Trusted Exchange Framework and Common Agreement Task Force

Transcript
June 3, 2019
Virtual Meeting

SPEAKERS

Name	Organization	Role
Arien Malec	**Change Healthcare**	**Co-Chair**
John Kansky	**Indiana Health Information Exchange**	**Co-Chair**
Noam Arzt	HLN Consulting, LLC	Public Member
Laura Conn	Centers for Disease Control and Prevention	Member
Cynthia A. Fisher	WaterRev, LLC	Member
Anil K. Jain	IBM Watson Health	Member
David McCallie, Jr.	Individual	Public Member
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin	Member
Carolyn Petersen	Individual	Member
Steve L. Ready	Norton Healthcare	Member
Mark Roche	Centers for Medicare and Medicaid Services (CMS)	Member
Mark Savage	UCSF Center for Digital Health Innovation	Public Member
Sasha TerMaat	Epic	Member
Grace Terrell	Envision Genomics	Public Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member
Lauren Richie	Office of the National Coordinator	Designated Federal Officer
Steve Posnack	Office of the National Coordinator	Executive Director, Office of Technology
Cassandra Hadley	Office of the National Coordinator	HITAC Back Up/Support
Zoe Barber	Office of the National Coordinator	Staff Lead

Kim Tavernia	Office of the National Coordinator	Back up/ Support
Alex Kontur	Office of the National Coordinator	SME
Morris Landau	Office of the National Coordinator	Back up/Support
Michael Bery	Office of the National Coordinator	SME
Kathryn Marchesini	Office of the National Coordinator	Chief Privacy Officer

Operator
All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning, everyone. Welcome to the TEFCA task force. We will go ahead and get started with a brief roll call. John Kansky.

John Kansky - Indiana Health Information Exchange - Co-Chair
I'm here.

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

Arien Malec - Change Healthcare - Co-Chair
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Do we have Carolyn Petersen yet? Aaron Miri.

Aaron Miri - The University of Texas at Austin, Dell Medical School, UT Health Austin - Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sheryl Turney. I believe she's going to be late. Sasha TerMaat.

Sasha TerMaat - Epic - Member
Hello.

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

Cynthia Fisher - WaterRev, LLC - Member
Present.

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

Anil Jain - IBM Watson Health - Member
I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Do we have Mark Roche? Andy Truscott. Denise Webb. David McCallie.

David McCallie, Jr. - Individual - Public Member
Here.

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

Mark Savage - UCSF Center for Digital Health Innovation - Public Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
That was David and Mark, correct?

David McCallie, Jr. - Individual - Public Member
Yes.

Mark Savage - UCSF Center for Digital Health Innovation - Public Member
Mark is here.

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

Noam Arzt - HLN Consulting, LLC - Public Member
I'm here today.

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

Grace Terrell - Envision Genomics - Public Member
Here.

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

Designated Federal Officer
Laura Conn.

Laura Conn - Centers for Disease Control and Prevention - Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Great. John and Arien, and I'll turn it over to you.

John Kansky - Indiana Health Information Exchange - Co-Chair
Great. Thank you. And to get us started, we are picking up on the matrix. And I should have asked before is it possible to display the matrix? And we are working through our Tier 1 and Tier 2 issues that we identified on earlier calls. We left off where we'll pick up today with meaningful choice, which is – well, it doesn't matter what page it's on because it will be displayed on the screen. And if you can make that any bigger that would be great.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead
Can you guys see my screen with the discussion matrix?

John Kansky - Indiana Health Information Exchange - Co-Chair
We can see the screen. It's just a little small. Oh, much better.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead
And so, this section is for meaningful choice if people want to look at their documents is 2.2.3, 7.3, and 8.3.

John Kansky - Indiana Health Information Exchange - Co-Chair
Okay. So, let me begin by I tried to put this in RAM for myself earlier with the ONC please checking that I don't mislead anyone. Meaningful choice is expected as described in TEF 2 is an all or nothing request expressed by an individual to the entity that it has a direct relationship with. And a request that their information not be used in any future exchange purpose transactions but that their information that was transacted earlier can continue to be used but only for things identified by exchange – I'm sorry. But only for exchange purposes. I have some questions related to that one. And that if a meaningful choice request is made by an individual, they can make that request to a participant member, a participant, or a QHIN.

And it's expected that that request be communicated up and down the network so that it is honored across the QHIN exchange network. So, let me pause there and ask if I screwed anything up in the process or if that's largely correct.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff

Lead

Yeah, that sounds correct, John. That's one clarification I would make is that they can ask whoever they have a direct relationship with. So, that can be either the QHIN participant or participant member but they do have to have a direct relationship with the individual. So, they can't just go knocking on anybody's door that they've never spoken to and exercise their meaningful choice.

John Kansky - Indiana Health Information Exchange - Co-Chair

Okay. Thank you. And so, one of the questions – so let's focus on the matrix document before I start asking things that I started thinking about. Exceptions for things like treatment, I wasn't aware of there being – if you are exercising your meaningful choice to request that your information not be shared, that's it. So, it will not be shared for any exchange purposes. There aren't exceptions for treatment if I understood that question.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

Correct. It's an all or nothing opt out of the network. So, currently as drafted, there are no exceptions.

John Kansky - Indiana Health Information Exchange - Co-Chair

And similarly, for the second bullet, meaningful choice as it relates to sensitive information as you just articulated, there currently isn't anticipated any specific granular choice. It's all or nothing. So, I assume that also addresses that particular question. But I wanted to ask since this made the list for discussion and inquire with the task force if anyone wants to weigh in, clarify, or comment.

Andrew Truscott - Accenture - Member

Hey, John. It's Andy. Quick question. How does that line up with the consent and the conveying of consent as were talked about with information blocking?

John Kansky - Indiana Health Information Exchange - Co-Chair

How does it line up with the consent or conveying of consent, is that the question?

Andrew Truscott - Accenture - Member

Yeah. Because we have four different definitions of consent. And I can see that someone might see that they don't want to have their health information shared at some point in the future. But then, what about their consent status and the four different types of consent status? Would that also then be embargoed? Or how does that work?

John Kansky - Indiana Health Information Exchange - Co-Chair

Yeah. As I recall, I think it was Zoe last time that had some very intelligent comments on consent that I couldn't possibly have made myself. Can anyone help me with Andy's question?

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff

Lead

Sure, I'll give it a shot. So, I think, Andy, what you're referring to like a local consent or a specific type of consent that's required through any other kind of applicable law. So, I guess, for example, if it's an opt in state like Rhode Island, for example, the opt in consent would have to be held also by the entity that has the direct relationship with the patient. And so, if I went to see a provider in Rhode Island, it would be the provider's responsibility to obtain and maintain that opt in consent for Rhode Island specifically. That's separate from the exercise in meaningful choice, which would also be held by the entity that has a direct relationship with the patient. But meaningful choice is sort of broader. It's a separate thing that is specifically for the use and disclosure of all EHI through the TEFCA network.

Arien Malec - Change Healthcare - Co-Chair

I just wanted to point out, John, that there's a pretty deep cue right now. And I think it's Laura, myself, Noam, Mark, and David in order.

John Kansky - Indiana Health Information Exchange - Co-Chair

Let's go there. Thank you. I'm sorry. Who was the first?

Arien Malec - Change Healthcare - Co-Chair

Laura.

Laura Conn - Centers for Disease Control and Prevention - Member

Hi. Good morning, Laura Conn from CDC. Can you hear me okay?

John Kansky - Indiana Health Information Exchange - Co-Chair

Yes, we can.

Laura Conn - Centers for Disease Control and Prevention - Member

Great. So, I just wanted to ask advice on the exceptions comment just to point out that reporting to public health when required by law at a state or local level can't be opted out of. And I wonder how that fits in with this meaningful choice from an individual level.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

Sure. I should have mentioned – sorry, John. Go ahead.

John Kansky - Indiana Health Information Exchange - Co-Chair

Go ahead, Zoe.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

I should have mentioned that there are no exceptions aside from anything that's required by applicable law. Applicable law always comes first, yeah.

Laura Conn - Centers for Disease Control and Prevention - Member
Okay. Thanks, Zoe.

John Kansky - Indiana Health Information Exchange - Co-Chair
Okay. Was it Mark next? Sorry, Noam?

Arien Malec - Change Healthcare - Co-Chair
I was next in the cue.

John Kansky - Indiana Health Information Exchange - Co-Chair
Okay.

Arien Malec - Change Healthcare - Co-Chair
So, just, in general, as a general policy matter, this seems like it's something that we should be addressing in the MRTCs less specifically. So, I think it's appropriate in the MRTCs to raise the notion of meaningful choice as expressed by the privacy and security tiger team. And in there, the notion of meaningful choice was to get away from the notion of opt in and opt out as the only two spectra and really to focus on meaningful participation and patient participation. And so, the way in my head the MRTCs piece should work is requiring of the RCE to establish appropriate flow down terms that obligate participants and participant members to provide appropriate meaningful choice as an affirmative obligation.

But the details about some of the stuff that we're debating about whether it's all in, all out, whether there are exceptions for sensitivity, how to inform people about aspects that they can't opt out of really should not be the matter of the MRTCs. And then, as a specific aspect of a problem that can get raised in this situation, I forget what state it was. I think it might have been Minnesota, but don't quote me on that, where when you followed the rules, it was hard to maintain the consent status because patients could opt out of existing, for example, any record locator service. Now, I understand, in this case, the meaningful choice is for participation in QHIN and QHIN exchange and does to relate to the local choices they had already made for whatever HIN that they're participating in that is enabling QHIN to QHIN exchange.

But, again, just a note that the more detailed we get this, the more we run into some potentially thorny holes like if a patient is opted out, how do we maintain their status or report back that hey, I've got some information but I can't deliver it because and those kinds of things that are generally practices here. So, again, just a plea for this one to pull it out of the MRTCs in the level of granularity it has and instead express policy goals relating to providing patients specific and actionable information and choice relating to the kinds of information flows that happen through the TEF and through QHINs.

John Kansky - Indiana Health Information Exchange - Co-Chair
Thank you. And I think I agree with all of that but I wanted to make sure I'm not misunderstanding something. And I don't think this is what you implied. But my understanding, ONC please clarify, that a request for meaningful choice made at any level in the tree has to go

up and down. So, if an individual makes a request at a participant level, they have to share that up to their QHIN who shares it across to the other QHINs but also down to the participant members because it's expected to be for exchange purposes honored across the network. Is that correct?

Arien Malec - Change Healthcare - Co-Chair

That sounds like a Zoe question.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

Yes. I am just grabbing the language. It just says up to the QHIN. It doesn't specify that it needs to be exchanged all the way down to the participant and participant members. So, it stops at the QHIN.

John Kansky - Indiana Health Information Exchange - Co-Chair

Okay. So, in as much as – but it also appears in 7.3 and 8.3?

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

Yes.

John Kansky - Indiana Health Information Exchange - Co-Chair

So, just help me.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

So, if a participant member in 8.3 receives the request for meaningful choice, they would have to send that up to the participant and the QHIN. And the same if the participant got the request, they would have to send it up to the QHIN. But the participant doesn't have to send it down to the participant member. It just goes up to the QHIN.

John Kansky - Indiana Health Information Exchange - Co-Chair

Okay. And so, that would be true of when the QHIN then communicates it to the other QHINs, they're like okay, got it. I won't transact this person's data. But they're not obligated to share it down through their participants and participant members either.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

No. There's no language obligating them to share it down to their participants and participant members. But it would stop at the QHIN. So, if they did receive something from one of their participants or participant members, they would know not to continue it on.

John Kansky - Indiana Health Information Exchange - Co-Chair

Okay. So, I want to get to the people in the cue but I just want to put an asterisk on that one

that maybe this is a fairly minor possibility but this is one of my questions was it seems that that person might get care or have encounters with others in TEFCA who might be in completely different QHIN chains who wouldn't be aware of their request not to transact. I guess it would get no farther than their QHIN.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead
Right.

John Kansky - Indiana Health Information Exchange - Co-Chair
Okay. Noam.

Noam Arzt - HLN Consulting, LLC - Public Member
Yeah. Hi. I wanted to thank Laura for drawing out that public health point. But there's another subtlety that concerns me with this sort of all or nothing aspect of this. And it's a concern that in jurisdictions where patients can opt out of public health submission, they may find through this all or nothing that they are opting out because it just goes along with it a public health registry inclusion when they might not really mean to. It's sort of the baby getting thrown out with the bath water. So, I have some concerns about that that patients might not really understand the implication of all or nothing. Does that make sense?

John Kansky - Indiana Health Information Exchange - Co-Chair
It does, absolutely. I think that's true of the concept of opt out of health information exchange or whatever you want to call it in general. But I agree with you. Thank you for bringing that point up. David McCallie and then, I want to acknowledge that Andy has his virtual hand up. So, David, you're up.

Mark Savage - UCSF Center for Digital Health Innovation - Public Member
Mark Savage has his hand up as well.

[Crosstalk]

John Kansky - Indiana Health Information Exchange - Co-Chair
My fault, my fault. Mark Savage. It's a virtue of my ineptitude in every time the hand goes down, the list bumps. It's my fault. Mark, I'm sorry. Go ahead.

Mark Savage - UCSF Center for Digital Health Innovation - Public Member
So, two quick points. And, actually, a question. I'm not sure that I understand how sensitive information, those kinds of information that are treated differently by a particular state and federal laws are being handled here. And I'm asking that question because they are applicable laws sort of like public health. There is a degree of granularity. So, I want to ask the broader question of why we're not able to build or why we're not choosing to build on a level of granularity around meaningful choice here, which would solve a good number of the problems that we're also here talking about. So, I want to raise that as an issue. And also, to raise some concern about the notion that if one exercises meaningful choice, nonetheless, anything

previously disclosed before that exercise continues to be used and disclosed for an exchange purpose.

And that is out of whack with what most people expect. They expect that when they say no more that it's no more going forward. And they're going to discover that that's not what it meant. And that's a big – that's not what most people are going to be thinking. So, I think it's a big issue worth talking through. Thank you.

John Kansky - Indiana Health Information Exchange - Co-Chair

Thank you. Let's spend a moment on that. I had a related question. Let me first give the ONC an opportunity to speak to the rationale. Was that a presumption? Was the rationale behind the perspective meaningful choice a matter of feeling that that was the most realistic to implement or was there some other thinking?

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

Yes. I believe it was a matter of the standards that are available and mature today for communicating such consent through network to network exchange and the reality of being able to do so and to, I guess, being able to do their right to be forgotten.

John Kansky - Indiana Health Information Exchange - Co-Chair

I guess it's right to be forgotten. It seems like it's not a right to be forgotten in the sense that all of the information that's previously shared continues to be shared. It's a right to be – well, I don't know what to call it. I also wanted to raise, if I'm understanding, the unintended consequence of the fact that you say I'm exercising my meaningful choice. If I understand it, in the future, my data won't be transacted for exchange purposes but my data that was shared previously can be shared or exchange purposes but nothing else. Well, given that the QHINs have the right to use the data for exchange purposes and other stuff that isn't prohibited by law, etc., it seems that they have to now say wait for a second, I'm a QHIN. I can no longer transact this person's data going forward for any exchange purposes.

And I can't use any of the data that I already have for these things I was using it for other than exchange purposes. That sounds like it's going to get a little complicated.

Kathryn Marchesini - Office of the National Coordinator for Health Information Technology- Chief Privacy Officer

This is Kathryn. I just wanted to add a little bit to what Zoe shared. Some of the other kind of additional background on this is this is similar to how a HIPAA individual authorization currently works around the right to revoke. So, some of the thought was that, under HIPAA, to the extent a covered entity took unreasonable steps or there was reasonable reliance on a valid authorization that's kind of where some of the thought is as it relates to the meaningful choice aspect if that's at all helpful.

John Kansky - Indiana Health Information Exchange - Co-Chair

Yeah. I'm sorry if I missed it as it went by. You are or you are not revoking – so you've

authorized a QHIN to use your information for an express purpose and it goes through date and whatever. Is exercising your meaningful choice revoking that authorization or not?

Kathryn Marchesini - Office of the National Coordinator for Health Information Technology-Chief Privacy Officer

Yeah. I didn't mean necessarily to mix the two topics. I guess the question earlier was what was the policy thought process behind some of the conversation and the language around the right to revoke or the right to make a meaningful choice. It's definitely not a parallel but the thought is that, similarly, under HIPAA, when there is the permission that is given, if there is a person exercising the meaningful choice, I thought the conversation was really around what we were discussing had to do with using the data in the future or not, if I understood one of Mark's comments. So, that's kind of where the policy thought process was.

John Kansky - Indiana Health Information Exchange - Co-Chair

I think we do get into that nuance rather quickly though because one of my questions was if a patient has authorized their data to be used so that the QHIN has data from the past, the patient has authorized their data for some use that's outside of the exchange purposes but then, they exercise their meaningful choice, does that necessarily void that authorization?

Kathryn Marchesini - Office of the National Coordinator for Health Information Technology-Chief Privacy Officer

It's a great question. How I understand your question is is an individual exercising their meaningful choice the same as revoking their individual authorization.

John Kansky - Indiana Health Information Exchange - Co-Chair

In that case and it's pretty nitpicky.

Kathryn Marchesini - Office of the National Coordinator for Health Information Technology-Chief Privacy Officer

Yeah. It's a great question. I'm not sure that that is explained in MRTC.

John Kansky - Indiana Health Information Exchange - Co-Chair

Okay. Thank you. We'll capture it. I'm sorry. I want to get back to, being careful, David McCallie and then, Andy.

David McCallie, Jr. - Individual - Public Member

Yeah. Can you hear me okay?

John Kansky - Indiana Health Information Exchange - Co-Chair

Yes, we can.

David McCallie, Jr. - Individual - Public Member

Okay, good. I wasn't sure I was connecting. I think that my biggest concern is that this is a very underspecified set of requirements that have just a gazillion complications, not the least of

which is that there aren't any good technical means to achieve it that have been tested on any kind of scale that we're talking about here. So, there needs to be, I think, some awareness that a lot of this will have to be flushed out going forward with the RCE and the stakeholders for any kind of practical implementation. So, the degree to which the policy goals can be clarified and the technical goals left open, it will help but as just this little discussion about the right to be forgotten retrospective kinds of things raises if this is a very underspecified set of requirements, which will lead to a lot of confusion in implementation.

One is the pause on that just general caution. And the second point, I think it might help going forward to think about rules that would apply to actors who are data reposers who actually have patient data in their databases versus actors who are querying and forwarding and moving data around because the rules about somebody who says I want to choose not to have the network pass my data around is pretty clear what that would mean to actors who are just moving data. They would stop moving that data. It's a lot less clear to me what it means to an actor who actually already has data about that patient in their database, particularly if that actor is a provider who has used that data for treatment decisions.

In general, once a provider has incorporated data from the outside world into their local EMR by way of one or more of the various kinds of interfaces and interoperability tools that exist today, the expectation is that they will keep that as the legal part of their record because they will have used it to make treatment decisions. So, that data is sort of unforgettable data. Data that's being reposed in say a regional AHI that has not yet been incorporated or is not inherently a part of an EHR maybe there's a different rule there so that you could say the right to be forgotten said that data hasn't been incorporated by a provider providing treatment. So, it can be turned off or removed. All of that is just to say this is a whole lot more complicated than these rules here or these proposals here cover.

And that coupled with the lack of any good technical means to achieve it that have been tested at any kind of scale makes me really cautious, urging caution about the degree to which this is pushed on to the QHINs as they evolve.

John Kansky - Indiana Health Information Exchange - Co-Chair

Thank you. As I was reading and thinking about it, I think I was appreciating perhaps not to the level that you just described it, the nuance that was being created. And I'll just throw onto that pile that the definition of meaningful choice that appears on my copy at Page 35 implies that it's revocable, which means that your information can be on, you can turn it off and turn it back on again. So, that's just amplifying, I think, some of the complexity that you're alluding to. Andy, finally, and then, we'll go back to Mark. Andy, are you still there? I think I waited long enough that we lost Andy. Mark Savage.

Mark Savage - UCSF Center for Digital Health Innovation - Public Member

Thanks. Back to David's point, just to be clear about my question, I think when information has been taken in before an exercise of meaningful choice, there is a general expectation that you can't delete it. The concern is the provision for ongoing disclosure and use, which means that's what I was saying I don't think is in the expectations of most patients and consumers across the board. So, my comment was not about the fact that it remains a part of the business record.

The second thing I forgot to say is, I guess it's a question, is there a provision for re-opting in? That does happen. People exercise meaningful choice to opt out and then, change their minds again. It's good practice to have a process for that. I don't know if we've got one in here.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

So, there's no process. But as John just pointed out in the definition of meaningful choice, it does say that it's revocable on a perspective basis if the individual gives written notice.

Arien Malec - Change Healthcare - Co-Chair

I just want to go on record as saying that talking about meaningful choice as equivalent to opt in or opt out actually is counter to the notion of meaningful choice, which is about the process of the patient participation information exchange and making sure that people clearly understand what's happening to the data and have reasonable means to exert control over it. So, I think it's more dangerous to refer to a meaningful choice as equivalent to an authorization decision, consent decision, or an opt in/opt out decision. Meaningful choice is the process and then, there's a decision. Some of the decisions that I think we previously discussed are not achievable because –

John Kansky - Indiana Health Information Exchange - Co-Chair

I agree with Arien and apologies if I messed all of that up. Yes, the focus is on meaningful and that's about the process.

Mark Savage - UCSF Center for Digital Health Innovation - Public Member

But it has to be doable at some point or it's not meaningful. It doesn't mean anything if the words don't actually cause something to change. It's not very meaningful if it's just talking.

David McCallie, Jr. - Individual - Public Member

This is David. I jumped in.

John Kansky - Indiana Health Information Exchange - Co-Chair

Yeah, go ahead.

David McCallie, Jr. - Individual - Public Member

I just wanted to respond to Mark's clarification and I thought it was a good point. But to just talk about how subtle this stuff gets, a provider who became aware of a patient's drug allergy through the network and chooses not to use a certain drug may wish to communicate that onward, even if the patient subsequently says I want to be off the network. So, previously encountered information will affect care going forward in irrevocable ways and appropriately so. So, if the data is incorporated in a treating provider's record, it's going to be really hard to forget it in any kind of sensible or meaningful way, not to make a pun on meaningful here.

On the other hand, a research database, we've covered that research isn't one of the use cases here but a regional repository that has just been building up a local copy, it makes a lot more sense maybe to think of not disclosing that even further, even though someone may have

looked at it in the past because it hasn't been incorporated into a treating physician's justification for their decision making. So, my point, I guess, is this stuff is really, really subtle. And the current specifications just don't cover enough detail to lead to a clear cut implementation. And so, either the details need to be a lot more granular or there needs to be a lot more trust placed in the RCE and stakeholders to figure it out within some kind of broad policy goal, which is, I think, the way it's headed right now.

John Kansky - Indiana Health Information Exchange - Co-Chair

Thank you.

David McCallie, Jr. - Individual - Public Member

I will say just one other third – just register this thought because it was actually kind of an exciting point when we first started CommonWell, we proposed a model that would allow the individual to make sort of a two-way decision or an asymmetrical decision around their providers that, unfortunately, we never actually implemented. So, I can't claim that it actually works. But a step in the direction of the kinds of things patients want in the real world is the ability to decide which providers can share their data with the network and which providers can receive data from the network. And you could imagine just to pick two extremes, you may enable your podiatrist to share data with the rest of the network about what they did to your sore toe but not to receive data from the rest of the network because you don't think there's any reason for them to know it.

And then, if you're a psychiatrist, you may choose to have them receive data but not share any data. So, you can imagine inversions where that kind of control would make sense at a provider/provider level. We had a model for that in CommonWell. Unfortunately, it was never implemented at scale so I don't know how well it would work. I do know that most patients will be confused by any of this and will just check the box. So, all of this stuff is friction. And even though there are a few patients for whom it is incredibly important, for many patients it won't be very important. So, you have to make sure the system doesn't break down if you impose the friction on everybody and then, simply break the network. That's another thing we discovered in CommonWell.

Arien Malec - Change Healthcare - Co-Chair

Again, just as a case study, we required an explicit choice and explicit registration process that included markers for that choice. And the technical requirement to collect and manage all of that information ended up being, as David said, friction for exchange. And we moved back to letting participant organizations manage their own requirements in a way that made good clinical sense without requirement specific technical means to achieve them. And there are, obviously, pros and cons there but, to some extent, you're really trading off friction in exchange in ways that actually don't reflect patient desires versus making sure that we've got adequate and appropriate patient participation in these decisions. Sorry, I jumped in before Sasha. Apologies, Sasha.

Sasha TerMaat - Epic - Member

No worries. I agree with your concern and experience. And I was just going to add another layer of nuance to David's example. I think the use of a research purpose and a clinical care

purpose both make sense to me but there are also even more gray areas. I was thinking about quality reporting as one in the middle where while it might not be – it's, I guess, less clear cut whether that data that's been incorporated into ongoing quality reporting or quality improvement initiatives can be removed or no longer used, even if someone is changing their preference midway through a particular quality reporting period or after a quality reporting period is finished. And so, I think I agree with David's concerns and point that there is more complexity than has been evaluated. I'd just also add that as maybe an example of where the boundaries get particularly challenging.

John Kansky - Indiana Health Information Exchange - Co-Chair

Thank you. I have one question I'm going to sneak in and then, ask Arien and ONC if we should be moving on to the next topic in the interest of time or if we want to let the discussion continue. And ONC, perhaps you could tell me am I just making trouble here or is this an interesting question. Let me see if I can get this out and then, I'll elaborate if I need to. Does a participant, participant member, or QHIN's failure to include info from prior to meaningful choice constitute information blocking? So, information blocking is all or nothing. It's got some complexities.

So, I received a request for meaningful choice. But meaningful choice, I guess, says I can use the data or I must use the data from prior. So, if it's as simple as they can keep it simple and say we're just going to, pardon the use of the term, opt out this patient then, that's probably not a problem. If they're expected to include that prior information in future exchange purposes as a must that might get weird. Can you help?

Morris Landau - Office of the National Coordinator for Health Information Technology-Backup/Support

This is Morris from ONC. I just want to – I'm going to piggyback after what Kathryn said and what Zoe said, I think, to give you some color or background on the policy behind meaningful choice before directly answering your question. One was to give individuals notice and to inform them of their exercise. And it is, for lack of a better term, their right to exercise meaningful choice and where their data prospectively is going. So, I'm just going up a little higher to say there were some basic policy purposes behind meaningful choice. One is notice. The second was that it would be prospective as opposed to retrospective. Part of that is because, as Sasha mentioned, some of the data is already baked into particularly quality reporting.

It's already baked into a lot of databases. And ONC thought that, prospectively, it would be similar to HIPAA. It would be reasonable reliance on past information. But once the individual exercised that meaningful choice, it could be the QHINs could operate based upon that individual choice. So, those are the basic policy goals regarding information blocking. Right now, the proposed rule talks about individuals. There is a proposed exception for exercising consent. So, information blocking is based on facts and circumstances and a lot of different factors. So, I just wanted to put some more color around meaningful choice. I don't know if that directly answers your question or not or provides some help on that.

John Kansky - Indiana Health Information Exchange - Co-Chair

No, it helps. I'm not sure it answers and I'm not sure the answer is no and it might just be one of those – I guess, I'm asking Zoe or anybody who wants to respond, did the question make sense?

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

Yeah. The question definitely makes sense and so I asked her to reiterate the question if EHI has been used or disclosed prior to the exercise of meaningful choice then, does not using or disclosing that information constitute information blocking.

John Kansky - Indiana Health Information Exchange - Co-Chair

Correct. Thank you.

Arien Malec - Change Healthcare - Co-Chair

And the second point I thought was equally valid that one of the exceptions granted in the NPRM is the patient's choices. So, it's not information blocking if you as a provider withhold data because the patient asks you to. That's how I read the exemption and I think that would cover John's case.

Morris Landau - Office of the National Coordinator for Health Information Technology-Backup/Support

This is Morris again. In the proposed exception, part of that is, obviously, the provider has to agree to that as well as one of the conditions.

Arien Malec - Change Healthcare - Co-Chair

Okay. Good point.

John Kansky - Indiana Health Information Exchange - Co-Chair

So, with that and no more hands raised, are we okay, Arien, others, to move on to the thing that I just turned onto the page? Hang on. I just got lost.

Cynthia Fisher - WaterRev, LLC - Member

Hi, this is Cynthia. I have my hand raised. I don't know if you see it.

John Kansky - Indiana Health Information Exchange - Co-Chair

Oh, I'm sorry. I do not see it but, Cynthia, you have the stage.

Cynthia Fisher - WaterRev, LLC - Member

So, the question I have and perhaps it's for Zoe to clarify is when you're talking about the prospective right or the ability for the patient to demonstrate their choice or articulate their choice to opt in or opt out, is that also showing the various ways that their health information is being transferred and utilized and the prospective places as well as the cookie trail or the audit trail of the provenance?

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

So, the instructions for how to exercise your meaningful choice need to be included in the written privacy summary that is published by whoever is the entity that's providing the individual services. So, the written privacy summary has information about the entity's privacy practices, including the examples of the type of exchange purposes that they facilitate and who they can contact for further information about the privacy policies.

So, that has some information. I think some of what you're getting at in terms of the future use and who is going to be using the data, what's going to be happening with the data that would come more with like a patient's approval after receiving – they have to receive the minimum information if there is going to be a future use of their data that's not one of the exchange purposes then, they need to receive written information explaining and detailing what's going to happen to their data, who is going to be using it, what it's going to be used for, auditing procedures, etc. But that's a little bit different than I think the use case that we're discussing right now.

Cynthia Fisher - WaterRev, LLC - Member

A quick question on that. I brought this up in previous calls and we just now are getting this from around the country, not only in Boston but other places where there's a vendor, for instance, an EHR vendor, whose software just has at the point of care a signature line so that "privacy" information isn't even disclosed. It's not even on the screen until you sign a blank page. Often times, they don't even have a laminated print out of what that privacy is or where that goes. And so, my comment would be to protect patients is when it's buried in fine print or not even provided as part of the EHR vendors or even eliminating it from being able to be read at point of care, I think it's really problematic because it's like this will be your privacy, whether it will go for research or for even potential future marketing purposes.

Who knows? But the patient really doesn't have full information. And so, I think ignorance is a problem there because that really does eliminate choice because we're seeing patients report to us that they're, essentially, encourage to just sign that blank line because we can't see you until you do. And that's your form that will deal with your insurance payment and your privacy. This is pretty consistent now on what's being seen. So, my concern is it doesn't really give the patient the ability to see the path or choose not to have certain paths and have control of the management of their information. So, I just want to bring that to the attention and think that we may want to empower the patients with clear information and kind of stop this practice.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

I just wanted to say that I think that Cynthia brings up a really great point. And there are one or two things that I just wanted to touch on from what she said. So, the first one is that in the definition of meaningful choice, it cannot be used as a condition for receiving medical treatment or for discriminatory purposes. And so, I really hear what you're saying about it just being a line item and it has to be signed or else the doctor or the provider won't provide care. And so, that's definitely something that we thought about and want to make sure that that doesn't happen.

And then, the other thing that I wanted to point out is in the definition of minimum information, which, again, the minimum information similar to a HIPAA authorization where if the data is going to be used or disclosed for a purpose outside of the exchange purposes in the trusted exchange framework and common agreement then, the individual needs to receive the minimum information, which has information on who is going to be taking the action, the specific purposes for how the data is going to be used, how long that's going to take, whether the EHI is going to be sold or licensed, and any privacy and security measures that are going to apply to EHI as it moves along the chain. And we also say in there that information in all capital letters cannot be used to satisfy the requirement that the minimum information be conspicuous.

And so, that was one protection that we had thought of where we often will see these kinds of approvals where they just put everything in capital letters but it's still really hard to find. So, we wanted to prevent them from just using that and not taking any other measures to make sure that the information is acceptable and understandable. So, any recommendations you have around other ways that we can ensure that that information is accessible to the individual I think would be really helpful.

John Kansky - Indiana Health Information Exchange - Co-Chair

Thanks, Zoe. And as you noted, it helps me to develop I'll call it my TEFCA intuition that I think there are direct analogies with the notice of privacy practices under HIPAA and then, the authorization under HIPAA. I think these processes as described in the second draft here are going to feel quite similar. So, to Cynthia's point, in as much as if we don't feel that patients are sufficiently informed by a HIPAA notice of privacy practices then, this is going to manifest some of the same challenges.

Arien Malec - Change Healthcare - Co-Chair

Yeah. And I would just encourage people to read the privacy and security tiger team work on meaningful choice. And it might be useful just to publish it out to this group. But that was exactly the point is, often times, opt in and opt out become a check mark on a form. And that's what we really intend here is patient informed decision making and to the mechanics. The more we concentrate on the mechanics, the more we're going to get check marks on the screen or something buried in an NPP. I think David is in the cue though.

David McCallie, Jr. - Individual - Public Member

Yeah. I think these are all great points. I don't think the QHIN or the TEF will change very much in this space, even if it was implemented as it's written. It is a teeny, tiny subset of the number of privacy practice notices that you will find when you go see a provider that would be covered by this. it doesn't flow down so any existing data connections that you have to other national networks such as pharmacy networks or your regional HIEs would be unaffected by these rules. This is simply going to affect the QHIN's ability to share that record to remote providers should you be in some remote place and need care.

It doesn't do anything else so it's pretty minimal. It's all important and valid stuff but it's not going to take away the painfulness of going through a new – registering to see a new physician

and signing page after page of notices, which you don't have time to read and which are written in language that's very hard to understand. None of that will be changed by any of this. So, let's not overstate what will be accomplished here.

John Kansky - Indiana Health Information Exchange - Co-Chair

Good point. And I'd also add that we're kidding ourselves if we think that a patient is going to understand what you just said that I'm constraining my information flow within the QHIN exchange network but not in other ways. They're not going to understand that.

Arien Malec - Change Healthcare - Co-Chair

I would suggest that we move on to the next topic because I feel like we've hit this one pretty hard and we'll come back again when we have formatted comments.

John Kansky - Indiana Health Information Exchange - Co-Chair

Thank you.

Arien Malec - Change Healthcare - Co-Chair

I'll take this one.

John Kansky - Indiana Health Information Exchange - Co-Chair

Yeah, go.

Arien Malec - Change Healthcare - Co-Chair

Yeah. So, there's a provision around EHI outside of the Unites States. Part of that provision makes specific reference to US based cloud providers. Maybe we're now in a world where there's a present assumption that all exchange activity is cloud. I think tactically or nit pickingly what's meant is that data both in transit and at rest needs to reside in the United States or that no data relative to QHIN based activity will be held outside of the United States. And I think that's a reasonable provision. The pieces of this that become more operationally difficult and as just a brief sideline set of experience, I've experienced getting patient engagement clinical access capabilities delivered worldwide, which by the way is another issue, for the DOD.

And getting DOD SRG ATO, which is a set of acronyms, which if you don't understand what I just said then, don't worry about it and just recognize that it's a pretty significant **[audio interference]**. And it made operating much more expensive and much more difficult. In particular, the need to make sure that we had on shore people doing all activities, even when it made more sense to leverage business relationships offshore. In some cases, there's a presumption that we have US citizens doing some aspects of activities or US nationals doing some subsets of activities. And so, the language as it's currently written in my mind is a little squishy. I would recommend making sure that we, first of all, clarify that we're talking about data being held in the United States, held and transmitted in the United States.

And then, secondly, I don't know if ONC had some intent relative to, for example, support people being on shore or offshore or if that was an unintended consequence of the way the language is written or if the focus really was data being on shore and subject to US privacy

laws. And then, when we get that clarification then, I will raise the issue of service members who were deployed worldwide who may want to participate in the QHIN and how the test contemplates that.

Debbie Bucci - Office of the National Coordinator for Health Information Technology - SME

This is Debbie Bucci - Office of the National Coordinator for Health Information Technology - SME. I would make a point that with GPDRD or GRPD, one of the two, I know that a lot of discussion is about where to retain data. And I would think that you would find that many companies are keeping some data stateside for reasons of working with international. But, certainly, we do acknowledge that there are state department people or people overseas that actually need to have access to the data. So, I think there is some recognition on both of those if that makes sense.

John Kansky - Indiana Health Information Exchange - Co-Chair

We've got a couple of folks in the cue.

Arien Malec - Change Healthcare - Co-Chair

David is in the cue.

John Kansky - Indiana Health Information Exchange - Co-Chair

And Sasha. Sasha is up.

Sasha TerMaat - Epic - Member

I guess I had a question. There seems to be a presumption in this that there would never be any exchange through a QHIN with another country. I guess I just want to raise that. That seems shortsighted to me and, I guess, I want to raise that for consideration. I think of a model where the healthcare system has some clinics in the US and some clinics across the border into Canada. And that healthcare system might be connected to current exchange networks. They might be connected to, in the future world, a QHIN. And it would seem unfortunate if a clinic located in Canada couldn't get data about a patient that shows up there through the connection to the QHIN if such data exists and would otherwise be there. I certainly understand the complexity of then trying to negotiate Canadian privacy law or the other privacy laws of other jurisdictions, GDPR and the European Union as another example.

But I guess I think we maybe deserve a broader conversation about if we want to categorically prohibit this from going there with these types of provisions. I also, I think, share Arien's concerns about if a support person is traveling in Canada and tries to assist with QHIN technical support from that location, it doesn't seem, I guess, maybe wise to completely rule that activity out either for the reasons that Arien described. So, I definitely think there is some complexity here to discuss.

Arien Malec - Change Healthcare - Co-Chair

I think we have David in the cue and then, Mark Roche.

David McCallie, Jr. - Individual - Public Member

Yes. I understand the spirit of this but it feels a little bit like requiring the use of a bullet proof vest that only covers maybe a quarter of your chest. The risks are so much greater than where the data resides that it seems silly to specify that as a requirement and not say anything about anything else. Would you go ahead and say you can't use Chinese manufactured network equipment in your data center? Would you say something about verifying the origin point of all requests that they come from within the United States? This seems like a tiny Band Aid on a potential gunshot wound. The very success of cloud providers proves that it doesn't really matter where the data is reposed. What matters is the network protocols and security protocols that govern network access.

That's where the focus ought to be, not on where the data lives. I would focus on security requirements for the networks, data encryption at rest, management of the keys, who has access to the keys, verifiability of access pathways. Those are the things that will protect the data, not worrying about where it happens to be in a data center, I think.

Arien Malec - Change Healthcare - Co-Chair

Okay. We have Mark in the cue and then, John Kansky.

Mark Roche - Centers for Medicare and Medicaid Services (CMS) - Member

Hi. So, let's say that a US citizen is permanently moved to let's say Mexico for his retirement. Does it mean that that US citizen would still be able to A) request access to his data from Mexico through one of the QHINs, and second, obtain that data for further care in Mexico or another Caribbean country?

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

For the provision in 2.2.11 does specify that there's an exception to the extent that an individual user requires that his or her EHI be user disclosed outside of the United States.

John Kansky - Indiana Health Information Exchange - Co-Chair

Okay. I'm going to jump in with my question. A two part – this does nothing to solve any of the legitimate concerns that have been voiced but a comment on the regulation. Is there any value in 2.2.11 II that has the problematic cloud based services given that we've already said that no QHIN shall use or disclose any EHI outside of the United States? I guess I'm suggesting is it possible to omit that whole paragraph and be clearer? And perhaps a more intelligent question or comment, Part 2, is and this is not an area I have a ton of expertise so feel free to chuckle if this is ridiculous. But I imagine large corporate entities that move data are already shall we say using EHI outside of the United States and perfectly legally?

And when we create TEFCA, are we saying that the data cannot be used or disclosed outside of the US for TEFCA stuff or for any stuff that they do as a corporate entity? And if so, how in the world will they be able to manage that other than pulling everything back into the US? And I apologize if that was already addressed earlier.

Arien Malec - Change Healthcare - Co-Chair

I think Sasha's example of a health system that's split across the border is a really excellent edge case. DOD and the state department is a really useful case where the data may well reside outside of the US. And the DOD may wish to participate or be a QHIN.

John Kansky - Indiana Health Information Exchange - Co-Chair

An example I'm thinking of is what about even something as simple as having radiology images read overseas, which have nothing to do with a TEFCA transaction but then, when that data – so now TEFCA becomes an active regulation, is it going to be practical, and maybe the answer is yes, to say when we're QHIN transacting that data can't leave the US but it's okay when we're reading radiology images and then, managing that process? It just seemed slippery.

Arien Malec - Change Healthcare - Co-Chair

If you have transcriptions that are done in Manila, which is a fairly common practice then, what portions of the QHIN's operation if they're retrieving transcribed discharge documentation or discharged imaging documentation would be considered to be in the US or outside of the US? These kinds of things that happen all of the time are exactly why I think the task force exists to provide this kind of reasonable information to ONC just as a way of resolving this. I do think notwithstanding David's comments that it is standard and usual practice for information exchange providers who would seek to be QHINs to have their business operations and data centers, notwithstanding whether they're in the cloud or physical on prem, etc., in the US, typically, around making sure that there's clear legal jurisdiction over the data and also to make sure – I mean, there are security risks to holding data overseas.

To David's point, some of the data risks exist whether you want them or not. And holding them in the US is maybe not the most impactful way of addressing the security risk. But it's a long way of saying I think the restriction to have a QHIN's operations, technical operations, data at rest in transit being in the US is a reasonable restriction that I believe most HINs already adhere to. I don't know of anybody who uses an outside the US data center, for example.

David McCallie, Jr. - Individual - Public Member

Yeah, I agree, Arien. It is reasonable because it's so common. I just want to point out that it doesn't guarantee much of anything.

Arien Malec - Change Healthcare - Co-Chair

Right. To your point, security risks and vulnerabilities, to give a classic example, my data is in China because OPR couldn't appropriately secure the data center that I'm 100 percent was physically located in the US.

David McCallie, Jr. - Individual - Public Member

Right.

Debbie Bucci - Office of the National Coordinator for Health Information Technology - SME

This is Debbie, again. When you bring up DOD, I'm certain about how there is the government grade cloud and, certainly, even like NIH has installations across Europe and Asia. So, to better understand how they align with those rules and regulations versus where the data actually

physically locates, at one point it was like everything needed to be stateside. It didn't matter because if you're in the cloud, you can certainly go over the internet as to where it resides at rest. And then, the other that a patient has the right to their data and, certainly, somebody that's across borders that needs emergency access, I think those rules and regulations are already in place.

David McCallie, Jr. - Individual - Public Member

And TEF doesn't address any of those other use cases like offshore radiology reading. That wouldn't go through the TEF anyway. And we're not changing any of those rules.

Arien Malec - Change Healthcare - Co-Chair

Why wouldn't a provider who does rad reading want a transcription provider want to participate in TEF?

David McCallie, Jr. - Individual - Public Member

I can't imagine they'd find any value in it, frankly, because they're doing piece work, contracted BAA governed piece work.

Arien Malec - Change Healthcare - Co-Chair

Yeah, okay.

[Crosstalk]

Debbie Bucci - Office of the National Coordinator for Health Information Technology - SME

Does the data physically have to move for the rad reading? There are huge –

David McCallie, Jr. - Individual - Public Member

Well, it moves at least at the pixel level to see it on the screen. So, any non-tempest computer could be read and copied down.

Debbie Bucci - Office of the National Coordinator for Health Information Technology - SME

Good point. But in theory, it's remote access.

David McCallie, Jr. - Individual - Public Member

Yeah. Disclosable data would flow outside of the country. The other thing is no data lives in only one place. Most data is replicated in many different places, for back up purposes and charting or speed of access. It's also not appropriate to talk about the place where the data lives. Now, you could say that all copies of the data must be in the US. I assume that's what you meant by the rule.

Arien Malec - Change Healthcare - Co-Chair

Yeah. And I think that might be the out here is just to clarify recommend that ONC clarify that the data at rest and exchange and technical capabilities for exchange operations by the QHIN be housed in the US and not introduce this weird notion of cloud providers that are distinct

from on prem data centers.

David McCallie, Jr. - Individual - Public Member

Agreed, good point.

Noam Arzt - HLN Consulting, LLC - Public Member

This notion of sort of viewing on the screen from an offshore location data that is TEFCA relevant is sort of goofy but I don't know. It's sort of given me pause for thought about all of this offshore stuff and what it really means and how precise the language really needs to be.

Arien Malec - Change Healthcare - Co-Chair

Yeah. Again, I just point out in the real world that you go to the hospital and there's a transcription that that transcribed report, you have no idea where it came from. And likewise for rad reading. I think we have all of these examples of really good reasons why data needs to flow across the border. And let's just make sure that we keep this thing tight. John, should we go on –

David McCallie, Jr. - Individual - Public Member

I guess you have to write a rule that says your browser cache has to be turned off if you're outside of the US because we wouldn't want that copy of the HTML to be on a local machine outside of the US, would we? Not going to happen.

Arien Malec - Change Healthcare - Co-Chair

Well, obviously, real trade craft says that you've got to leave your phone in the US and keep a burner phone only for use overseas and then, destroy it when you're done because that's, as we say, neither here nor there and out of the bounds of this discussion.

John Kansky - Indiana Health Information Exchange - Co-Chair

I agree, Arien. We're ready for a summary of disclosures. Do you want to pass the baton back or keep going?

Arien Malec - Change Healthcare - Co-Chair

Go for it.

John Kansky - Indiana Health Information Exchange - Co-Chair

Okay. So, we're moving down the matrix of Tier 2 to the issue of summary of disclosures, which is a requirement under 9.5. I will seed the clouds a little bit by trying – I went back and tried to refresh my memory. An individual submits a request for a summary of disclosures to any participant, participant member, or QHIN with which they, again, have a direct relationship, the defined term. But I was curious as to whether are they asking the question of the entire network. Let's start making this a question to ONC. I have a direct relationship with a participant member. I make a request for a summary of disclosures. Am I asking every QHIN across the country and any participant or participant member, am I giving them 60 days to communicate a summary of disclosures?

And I noted that in the rule, it says for a covered entity, it's just like HIPAA but for electronic health information and not protected health information. Well, the summary of disclosures under HIPAA is pretty hard as it is. And EHI being a different definition that's going to be somewhat challenging. So, let me shut up for a second and ask if I've correctly characterized that no matter where the request is made if the individual has a direct relationship, they're kind of asking the whole TEFCA ecosystem, is that correct? Or alternatively, are they asking for specifically disclosures made by their point of contact?

Debbie Bucci - Office of the National Coordinator for Health Information Technology - SME

This is Debbie. I believe there's a discussion that participants in TEFCA may not be covered by HIPAA. And accounting of disclosures may mean different things. But I do recall a conversation that accounting disclosure doesn't necessarily mean like accounting where the data has gone that they're under – I'm not a HIPAA expert. But I do recall there may be a subclass of data that are not captured by that. But, essentially, we do want an accounting of where that data has gone.

John Kansky - Indiana Health Information Exchange - Co-Chair

Thank you. So, is it an accounting of the TEFCA transactions by the organization with which the individual has an underlying direct relationship? Or is the organization that the individual has a direct relationship with just the organization they go to to make the request of their summary of disclosures that have been made across the TEFCA ecosystem? Let's start with that one.

[Crosstalk]

Morris Landau - Office of the National Coordinator for Health Information Technology-Backup/Support

So, to answer your question, I think the notion was to give some policy background. It was to be somewhat parallel to an accounting of disclosures under HIPAA under 164.528. And the notion is that if an individual requests a summary of disclosures in which it had a direct relationship, that entity would not necessarily have to go out to the entire ecosystem but would have to, within their purview, provide a summary of content in which they had in the contours of the direct relationship.

John Kansky - Indiana Health Information Exchange - Co-Chair

And that would be analogous to HIPAA and, obviously, much simpler to implement. So, I understood your answer to be the individual is asking the organization with whom they had a direct relationship to disclose their summary disclosure. So, they would get one summary of disclosure from one organization.

Morris Landau - Office of the National Coordinator for Health Information Technology-Backup/Support

That's correct and that was the thought behind it. But, again, we're open to whatever comments, suggestions, thoughts you have about this request.

John Kansky - Indiana Health Information Exchange - Co-Chair

That certainly blows my mind less than the alternative so I like your answer as a future implementer of the regs. I will take and I'm just, again, trying to seed the clouds here a little bit, follow up with given that – because I inferred that what you just said earlier was that we're trying to do something similar to HIPAA accounting of disclosures. But then, I looked up the definition of disclosure that's referenced in Rule 160.103. And it's broad. Whereas under HIPAA, while the term disclosure is broad, the disclosures for which one must account is outside TPO. And if there's anybody on the phone that wants to correct me if I'm mistaken. So, in other words, if you ask for a HIPAA accounting of disclosure, you're getting sort of the stuff that's on the margins of what did you do with my data that wasn't the normal TPO stuff.

That's what's in an accounting under HIPAA. So, I didn't see that there was such a constraint on the summary of disclosures under TEFCA. So, it appeared that it would include every transaction made by that organization whether it be TPO or any other circumstances. Have I read that correctly?

Morris Landau - Office of the National Coordinator for Health Information Technology-Backup/Support

Yes, you have read that correctly.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

No, sorry, no.

Morris Landau - Office of the National Coordinator for Health Information Technology-Backup/Support

I'm sorry. Let me be really clear here because I don't want to trip myself up. And Debbie, feel free to chime in to make sure we have this correct. So, let me just sort of level set. And so, in 9.5.2, we lay out what the content of the summary should include. So, I don't know, Debbie, go ahead and chime in as well. Is that Zoe, I'm sorry.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

No, sorry. Yeah, it's Zoe. In 9.5.3, it does lay out the exception for the summary of disclosure, which is the same as the exceptions that are found in the accounting of disclosures within HIPAA. So, it is not required for treatment payment options.

Morris Landau - Office of the National Coordinator for Health Information Technology-Backup/Support

Right. Exactly. Good point. Thanks, Zoe.

John Kansky - Indiana Health Information Exchange - Co-Chair

Thank you. We have no hands raised.

Arien Malec - Change Healthcare - Co-Chair

Let me just understand, John, from my perspective as also somebody who would have to implement this stuff. So, my understanding just based on this discussion is the accounting of disclosures requirement is that a HIN operator, which is to become the QHIN must maintain records of disclosures that are beyond TPO and must make those accounts available to participant members who request it, participants and participant members who request it inside of the network. And that, presumably, the intent here is to flag information access requests that come through the TEF. Is that what I understand?

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

So, it's only if available to individuals that use the QHIN participant or participant member for individual access services. So, the QHIN only has to do it if they provide individual or direct to consumer services.

Arien Malec - Change Healthcare - Co-Chair

So, does the individual have to specifically request the QHIN accounting of disclosures or is it secondary to the individual asking for the accounting of disclosures of the participant or participant member who would then have the obligation? I may be just a little lost in terms of the –

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead

Yeah. The way the obligation is drafted right now, it's only the entity that has a direct relationship with the patient. So, if it was the participant, the patient would ask the participant directly. And they would only get the disclosures that the participant did. So, the participant wouldn't be required to go up to the QHIN.

John Kansky - Indiana Health Information Exchange - Co-Chair

We've been gently reminded that it's time for public comment if this is a good place to stop.

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

Operator, can you open the public lines?

Operator

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

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

Thank you. And do we have any comments in the cue?

Operator

Not at this time.

John Kansky - Indiana Health Information Exchange - Co-Chair
Okay. Thank you.

Arien Malec - Change Healthcare - Co-Chair
We have seven minutes left. So, we could either let people off early or try to chew through the seven minutes of more discussion. Do we have an easy one next? Oh, no, we don't have an easy one next.

Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead
Well, I think we wanted to talk about auditable events in the context of the summary of disclosures.

John Kansky - Indiana Health Information Exchange - Co-Chair
Thank you. So, can someone help me tee that up because from those four words, I like **[inaudible] [01:22:44]**.

Arien Malec - Change Healthcare - Co-Chair
I think the context was that there was specific language around the auditable events that a QHIN must maintain. And we want to make sure that those requirements are in line with the accounting for disclosures for summary disclosures.

John Kansky - Indiana Health Information Exchange - Co-Chair
Oh, there it is. Thank you.

Arien Malec - Change Healthcare - Co-Chair
So, I think it's strange to refer to the QTF in the context of the MRTCs because the QTF is going to change. So, I'd recommend that this language be at the policy level rather than make a full reference to QTF. Sorry, David.

David McCallie, Jr. - Individual - Public Member
No, that makes good sense to me and I would also say that the energy ought to be put into finding the auditable events and then, disclosures can only exist in the context of an audited event. So, the driver ought to be auditable events, not disclosures.

Arien Malec - Change Healthcare - Co-Chair
That's right.

David McCallie, Jr. - Individual - Public Member
If you don't audit it, you can't disclose it and not vice versa. So, we should probably have reversed the order that we thought about this.

Arien Malec - Change Healthcare - Co-Chair

Yeah. And then, we should make the point that the auditable events should not delegate all of the hard work to the QTF but instead describe the policy of audit, audit retention, what's audited, what's required to be audited, etc.

David McCallie, Jr. - Individual - Public Member

Yeah. And then, you can debate –

John Kansky - Indiana Health Information Exchange - Co-Chair

That moving things to the QTF does or doesn't solve the problem?

Arien Malec - Change Healthcare - Co-Chair

No. So, to the extent that there are important policy outcomes that A) QTF need to adhere to, those should be described in the MRTCs at a policy level rather than delegate the hard work forward to the QTF.

David McCallie, Jr. - Individual - Public Member

This is David. It seems to me –

Arien Malec - Change Healthcare - Co-Chair

The QTF is going to change over time. Sorry, David.

David McCallie, Jr. - Individual - Public Member

No, I agree. And I think a modern reasonable assumption at the policy level would be that every transaction that a QHIN or participant has with respect to a patient should be audited. And then, the debate can be around exemptions to that and definitions of what subset of the data actually needs to be kept in the audit log. I would expect that. If my data is flowing through a QHIN, I would expect that it's kept a record of that. I think any sane data implementation would do that regardless. But it seems like a reasonable policy goal.

Arien Malec - Change Healthcare - Co-Chair

Is there an audit retention goal here? Should we go back to the PDF? Is there anything lower? Okay. You've got to audit it but you don't have to retain it.

David McCallie, Jr. - Individual - Public Member

But you have to be able to disclose it for six years so that's a backwards way of imposing retention.

Arien Malec - Change Healthcare - Co-Chair

A six year retention.

David McCallie, Jr. - Individual - Public Member

Yeah. That should be switched around and be part of the audit. And then, you could have variable degrees of disclosure. You must do the disclosure for up to X years, even though the audit log might have a different number for some reason I suppose.

Debbie Bucci - Office of the National Coordinator for Health Information Technology - SME
This is Debbie. That's a good reason to define exactly what you need to audit because that's a lot of data.

Arien Malec - Change Healthcare - Co-Chair
Yeah, exactly. Right. Yeah.

David McCallie, Jr. - Individual - Public Member
At a minimum, the fact that a transaction happened but probably you want a little bit more than the minimum.

Arien Malec - Change Healthcare - Co-Chair
All right. We've got two more minutes.

Mark Savage - UCSF Center for Digital Health Innovation - Public Member
It looks like lunch time to me.

[Crosstalk]

Arien Malec - Change Healthcare - Co-Chair
Yeah, exactly.

John Kansky - Indiana Health Information Exchange - Co-Chair
We're leaving off at the end of – we're going to pick up tomorrow with CUI on Tier 2. And our goal for the call tomorrow, and we are in some of the lower tiers and we're picking up speed a little bit, is to hopefully finish out the remainder of the issues on the call tomorrow so that we can be drafting some draft recommendations to be kicking around as a task force by the next meeting.

Arien Malec - Change Healthcare - Co-Chair
Yeah.

John Kansky - Indiana Health Information Exchange - Co-Chair
Thank you, everyone. And we'll chat again tomorrow.