare providers, certainly, are capable of recognizing the kind of consent they're asking for.

And if they are aware that they need to check with someone whose purview would be included in the advanced directive, they could note that if they were aware of which individuals were to be contacted for what types of decisions.

Terrence O'Malley – Massachusetts General Hospital - Member

This is Terry again. That's, again, kind of a very nuanced position. I'm just trying to think clinically. What usually happens is there's usually someone who is designated as the healthcare proxy who would be invoked if and when you were unable to make decisions on your own. And it's those level of decisions that we're concerned about. If you are competent to make your own decisions then, your healthcare proxy is not activated and the designation is really moot. So, I guess, what I'm saying is that I think this captures, in very broad terms, the need for someone who can consent for any treatment that you are unable to consent for and then, secondarily, share your information. I'm not sure that that level of detail is possible for us to parse out in a reasonable way.

Carolyn Petersen – Individual – Chair

I can't speak to the mechanics of building the functionality. My point simply is that sometimes individuals – the person that you wish to consent for treatment is not the person that you have

consented for life and death decisions like removing life support. In the real world, certainly, if a friend was taking me in for something, I would share with them the advanced directive. But if the health provider speaks directly to the friend who is supposed to hand it off to the people in the advanced directive, in the case of a life threatening situation doesn't understand that or the providers aren't clear or they're not understanding that the friend is not the person to deal with and the friend doesn't understand the depth of the decision, I think that it's possible that things happen that are not the wishes of the patient.

That's why I'm suggesting that there could be some way to indicate who can make local routine types of treatment decisions and who is required for the larger advanced directive type of decisions.

Christina Caraballo – Audacious Inquiry – Member

So, if we just add – right now, it says individuals with the authority to consent to treatment and data use including name, contact information, and relationship. If we do an addition of just authority level. I had a word in my head and I just lost it. But we could add that level of decision authority. What's the right word? Someone help me out.

Andrew Truscott – Accenture - Member

I'm not sure what we're actually recommending here. Can someone just encapsulate it?

Robert Wah – Individual – Chair

So, this is a discussion on Recommendation 4. I'll take a crack at it. I don't know if I have it right or not. But I believe we're discussing Recommendation 4. And Carolyn is bringing up an issue about the spectrum of people who can be listed in this authority to consent for treatment and data use. I'm struggling to capture that succinctly. And maybe, Carolyn, if you want to restate that and that's fine. But I'd like to try to find a way forward here. If we can either approve this group of patient demographic recommendations as a group and deal with this issue that you're bringing up because it needs to be separately or if there's a modification or amendment of Recommendation 4 that can be done that will capture that then, let's work on that.

Carolyn Petersen – Individual – Chair

Right. I'm looking at the language in the transmittal letter. And I think it could be fairly straight forward to add an additional sentence to that.

Robert Wah – Individual – Chair

Okay. Do you have a recommendation?

Carolyn Petersen – Individual – Chair

Yes. The text currently reads software should support the collection of the identity of the individual with the authority to consent to treatment and data use including name, contact information, and relationship. The added sentence could read software should also support the collection of the identity of the individual with the authority to make decisions included in the advance directive.

Robert Wah – Individual – Chair
Okay. Let's see how we can do this. Unfortunately, this is a PDF.

Andrew Truscott – Accenture - Member
Rob, can I contribute?

Robert Wah – Individual – Chair
Yes.

Carolyn Petersen – Individual – Chair
In the interest of time, would you prefer that I email this during the break and –

Robert Wah – Individual – Chair
I think we might be able to take care of this. Hold on. Let me see if I can do this on the fly. This is tricky trying to talk and type at the same time. So, I'm looking at Recommendation 4 in the transmittal letter. And tell me again where you want to make the change after software should support.

Carolyn Petersen – Individual – Chair
After that sentence, an additional sentence.

Robert Wah – Individual – Chair
After the entire sentence that says software should support, you want a new sentence?

Carolyn Petersen – Individual – Chair
Yes.

Robert Wah – Individual – Chair
Okay. Go ahead.

Carolyn Petersen – Individual – Chair
The software should also support the collection of the identity of the individuals with the authority to consent to decisions described in the advance directive.

Robert Wah – Individual – Chair
That is going to take too long. I can't capture that on the fly. So, can you type that out and send it to me? And let's do this. Let's take out Recommendation 4 from this group of demographic recommendations for right now. And very soon after you send that to me, I'll project what your recommendation of the change is. And then, we'll take care of that. So, are there other comments about the patient demographic grouping of recommendations? Andy, I see you have your hand up.

Andrew Truscott – Accenture - Member

Yeah. So, when you're considering – can you hear me?

Robert Wah – Individual – Chair
Yes, go ahead.

Andrew Truscott – Accenture - Member
Okay. When you're considering that consent directive related redrafting, it will be helpful if we ensure that we don't inadvertently exclude some of the other types of consent. So, privacy consent directives, medical treatment consent directives, research consent directives, and advanced care directives are like the four big blocks around consent. And let's just make sure we don't inadvertently have unanticipated consequence of excluding one of them as we're redrafting

Robert Wah – Individual – Chair
Okay. Is that a comment or a recommendation? I think it's a comment, correct?

Andrew Truscott – Accenture - Member
Well, it's a comment for whoever is drafting the recommendation.

Carolyn Petersen – Individual – Chair
I can email you offline, Andy, during the break and you can **[Inaudible] [01:25:41]**.

Andrew Truscott – Accenture - Member
Thank you, ma'am.

Cynthia Fisher - WaterRev - Member
Hi, this is Cynthia. I cannot raise my hand because I can't my app to work. So, I'm just commenting on from a patient's perspective, this does not have to be so over prescriptive because if we really empower the patients with their own information, I think of other applications that are used today in a more fluid way where the patient can be in control. And I'll give you an example. We just came off of Mother's Day. Many parents have their children go with other parents to a remote soccer tournament or someplace where they have to – you allow someone in a fluid way to be in charge of the healthcare of your child. And so, if you think of how Life 360 or Find My Friends work, you can simply time in a GPS locator or a visibility.

And there's no reason why we couldn't allow of open APIs or apps to empower the patient to time in and time out based upon circumstances the authority for different individuals to oversee the care of, for instance, a child or an aging parent or something like that. And those would be the care proxies. But they may be fluid. They may not be the advance directive. It may be circumstantial. But if we over prescribe the software has it built in just for that physician or provider encounter built into a clunky software system then, you don't have the real life fluidity is what I'm saying. So, my concern is over prescription of field requirements versus real life works in a much more fluid way. And if we truly move towards the future of how we live our life in apps today that should be empowered by the patient. I just throw that out there to say that I don't want us to over prescribe.

Robert Wah – Individual – Chair

Okay. And I think what I heard from the chairs was that they were seeking to be general in these recommendations and that couldn't be more all-encompassing. So, thank you for that. Other comments or questions about the patient demographic groupings of recommendations? Seeing none, except for Recommendation 4, which we're going to re-project soon, I'll take a vote on the recommendations under patient demographics to 1 through 7. All of those in favor of those recommendations, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Okay. Christina and Terry, why don't you move on to the next group?

Terrence O'Malley – Massachusetts General Hospital - Member

Okay. The next section is provenance. Can we have the next slide, please? Back one. Back one. There we go. Okay. So, again, we just sort of considered several use cases as we went through. Next slide, please. And ONC proposed author's organization, author and authors time stamp. And so, we have several recommendations following this. So, regarding the author organization, we recommend accepting that as proposed by ONC without any modification. And then, Recommendation 9 says that we also accept the author as proposed by ONC but with some following additions. And the addition 9A is that this should be required for certain data classes where the author is straightforward and important such as a clinical note, medication prescription where it's pretty unambiguous and knowing the author adds to provenance.

And Recommendation 9B is sort of the flipside of that that says if it's other than clinical notes and medication prescriptions, we should use the designation author's organization for all other data classes. And that encompasses 8 and 9. So, Robert, do you want me to just go through all of them?

Robert Wah – Individual – Chair

Yeah. Let's just do the provenance ones.

Terrence O'Malley – Massachusetts General Hospital - Member

So, we go to 12.

Robert Wah – Individual – Chair

Go ahead and do them all.

Terrence O'Malley – Massachusetts General Hospital - Member

Okay. And then, Recommendation 10 was to amend author's time stamp to be consistent with what we said in 9 and also change it to time stamp since we weren't sure whether it was going

to be the author or the author's organization. And I think the important point here was that time stamp is something for each locality to do. However, its system applies a time stamp that's okay. We're not proposing how to propose a time stamp or when. It's that the local system, most of which have audit trails, etc., are able to apply their own time stamp in order to assert provenance. And then, Recommendation 11 was to include some additional data elements. And one would be a unique organization identity. We were unable to come up with a good candidate standard or taxonomy for organization. But if there is one, our recommendation to ONC is to apply that because organization becomes a critical part of provenance.

And Recommendation 12 is the software should be able to indicate when the patient is the author of the data. And those are our recommendations for provenance.

Robert Wah – Individual – Chair

Okay. Great. Comments or questions about the provenance recommendations? Carolyn, I see your hand up.

Carolyn Petersen – Individual – Chair

I'll take it down for you.

Robert Wah – Individual – Chair

No problem. All right. Other comments or questions about the provenance recommendations that Terry just went through of 9 through 12? Okay. Hearing no comments or questions, let's vote on provenance Recommendations 9 through 12. All of those in favor of the recommendations please say aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Okay. Terry, next set.

Terrence O'Malley – Massachusetts General Hospital - Member

Okay. Next slide, please. On to clinical notes. And, again, these are the use cases that we consider in thinking about clinical notes. If we can have the next slide, please. So, ONC proposed the following eight clinical notes. Consultation, discharge summary, history and physical, image narrative, laboratory report narrative, pathology report narrative, procedure note, progress note. Next slide, please. So, the task force recommendations were to accept the consultation, discharge summary, history and physical, procedure note, and progress note as proposed by ONC. And then, we had additional recommendations regarding the other note types that ONC had called out. So, one was to amend imaging narrative as proposed by ONC to diagnostic imaging report. The reason for this is that this diagnostic imaging report type is rapidly gaining space. And it would be confusing and duplicative to include imaging narrative in the presence of a diagnostic imaging report.

So, we advise amending imaging narrative. Recommendation 15 was to omit the laboratory

report narrative because this is also contained within the laboratory results data class and we thought it would be duplicative. And for the same reason, omit the pathology report narrative, again, a duplicate for laboratory results. And I think the next slide, please. Then, we made additional recommendations for note types to be included. So, one is the continuity of care document. This was made popular in meaningful use attestation. And it's a commonly used note and is sort of a subset of what's in a discharge summary. We also wanted to include an operative note. And, again, you should note that these requirements really should probably only apply to settings where they are appropriate for the activities of that setting. So, if you're an ambulatory care practice, you probably don't use an operative note.

And you probably wouldn't necessarily be required to support it. Recommendation 19 was to include a miscellaneous note. Basically, a catch all for any other type of note where we don't have an appropriate note type for the information wishing to be transmitted. And this note type will change over time. It would be used differently at different times. But our one restraint on this was that if the information can be better transmitted in a more specific note that it should be. And the miscellaneous note should be left for things that have unspecified note type. And we are also proposing to include a transfer summary note. This is optional. So, the next three recommendations are optional for the coming version. And the transfer summary is an interesting document.

It contains all of the information that the next care team or site of care needs to continue the care of the individual safely and efficiently. It is different from the discharge summary. Its timing is different and its content is different. So, we're calling it out as a separate note type. And the next note, and I'm sorry, there's a typo here. So, 21 is okay. It's an advanced care planning note that is optional next year. And Recommendation 22 should actually be strike advanced. It should just be add a care plan note as optional in Version 1. And those are our clinical – if we could have one more slide. There we go. And then, the final two recommendations, this is a heads up for future iterations of USCDI. And that is we look to include a referral note. And then, finally, as a bridge between medical services and support services, include long term services and supports care plan note type. So, those are our recommendations for clinical notes.

Robert Wah – Individual – Chair

Thanks. Comments or questions on the group of clinical note recommendations ending in Recommendation 24? And I don't see any hands. I don't hear any comments. Let's go ahead and vote on this block of recommendations as Terry noted as a small, one word change in Recommendation 22 with deletion of advanced. All right. All of those in favor of the clinical notes recommendations, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Okay. Terry, next group.

Terrence O'Malley – Massachusetts General Hospital - Member

Next slide on. So, pediatric vital signs so really exchange of vital signs and calculated values. And

if we could go into the next slide, please. So, ONC recommended three items. The first two are calculated. So, one is a BMI percentile per age and sex for youth 2 to 20. And that really requires weight, age, and sex. And the second one, weight for length percentile for age and sex for youth 2 to 20. That also is a calculated value. And the third value, occipitofrontal circumference for those under 3 years old is a real standard measuring not requiring any calculation. That's an observation. So, our recommendation starting with 25 is that we accept BMI as proposed by ONC but with the following additions. And one is to require this data element if the IT system already stores it and otherwise require that weight, age, and sex are shared for all patients so that a recipient system can perform their own calculations using their own nomograms.

And we also said that you should require the storage of this data regardless of format whenever it's provided to the patient or guardian or to another clinician. The reason for these two comments is that Recommendation 25A is we recognize the burden of having to reprogram, to calculate and store this value when it may be something that just appears transiently on the screen and is used for real time clinical decision making. And the second one was to recognize that if you were having to store this, it didn't really matter what the format was. You could store it as a PDF or a screenshot of a nomogram. So, that's 25. Go on to the next slide, please. And 26 is basically the same argument, except that the way this element is phrased, weight for age per length, we're actually amending it to weight for length percentile by age and sex for youth 2 to 20 thanks to our esteemed family medicine practitioner, Dr. Lane.

And otherwise, the comments are the same as they were in 25. If you store it, send it. If you don't store it, send the basic data and that you must store it if you're giving it out to the patient or guardian. And then, finally, Recommendation 27 is accepted as proposed. And those, I believe, are all of the pediatric vital sign ones. We didn't have –

Robert Wah – Individual – Chair
Go ahead. Anything else, Terry? I'm sorry. I cut you off.

Terrence O'Malley – Massachusetts General Hospital - Member
No, I'm sorry. That's it.

Robert Wah – Individual – Chair
Okay. Andy, do you have a comment about the pediatric vital sign grouping of recommendations?

Andrew Truscott – Accenture - Member
Yeah. When we say the word require, who are we requiring?

Terrence O'Malley – Massachusetts General Hospital - Member
That ONC requires it as part of the certification for handling USCDI data.

Steven Lane – Sutter Health - Member
It's part of the core data set.

Andrew Truscott – Accenture - Member

Okay. So, we're saying if you're already doing it, we require that you do it.

Steven Lane – Sutter Health - Member

We're saying if you already do it, we're requiring that you send it.

Andrew Truscott – Accenture - Member

That's a nice distinction. I like it. Okay. I was just getting caught in a loop there. It would be nice to do stuff I already do. That's good.

Robert Wah – Individual – Chair

Okay. Other comments or questions about the pediatric vital sign recommendations? All right. Hearing and seeing no other comments, let's go ahead and vote on the pediatric vital signs recommendations that end in Recommendation 27. All of those in favor, please signify with saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? All right. Home stretch here. Terry, next.

Terrence O'Malley – Massachusetts General Hospital - Member

Next slide, please. So, we were also asked to comment on data elements that we thought might be included in some of the other data classes, which have been previously settled. And Recommendation 28 is that we are requesting demographic data for care team members. And it includes name, contact information, and some sort of identifier. So, this is to know who is on the care team. And I think subsequent renderings of this type of information can get much more granular in later USCDI versions down to the level of role, for example. But we thought we would start here in just getting the contact and who it is. Recommendation 29 is in the medication data class. We recommend adding the indication and/or associated diagnosis for each medication and that we make that a requirement in the USCDI.

And No. 30, which is the final one under the extra data elements is include a designation and address entry standards for individuals without a current fixed address. So, those who are homeless or displaced or refugees. And this is because it's such a high risk population and it's very difficult to do patient matching on folks who are temporarily without a home. So, we wanted to also include in this address the ability to put null so that you may have no address in your address entry. So, those were our additional recommendations for data elements we would propose to include in this version.

Robert Wah – Individual – Chair

Terry, why don't you go ahead and finish off with 31 and 32 as well and just complete this.

Terrence O'Malley – Massachusetts General Hospital - Member

Okay. Next slide, please. So, these are really two very broad issues that don't really neatly fit into any data class. And one is to begin a process to develop a quality measures data class. There's certainly a huge value in being able to exchange quality data between payers and providers, payers and patients. And we thought that the first step might be to construct a data class of measures that are currently in USCDI V1 that are used in quality metrics and bring them together in one place. In a sense, start the process of identifying data elements in USCDI that have a role in quality measurement. That's one recommendation. We just start the process. Where it leads, we'll see but begin. And then, the second Recommendation 32 is to begin a process again to assign a unique and persistent identity for each data element in a governance structure to oversee its use.

And this really gets to the heart of two huge challenges right now, which are data de-duplication and data versioning. So, these are our last two recommendations. And they are to begin the process.

Robert Wah – Individual – Chair

Thank you very much. So, we have before you the missing data element recommendations and the additional issue recommendations. Carolyn, do you have a comment on one recommendation?

Carolyn Petersen – Individual – Chair

Yes, I do, thanks. This question relates to Recommendation 28. I'm wondering if the task force had any thoughts or wanted to include language about how to deal with providers who don't have an identifier. I'm thinking, for example, if a situation perhaps where an older person is getting some exercise classes as an alternative to physical therapy in the community perhaps through a senior center or YMCA. And the individuals who teach those classes report attendance at the classes but they're not doing other types of provider type behavior like ordering medication or using decision support and thus, don't have a provider ID. Is there any thought to how that might be handled?

Terrence O'Malley – Massachusetts General Hospital - Member

Carolyn, it's a good point and we did address it. There are some folks who just do not have an identifier.

Clem McDonald - National Library of Medicine - Member

Can I insert? This is Clem. Taxi drivers, if they charge Medicare, they can for sure get one. Taxi drivers have them. And if they don't charge them, I think they can also get one but that I'm not as certain about.

Steven Lane – Sutter Health - Member

But, again, I think this is another one of those data elements where the language should be if you have it, you should send it as part of complying with USCDI. Obviously, if you don't have it, you don't have it.

Clem McDonald - National Library of Medicine - Member
Correct, yeah.

Carolyn Petersen – Individual – Chair
And the functionality would allow the transaction to go through without an identifier number?

Steven Lane – Sutter Health - Member
That would seem necessary.

Terrence O'Malley – Massachusetts General Hospital - Member
Steven, is that an amendment to include an identifier, e.g., if available?

Steven Lane – Sutter Health - Member
Yeah. I think that makes sense because I think we've done it that way with a number of other items.

Carolyn Petersen – Individual – Chair
Thank you.

Robert Wah – Individual – Chair
It sounds like we're talking about an amendment to Recommendation 28C, Charlie, where it says include an identifier and add the words where available.

Andrew Truscott – Accenture - Member
Steven, it's Andy. On this one then, how would you ensure or through policy or whatever that it's included if it is available as opposed to well, we just won't bother with that because it's optional now?

Steven Lane – Sutter Health - Member
I defer to Christina and Terry, although I also don't understand the question.

Terrence O'Malley – Massachusetts General Hospital - Member
The intent of the demographic data for care team members is to be able to really identify who they are and contact them. The identifier, in my mind, adds less than the first two. So, if it's optional and not included, I don't think we lose a great deal. If we have it then, it's one more way to pin down who it is that's on the care team.

Carolyn Petersen – Individual – Chair
I just didn't see any notation in the recommendation that the identifier is not required. That the lack of an identifier would not end the transaction.

Andrew Truscott – Accenture - Member
I'll go back to try and clarify my question. If we make the identifier optional, which there is a very

good reason why it should be, where we would believe it to be required, is it, therefore, a local policy decision on including it or not?

Terrence O'Malley – Massachusetts General Hospital - Member

That's a good question. We're going to punt that one to ONC because I think just include identifier if available. Then, it certainly will be a lot of local regs but it all depends on how hard ONC pushes to get that part of the certification. So, I will defer to ONC.

Andrew Truscott – Accenture - Member

Okay.

Robert Wah – Individual – Chair

So, first, let me just deal with this adding the two words if available or where available after the identifier. Do we want to make that amendment, Terry?

Terrence O'Malley – Massachusetts General Hospital - Member

Yes. I think that would be great.

Robert Wah – Individual – Chair

Okay. So, let's deal with that first. We're going to amend Recommendation 28C as in Charlie after the word include identifier maybe put comma where available. Does everyone understand that small amendment? Other comments or questions about that amendment? Hearing none, all those in favor of that amendment, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All opposed say no. Any abstentions? Okay. So, now we have the amendment to Recommendation 28C. And we have the entire grouping of missing data elements and additional issues. Any further comments on those recommendations? Hearing none, all of those in favor of the missing data element recommendations and the additional issues recommendations, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Okay. The last issue on USCDI is the comment that Carolyn made before about the additional information. So, I'm going to try to share my screen here with the verbiage that Carolyn proposes. And let me just see how we can do this. Hopefully, this is going to start coming across to you. I can get back to the screen. Are you all seeing this with the red letter modification?

Steven Lane – Sutter Health - Member

Yes.

Robert Wah – Individual – Chair

Okay. So, the verbiage is in red underline and bolded. I'll read it again for those that might not be able to see it. We're proposing to add the words software should also support the collection of the identity of the individuals with the authority to make decisions outlined in the patient's advanced directive including name, contact information, and relationship. Questions or comments about the addition of that language? Hearing none, let's go ahead to vote to amend Recommendation 4 with the language that you see displayed now. All of those in favor of this amendment, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Great. Now, we have amended the recommendation. Now, it's a vote on the amended recommendation. All of those in favor of the amended Recommendation 4, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Okay. I believe we've completed the USCDI recommendations. Am I correct? Terry or Christina, any final comments?

Terrence O'Malley – Massachusetts General Hospital - Member

Thanks to the task force for all of their really hard work and for the ONC support that made it all possible.

Robert Wah – Individual – Chair

And thank you to your leadership, you and Christina leading that group as well as your task force group. Okay. Now, we're a little bit behind. And we have somebody on the phone that can only be on for a limited amount of time. So, I'm going to immediately turn it over to Carolyn for the next group.

Carolyn Petersen – Individual – Chair

Thanks, Robert. We will move relatively quickly through this presentation because we are, in essence, recapping what we have previously discussed noting the changes that we have made based on HITAC feedback. And we will take your questions and, hopefully, be able to vote on the recommendations today. If I could have the next slide, please. So, this is the individuals that were on our task force. Next slide, please. And our overarching charge specifically looking at the 10 ONC recommendations from certification and criteria for supporting certification, the pediatric

technical worksheet, the S4P, and consent management for APIs, and ways that health IT can support the opioid response. Next slide, please. So, recapping, the summary of the ONC pediatric health IT recommendations, we recommend retaining the 10 pediatric recommendations for voluntary certification.

We've provided some recommendations for development or nonregulatory informational resources that are provided to additional technical support. Next slide, please. In summary, we have expressed great enthusiasm for the planned voluntary pediatric certification of EHRs as we are expecting significant improvements in the care of children and a reduction in burden for providers caring for the children. The task force further notes that these implementation considerations should be regarded as a starting point to achieving full pediatric functionality and that further work still is needed to prove and advance this functionality. We now have some sides that will highlight our edits. Next slide, please. With regard to Recommendation 2, there were some questions about the additional implementation considerations. We have noted in the right column that the minimum standard is limited to liquid enteral medications that are dosed based on weight.

Next slide, please. This has to do with the supplemental. Here we have additional implementation consideration to encourage more robust nomenclature development towards a standard in future to reference that would look at the USCDI and others as has been previously requested. We're also suggesting to allow the user to choose from a vendor provided terminology of authorized non-clinician viewers as requested by HITAC. Moving to the next slide, within the additional implementation considerations, we're noting that a user should be able to identify items that they want to be protected. This relates to the segmented access to information. And then, on the next side, this is Recommendation 7. We were additionally suggesting that we should distinguish authority to access a patient's data versus the medical decision making authority. Next slide, please.

This brings us to a recap of the request for information on health IT and opioid use disorder prevention and treatment. We had provided recommendations that ONC should consider for future activities. We have made no substantive changes since the previous HITAC meeting presentation. In that environment, we discussed some various topics around how health IT can support the treatment and prevention of opioid use disorder. And here are, again, the things that we had previously discussed and that HITAC had been in alignment with. Next slide, please. The task force had also discussed topics around health IT solutions and effective approaches to improve opioid prescription practices and clinical decision support for OUD. We were exploring issues of burden, usability, and trigger for CDS hooks implementation being as simple as possible, functionality at the point of care, and creation of a standardization order set to bring more effectively and quickly support into the treatment of this disorder. Next slide, please.

And finally, relating to the neonatal abstinence syndrome, we support the idea of health IT policies, functionalities, and standards to support providers engaged in the treatment and prevention of OUD. Next slide, please. This gets at the data segmentation for privacy and consent management for APIs certification criteria. ONC proposes to remove the current 2015 edition DS4P send and receive and replace them with three new criteria, two for the CCDA and one for Fyre. The task force supports this proposal and acknowledges that DS4P would help opioid management and provide greater confidence in sharing OUD information. We also recognize that

the consent management for APIs proposal would further aide in the exchange of information. The task force believes that with appropriate protections in place, health IT can help providers electronically use and share data.

We note that further work is needed to develop patient policy best practices for universal adaption. Next slide, please. In the previous meeting at HITAC, we received some feedback that there were concerns about data segmentation, specifically that providers are concerned about not being able to access all of the information about a patient and access to all of that data. So, we went back to our subject matter experts who presented to the task force and have put together this list of published resources that would help inform the development of the privacy practices that we believe need further work. These take a broad view of information that individuals somethings wish to protect such as that related to mental health and substance abuse, domestic violence, other types of trauma, things that relate to SDOH and to biases against particular populations and so forth.

We feel that these are resources that ONC, and that should HITAC take up this issue, use to inform the discussion and help develop more descriptive guidelines. Next slide, please. We also note three resources or historical purposes that may also be relevant in developing guidelines and policy around this area. This would have to do with the patient consent for electronic health information exchange interoperability, the health information technology privacy law and policy, and the health information technology reference all three here with URLs on the slide. Next slide, please. So, in summary, what the care continuum task force is recommending to HITAC would be to retain the 10 ONC pediatric health IT recommendations, to retain the correlated existing and proposed new or updated certification criteria, to remove or retain supplemental children's format requirements as identified by the task force, to support task force recommendations that ONC consider for any future activities related to the opioid use disorder RFI.

To support task force recommendations on the proposed DS4P certification criteria and the identified published resources to help inform the development of privacy practices. We have also sent out our transmittal letter with all of that language prior to this meeting. And we're now interested in entertaining discussion and we hope a vote on these recommendations.

Robert Wah – Individual – Chair

Thank you, Carolyn. Chris, did you have any comments?

Christoph Lehmann - Vanderbilt University Medical Center - SME

Well, Carolyn did a fantastic job. Thank you.

Robert Wah – Individual – Chair

We appreciate you dialing in. I know you have a time limit here. Okay. I see two hands up. Steven?

Steven Lane – Sutter Health - Member

Thank you. Back up on Slide 10, you have authority to access patient data. I would suggest a slight amendment that it says authority to access and/or release patient data. This was sort of gnawing at me during the prior USCDI recommendation but I think that those are probably, typically, the

same authority. I can't imagine a situation where they would be different. But it is the authority to access or release the data.

Christoph Lehmann - Vanderbilt University Medical Center - SME
I don't think that would be a problem.

Carolyn Petersen – Individual – Chair
So, your terminology was accessed and/or released patient data, is that correct?

Steven Lane – Sutter Health - Member
I think that makes it most flexible and clear.

Andrew Truscott – Accenture - Member
Isn't the word that you're using, Steven, access, exchange, or use?

Steven Lane – Sutter Health - Member
There you go. I like that.

Carolyn Petersen – Individual – Chair
Access, exchange, and/or use?

Andrew Truscott – Accenture - Member
Yeah. And that is the common language I was using as well.

Christoph Lehmann - Vanderbilt University Medical Center - SME
Often, the discussion was important to differentiate it from consent. So, that's why we didn't dive into the details. I do appreciate this amendment.

[Crosstalk]

Steven Lane – Sutter Health - Member
It doesn't need to be and/or. It can just be or, which, again, I think is the standard ONC terminology.

Robert Wah – Individual – Chair
Is this the right slide that's being displayed?

Steven Lane – Sutter Health - Member
No, I don't think it is. It was one of the three column slides. It was Slide 10 in the one that was sent around.

Carolyn Petersen – Individual – Chair
That's Recommendation 7. It is Slide 10.

Robert Wah – Individual – Chair
On this group, okay, here we go. I think this is it, right?

Steven Lane – Sutter Health - Member
Right.

Denni McColm – Citizens Memorial Hospital - Member
This is Denni. I'm sorry, I can't raise my hand. I don't have the Adobe up. But are we saying that it's one person that can access, exchange, or use or access or consent to release? Because in the real world, we have a lot of cases where people can access but they aren't authorized to release.

Steven Lane – Sutter Health - Member
That's why we've got or. So, this would simply say distinguish authority to access, exchange, or use patient's data versus medical decision making authority.

Robert Wah – Individual – Chair
We're talking about modifying the language that's highlighted in yellow on this current slide that's displayed.

Clem McDonald - National Library of Medicine - Member
This is Clem. My hand is up but if someone else's hand is up first, I'll wait.

Robert Wah – Individual – Chair
Clem, if you're on this point, go ahead.

Clem McDonald - National Library of Medicine - Member
I'm really worried about this whole DSP form. And I have been for a long time. So, 1) is there a better discussion on how that we can deal with the fact that narrative is included in lots of report and content?

Robert Wah – Individual – Chair
Clem, just a second. We're discussing modifying language that's currently displayed in yellow.

Clem McDonald - National Library of Medicine - Member
Well, I was responding to the report in total. Is there another place to –

Robert Wah – Individual – Chair
Let's hold that comment for right now. What I'd like to do is finish this discussion because there was a recommendation to modify the language that's highlighted in yellow on the screen right now about distinguish authority to access patients' data. And there was going to be some additional language there. So, I just want to finish that discussion and then, we'll move on to the next one. And can someone please articulate the language to be added to the highlighted yellow

language that we have on the screen?

Carolyn Petersen – Individual – Chair
Access, exchange, or release patient data.

Steven Lane – Sutter Health - Member
Or use.

Carolyn Petersen – Individual – Chair
Thank you.

Robert Wah – Individual – Chair
Read it one more time all the way through.

Carolyn Petersen – Individual – Chair
Distinguish authority to access, exchange, or use patient data.

Robert Wah – Individual – Chair
Okay.

Christoph Lehmann - Vanderbilt University Medical Center - SME
From medical decision making authority. I think that's really – the point was medical decision authority is different than having access to the data. And that's the point that still needs to be made. I appreciate the clarification, really, the important piece was the second part.

Andrew Truscott – Accenture - Member
A minor point on this same thing, you say patient apostrophe S data. I think you mean patients data with no apostrophe or actually patient data full stop. So, just patient data, not patients data. We don't want to get into the legal ownership thing.

Carolyn Petersen – Individual – Chair
Thank you.

Robert Wah – Individual – Chair
Okay. I think let's read it one more time. Distinguish authority to access, exchange, or use patient data –

Carolyn Petersen – Individual – Chair
From medical decision making authority.

Robert Wah – Individual – Chair
Okay. Is everyone clear on that?

Clem McDonald - National Library of Medicine - Member

This is Clem. On that point, does that mean the medical decision authority can't use it or they can do other things that this rule doesn't apply to?

Christoph Lehmann - Vanderbilt University Medical Center - SME

They are two different things. Just because you are the DCS worker who has access by court order given access to the patient's data doesn't mean that you have at that point decision making authority for the treatment of the child.

Clem McDonald - National Library of Medicine - Member

I'm looking at the other case. That is if they don't have the ability to use it, they can't do anything medical at all then, right?

Christoph Lehmann - Vanderbilt University Medical Center - SME

Yeah. Generally, the authority to – I think your point is well taken. Generally, the authority to make medical decisions also includes the ability to be able to access the data. So, Part 2 usually has the rights to Part 1. Whereas Part 1 doesn't necessarily have the rights to Part 2.

Clem McDonald - National Library of Medicine - Member

Okay. That helps my other worries.

Robert Wah – Individual – Chair

Okay. So, Sasha, you have your hand up. Are you wanting to speak on this specific point?

Sasha TerMaat – Epic - Member

No, I'm waiting for a different point. Thanks.

Robert Wah – Individual – Chair

Okay. Thank you for that. Okay. I want to take any and all other comments about this particular addition of these words to the yellow highlighted language that you see before you. Any other comments about that? Hearing none, let's close this out. Let's vote on the amendment to add those words in this yellow highlighted section. All of those in favor of adding that language, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Okay. If we're complete with that, we have, again, an obligation to the public where we have listed 11:45 as the comment period. So, I'd like to move to that and suspend discussion of this last set of recommendations. And then, we'll go back to this when we finish the public comment period. So, Lauren, I'm going to turn it over to you to run the public comments.

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

Operator, can we please open the line?

Operator

Certainly. If you'd like to make a public comment, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in the cue and you may press star 2 if you would like to remove your comment from the cue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

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

Thanks. And so we have any comments in the cue?

Operator

We have none at this time.

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

Okay. Robert, I'll hand it back to you. And I would just check offline to see if we get any additional public comments during the comment period. But I'll hand it back to you to continue the discussion.

Robert Wah – Individual – Chair

Thank you very much. Yes, just alert me if there is a public comment that comes online and we'll take a break and go back to that. Okay. So, let's go back to the summary slide is displayed. Sasha, you had a comment about the overall and, Clem, you are on the list as well so I haven't forgotten about you.

Sasha TerMaat – Epic - Member

This is Sasha. And I think that both Clem and I had questions about the DS4P provision. I had maybe a question and then, some contextual concerns. So, I appreciated the recognition from the task force of the need for policy to inform how a technical requirement like DS4P would be implemented because I do think that, and this is maybe a tribute to Arien who made the point in a previous meeting, there are significant governance issues related to how it would be implemented and used. When the task force recommends the development of privacy practices around DS4P, who would be doing that development?

Carolyn Petersen – Individual – Chair

We have not identified specific parties in that development. These are our recommendations to ONC but, of course, we can't dictate activity or future work.

Christoph Lehmann - Vanderbilt University Medical Center - SME

And, unfortunately, Sasha, it was just like everything related to pediatric informatics, we are the

red headed stepchild of the informatics world as we have to deal with 56 different state and territory privacy laws. So, I think there is a need for some federal effort in identifying some of these privacy practices. But, ultimately, a lot of this work will be dependent on what the local state and territory rules are.

Sasha TerMaat – Epic - Member

Thanks for clarifying that. I agree it would certainly be very helpful if the variety of local regulations could be expressed in a standard way. A machine readable way would even be better to help folks understand that.

Christoph Lehmann - Vanderbilt University Medical Center - SME

Amen.

Sasha TerMaat – Epic - Member

And then, I guess, just to give some of the concern for recommending DS4P whether it's for an opioid use case or a pediatric use case or both. I think that it is as proposed a very large development project. But I think that the proposed use cases are actually narrower than the way the standard is proposed. The Trade Association, the Electronic Health Records Association has been estimating the development impact of the different proposed requirements of this rule. And developers estimate DS4P as one of the largest projects that's proposed in the rule with an average development estimate of about 20,000 hours to incorporate it into one particular health IT product.

And that is a very large development project for something where I think there is still, as the task force has identified, a very large number of questions about how it would be implemented from a medical legal recordkeeping standpoint, from a safety standpoint, from a leakiness standpoint as Clem pointed out, when there are narratives within particular documents or particular health IT systems that won't be able to be filtered in a machine based way in the same fashion that structured data might be able to. And I think that all of those considerations would lead me to recommend that we focus on very specific use cases, maybe ones that come out of the most frequent of a particular state based variation to figure out some of these policy issues prior to the expectations of the broader proposal as written in the draft.

Christoph Lehmann - Vanderbilt University Medical Center - SME

And if I may respond to that, I think your points are well taken, Sasha. And I want to put it in a context. This particular task was given to us in addition to the pediatric certification on a side note. And the task force looked at it from a perspective of would this address some of the adolescent privacy issues that are so prevalent in EHR currently. And that's the angle from which we looked at it. And we concluded that it has potential. But I think the discussion that you are trying to trigger here is bigger than the task force work order. So, while it's appreciated, I think that discussion was outside of our scope.

Carolyn Petersen – Individual – Chair

This is Carolyn. I would also add that I think looking at specific use cases can be helpful in teasing out the variety and number of issues that relate generally to DS4P. However, there are some

issues that don't tie specifically to particular use cases. For example, the biases against people of particular ethnic backgrounds, people with disabilities, people who have had specific events in their prior life, whether those be medical like substance abuse or situational like spousal abuse or domestic violence. And really, our efforts are to provide some very general feedback and guidance about some issues that are expanded beyond particular use cases. I think that is part of it but certainly not all of the work that needs to be done.

Clem McDonald - National Library of Medicine - Member

Is it my turn yet?

Robert Wah – Individual – Chair

Clem, go ahead.

Clem McDonald - National Library of Medicine - Member

I have a number of concerns. One of them is the issue of patient care. And if the decision authority trumps the other things, I'd feel better about it. But that certainly has been clear to me in the past because the physician is not going to know what's going on. He's going to get sued. So, there are a lot of cases that could really screw up care. That's No. 1. And I don't think it's been addressed enough because the focus has been on the minority of people who have this privacy problem, not on the average person's got to get it taken care of. The second thing is the narrative stuff, I think, is best to this proposal. Almost everything is going to have the option for narrative in it and that means that you can't deliver any of it if it's got narrative. And that's what kind of knocked down the last round of proposals. That is it was just dealing with the narrative. And everything got knocked out. You couldn't send it.

And the third thing is the issue about the responsibility once you accept it has not been highlighted as I read the original thing. It might have changed. There are substantial penalties to screwing up if you get this private information once it's labeled as such. Much more than just regular data. And I think that should be highlighted and dealt with because that could really inhibit the interest in touching any of this stuff. And I work in the inner city and I've dealt with drug abuse and I've dealt with alcoholics. And my experience was they would tell you everything if they wanted to. And if they wouldn't want to, you wouldn't get it in this electronic form either. So, I have heard some vendors, manufacturers, this was two years ago, say it's not implementable, especially when you take the intersection with all of the different state rules. So, I think it's got to be given a lot of thought before it's going to be implemented in a severe way.

Carolyn Petersen – Individual – Chair

And I appreciate that comment and the thoughts behind that. I think that will be helpful for ONC as it goes forward in looking at how to work on the aspect of our charge.

Christoph Lehmann - Vanderbilt University Medical Center - SME

And just to add to that, I agree with you, Clem, that this is not going to be easy but one comment that you made earlier, in our discussion, we felt as a task force that the right of the individual patient to decline information to be known to physicians outweighs the physician's right to know everything about the patient. So, I understand that you as a physician want to know everything

there is to know that might have an impact on the treatment and diagnosis of your patient. But patients have the right to not share things with you. That's their prerogative.

Clem McDonald - National Library of Medicine - Member

If it were symmetrical then, a physician would have a right not to take care of them. But I don't think that's available.

Christoph Lehmann - Vanderbilt University Medical Center - SME

I think that clearly is not correct. Physicians can dismiss patients from their practice. And I think this is a personal preference of individuals that I think we're obligated to respect that potential choice. And this is what the task force, in this case, recommended. I can perfectly understand that there are different opinions on that.

Clem McDonald - National Library of Medicine - Member

I'm not disagreeing to have those rights. And, actually, what they'll usually do is just not tell it to anybody, which doesn't get into the complexity of what's in the record. I just think that we are rushing this thing ahead because there are clearly use cases, which would be useful. But the net might be very damaging to healthcare.

Robert Wah – Individual – Chair

Other –

Christoph Lehmann - Vanderbilt University Medical Center - SME

Yeah. I just want to say I appreciate that. We looked at it from the point of it has this potential to address some of the privacy issues that we are concerned about taking care of children or taking care of people with specific vulnerabilities and we saw potential. We don't disagree that this is a potentially double edged sword and it has to be done very carefully.

Sasha TerMaat – Epic - Member

So, just from a logistics perspective, are there particular recommendations the task force is making that are endorsing DS4P? I see it, for example, in Slide 9 on Recommendation 4. But then, the later parts are just about sort of developing a policy, not about endorsing the use of the standard, if I'm understanding correctly.

Carolyn Petersen – Individual – Chair

Sasha, I'm just flipping through the transmittal letter right now. We have what is stated in the – I won't read you all three paragraphs but the paragraph that speaks to recommendations states as an implementation consideration, the task force recommends that a user should be able to identify items that they want to be protected. The task force also acknowledges a need for the development of a minimal data set description to represent stakeholder consensus on what data is considered private. The task force notes that further work is needed to develop patient privacy best practices for universal adaption. And then, we identify the resources that we listed on those last two sides. But we are not making a specific recommendation in the format that we've seen with the previous two task force presentations.

Sasha TerMaat – Epic - Member

So, if wanted to amend or note the conversation we're having here to say, for example, that some of these concerns may be addressed prior to expecting the standard to be implemented or to note that in our voting, where would that be reflected?

Carolyn Petersen – Individual – Chair

We would need to adjust the text in the transmittal letter and it would be just part of paragraph text, pre-text.

Sasha TerMaat – Epic - Member

In 3.3.1?

Carolyn Petersen – Individual – Chair

Yes.

Sasha TerMaat – Epic - Member

Or 3.1.1?

Carolyn Petersen – Individual – Chair

In 3.1.1.

Robert Wah – Individual – Chair

So, I'm conscious of time here a little bit and I never want to limit our discussion. Perhaps a way to do this is, Sasha if you have proposed language changes for the transmittal letter now that Carolyn and you have sort of set the location, we can revisit that proposed language later today. But I don't think we have time to deal with it right now. Is that amenable to both of you?

Carolyn Petersen – Individual – Chair

Yes.

Sasha TerMaat – Epic - Member

Sure.

Robert Wah – Individual – Chair

Okay. So, I'd ask you to work on the proposed language you'd like to make in the transmittal letter, transmit that to Carolyn and myself, and we'll put it back into the conversation later today.

Clem McDonald - National Library of Medicine - Member

Sasha, I hope you can do something good there.

Robert Wah – Individual – Chair

Maybe if you and Sasha want to work on this together, that's great. But I'm just trying to move the conversation to the appropriate time we have –

Clem McDonald - National Library of Medicine - Member
Yeah. I'll call on her.

Steven Lane – Sutter Health - Member
And, Sasha, this is Steven. I'm happy to review a draft as well.

Robert Wah – Individual – Chair
So, Sasha, you've got lots of volunteers to help you here. So, Andy, any comment that you have here as well?

Andrew Truscott – Accenture - Member
Just briefly. I'm just looking for some clarity as to what Clem and Sasha are happy and can move forward with versus what we need to go back and revisit because I must confess, I listened to some very compelling discussion there and I am borderline ignorant in the specifics and nuances, etc., of pediatric care. But it sounds, certainly from Clem's comment that there is a double edged sword here. And we would have unintended consequences outside of pediatrics.

Robert Wah – Individual – Chair
Okay. So, what I believe we're at right now is to – and I don't mean to call Sasha out but because she brought it up and I think there was some discussion about the exact area of the transmittal letter but the language would fit I will, I guess, make her the focal point. But anyone who is interested in this proposed language, maybe offline you guys can have a conversation either on email or do you want to jump on the phone or whatever you all want to do. And then, I'll ask Sasha to be the point of contact to bring that information back to Carolyn and myself. And we will fit it into this discussion. I believe, however, we can move forward on the recommendations from this task force with the understanding that will revisit the transmittal letter exact language whenever this new opportunity comes up.

So, if I can, I'd like to call for a vote on the recommendations of the task force with the caveat that we're going to revisit the final language of the transmittal letter when the Sasha led group comes back. Is that, hopefully, amenable to everybody? Okay. So, any other comments or questions about this task force set of recommendations? I hear some background noise. Is that a comment? Hearing none, let's go ahead and vote on the task force recommendations, again, with the caveat that we're going to revisit the final language of the transmittal letter when we get the feedback from the group that's concerned about this one aspect. So, all of those in favor of the recommendations from this task force, please signify by saying aye.

All
Aye.

Robert Wah – Individual – Chair
All of those opposed say no. Any abstentions?

Clem McDonald - National Library of Medicine - Member
Yeah. This is Clem, I'll abstain.

Andrew Truscott – Accenture - Member
Abstain.

Robert Wah – Individual – Chair
So, I think I have two abstentions then.

Andrew Truscott – Accenture - Member
It's Andy. I abstain.

Robert Wah – Individual – Chair
Yeah. Andy and Clem, I think I have you down as abstentions. Great. So, we're about five minutes behind schedule but we would like to stay back on schedule. So, unfortunately, I'm going to take five minutes away from your break. Let's come back at 12:30. Is everyone clear on that? We'll be back here at 12:30 p.m. Eastern time. Thank you all and we'll see you back at 12:30.

[Break]

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Katie, is the public line reopened?

Accel Solutions LLC
Yes, we're connected.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. With that, Robert, I'll hand it back to you and Carolyn to open us up for the information blocking.

Robert Wah – Individual – Chair
All right. Great. Welcome back, everyone. I hope you had a good, albeit a little bit short, break. We're now into the information blocking afternoon. We do have a couple of other pending issues that we'll bring into the discussion as we can. But without further ado, we will turn it over to the chairs of the task force on information blocking, Michael Adcock and Andrew Truscott.

Andrew Truscott – Accenture - Member
Can you hear us?

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

We can hear you.

Andrew Truscott – Accenture - Member

Okay. I'm on the public line. I'm not into the presenter line. Okay. Could we go to the first slide, please? So, we worked through work group one and work group three with the committee before. And we have got some additional comments from task force members, which came through very late in the day on Friday evening. And as such, we haven't had a chance to work through that as a task force yet. We are doing so and then, we're going to come back to the committee with some updates around work group one and work group three then. What we're going to do in the meantime now is to work through the exceptions, regulations, recommendations, which we haven't had an opportunity to really delve into with the full committee. Is that okay, Rob and Carolyn?

Robert Wah – Individual – Chair

Okay.

Andrew Truscott – Accenture - Member

Okay. So, if we can move forward to work group two exceptions, please. And for those of you who have the draft recommendations up, we're jumping to Page 15 thereon, which is the beginning of the exceptions section. I'll let everyone catch up. And Mark Knee is going to share the original regulations drafts as well so people can see what we're actually commenting on. I can't share my screen because I'm not part of the presenter's view.

Mark Knee - Office of the National Coordinator – Staff

Hi, everyone. This is Mark. I think, actually, Katie is going to share her screen. So, Katie, can you pull up the draft of the rule that I just sent you and go down to Page 685.

Accel Solutions LLC

Sure, that was 685?

Mark Knee - Office of the National Coordinator - IB TF Staff Lead

Yeah.

Accel Solutions LLC

Okay, one moment.

Mark Knee - Office of the National Coordinator - IB TF Staff Lead

And just scroll down a little bit so we're focused on 171.201.

Andrew Truscott – Accenture - Member

That's the first – yeah. So, to begin with, our recommendation was that we said rather than writing the following, we actually say writing from any of the following. Okay. I can't see. Okay. That's Recommendation 14. Recommendation 15 is that we modify to read technically corrupt defined as data that has lost its base integrity and is no longer understandable by the information

technology system that created it or inaccurate data accessing a patient's electronic health records or intensive action exchange or use. That was purely so we could align the language with the use elsewhere in information blocking of access, exchange, or use and also provide some boundaries around the term corrupt. The intent was to make this technically corrupt and what that definition of technically corrupt means.

And we'll go back to these on screen shortly. Recommendation 16 was down in Section D, please. Can we scroll down? Section D, please. Mark, can you help navigate, please?

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

Can you just scroll back up a little bit?

Mark Knee - Office of the National Coordinator - IB TF Staff Lead

Sorry, we were on mute. What I was saying is I think you're on Recommendation 16, right, Andy?

Andrew Truscott – Accenture - Member

Sixteen, yeah.

Mark Knee - Office of the National Coordinator - IB TF Staff Lead

So, the issue is I think there is not a D section.

Andrew Truscott – Accenture - Member

Oh, sorry, yeah. It's to add it, yeah. You're right. Sorry, guys. So, at the end of 17, so 171.201, to add to the regulatory text as a sub item D that the practice should be documented in the electronic health record or system according to the EHI by the appropriate user with the exception arising from using Conditions A through C must contain the reasoning and criteria used of the judgment of the user who is engaging in the practice under this exception. So, basically, the point here is if you are claiming an exception in the first boundaries around this then, you actually have to record that you're claiming that exception.

Robert Wah – Individual – Chair

So, Andy, I understand what your goal is here. But it might be easier to stay with the slides than putting up the text of the proposed rule.

Andrew Truscott – Accenture - Member

That's fine. I'm happy to do it that way. In about 10 minutes, you'll say can we have a look at the original text as well.

Robert Wah – Individual – Chair

No, if somebody has a question about the original text, I think we can move back to it. Let's try it this way. Let's go back to the original slides that you prepared for the presentation. Everybody else has had a chance to review. Everybody also remembers the 700 pages in the rule but I don't think they're going to want to – so I think it might be a little easier to go through the prepared

slides for right now.

Andrew Truscott – Accenture - Member

I'm happy to. It's why we prepared them. So, Recommendation 16, I'll just quickly go over is basically saying that if you claim an exception under preventing harm that you need to record why that exception exists. Recommendation 17, use practice. We found that to be slightly confusing so we suggested perhaps rephrasing that to say that if a practice relies on organization policy. So, just the use of the term practice could mean something different in a clinical sense to what was actually intended by this regulation. So, we made that suggestion. Recommendation 18, please. Next slide. We recommended adding a sub item to the regulatory text in B. Again, those organizational policies should be reviewed by the organization to ensure consistency with the regulations so that there isn't a conflict between organizational policy and the information blocking regulations.

Recommendation 19 was we recommended some clear guidance in the preamble of when this exception should be utilized and leveraged. And we should **[inaudible] [03:07:12]** exceptions for other purposes like infeasibility and maintenance. So, just give some clear examples so organizations are completely aware of where these exceptions are appropriate and where they're inappropriate. And then, lastly, in the preventing harm section, we recommend that they consider adding some specific examples of where the prevention from harm from corruption or inaccurate data can interact with that exception for infeasibility as well. So, this is just using the preamble to provide clarity as to the intent of the regulation. That's the entire section on preventing harm. Has anybody got any questions?

Robert Wah – Individual – Chair

Thank you. So, I think we will take these pretty much as a group. We may need to modify this plan as we go forward because we have a lot of recommendations here. But I'd like to try to group these under preventing harm right now. Any comments or questions for the task force chairs on the preventing harm set of recommendations that we just heard from Andy? All right. Hearing and seeing none, let's go ahead to vote to approve these recommendations under preventing harm that ends on Recommendation 20. All of those in favor of the preventing harm recommendations, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

Any opposed say no. Any abstentions? All right. Andy, next set.

Andrew Truscott – Accenture - Member

Thank you, team. The next section, promoting the privacy of EHI. So, the task force believes that legitimate privacy concerns are absolutely a sound basis for an exception to the information blocking provision. The task force does, after much discussion, believe that there should be these following recommendations and there are six of them that should be incorporated into the final rule. First up, we do recommend having language to those organizational policies should comply

with both federal, state, and local law. Recommendation 22, we're recommending that where express consent or dissent is given that that should be documented and recorded. Recommendation 23, we recommend that where a reference to notice is made, rather than saying that notice should be meaningful it should be clear and prior. So, just to give that definition around what is meant by meaningful.

Obviously, meaningful is a term, which is imbued with many different meanings to misuse it, to define itself. Recommendation 24, we're recommending that where organizational practices are extra to HIPAA and other legislation, they should be clearly forbidden. So, we gave an example here. Policies that restrict transmission to an individual's file email where that is the requested form and format of access by the individual. So, where organizational policies go beyond that which is reasonably required to conform to legislation and those practices should be forbidden from taking place. Next slide, please. Recommendation 25, we believe that the final rule should implement policies, which ensure compliance with patient consent to information sharing or patient consent of a lack of an information sharing because the patient is fully within their rights to say yes I consent to this or, actually, no, I dissent to that and express those sentiments and feelings.

And then, lastly, the task force is recommending that if an actor functions in multiple states, some of which have more restrictive laws then, the actor should implement policies and procedures that accommodate those more restrictive laws only in circumstances where they're required and not extend that greater restriction to situations where they're not required by law. So, for example, where you have a multi set of either, rather than saying we're going to have one organization policy, which manifests the most restrictive privacy laws that we have, actually, we believe as a task force that that would be too far. And the provider should actually implement laws within the locales that those laws are valid. That's the end of the section on the promotion of privacy of EHI.

Robert Wah – Individual – Chair

Andrew, did we lose you? Oh, I'm sorry. You were breaking up there at the very end. That's the last of the promoting privacy of EHI recommendations, is that right?

Andrew Truscott – Accenture - Member

That is correct, yes.

Robert Wah – Individual – Chair

Okay. So, we're taking now discussion questions or comments about the set of recommendations under the heading promoting the privacy of EHI. Any comments or questions? Hearing nothing on the hands raised, hearing nothing, let's go ahead and vote to approve these recommendations. So, the vote is to approve the recommendations under the heading of promoting the privacy of EHI ending in Recommendation 26. All of those in favor of these recommendations, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Andy, back to you.

Andrew Truscott – Accenture - Member

Thank you, sir. So, promoting the security of EHI, next page, please. So, the task force, in general, is concerned that actors may leverage this exception to affect information blocking masquerading as a legitimate concern to protect the integrity of patient information. As such, Recommendation 27 where we're recommending that if the entity requesting patient information can reasonably be considered legitimate and that they have past the relevant authentication mechanisms and can reasonably leave appropriate organizational policies in place to protect patient information, ignorance of that request as specific controls is no reason to claim this exception. So, what we're saying an actor can't say just because I'm unaware of exactly the controls you have in place to protect patient information, I can't say no I'm not going to share this with you because you are a provider organization who could be reasonably expected to have those in place.

I have to share. Recommendation 28, we recommend a modification to the regulatory text to request that if the requester is the patient so the data subject themselves and the patient is fully informed to the risk of their information not being appropriately secured, the exception cannot be claimed. So, if the patient says I want you to do this and the patient is saying I get the security concerns allowing me to have the information, etc., you still can't say, actually, you don't know what you're talking about or we're not going to share because we don't know exactly what controls we have. So, we're saying that we want to empower patients to be able to make their own decisions around this.

And then, Recommendation 29, we're talking about actors should not have the flexibility to adopt security practices even when grounds in some standard that are commercially unreasonable where it could lead **[inaudible] [03:14:58]** for sensitive data in ways that limit and restrict access to data for permissible purposes unless there is some overriding legal obligation. So, here's a good example. As an example, although FedRAMP High or SIG High are defined standards requiring FedRAMP High ATO as a standard for any data requester will still deliver interoperability unless there was some overriding concern. And there may be several here around military health service or BHA records that might contain relevant data to national security. So, those are the three recommendations around promoting the security of EHI from the information blocking task force.

Robert Wah – Individual – Chair

Comments or questions on the three recommendations under promoting the security of EHI? Hearing and seeing none, all of those in favor of approving Recommendations 27 through 29 under the heading of promoting the security of EHI, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Great. Next set.

Andrew Truscott – Accenture - Member

Thank you very much. Okay. Recovering costs reasonably incurred. So, this is I anticipate some discussion here amongst the committee. And I would also call on my task force colleagues to help reflect some of the discussion points we've had because this was a topic of significant discourse for us. So, the task force believes that there's going to be a high practical burden to apply the combination of both 171.204 and 171.206 to determine appropriate fee structures. And by splitting the discussion about permissible fees over two separate exceptions, the proposed regulatory text does obscure the critical decision of which fees are permissible and impermissible. So, we fully understand that the intent of the drafting was to address problematic pricing behavior by discouraging rent seeking behavior and extractive pricing whilst providing for market based pricing to allow innovation.

As such, the task force believes that the net force at the proposed rule will be to raise prices by raising compliance burdens, accounting controls, pricing controls, and other pricing compliance activities and limit the supply from value added interoperability services across all players inside of the healthcare ecosystem. So, the combination of the broad definition of EHI, the broad definition of health information network, and the unlimited applicability for the original drafting of 171.204 and 171.206 for all actors and all access exchange and use have the affect of putting nearly all interoperability products and services under federal price controls. And this approach lumps all interoperability in the category of problematic rent seeking behavior requiring regulation.

It places, for example, standards placed EHR interoperability interfaces where high prices disincentivize access and discourage an actor from making interfaces self service and innovative services such as a patient comparison shopping and bill payment or AI based risk scoring on exactly the same footing. And the task force believes that this sets the price for interoperability. This should be built into too high where it discourages value added services from discovering the appropriate market based price. So, the task force finds that pricing related to access to what various members term the "legal medical record" or "the designated record set" and/or the raw data of the record is the most problematic with respect to information blocking. The task force also finds that intellectual property rights essential to basic access are critical. And we accordingly believe that pricing regulations should be targeted to those fees that impede what might be termed basic access.

The task force believes that basic access should be defined as activities essential to represent and interpret clinical pricing and related data in certified exchange standards. Along these lines, the task force has discussed the term reasonable with respect both to IPR and cost based pricing. So, that's 171.206 and 171. 204. And the task force believes what is reasonable varies according to the type and class of interoperability capability. In particular, the task force believes that a lower feel is reasonable for essential capabilities that define certified standards based exchange of the legal medical record held, for example, in an EHR. In other cases, such as the value added services not essential for basic access or essential for ordinary exchange and use, what is reasonable should be defined by the market mechanism. So, as such, we're recommending these nine recommendations that we have here.

So, I'll attempt to go through them at a pace. So, if possible, we recommend the combining of the regulatory text supplied for 204 and 206 into a single allowance for the exception duly defines what's allowed and disallowed for fee categories. And ONC uses terminology to distinguish between pure cost or expense recover with no provision for marginal profit where this is intended and use terms such as "cost based pricing" where marginal profit is allowed and "market based pricing" with no restrictions needed. Recommendation 32, where cost based pricing mechanisms are required, the task force recommends that the method for assessing the cost basis be reasonably associated with the complexity or costs of providing capabilities. So, such methods could include reasonable heuristics estimates or other common new methods.

For example, the size of an organization as **[inaudible] [03:21:18]** are commonly used **[inaudible] [03:21:21]** to define pricing for exchange services because revenue and expenses are commonly available and directly correlated for patient flow and that is correlated with data volumes. Requiring activity based accounting mechanisms sufficient to account for the direct cost of providing, for example, access services is burdensome and is not a common or usual accounting practice. The task force believes that reasonable heuristics or estimates or sufficient to avoid arbitrary fees that could constitute information blocking without facing undue burden on access. I'm pretty certain there's a lot in there to go through and I appreciate that everyone has been looking at this outside. Is that a question?

Robert Wah – Individual – Chair

I don't believe so. Keep going.

Andrew Truscott – Accenture - Member

Recommendation 33, next page, please.

Cynthia Fisher - WaterRev - Member

This is Cynthia. Just on Recommendation 32 and what you're saying is there is some plain English – your last sentence in 32, I think, exemplifies complexity unnecessarily built in. I think I'm on this committee but trying to understand what you're saying in 32 is not simple. And I think we have an opportunity to not make this more complex than someone can just basically understand what you're saying. You have 33 up but I have 32 up if you would look at 32.

Andrew Truscott – Accenture - Member

Okay. Cynthia, thanks very much for that. And I think you're right. And one of the reasons that we're making these recommendations is to reduce the complexity. And yes, you've been an integral part of the task force as we've been forming this language so take into account your concerns.

Cynthia Fisher - WaterRev - Member

Well, this is a valid concern. Just even reading the last sentence of 32. What's being said there? I don't understand. And I think we owe it to ourselves to just be very clear.

Steven Lane – Sutter Health - Member

Cynthia, can I take a stab?

Andrew Truscott – Accenture - Member

Please do, Steven.

Steven Lane – Sutter Health - Member

I think the co-chairs have worked hard on this language. Essentially, what they're trying to get at is that pricing by the size of the customer organization is a reasonable heuristic and a reasonable way to do pricing. It's one that's done a lot in our industry. And they're trying to include in this recommendation the idea that that should be allowed to continue.

Andrew Truscott – Accenture - Member

And the counterpoint is that other types of accounting might not be appropriate or reasonable. Cynthia, what's your confusion on that sentence?

Cynthia Fisher - WaterRev - Member

I just look at Section 32. The entire bucket could be more clearly stated. And I think it's – I guess I push to what ONC's intent was and where recommendation 32 differs and being very clear about that.

Arien Malec - Change Healthcare - Member

Maybe I could take a stab at it just in terms of language even though –

Andrew Truscott – Accenture - Member

Go ahead, Arien. We were rewriting this. Go on.

Arien Malec - Change Healthcare - Member

Even though I'm responsible for some of the unplain language. So, ONC was concerned about pricing practices that could be discriminatory. And in particular, they were concerned about pricing practices that would discriminate based on the value the data could provide to various actors. And so, they wanted to make sure that you didn't have pricing practices that charged some groups of actors more than others where those weren't tied to the cost and complexity of providing access. At the same time, one of the categories that they included was the size of the organization, revenue, cost.

And it turns out that these are really useful proxy measures for size and complexity of an organization. So, for example, if you just tell me the operating expense for patient revenue of a hospital, I can guess at how many visits, beds, and other kinds of measures that are more directly – how many interfaces are more directly tied to the cost of providing interfaces. So, what we're trying to do here is to say hey, we get your intent but these particular categories like operating expense, operating revenue are really useful ways of looking at the cost and complexity of providing interoperability services for a particular actor and they should be allowed to stand.

Andrew Truscott – Accenture - Member

Thanks, Arien. I think that's very helpful. I think part of the complexity that Cynthia is referring to is because our overarching recommendation is to collapse the two regulations into one. And, Cynthia, we concede to – if everyone is happy with the sentiment then, it might be that there is some rewording in the final version of the transmittal letter to make it more accessible. Okay?

Cynthia Fisher - WaterRev - Member
Thank you.

Andrew Truscott – Accenture - Member
Let's move on to Recommendation 33 now.

Denise Webb – Individual - Member
Andy, this is Denise. Let me just say one thing. I had my hand up. I wasn't close to this work. I was on the task force and I was the one that I didn't know I was not on mute but made a comment that said oh, yeah, that makes sense. I actually think you all dealt with a very difficult area, the work group did. And for me personally, and I wasn't close to this, I thought 32 made sense. But maybe that's because I come from that world, the HIE world and all of that and how they set rates.

Andrew Truscott – Accenture - Member
Thank you, Denise.

Denni McColm – Citizens Memorial Hospital - Member
I'm sorry, I'm not on the Adobe. This is Denni. Can I have a second?

Andrew Truscott – Accenture - Member
Go ahead.

Denni McColm – Citizens Memorial Hospital - Member
I'd just like to say that from a provider's standpoint, sometimes, vendors deliver to us the exact same thing, one radiology interface. Yeah, because we're a little bit bigger, we might use three or four times. They did the exact same thing. They just charge more because we're bigger. So, could it be worded to –

Andrew Truscott – Accenture - Member
Denni, are you making a suggestion for a change?

Denni McColm – Citizens Memorial Hospital – Member
Well, I'm sorry I haven't been in the task forces. I should have. There are cases where **[Inaudible] [03:28:25]**.

Andrew Truscott – Accenture - Member
I'm sorry, Denni, you're breaking up to me. Are you breaking up to anybody else or is it me?

Denise Webb – Individual - Member

She's breaking up.

Cynthia Fisher - WaterRev - Member

I'm sorry, who is commenting, please?

Denni McColm – Citizens Memorial Hospital - Member

Denni McColm from Citizens Memorial Hospital. So, I was just saying that sometimes, it's appropriate to use size and complexity of the organization or some proxy for that. But sometimes, that's applied when it's not appropriate. And I wonder if that's not what ONC was trying to get at.

Mark Knee - Office of the National Coordinator - IB TF Staff Lead

Hey, this is Mark. And, Arien, I think it might be a good time to maybe just have some clarification. Can you explain the difference with this recommendation as compared to what ONC is proposing as far as the factors for considering costs? Because a lot of what you're saying, I think we talked about it, is similar to what we have in there. But I think you're proposing a different approach really. And can you just explain that to the task force a little bit more or to the whole HITAC a little more clearly?

Arien Malec - Change Healthcare - Member

Yeah. I think Andy is going to get into the later sections, which deal with the proposed approach. This is more than if you have factors to look at pricing discrimination. And maybe the nuance to the comment that was just made is that where OE or patient revenue is directly associated with volume or directly associated with cost and complexity that those are reasonable heuristics. The pricing language in 171.204 specifically prohibits the use of revenue or profit or margin or expense as factors for pricing. So, this is more by way of making sure that if ONC includes those factors that they are used as heuristics directly tied to volume cost and complexity providing interfaces. And to the previous point, not as arbitrary mechanisms for increasing or decreasing prices.

Mark Knee - Office of the National Coordinator - IB TF Staff Lead

Yeah. I don't know that that's in conflict with what we have in the rule. But as you said, I think it's in the larger framework of what maybe you're recommending.

Andrew Truscott – Accenture - Member

Bear in mind that we are proposing here, as I said earlier, a collapsing of two existing regulations into a single one. And we just want to lay clearly out the basis for that single one.

Arien Malec - Change Healthcare - Member

And the good news is if you actually think it's already in line and we were just confused then, it should be an easy fix.

Andrew Truscott – Accenture - Member

Okay. I'm going to move on in the interests of time. Recommendation 33, next page, please. So, the task force is recommending that ONC clearly distinguishes between basic access and other forms of value added access. So, we've tried to help here with a definition of what that basic access would entail. So, it's to data for facts about the patient or patients, to the legal medical record or the designated record set as a defined term, including perspective patient specific pricing for procedures, etc., through standards. So our access is basic in terms of this information and then, the access is provided through standards from the core standards list is reasonably required to enable exchange or implement the intended use of certified technology. So, the example there that we get there is around the use of lab interfaces that results in order capability or script standards for prescribing capability, etc.

So, that's the kind of scoping out of the basic access. And we include one note in there. Patient specific pricing for procedures as well. And then, we have other forms of value added access, exchange, and use. And we give some examples there. Infrastructural systems, translation capabilities, decision support capabilities, AI or machine learning, providing novel or clinically validated rendering of data. So, some broader value added type capabilities that could be provided as well. No one has got their hand up so I'm going to assume I can just move on to 34.

Steven Lane – Sutter Health - Member

Sorry, I'm not moving fast enough here.

Andrew Truscott – Accenture - Member

Go on, Steve. I saw your hand come up.

Steven Lane – Sutter Health - Member

I question the words or clinically validated. I would hope that many renderings of data are clinically validated. I think the point here is that novelty that you're trying to get at. So, I would propose removing or clinically validated.

Andrew Truscott – Accenture - Member

That's fine. That's an example. I think we might have a quick discourse with you about new actors coming into play who might provide more consumer driven type services to render data as opposed to those renderings, which have been coming from more of a clinical background. But I take your point. And if everyone is happy with me to drop or clinically validated from there then, that would be fine. Is that a recommendation, Steven?

Steven Lane – Sutter Health - Member

That's my proposed amendment, yes.

Andrew Truscott – Accenture - Member

Okay. Robert, do you want to vote on that proposed amendment right now?

Robert Wah – Individual – Chair

Yeah. Why don't we take that now while it's still on the table? I think that's probably easiest to do.

Andrew Truscott – Accenture - Member
So, to remove the words or clinically validated.

Robert Wah – Individual – Chair
And that's on which line now?

Andrew Truscott – Accenture - Member
It's on the last line of Recommendation 33.

Robert Wah – Individual – Chair
Okay. All right. Other comments or questions about this proposed amendment to remove these words –

Andrew Truscott – Accenture - Member
Yeah, Ken Kawamoto.

Ken Kawamoto – University of Utah Health - Member
No, I'll go after this amendment is discussed.

Robert Wah – Individual – Chair
Okay. Great. Other comments or questions about this proposed amendment to remove the words at the end of Recommendation 33? Seeing no other hands or comments, the amendment would be to remove those words clinically validated, is that what we're doing?

Andrew Truscott – Accenture - Member
Or clinically validated.

Robert Wah – Individual – Chair
I'm sorry, three words or clinically validated. I just want to make sure that everyone including me understands. Okay. All of those in favor of this amendment, please signify by saying aye.

All
Aye.

Robert Wah – Individual – Chair
Anil, you're not talking about this point.

Anil Jain – IBM Watson Health - Member
I was but I think there is probably just a bunch of words that got jumbled here. But I think the whole point of that last part of that sentence was to be sort of clinically enriched. And I think it's

already captured in other parts of that sentence so I think it's good if we strike it. But I think the word clinically validated really wasn't what was intended here.

Robert Wah – Individual – Chair

Okay. I didn't mean to stop in the middle of voting but I want to make sure we get all the points made. So, let's start that again. We're voting to amend Recommendation 33 to remove the word or clinically validated. All of those in favor of that proposed amendment, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? So, it's amended Recommendation 33. So, I'm going to – Ken, did you have a point that you want to make on what's already been discussed or do you want to let Andy continue on through the recommendations?

Ken Kawamoto – University of Utah Health - Member

If I could just ask a question around 33. With the pricing, is that included in – maybe I missed it. Is that included in USCDI because it's listed as basic? For example, for medications, if it's not readily available or easy to do at all now, I just question it being called basic when it's actually certainly not basic functionality in terms of what we're able to get now.

Andrew Truscott – Accenture - Member

So, let's go across our USCDI co-chairs for comment.

Arien Malec - Change Healthcare - Member

Hold on, this is Arien. Basic does not necessarily mean easy. So, I think the perspective here is that the patient has under their HIPAA rights and also under the broader set of policy direction of the nation has the right to perspective pricing for procedures. And where that's available that should be part of the basic access. Nobody is saying that it's easy or readily available via standards.

Ken Kawamoto – University of Utah Health - Member

I guess maybe just clarifying that. Just asking if we're saying and this is related to, I believe, APIs and we're saying you can't –

Arien Malec - Change Healthcare - Member

This is not related to APIs. Just as a point of clarification, the information blocking is not specific to APIs. It's related to any activity that impedes access, exchange, or use. And we're seeing, in this case, to make sure that we're appropriately limiting the pricing restrictions relative to access, exchange, and use to make sure that we have the broadest amount of information flowing. And as part of that, we wanted to make sure that that broad amount of information did not preclude patients that are price transparency.

Ken Kawamoto – University of Utah Health - Member

Just to clarify, basic access is being defined by it is required by law, is that, basically, how its basic access is being defined?

Arien Malec - Change Healthcare - Member

Probably, the best way is just to – again, I think there is some confusion between information blocking relative to the API section of the information blocking rule and then, the more generic information blocking provisions, which are in Section 171. If you look at Cures, Cures requires access, exchange, and use for all information not subject to API. So, ONC did some work to take the information blocking requirements and apply them specifically to APIs. Where I think you're commenting quite appropriately that we just don't have the standards enablement for this right now. But this section is much more general and broad relating to Cures provisions for making sure that any actions that would limit access, exchange, or use are permissible.

And here, we're trying to make sure that we're providing the appropriate distinction to enable broad based access while preserving the ability to offer value added services to industry. And then, we're seeking in the definition of basic access to the extent that perspective pricing information is available to make sure that that's clearly included as part of that basic access. So, hopefully, that clarifies it.

Ken Kawamoto – University of Utah Health - Member

Go ahead.

Cynthia Fisher - WaterRev – Member

This is Cynthia. I had my hand raised.

Andrew Truscott – Accenture - Member

I'm sorry, Sasha had her hand raised first, I'm afraid.

Sasha TerMaat – Epic - Member

Oh, thanks, Andy. So, I had, I think, a similar concern to Ken in particular because Recommendation 33 is pretty related to Recommendation 36 where the task force is proposing that anything that's in this basic access category not be allowed to have any profit because it would be pure direct cost recovery basis only. So, that's a pretty dramatic assertion if there are software development or technology developing projects that would have to be done at cost with no opportunity for profit. Recommendation 36 expects those to be minimal because they're expecting widely deployed consensus based certification standards, minimal direct costs.

And then, we need to, I think if Recommendation 36 is to stand, ensure that Recommendation 33 is crafted in a way that actually relies on those same standards in an appropriate way or we will inadvertently apply broad pricing no profit restrictions to large sections of the industry. I agree I guess, with Ken that I think Recommendation 33 could be more precise.

Andrew Truscott – Accenture - Member

Okay. Thank you, Sasha. Cynthia.

Cynthia Fisher - WaterRev - Member

Yes, thank you. I think there's one significant thing is that patients not having access to prices is information blocking. And so, one of the things in this proposed rule is that we want to make sure that patients do have broad access to seeing prospective pricing. To my understanding, there is a standard already and Arien was right that the patient right to access under the HIPAA definition is inclusive of payment. And there's already an existing standard, to my understanding, for payment and existing protocol for the exchange of data of payment. So, prospective payment is pricing. And from the patient's perspective, if we don't get price is part of information blocking. It is something that is drastically being blocked from patients' awareness today in their choices of their co-pays, their payments, and the portion of their wages that goes to premiums and insurance.

That being said, I'm also concerned about the language that says including prospective patient specific pricing for procedures. So, patients not only having their own patient specific pricing is good but patients also need broad access to pricing for procedures and empowerment of choice. So, I guess, I just would say that we don't want to be limiting down a narrow rabbit hole the patient's view at pricing. And I think we want to give them broad access of pricing through those providers and payer relationships. Thank you.

Andrew Truscott – Accenture - Member

Thanks, Cynthia. Are you suggesting then, just for clarity sake, that patients should have access to broad pricing that has not been individualized for them?

Cynthia Fisher - WaterRev - Member

As well as individualized.

Andrew Truscott – Accenture - Member

Correct. Yeah. As well as.

Cynthia Fisher - WaterRev - Member

Then, I would also respond to Sasha to say the cost of doing business is to show prices across the board. It's sort of built into doing business wherever we transact. And I think that what concerns me also is if we're looking at fees upon fees to get access to seeing fees will downstream be substantially added to the patient at the end of the day. And this data is all there. It is a matter of providing visibility. And I agree with ONC's previous position and even more so to say that it should be free to the patient but also the minimum is to be able to just open up access.

Andrew Truscott – Accenture - Member

Thank you, Cynthia. Mike Lipinski, you've got your hand raised.

Michael Lipinski - Office of the National Coordinator - Staff

Yeah, thanks, Andy. I just have a quick clarification question as to basic access and you may get to this later in how you define EHI because it seems to me you're defining a type of EHI data or

facts. Because some data will change using an algorithm, AI, and what have you. And I guess the question I have for you because it sounds to me like you are going to probably head down the road of allowing charging for the other types of data, is what do you do in a situation where the entity or the actor **[inaudible] [03:46:28]** and no longer stores it in a basic format?

Arien Malec - Change Healthcare - Member
Mike, I think Recommendation 34 covers that question.

Andrew Truscott – Accenture - Member
Yeah.

Michael Lipinski - Office of the National Coordinator - Staff
Okay.

Andrew Truscott – Accenture - Member
Would it be helpful at this point, Robert, if we walk through the remaining recommendations and then come back and look at those, which we can block vote and those, which are going to require some greater scrutiny from the task force?

Robert Wah – Individual – Chair
Sorry, Andy. You broke up. I didn't get all of that.

Andrew Truscott – Accenture - Member
Shall we carry on and work through the recommendations and then, look at those, which we can block vote through and approve and those, which might require some rework or some reconsideration from the task force?

Robert Wah – Individual – Chair
Yeah. I think where we are is as comments and questions up on the recommendations **[inaudible] [03:47:23]**. But let's keep going through.

Andrew Truscott – Accenture - Member
Somebody's phone is vibrating and it sounds like a foghorn. Okay. Recommendation 34. Notwithstanding the recommended distinction between basic and value added capabilities as we've just been discussing, we're recommending that when there's an output of value added services that were incorporated into or form an essential part of the legal medical record or to be used for decision making, they constitute part of a set to which basic access is required. So, let's run over that again. So, if we use – if value added services are used to be an integral part of the legal medical record or are used for decision making then, they are considered to be basic access. Next page, please.

Leslie Lenert - Medical University of South Carolina - Member
I have a clarification question. So, 34 is an exception to 33 is what you're saying and that 33 is really to create two classes of API access based on the function of the –

Andrew Truscott – Accenture - Member

Yeah. We're not seeking to create classes of API. That's an implementation detail and it's been addressed elsewhere. We're just saying **[inaudible] [03:48:50]** there are two reasons for access, basic and value added.

Leslie Lenert - Medical University of South Carolina - Member

And the idea is to be able to charge more for value added access?

Andrew Truscott – Accenture - Member

Correct. But with the exception that when output from a value added service is incorporated into the legal record or part of the legal medical record or routinely used **[inaudible] [03:49:20]** they are considered to be basic access.

Leslie Lenert - Medical University of South Carolina - Member

Why?

Andrew Truscott – Accenture - Member

Why?

Leslie Lenert - Medical University of South Carolina - Member

Yeah. Why should there be a higher charge for and a distinction between the access not based on the data elements but on the implied function of what you were doing?

Andrew Truscott – Accenture - Member

Well, the task force considered that it's almost the reverse of what you were saying there. If you're routinely using this, it's part of the basic general legal medical record that's getting exchanged, accessed, or used then, that shouldn't be subject to an additional charge.

Cynthia Fisher - WaterRev - Member

Andy, this is Cynthia. I can give you a specific example of a patient case where it was a very difficult labor and shoulder dysplasia. I'm not a physician.

Steven Lane – Sutter Health - Member

Dystocia.

Cynthia Fisher - WaterRev - Member

Okay, sorry. Thank you. So, shoulder dystocia and there was some delay with the child. And the mother could not get access to the medical records nor get access to the APGAR score and came to us after trying for about six weeks and not being able to get access to see a specialist or to get early intervention. To this date, she still hasn't gotten it. And then, she went to hire a lawyer because she hasn't been able to get her records either from the pediatrician or from the hospital or from her OB. So, if you're going to charge more for value access, sometimes patients **[inaudible] [03:51:08]** who are just trying to get care. And it's not to go to a lawsuit or anything

like that but they're not getting access for unbeknownst reasons. But we're trying to help out in this case just to try to get access to records. But I just throw that out there to say is this where you're talking about the value charge being higher or basic access?

Arien Malec - Change Healthcare - Member

Yeah, Cynthia, just to be super clear – it's a great point. And just to be super clear, the example used is a proprietary risk scoring method that rescores patients based on a machine learning or AI algorithm. These are exactly the kinds of value added services that we want the market to incent creation and adoption for and believe are part of the value added world that should be assessed on market based rates. At the same time to your exact point, when there is a patient specific risk score that is used for clinical decision making that then becomes part of the basic record. That's actually part of the definition, as you know, of the designator record set is that if any information that's used for routine decision making for the patient. So, in those cases, we don't want to create a world where the proprietary risk score has a separate fee associated with it when it's actually used by physicians in clinical practice to your exact point.

Cynthia Fisher - WaterRev - Member

And to our point, three players here would not release that data to the patient when she's just trying to get appropriate care for her child, the mother. So, obviously, they're in fear of significant lawsuits. So, my concern is information blocking through this nuance, do you see what I'm saying, and leaning on a legal modality providing it easily and accessibly and free as part of the basic record to the patient, which is the patient's right.

Andrew Truscott – Accenture - Member

Okay. Thanks, both. Ken Kawamoto, you've got a comment?

Ken Kawamoto – University of Utah Health - Member

Yes. So, it relates to the earlier one about distinguished between basic and what not, too, but this notion of if you use it for clinical decision making, it's basic. I think that definition would put almost every piece of data you would care about about a patient, whether it's how much medication is going to cost, really any data point about a patient considered basic access. And my worry there is that I'm all for getting all of this access, I'm afraid that from the EHR vendor and other vendors' perspectives, they're going to become incented to do nothing else than what's minimally required because all of the incentive is gone. And I think we have to carefully consider the implications of saying everything should be basically at cost because I would assume that would mean a lot of the data we do want access to will never get developed, the interfaces.

Andrew Truscott – Accenture - Member

So, I think I'm just going to put a big, broad brush stroke across your suggestion there, Ken. Your suggesting actually all data exchange, access, or use should be at cost.

Ken Kawamoto – University of Utah Health - Member

No. What I'm saying is I think that would be an ideal state and that's what they're getting at. But I think the reality is what we don't have and what aren't mandatorily required through say USCDI, the pace of development those interfaces will dramatically decrease. So, I'm thinking specifically,

for example, novel ways to get patient specific co-pay pricing. I literally spent the whole weekend trying to troubleshoot how to get that to work because the existing interfaces and the way they're employed will get us probably only about one-third of the prescriptions we care about in our health system. And I wonder if this kind of regulation means that people are not incented to improve on it. That's the reality that we will live with for 20 years rather than something that gets solved in three years or five years because somebody is incented to fix it.

So, I think, of course, as consumers of healthcare, etc., that's what we want. I think the unintended consequence here could be pretty large.

Andrew Truscott – Accenture - Member
Unless it's an intended consequence.

Clem McDonald - National Library of Medicine - Member
I think that Ken has got a good point.

Andrew Truscott – Accenture - Member
Thanks, guys. Let's carry on through the recommendations and it might well be that we are having more discussions about these going forward. So, Recommendation 35. We're recommending that ONC distinguishes between **[inaudible] [03:56:09]** and IPR for value added services. So, the former is going to include any standards of central IPR or any IPR licensing that's associated with terminology and that it's either defined in the certified standards list or reasonably required based on the regulatory requirements or customary use. Recommendation 36 and this is more of a **[inaudible] [03:56:39]**. So, we're recommending that allowed fees for basic access are on a pure direct cost recovery basis only. And Ken, I know this is echoing into exactly what you just talked about and concerns you raised.

So, in many cases where basic access is provided by a widely deployed consensus based certified standards built into health IT, such direct costs would be minimal. So, we don't recommend that the cost to develop standards be part of the cost basis for fees based access. Rather that any such costs should be a part of the fees for the health IT itself. The task force believes that this approach provides a significant incentive to adopt standards and actors who do not provide access to widely deployed consensus based standards would have an incentive to do so and to reduce the total cost structure of access. So, the task force recommends, and this is a bit of a compound in here, that the cost basis with fees basic access not include reasonable mapping to standards and such mapping would include mapping of proprietary terminologies used internally to the standard terminologies and **[inaudible] [03:57:47]**.

Exceptions would include cases where data or terminology sets exist but then not reasonable to include in mapping to standards and where sufficient mechanisms of basic access exposing the normal standard data already exists. And in these cases, there are market based mechanisms sufficient to set prices for nonstandard data mapping. Next slide, please. Okay. So, the task force is recommending that allowed fees for access exchange and use essential IPR be set on a RAND basis. So, reasonable and nondiscriminatory. Such fees would not be reasonable if they materially discourage access to the exchange or use or impeded the development of competitive markets for value added – sorry, has someone got their hand up? I can't see the presenter screen so I

don't know.

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

No, there are no hands up, Andy.

Andrew Truscott – Accenture - Member

Sorry, where was I? I'll go back to the beginning. So, the task force recommends that the allowed fees for access exchange and essential IPR be set on the reasonable and nondiscriminatory basis. Such fees would not be reasonable if they materially discourage access, exchange, or use or impeded the development of competitive markets for value added exchange and use services. So, we recommend that the access exchange and use of essential IPR license grants be sufficient for actors to provide access or deliver exchange and use services. And here's an example. So, intellectual property right grants for terminology **[inaudible] [03:59:29]** are access, exchange, and use essential should be sufficient to allow access, exchange, and use for permittable purposes. So, we have another way of putting it. Actors would not be able to accept IPR licenses to restrict access only to those who also have IPR rights.

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

Andy, sorry, it's Lauren. I do see that Carolyn has her hand up. Sorry, Carolyn, I didn't see you before.

Carolyn Petersen – Individual – Chair

No, that's cool. This relates to 37.

Andrew Truscott – Accenture - Member

Okay. Go on, Carolyn.

Carolyn Petersen – Individual – Chair

Okay. It's Carolyn. So, to be clear, earlier in this transmittal letter, we have not defined patients as actors. Is that correct?

Andrew Truscott – Accenture - Member

I believe so. No, no. Our patients were not considered actors. Actors are health IT developers of certified health IT, health information networks, health information exchanges, and providers.

Carolyn Petersen – Individual – Chair

Okay. So, as I was reading this, the thought occurred to me where does this as written leave patient powered research network members? These would be research networks operated and managed by patients contributing their own data. They may wish to transfer, exchange, use data. I'm wondering if this is an argument for making patients actors, in this case, or how this would work. It feels like there's an impact here that maybe we don't want to create.

Arien Malec - Change Healthcare - Member
Nothing in this limits the ability of patients to do any of that exchange.

Andrew Truscott – Accenture - Member
It does not have a mandate for the patients.

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

Andrew Truscott – Accenture - Member
I think that's Carolyn's point though. Maybe to better enable patients and actually making patients a mandated actor might well be – I have to think about that some more with the task force.

Arien Malec - Change Healthcare - Member
I think there's a legislative mandate issue there and that Cures doesn't provide any avenue for regulating what patients can or can't do and that patients, basically, are free actors to do whatever they want with their own data. And if we restrict that in any way, we're actually saying that patients aren't free actors to do whatever that they want with their own data.

Andrew Truscott – Accenture - Member
Okay. I think we should park that one because it's not specifically in the scope of what we're trying to discuss now. But I think it's a good, important one that needs to be captured and addressed elsewhere. Carolyn, is that okay?

Carolyn Petersen – Individual – Chair
All right. Thank you.

Andrew Truscott – Accenture – Member
I rely on the co-chairs to do that. And then, the final recommendation in this section is we're recommending that no further restrictions on permitted fees can be put in place. We think that what we've discussed above is sufficient to address both monopoly, rents, or gatekeepers and to ensure market based pricing for additional services. So, **[inaudible] [04:02:45]**, which was in the proposed regulations we are proposing that that actually get dropped and removed. This is the end of the section on recovering reasonable costs.

Arien Malec - Change Healthcare - Member
Hey, Andy, just because people maybe haven't been through all of the information blocking stuff that the information blocking task force has been through, it might be just worthwhile lining up the baseline of what the information blocking rule proposes. So, the information blocking rule proposes that access, exchange, or use of EHI be subjected to restrictions on or allowed fees and those allowed fees to be either on a cost basis or an IPR RAND licensing basis. So, if you're objecting that the carve out is too big, just remember that the carve out is by definition smaller than the existing set to which pricing regulation is being applied in the existing baseline rule. So,

this is trying to create a sensible and reasonable carve out that provides appropriate pricing mechanisms for access as well as seeking not to impeded exchange or use of information. And we can maybe debate the boundary lines but just remember that the baseline is a much broader set to which information and pricing regulation is being applied.

Robert Wah – Individual – Chair

Carolyn, did you have your hand up again?

Carolyn Petersen – Individual – Chair

Sorry.

Robert Wah – Individual – Chair

So, other comments? Oh, Sasha?

Sasha TerMaat – Epic - Member

Yeah. So, just a clarification. In 31, the task force recommends kind of three different buckets if I understand 31 correctly. Pure cost or expense recovery with no provision for margin or profit, cost based pricing where margin or profit is allowed and then, market based pricing. But then, the subsequent proposals that we've discussed, 34 and 36, only use two of those categories, pure cost recovery, and market based pricing. Or did I miss somewhere where cost based pricing is in there?

Arien Malec - Change Healthcare - Member

Sasha, let me provide some comment there. The first bit is basically providing ONC some helpful language for thinking about the categories that might be applied. You're right that only two of the categories are applied in practice. But the intent is to provide ONC maybe a framework for thinking about this if they don't agree with our recommendations.

Robert Wah – Individual – Chair

Other comments, Sasha? Hello? Okay. I hear no further comments or questions about the recovering cost section.

Sasha TerMaat – Epic - Member

Are we going to re-discuss given the discussion about some of the line drawing that Arien mentioned in the definitions or are folks prepared to vote?

Michael Lipinski - Office of the National Coordinator – Director of the Regulatory Affairs Division

Can I ask a question? This is Mike Lipinski with ONC. Since the rule proposed a distinction between requesters and that any patient's request would be free if it was electronic access to EHI, are you saying then, if I understand this correctly, if it falls in the category of value add, they could be charged?

Arien Malec - Change Healthcare - Member

That's an interesting comment. And, Mike, I'll ask this question. I think the language in free access was relative to already existing HIPAA access rights. And I don't think any of this language would affect HIPAA access rights. And I actually think the definition of basic inclusion that anything that ends up being patient specific or part of the medical record would be subject to that basic access. So, that was really the intent of, I think, it was 34 is to say if I've got a proprietary risk score based on AI and methodology but then, the output of that risk score is used in the chart for decision making that it becomes part of the DRS that would be then, subject to the rest of the fee structure. So, I think the answer is no but you may have – you've obviously thought long and hard about this in different ways than we have. That was never the intent, I guess, is what I'd say.

Michael Lipinski - Office of the National Coordinator - Staff

Gotcha. Yeah. I'm just probing trying to fully understand this. and I really appreciate the time and effort into all of these recommendations.

Arien Malec - Change Healthcare - Member

And I don't think anything that we're talking about creates any limits on patients themselves buying or provisioning services that are value added in nature at a market based cost. This is really relative to access to the record.

Andrew Truscott – Accenture - Member

Yeah. And Michael, there was an overwhelming sentiment across the task force in all its deliberations that incurring patient costs on getting access to their records about their healthcare was not the intent and we should be dissuading that as much as possible.

Michael Lipinski - Office of the National Coordinator – Director of the Regulatory Affairs Division

Okay. And you did put the recommendation in about essential, right? **[inaudible] [04:09:30]** but just generally, you do have that word in there about determining what's essential to the record, too, right? In one of your prior recommendations, I believe you said when they combine it or make it part of the record.

Arien Malec - Change Healthcare - Member

Yeah, that's right.

Michael Lipinski - Office of the National Coordinator – Director of the Regulatory Affairs Division

Okay.

Cynthia Fisher - WaterRev - Member

This is Cynthia. I just want to **[inaudible] [04:09:50]** Michael's comment and concern. I think we really need 34 to be very clear that even if this whole bit about the value add, that's part of the patient record. And it should be free. And I just think that the value add exception is disconcerting because of creating an intentional barrier for misinterpretation and a potential barrier for patients then, whatever party you're acting on behalf of the patients for getting access.

Arien Malec - Change Healthcare - Member

Cynthia, that's certainly the intent of Recommendation 34. And if you don't think the language strikes that intent then, maybe if you're got alternatives to that, I think we'd be happy to consider it. But that's certainly the intent.

Cynthia Fisher - WaterRev - Member

Yeah. But I think that was Michael's question even with ONC saying are we looking for the patients to be charged. So, I think to have an explicit sentence, I would recommend to Andy, to write a specific sentence that clearly that even value – whatever it's saying for basic access and value add would be free of charge for patients to get access to that. And for information blocking, I would also add that not just patient specific pricing but that broader access to pricing for the patients as well.

Robert Wah – Individual – Chair

Other questions or comments about the recovering costs, other recommendations?

Sasha TerMaat – Epic - Member

So, in 36, there is a distinction between the direct cost recovery portions of standards and other health IT. And I think that distinction is critical to avoiding the unintended consequences that Ken talked about earlier where large swathes of health IT development are disincentives by no opportunity to make RND investments and earn a profit. But I remain concerned that the distinction of what falls into the pure direct cost recovery basis piece and what falls into the rest of health IT in this distinction of buckets is ambiguous. And I'm worried that we don't really want to arbitrate that with a lot of information blocking lawsuits. And so, I think it would be advantageous to clarify that so that it can be unambiguous in interpretation and draw these distinctions in a way that I think the task force intends.

Andrew Truscott – Accenture - Member

So, Robert, my suggestion is that we might not vote on this at this point.

Robert Wah – Individual – Chair

Are we talking about this entire block or these particular recommendations?

Andrew Truscott – Accenture - Member

I'm talking about the block because I think there are different recommendations hanging on other recommendations. It might be easier if we as a task force take it away, work through it again, refine. There have been some excellent contributions from the committee here. And then, we bring it back and present it again.

Robert Wah – Individual – Chair

Okay. We're running out of chances to bring it back but yes. And if in your assessment you've heard enough information that you feel it needs to go back to the task force, I think that's a reasonable course. Okay. So, let's then table voting on the recovering costs block of the recommendations. Do you want to move to the next block on this?

Andrew Truscott – Accenture - Member

Yeah. I'm going to hand over to my learned co-chair, Mr. Michael Adcock, to talk through this section.

Michael Adcock – Individual – Member

Andy, I just sent you a message. I'm not in front of my computer right now, Andy.

Andrew Truscott – Accenture - Member

Okay. I shall carry on and lead us through this section then. That's fine. So, the task force believes that this exception must not be used simply because it would be inconvenient or have some limited cost to comply with the regulations. And the task force is making some minor suggestions to aid the drafting of this exception. And I'm about to go through those. So, where you're defining whether the request is infeasible and the answer must demonstrate that complying with the request and the manner of request it would impose a substantial burden. And also, as a judgment in here is whether similarly situated actors provide similar access, exchange, or use. So, where you're saying that we could not comply with that, well, if other actors are also saying they can't comply and there are similar actors that that would be their rationale. Sorry.

In response to the request, we've done a little bit of tweaking to this to put a bit a more definition and structure around the use of the word timely. And we're just saying here that instead of just saying timely respond, we're saying actually you've got to respond in a timely manner. And that's not any longer than 10 business days. So, within 10 business days, you've got to give a written explanation of why you cannot accommodate the request. Again, we've updated around here to say that the actor has got to work with them in a timely manner to provide a reasonable alternative to how to access, exchange, or use the electronic health information. And that's just saying there that there has to be a boundary upon that response. Next slide, please. Okay. We're recommending some updates in – actually, no. This is RAND terms. Just go back. This is it. One recommendation in this present and infeasible, this is it.

Robert Wah – Individual – Chair

There's just the one, right?

Andrew Truscott – Accenture - Member

Yeah, that's it.

Robert Wah – Individual – Chair

Okay. So, questions or comments about this Recommendation 39. Hearing none, let's go ahead and vote on this. All of those in favor of Recommendation 39, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Andy, next one.

Andrew Truscott – Accenture - Member

Thank you. So, the license of **[inaudible] [04:17:10]** on RAND terms. So, the task force spent considerable time discussing and expounding the RAND terms as reasons for legitimate exceptions. So, in conjunction with the preamble, the task force felt that the majority of the regulation text as drafted is appropriate and we have some minor recommendations regarding intent and guarantee as we sort of detailed in here below. So, we said that when you respond to a request, you should actually begin the negotiations with the intent to furnish a quotation for a license. And the task force felt that it might not be possible all of the time to just give a license. There is actually a negotiation process, which goes along with that. And so, that should be included in here.

And then, we felt that the language around 1I, around developing products or services that are interoperable that was a little bit confusing with the under your control, etc. And, actually, we focused here around the developed products and services, which are interoperable with the license **[inaudible] [04:18:19]** elements. And we thought that was a much neater way of expressing that clause. Again, that should be it.

Robert Wah – Individual – Chair

Why don't we go ahead and do 41 and 42 as well?

Andrew Truscott – Accenture - Member

I'm taking my results when I can. Okay. The next one, maintaining and improving health IT performance. So, we recommended, you can see the text here, this generalized and maintenance exception so that we cover late limiting or disabling the use of health IT by user or actors if use is unusual and called degradation of local performance. We felt that there are reasonable and usual practices where service level agreements or maintenance windows are not named inside the contract. We also felt that out of SLA performance would be using a good faith activity to restore service in a timely manner is legitimate. And false **[inaudible] [04:19:25]** or other highly unusual events are out of control of the actor, again, are legitimate.

So, if we don't consider those as exceptions, it raises the risk that ordinary failures to achieve good faith service provision could be adjudicated as information blocking rather than to through the normal contractual resolution processes. And that creates a paradoxical incentive for actors to insist on negotiating lower SLA achievement rates, which is not the intent. So, it's a law of unintended consequences here. We understand that some actors have caused information blocking by abandoning technology. We believe that these instances are rare and would not trigger the exceptions noticed above. And then, Recommendation 42, we have some recommended mark up here to the exception. So, we want to emphasize the reasonable and good faith activity that was required and mentioned above. We felt that clause three around the **[inaudible] [04:20:31]** being initiated by health IT developer or the network was inappropriate and should actually be removed.

And then, we said look, where the request is unfeasible if the **[inaudible] [04:20:43]** issue is a highly unusual offense out of the control of the actor according to the comments we made earlier that that should, therefore, be included in there. And that's the end of this section.

Robert Wah – Individual – Chair

Okay. Questions or comments about these two sections, Recommendations 40, 41, and 42. Seeing none and hearing none, let's vote to approve Recommendations 40, 41, and 42. All of those in favor, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? All right. Back to you, Andy.

Michael Lipinski - Office of the National Coordinator – Director of the Regulatory Affairs Division

Andy, this is Mike Lipinski. I was going to ask you a question but you guys already approved it so it's all good. I was just going to ask you –

Andrew Truscott – Accenture - Member

Ask the question.

Michael Lipinski - Office of the National Coordinator – Director of the Regulatory Affairs Division

All right. I was going to ask why you had removed three because, in the preamble, we discuss practices, contract for these services by these entities identified there. And without a consultation with them as to bring down the system that this seems like it would allow the actor, in this case, let's say a developer, to make that choice without any consultation with the entity that they're providing the services to. And so, I guess that was part of why that – I'm just wondering why you had made a decision because **[inaudible] [04:22:28]** the basis of this proposed exception was that other instances wouldn't cover this. So, if there was a security one, they could go for the security exception why they were taking the system down or if it was a harm one, they could avail themselves to the harm exception to bring it down.

But what why we proposed this discussion, as we discussed in the preamble, there may be situations just from a practical business sense, it would be better to take the system down on such and such day because for the user that would be more financially advantageous or just in what they're doing so they can agree to it. But when we proposed this exception that situation wasn't covered by any of the other exceptions so we wanted to allow for those types of business reasons we discussed in the rule. So, I guess I'm asking what the thought process was with removing No. 3 and what you were thinking more generally about those revisions.

Andrew Truscott – Accenture - Member

Okay. So, as the task force went through this, obviously, you just outlined the perfectly legitimate reasons this was covered by other exceptions. So, we'll park all of those out of the way. We thought that there was, obviously, a fourth legitimate rationale, which we put in place here as well. And the task force, as we discussed it through, and task force members, please feel free to

jump in as well, it was felt that we didn't want to allow an exception to be claimed, which just wasn't in the interest of the providing care around health IT performance per se. Does that make sense? Actually, that probably isn't the question you're asking me. But it was felt that it could be inadvertently misused and cause information blocking. And actually, we should be more proactively encouraging actors to ensure that information is routinely being shared, isn't being blocked, and have more appropriate system management approaches to ensure that. Is that helpful?

Arien Malec - Change Healthcare - Member

I would just add to that that there was a basic concern that most contracts already address maintenance windows and SLAs. And we didn't want down time outside of maintenance windows and outside of SLAs, which happen in the real world as long as they're reasonable and in good faith and with reasonable approaches for service restoration to be subject to the penalties associated with information blocking. So, we didn't feel it was appropriate for information blocking to be over and above or provide extra tools that were already addressed through contract requirements. Obviously, ONC can disagree.

Michael Lipinski - Office of the National Coordinator – Director of the Regulatory Affairs Division

Okay. Thank you.

Robert Wah – Individual – Chair

Andy, do you want to wrap up the rest of these other groups?

Andrew Truscott – Accenture - Member

I'd be happy to. Go to the next page, please. Okay. Recommendation 43. So, we've asked for some additional exceptions on RFI. And it ticks in a little bit to what Mike and Arien were just discussing. Contractual obligations may and often do conflict with the board's requirements for information blocking. The preamble text discusses multiple situations where contractual terms are used by actors to restrict the use of information. The preamble did not address situations where actors are dependent on contractual terms from other parties that might conflict with information blocking provisions. So, an example could be that business associates have only the data use rights granted under a business association agreement, BAA. These data use rights may not allow access for all permissible uses. Contractual terms that limit BA data use rights are quite common.

And should counterparties not change BAA terms, BAs would be in a difficult position forced to choose between canceling contracts, which are often subjecting BAs to penalties under contracts and sometimes opening BAs to information blocking enforcement, complying with the contractual terms and risk information blocking enforcement, or complying with information blocking provisions whilst violating contracts and possibly open HHSO enforcement for violating BAA terms. So, in other examples, confidentiality provisions of contracts have been used to litigate data use for price transparency, even when such data use is permitted by data use terms in BAAs. Similar situations could apply for IPR, licenses, terminology sets, etc., that may have provisions preventing information sharing of the information requested at those IPR levels. So, we recommend that the status of contractual obligations that may be in conflict with information

blocking obligations be explicitly clarified by ONC as being void.

The simple solution would be to interpret the intent of congress to preempt specific contractual terms, which are in conflict with the Cures Act. But we're recommending that as a very explicit clarification by ONC for that. Does anyone want to discuss that at this point? Because the next recommendation is a different subject matter.

Robert Wah – Individual – Chair

It is a different subject matter but maybe they're both sort of request for information. That's the way I interpreted it. Maybe you just do them together.

Michael Lipinski - Office of the National Coordinator – Director of the Regulatory Affairs Division

I'll crank on to it. So, a second point is around the trusted exchange framework and common agreement noting that there is another task force who is enjoying working through that right now. In the proposal, ONC noted they're considering whether they should propose in a future rule making a narrow exception to the information blocking provisions for practices that are necessary to comply with the requirements of the common agreement. The release of the second draft of the trusted exchange framework was quite late in the public consultation period for the proposed rule but it has given the task force the opportunity to comment on the TEF and the CA. So, we had a specific session around this and considerable discourse has taken place with two distinct views being articulated that compliance for the TEF should provide a safe lane to demonstrate to ONC, HHS that information blocking is not taking place.

[inaudible] [04:29:26] is that providing a safe lane is **[inaudible] [04:29:30]** approach, which should not be adopted. And the TEF should be a series of good practice guidelines. We urge ONC during the rule making process to consider carefully the enduring demand of the Cures Act to promote information sharing and prohibit information blocking amongst all actors involved in the provision and administration of care. We believe that a careful balance needs to be struck to encourage compliance to the information blocking provision potentially through the adoption of the TEF and the need to investigate information blocking activities where warranted and not in the event that we provide bad actors with an opportunity to circumvent regulation compliance. And that's the end of this section.

Robert Wah – Individual – Chair

I'd go ahead and finish up 45 and 46. They're a slightly different topic but, again, you're just adding some information that you're trying to seek.

Andrew Truscott – Accenture - Member

Okay. No problem at all. So, the task force, on the complaint process, you can see it on the screen, we're completely comfortable with what is written and we've got no further edits or comments to make to it. If the HITAC as a whole has some additional recommendations or thoughts around complaint process then, the task force will, obviously, consider those. Next slide, please. So, disincentives for healthcare providers. There was a request for information here. The task force believes that while some types of problematic activities relating to information blocking are more typical of health IT developers or other similar actors, other refusals to share data, including using

over interpretation of HIPAA and other privacy laws, stricter than necessary organizational policies, or concerns of patient "leakage" to competitive institutions are more typical of provider organizations.

So, the task force believes that disincentives must be sufficient to discourage problematic behavior, encourage compliance, and incent providers to work with OIG and others to address and remediate problematic behavior. So, that's why we came up with these two recommendations. Firstly, the task force recommends that ONC works with CMS to build information blocking disincentives into a broad range of CMS programs and that ONC works with other federal departments and agencies that contract with providers to similarly build out information blocking disincentives into contracting and other programs.

And the last recommendation of this section, the task force recommends that providers will test to comply with information blocking requirements as part of the conditions of participation, conditions for coverage, contact, and any other similar relationships covered in both fees for service, value based care, and direct payment relationships and that findings and information blocking by OIG, findings in violation still related to information blocking attestations, False Claims Act or FTC, or other similar enforcement actions trigger disincentives up to and including removing organizations from participation or coverage.

Robert Wah – Individual – Chair

Okay. I know it's a big, diverse group but I wanted to try to maybe bundle it together. Any comments or questions about these two areas that are a response to the request for information, which are Recommendations 43, 44, 45, and 46? All right. Hearing none, let's go ahead and vote to approve 43, 44, 45, and 46. All of those in favor, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? All right. Great. Andy, you wanted to go to another subcommittee of your task force?

Andrew Truscott – Accenture - Member

We'll carry on through the next section, conditions and maintenance of certification and enforcement, please. So, around information blocking – there's that noise again.

Clem McDonald - National Library of Medicine - Member

Somebody has got a cell phone on the table.

Andrew Truscott – Accenture - Member

That's what it sounds like. Okay. So, the task force supports and proposed some information blocking conditions and certification as it's written in the proposed rule with no further edits or comments. Okay. Next slide, please. Assurances. So, the task force considered this condition of certification and maintenance of certification for certified health IT at length. The discussions

were focused upon the transparency of a certification process, recommendations concerning honesty in communications by a vendor and mandating the certified health IT product list for CHPL for publishing product certification periods. In addition, setting a minimum retention period for record keeping in the event that an IT vendor removes a product from market was felt to be appropriate to ensure that potentially short lived products would inadvertently not have their documentation maintained.

And that's what you see in this mark up here. So, to begin with, the health IT developer is obligated to provide honest communication and expert advice and is required by users with different user requirements. The mark up in Section 1.iii, if for a shorter period of time, a period of three years from the date of withdrawal by the health IT developer of the certified health IT products. And then, in 2.ii, we just removed the within 12 months, whichever is longer. And then, in Section 3, the preserving of the CHPL, the start and end dates of each previously settled by health IT product. Section 3 there is standard practice already. However, it was felt that putting it into the regulation would just codify the practice, which is already undertaken by ONC. And that was good advice and proper thing to do. The next section, Robert, is actually currently under draft still, Recommendation 48.

Robert Wah – Individual – Chair

Oh, it is? Okay. I thought this was –

Andrew Truscott – Accenture - Member

It's only Recommendation 48, not 49.

Robert Wah – Individual – Chair

Okay. So, do you want to tell the committee where you – update on where you are with Recommendation 48 and we won't vote on it? Is that what you're asking to do?

Andrew Truscott – Accenture - Member

Yeah. Well, this 48, astute members will notice that it's very closely related to the one we've just voted on and approved. And it might well be taken out because it's been **[inaudible] [04:36:22]** but it made its way into here as a recommendation so it might actually be removed.

Robert Wah – Individual – Chair

Okay. Why don't we vote on Recommendation 47? Actually, let's take any comments or questions about Recommendation 47 first. Seeing no comments or questions, all of those in favor of Recommendation 47, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? Okay. So, we're going to let 48 go back to the committee's consideration. I think the next series –

Andrew Truscott – Accenture - Member
It's 49, communications.

Robert Wah – Individual – Chair
Do you want to go through those?

Andrew Truscott – Accenture - Member
Yeah. Okay. So, quite a lot of discussion. There was quite a lot of consideration on the timelines for adoption here. And the task force considers that the actual updates to contracts, etc., can take some period of time. Now, this should be thought about in reference to the previous recommendation that we've already approved around contractual provisions, which conflict with information blocking regulations. They should be null and void. So, this was just simply saying that the timeline contractual updates should be extended. And this is purely just because there is a burdensome nature through contractual discussions sitting down with two sets of lawyers plus two separate business actors looking through contractual amendments can take a significant period of time.

There was also a feeling from the task force that because contracts are negotiated on an almost bespoke and artisan basis between different contracting parties that to enforce an undo haste upon that would actually have an unintended consequence of poor contracting practices, etc. And, again, I draw your attention back to the previous recommendation we've made that contractual terms, which were not aligned to the regulations would be rendered null and void. So, the actual disposition would be unchanged. It gives people a longer time to get the contracts poured through and worked through. That's 49 in a nutshell. Next section, please.

Robert Wah – Individual – Chair
Are there comments about Recommendation 49 or do you want to –

Cynthia Fisher - WaterRev - Member
Andy, I have my hand up about 49.

Andrew Truscott – Accenture - Member
I can't see hands.

Robert Wah – Individual – Chair
All right. Why don't we take comments about 49 first and then, we'll go to 50? Cynthia, go ahead. Cynthia, are you still there?

Andrew Truscott – Accenture - Member
I guess she's dropped. Should we come back to it when she comes back on?

Robert Wah – Individual – Chair
Raj, did you have a comment about 49 specifically?

Raj Ratwani – MedStar Health - Member

Yeah, I have a question about 49, thanks. If Cynthia jumps on, I can stop or we can negotiate it. Andrew, thanks for this. So, I need clarity on what this is stating exactly because you made some reference to previous recommendations, which I'm not sure which ones those are. So, this recommendation is that the health IT developers would have up to five years to make the official changes to the contract, is that correct?

Andrew Truscott – Accenture - Member

Yes.

Raj Ratwani – MedStar Health - Member

But if the proposed rule is saying that – my question is is this taking effect immediately and we're just allowing five years for sort of dotting the I's and crossing the T's? Or is this that there are some challenges with communication in that five year window? That's my concern.

Andrew Truscott – Accenture - Member

So, Raj, it's exactly that we're trying to achieve what you said in the first part of that statement. If you look back at Recommendation 43, which we've already brought through, we say that we recommend that the status of contractual obligations that may be in conflict with information blocking obligations be explicitly clarified by ONC as being void.

Raj Ratwani – MedStar Health - Member

Got it, okay.

Mark Knee - Office of the National Coordinator - IB TF Staff Lead

This is Mark. Just to be clear, that's what we say in the rule as well currently.

Andrew Truscott – Accenture - Member

Yeah. We just wanted to be absolutely explicit. We felt it wasn't as explicit as it could be. That's what we're saying.

Raj Ratwani – MedStar Health - Member

Perfect, thank you.

Andrew Truscott – Accenture - Member

No worries, Raj.

Michael Lipinski - Office of the National Coordinator - Staff

This is Mike, too. So, if could just **[inaudible] [04:41:28]** you want to give them more time because it takes time to update contracts, which I understand that. Just for clarity for the rest of the task force that's not as in deep with this as you guys are, and it was said that as the rule drops and is effective, they're not supposed to be there. And while they may not update the contract yet, we also have a requirement that says they have to send a notice out every six months to say that

until they do revise the contract. So, I assume the task force is still recommending keeping that though, right?

Andrew Truscott – Accenture - Member

Absolutely. This is purely because the task force members recognize there is a level of burden upon particularly provider and vendor organizations around contractual negotiation and picking up every single contract that people have right now and subjecting them to lawyer scrutiny could be quite a heavy lift. And it's also why we included the addition of the term renew in 2.i because we recognized that if you're going through a renewal process then, you should really put this into it.

Robert Wah – Individual – Chair

Cynthia, did you come back on?

Cynthia Fisher - WaterRev - Member

Yeah. Sorry. My call had dropped. The challenge is the five years. And the ONC was two years, correct?

Andrew Truscott – Accenture - Member

Yeah. Because I don't know if you were on and heard the conversation, in Recommendation 43 and, as Mike Lipinski has pointed out, elsewhere inside of the rule, there is clear language that if there are contractual terms, which are conflicting with the information blocking, they're void as soon as this law happens. That's it. All we're saying in here is that there is quite a burden for the renegotiation of contracts and to get that renegotiation done within two years is fairly burdensome to organizations and might have an unintended consequence of causing stuff just not to happen. Because those provisions are void already, there is no negative impact of just making this longer.

Cynthia Fisher - WaterRev - Member

Andy, in all due respect, you're a consultant, too. Really, if you look at even businesses, two years is really a reasonable timeframe. Going out five years is a very, very long term. Any of us couldn't even predict what five years would look like. But to say that it would take that long to give five years concerns me that it would be a drag and a delay of game.

Andrew Truscott – Accenture - Member

And Cynthia, this is not my personal view. This is from the task force. If I put my personal view onto this, as a consultant, you're right, I am employed by a consulting organization. I can understand the sentiment because I have been privy to many, many different types of contractual negotiations, which do drag on. Now, if we look at just one or two contracts, I could absolutely see why two years is completely reasonable as a period of time. Absolutely. And I'm agreeing with you on that case. But where we have a small number of organizations, for example, the health IT vendors who hold a large number of contracts, conducting all of those negotiations in parallel might place an unintended burden upon them. That was the consensus and the feeling that came out of the task force. And that **[inaudible] [04:45:25]** this recommendation.

Denise Webb – Individual - Member

Andy, this is Denise.

Cynthia Fisher - WaterRev - Member

[inaudible] [04:45:31] many different businesses that have substantially even more levels of engagement or contracts. I just think we're allowing a drag and anywhere there's such a substantial delay, we could do harm to the patients and providers not getting access to necessary data. I just –

Andrew Truscott – Accenture - Member

Cynthia, given that the contractual terms are voided already, what is your concern?

Michael Lipinski - Office of the National Coordinator – Staff

Andrew, I think Cynthia may have missed the conversation we had about when it takes effect. So, maybe if you just restate that that might help.

Andrew Truscott – Accenture - Member

I thought I had. I'll just go back to Recommendation 43. The task force recommends that the status of contractual obligations that may be in conflict with information blocking obligations be explicitly noted by ONC as being void as of as soon as this rule is made final. And Mr. Lipinski verified that is touched upon already inside the rule text.

Denise Webb – Individual - Member

Andy, this is Denise. I can't raise my hand because I just lost my internet connection.

Andrew Truscott – Accenture - Member

That's all right. Go for it, Denise.

Denise Webb – Individual - Member

Okay. So, I came at this from the healthcare provider health system point of view. And Cynthia, with all due respect, I'm telling you that two years is a very short period. We were going through several mergers and acquisitions and we had to change every health IT contract. And in two years, we still didn't have it finished because every one our lawyers had to touch. And in the proposed rule, there were no time estimates provided for any legal involvement. It was all a clerk. And so, it's on both sides. Not only does the health IT vendor have to deal with every client but every client has multiple health IT contracts. So, we all thought that it was fair to say get the contracts revised within five years but we did not negate the part of the rule that said it goes into effect immediately. Those contractual terms are void and you must notify your customers but then, you would have time to get the contracts up to date because that was not a small task to update contracts.

Andrew Truscott – Accenture - Member

Thanks, Denise. And it's good to get the provider perspective. So, any other comments?

Robert Wah – Individual – Chair

Okay. We move on to the next recommendation, 50, I think.

Andrew Truscott – Accenture - Member

Sure. Recommendation 50. So, this was specifically around the requirement around enumerating what on screen had actually come from the third party. And it was felt that as dynamic as health IT is, enumerating what is on every single screen each time it's just better to say that's coming from a third party that wasn't as stable to do. So, it's felt that a health IT developer could provide a list in this back screen or front platform or whatever that recognizes the third party content that could be present. And that's what this update was for. So, in 51 there was a discussion and, Sasha, I might lean on you just for a bit of input here, about whether you could unintentionally reveal with administrative functions of health IT the intellectual property of health IT developers. So, the security configuration of health IT, for example, that's actually less important in meeting the needs of communications that are protected under the Cures Act.

So, we suggested that in the preamble, administrative functions of health IT could be included as non-user facing aspects inside that definition that's already provided because those types of communications are not inside the purpose of the Cures Act. So, this is kind of like as we looked at Cures, we felt that this was an unintended inclusion, which just hasn't been necessarily thought through. Sasha, I know you had great input on this. Has that summed it up nicely?

Sasha TerMaat – Epic - Member

Yes. I think you hit on the fact that we had concerns that administrative function might reveal too much intellectual property but also potentially reveal too much about how healthcare systems have configured things and introduced security risks. That was one of the security configuration examples that we discussed.

Andrew Truscott – Accenture - Member

Cool. Yeah. Thanks so much. And it wasn't the intended purpose of Cures and so should be put out. Next slide, please, Recommendation 52. Okay.

Michael Lipinski - Office of the National Coordinator – Director of the Regulatory Affairs Division

Andy, I'm sorry. I should be trying to raise my hand. This is Mike Lipinski. Are you going to give an example of the administrative function where you think it creates a security issue? Because I guess the only, and this is not a push back, but it's just that it does say that they should be able to share security concerns, too. So, if I understand correctly, what you're saying is that's not the issue here. It's that if you show too much, it may actually create a situated concern because you'll now how you developed it and try to reverse engineer or something of that nature. Is that what you're getting at?

Andrew Truscott – Accenture - Member

Yeah. That's one aspect to it. And the fact that low base access control configuration for a provider is not something you pick up and set elsewhere. And so, we can definitely look at providing some additional examples to help outside of the rule making process if that's useful

here.

Michael Lipinski - Office of the National Coordinator – Director of the Regulatory Affairs Division

Yeah. It would definitely be useful. So, I appreciate that. Thank you.

Andrew Truscott – Accenture - Member

No worries. We're happy to do so. Recommendation 52, this is around the fair use communication of screen shots. So, we had a great discussion across the task force on this. And we wanted to ensure that screen shots could reasonably be shared for fair use. And, Raj, I know this is an area that you picked up when we discussed this before in full committee. And no, we're not looking at saying the actors are responsible for all downstream use of those screen shots. We're just – hang on a second. This text has dropped back to a former version. Mark, I'm not sure what's happened with this one.

Mark Knee - Office of the National Coordinator - IB TF Staff Lead

What's the issue?

Andrew Truscott – Accenture - Member

A2.iiD with the understanding that any actor disclosing the screen shots are responsible are responsible for ensuring that each use is being put to fair use. That's not what the text should say.

Mark Knee - Office of the National Coordinator - IB TF Staff Lead

Okay.

Andrew Truscott – Accenture - Member

Guys, we'll park this one and come back to it. Raj, from the conversation we had previously, we had clarified this text. And yes, the understanding that you can only be responsible for your uses but you are to communicate that the use of other actors should be fair use. So, Raj, I think that was your concern, right?

Raj Ratwani – MedStar Health - Member

Yeah. That's correct. The person posting or whatever it is should not be responsible for others' use of it. And so, striking that language would be good. And I think being careful on what would constitute the poster's advertisement of fair use. That would just have to be reasonable.

Andrew Truscott – Accenture - Member

Yeah. We drafted that. It just hasn't made it into here. I apologize for that. We were listening and did take it forward. Recommendation 53, we think it's reasonable for health IT developers to request that they're going to be notified when there is a disclosure to take place. And that was a combination in the current regulatory text. But we felt that notification to health IT developers prior or simultaneous with if prior was not possible public reporting would be beneficial to resolving security liabilities prior to the knowledge being widespread. So, this is around – you see

this commonly across other industries, ensuring that the health IT developer actually is kept aware and ahead of general public publications of any security concerns. In Recommendation 55, we thought that it would be potentially specific whistle blowing type protection so the protection is afforded to individuals who are alerting information blocking issues.

And that's what this text was updated for. Any questions on any of these three before we move to the next page? Okay. Next page, please. So, in this section, in Recommendation 56, we were looking at updating the text to allow for specific other communication types. And we've done some fairly exhaustive preamble recommendations around this. But, basically, defining other types of unprotected communications, which could be received by other – protected already by other law or regulation or that, frankly, is a false or unlawful communication. So, they would not be afforded protection for two very distinctly different reasons. One is that they're untrue for ii, and the other being on Point 1 that there is actually some other legislation or regulation, which already affords them protection. Next slide, please. That's it. Okay. That's all of that section.

Robert Wah – Individual – Chair

Yeah. That's all of the communication ones.

Andrew Truscott – Accenture - Member

Yeah. With the exception of 52, which needs updating.

Robert Wah – Individual – Chair

So, 52, if I understand correctly, that slide that you presented was not an accurate reflection of your task force final recommendation.

Andrew Truscott – Accenture - Member

It's not. The text inadvertently got – yeah. We'll update that part in line with the discussion that I had with Raj. So, if members are able to vote on it in line with that principle that would be good.

Robert Wah – Individual – Chair

Okay. We'll omit that from the communications bundle.

Andrew Truscott – Accenture - Member

Okay.

Robert Wah – Individual – Chair

Is it fixable on the slide? I don't think it's fixable on the slide.

Andrew Truscott – Accenture - Member

If there was agreement that what Raj and I just discussed is the principle that would be fine. I'm not going to fix it in the text on the slide.

Robert Wah – Individual – Chair

I think we're going to have to have another meeting anyway so I'm just going to let you do that.

Andrew Truscott – Accenture - Member

That's fine.

Robert Wah – Individual – Chair

Again, our obligation to the public is at 2:30. So, I want to see if there are comments about this series of communication recommendations. And Raj, I see your hand up. I don't know if this is in reflection of 52 or something else.

Raj Ratwani – MedStar Health - Member

No. This is a general comment. I was wondering if you could decide whether there is discussion around the definition of screen shot because that seems – I think most people would characterize a screen shot as a static image. And to me, that seems very narrow when we're talking about communications here. So, for example, you might want to have a 10 second video showing a specific perhaps usability challenge. Does that constitute a screen shot or is that outside of it?

Andrew Truscott – Accenture - Member

Okay. So, we briefly touched upon this. There was not an exhaustive discussion on the basis that we kind of all felt that that would be included. So, we need to come up with another word of a lexicon for videos or screen footage.

Robert Wah – Individual – Chair

Okay. So, I put this under the same category of you're going to work on the final recommendation that you're going to take back, correct?

Clem McDonald - National Library of Medicine - Member

You could call it media or multimedia.

Robert Wah – Individual – Chair

So, are there other comments about the communication recommendations? Because if there aren't any other comments, I'm going to go ahead and take a vote and then, we'll go to the public comment period. And, again, I'm not trying to rush it. I just want to make sure we're complete but also effective here. All right. Seeing no other comments about the communication set of recommendations, let's go ahead and take a vote on all of the recommendations minus Recommendation 52, which the task force will take back to finalize the language on. So, all of those in favor of the communications recommendations, which I have listed here as 49 through 56 minus Recommendation 52, all of those in favor, please signify by saying aye.

All

Aye.

Robert Wah – Individual – Chair

All of those opposed say no. Any abstentions? All right. At this point, we're going to take a break to fulfill our obligation to the public about the 2:30 public comment period. And I'll turn that over

to Lauren.

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

Operator
Certainly. If you'd like to make a public comment, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in the cue and you may press star 2 if you would like to remove your comment from the cue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

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

Operator
None at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. So, we'll use the last 13 minutes or so for any additional conversation around information blocking or unless, Robert or Carolyn, you have any other general items.

Robert Wah – Individual – Chair
Well, why don't we see how much we can get through the first work group of the task force?

Andrew Truscott – Accenture - Member
Robert, we're not ready to proceed on the first work group.

Robert Wah – Individual – Chair
Oh, okay. Thank you.

Mark Knee - Office of the National Coordinator - IB TF Staff Lead
There are still a few more recommendations after 56. There are 60 in total.

Robert Wah – Individual – Chair
That's all right. We're not quite finished with this work group, right? We did communication but I think we've got two more. Somebody advanced the slides. So, I'm sorry, I don't have the – is it just 58 and 59 we have to do? Yes. We have to do 57, 58, and 59 and 60, is that right?

Andrew Truscott – Accenture - Member
Yeah. Okay.

Robert Wah – Individual – Chair
So, 57 to 60 we have not done yet.

Andrew Truscott – Accenture - Member
Yeah. I shall do those right now.

Robert Wah – Individual – Chair
Okay.

Andrew Truscott – Accenture - Member
So, the first one is Recommendation 57. We were concerned that the idea that directly viewed communications could be serious in consequence. And then, specifically relying on email could be problematic if the person or persons sitting at the other end of that email box could be on vacation, could be out of the office, could have left the organization. So, we actually updated that to say that the notice and initiating direct review suspensions, for post termination, termination or ban have to be issued simultaneously by certified mail as well as email. Next slide, please. Recommendation 58 is the sense of the task force was that knowledge of past bans is important for all stakeholders and, therefore, we should indefinitely retain past records. So, a ban with a start and an end date if it was lifted seems appropriate.

So, our recommendation that we had indefinite communication of past records. And 59, we do not recommend establishing a minimum time period over which a ban must last, even if the health IT developer is a repeat offender. We felt that minimum ban time periods could have unintended consequences. That's it.

Robert Wah – Individual – Chair
No, 60, right?

Andrew Truscott – Accenture - Member
We can do that if you want. That's for self-developers, sure. The provisions of the information blocking and the assurances and conditions of certification also apply to self-developers. So, most of the provisions are fine. So, we identified one area that requires modification to self-developers and that's in A2.iiiA here where we noted that employees of the developer can have their communications restricted but this could have the consequence of limiting communications of users of the self-developed health IT for the reasons identified under Cures. So, we said healthcare organizations that are self-developers are not permitted to restrict the communications of the user employees with respect to these provisions. And that's it.

Robert Wah – Individual – Chair
Thank you. Questions or comments about Recommendations 57 through 60 that have just been outlined? Cynthia, you have your hand up but I think maybe that was from a prior comment but I want to make sure that this isn't for 57 through 60. Other comments about Recommendations 57 through 60. Okay. Hearing none and seeing none, let's go ahead and vote on Recommendations 57 through 60 that have just been outlined. All of those in favor of

Recommendations 57 through 60, please signify by saying aye.

All
Aye.

Robert Wah – Individual – Chair
And all of those opposed say no. Any abstentions? Okay. So, I think we're through that portion of the task force meeting.

Arien Malec - Change Healthcare - Member
Correct.

Robert Wah – Individual – Chair
Can you all still hear me?

Denise Webb – Individual - Member
Yes.

Robert Wah – Individual – Chair
I'm having a little trouble with my phone here it seems like. So, and we're not able to do the first part of the task force. Terry, you wrote something in the general public comments.

Terrence O'Malley – Massachusetts General Hospital - Member
I wrote it in the chat to request an amendment to USCDI 28C if we have time.

Robert Wah – Individual – Chair
We have a couple of minutes here. So, can we project the USCDI and get to Recommendation 28C? Terry, while they're bringing up the screen if you can maybe refresh **[inaudible] [05:06:39]**.

Terrence O'Malley – Massachusetts General Hospital - Member
Right. This is adding team member demographics. So, 28C was to include an identifier. And the amendment is, which I can read if you'd like, is that the use of an identifier is mandatory if you have an identifier provided managed by a national or regional accreditation body. If there is no identifier provided by a national or regional accreditation body then, the user shall indicate that no such identifier exists. And the reason for this is not to have it be permissible for someone to say no or none when one exists. So, they really have to attest to the fact that something doesn't exist.

Robert Wah – Individual – Chair
All right. Can everybody see the chat? It's the box in the center of the screen at the bottom level counting from the left side three boxes over from the left side on my screen. I don't know what it is on yours. Terry has provided all of the text he just read. I think people might recall the discussion we had when this came up about the identifier issue in 28C. Other comments or questions from the group about this amendment that's being proposed by the chair of the task

force?

Steven Lane – Sutter Health - Member
I think this is a beneficial amendment and I support it. This is Steven Lane.

Carolyn Petersen – Individual – Chair
And this is Carolyn. I think that addresses the concern that I brought up and I would support it also.

Robert Wah – Individual – Chair
Other comments or questions from the group about this proposed amendment?

Steven Lane – Sutter Health - Member
There was just a public comment introduced.

Robert Wah – Individual – Chair
Right, I see that. Terry, can you see that about not all entities enumerate accreditation providers?

Terrence O'Malley – Massachusetts General Hospital - Member
Yes. That's a good point. So, maybe we'll have to take this back and rework that. In the minutes that we have left, I don't think we'll get to that.

Carolyn Petersen – Individual – Chair
Sounds good.

Robert Wah – Individual – Chair
A valiant effort and we appreciate it. Okay. Well, listen, it's clear. I think you all remember we put out a note to hold your calendar for May 22 in the chance that we were not able to complete our work today to finalize all of our comments on the proposed rulemaking. And it now appears that we are going to need that date of May 22 so please, take the pencil status off and make it an official notice that we will have an additional meeting on May 22. It looks like we have some more recommendations coming from the information blocking task force that will be dealt with at that time. I think Carolyn's task force is going to take back Sasha's comment and make sure that that is fully vetted across the task force. And they will bring back their recommendation to the committee.

We now have 28C of USCDI to deal with. And I think that completes it. There was an overarching question that was brought up early in the meeting that we will find an agenda spot for as well. So, I think that will round out our meeting on the 22nd. And I appreciate everyone's patience in trying to get all of these comments and recommendations together for this important rule making process. Carolyn, do you have other comments as we wrap up here?

Carolyn Petersen – Individual – Chair
I don't. I just want to say thanks to everyone for your continued attention today. We have gone

through an amazing amount of information and consideration. And I know it's really hard to hang with it after the first couple of hours. And I so appreciate the energy and effort people are bringing to this process. Thank you so much. And thank you also to our ONC who have worked so hard to prepare this for us.

Robert Wah – Individual – Chair

I'll echo that comment. Again, your chairs are trying to make this an efficient and effective process. As I've said many times, I do not want to exclude conversation or comments on anything but we do need to move through the material. And I appreciate everyone's indulgence as we do this. Lauren, any final comments logistically?

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

No, Robert. I think you covered it. Mainly just confirming now that we will have the meeting on the 22nd. And also, just as a reminder, the TEF task force, which they started last week, they have their second meeting tomorrow on the 14th at 12:00 noon Eastern if anyone is interested in joining who is not on the task force already. But otherwise, that's all I have. And I guess we'll talk again in a couple of weeks.

Robert Wah – Individual – Chair

Okay. Again, thank you all and have a good week and we'll all be talking to you soon. And keep your email open for more batches that will be coming soon.

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

Okay. Thank you, everyone.

[Event Concluded]