Health Information Technology Advisory Committee

Transcript
May 22, 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
Terry Adirim	Department Of Defense	Federal Representative
Laura Conn	Centers for Disease Control and Prevention	Federal Representative
Kate Goodrich	Centers for Medicare and Medicaid Services (CMS)	Federal Representative
Mark Roche	Centers for Medicare and Medicaid Services (CMS)	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
IB TF Speakers		
Name	**Organization**	**Role**
Andrew Truscott	Accenture	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**
Seth Pazinski	ONC	Designated Federal Officer

Jon White	ONC	Deputy National Coordinator for Health Information Technology
Mark Knee	ONC	IB TF Staff Lead

Operator
Thank you. All lines are now bridged.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Okay, thank you. Hi, this is Seth Pazinski. I'll be the designated federal officer for today's call. So, we're going to go ahead and start the May 22nd meeting of the Health IT Advisory Committee. And we'll begin with a roll call. Carolyn Peterson?

Carolyn Petersen – Individual – Chair
Good morning.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Robert Wah?

Robert Wah – Individual – Chair
Present.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Michael Adcock? Christina Caraballo?

Christina Caraballo – Audacious Inquiry – Member
Present.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Tina Esposito?

Tina Esposito – Advocate Aurora Healthcare – Member
I'm here.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Cynthia Fisher? Cynthia, can you announce yourself? I believe you're on the call. Valerie Grey?

Valerie Grey – New York eHealth Collaborative - Member
I'm here.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Anil Jain? Okay, Anil did email that he may be joining late. John Kansky?

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

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Ken Kawamoto?

Ken Kawamoto – University of Utah Health – Member
Here.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Steven Lane?

Steven Lane – Sutter Health – Member
Good morning.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Okay. Leslie Lenert?

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

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Arien Malec?

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

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Denni McColm?

Denni McColm – Citizens Memorial Healthcare – Member
Present.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Clem McDonald?

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Aaron Miri?

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

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Good morning. Brett Oliver? Terry O'Malley?

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Present.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Raj Ratwani?

Raj Ratwani – MedStar Health – Member
Good morning.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Okay. Steve Ready? Patrick Soon-Shiong? Sasha TerMaat?

Sasha TerMaat – Epic – Member
Present.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Andrew Truscott?

Andrew Truscott – Accenture – Member
Present.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Sheryl Turney?

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

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Denise Webb? Laura Conn?

Laura Conn – Centers for Disease Control and Prevention – Federal Representative
Here.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Mark Roche? Kate Goodrich? Terry Adirim?

Terry Adirim – Department of Defense – Federal Representative
Present, thank you.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Ram Sriram? Okay. That concludes the roll call. Also with us from the Office of the National Coordinator is Dr. Jon White, our Deputy National Coordinator for Health IT. And I will turn it over to John to make some welcoming remarks.

Jon White – Office of the National Coordinator – Deputy National Coordinator for Health IT
All right, fantastic. Thank you, Seth. Good morning, everyone, and welcome to the call. On behalf of all my colleagues here at ONC, I want to thank you all for agreeing to meet again in such a short amount of time. Your input has been tremendously valuable and thoughtful and represents a huge amount of effort. And we appreciate it.

So, today is the last meeting and opportunity for the HITAC to provide input and vote on a final set of recommendations for ONC's proposed rule. We accomplished quite a bit at our meeting last week, and we are looking forward to wrapping up today and reviewing your recommendations in full detail soon. Some general dates and reminders for you. As a reminder for you and for the public, ONC has two public comment periods that will close in June. ONC's Proposed Rule public comment period closes on June 3, 2019. And our Trusted Exchange Framework and Common Agreement public comment period closes on June 17, 2019. The TEFCA Taskforce has met twice since our last meeting. Thank you again for that. And we are looking forward to a more in-depth update from that group at the next HITAC meeting on June 13, 2019.

That's all from me. Thank you again for everybody here. I will now turn it over to our co-chairs, Carolyn and Robert, for additional remarks.

Carolyn Petersen – Individual – Chair
Thanks, John, and good morning, everyone. It's great to see us moving into the home stretch on our work on the NPRM comment and transmittal letter to ONC. This morning, we have three – what we hope will be the end results of some work done by the U.S. Core Data for Interoperability Taskforce, the

Health IT for the Care Continuum Taskforce, and the Info Blocking Taskforce, wrapping up our recommendations and getting a vote. So, with that, I will pass the mike to Robert, and we can move forward.

Robert Wah – Individual – Chair
Well, thank you, Carolyn and John. Good morning, everyone. Thank you again, like has been mentioned, for joining on our meeting this morning, as well as all the work of the taskforces and work groups bringing together the recommendations for the overall committee.

A couple of notes. Meeting notes from the last meeting are not yet available for review, so we're not doing our typical review and approval of the meeting minutes of the last meeting because it was just so recent. We'll use the same process for voting as we have in the past calls. At the end, we'll have some announcements about future meetings, one in particular about an NCVHS meeting on prior authorization that follows up the meeting that we had and open forum that we had on prior authorizations at one of our HITAC meetings.

With that, I think we'll turn it over to Christina and Terry for the USCDI Taskforce recommendations.

Christina Caraballo – Audacious Inquiry – Member
Great, thanks. We can go ahead and move to the next slide. We actually only had two changes to the letter that is in your inboxes right now. The first change was for recommendation four, which was already voted on, so we're not going to discuss here, but I wanted to draw attention to that. And the second is the one you see on your screen. So, we're just going to review this, and I'll pass it back to Robert for a vote. For this one, we made one change. We're removing the word "accreditation" and replacing it with "professional." So, this is under the provider demographics, to include an identifier. This is to use an identifier is mandatory if an identifier is defined, provided, managed by a national, regional, or professional body. If there is no identifier provided by a national, regional, or professional body, then the user shall indicate that no such identifier exists.

We made this change to ensure that we were not inadvertently excluding identifiers used by diverse care teams that might not actually use an accreditation for their identifiers. So, with that, I will pass it back to you, Robert.

Robert Wah – Individual – Chair
Oh, thank you, Christina. So, we have the four as recommendation 28 with the changes highlighted on the screen. At this point, we'll have any discussion, questions, comments about this recommendation 28 from the taskforce. Hearing no additional comments or questions, let's go ahead and vote on recommendation 28 as you see. All those in favor of recommendation 28, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say nay. Any abstentions? Great. Next? Christina, I think that's it for your committee taskforce, I'm sorry.

Christina Caraballo – Audacious Inquiry – Member
That's correct. Thank you.

Robert Wah – Individual – Chair
Great. All right. Thank you again for all your hard work, for both the co-chairs as well as the entire taskforce. Thank you very much. Let me see. I think the next one – Carolyn, the next one is . . . I think we're a little bit ahead of schedule. Are we going to be able to do this without Chris, or are we going to –

Carolyn Petersen – Individual – Chair
Chris will be able to dial in at 11:00, so I will start the presentation, and hopefully finish up about the time he calls in so that we're able to do that so he can be there. So, good morning, everyone. We're hoping today we can resolve one last question that had to do with language in the transmittal letter for the Health IT for the Care Continuum Taskforce. We'll review the members and the charge, and then recap where things fit with regard to the data segmentation for privacy and consent management for API certification criteria. We will have some questions and whatever discussion we need, and then hopefully be able to get to a vote today on the language.

So, if we could have the next slide, please. And this is the membership of our taskforce. As you may recall, it's a bit different from other taskforces in that the majority of our members come from the public. We have three physicians and two members of the developer community, along with myself and Aaron Miri. If we could have the next slide, please.

So, our overarching charge, again, was to provide recommendations and deal with some matters related to the 2015 edition certification criteria. Specifically, we were providing recommendations on the 10 recommendations to support voluntary certification of health IT for pediatric care. We were looking at the identified 2015 edition criteria for supporting the certification of health IT for pediatric care in practice settings. We worked through the pediatric technical worksheet. We had the 2015 edition DS4P and consent management for API certification criteria. And we were also looking at how health IT can support the treatment and prevention of opioid use disorder, in alignment with HHS's strategy to address the opioid crisis.

Next slide, please. So, as you probably recall, we have gotten through all of the material related to the pediatric criteria, and we are now left with the data segmentation for privacy and consent management for API certification criteria. We had some discussion at the April 25 meeting, and then again at the May 13 meeting. And there was some interest in changing the language that was in the transmittal letter. We took that back to our taskforce, which meant last Friday, May 17th, and did some more work on that language. And that is what we're here to look at today.

So, to recap, ONC proposes to remove the current 2015 edition DSVP send and receive certification criteria, and to replace them with three new criteria. That would be two for the CCDA and one for FHIR. The taskforce supports this proposal and acknowledges that DS4P would help for opioid management and provide greater confidence in sharing OUD information. The taskforce also recognizes that the consent management for APIs proposal would aid in furthering the exchange of information.

There was an element of encouraging stakeholders to collaborate to create viable solutions for the implementation of DS4P being crucial for improving interoperability, while also protecting patient privacy. The motivations for completing this work include, first, that a patient's privacy must be maintained wherever information flows in the healthcare continuum; and second, that accurate and complete health information must be shared to enable providers to make appropriate decisions at the point of care. So, we're really looking to protect dual interests here, patients' and providers'. We also

understand that without solving this problem, patient care and the safe transfer of information are compromised.

May we have the next slide, please? The taskforce acknowledges barriers to optimal implementation of DS4P, such as safety implications, medical legal record-keeping requirements, leakage, or the concern that segmentation will not meet user expectations – that would be in particular regarding narrative content; and that the significant scope of development efforts to implement DS4P in health information technology systems is significant. The taskforce recognizes that governance will be necessary to prioritize these cases for industry consideration to address barriers and facilitate consistent implementation. However, the taskforce agrees that it's crucial to initiate future work to advance DS4P now, including efforts on both the technical and policy front. We think that failure at this point to do this would be a loss of great opportunity and could hamper future interoperability efforts. We think that the work could be accomplished in part through multi-stakeholder collaborative work and testing of the DS4P standard to enable priority use cases.

May we have the next slide, please? So, here we have the language from the transmittal letter. This is the part that we worked on in the last week-and-a-half of the previous HITAC meeting. The initial paragraph remains the same. Then we've added additional language here. I'll give you a chance to review that. As an implementation consideration, our recommendation is that a user should be able to identify items that they want to be protected. The taskforce also acknowledges a need for the development of a minimum dataset description to represent stakeholder consensus on what data is considered private. The taskforce notes that further work is needed to develop patient privacy best practices for universal adoption.

So, that's how we're framing the recommendation. And that is what we hope to be able to vote on today. I think we're a little bit ahead of schedule. Chris will be joining us in a few minutes. But I'm happy to start the discussion now.

Robert Wah – Individual – Chair
Arien, I see your hand up?

Arien Malec – Change Healthcare – Member
Yeah. Thank you, and thanks for the recommendations. Relative to data segmentation for privacy, I think we've been in a place for a while where we have standards that allow people to expose privacy preferences or sensitivity preferences, but we don't have policy enablement, or EHR behavioral expectations, or functional expectations that go along with that data. And to my knowledge, I haven't seen additional guidance in that area. And where that becomes concerning is that an EHR may get certified for the DS4P standard. I don't actually know how many EHRs have been certified for DSVP. But we don't have clear policy guidance in terms of what's actually expected of the EHR.

And to re-raise questions that I've raised previous and just literally don't know the answer to, if under – for example, if I receive data from a SAMHSA behavioral health clinic, and it is tagged with DS4P, and I have equivalent information in my chart, is that okay? What information can and can't I re-disclose? If the patient later tells me information that's also included in a DS4P report, is that okay to re-disclose or not? If I use data in DS4P for medication reconciliation and there's safety-critical information, what are the constraints in terms of when I can and can't receive and re-disclose information? The functional requirements here are, at least to my mind, a bit murky. I don't know if Sasha's on and can provide

comment from an EHR developer perspective. But I think this is an area where I would welcome greater ONC and wider HHS policy governance, and policy recommendations and enablement.

And without that, I just – I don't understand what it means to certify to the particular standards. So, maybe callout, A, to Sasha to see if she shares my concerns, and B, a strong recommendation, at least for me, that ONC convenes both HHS and privacy stakeholders to clarify the functional requirements associated with DS4P.

Sasha TerMaat – Epic – Member
This is Sasha. If I could be considered to have my hand up, please?

Robert Wah – Individual – Chair
Sure, go ahead. This is specific to this point that Arien's brought up.

Sasha TerMaat – Epic – Member
Yes. So, thank you. And Arien, I do share your concern. I appreciate the work that the taskforce did incorporating additional language into the letter, and that it recognizes that there is important work that would have to happen in order to make data segmentation effective. I shared at the last meeting, and I think part of what prompted some of the additional language to be put into this letter, that EHR developers have discussed the proposed updates to the data segmentation for privacy and consent management standard. There is a general fear that the changes to the standard that are proposed are minimally adopted in their current form and very new in the proposed form.

The estimates that EHR developers put together when the association polled it's members for estimates on implementing DS4P came back with requiring extensive development, with estimates that it would take greater than 20,000 hours of development per product to implement the proposed DS4P standard. And I think our big fear is that we would invest significant resources into implementing this standard, and we're not confident it's going to meet the need. Without the policy decisions and guidance that Arien described very eloquently, the development decisions will be approached inconsistently, because each developer will have to make their judgments on what is really intended, how is the functionality intended to be used. I think it will have detrimental consequences to clinician and patient workflow if there's not clarity around how these decisions are expected to be exercised so that that can be consistently done.

And ultimately, if there isn't confidence in governance, that decisions indicated in one system are going to be respected consistently in another system without the type of leakage that I think we're concerned about, particularly around narrative information, that it will not meet the need, and we'll have invested a significant amount of resources at a pretty significant opportunity cost of other things we could be investing in, without having really advanced the goal of respecting a patient's privacy choices. That's, I think, the concern from the perspective. I'm glad that the letter has incorporated many of those concern elements in.

The concern that remains from my perspective is the sequencing. I think that it is important to do further work on understanding what would be the policy implications of such a standard. But I don't think it's appropriate to recommend such a standard for EHR certification prior to those policy elements being further explored and come to some sort of guidance and consensus.

Arien Malec – Change Healthcare – Member
Thanks. Thanks, Sasha. Again, very similar concerns or identical concerns. And I think, as an additional point of commentary, I think this is an area where the standards developers have always pointed towards policy as the critical enablement. And unfortunately, the policy folks have looked at DS4P and just assumed the DS4P solves all the policy problems. And I think this is an area where significant investment in policy guidance, that is, involves close collaboration between policymakers and clinicians and EHR developers, would go a long way towards defining clear functional requirements that could be implemented in practice in ways, as Sasha notes, that actually would be commensurate with the level of effort and development that's required in order to make this stuff work.

Carolyn Petersen – Individual – Chair
And this is Carolyn. If I could add something for clarification. I don't think the taskforce members just assumed that things would be fine, in reference to your remark. I think there is actually a very broad and concerned recognition that there are technical challenges here. However, there was also a strong desire that we do not say, oh, well, it's hard, so gosh, we'd just better back away from it and not do anything.

Arien Malec – Change Healthcare – Member
Yeah. And again, I hear that. And all I'd say is that I don't believe this is a technical challenge. I think there is hard work, hard implementation work to be done. The issue right now is that it's not like – I don't hear Sasha saying it's a lot of hard work, and we shouldn't do it. I hear Sasha saying, it's a lot of hard work, and we should do it. But once we do it, we should know that it's been done consistently, correctly, and in accordance with policy recommendations. And it's the policy side of the house that just hasn't been done. So, anyway, that's the comment that I'll be making. Thanks.

Clem McDonald - National Library of Medicine - Member
So, I got my hand up. This is Clem, but I don't know if someone's ahead of me.

Robert Wah – Individual – Chair
Clem, we've got you, and Steven Lane's also had his hand up. I also want to bring in Chris, who's a co-chair of this taskforce – he's just now joining us – and give him an opportunity to comment first. Clem, if you can just hang on.

Clem
Okay.

Robert Wah – Individual – Chair
And Chris, I know you are now on the call from –

Christoph Lehmann – Vanderbilt University Medical Center – SME
Thank you. Yes. Thank you. Can you hear me?

Robert Wah – Individual – Chair
Yes.

Christoph Lehmann – Vanderbilt University Medical Center – SME
All right. I apologize. My invitation from ONC was for 11:00 Eastern, and if it hadn't been for Carolyn emailing me, I would still be not online. I heard the backend of Sasha's comment. And there is one thing that I wanted to add to the flavor of this discussion. I appreciate her concerns, and I also appreciate, I

think, the last time she told us this would take about 20,000 developer hours. And we discussed this. And the taskforce had vendor representation on there. And it was quite clear that those vendors that are already specializing in the pediatric field – and this was given to us because this is a specific issue that is critically important for the care of adolescents to prevent them from not seeking care, from encouraging to use healthcare resources and seek help when they need it without having to be concerned about privacy and leakage of their data.

The pediatric vendors were very adamant that they believe that it is time for us to work on this; that there is a real need that is currently unmet, resulting in poor adolescent adherence to seeking care when they need it; and that they felt quite strongly at the taskforce level that, yes, it would be a significant effort, but they were willing to put that effort in because they thought it was the right thing to do for improving the workforce processes for pediatricians and improving the care for children. So, at the taskforce level, it was pretty unanimous that we shouldn't cast this aside because it's going to be challenging, but we should proceed with this in a careful manner, with oversight from the ONC to make sure that the governmental and the policy issues are addressed before implementation is really being conducted.

Robert Wah – Individual – Chair
Thanks. Carolyn, did you have other comments? Just to note, Chris, you may not have heard Arien's initial comments that started this discussion. You just came in at the time that Sasha was talking, so. I'll turn it back to Carolyn for other additional comments.

Carolyn Petersen – Individual – Chair
No, I think I would just reiterate what Chris had said about the taskforce and developers of pediatric EHRs on the taskforce feeling quite strongly that this is something we need to move on now; that it is functionality that is really quite important in the pediatric setting, and something that we should not be waiting on. Please go ahead and –

Robert Wah – Individual – Chair
And just to make sure I understand too, Arien, are you suggesting a change in the transmittal letter or the recommendations here from the committee? Either you or Sasha, I guess, the comments that you said?

Arien Malec – Change Healthcare – Member
Yeah. I am suggesting that ONC, that the transmittal letter recommend that ONC urgently drive a policy and EHR policymaker, an EHR developer and provider workgroup, or a similar effort, to define and address the policy needs and the functional requirements that are associated with DS4P to ensure that there's actionable policy and functional requirement guidance, so that we can implement privacy sensitivity in a way, to Sasha's point, that's consistent and addresses – that's consistent across the HR vendors, addresses the true policy and privacy needs, goes against a clear set of policy items that – some of which I've raised, some of which other folks have raised, and actually drive the benefit for the work that's being recommended.

And again, just to be clear, I don't think anybody's saying we shouldn't do this work. I think everyone recognizes that there are many domains that are privacy-sensitive and where segmentation is incredibly necessary in order to drive the twin benefits of safety and improved care and additional privacy. The basic concern that I'm raising is that we do not have the policy recommendations that align with the

technical specifications. And everyone seems to believe that the technical specifications are sufficient. And I think Sasha and I are just raising the issue right now that they are not. And so, the recommendation – the request to the taskforce is to include recommendations to ONC to convene the policy work relatively urgently so that we can actually address the key functional requirements.

Robert Wah – Individual – Chair
So, Clem, just to make sure I frame this correctly, we have the recommendation from the past letters that you see before you on the screen. Arien and, I guess, Sasha, second to that, are recommending an addition to that about having ONC clarify the policy and functional requirements, along with what you see on the screen. I'll ask Clem and Steven if you have comments specifically on that topic. I'll take that now. So, Clem, is that where you are at?

Clem McDonald - National Library of Medicine - Member
Yeah. Well, I don't know which sentence, but this issue about the final recommendation, I'm certainly on. I don't know what the "it" is, so it makes it really hard for me to – and I've been following DSP4 [sic] since it was born. I just had to review a couple of things. So, this was stimulated by the need for drug and alcohol treatment initially. But no one's enumerated – now, this broadened a bunch of state laws, but I haven't seen any enumeration of what's counted. It worries me to death as a clinical caregiver, is what's going to be subject to redaction? Is that going to include medication treatments, which could be very dangerous to be hiding those? Big safety risk. Are there any break the glass exceptions? Who really won't be able to see this in the general case? The local doctor, the emergency doctor?

Libby Zion's death was not due to tired interns. It was due to the fact that she vehemently denied the use of cocaine, and their interns believed her. If there had been a record of cocaine they could have seen, they would have saved her life. Will that redacted data be available to public health? If not, how will they deal with outbreaks related to protected content? Drug abuse indicators are the thing to be most likely redacted highly. How will we keep that in public health data? What protection will providers have against malpractice when they make decisions that would have been contraindicated if they'd known the facts?

It would be one thing to comment on the requirements of the state laws, but I think it's – in the last line of this, it also suggests that patients can ask you to pick any of their data they want to hide and that providers should be – and one thing I read, should be encouraged to help pick out the things they should hide. Where are they going to get the time to do that? And then you've got really a mess because you can automate the process in a future fashion, whereas you probably could with the ones that are numerated by law. So, I don't think we're very clear on what the "it" is, and I'd like to sur see that happen as part of the process of improving it. I think the state law stuff is at least doable if it can be enumerated and the things identified.

And the last thing is the narrative. So, there has been DS4P. It was implemented in the last round, and it was deemed a failure, either because they couldn't hide everything, or they just took out the whole record, I think is what had – that was the only choice they had. I don't see how that's going to change as long as you've got narrative in the text unless we're planning also on abolishing narrative and making providers click everything in as mouse clicks. So, I think we should look before we leap. And I think it's something worth pursuing, but I don't think it should become a regulation in the next round. At least until it's clarified better.

Robert Wah – Individual – Chair
Chris or Carolyn, do you want to respond to that first?

Carolyn Petersen – Individual – Chair
So, well, I have an additional text bit to add to the transmittal letter to propose, but I'll first give Chris a chance to respond to Clem's and other comments.

Christoph Lehmann – Vanderbilt University Medical Center – SME
Thank you. I appreciate the concerns that Clem voiced. But respectfully, I want to point out that it's a very paternalistic view of the patient/provider relationship. There is no – physicians don't have the right to know everything about their patient. As a patient, I feel very strongly that I should have the right to hide information that I don't want providers to know, or that I want to be sequestered from information that's known about me. And that is something that potentially could jeopardize my life, as Clem rightfully pointed out. But it is, I believe, a patient's right to make these kinds of choices, just like a patient can decide that he or she doesn't want to have a blood transfusion.

So, I think there is – this freedom of choice of treatment extends to the amount of data that is known. And I think the comment that this is a potential liability, I do appreciate that as well, but I think it is very clear that malpractice is something where a provider acts against the standard of care, based on the facts that are provided to him. So, if that information's not accessible, I think that limits the exposure to physicians who do not choose the treatment that would resolve the problem because they were unaware of it. So, I appreciate the comments. I really do. And I think Clem's absolutely right. There's a lot of thinking and a lot of policy work that needs to go into this.

Clem McDonald - National Library of Medicine - Member
Well, I just want to clarify. I don't say patients shouldn't hide stuff. But I'm saying they just shouldn't – and what my experience has been, and I practiced in an inner-city hospital for 35 years, they don't tell you if they want to hide it. And I don't object to that. They don't have to say it. But the problem managing this data flow is a big burden and a lot of complications. And they have the right to not say it. So, they already have that control.

Christoph Lehmann – Vanderbilt University Medical Center – SME
That is correct for some information. But there's other information that the patient does not have a choice not to disclose. So, if a lab test has been – if you obtain a lab test that suggests that the patient has an infectious disease, he doesn't have to tell you that he knew he had HIV or something like this. But your lab test might discover it in an indirect way or some other way. So, there is information that the patients do not have control over that it doesn't get disclosed to the physician at some point over time. And the expectation that it then can get sequestered and is not further shared, I think, is a reasonable one.

Robert Wah – Individual – Chair
Steven, did you want to comment on this particular point as well?

Steven Lane – Sutter Health – Member
Absolutely. Thank you so much, Robert. So, I have put the bulk of my thoughts into the public comment chat. But I want to agree with the perspectives that have been brought by all of the commenters thus far on this point. This is a thorny problem and one that we all want to solve. I did suggest some specific

modifications to the text that is showing on the screen, which I'll read briefly. This is in the last couple of sentences of the recommended text, which I would like to formally propose. It sounds like Carolyn may have a plan here, but I do want to propose that we focus on developing stakeholder consensus regarding what data may be restricted by the patient and what data must be transmitted to support safe coordinated care. I think that the current wording leaves this a little bit murkier than it could be. So, I wanted to propose that.

I also want to comment on the conversation that we've been having. And that is that I support the right of the patient to restrict their data, but I think it really needs to be balanced by the need for any clinician or caregiver to know that specific data has been restricted and to be informed about how that could potentially impact their car. I don't think that's to say that the provider should have a choice whether or not to provide care in that context. All clinicians know that you're never playing with a full deck and that you – often, there are gaps in information. But it's one thing to be dealing with known gaps in information simply for lack of ability to go out and find out. It's another thing to know that you're dealing with a gap in information that was placed intentionally. That carries additional clinical information, beyond the fact that there's missing information. Just the fact that information was restricted from access does itself provide information to inform the care we provide. Thank you.

Robert Wah – Individual – Chair
All right, Chris, thanks. So, just to tell the group where we are as well, as you can see on the screen now, for those of you that are on the application, there's sort of this omnibus thing written as Notes 9 that captures both this issue about patients having the ability to choose what information they divulge, clinicians acknowledging that they may not have a full information set on which to make decisions, and then also the need for stronger policy recommendations in the area of DS4P, and urging the ONC to have a workgroup that brings together policymakers, developers, and providers to address the policy needs and functional requirements.

So, Notes 9 is catching, I think, a lot of what we've had a discussion on already. I think we'll continue to have a discussion using Notes 9 as a framework, and eventually, we'll consider this as an amendment to the transmittal letter. I guess an amendment by addition of this language to go in the transmittal letter in this area. So, let's continue the discussion. Chris, let me just have you comment about the Notes 9 that's been created here, and then I'll go to Clem after that.

Christoph Lehmann – Vanderbilt University Medical Center – SME
Thank you. I appreciate what's in this note, and I just have one comment about the second part of the first sentence. I'm not quite sure whether clinicians have a right to know that there's a restriction. But let's assume we agree with it. There is a potential that by knowing that there is data missing, that the content of the missing data actually can indirectly be deducted and thus revealed. So, I am a little bit leery of this right to know. I'm not quite sure that that is something that really is a clinician's right. But I would make sure that if there is the information related to clinician that there is a restriction, that it is broad enough and global enough that it does not reveal the underlying restricted information by the fact that it's mentioned that there's a restriction.

Robert Wah – Individual – Chair
So, Chris, if I could ask you to consider if there's a change in Note 9 language that you'd recommend, and then I'm going to go to Clem for his comments. And then maybe you could come back and suggest specific language that you'd like to see made in this – geez, that's a second amendment to the

amendment, but that's okay. We'll deal with that. But I think we're going to need some specific language to deal with your – and I want to have it clear to the group what they're considering if we can. So, if you have a specific recommendation for modifying what you're seeing on the screen for Notes 9, if you could, Chris, clarify that in a minute, I'll give you a chance to make that recommendation.

Christoph Lehmann – Vanderbilt University Medical Center – SME
Thank you.

Robert Wah – Individual – Chair
Clem, did you have another comment?

Clem McDonald - National Library of Medicine - Member
Well, yeah. I still don't – well, there's two parts to it. There's that I don't think what we're planning to do and the consequences are well enough explained. Well, for example, are there no exceptions? There's no break the glass? There's no – public health can't get at any of it? Is that the case now? I wasn't clear on that. I would change my thoughts about it if I did. And then, how can this actually be done? I've been doing computer stuff. How can we actually accomplish it as long as there's narrative in the notes? It's mostly narrative still. So, how are we going to – are we going to have to have extra clerks read through and redact? I see it is not feasible. What's the feasibility? How are we going to do it? But I'd like to hear someone say how we can do it as long as we have narrative.

Carolyn Petersen – Individual – Chair
Clem, this is Carolyn. Within the charge that the taskforce received from ONC, they were really looking for a general recommendation, you might say some direction, rather than specifics about design principles or a framework for how developers would be directed to build out the functionality that we're talking about. And that's in part why I have proposed in this language that's up on Note 9 this convergence of a group to work on more of those specifics. Clearly, there are some really strong feelings about this on the HITAC. As a committee, as a whole, we really have to provide ONC with some direction on this topic. But what is in this note would facilitate the group that could do the more specific work and get at more of the detail about that.

Clem McDonald - National Library of Medicine - Member
Well, that was a rhetorical question. I don't think it's feasible as long as we have narrative. And we're being asked to do something that's never going to make people happy because there'll be leakage into the narrative, and it's not possible with today's technology to kind of peel out anything that might be classified. And I would at least see some – I'd buy, okay, yeah, hide HIV. The pediatric stuff is pretty well-defined. But a lot of it is not. And we need some definitions to figure out something about this thing. And I think we've got to look before we leap. I'm in favor of doing something. But I think this something is now very, very mushy. And I don't know that it actually can be done.

Sasha TerMaat – Epic – Member
Does Note 9 replace something in the current transmittal letter, or where is it incorporated?

Carolyn Petersen – Individual – Chair
I did not expect that it would replace anything. I expected that it would be added to the text. And I have not put it in a particular place in the text. I think we first need to agree on what should be in Note 9, and then we can worry about where to place it in the transmittal letter.

Steven Lane – Sutter Health – Member
Carolyn, I'll point out that my suggested text was specifically meant to be a replacement in the last two sentences of what's on the screen now, which I feel – I think the notion of – I think the language as presented is faulty. And all data is private. The notion of creating a consensus of what data is private seems very odd to be. All PHI is private. **[Crosstalk] [00:48:12]**

Sasha TerMaat – Epic – Member
I think another area we will want to look at is the first paragraph, where the taskforce endorses ONC's proposal to incorporate this into certification. It seems like we would want to indicate that that is dependent on the work that we're describing here happening first.

Clem McDonald - National Library of Medicine - Member
Yes. Yeah. But in defense, a little bit, of Carolyn, I think, yes, all that is private. But I think it would be nice to have an enumeration of those high areas because then you start to have a way to comb down and find some solutions. And if we could enumerate the things that people are really worried about and discretely focus on those, I think then they're more likely to get solutions. I mean, we could find the test results that show sexually transmitted diseases automatically. So, to that degree, having an enumeration or category would be helpful. So, I would agree with Steve. It's all private.

Carolyn Petersen – Individual – Chair
So, what changes are we then – Robert, do you have a list of changes, or how do you want to approach dealing with these? I feel like we're looking at 12 things all at once, and that's a little hard.

Robert Wah – Individual – Chair
Yeah. I mean, initially, I thought we could incorporate all these into what I was calling sort of an omnibus statement. But it's looking more like it is not going to be possible to address all the concerns that have been voiced simply with Notes 9. And again, as one of the co-chairs here, I want to make sure we're helping clarify the issues before the entire committee without making a – I don't personally want to make a recommendation to the entire committee here on what they should do. But it appears to me that there are more issues than can be addressed simply with the Notes 9 language that I see here. And now we're modifying that a little bit. And Chris has now added his suggestion to changing Notes 9, which, again, thank you for that, Chris. But I guess I'll ask you, Chris and Carolyn, how you see Notes 9 addressing all the things that have been said. I'm of the opinion that Notes 9 probably is not going to be adequate to address all the issues that have been discussed simply by the addition of Notes 9 to the transmittal letter.

Christoph Lehmann – Vanderbilt University Medical Center – SME
Yeah. I think this is indeed a complex and thorny issue, and I wanted to first comment on the fact that all data are private. I think it's becoming very apparent from the discussion here that we are actually talking about different levels of privacy, right? If data is in the electronic health record, any clinician who is currently taking care of this patient has access to the whole gamut of the data. And that, with the notion for data segmentation, has introduced a new level of privacy that you can actually keep data private from the treatment team. So, clearly, the privacy that we are used to is pointed out – with just going into this direction, it's identified as being incomplete for the needs of patients who actually want to keep the data hidden also from providers.

So, it is a complex issue that introduces really a new definition of what private is. And I think what we have here on the screen is an approximation that I could live with. But I'm not quite sure that your group is currently willing to agree to that. So, it would work for me, though.

Steven Lane – Sutter Health – Member
Yeah, Chris, this is Steven. I have no concerns about your suggestion that we restrict the data type that has been withheld. And I put it in public comment regarding why I feel that way.

Robert Wah – Individual – Chair
Steven, I'm sorry, you broke up for me. Can you just repeat what you said?

Steven Lane – Sutter Health – Member
I'm sorry. Can you hear me? Let me make a change here, see if it helps. Within my public comment. Here, let's see if that helps. So, as I put in the public comment, the patient may not remember what data they've restricted in the past. And having spent a lot of time talking to patients about their concerns about their privacy, and interoperability, and their desire to restrict data, typically, their concerns are fairly global – that they're just afraid that people they don't want to access their data will access it. And when they are having a face-to-face discussion with a clinician about the care they're receiving in real-time, they are typically very forthcoming, understanding that data is being shared within the private sphere of a specific provider/patient relationship.

But again, I think patients may not remember that five years ago, they put a restriction on something. And unless the system can say that an allergy is missing, or a drug is missing, or a specific piece of surgical history is missing, then the provider can't have a meaningful discussion with the patient about that. If, as Andy suggested, you just say, well, there's some secret information back there somewhere in the last 60 years that somebody decided to hide, the patient may not recall what that was, and misses the mark in terms of support and safe care.

Carolyn Petersen – Individual – Chair
This is Carolyn. I would wish to respectfully disagree with that. I think that much of the information that patients wish to segment in their records to keep people from seeing is a reflection of a broader desire that information, particularly about things that happened in the past, not come to light in any environment. For example, if a person has been treated for a mental health condition many, many years previously, or received diagnoses of mental health problems as a child and has spent some years living hopefully without problems, a life that most would consider acceptable without medication, without criminal behavior, domestic violence, or other things that we would consider issues of concern for that individual's health and safety, as well as for the health and safety of others, that may be something that they very much are aware they have suppressed and are trying to avoid being made public in other areas of their life.

For example, to employers, to potential life partners, on social media, and in other places. I think certainly if someone perhaps doesn't want one drug for some reason suppressed, maybe that would be something. But I can't think of any plausible situation in which I might say, we're not going to talk about my use of penicillin when I had an allergic reaction in 1997 and then forget about that. I think really, people want to segment data so that they can put things behind them in the past.

Clem McDonald - National Library of Medicine - Member
So, Carolyn, when you talk about specifics, it all seems doable. But so, I wish we could again get to enumeration of what we really want to try to segment, instead of whatever happens.

Carolyn Petersen – Individual – Chair
Well, I think it's not so much what we as HITAC members want to segment. It comes down to what patients feel in their life is relevant to be segmented.

Clem McDonald - National Library of Medicine - Member
Right. But when you talk about specific things that make sense, it's easier to think about how you could accomplish it.

Carolyn Petersen – Individual – Chair
Well, I appreciate there's value in use cases, and that is something that perhaps can be addressed with another group or a further extension of this taskforce. But I think that's not for us to do today in terms of dealing with the charge.

Clem McDonald - National Library of Medicine - Member
Well, the other thing you brought up, insurance. And mostly, people sign away everything to the insurance company. Will they be blocked?

Carolyn Petersen – Individual – Chair
We don't have specifics in front of us, Clem. I can't answer that question, and I think you know that.

Christoph Lehmann – Vanderbilt University Medical Center – SME
I'm not sure I understand the question, Clem. I mean, currently, I got really – I'm set to give you – since we'd like to have use cases and talk about real life circumstances, my daughter sought healthcare. And since she is still on my health insurance due to the current legislation, I was able – I got the bill, and the bill clearly identified what type of provider she was seeing, allowing me the opportunity to deduct from that what her healthcare needs were. So, there are real problems currently with the way insurance billing is done, but I don't think that this is really the issue that we're trying to address here.

Robert Wah – Individual – Chair
All right. So, Andy, I see your hand up, and there's a number of comments on the public comment site as well that are outside the discussion that we're doing right now. Or maybe not outside, but in addition to what we're also discussing. I want to try to bring us to a point in which we can move forward with – either move forward or not with the transmittal letter. What has been proposed is on the screen under Notes 9 with the suggested change by Chris. Let me entertain some more comments on whether or not Notes 9 is sufficient to address these issues, and how it would be then put into the transmittal letter. I've heard a comment that some of the language in the transmittal letter would need to be replaced by what's in Notes 9 as opposed to just adding Notes 9 in there. But I want to try to get us to a point where we can either amend the transmittal letter with something, whether it's Notes 9 or some modification of Notes 9, or somewhere.

But I think this has been a great discussion. But my concern is we need to move forward with the proposed transmittal letter from the taskforce. And so, at this point, I'd like to just take comments about how best we can use what's on the screen in Notes 9 to improve the transmittal letter. And then if we can get there, we'll then have an amendment that we will then forward on and incorporate into the

transmittal letter. So, Andy, you have your handbook, and I know you've typed some things into the discussion, public comment. But I think we've had a good discussion on the issues. What I'd like to now get us to is taking that discussion and making a change if we need to to the transmittal letter, and so we can wrap this up. Andy, do you have a comment on that point?

Andrew Truscott – Accenture – Member
Okay. Yeah. So, I would suggest that we take the drafting that's in the notes right now. I'm very comfortable with that. I was uncomfortable with the original drafting of the transmittal letter, so I would suggest taking what's on the screen, with the addition that's **[inaudible] [01:01:40]** workgroup or something, I would take it forward as a taskforce, an asset taskforce to make continuing recommendations around this section.

Robert Wah – Individual – Chair
Thank you. Steven?

Steven Lane – Sutter Health – Member
Hi. I just want to express my persistent concern regarding the strategic type of data that has been restricted. I fully respect Carolyn's comments and believe that one can incorporate patient right to privacy and needs for putting things behind them. If a provider simply knows that there's an element from the past surgical or medical history that's been restricted, he can have a discussion with the patient, and the patient can simply say, "I don't want to share that with you," or it's irrelevant to the care we're providing. I think that's enough. Privacy's respected. Clinicians have the data they need to provide safe care.

Clem McDonald - National Library of Medicine - Member
There was a statement in the original policy, one sentence talking about a balance between safety and care in privacy. That, I think, could be helpful for the discussion to make sure there's appropriate balance, paternalistic or maternalistic, whichever you want to call it.

Robert Wah – Individual – Chair
Well, Clem, do you have a specific change to Notes 9 that you're suggesting?

Clem McDonald - National Library of Medicine - Member
Well, if I got back to that sentence – it was in Carolyn's original one. I think I could pull it out of it. I don't see it now. It talked about balance. And this version effort would include examining the balance between safety and privacy. There was a sentence. Carolyn, do you remember what it was or where it was?

Carolyn Petersen – Individual – Chair
Let's see if I can pull up the slides on my own computer to get to that.

Clem McDonald - National Library of Medicine - Member
That would fall under the functional requirements, I think.

Sasha TerMaat – Epic – Member
Just so I understand Notes 9, it says replacement language for the first sentence. Is that replacement language for the first sentence of the previous Notes 9, or the first sentence of the paragraph on the slide that we had been looking at prior?

Christoph Lehmann – Vanderbilt University Medical Center – SME
It was a suggested change to the first sentence on Note 9, the top sentence. That's what I had intended there.

Sasha TerMaat – Epic – Member
Thanks, Chris. I think it would be helpful if we're going to vote on this to put the note in a context so we can see the full proposal all together.

Robert Wah – Individual – Chair
Yeah. So, Chris clarified, I think his comment is to change the Notes 9 language that's there. And Sasha, to your point about where Notes 9 would go in the transmittal letter, which is what I was trying to also get to, I believe the original proposal was this would be an addition to the transmittal letter, that language that was already on the screen. I'm trying to . . .

Carolyn Petersen – Individual – Chair
If it would be helpful, Robert, I could take this note offline and incorporate the changes that I think people are asking for, and show it embedded in the transmittal language, and we could perhaps bring that back after the Info Blocking group. I know they need a significant chunk of time, and clearly, we do need to come up with something to say about DS4P for the transmittal letter. Would that be helpful?

Robert Wah – Individual – Chair
Yes, thank you very much. I think that would be good. I'd want to make sure before you do that, any last comments for Carolyn's benefit as she crafts the new version of Notes 9 and how it fits into this?

Christoph Lehmann – Vanderbilt University Medical Center – SME
Yes. One quick response to Steven Lane. I think I appreciate your comment, and I'm realizing that what I'm doing is kind of redundant. As long as you can't deduce the content of the restricted data, then I don't object to some general types that the physician is aware of. So, maybe we want to just delete what type.

Steven Lane – Sutter Health – Member
Thanks, Chris.

Robert Wah – Individual – Chair
Okay. Other comments before Carolyn goes off and crafts this change?

Clem McDonald - National Library of Medicine - Member
Oh, I think, yeah, we can then see it all together. Sasha's suggestion –

Robert Wah – Individual – Chair
Yeah. I think we'll also look at a way to display it so everyone's clear on what we're voting on. I appreciate that. Okay. So, Carolyn and Chris, what else do you have in your recommendations? I can't remember, is this . . . I want to wrap up the task.

Carolyn Petersen – Individual – Chair
Yeah, these are just the resources that we had that informed us in our discussions as a taskforce.

Robert Wah – Individual – Chair
Okay. So, this was the only issue you're bringing before the committee. Is that right?

Carolyn Petersen – Individual – Chair
That's right.

Robert Wah – Individual – Chair
Okay, great. So, thank you for taking that offline. We will come back to that. Just let me know when you're ready to do that, then I'll put it back into the discussion. We're a little bit behind time, but I think we're fine. Next, let's move to Information Blocking because they have a great deal of material that we did not get through in the previous meetings. So, Andrew, I'll turn it over to you.

Andrew Truscott – Accenture – Member
Thanks very much, sir. Good morning, everybody. Yeah, we're going to work through the – principally the workgroup one recommendations that we didn't get through last time, and a couple of ones from workgroup three as well. We'll just come back to just one part we couldn't get. So, if we'll crack on, please. Okay, I think we're all aware and familiar with the Information Blocking Taskforce charge. Next slide, please. Next slide, please. Okay.

So, the first pair of recommendations we made here, and these are around the – actually definitions around health information network and also health information exchange. As we considered these, we were thinking about, okay, what's the scope of impacted actors which would fit inside this? And we were very keen to preserve the intent of Congress. We had a great deal of discussion about whether exchange was a group, an organization, or a verb, and the way that different bits of legislation and different references within 21st Century Cures actually referred to exchange in different ways. And what we decided to do as a taskforce was to look at the definition of health information network and trying to make it clearer by removing the affiliated or the – we used to have affiliated or unaffiliated. So, we said, okay, a health information network is an individual or entity that satisfies one or several of the following.

And that's these two conditions here – that they determine, oversee, or manages the control or sets policy or makes agreements that define business, operation, or technical, or other conditions or requirements of a health information exchange between or among two or more individuals or entities; or provides, manages, or controls any technology or service that enables or facilitates health information exchange between or among two or more individuals or entities. And the reason we've structured it like that was so that we felt that it would refer to the various organizations who conduct health information exchange, and whether or not they are between members of that exchange or network, or whether they are organizations which may seek to use it but not be members of. So, we wanted it to be unrestricted and broad in that regard. If we could go to the next slide, please.

And then by looking at the definition of a health information exchange, we said, okay, if you're not considered a health information network, not considered a provider, not considered a developer of health IT, but you are conducting access, exchange, transmittal, processing, handling, or any other such use of electronic health information, therefore, we would say that you need to be caught up in this definition of health information exchange. So, the two taskforce recommendations here are seeking to bring about clarity and precision in the use of the definitions. Has anyone got any comments?

Robert Wah – Individual – Chair
Andrew, you've got, I think, four recommendations that deal with definitions, right? The first four?

Andrew Truscott – Accenture – Member
We do, yeah, yeah. I'll ask for comments at this point.

Robert Wah – Individual – Chair
Yeah, why don't we go through one through four, and then we'll take comments about what I consider the definition recommendations?

Andrew Truscott – Accenture – Member
Okay, sure. We'll get those as quick as we can. Okay, so secondly, the taskforce believes the – next slide, please, sorry – the proposed definition of electronic health information is a strong definition, and it covers a great breadth of data that should be being addressed inside the regulations. We made some recommendations, some slight modifications to the language to cover both the current future and tenses – "can" versus "could," etc. And we also looked at whether in the CURES Act, Congress was seeking to aid transparency across the healthcare ecosystem, and whether a definition should be limited to identifiable health information, or whether it should include all information within healthcare. And the taskforce felt as a whole that the use of the term identifying the individual was very specific around health information associated specifically with the care provided to that individual.

However, in these augmentations we made, principally number three here, electronic information which can reasonably be used to inform care decisions by a provider or patient, including pricing information, which can be attributable to an individual patient, we felt that that was bringing about or promoting the level of sharing of pricing information that we are actively seeking with the pricing transparency initiatives that could be attributable to individuals. So, not necessarily identifying the individual, but that could be attributable and relevant to their care. So, that was the thinking behind that.

And then, kind of tying in with the previous conversation we've had with the previous taskforce, this item 2ii, on the two-year anniversary of the effective date of the final rule, so within two years, an individual's consent directives for privacy, medical treatment, research, and advanced care. The reason for that two-year would be to tie in with the capabilities of the standards to communicate those. So, that's where we got to on electronic health information. Next slide, please.

Okay. So, there is a minority opinion from within the taskforce. The minority opinion within this taskforce is that the definition of EHI is overly restrictive in the current regulation. And the demands that an individual should be identified is felt to be overly restrictive, and it should – the definition of EHI should be opened up when the full definition of health information is defined within HIPAA. And this information should be completely unblocked in some places. The taskforce considered this minority opinion and felt that with the wording, it just seemed on the previous slide around information that could be attributed to a patient, if not identifiable, felt that that was a good position to be taking. However, the minority opinion felt that that was insufficient. And this opinion is being made, and we are including it inside the transmittal letter. Next slide, please.

Okay. We've made an additional recommendation to go into the preamble around electronic health information, that we should be referring to both human readable information – so narrative, clinical notes, etc. – as well as machine readable information that's codified, etc. Next slide, please.

Robert Wah – Individual – Chair
Why don't we stop there and just take comments? I'm sorry. My reading of this was that there was a grouping of four recommendations that were pertaining to the –

Andrew Truscott – Accenture – Member
Let's go back in the slides. That's probably reasonable, to stop there. Yup. Let's go back a slide. Yup.

Robert Wah – Individual – Chair
And so, why don't we take comments about these first four recommendations as laid out by the co-chair of the taskforce. John, do you have your hand up?

John Kansky – Indiana Health Information Exchange – Member
Yeah. Andy, I had a comment related to the health information exchange definition. And I don't know if I just realized this or if something got tweaked. Something I really, really like about the proposed recommendation to the health information exchange definition that says, if you're not one of these other things, you must be an HIE, is that it clarifies for a provider or a provider network that clearly meets the definition of a provider, they won't end up being an HIE. I think that's really good. What the unintended consequence that I may have just realized is that it makes HIE sort of the last definition that would end up applying to an organization than one of the others. And I'm not sure I remember that being what we discussed.

So, in other words, using my organization as an example, at the Indiana Health Information Exchange, we do have one piece of certified technology that we produce. We would be an HIT developer, and therefore wouldn't be an HIE. And if we meet the definition of an HIN, which I think we reasonably might, we would be one of those, and we wouldn't be an HIE, which might be fine, but I'm not sure that's what we intended.

Andrew Truscott – Accenture – Member
Yeah, I think we discussed this. I think the intention was that you could be considered – and this also ties into the public comment that's just been made, that these are not mutually exclusive. So, you could be an HIN as well as being an HIT developer. You could be an HIN as well as being an HIE. But if you were not an HIT developer, you were not an HIN, you were not a provider, and you were accessing, sending, or otherwise processing EHI, you would be considered an HIE.

John Kansky – Indiana Health Information Exchange – Member
So, the clarification is that – but you can be one of those things and an HIE. It's just that if you're not one of those things, you might be an HIE if I said that right.

Andrew Truscott – Accenture – Member
I think you said that right. Yes. Does that need clarification in the text, or is that a preamble explanation?

Robert Wah – Individual – Chair
Can we roll back to the – I think it's recommendation two? This is the one you guys are talking about, right?

John Kansky – Indiana Health Information Exchange – Member
Correct.

Andrew Truscott – Accenture – Member
Because it says that you're not considered a provider, not considered an HIN, not considered an HIT developer, but you're doing access, exchange, transmittal, process, handling, you would be an HIE. And you're saying, let's say I am in HIN. Could I also be an HIE?

John Kansky – Indiana Health Information Exchange – Member
The way I read this through my own eyes with my EHI hat on is, oh, okay. Well, I'm not an HIE now, because I do meet the definition potentially of an HIN or an HIT. Now I have to figure out which of those I am.

Andrew Truscott – Accenture – Member
I think, yeah, okay. So, from what you're saying, this recommendation has actually raised into your consciousness a scenario that we probably need to explain clearly, which is, what about people, or organizations or entities who are members of more than one group of actors?

John Kansky – Indiana Health Information Exchange – Member
Right. And I mean, the one solution which selfishly, I'm not crazy about, but might be good from a HITAC perspective, is just to say that an HIE that – how do I say this? I'm not using the right words, but if you are one of those things and an HIE – we would have to make it so that it's – the intent of what we're trying to say is that if you meet – if you do some of this stuff and you're not one of those things, you get caught by this definition. If you do some of these things and you do some of those things, you may well be both, and you need to consider that in compliance with the regs, which is frankly one of the things I don't like about adding that. But that's one solution.

Robert Wah – Individual – Chair
So, that's one of them. I think that's a good demonstration of how hard it is to craft this on the fly. It just shows the challenges involved. So, I guess, John, if you want to perhaps suggest a – I'll give you some time to come back – suggest some changes to – I think it's recommendation two that you're looking at changing.

John Kansky – Indiana Health Information Exchange – Member
It is specifically two, yeah. Let me see what I can do.

Robert Wah – Individual – Chair
Yeah. I don't want to put you on the spot while you're talking to craft that. But if you can spend a bit of time on putting that together, then we'll come back to this. Other discussions about the first four recommendations on the definitions from the rest of the committee? Okay. So, let's see.

Andrew Truscott – Accenture – Member
Actually, just a quick question to John on that. John, have you considered whether two needs a change, or whether it needs an explanation in the preamble, and actually whether you want to clearly say if you're an HIN, then you wouldn't be considered an HIE? But if you're not an HIN, not a provider, not a developer, but you are doing access, exchange, transmittal, processing, handling, then you're considered an HIE. Because I think that was the intent we had as we drafted this as a taskforce.

John Kansky – Indiana Health Information Exchange – Member
Correct. I think I know what you just said, and I will consider that and may come back with two options.

Andrew Truscott – Accenture – Member
Thank you, sir. Robert, back to you.

Robert Wah – Individual – Chair
Okay. So, I think, hearing no other comments about the first four recommendations but still not seeing the specific language from John, let's move on. Andy, we'll have to come back to these four when John has that recommendation.

Andrew Truscott – Accenture – Member
Yeah, that's fine. No problem at all. So, let's move forward with this. Yup. Okay. So, this is a consideration around price information transparency. So, as a taskforce, we absolutely agreed that we want to enable price transparency. And we were very keen as a taskforce to ensure that we did nothing inside the information blocking regulations which would delay or defer any kind of price transparency from being publicly available to patients, providers, and any other decision makers around healthcare. So, that's why we crafted the definition of electronic health information so carefully, to ensure that our recommendations would include and promote past, present, and future payment information, as well as pricing information which could be attributable to a patient. So, that was why we put that in place. And we felt that was really in the realm of what we could do with the current regulation.

Now, we did consider whether we would be able to make some additional recommendations around additional regulations, perhaps to continue price transparency initiatives. We were very conscious that we are the Health IT Advisory Committee, and we could inadvertently stray into broader areas of health policy. And that was definitely not our intent. But like I said, we wanted to make sure that there would be nothing restricted from health IT to enable this to happen. So, we made a recommendation here that ONC put in place a taskforce that was specifically charged with future rule-making to improve price transparency across the ecosystem. One of the great luxuries we have on our taskforce was a very heterogeneous group of members who represented every single facet of the healthcare ecosystem in some way.

And they recognized as a collective the complexities of enabling this to happen, whilst also knowing that it is of paramount importance that we do enable price transparency to take place. So, you can see from these bullet points here, the considerations that we would suggest and recommend that this newly appointed taskforce would go through. And this was our recommendation around price information. We believe that this needs to be given a focus. We believe that we do not want to slow down any of the information blocking rules around promoting pricing information to be shared. And so, we felt that this was a good balance to enable that to take place.

Robert Wah – Individual – Chair
All right. Comments on the price information recommendation you see on the screen, recommendation five. Hearing and seeing none, why don't we vote on this, then. All those in favor of recommendation five for the new Information Blocking Taskforce – was somebody trying to get in? I'm sorry.

Andrew Truscott – Accenture – Member
There's paper rustling, I think. Bullocks.

Robert Wah – Individual – Chair
Okay. I just want to make sure I don't rush the vote here. So, all right. We're voting on approving recommendation five. All those in favor of recommendation five, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say no. Any abstentions? All right, great. Recommendation six?

Andrew Truscott – Accenture – Member
Thank you all. Okay, so, health IT developers. We recognized, and this was a long discussion we had as well, nearly as long as price transparency. The way that the CURES Act is currently structured, there is a reference to a health IT developer as an actor, and then there is a reference to the enforcement mandates being afforded too upon the health IT developers of certified health It. And that's a slight dichotomy. And as a taskforce, we felt that whilst the CURES Act doesn't provide the necessary statutory power to promote sanctions against all health IT developers, it was important that the regulations we felt would apply to them. And ONC could dutifully go and explore exactly what that would mean in the final rule. So, what we didn't want to inadvertently create would be a two-track system where you could be – if your health IT you were developing was certified, you were subject to the regulations; whereas if your health IT you're creating is not certified, you wouldn't be subject to the regulations.

And there was this additional grey area in the middle, where if you are – in the current drafting, if you are a developer of one certified health IT product, then all of your health IT products, whether they're certified or not, would be covered and bound by the regulations. And we felt that that was probably not the intent of CURES, but we absolutely do not want to stifle or restrict innovation in any way, shape, or form. So, we look upon the work that's going on right now with TENIF to provide that level of clarity and accessibility and understandability on how organizations who might be legitimately innovating and developing great new approaches around health IT should not be restricted or held back from doing so. That said, we want to ensure that there is, A, a level playing field for all health IT developers, and B, that the regulations apply equally.

We felt that with the current drafting, an unintended consequence could be that you may have developers of health IT that do not seek certification, and actually actively promote information blocking and restrict access to information because it behests them to do so, and they're not bound by the regulations forbidding it. So, that's where this recommendation comes from. Next slide, please.

Robert Wah – Individual – Chair
All right. So, Andy, I think seven onward all refer to blocking. And so, I thought maybe we'll group those as a group. But this one sort of stands alone, in my view. So, let's take comments on this recommendation six, vote on that, and then we'll do the next series of recommendations as one. Ken, I see your hand up.

Ken Kawamoto – University of Utah Health – Member
Yeah, hi. So, by saying that the definition should apply, but there's no authority, I guess is it saying basically, we realize ONC can't really do anything based on this recommendation to expand the

definition of a health IT developer, but we think it should in the future? Could you clarify that a little bit more?

Andrew Truscott – Accenture – Member
Yeah. So, Ken, we recognize that there is nothing inside the CURES Act right now around enforcement powers around developers of noncertified health IT. And the sense from the taskforce was that this may or may not be an oversight inside CURES, and that is for others to consider. But it also then would leave the option for any other kind of litigation around noncompliance with regulations, even though it's not enforced. So, you could potentially have a court going after – sorry, a court being requested to adjudicate on that, or something like that. That was kind of the sense we're coming from. The point was that there was a gap, we think, between intent and actuality. Does that make sense? Ken?

Robert Wah – Individual – Chair
Other comments or questions?

Ken Kawamoto – University of Utah Health – Member
This is Ken if I can. Maybe if you could provide a few examples, I think that would be clarifying. I have a few in my mind, but just want to make sure I understand it. So, it's saying things like, let's say Apple Healthkit or Redox, etc., or other health information exchanges, they might not be certified, but they have access to large amounts of data, or let's say pharmacies, or let's say Appriss for their PDMP data, that we're saying here, we know you may not have authority over them, but we think you should. For example, to only be able to charge on an actual cost basis for access to that data. Is that basically what this is getting at?

Andrew Truscott – Accenture – Member
I think that's the implication of this, yes. I'm not going to go through the specific examples you raised, but I think some of them are very valid. But where there is patient information, which is being accrued, we don't want to inadvertently have a class of health IT developer who could block access to that information. And that's partly to do with the wording around the health information exchange actor as well. If you have a developer of a data platform, and who are providing access, exchange, use services, then as well as being a health IT developer, they could also be a health information exchange or be implicated that way. It's a complicated issue, which we spent many, many hours on.

Robert Wah – Individual – Chair
Other comments or questions about recommendation six? Hearing none and seeing none, why don't we go ahead and vote on recommendation six. All those in favor of recommendation six, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say no. Any abstentions? Okay. So, Any, I'm going to have you go through the next series to the end of your taskforce, which again, I believe are specific to information blocking, is that right? Yeah.

Andrew Truscott – Accenture – Member
You mean seven through 13.

Robert Wah – Individual – Chair
Yes.

Andrew Truscott – Accenture – Member
Yeah. Okay. There's number seven, which was **[inaudible] [01:34:04]**. Actor versus the information type. We've removed that recommendation completely. It's been superseded by other considerations. The taskforce believes that pricing information is an area that could readily implicate the information blocking provision. This information is not routinely exchanged right now and is going to require the focus of multiple actors to ensure that the intent of Congress within CURES is met. We addressed that in more detail in an earlier recommendation, but we feel that patient access to information about them is likely to have implications that relate to the information blocking provision. So, what's being requested here is for insight into particular practices which might implicate. And so, if it's not allowed to take place, then information blocking will come into play. And so, in addition to the parameters which have been outlined in the preamble, we felt that patient access, if patients aren't given open access to information about them, then that would implicate the provision. Next slide, please.

Okay. Recommendation nine was when we were discussing the parties that are affected by information blocking original exceptions. That's also been superseded by other recommendations. We believe that there is an opportunity for confusion that these are the parties which are implicated by the information blocking provision exceptions. And as you can see from our discourse that we've had on this call so far with the definitions before, actors, we've been actively seeking to remove that. But we recognize that the preamble could be updated to give some greater specificity as to the various organizational types who could fall into the various categories of access.

So, Ken, to your point you were making there just earlier, for example, retail pharmacies who curate patient information that has prescriptions, medications, clinical histories, etc. That is considered EHI and should not be blocked. The taskforce as a whole, we believe that a retail pharmacy should already be considered a provider, so an inclusion as a subpart of all pharmacies. But we should confirm that. So, I think there was a sentiment from the taskforce that not all retail pharmacies perceive themselves in the same genre as other providers. We specifically called out insurance companies who do curate patient information. And then we looked at retailers who provide patient information services to IoT devices. That's not necessarily someone just because they sell an IoT device – not at all. But if you provide a service which curates patient information from across those devices, then you should be a party who's implicated inside this.

And lastly, we live in a very, very changing environment, and healthcare is under a constant reinvention right now, even as we speak. And parties will move from time to time in and out of different actor definitions. And the regulations should be recognizing of that. And we've actually got a recommendation we'll come to later that is seeking to embrace that as well. Next recommendation, please.

Okay. So, recommendation 11 is that we're saying that we should also, in calling out the specific organizations who should be included, we're sure to call other specific organization types who are not included. So, organizations where a patient has expressed their – expressed dissent from information-sharing, social media networks who have nonspecific patient attributable health information, and then analytics companies who look at nonspecific patient data as a whole. And then, yeah, that's pretty self-explanatory.

Recommendation 12, please. Okay. And this is tying into looking at how we implicate various organizations. So, we felt that – and it's why we updated health information exchange the way we did. We'd like to think that we've encapsulated the broad definitions of access of organizations who would be implicated by information blocking, and done it appropriately so that there aren't unintended consequences of organizations slipping around the net. And we were also considering that actually, what we're concerned about is electronic health information which would be being accessed, exchanged, or used, or prevented from being accessed, exchanged, or used.

So, if you had an organization who fell outside any of the actors but were still doing that, putting a patient at a disadvantage, we wanted to be able to step in front of that. So, we recommended that there could be a potential for including or having a position for implicating based upon an actor's exchange, access, or use of EHI, as well as their particular role. So, and that's actor with a lowercase A. So, if you're not an HIE, you're not an HIN, you're not an IT developer, you're not a provider, but you are accessing, exchanging, or using health information, then you need to make sure that that's not blocked as well.

And then we made a recommendation 13 around adding some text to the preamble, just to reflect our acknowledgment that the healthcare environment is able to change, and that by having very, very tight actor definitions could have the unintended consequence of actually being too tight, and not including the broad range of organizations who are involved and will increasingly be aboard, involved in the healthcare ecosystem. Next slide, please. Oh, and that's it. Robert.

Robert Wah – Individual – Chair
Great. Thanks for that. John, you have your hand up. Oh, maybe John doesn't have his hand up. Comments or questions then on this series of recommendations that Andy just went through? Ken?

Ken Kawamoto – University of Utah Health – Member
I think this is a bold and, I think, good direction. I do think there's a lot of implications that have to be thought through. But in general, I think the idea that everyone who's in this ecosystem should be sharing data, I think, is a good one. I do think it could be highly disruptive for some folks who haven't been in the certified EHR realm, but I think this will be very valuable, so I support it.

Andrew Truscott – Accenture – Member
And that was the sense coming from the taskforce as well.

Robert Wah – Individual – Chair
Okay. John, I see your hand is back up, and I saw your note in the comments. Do you have a comment, John Kansky? I'm a little concerned that maybe you're not dialed in, even though you're logged into the application.

Andrew Truscott – Accenture – Member
He's dialing back in.

Robert Wah – Individual – Chair
Yeah? Okay. Other comments or questions on this series of recommendations. Okay. Let's get John back in if we can. We'll just take a moment. And let's see. Was John coming back also on the earlier recommendation, I guess? Okay. Let's see here. I'm trying to be efficient with the time. I think John was also going to come back with a specific recommendation of language in the –

John Kansky – Indiana Health Information Exchange – Member
Can you hear me now?

Andrew Truscott – Accenture – Member
We can hear you now, John.

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

Robert Wah – Individual – Chair
I'm sorry?

Andrew Truscott – Accenture – Member
John's back.

Robert Wah – Individual – Chair
John, are you in?

John Kansky – Indiana Health Information Exchange – Member
Yeah, I'm here. Is this a bad time to jump back in?

Andrew Truscott – Accenture – Member
No, we're waiting for you.

John Kansky – Indiana Health Information Exchange – Member
Sorry.

Robert Wah – Individual – Chair
We're on the series of recommendations seven through 13.

John Kansky – Indiana Health Information Exchange – Member
Tell me when you're ready to circle back to recommendation two.

Robert Wah – Individual – Chair
Oh, okay. All right. So, you're coming back for recommendation two. Okay. **[Crosstalk] [01:43:26]**

John Kansky – Indiana Health Information Exchange – Member
I just need a little guidance, thanks.

Robert Wah – Individual – Chair
Okay. So, let's just finish any other comments, questions about recommendations seven through 13. Hearing and seeing none, let's go ahead and vote on recommendations seven through 13. All those in favor of recommendations seven through 13, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say no. Any abstentions? Okay. John, let's go back to recommendation two, the definition of HIE.

John Kansky – Indiana Health Information Exchange – Member
Thank you. So, Andy, help me out, because I need to narrow down some options. What is harmed if we delete the phrase "who is not considered" blablabla? What was the purpose of trying to – I mean, I like the idea of clarifying which definition category you're in, but some of the options I'm creating, I don't want to lose the purpose of that exclusion.

Andrew Truscott – Accenture – Member
The sense of the taskforce at the time was that by having that text in there, we would specifically capture organizations who were not a provider, HIN, or HIT, and say, okay, if you are performing access, performing exchange, performing transmittal, performing processing, performing handling, or anything similar, and you're not a provider, an HIN, or Hit, we think of you as an HIE.

John Kansky – Indiana Health Information Exchange – Member
And so, that's still true if you delete the latter half of this sentence. Any entity performing accessing, exchange, transmittal, processing, handling, or other uses of electronic health information, stop. If you do that, you're an HIE. True?

Andrew Truscott – Accenture – Member
I think so. But we debated this one and felt we should have it. I actually was going to make a suggestion. What if we wrapped the sentence around and say, any entity who is not considered a provider, HIN, or HIT developer, because then immediately, if you say, okay, if you are considered one of those, then stop reading, okay? So, any entity who is not considered a provider, HIN, or HIT developer who performs the access, exchange, transmittal, processing, handling, or other such use of electronic health information is considered an HIE.

John Kansky – Indiana Health Information Exchange – Member
That's fine, but it doesn't change the problem that so, I stop reading after the first half of the sentence because I'm already one of those other things.

Andrew Truscott – Accenture – Member
That's fine.

John Kansky – Indiana Health Information Exchange – Member
Yet – oh, okay. Well, that's going to be weird. Then I guess – all right. So, then we do need in – I recommend in the preamble that we address that one can meet the definition of more than one thing.

Andrew Truscott – Accenture – Member
Well, I think, so the sense of things from the taskforce was that you couldn't be an HIE plus another actor.

John Kansky – Indiana Health Information Exchange – Member
Okay.

Andrew Truscott – Accenture – Member
You could be a combination of the other actors. So, you could be a provider who's also an IT developer. You could be a provider who's also an HIN. You could be an IT developer who's also an HIN. But if you weren't any of those three, and you were doing access, exchange, transmittal, processing, handling, or other such use of EHI, then we'll consider you an HIE.

John Kansky – Indiana Health Information Exchange – Member
Okay. So, then perhaps all that's needed because I understand your point – perhaps all that's needed is to address in the preamble, it's a relatively small group of actors, but you're going to dramatically confuse the HIEs because they're all going to be HINs, which is fine. And this thing that they think they are, an HIE, is going to pertain to a whole bunch of other organizations – a whole bunch of other organization. Because I just want to point out, we do not have in this definition the words between or among two or more individuals or entities.

Andrew Truscott – Accenture – Member
And that was deliberate from the taskforce, wasn't it, that that language was removed. And I remember the time we had this conversation, and you were a great advocate for the clarity in here, of saying a health information network is X. And that's why the definition of health information network we've got has been refined to bring that level of clarity as well. So, I think your actual organization would fall under the HIN definition, even though you call yourselves an HIE.

John Kansky – Indiana Health Information Exchange – Member
Correct. And I will stop reading after you flip this sentence before the comma.

Andrew Truscott – Accenture – Member
Okay. So, your proposed recommendation, I think, is to flip the sentence.

John Kansky – Indiana Health Information Exchange – Member
I think it helps a little bit, but it says the same thing.

Andrew Truscott – Accenture – Member
Yes.

John Kansky – Indiana Health Information Exchange – Member
And that the preamble will need to speak, kind of explaining what we're saying in words, is that, hey, if you meet one of these definitions, then go with that definition when you comply with the regulation. You're not an HIE if you don't meet one of those definitions, but you do this, then you are an HIE. It's going to be a confusing use of the term, but I think in the context of the regulation, it achieves what the taskforce intended to achieve.

Andrew Truscott – Accenture – Member
Yeah. I think then the other, just so the whole of HITAC is aware, the conversation we had in taskforce was also the use of the term health information exchange is one that's used in very many different ways anyway, both in the industry and also within 21st Century CURES. If you read the rest of the transmittal letter preceding this recommendation, you'll see that we've actually drawn out the various different uses of the term health information exchange inside 21st Century CURES by itself, and they are conflicting.

John Kansky – Indiana Health Information Exchange – Member
So, for the benefit of ONC, the thing that's going to be confusing, the health information exchange – it would be helpful in the preamble if it said something to the effect of, we expect many organizations who the industry calls health information exchanges to meet the definition of HIN.

Andrew Truscott – Accenture – Member
Yes. So, Robert, how do you want us to move forward?

Robert Wah – Individual – Chair
Yeah. So, okay, let's work on what's on the slide right now. What I think I believe I heard you say was you wanted to change the order of the words in that last paragraph, and it would now read health information exchange or HIE means any entity who is not considered a provider, health information network, or health IT developer, who does perform – yeah, and then just go on after IT developer, say performing the access, exchange, transmittal, processing, handling, or other such use of electronic information. Period. Is that –

Andrew Truscott – Accenture – Member
Yes, that's correct.

Robert Wah – Individual – Chair
Put a period at the end of health information in the second line, and take that block of words after that, is who is not considered, and move that up to follow any entity. I think that's right.

Andrew Truscott – Accenture – Member
Robert, we've been asked the question from the public floor from Laura Konn, can you clarify why the definition of HIE purposely meets that between organizations? I can, because the taskforce didn't want to say between organizations, and leave out within organizations. And we felt that the clarification around HIN would cover those services that are provided to connect organizations.

Robert Wah – Individual – Chair
Okay. So, maybe I'm not – I want to make sure the group understands what we're going to do here. Because what we're going to do is we're going to make this change. Well, we're going to vote on making this change in the order of the words that you see on the slide here, and then we're going to vote on the newly amended change of the words.

Andrew Truscott – Accenture – Member
Could we put a note up that has the revised text on it?

Robert Wah – Individual – Chair
Yeah. Let me see. I don't know that I can do it. Maybe the team can do it. Let's see here. Can the team take that language we just described and make a note for us? Oh, looks like it's happening. Good. Sorry, everyone. This is a lot happening here at the same time. Go ahead, John, if you have something.

John Kansky – Indiana Health Information Exchange – Member
Yeah, thank you. While we're accomplishing that, Andy, is it possible for clarity to give an example of an organization that we see gets sort of caught in this net of health information exchange that isn't exchanging – to Laura Conn's point, I want to make sure this is clear, can we offer an example of a type of organization that isn't exchanging between organizations, but meets the definition of an HIE? Or even if they do exchange between organizations, it doesn't get caught by the HIN definition?

Andrew Truscott – Accenture – Member
Thinking on the fly . . .

John Kansky – Indiana Health Information Exchange – Member
Yeah, sorry to put you on the spot. I'm just imagining that a lot of organizations that perform access, exchange, transmittal, processing, handling of EHI, period. I guess the point of the taskforce is that if there are examples of organizations that fit in that category, they're still subject to the regulation. That's really the point. Fair?

Andrew Truscott – Accenture – Member
Yes. Yeah, that's the revised text.

Robert Wah – Individual – Chair
Okay. Let's see here.

Leslie Lenert – Medical University of South Carolina – Member
Can I make a comment?

Robert Wah – Individual – Chair
Yes.

Leslie Lenert – Medical University of South Carolina – Member
I'm a little concerned that research organizations would come under this definition. Can we say for the purposes of – this is Les.

Robert Wah – Individual – Chair
So, are you commenting on the language that's in Notes 10, or the bigger issue of what –

Leslie Lenert – Medical University of South Carolina – Member
Yes, the language in that.

Robert Wah – Individual – Chair
Okay. Because I think 10 – notes are –

Leslie Lenert – Medical University of South Carolina – Member
We already just approved 10.

Robert Wah – Individual – Chair
No, no, we haven't.

Andrew Truscott – Accenture – Member
So, Les, let's have a conversation. And so, your concern is that a research organization will be included in the definition. And why would that be a concern?

Ken Kawamoto – University of Utah Health – Member
Les, you're muted.

Leslie Lenert – Medical University of South Carolina – Member
Yeah, no, I'm trying to come up with a general purpose explanation of this, but I'm running a multicenter clinical trial, and I've got health data coming from the EHR as part of my multicenter trial. And I'm exchanging that information. I'm now an HIE?

Arien Malec – Change Healthcare – Member
That is fantastic.

Andrew Truscott – Accenture – Member
Would we want the organization that's running the trial to not be bound by the information blocking regulation, to begin with?

Leslie Lenert – Medical University of South Carolina – Member
Yeah. And then we could add that anyone – again, a public health agency that was receiving information upon, let's say, vaccines to a central repository would also be considered an HIE.

Andrew Truscott – Accenture – Member
So, going to the conversation, to the point here, would we want those types of organizations performing those functions to be covered in **[inaudible] [01:57:38]**? Yeah.

Leslie Lenert – Medical University of South Carolina – Member
I think my point is that those organizations probably shouldn't fall under the information blocking regulation, like with the public health organizations or someone running a randomized trial across multiple organizations.

John Kansky – Indiana Health Information Exchange – Member
And Andy, this is John. Despite the discussions in the taskforce, I think my answer would be, no, I don't think we do, but it doesn't matter what I think. I don't think it was the intent of Congress in 21st Century CURES, and ONC can comment, to pick up organizations that are outside the existing national interoperability ecosystem.

Leslie Lenert – Medical University of South Carolina – Member
Yeah. So, perhaps we could add to Note 10, for clinical care.

Andrew Truscott – Accenture – Member
Do we mean that?

Robert Wah – Individual – Chair
Les, what are you saying, clinical care?

Andrew Truscott – Accenture – Member
Yeah. So, he said for clinical care, just as a **[Crosstalk] [01:58:52]**.

Leslie Lenert – Medical University of South Carolina – Member
For any other use of health information for clinical – instead of period, for clinical care.

Robert Wah – Individual – Chair
Oh, for clinical care. Okay. **[Crosstalk] [01:59:04]**

Andrew Truscott – Accenture – Member
Les, do you mean for clinical care, or do you mean for care? Does it have to be by a clinician, or can it be by another group of providers?

Leslie Lenert – Medical University of South Carolina – Member
Okay, that would be fine for me.

Andrew Truscott – Accenture – Member
Okay.

Steven Lane – Sutter Health – Member
And does it need to be care, or should it be services?

John Kansky – Indiana Health Information Exchange – Member
TPO.

Andrew Truscott – Accenture – Member
So, Steven, you're suggesting access, exchange, transmittal, processing, or handling services.

Steven Lane – Sutter Health – Member
I'm talking about – no, no. I'm talking about for clinical services. Because clinical, as John just said – I mean, clinical, we do treatment, but we also have to manage payment for operations.

John Kansky – Indiana Health Information Exchange – Member
Can't we lean on treatment and operations? Because the examples that have been offered have been research and public health, things that are specifically well thought out in HIPAA as outside of TPO. And TPO is a nice tried and true industry-understood definition.

Andrew Truscott – Accenture – Member
But don't we have that, because of the definition of electronic health information?

John Kansky – Indiana Health Information Exchange – Member
We do?

Andrew Truscott – Accenture – Member
I'll ask the question. If electronic health information, we've got that as a defined term, and we have a defined scope around that, so –

John Kansky – Indiana Health Information Exchange – Member
Yeah, but once it's in the hands of these entities, Andy, it doesn't cease to be EHI.

Andrew Truscott – Accenture – Member
Would it even be included in the definition of EHI? Because the definition of EHI refers back to HIPAA, at least.

Sasha TerMaat – Epic – Member
Or maybe a permutation of Andy's question, TPO would seem to cover primarily covered entities who might be part of the other definition. So, I'm wondering if, even though that's an elegant solution to carve out research in public health, which are already identified under HIPAA, if it is actually narrower than the consensus of the taskforce's discussion.

Andrew Truscott – Accenture – Member
Your suggestion, Sasha, is to remove the other such use.

Sasha TerMaat – Epic – Member
I was more proposing to edit John's suggestion, so I've lost track of, I guess, what exactly his current proposal is, sorry.

Andrew Truscott – Accenture – Member
The current proposal's what's on the screen. Les has postulated that we put some boundaries around this to exclude public health and clinical research.

John Kansky – Indiana Health Information Exchange – Member
So, one option is to specifically name public health and clinical research as outside of that, but then what didn't we think of? If we say use of electronic health information for treatment, payment, and operations, I'm not grasping what harm that causes, since my definition, no pun intended, this allows other organizations to meet the provider HIN or HIT developer definition before this one applies. Yeah, go ahead.

Andrew Truscott – Accenture – Member
I was going to say, so what would happen, for example, a commercial pharmaceutical providing clinical trials, and as part of that, those participants in those clinical trials are already provided their entire healthcare services by that commercial entity, which does happen? Would that information be considered subject to the information blocking regulations or not? Because my instinct is the broader care information around a patient, we don't want that be blocked, I believe. However, Les's position there is that the clinical trials information specifically should be. Les, is that your position? **[Crosstalk] [02:03:39]**

Leslie Lenert – Medical University of South Carolina – Member
I have trouble understanding sometimes exactly because we're getting so convoluted. I don't believe that a public health agency should be considered a health information exchange or an entity running multicenter clinical trials should be considered health information exchange. So, I like for the payment, treatment, and operations line, because that pretty much sums up what I meant by clinical care.

Andrew Truscott – Accenture – Member
Okay, so how would you like to go about this, Les? Do you want to – let's create these through – I just started typing there, accepting a public health organization, and specifically call out those organizations which should not fall into here. We run the risk then of inadvertently missing somebody. Val is raising a good point about whether a health plan should be considered an HIE in this regard as well. So, we have a completely different class to think about.

Sasha TerMaat – Epic – Member
So, I'd like to make a suggestion about research. I don't think we want to carve clinical research, which is important, out in the definition of health information exchange, because clinical research could be conducted by multiple entities who would otherwise be considered information blocking actors. I actually think that we might want to suggest an exception to information blocking specific to the purpose of research, and that there might be purposes of conducting clinical trials, for example, which would mean that it would be appropriate to not share certain information, which otherwise might be expected to be shared by that author.

So, I think my suggestion would be to not address it in a health information exchange definition. If research is being conducted by someone who would otherwise meet the definition of health information exchange, then address the research use case with a separate exception. It seems cleaner and also deals with the situation where research might be conducted by a provider or another entity.

Andrew Truscott – Accenture – Member
Well, I think that's a really good vote, that we actually make a recommendation, have a specific carve-out for those types of organizations. I think that would – yeah.

John Kansky – Indiana Health Information Exchange – Member
What about public health?

Andrew Truscott – Accenture – Member
Public health, research, etc. And we actually – we thoughtfully – Robert, I'm sorry, and ONC guys, I'm sorry, but we thoughtfully said, okay, we'll sit down and consider how to structure that exception and make that a strong recommendation without a carve-out for types of organizations. Les, would that be something that you would be comfortable with?

Leslie Lenert – Medical University of South Carolina – Member
Yes, it would.

Robert Wah – Individual – Chair
So, maybe we're talking about a new recommendation be drafted here, another one, at this point?

Andrew Truscott – Accenture – Member
We are. We're talking about a new recommendation, 59, 60, whatever.

Robert Wah – Individual – Chair
Okay. Well, we'll make it a subset in this area. I think it ought to be in this area, maybe. It still fits in this area, recommendation one through, or yeah. So, okay. We had a good discussion here. I think we've got Notes 10 displaying the changes that we initially proposed to recommendation two. Let's just finish this off. And then if we have to come up with another recommendation, we'll do that separately. Any more comments about the language you see displayed on Notes 10 to replace the language that's just below it on recommendation two? Just a reordering of the words. Any other questions or comments about that?

John Kansky – Indiana Health Information Exchange – Member
And if we're going to vote on this, we're committing to the idea of creating this other exception recommendation, or do we just need to note that we're approving this pending the exception recommendation?

Robert Wah – Individual – Chair
Well, we're going to approve this amendment to recommendation two, and then I'm going to call for a vote on the first four recommendations, which I call the sort of definition recommendations, as a block. Unless somebody wants to extract one of them. But if everybody's okay with voting on those four recommendations as a block, then after we amend recommendation two, I'm going to put up the amended recommendation two into that block of four, and then we're going to vote on the block of four. I hope that's clear to everybody. So, one final call. Any other additional comments about the proposed amendment to recommendation two, which is embodied in Notes 10 on the screen?

All right, hearing none, let's go ahead and vote on the amendment of recommendation two, which is shown on Notes 10. All those in favor of amending recommendation two with the language displayed in Notes 10, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All those opposed, say no. Any abstentions? Okay. So, we've now – I'm sorry. Go ahead.

Valerie Grey – New York eHealth Collaborative - Member
Hi, it's Val Grey. I'm going to abstain.

Robert Wah – Individual – Chair
Okay, thank you. I didn't mean to rush you on that. So, we now have amended recommendation two. What we have before you now is recommendations one through four that basically cover definitions. Any additional comments on recommendations one through four?

Andrew Truscott – Accenture – Member
This is Andy. Yeah, I think I was about to say what your caveat is. Your caveat is, we would craft an exclusive recommendation for those types of organizations that should not be included in information blocking.

Robert Wah – Individual – Chair
Yes.

Andrew Truscott – Accenture – Member
I suspect that's why Val abstained as well.

Valerie Grey – New York eHealth Collaborative - Member
Yeah. Andy, it's Val. I think my abstention is more with just sort of feeling like we still don't have real clarity on the definitions. But I also am fully aware that we're under the gun to get recommendations in. So, I just feel more comfortable simply abstaining.

Robert Wah – Individual – Chair
Thank you. Okay, other comments about the first four recommendations, one through four? Hearing none, we'll go ahead and vote. All those in favor of recommendations one through four, please signify by saying aye.

Group
Aye.

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

Valerie Grey – New York eHealth Collaborative - Member
It's Val. I'm going to abstain again.

Robert Wah – Individual – Chair
Okay, thank you. So, Andy, will you create an additional recommendation about the exclusions?

Andrew Truscott – Accenture – Member
I will create it. Les and Mr. Kansky and Ms. Grey, I'd like to engage with the three of you as we draft that if that's okay.

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

Robert Wah – Individual – Chair
Somebody's taking it on, though, because we're going to try to bring that back before the end of this call.

Andrew Truscott – Accenture – Member
Oh. Well, okay. I can't do it at the same time as doing the call.

Robert Wah – Individual – Chair
I know. That's why I just realized I'm asking you to run the rest of the recommendations.

Andrew Truscott – Accenture – Member
Okay. John, seeing as you seem to be crafting things in the background, could you take the first stab at that?

John Kansky – Indiana Health Information Exchange – Member
All right, it'll be a rough draft, but yes. And then, how do I get it in front of the group? Can I just email you, Andy?

Andrew Truscott – Accenture – Member
Email me and Robert and we'll get it up there somehow.

John Kansky – Indiana Health Information Exchange – Member
Okay, thanks.

Andrew Truscott – Accenture – Member
Thank you.

Robert Wah – Individual – Chair
Okay. Andy –

Andrew Truscott – Accenture – Member
Recommendation 13?

Robert Wah – Individual – Chair
Yes. Your next group.

Andrew Truscott – Accenture – Member
Okay. So, Recommendation 13, which is Slide 18, please. Slide 36 in your – okay. Many of these we actually worked through previously. But we didn't actually vote on them. So, I'll come back to this. So, this was around the reasonable cost recover. We felt that 171.204 and 206 having these exceptions outlining how organizations could make reasonable fees was actually unclear. So, we recommended bringing them together into a single definition that is very clear about what's allowed and what's not allowed. We then suggested that we ONC uses very clear terminology that makes it clearly distinguished between what's the pure cost of expenses recovery when no provision for marginal profits can be made and use terms like cost based pricing, etc., but where marginal profit is allowed and use market based pricing.

So, it's just about consistency and keeping things clean. Next slide, please. So, our recommendation here is that cost based pricing should be reasonably based upon the level of complexity or the actually cost of providing the capabilities. So, this would be some reasonable holistics or estimates or commonly used methods that are put in place to determine whether cost based pricing is reasonable or not. And I'm glossing over this quite quickly because we talked about this last time. But then, Recommendation 33, which is the next slide, this is where we've actually done quite a bit of mark up. And this was the discourse we had between basic access and value added access. And we wanted to be clear and crisp over what basic access is and then, clear and crisp over what value added access is. I'll read through these bullet points so that HITAC has a chance to consider what we're suggesting here.

So, around basic access, we're basically saying the concept of a designated record set made sense for the task force but not every single actor is a covered entity. And, therefore, the definition doesn't apply to them. So, we said if you are a covered entity, it's designated record set. Access to that is basic access. If you're not a covered entity then, the definition of a designated record set as per 45CFR164.501 is that definition and if your provider is not a covered entity. If you're an HIN or developer of health information technology so the other four actors then, it's the information that's been collected on behalf of a covered entity or non-covered entity. So, what's inside those first two bullet points. And basic access also includes the basic transformation of data that's required to implement the standards, which are on the core standards list that is reasonably required to enable the exchange.

And we felt that those four bullet points actually put a good series of constraints around what basic access is, not in a way that's intended to be a negative use of constraint but to actually say these are the boundaries. This is what basic access is. And then, value added access that's not included in the basic access and we go through examples around those. So, infrastructural systems, capabilities, translation, transformation, localization, decision support, complex transforms, artificial intelligence between learning, etc. And that would be value added access. Next slide, please. Again, these are areas where we touched upon last time. Recommendation 34, notwithstanding that definition we just talked through of basic and value added capabilities, we're recommending that when the output of a value added service is incorporated into or that's a typo there, it's actually or from, an essential part of the legal or medical record or routinely used for decision making, they constitute part of a set to which basic access is required.

So, if a vendor adds some kind of value added service upon basic data access data then, they are considered to be part of that basic access data set. And then, Recommendation 35 was our recommendation that ONC distinguishes between intellectual property rights essential for access. So, basic access and we should probably write to allow for value added services. So, if you say the way we distinguish between basic and value add then, intellectual property rights should also follow that definition as well. Next slide, please. So, aligned with the principle of basic access then, cost recovery should be pure and direct cost recovery basis only for basic. I'm not going to go into the details of this one but that's just tying then the fees that would be accrued to the definitions of what the access would entail. Next slide, please. We made a further recommendation that IPR is set on a RAND basis. So, it has to be reasonable and nondiscriminatory for the fees to intellectual property rights.

And we didn't want to discourage access of the exchange or use by having unreasonable fees in that regard. And then, last of all, we recommend that with these recommendations being made, there are no further restrictions on permitted fees that should be made. And that should address the existing

language that ONC had drafted around both monopoly rent or gatekeepers and would enable market forces to be there as well whilst affording the basic access and the information sharing that we're looking for with the information blocking regulations. Arien, have you got any additional comments as I've gone through those, particularly on Recommendation 33 because that's the one that's materially different from last time we discussed?

Arien Malec – Change Healthcare – Member
Yeah. I don't think it's materially different. I think we did maybe a better job of clarifying that the high level policy intent, there are a lot of words here, the high level policy intent is to define basic access relative to value added access and to appropriately target the pricing regulation relative to basic access and to make sure the basic access is sufficient for addressing the rent seeking and gatekeeping behavior while making sure that the pricing regulations and other sorts of regulatory frameworks don't sideswipe a lot of other activities. And I think there was a concern in the last HITAC call about pricing transparency in particular. And I think we all recognize that real price transparency requires assembling data and intelligence from multiple sources and deploying it on behalf of the consumer. So, we're not trying to create a magic solution to a hard problem, hard because of, as an editorial, somewhat unneeded healthcare complexity just by writing a few sentences.

Really, what we're trying to do is make sure that all of the base data that would be included in the calculation for pricing transparency is included in the definition of basic access. So, I think, as I said, that was a concern last time that the language was being perceived as making hard things, things that are actually hard, relatively simple. And really, the intent here is to make sure that we expose all of the patient's data through their access rights and that we have appropriate clarity there. So, again, the two big changes her are 1) making it really clear that the high level policy distinction is this distinction between basic access and value added access. And 2) is clarifying the intent relative to basic access, particularly relative to what information would be covered there.

Andrew Truscott – Accenture – Member
Thanks, Arien. Robert?

Robert Wah – Individual – Chair
Any other comments before we take comments from the group? Go ahead. Okay. Sasha, you have your hand up.

Sasha TerMaat – Epic – Member
Thanks. I was wondering if I could just make sure I understand the drafting of Recommendation 33, which I know has been clarified a little bit since the previous meeting. Let me just say how I understand what's drafted in 33 with an example and if maybe others could confirm that's how they understand it also or if they have a different understanding. If you take a hypothetical example that's say a health information technology application that collects vitals and does some things with them, displays growth charts with cool visualizations, exchanges the vitals using Fyre APIs and maybe is experimenting with some innovative ways of collecting data, if I'm understanding what 33 is proposing, it would divide that application and different components of it some of which might constitute basic access and some might be valued access.

So, for example, the exchange of vitals information that's collected might fall into that core standards list represented in a certified technology using, for example, Fyre APIs. But other elements like the

innovative ways they're collecting data or the visualizations that the app is using on top of the vitals that are collected would fall into the value added access. And so, the cost recovery of this particular application that I made up in my example would have to have different components some of which fell into the basic access proposal, others of which fell into the value added access proposal. Is that a fair interpretation of this recommendation into an example?

Arien Malec – Change Healthcare – Member
Yeah. That's absolutely correct. And then, just to add one more thing, which would be let's take your advanced analytics on vitals. To the extent that those advanced analytics, the output of those advanced analytics, is used to drive patient decision making, it would become part of the designated record set that's already part of relative to patient access. But the actual algorithm and capabilities that are associated with that would never be part of basic access.

Sasha TerMaat – Epic – Member
Right. So, the patient would be entitled to have the output of the data in their record.

Arien Malec – Change Healthcare – Member
Correct.

Sasha TerMaat – Epic – Member
But the developer of the algorithm would still be able to patent the algorithm, license it, and consider that a value added access investment.

Arien Malec – Change Healthcare – Member
Correct.

Sasha TerMaat – Epic – Member
Now, I think that's helpful and thanks for confirming I understand it. Is there something specific that's in mind when it says implement standards from the core standards list? What is the core standards list?

Arien Malec – Change Healthcare – Member
Yeah. The original definition said certified standards. I think that's really the intent here is to exclude, for example, if you go out of your way so let's take your hypothetical and you go out of your way to experiment with and address other standards. Just because it's a standard doesn't mean it should, therefore, fall under the definition of basic access. You may be offering additional capabilities that other folks don't through exposing information that way. But once that standard becomes part of something maintained on certified standards or otherwise maintained by ONC then, it would become, at that point, part of basic access. And the intent here is not to dissuade people from implementing or trying new standards because they wouldn't be able to recover any of the value that they created through that.

But also, to create clear incentives to adopt and implement standards because if you don't adopt and implement standards relative to basic access then, presumably, you'll have a more costly and less effective way of exchanging information that would also be subject to the cost recovery portion. And so, your overall expense load and time, energy, and effort load would be higher relative to standards. Again, the key here is let's make sure that just because you implement something via some standard somewhere that it doesn't inherently become part of basic access. We're really intending this to be relative to certified standards.

Sasha TerMaat – Epic – Member
I think certified standards makes sense. I like the distinction, Arien, between an accepted standard. In my vitals app example, if the app exchange is vitals via Fyre, not falling into basic access seems reasonable. If the app wanted to experiment with whatever block chain exchange of Fyre that will follow of vitals and do something that is innovative and pilot something new, it does make sense to me that that would not be basic access, at least not at first. I just was hesitant. I didn't know if it was intended to refer to the ISA, which I would consider too broad for the purpose in question.

Arien Malec – Change Healthcare – Member
Yeah, I would concur with that. I think certified standard is the better term here. Maybe I'll defer over to Andy relative to, I didn't make that language change, the motivation for that language change.

Andrew Truscott – Accenture – Member
Yeah. So, where are proposing changing it on screen?

Sasha TerMaat – Epic – Member
In the fourth bullet where there's a parenthetical that says from the core standards list. We're proposing an amendment to say that it would be from certified standards.

Andrew Truscott – Accenture – Member
That's fine. Actually, I thought the core standards list was certified standards.

Sasha TerMaat – Epic – Member
If that was the intent then, I think it would be more clear to say certified standards because the core standards list does not have –

Andrew Truscott – Accenture – Member
That's fine. No, that's fine. That was the intent and we'll just reword that.

Robert Wah – Individual – Chair
Okay. So, let's deal with that right now, I guess. So, the words in question are in the fourth bullet under basic access in the parentheses that currently reads "from the core standards list". Andy, can you tell me what the correct language that we want to amend in – I'm sorry. What language do you want to amend into that?

Andrew Truscott – Accenture – Member
I think, and Sasha, correct me if I'm wrong, from the certified standards list. So, to be certified.

Robert Wah – Individual – Chair
Okay. I think that's simple enough. It's a one word change. Let's just finish this off. Any other discussion about replacing the word core with certified under Recommendation 33? No other comments or questions. Let's go ahead and vote on that amendment. All of those in favor of amending Recommendation 33 to replace the word core with certified on the fourth bullet under basic access, all of those in favor of that amendment – is somebody trying to get in?

Group
Aye.

Robert Wah – Individual – Chair

All of those in favor, please say aye.

Group
Aye.

Robert Wah – Individual – Chair
All of those opposed say no. Any abstentions? Okay. So, we've amended Recommendation 33. Sasha, did you have more points on 33? Otherwise, I'm going to go to Ken who patiently had his hand up as well.

Sasha TerMaat – Epic – Member
Those were my concerns. Thank you.

Robert Wah – Individual – Chair
Ken, you had your hand up.

Ken Kawamoto – University of Utah Health – Member
So, my question is around the same one. So, just to understand, there's a left parenthesis before the first bullet point and a right parenthesis before the and in the third bullet point, is that right? So, it's saying it must be one or two or three and any of those plus always Point No. 4. That's the intent, is that right?

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

Ken Kawamoto – University of Utah Health – Member
Okay. So, I think that makes sense. So, a simplistic way to think about it might be basic access is what's covered in USCDI and value added access is everything outside. That would be one potential way to implement this in policy. Is that the idea?

Andrew Truscott – Accenture – Member
Ken, you've been listening to our task force calls, haven't you? Yes. We had that debate and we decided upon this language so we didn't bind ourselves to what was listed in progress.

Arien Malec – Change Healthcare – Member
Yeah. Also, as a technical matter, I just want to add there as a technical matter because of the way that congress drafted Cures, it refers to all of the data. And to the extent that USCDI has a manifestation, for example, through the document list and there have been a number of conversations. For example, Josh Mandell has been working on a proposal to expose via unstructured documents "all of the data" then, USCDI would actually be a great target for being able to do this. But that's just the reason not to name USCDI but make this a little bit general. And the hope is that USCDI and Fyre based implementation that includes delivery of data via unstructured documents would be sufficient to address all of the Cures sharing requirements.

Ken Kawamoto – University of Utah Health – Member
Okay. That sounds great. thank you.

Robert Wah – Individual – Chair

All right. Other comments about this group of recommendations. Okay. Hearing and seeing none, let's go ahead and vote on this block of recommendations that goes from, Andy help me out here, Recommendation 30 to Recommendation 38 with the small one word change we made in Recommendation 33. That's what we're voting on. All of those in favor of that group of recommendations, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All of those opposed say no. Any abstentions? Okay. Andy, you have one more work group of recommendations, don't you?

Andrew Truscott – Accenture – Member
Very briefly. Yeah. It just touched upon Work Group 3. So, Recommendation 48, we've actually removed it was duplicative. And then, Recommendation 27, we're recommending this update, which had not made it through to the proposed text. Apologies to my colleague –

Robert Wah – Individual – Chair
So, 52, do you mean?

Andrew Truscott – Accenture – Member
Recommendation 52, yeah. And Raj, specifically, I think this update is in line with your thinking. So, a health IT developer does not prohibit the fair use communication of screen shots of developers of health IT subject to the limited restrictions described in the paragraph of this section and with the understanding that any actor disclosing the screen shots is responsible for communicating that each use is to be put to fair use.

Robert Wah – Individual – Chair
All right. Great. Comments or questions about Recommendation 52. All right. I'm sorry, Andy, did I cut you off?

Andrew Truscott – Accenture – Member
No, it's fine. Go ahead.

Raj Ratwani – MedStar Health – Member
This is Raj. Am I reading this right? And with the understanding that any actor disclosing the screen shots, shouldn't it be not responsible?

Andrew Truscott – Accenture – Member
No, the point was that when you disclose it, you communicate that any subsequent use is to be fair but that's it.

Raj Ratwani – MedStar Health – Member
Yes.

Andrew Truscott – Accenture – Member
As opposed to you're responsible for ensuring that each use is to be put to fair use. So, you're just responsible for communicating it.

Raj Ratwani – MedStar Health – Member
Yeah, got it.

Andrew Truscott – Accenture – Member
Cool.

Robert Wah – Individual – Chair
I'm sorry. It broke up for me. I don't know about anybody else. That little exchange broke up. Other comments about Recommendation 52. Hearing none, let's vote on Recommendation 52. All of those in favor of Recommendation 52, please signify by saying aye.

Group
Aye.

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

Raj Ratwani – MedStar Health – Member
This is Raj. I'm going to abstain.

Robert Wah – Individual – Chair
Okay. Thank you. All right. I think that completes your recommendations, Andy, is that correct?

Andrew Truscott – Accenture – Member
We have Recommendation 4B.

Robert Wah – Individual – Chair
Yeah. But you're done with what was in the slides, right?

Andrew Truscott – Accenture – Member
Yes, we are. Yeah.

Robert Wah – Individual – Chair
Okay. Let's go ahead and circle back to the preamble change I think is how we were referring to it. I think it's Notes 10 and we can slide that in front of everybody.

Andrew Truscott – Accenture – Member
I think John was actually drafting it as a full recommendation for – John, were you drafting this to be a regulatory text insertion or a preamble clarification?

John Kansky – Indiana Health Information Exchange – Member
I was trying to be of service to the committee. It was characterized as a recommendation.

Andrew Truscott – Accenture – Member
Yeah. To preamble or to regulatory text?

John Kansky – Indiana Health Information Exchange – Member
Wherever it needs to go – it seems like it needs to be a recommendation to the regulatory text. I don't know. You guys tell me.

Sasha TerMaat – Epic – Member
I think it's an exclusion. So, ONC had requested public comment on additional exclusions or they called it exceptions. I'm blanking.

Andrew Truscott – Accenture – Member
Exceptions.

Sasha TerMaat – Epic – Member
Thank you. And I think we would want to propose it as an additional exception. And, John, I appreciate your drafting. I wouldn't frame it around actors. I would frame it around activities because I think that we don't necessarily want to exclude organizations engaged in research. We want to exclude the research activities regardless of whether they are conducted by an organization who would otherwise be an actor.

John Kansky – Indiana Health Information Exchange – Member
Yeah, I considered both options. And you have to pick one or the other. And hence, the second part of that sentence on research organizations was to try and solve that problem.

Sasha TerMaat – Epic – Member
Yeah. I guess I worry with this construction that a provider engaged in research might still have to disclose their research information, which doesn't fully account for that concern.

John Kansky – Indiana Health Information Exchange – Member
No pride of authorship. Just trying to get the conversation started.

Sasha TerMaat – Epic – Member
What if we defined it receive that public health activities and research activities could be that way defined regardless of what actors conduct them?

Andrew Truscott – Accenture – Member
Yeah. I'm just wondering in real time thinking that, actually, I agree. I think the access is misleading. I think we're just saying the following activities are excluded from being implicated under the rule.

Sasha TerMaat – Epic – Member
It should be exceptions to information blocking.

Andrew Truscott – Accenture – Member
Yeah. And Robert, I know you suggested putting it in the first section but we can actually insert them as a recommendation into proposed exceptions in the second section of our letter.

Robert Wah – Individual – Chair
Okay. I'm fine with not necessarily needing to debate the placement of the recommendation. So, let's just get the language and then, I think, if we have the consent of the overall committee to find the proper placement of this language, I think that will probably suffice. So, what we're proposing here is the language that you see on Notes 10. Andy and Sasha and everybody else, are you guys happy with that?

Sasha TerMaat – Epic – Member
Oh, it's being edited now. I see. Can we amend the second bullet to not be about organizations since we

changed to activities instead of actors and just say research? And I think we could look at the definition of research from HIPAA.

Robert Wah – Individual – Chair
And we probably need to take out the parentheses as defined somewhere official.

Andrew Truscott – Accenture – Member
Well, it's true.

Sasha TerMaat – Epic – Member
Yeah. And we should remove the stuff after the parentheses, too, because that was about the actor based definition.

Andrew Truscott – Accenture – Member
Okay. So, we want ONC to help me at this juncture.

Mark Knee – Office of the National Coordinator – IB TF Staff Lead
Sorry. This is Mark Knee. What did you need help with, Andy?

Andrew Truscott – Accenture – Member
Where is research defined inside of HIPAA? I've got 45CFR160.

Mark Knee – Office of the National Coordinator – IB TF Staff Lead
Let me know. It's probably 103, I would think. But I'll take a look.

Robert Wah – Individual – Chair
Also, the first bullet you have activity in brackets. Is that to be –

Andrew Truscott – Accenture – Member
Yeah. Les, you raised this one. Is it all of the activities of public health authorities or is it specific activities or public health authorities that you were concerned over?

Leslie Lenert – Medical University of South Carolina – Member
I think all of the activities probably. So, activities being conducted by –

Andrew Truscott – Accenture – Member
Okay.

Arien Malec – Change Healthcare – Member
Sorry, I don't have my hand raised. But I would descent with that. I think there are some activities like public health, for example, immunization registries that are essential parts of providing continuity of care that I think we'd want to make sure are included. So, I don't think a blanket statement is applicable.

Andrew Truscott – Accenture – Member
And you raise a good point that it's activities coming in on public health authorities but not public health activities. I think we've got that. Sasha?

Sasha TerMaat – Epic – Member
I think Bullet 2 still has lingering stuff after the CFR reference. Thank you. And I would agree with Arien. I can imagine the types of exchange conducted by public health that are important. And I guess it would merit consideration as to whether those ought to be excluded.

Andrew Truscott – Accenture – Member
So, Les, what were the specific activities that you were concerned over being implicated?

Leslie Lenert – Medical University of South Carolina – Member
Well, syndromic surveillance, other forms of surveillance, case investigation by public health. Immunization registries are a special case. So, do you really want – if an immunization registry cannot respond to a query, they're guilty of information blocking and subject to fines? Because that's kind of an underfunded still part of public health, even though there is some wide dissemination of that. That's what we're getting at with this here is that they can't really – my view is that it doesn't seem to be practical to require something without substantial investment in public health infrastructure is likely to be implementable.

Sasha TerMaat – Epic – Member
Well, Les, they would then fall into the feasibility exception, right?

Andrew Truscott – Accenture – Member
Yeah. And Les, I agree with where you're coming from. It's the original sentiment.

Leslie Lenert – Medical University of South Carolina – Member
So, if you want to just say the public health activities that are the non-direct clinical care activities then, that sounds fine.

Andrew Truscott – Accenture – Member
Okay.

Robert Wah – Individual – Chair
Les, do you think that's clear, non-direct clinical care?

Leslie Lenert – Medical University of South Carolina – Member
Not particularly.

Andrew Truscott – Accenture – Member
Well, let's make it clear. How would you phrase it?

Leslie Lenert – Medical University of South Carolina – Member
I would probably say surveillance and outbreak management.

Robert Wah – Individual – Chair
You don't want to limit it either.

Leslie Lenert – Medical University of South Carolina – Member
Yeah, I know. So, maybe non-direct. That's what I'm thinking. Non-direct clinical care activities.

Robert Wah – Individual – Chair
All right. If you can live with non-direct clinical care then, let's put it. We've discussed it. Other comments about this proposed recommendation that you see under Notes 10 on the screen. Other changes, suggestions, comments.

Mark Knee – Office of the National Coordinator – IB TF Staff Lead
Robert, this is Mark Knee. I just wanted to make the correction that HIPAA is 154.501, I believe, is where research is defined.

Robert Wah – Individual – Chair
Okay. I think that's what we made on Notes 10. Thank you for that. Andy, are you still typing? Oh, you're just putting it in there. Okay. And the caveat here is also we're asking the indulgence of the committee to find the proper place. We won't abate the exact location of where this will be inserted but I think people understand that the task force chairs and your committee chairs will find the appropriate place to put this in in the transmittal letter. So, there are two parts to this recommendation. One is the text that you see before you and the understanding that the location would be appropriate to the chairs.

Andrew Truscott – Accenture – Member
Robert, a comment has just been made on the floor that just having public health authorities screws other organizations engaged in research by Harriet Simpson. My understanding of the drafting is that this is an either/or. Non-direct clinical care being conducted by public health authorities and research as defined by 45CFR164.501. Those the following activities are specifically excluded. ONC drafters, is this recommendation an either/or? Does that word and at the end of the first bullet need changing to or?

Mark Knee – Office of the National Coordinator – IB TF Staff Lead
This is Mark.

Leslie Lenert – Medical University of South Carolina – Member
Remember, it's all together. It says the following activities just from the and.

Mark Knee – Office of the National Coordinator – IB TF Staff Lead
Yeah, that would work.

Robert Wah – Individual – Chair
So, I think and is –

Andrew Truscott – Accenture – Member
Leave it or change it?

Robert Wah – Individual – Chair
I think I heard delete it. Is that true? Any other comments. Other comments about the proposed language you see before you on Notes 10. I'm sorry, did somebody say something? Other comments or questions about the language on Notes 10. Okay. Hearing none and seeing none, all of those in favor of the recommendation you see before you on Notes 10, please signify by saying aye.

Group
Aye.

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

Valerie Grey – New York eHealth Collaborative - Member
This is Val. I'm going to abstain.

Robert Wah – Individual – Chair

Andy, I think that completes – okay, thank you, Val. Andy, anything further from your task force?

Andrew Truscott – Accenture – Member
There is nothing further.

Robert Wah – Individual – Chair
All right. Thank you very much to you and your other co-chair as well as your task force on taking on information blocking. I think we've got a few minutes here. Let's bring back Carolyn to update us on the HITCC slide.

Carolyn Petersen – Individual – Chair
Okay. If ONC could put up the slide with the revised text. We, basically, while the info blocking task force discussion was underway, my co-chair and I revisited what we had discussed today and the discussions of the task force, the material, and the presentation by our expert on data segmentation, Dr. Hannah Galvin. What you see on the slide on the screen now is a bit changed to reflect today's discussion. The first three paragraphs are the same. That text has not changed. What we did do was to remove the last paragraph on the previous slide, the one that had the longer, bolded recommendation at the bottom. We've added text here in the fourth paragraph. The HITCC task force recognizes that patients do have the right to choose to restrict information.

At this time, stakeholder consensus regarding what day may be restricted by the patient and what data must be transmitted to support safe coordinated care is lacking. The TS is concerned that the health IT community currently lacks the policy recommendations to move forward with DS4P. So, the recommendation that we proposed to vote on is the task force recommends that ONC stand up a multi stakeholder work group to identify and define policy needs and functional requirements to address patient privacy and provider needs. And, again, our text in the first three paragraphs brings in some of the concerns that were mentioned at previous HITAC meetings. We are hoping that this will put us in a place where we can have these fuller and more nuanced discussions where we revisit past work and can go forward with whatever we need to get to something that as HITAC we can have consensus around informed by existing statutes and previous work.

Clem McDonald - National Library of Medicine - Member
That's perfect.

Andrew Truscott – Accenture – Member
Top banana.

Clem McDonald - National Library of Medicine - Member
You did a masterful job.

Carolyn Petersen – Individual – Chair
Well, it is very complex. And in reviewing some of the notes that I made about today's discussion and previous discussions, we recognize that we have the data segmentation issue. But there are also some broader concerns and thoughts and differences around privacy and what that means for different stakeholders. So, we think that just a broader approach maybe will be more helpful with greater involvement by more stakeholders and parties. There's a lot here.

Robert Wah – Individual – Chair

Thank you, Carolyn. Other comments or questions about the proposed language you see before you from the committee or task force, sorry?

Steven Lane – Sutter Health – Member
Is it still accurate at the top of the first bullet that the task force supports the proposal?

Carolyn Petersen – Individual – Chair
I would say we support further discussions and further efforts around this work. The task force is not saying we shouldn't deal with DS4P or it should just go away. We are definitely supporting additional work and discussion and efforts to move forward in whatever way can be supported and is feasible at this time recognizing the needs of all stakeholders.

Clem McDonald - National Library of Medicine - Member
I think Steve has a little bit of a point though.

Sasha TerMaat – Epic – Member
I think what you said is accurate but the proposal is actually a very specific statement about certification criteria, which is not necessarily consistent with the concerns expressed below. I would propose amending that sentence to say something like the task force recognizes the importance of this area rather than supports this proposal.

Steven Lane – Sutter Health – Member
That would be better.

Carolyn Petersen – Individual – Chair
Which paragraph are you in?

Steven Lane – Sutter Health – Member
The top, the second sentence.

Carolyn Petersen – Individual – Chair
The task force acknowledges the DS4P would help in opioid management and provide greater confidence in sharing OUD information.

Sasha TerMaat – Epic – Member
Yes. I think if you cut the supports this proposal, which refers back to the proposal about certification criteria, it avoids the implication that the certification criteria solve the problems that we have below, which is what we're questioning at this moment.

Carolyn Petersen – Individual – Chair
I think we can take out those four words, supports this proposal so that it would read the task force acknowledges the DS4P would help in opioid management and provide greater confidence in sharing OUD information.

Robert Wah – Individual – Chair
Okay. Let's take that as an amendment. Is everyone clear? We're looking at a first bullet, second line, middle of the second line, delete the four words after the word task force supports this proposal and. Let's take any other additional comments or questions about this amendment. Hearing none, all of those in favor of that amendment, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All of those opposed say no. Any abstentions? Okay. Any additional comments about the now amended language that you see before you on the screen. I'm sorry, I heard somebody.

Carolyn Petersen – Individual – Chair
Someone needs to be on mute.

Robert Wah – Individual – Chair
Is somebody trying to get in the conversation? I'm unclear. Okay. Seeing no additional comments or questions about the amended language you see before you, all of those in favor of this amended language before you, please signify by saying aye.

Group
Aye.

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

Steven Lane – Sutter Health – Member
Wait, when you say the language, this is with the change in the second sentence?

Robert Wah – Individual – Chair
Yes. Unfortunately –

Steven Lane – Sutter Health – Member
It's just the way you phrased it.

Robert Wah – Individual – Chair
We've already amended the language that you see before you. That's why I specifically said the language as has been amended because I can't display the deletion of those four words. I'm sorry. I wasn't clear. Okay. Let's just make sure we're clear on this. We're displaying this language but there are four words removed by the prior action of the committee. So, what I want to do is one more time take a vote on this language that you see displayed understanding that the four words have been removed. All of those in favor of that, please signify by saying aye.

Group
Aye.

Robert Wah – Individual – Chair
All of those opposed say no. Any abstentions? Okay. Carolyn, I think that completes your task force's work and recommendations.

Carolyn Petersen – Individual – Chair
Yes, it does.

Clem McDonald - National Library of Medicine - Member
And you deserve applause, Carolyn, from handling all of those different stresses and pulls and pushes and coming to some closure.

Robert Wah – Individual – Chair
I think all of the task forces faced a lot of issues that they had to deal with on this so this has been great. Okay. And that happens to coincide with our time for public comment. Seth, do you want to take over on that process?

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Yes. Operator, can we please open up the line for public comment?

Operator
If you would 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. 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. There are no comments at this time.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Okay. Thank you. With that, that closes the public comment. I'll turn it back over to Carolyn and Robert for any closing remarks.

Carolyn Petersen – Individual – Chair
Well, I just want to thank everyone for putting in such a significant effort on all of the work related to the NPRM, all of the excellent discussions and energy at the task force level and, in particular, everyone's participating in these larger deliberations at the full HITAC. I know that sometimes it has been very, very draining but it is really critical in terms of bringing all of the stakeholder perspectives to these initiatives and getting out on the table issues that affect different aspects of our healthcare system in the country. So, I do appreciate everyone's efforts in this area and look forward to working with you all more on future initiatives. Thank you.

Robert Wah – Individual – Chair
Thank you. Okay.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Robert, any final comments?

Robert Wah – Individual – Chair
No.

Seth Pazinski – Office of the National Coordinator – Acting Designated Federal Officer
Okay. So, with that, just a few reminders. The TEFCA task force work is ongoing. Their next meeting is on May 23 and we'll be talking about the updates from that task force at our next meeting of the full HITAC committee, which will be on June 13. And the final transmittal letter for all of the recommendations discussed today, once received, will be available up on healthit.gov. With that, I think we can bring the meeting to a close. Thank you, everyone.