Trusted Exchange Framework and Common Agreement Task Force

Transcript
May 9, 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 (CDC)	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
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 Berry	Office of the National Coordinator	SME
Debbie Bucci	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 afternoon, everyone, or good morning depending on where you are. Welcome to the Trust Exchange Framework in Common Agreements Task Force. As a reminder, this is the second iteration of the task force, looking at the draft two versions of the TEFCA that was released a few weeks ago. So with that, we have a full meeting today. I will take role call, then I will turn it over to our co-chairs. John Kansky?

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
This is Mark Savage.

John Kansky – Indiana Health Information Exchange – Co-Chair
John Kansky is here.

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

Arien Malec – Change Healthcare – Co-Chair
I'm here.

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

Carolyn Peterson – Individual – Member
Good morning

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

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

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
I saw a note from Sheryl, she may be joining us late. Sasha TerMaat?

Sasha TerMaat – Epic – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Steve Ready? Cynthia Fisher? I think I saw her on the Adobe. Anil Jain? Kate Goodrich? Andy Truscott?

Andrew Truscott – Accenture – Member
Good evening.

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

Denise Webb – Individual – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
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, we know he's on.

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
Noam Arzt? And Grace Terrell?

Grace Terrell – Envision Genomics – Public Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. With that I will turn it over to John and Arien, our co-chairs, to get it started.

Arien Malec – Change Healthcare – Co-Chair
Excellent. Good morning. Welcome. I think we all know each other since this is our second past at the Trusted Exchange Task Force Recommendations. We delivered, – I think – I went back and relooked at our recommendations for our draft one or stage one TEFCA recommendations, and I feel like we gave ONC good and strong advice. And as punishment for doing a good job, we're being asked to do it all over again for the TEF draft two.

So just flow of events is that I'm going to do a brief overview of the task force charge and membership. We're going to turn it over to Zoe who is going to give us a deep dive on all things TEF two. And then, John is going to lead through a discussion on using definitions, applications, onboarding, and designation. And then we will do our normal break for public comment and give you all some homework to occupy your otherwise uneventful and unbusy lives. Can we have the next slide?

So, as everyone knows, ONC announced and released the TEFCA draft two, and quite recently. And we are reconvening to provide recommendations relative to draft two. And in particular, we are being asked to give recommendations on the MRTCs and the QTF. We have a whole new set of acronyms to learn, which is always pretty exciting. And in particular, some sub areas of definition structure for QHINs, so as a reminder, we have defined HINs in the information blocking work. And there are some proposed revisions to the HIN definition coming out of the HITAC, or presumably coming out of the HITAC. But as Zoe will describe, there is a process for going from a HIN to a QHIN, and John will lead us through, today, some discussion related to that activity. Then we will go and cover exchange, purpose, and modalities. So really describing what a QHIN does. And how that overlaps with the MRTCs and the other RTCs. And we will talk about privacy, security, and on the next slide, do we have the QTF? Nope.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
We will be doing the QTF somewhat in parallel to these four major categories. And we are going to introduce the QTF at the next call on May 14th.

Arien Malec – Change Healthcare – Co-Chair
Okay. Perfect. So we will cover the QTF in line with these activities. So next slide. We have a very strong task force, with amazing support from ONC. And we are in really – as I said, we did a great job last time. So I have high confidence we will do a great job next time. I just want to acknowledge with some sadness, we have brought David McCallie in from the cold, and really…

Andrew Truscott – Accenture – Member
You sound excited we brought him back in.

Arien Malec – Change Healthcare – Co-Chair
We are incredibly excited that we brought him back. We are excited that we brought them back in, I'm not sure he's quite so excited. But I just want to honor and thank David for his amazing career at Cerner, and we look forward to great things now that he has been refreshed and taking pictures of hummingbirds and flowers and other things. So we'll get even more brain power out of David.

David McCallie, Jr. – Individual – Public Member
I'll have to put down the margarita for a few weeks.

Arien Malec – Change Healthcare – Co-Chair
Exactly. So any questions on our charge membership flow of activities? Oh, do we have the calendar here?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
We have the workbook. I'll cover the work plan. I am going to go through the work plan and the calendar at the end of my presentation.

Arien Malec – Change Healthcare – Co-Chair
Okay. I'll just give you a warning that just like last time, but even more so, we have a ridiculously short amount of time to provide recommendations. So we are going to be going at a pretty punishing pace. And our goal is to get through discussion and submit ideas. And then, really quickly get to a recommendations letter templet and framework, and then spend most of our time debating the

appropriate recommendations. But I just want to warn everybody to set expectations for a lovely fast, wonderful ride. And with that I will hand it over, I think, now to Zoe.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
Arien, Arien, this is Mark. I just want to say, especially thank you to the co-chairs and staff. Because it may be a full schedule for us, it's a really full schedule for you all, so thank you.

Arien Malec – Change Healthcare – Co-Chair
Yes. I just got a comment that being a task force co-chair is the hardest job. I have been a co-chair of the overall committee, and I have been co-chair of various task forces. And I can tell you without hesitation, being a co-chair of a task force is a much harder job.

Andrew Truscott – Accenture – Member
And Arien, Arien, frankly, coming out of the Information Blocking task force, I was co-chair and you then you remember, I'm looking forward to this dynamic.

Arien Malec – Change Healthcare – Co-Chair
Absolutely. You want to be the guy in the peanut gallery throwing peanuts. And I'm the guy – John and I are the folks trying to steer everyone towards common consensus so.

Andrew Truscott – Accenture – Member
Peanuts? I've got walnuts, my friend.

Arien Malec – Change Healthcare – Co-Chair
Good. Good for you. Coconuts maybe. All right. Now we will turn it over to Zoe unless there are other questions about the overall charge and charter.

John Kansky – Indiana Health Information Exchange – Co-Chair
Or other comments from the walnut gallery.

Arien Malec – Change Healthcare – Co-Chair
Or other comments from the coconut gallery.

Andrew Truscott – Accenture – Member
It's all nuts. Go ahead.

Arien Malec – Change Healthcare – Co-Chair
All right, Zoe. Over to you.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
All right. Great. Thank you so much, Arien. I am really excited to be here. Some of you guys, or hopefully most of you guys remember me from last year when I led the task force last year. As Arien mentioned, we did get some really great recommendations from the task force. And we have spent the past year really digging in and understanding those recommendations and updating the TEFCA to include both the recommendations from the HITAC and what came out of the public comment period.

So, I'm really excited to be here. I am going to be your lead. I also have a bunch of ONC staff that are going to be joining the calls. They are going to be helping out throughout this process. So first we have

Kimberly Tavernia who is going to be my co-lead. She is going to be providing support in case I need to miss a call or something like that. Kim, can you say hi so everybody can hear your voice?

Kim Tavernia – ONC – Back Up/ Support
Hi, everyone.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
We also have Alex Kontur who is going to be our subject matter expert for the QHIN technical framework. He led the development of the QTF, as well as authoring many of the operational provisions with then MRTCs. Alex, can you say hey?

Alex Kontur – Office of the National Coordinator for Health Information Technology – SME
Hey, everyone.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
And we have Michael Berry, who is our subject matter expert for the recognized coordinating entity. He is leading the RCE and the notice of funding opportunity activities. Mike?

Michael Berry – Office of the National Coordinator for Health Information Technology – SME
Hello, everyone.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
And then finally we have Morris Landow, who some of you might be familiar with from the info blocking task force. He is our subject matter expert for all things HIPAA and privacy and security. Morris, say hey.

Morris Landau – Office of the National Coordinator for Health Information Technology – SME
Hi, everyone.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Great. So feel free, if you guys need anything or have questions, please feel free to email Kim or me. And, you know, as always, including Lauren. I know you guys are all old hats at this by now. So, anything you need, we are here to help. So, go to the next slide, please.

All right. So, first off, I want to start by giving a little bit of an overview and tour, if you will, of the MRTC. And I also want to note that this task force is specifically, as Arien mentioned, we are specifically going to be focusing on the MRTCs and the QTF. So I know that last year the terminology was TEF, we are moving away from the TEF acronym, at least for the purposes of this task force. So, when we are discussing the provisions within the MRTCs and the QTF, we can call it the common agreement, or we can call it – we should call it the MRTCs or the QTF specifically. If you are talking about the TEF, you can say TEF, obviously, but only if you are actually talking about the TEF.

So, the MRTCs are broken down into nine sections. And it's done this way so that we were able to flow down certain provisions from the QHIN obligations down to participants, participant members, and individuals. So the first section includes the definition. Then sections two through six are QHIN obligation only. Anything you see in sections two through six refers only to QHIN. Section seven is participant obligations. Section eight, participant member obligations. And then section nine is individual rights and obligations.

So, I want you guys to be aware that as you guys go through the MRTCs, you are going to notice that while many of the provisions that are replicated in sections seven and eight are mostly similar to what you may find in the QHIN section. However, you have to be careful as you are reading, because there are slight nuances between the different sections.

So to give you an example, sections seven and eight include an exception for entities that are providing individual access services only. I'm going to go into a little bit more detail on what that means, but that exception only applies to participants and participant members. So you will not find that language in the QHIN section. Another example is that we have operational language for a summary of disclosures that are actually found in section nine, but there are references to it in sections six, seven, and eight.

So, we understand that this is very complex, and it can be kind of confusing. And we are trying to make it as accessible and understandable as possible. So we created a tool to help guide you through the MRTCs that identify some of the crosscutting topics, and where the relevant sections are located within the MRTCs. So if we could actually switch over to the mapping document.

So, you guys should all have this in the package of materials that was sent to you this morning. And as you can see, we just identified some of the major topics throughout the MRTCs, and then we show you the relevant definitions, and then previsions within the QHIN, participant, participant member, and individual sections.

All right, so you can go back to the slide deck and go to the next slide. Great. So now I also want to orient you all to some of the common terms and definitions that we are going to be using throughout the task force that applies to kind of the MRTCs as a whole. So before each column, before each topic, we are going to give you homework and reading that will include specific definitions that are relevant to that section, but what we have here are some common terms that really apply to the entirety of the MRTCs and the QTF.

So the first one is the concept of the framework agreement. So framework agreements are the legal agreements that include the common agreement, the participant QHIN agreement, and the participant member agreement. And actually, if you could just switch the next slide really quickly.

You can see here that the common agreement itself is actually an agreement between the RCE and the QHIN. So when we refer to the common agreement, we're really only talking about the QHIN obligation. We then have a participant QHIN agreement that will incorporate the relevant provisions that are found in section seven, and that is an agreement between the participant the QHIN. And then, you have the participant member agreement, which should have the relevant provisions from section eight. And that is the agreement between the participant and the participant member.

So collectively together we refer to these as the framework agreement. If you go back one slide. We also have this term that we define in the QTF, it's the first or second page of the QTF, called the QHIN exchange network. And this refers to the network of interconnected QHINs that are enabled by the framework agreement. So, kind of similar intent on how this term is used and what it means. But it is actually referring to the technical network that is enabled by the legal agreement.

Next, we have QHIN participant and participant member. These are obviously good for you guys to get acquainted with. We are going to go through what the prerequisites are to be a QHIN in the second

half of the call today. And then we also have individual and individual user. And an individual, per our definition, includes both the person who is the subject of the EHI being requested, as well as a personal or legal representative who has authority to act on behalf of the patient. So any time that you see individual capitalized, it is because we are referring to that somewhat expanded definition that we have in the definition section of the MRTC. And then, an individual user refers to an individual who is connecting to the QHIN exchange network for the purpose of individual acts of services.

We then have the term direct relationship, which is a term used to describe who that individual user is connecting with, whether it's a QHIN participant or participant member. So, something to understand is that individual users are allowed to connect at any level within the exchange network, that makes sense for them. So, anyone, a QHIN, a participant or a participant member can offer individual access services. And individuals have the flexibility to choose who they would like to receive those services from. So, we say direct relationship, often when we're talking about whoever has a direct relationship with the individual is responsible for certain things.

Next, we have electronic health information, which is a term you that you guys should all be familiar with from your other task forces.

Andrew Truscott – Accenture – Member
Yay.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Similar to the definition of health information network, we are going to try to refrain from getting into too much discussion on EHI and HIN and try to refer as much as possible to the recommendations that have come out of the other task forces. Then we have TAF MRTCs and QTFs, so I already went over that. We are going to try to refrain from calling it the TAF unless we actually mean TAF. And then we have use and disclosure, which are used throughout the MRTCs and have the meanings assigned to them within HIPAA at 45CFR160103. But it is important to note that we have expanded the definition of use and disclosure to apply to all electronic health information, not just PHI. Next slide. Next slide.

And I think we do have one question in the queue from David. Go ahead, David.

David McCallie, Jr. – Individual – Public Member
Yeah, and just a high-level question to queue you up as you go through this. There is a conflict when I read this, or at least confusion on my part, between words like required, voluntary, minimum required, may, etc. So if you could, as we work through the details, clarify where the binding power of some of these things is? Is it just at contract level or is it deeper than that? And what is actually required versus voluntary, may be adopted? Just as a broad principle. I found the document somewhat confusing on that.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Absolutely. I appreciate that feedback, David. So generally speaking, when we say "shall" in the legal language, that means required. Some places say "may" which is voluntary. If other terms or nuances are used as we go through, maybe we could try to bring them up as we go through if there is any confusion and tackle each one individually.

David McCallie, Jr. – Individual – Public Member

Well, just the one that jumped out at me, just to give you a specific example. Unfortunately, I don't have it in front of me anymore, is in the very introduction of the minimum necessary requirements, it may be adopted. So how is it a minimum necessary requirement if it is optional? That was the confusion I had. Minimum necessary sort of sounds like you must or shall, but it may be adopted. That was the point of my confusion.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Maybe if you could point me to them…

Michael Berry – Office of the National Coordinator for Health Information Technology – SME
Hey, yes. My recommendation here is that it sounds like, David is raising some issues about making sure we are clear about what is required, what's optional, and then the binding power requirement. So let's just makes sure that we've got that as an item that we are pushing through.

David McCallie, Jr. – Individual – Public Member
And Zoe, just to look into it later, it's page nine, and we can come back to it later.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Page nine. That's great. Thank you so much. And it is important to note, the introduction was intended to be written in a clear layman's terminology as possible, to try to break down some of the more complex legal languages. So, understanding if there is a discrepancy or we don't use the "shall" and we use that in the legal language, that is a really good thing to point out. And we would definitely appreciate that comment, so.

David McCallie, Jr. – Individual – Public Member
Thanks.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Okay, so moving on here. Here we have the summary of the key changes. I am going to go into each of these in a little bit more detail. So, we first have the QHIN technical framework that was added. We have updated the exchange purposes. We have updated the exchange modalities and included a modality for QHIN message deliver or a push transaction. We have modified the fee proposals between QHIN, expanded the definition of QHIN and actually moved the requirements into prerequisites for QHIN eligibility. And then, added the application process that we are going to talk about today. And then we have expanded many of the privacy and security protection for all the participating entities.

So if you go to the next slide. So, we received many comments, including from the TEF task force, that we should as much as possible try to refrain from naming particular standards or implementation mechanisms in the common agreement itself, and instead work with the RCE and the industry to develop an implementation guide that addresses the technical requirement for exchange among QHIN. So that is what we have attempted to do in this first draft of the QTF. The purpose of this first draft is really to tee up the technical issues that the RCE and the QHINs will work together to resolve. We expect that the RCE will be working, once they are awarded, they will be working closely with the industry to develop a second draft, which could include new specifications to meet the requirements of the common agreement.

And our goal here, really, by separating the technical specs from the legal requirements, is to allow the industry to stay on pace or to allow participants to stay on pace with the industry, without having to revise the entire common agreement every time a new standard is adopted. Next slide, please.

Okay. So here we have updated the exchange purposes in the first draft. We had six exchange purposes that included treatment, payment and operations, benefits, determination, public health, and individual access. We received comment from the HITAC that we should more clearly define treatment per its HIPAA definition, and also, clearly define some of the sub-purposes for exchange for purposes such as payment and healthcare operation.

Commenter's noted that some of the uses and disclosures that are included in payment and healthcare operations still require broader scale testing and additional standards and policies before they are ready for broad-scale national deployment. So taking that feedback to heart, we narrowed the purposes of treatment, payment, and healthcare operations to be treatment, utilization review, which is a sub-purpose underpayment. And then quality assessment and improvement, and business planning and development, which are two sub-purposes under healthcare operation.

There four purposes are defined as they are defined in HIPAA at 45CFR164501. And that means that they only apply to protected health information and to covered entities and business associates.

Public health and benefits determination remained largely the same from the first draft. Public health includes the user or discloser permitted under the HIPAA rules or any other applicable law for public health purposes and activities. And benefits determination includes the determination made by any federal or state agency as to whether an individual qualifies for federal or state benefits for any other purpose than health care. So, like disability benefits. And to the extent permitted by applicable law.

Now we are going to talk a little bit about individual access services, which we are going to get into more on the next call. If you could go to the next slide. So individual access services cover two main use cases. And this includes the right of the individual to request access and to obtain a copy of their EHI. And the right for them to direct that their EHI be sent to a third party under applicable law, any of the framework agreements, and then we called out these three specific provisions in HIPAA, in 164524.

So the first is 524A, which is the right of access to inspect and obtain a copy of your EHI. We then have 524C2, which refers to the form and format for which the EHI can be sent. And then, 524C32, which is if the individual wants to direct the EHI to a third party, they just need to meet the conditions at C32 and submit the request in writing.

And it is very important to note here, that unlike what we did for treatment utilization review, business planning and development, and quality assessment and improvement, the individual access services use case is expanded to apply to all participating entities, regardless of whether or not they are a covered entity or a business associate. And expanded to all EHI, not just PHI.

So participating entities, well first, for all of the exchange purposes, participating entities must respond to query requests for all the exchange purposes with the EHI they have available. However, there is an exception. And this is what I was referring to before. And this is found in section 7.12 and 8.12. If you are a participant or a participant member that only provides individual access services, so you're a third-party app that is only doing that one-use case, then you only need to respond to queries for

individual access services. So if somebody sends you a query for quality assessment and improvement, you do not have to respond to that request.

We have also, in this, was a recommendation that came out of the task force last time, is that we have made it very clear that the response must be given whether or not the request was promoted by the individual user them self, or by an entity acting on behalf of the individual user.

And then finally, once EHI is received by a QHI participant or a participant member for individual access services, it can only be exchanged, retained, aggregated, used, and disclosed, for individual access services. And the reason for that, if you go to the next slide, that dovetails with the fee provision, or the fee requirement, that we have where we say that QHINs may not charge another QHIN any amount to exchange EHI for individual access services.

So what we are trying to prevent is a situation where you have an entity that is only pulling in data for individual access services at a charge and then going and reusing it and aggregating it for a population assessment pool or something like that and building profit off of that.

Some of the other things within the fee provisions is that if QHINs are going to charge fees to each other, they must use reasonable and non-discriminatory criteria, RAND, you guys are familiar with that at this point. QHINs may not impose any other fee on the user discloser of EHI once it is accessed by another QHIN. And then, the RCI is going to be responsible for developing any addition fee requirements in the ARTCs, which will be approved by ONC. Next slide.

Okay. So, QHIN exchange modalities. So, here you guys will recognize that we still have the QHIN broadcast query and QHIN targeting query from the first draft. But we have added, in response to many comments, we have added a modality for QHIN message deliver, or push notification. And this will be very useful for public health use cases, care coordination, and other push-based use cases. And we have also removed the population level query modality for the time being, as we received a comment that it wasn't quite ready for a broad network exchange environment. Next slide.

All right, here we have the QHIN application process, and again, this is what we are going to be talking about today, so I won't get too detailed into it right now. But essentially, we have defined this application process, and we have revised the definition of a QHIN from what was in the first draft. And in how we defined these prerequisites and established the application process, we had three goals in mind as we were drafting this.

The first goal is to be neutral and acceptable to all parties. We want to allow a diverse array of entities to apply to be designated as a QHIN. Second, we want to maximize efficiency, and third, we want to minimize failure. So, while we want this opportunity to be open to a diverse array of entrants, we also want to make sure that those being designated as QHINs have the proper infrastructure, functionality, and personnel necessary to be successful. And so, as we look through the prerequisites and the application process, please keep those three goals in mind.

So basically, just to quickly go through how the application process works. The health information network would submit the application to the RCE, who would evaluate the application and either approve or reject the application. And then, if you go to the next slide, if the application is approved, the HIN and the RCE would both sign the common agreement, and at that point the HIN would receive

provisional status and be put into a cohort to implement and onboard all of the requirements of the common agreement and the QTF.

Once they have gone through that cohort period, the RCE will perform testing and surveillance to ensure that they have met all the requirements and can exchange data. And then, and only then, will the provisional QHIN be officially designated as a QHIN. Next slide.

Or a participant member There's pretty small writing here, I realize now. So, the last two topics that we are going to dive into our privacy and security. And we didn't spend too much time on the last task force getting too detailed into the privacy and security sections. I think we only had a couple of recommendations that came out of it. But this time around, we really spent a lot of time diving into all the privacy and security content and making sure that the proposals in here are aligned with HIPAA and other applicable law.

So, the first thing to know within privacy will be talking about breach notification requirements, which we have included the requirement for all participating entities and pointed to the HIPAA breach notification rule at 45CFR164400-414.

Next, we have the concept of meaningful choice, which provides individuals with the opportunity to request that their EHI not be used or disclosed via the framework agreement for the QHIN exchange network. We have also included a requirement that all QHINs, participants, and participant members, regardless of whether they are covered entities or business associates, must abide by the minimum necessary requirements in HIPAA.

There is a requirement that the QHIN participant and participant member who has the direct relationship with the individual, will be responsible for obtaining and maintaining any copies of their consent and communicating that consent to anybody else on the network. We have a requirement that any QHIN participant or participant member that is providing individual access services must provide a written privacy summary describing their privacy practices. And it should be similar to ONC's model privacy notice and include information on contact for who the individual can call if they have a question or complaint and instructions on how the individual can exercise their meaningful choice. And then finally, we have a summary of disclosures requirement that points to the requirement in HIPAA under 45CFR164528, that refers to an accounting of disclosures. Next slide.

And then next we have our security requirements. So the first to note is that we have a minimum-security requirement that all QHINs regardless or not they are covered entities, and business associates must comply with the HIPAA privacy and security rules as if they pertain to all electronic health information. If you are a participant or a participant member that is not a covered entity or a business associate, we require that they take reasonable steps to promote the confidentiality, integrity, and availability of EHI.

We also require QHINs to evaluate their security programs for the protection of controlled unclassified information or CUI. And that they should comply with the requirements of the NIS special publication 800171.

Next, we have a prevision on not using or disclosing EHI outside of the U.S. We have specifically asked for comment on this. And we say that QHINs shall not use or disclose outside the U.S. except as

required by applicable law, or to the extent an individual user requests that their data exchanged or disclosed outside the U.S.

We have provisions on data integrity, authorization, identity proofing, authentication, these are all things that were in the first draft. There is a prevision on transport security, auditable events on all QHINs participants and participant members must abide by the auditable events requirements that are described in the QHIN technical framework, concerning the exchange purpose that they perform. There are certificate policy requirements that apply only to QHIN. And then finally, we have a request for comment that is actually in the introduction, and there is no operative language in the MRTCs. But we request comment on the use of security labeling and the inclusion of a new requirement regarding the use of confidentiality codes and security tags, that would promote the ability to exchange sensitive data under the common agreement.

So I just threw a lot at you guys, in a pretty short amount of time. So I'm going to pause, or actually, maybe I should go over the work plan. If you could go to the next slide, I'll quickly go over the work plan, and then I will pause for questions. Next slide.

So as Arien mentioned, we have a very, very tight timeline to get through all of the major topics. So today, in 20 minutes, we are going to kick off our discussion of the QHIN eligibility requirements and the application and onboarding process. Tuesday we are going to tee off our discussion on the QHIN exchange purposes, modalities, EHI reciprocity, and primitive and future uses of EHI. And we will have a very brief presentation on the QHIN technical framework to kick off that call. We will continue that discussion on May 16th, then we will present to the full HITAC on the 22nd. On the 23rd, we will kick off our privacy discussion, next slide. On the 24th we will try to begin the security discussion and continue that on May 28th. And then, in here, on Monday, June 3rd, there are some additional provisions that if we have time, we will try to get to, but we will have to see where we are, come June 3rd.

So, I will pause there and take any questions or comments from the task force. And I think David has his hand up again. Go ahead, David.

David McCallie, Jr. – Individual – Public Member
Yes, Zoe, thanks. You went through the work list assignment pretty quickly so I may have missed it. But will there be an opportunity to discuss the broader notion of whether or not the messaging requirement that was added, it makes sense? I see that we are focusing on the lower level details, but that broad notion of you dropped population health, but you've added the direct messaging. Is there some point where we can discuss that, or is that considered off the table?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
No, absolutely. That is definitely within scope. And that is something that we will discuss on the call on 5/14 and continue discussing May 16th if necessary.

David McCallie, Jr. – Individual – Public Member
Great. Thanks.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Just so people know, in the email that I sent you all with the package of documents and background materials, the work plan is included in there. And the reading assignment for each topic is also included in that work plan. So if you want to know what definitions are going to be relevant and which sections

are going to be relevant, please reference the work plan. And you can also reference the mapping tool if you want additional details.

Andrew Truscott – Accenture – Member
Hey, it's Andy. I have got my hand specifically raised because I'm not on the Adobe. Okay.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Oh hey, Andy. Yes. Go ahead.

Andrew Truscott – Accenture – Member
Yeah, hi. Will we get an opportunity, similar to what David was saying but, on another area, on the ability of TEF to demonstrate – or any of the other acronyms within TEF to demonstrate alignment to the information blocking speculations, and potentially alleviate any implication you might have of implicating those regulations? So, the safe lane type concept?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
So I might refer – I think Mike Lipinski's on the line, that is a conversation that we are open to, and we definitely want comments on it. But not, I believe that would be out of the scope for this task force.

Arien Malec – Change Healthcare – Co-Chair
Yes. I don't know that it would be out of scope. So, I think the specifics, I think, would be out of scope for this task force. I think it is in scope for this task force to ask the question of from a policy perspective, what do we expect out of the TEF? And what success would look like? And then to evaluate TEFCA 2 according to that success criteria. And if – I won't go into detail. I'll try just…

Andrew Truscott – Accenture – Member
No, no. Arien, Arien, I agree. I mean, I agree with you. We have an opportunity to potentially alleviate some of the burden, which is already being talked about around information blocking. If we can, we should, and it's a great place to talk about it. If it is not going to be discussed here, where is it going to be discussed?

Arien Malec – Change Healthcare – Co-Chair
Right. So what I would recommend is that we set aside some time to explicitly discuss what we expect the TEF to do and what success for the TEF would look like. And you know, we might want to frame broad objectives like this patient in the TEF is a reasonable and necessary requirement to achieve or a reasonable means to achieve adherent to information blocking. And that it should be sufficient to address information blocking requirements. Versus a narrow framing of the goal of the TEF is to get HINs to talk to each other and if HINs are talking to each other, the TEF is successful.

And I don't want to have the debate here, but I think framing that **[inaudible] [00:45:40]** is useful.

Andrew Truscott – Accenture – Member
Yes. Let's not litigate it here. Let's have a session specifically for that. Because I think it is very important, personally.

Arien Malec – Change Healthcare – Co-Chair
Agreed. Thanks.

John Kansky – Indiana Health Information Exchange – Co-Chair
And just for clarification, this is John. Andy, originally where I thought you were going, and maybe you were, in terms of info blocking and its relationship to this task force, while I understand we don't want to dive into definitions like HIN that were debated and discussed in great detail in the info blocking task force. It occurs to me that that definition, looking through a lens of info blocking and looking through a definition of how it will be applied, for example, for QHIN eligibility is a different frame of reference. And so, does that matter, and is it still out of scope?

Arien Malec – Change Healthcare – Co-Chair
Yes. Let's make sure we're capturing it.

Andrew Truscott – Accenture – Member
That was another part of where I was going to head as well. So thank you. Yes.

Arien Malec – Change Healthcare – Co-Chair
Let's make sure we are capturing that, Zoe, as discussion items for a well-defined discussion. I see David has hand up.

David McCallie, Jr. – Individual – Public Member
Yes. Just to add to that list. The thought of whether or not there is alignment around some of the privacy and security requirements under TEF, as enumerated so far with compared to the NPRM. To avoid sort of back-channel confusion. Like, you can get the data through this rule, but you can't get it through that rule because the security and privacy rules don't align. I think that would be something to be thoughtful about. So API access versus access through a QHIN ought to follow the same rules, it would seem, in general.

Arien Malec – Change Healthcare – Co-Chair
Cool. Great point.

John Kansky – Indiana Health Information Exchange – Co-Chair
Zoe, I had a terminology question. I understand your encouragement to redefine only say TEF when we mean TEF. So my question is, I found, and a lot of people have found the term, like TEFCA ecosystem as a good way of describing this whole enchilada. Is the term QHIN exchange network synonyms with the ecosystem, or what terminology would you like us to use so that we can communicate clearly?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
That is a great question. Yes, so I would say, we have been using the term QHIN exchange network and framework agreement to sort of referring to that overarching TEFCA ecosystem. We are definitely open if you guys have suggestions for what that one good phrase to talk about that could be. We definitely welcome that suggestion. We use TEFCA ecosystem sometimes too.

Andrew Truscott – Accenture – Member
Go on. Go on. Go on.

Arien Malec – Change Healthcare – Co-Chair
Sorry. Just trying to get maybe a little more discipline on who is raising their hand. So, are there folks on the phone who can't raise their hand via the interface wanting to get in with some additional comments?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
I think it was just us ONC folks. We are all in a room together, so.

Arien Malec – Change Healthcare – Co-Chair
Got it. Okay. So the TEFCA ecosystem is the TAFE.

Andrew Truscott – Accenture – Member
Arien, I'm raising my hand. If you are looking for a good word, the pantheon is a good word. But maybe not. Maybe that's a word too far. We need not create new acronyms though, okay. We have too many.

Arien Malec – Change Healthcare – Co-Chair
Yes. Having a good acronym is the prerequisite for success in ONC land. Okay.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Part of the application to get in.

Arien Malec – Change Healthcare – Co-Chair
Exactly, exactly. It's part of the test. It's certainly part of the Posnack test. Okay. I'm not hearing other hands raised or virtual hands raised – or seeing any virtual hands. Oh, Mark has his virtual hand raised.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
So, I want to go back to a slide, I think it's 12 on individual access services. And just check the question that I put into the chat box. I think it's the last bullet. And I haven't read through any of this, so forgive me if it's already answered. But, Zoe, you said that once the EHI is received, it can only be used for individual access services. And I was thinking about the range of users with this single onramp. And so, I put in a comment about all of us trying to gather individual information for research purposes. Is that then use of the framework that is not permissible? Or is there a definition of individual acts or services that make that work? I just wanted to understand how that limitation might or might not have unintended consequences.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Absolutely. It's a great question. So, first, just to clarify, only if the data or the EHI is received for the purposes of individual access services, only then can it only be reused, exchanged, disclosed, for individual access services. And that is specifically in compliment with the fee restriction that QHINs are not allowed to charge another QHIN for exchange EHI for individual access services.

Now to talk about the research question. Research is not a permitted exchange purpose within the TEFCA. However, we do have an exception in sections 2.2.2, 7.2 and 8.2, that you can reuse the information for another purpose if you have the individual's authorization to do so. And we defined the term minimum information. So, basically, if you wanted to reuse that data for research, you would need to get the consent of the individual and send them something that had all of the minimum information needed to get their consent.

So it is sort of similar to a HIPAA authorization. And it speaks to what the data is going to be used for, who it is going to be sent to, and any other type of information that we would want the individual to know before providing their consent for that data to be used for research purposes.

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

Okay, thank you.

David McCallie, Jr. – Individual – Public Member
Just a running comment on that. This is David. However, if the individual requested all of their information, they could opt to direct all of it under their own terms to a research entity outside of a HIPAA consent requirement, correct? Zoe?

Arien Malec – Change Healthcare – Co-Chair
That's not a QHIN obligation, that's an individual obligation, right? That wouldn't be necessarily how to scope for the QHIN. So, the answer to – I think you're right. I think the answer to Mark's question is there is a QHIN side of the boundary and an individual side of the boundary. Sort of to the individual's side of the boundary, they can do anything that they want with it including spray paint it on a wall.

David McCallie, Jr. – Individual – Public Member
Right. And the All of Us program has a route to capturing data through individual contribution. They could use IAS access to get their data and then contribute it. That channel is not precluded by anything going on here.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
That's what I think I heard from Zoe.

David McCallie, Jr. – Individual – Public Member
Yes, sorry for jumping in but, it's one of the broad topics to focus on.

Arien Malec – Change Healthcare – Co-Chair
Hold on. I'm trying to steer a conversation. I saw Chris had his hand up and then put his hand down.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
So, Chris isn't a member of the task force. We will ask him to participate during the public comment period.

Arien Malec – Change Healthcare – Co-Chair
Okay. Got it. Any other virtual or voice hands raised? Hearing none, we are going to turn it over to John Kansky to lead us through a discussion of definitions and stuff.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yes. And I'll just quickly – I'll just do another quick overview of the definitions that we have here. So, we are going to get into the conversation about the application process and designation process. So these definitions are important to know as we get into this discussion.

So, obviously, first, we have QHIN, which is – it's a pretty straightforward definition, the real meat of the QHIN stuff is in the eligibility requirements in the prerequisites. We then have a QHIN application which is the written application of a health information network that wishes to become a QHIN. And then there is the concept of the cohort, which is a group of one or more provisional QHINs, specified in writing by the RCE, that are attempting to be Designated by the RCE as QHINs. Cohort deadline, pretty straightforward, the RCE will establish a date for completion for each cohort that it convenes. And then, Designation of course, with its correlative meaning, designated, designated, and designating, is

the RCE's written confirmation to ONC that a provisional QHIN has met all of the requirements of the common agreement and QTF, and is officially a QHIN.

Onboarding, all implementation and other actions necessary for a QHIN participant or participant member to become operational in the live environment of the framework agreement. And then provisional QHIN, which is the health information network that has signed the common agreement and is in the cohort process to be designated as a QHIN.

So if you go to the next slide, I'll pause on this slide. We can kind of go-between, there is a second slide after this that finishes the application process, and the definition slide as we talk. So, handing it over to you, John.

John Kansky – Indiana Health Information Exchange – Co-Chair
Thank you. So, Zoe, is it fair that in addition to the actual definition of the QHIN on slide 23, that the implied QHIN eligibility requirements are also in scope for discussion?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Correct, yes.

John Kansky – Indiana Health Information Exchange – Co-Chair
Okay, so with that, I'll try and tee things up. A couple of initial comments I wanted to make. Obviously, we want unfettered discussion and need to cover a lot of territories. I am going to apologize in advance for any undiplomatic or abrupt re-centering of the conversation. So, I just I'll probably apologize before every call, but just need to keep things on task.

Also, I wanted to address the use of examples. Something that I found in other task force calls, examples are extremely helpful to understand or clarify the meaning of questions or answers to questions. Meaning examples from the industry of specific organizations. I've used the example of my organization, the Indiana Health Information Exchange, in several previous task force calls. No one seems to be offended by that. And I think we need to be able to use examples when helpful and necessary. Just asking that people be kind of egalitarian and diplomatic in their choice or how they might represent any specific companies or organizations if that makes sense.

With that, I have this theory, before I throw things open, that there is going to be more discussion on definitions and QHIN eligibility than there is going to be on the actual process of application, onboarding, and designation. That may prove to be false. So, is there anybody that has a burning question that they want to start with, or I can throw pebbles on the pond? And I cannot see raised hands, so if the ONC folks can help me, that would be great.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
No hands at this time, John.

David McCallie, Jr. – Individual – Public Member
I'll start. I'm on the call late. I'll start. Just, it's a real technicality question, but I just can envision these rules, between now and the time that the RCE becomes operational, somebody may question the definition of already operating a network mean? Is already as of the liveness of the RCE, could

somebody scramble and put together a network specifically between now and then to become a QHIN? Or does already mean as of today?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
I would say that it would be the time that they submit the application to the RCE.

David McCallie, Jr. – Individual – Public Member
Okay. So, all right. So, somebody could start from scratch, build a network, and then apply to become a QHIN in the future?

John Kansky – Indiana Health Information Exchange – Co-Chair
As long as it was operational and met the definitions by that date, that's my understanding pending any clarification from ONC.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
I will say – go ahead, John.

John Kansky – Indiana Health Information Exchange – Co-Chair
No, go ahead.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Just to keep in mind, as we're thinking through these prerequisites, the three **[inaudible] [01:00:43]** goals that we have in mind for QHINs, right. So we want them to be neutral and accessible to all parties. You want to maximize efficiency and minimize failure. We want to make sure that those who are being designated a QHINs have the proper infrastructure, functionality, and personnel necessary to be successful.

Arien Malec – Change Healthcare – Co-Chair
And it's my assumption in this conversation, just relative to the already in production comment, that the goal is not to have a single cohort of QHINs, but the goal is to have an expanding and properly changing set of QHINs over time. Or do I read the word cohort as implying a single, once and done activity? Or do I read the word cohort as a group of HINs that is applying at that time to be a QHIN?

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
Yeah, the cohorts are going to be an ongoing process, so.

Arien Malec – Change Healthcare – Co-Chair
Right.

John Kansky – Indiana Health Information Exchange – Co-Chair
An ongoing process, but I made the assumption, asking for clarification, that when you submitted your application, you are assigned to a cohort you kind of go through with. But once you're in or your whole cohort was in, that that cohort has kind of lost its meaning because you had become Designated? Is that not correct?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
You don't become Designated until the end of the cohort period.

Arien Malec – Change Healthcare – Co-Chair
Right. And once that period is complete, the word cohort has no meaning, because the cohort only applies for the intro application to the designated period? Correct?

John Kansky – Indiana Health Information Exchange – Co-Chair
That was my understanding, yeah. Okay. Along the same, and again, there are hands raised.

Arien Malec – Change Healthcare – Co-Chair
Just a quick, sorry John. Just close out that topic. So I think that's the answer to David's question, which is that because this is intended to be an evergreen process, the introduction applies to the time of application as part of a cohort.

John Kansky – Indiana Health Information Exchange – Co-Chair
That's what I understood. I think there is – and I'm going to throw a couple pebbles on the pond because I think there are some related topics, that I may have been overreading the QHIN eligibility, that operates a network that David called out was one of them that I keyed on. I think in an offer for clarification or discussion, there are industry terms we use of framework or network. But in as much as network is not – and again, in the spirit of offering examples. I think one of the poster child frameworks known in the industry, cares equality as an example of a framework, common well as an example of a network. My understanding of the word network in HIN already operates a network. Not being a defined term, the intent isn't necessarily to a specify network and preclude framework in this context. If there's any clarification – I'm trying to phrase that as a question. Is that correct?

Arien Malec – Change Healthcare – Co-Chair
I would have interpreted operate a network as actually facilitate exchanging data. Not offers governance. But these are going to be interesting topics as, again, just picking in care quality. Is care quality – are their activities primarily RCE activities, or are the networks? What's the relationship between being an RCE and a network? And what are the entry criteria, definitional criteria for being a HIN relative to entering into a cohort?

John Kansky – Indiana Health Information Exchange – Co-Chair
So, I have some comments and questions there, but are there raised hands?

Arien Malec – Change Healthcare – Co-Chair
David has his hand up.

David McCallie, Jr. – Individual – Public Member
You see, I've been off-line for a whole month in retirement, so I have pent up energy. Sorry about that. I was going to approach; I mean this is a fairly broad and inclusive definition of things that could become a HIN. I would be curious to try to explore entities that might not be able to become HINs. And following John's notion of examples. So for example, would a vendor's internal network that exchanges data across its customer success and following perhaps even the same standards of the QTS, would that be able to become a QHIN? The exchange is internal and not – well, I'll just stop there. Would they be able to become a QHIN? Do they qualify?

Arien Malec – Change Healthcare – Co-Chair
I think these boundary tests are really interesting. So I think we pose the issue of is care quality a network under this definition, or would it be a perspective RCE? Is a vendor-specific network a network

under this definition? Some of these boundary condition tasks I think are going to be useful to draw the surface area.

Andrew Truscott – Accenture – Member
Arien?

John Kansky – Indiana Health Information Exchange – Co-Chair
Go ahead, Andy.

Andrew Truscott – Accenture – Member
Oh, yes. So we did go to these boundary type of issues, quite specifically, Arien. As your way of on the information blocking task force with the definition of health information network versus health information exchange. There was some drafting in the draft rules around whether organizations were affiliated or unaffiliated. Depending on where the recommendations go, as that being considered by ONC, I think that would inform this discussion as well.

So, you know, with the care quality example, whether it's affiliated or unaffiliated, that could have a definite implication on that. But I do see and understand that the way you have exchange information going on, it might be within a company's closed network to its clients, but it's still between clients. It's not just within that company. Does that make sense?

David McCallie, Jr. – Individual – Public Member
This is David. I think that is an interesting example. I think you could take it a little further and suggest possibly some large integrated delivery networks may run their own internal network that exchanges across their member provider groups. And then they can get on their own or with third-party software, that has nothing to do with their EHR vendor, per se. They just run an internal network. Would that be enabled to be a QHIN? I'm assuming the answer to all these is yes, but I'm looking for some clarifying exemptions that say no, that doesn't qualify.

Arien Malec – Change Healthcare – Co-Chair
So, I think what we're – and we should continue to explore this a little bit because what I'm hearing and what I believed coming into this conversation was that QHIN eligibility is a little foggy. And I think the answer, and I'll request some clarification from anyone at the ONC after I get this couple of sentences out, is that ultimately the decision is that the RCE will evaluate QHIN applications against the eligibility. And they'll determine whether an organization is eligible or not. But with that rather unsatisfying answer, it would be helpful to have any clarification of what the eligibility words in the draft mean today.

So, for example, and we alluded to it, is the HIN/HIE definition that we discussed in info blocking was deliberately broad. And maybe it can apply here without modification. But I'm concerned that it was not in the same frame of reference.

David McCallie, Jr. – Individual – Public Member
Right. So one question for clarification from our ONC team. Is entity – so I thought the term was individuals, and this now says, persons. So is there a difference between an individual and a person. And then, an entity as a defining term. What does entity mean in the context of this definition?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
I'll say, we don't have a definition of persons, per se, but remember the definition of an individual includes both the individual who is the subject of the information and a person or legal representative. So that may be why it says persons and not individual. And there is not a definition of an entity.

John Kansky – Indiana Health Information Exchange – Co-Chair
Zoe, are you comfortable commenting – what are you able to say in terms of your impression – your advice on reading or overreading, hanging on words like live clinical environment, locate and transmit, operates a network, and then hanging on those words. Do you have any guidance for us in terms of the intent of the way it was written?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yes, sure. So, I would pay most attention to words that have definitions. So if they're capitalized, that means that they have a definition. Otherwise, I guess I'll kind of keep saying, we wrote this with those three policy goals in mind. Neutral and accessible, maximize efficiency and minimize failure.

Andrew Truscott – Accenture – Member
So, Zoe, is it fair to say that the definitions that come out of the information blocking taskforce, and once they have been communicated through the rulemaking process, they will be the definitions that this TEFCA, TEFCA 2, NCCS, etc. that they will be the same definitions?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
I don't want to make any definitive statements necessarily, but in this draft of the TEFCA, the definitions between HIN and information blocking and EHI all align to the NPRM.

Andrew Truscott – Accenture – Member
Got that. Now, depending on if they change going through the rulemaking process coming out of the process you've just been through, how are we going to make sure those changes are reflected in here? Because the timing doesn't seem quite to line up.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Well, we worked very, very closely with our partners here at ONC. I think Michael can – he's on the line as we speak. Mike, if you want to say hi.

Michael Berry – Office of the National Coordinator for Health Information Technology – SME
Hey, how are you guys doing? It's a fair question, Andy. I mean, our goal at the time, obviously, was to align them as you see that the definitions are the same in both the proposal and the second draft of TAFCA, based on all public's comments we get, including your recommendations from the HITAC. We'll consider what the final definitions should be for info blocking purposes. And then, whether that should remain aligned for TEFCA.

Obviously TEFCA, our timing – well, I can't really speak much about the timing yet, on both the final rule and this final TEFCA. But I think we'll take it under consideration. **[Inaudible] [01:13:08]** we

wanted them aligned was that if it was for clarity to the market, right. Like if you are a health information network, you know can both attest to TEFCA under the statue and you will still be subject to information blocking, versus having two definitions participating in both. And the obvious liability issues that would come up with that and so forth and concern.

So, that's about what I can say at this point. I get your point about, well, we have to see what that final definition is before we say it should apply to here. But I think you could also take your current philosophy of what you think the definition of the HIN should be for info blocking and see if that makes sense for this, for TEFCA, and then you could make the similar recommendation. I'm not putting words in your mouth, as the way to go. But just a thought. You know.

Andrew Truscott – Accenture – Member
Yes, Mike. We get the – well, I get it. I understand directly what is going on. I think the general question is for you all, we shouldn't be saying what these have to be kept in absolute vigorous lockstep with each other, so we can't change what is in information blocking because TEFCA's going on and vice versa. But we just need, as the definitions potentially get changed and solidified, we just to make sure that we're aware of that here and reflect it in both of these.

John Kansky – Indiana Health Information Exchange – Co-Chair
So, Andy, I get the **[inaudible – crosstalk] [01:14:34]**.

Arien Malec – Change Healthcare – Co-Chair
Hold up. Hold up. I'm playing time cop here and also serving as John's eyes and ears because David has his hand up.

John Kansky – Indiana Health Information Exchange – Co-Chair
Thank you. David?

David McCallie, Jr. – Individual – Public Member
I'm sorry. I was on mute, sorry. Continuing in the spirit of testing boundaries as a way to flush out a definition, I have sort of bootstrapping questions. Which is, if the definition requires networks that are already operating and exchange successfully to qualify to be a QHIN, why would those networks decide to become QHINs if they are already successfully exchanging data? Is there something that is QHIN lets you do that you can't do without being a QHIN? Or will you be no longer allowed to do what you were doing at some point the future unless you become a QHIN? What's the forcing function for an already successful network to become a QHIN?

John Kansky – Indiana Health Information Exchange – Co-Chair
So this is an interesting question in that my answer, as just a member of the task force, as well, you are outside the ecosystem unless you are a QHIN or you participate in one, or you are a member of a participant. And so, what does the world look like if you are a successful network that chooses to remain outside of the ecosystem, is I think my version of the question you are asking, and I am interested in comments from anyone else.

Arien Malec – Change Healthcare – Co-Chair
Yes. I comment that this probably should be part of our discussion when we talk about the strategic question of what are the goals of TEFCA or the TEF ecosystem. The TAFE. Because that should answer the value proposition for what would a HIN want to be a QHIN, and might also answer, maybe I'm

reading into David's comments, but also the bootstrapping issue is, post-TEFCA, is there any room for a HIN to be a HIN before it's a QHIN?

John Kansky – Indiana Health Information Exchange – Co-Chair
Or a HIN to be a HIN after there are other QHINs?

Arien Malec – Change Healthcare – Co-Chair
Right. That's exactly…

David McCallie, Jr. – Individual – Public Member
What's the benefit to drive someone to go and meet these additional requirements? And I understand. I'm trying to be nasty about it. I'm just sort of saying, businesses will operate rationally. What's their rational motive to do this?

John Kansky – Indiana Health Information Exchange – Co-Chair
No, I think it's a great question. And I think, Arien, you started a list of for the ONC of things to capture for that. I think that's perfect for that. And I'll try to withhold my own rabbit hole interests on that one until then. I wanted to circle back really quickly to Andy's comment.

Arien Malec – Change Healthcare – Co-Chair
Okay, John, before you do that, I just want to note that Mark and Sheryl are both in the queue.

John Kansky – Indiana Health Information Exchange – Co-Chair
Let's go there. Let's go with Mark. Whoever was first, sorry.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
Yes. And maybe this is what you were going to say. I just wanted to circle back to the comment that we didn't have to keep requirements in the QTF, TEF, whatever we should call it, aligned with the information blocking rule, that they didn't have to be in lockstep. So I appreciate that. But I also just wanted to throw out the additional framing that we – there is probably, all things being equal, it is kind of better than they are aligned, and that that is sort of a framing that we perhaps bring to the work here, is to try to make them consistent. Thanks.

John Kansky – Indiana Health Information Exchange – Co-Chair
Thank you. Sheryl?

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
Thank you. I wanted to pile onto what David was talking about. Because quite honestly, without a lever of mandate or an incentive, what is the advantage of any of these HIEs or health information networks to move towards this process. To me, I think that is a series gap.

John Kansky – Indiana Health Information Exchange – Co-Chair
Thank you. And I think we will have an opportunity to dig into that one more deeply in the imaginary call that we are going to set up later to be made real.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
There was one other point, though, that I wanted to bring up and I wasn't able to be because I was just joining the meeting. But on the population health thing, the way I was reading the revision is they sort

of took out the requirement to be able to satisfy population health requests. So I think that is something we should be commenting on as well. Because although there might not be a pilot example for population health, it is one of the DaVinci use cases, and hopefully soon we will be having some work being done in that area over the next few months. So I don't think it should be completely removed, just because prior comments from people that reviewed it felt like it wasn't mature enough.

John Kansky – Indiana Health Information Exchange – Co-Chair
So, Sheryl, your comment is that when we get to modalities that just because the bulk query is out, that we shouldn't consider making a comment. Is that what – I'm trying to reframe what you said.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
Yes, I think we should comment about that. Because I don't know if we – I don't know, myself, I don't know if that is the right way to go forward, is by not having a bulk query, just because one hasn't yet been matured.

Arien Malec – Change Healthcare – Co-Chair
Hey, I want to put a placeholder in this conversation. It is a really important conversation, but it belongs in the next task force meeting discussion. Mr. Miri?

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
Yes, hey, it's Aaron. I quick question, and this is just for my clarification. I'm in my mind wrestling, Arien, you brought up a good point. Can a HIN operate as a HIN before coming to a QHIN? I think that is a great question. And I am thinking about it the academic medical center perspective, particularly mine. As you can imagine, all of the University of Texas systems, we are linked together, called a LEARN network, which is a fiber backbone, really for research and whatnot, but also the health side of things also participate.

Again, going back to research. To the degree of it, it does make wonder what the incentive for the academic medical centers to want to tie together because they already are sharing information is. Often through a dedicated fiber backbone that does not go across the public ISP space.

So it is just interesting. I think we should keep academic medical centers and the research component of this in the front. I think as Zoe said, with consent, research is allowed as part of this process. Again, given proper consent and proper privacy and security. And I think we would behoove us to remember that a large portion of the health continuum does traverse academic medical centers and academic care.

So it is going to be an important question to answer is, how do we really make sure that those academic medical networks and those HINs do become QHINs or want to become QHINs?

John Kansky – Indiana Health Information Exchange – Co-Chair
Thank you. Is the queue empty? Because I have a question. Okay, circling back to – hey, Andy, I get to put you back for all the times you put me on the spot on the info blocking task force. So I have a question about applying the HIN definition that, to your point needs to be adjudicated. But the HIN/HIE definition in the recommendation coming out of the info blocking task force was very broad. But my question to you is, do you think that, given that we have this filter the RCE is going to apply of neutral, sufficient, and successful, or lack of failure, that having a large number of organizations that are eligible or at least meet the HIN definition going into a potential QHIN application process. Is that problematic?

And if Andy doesn't want to answer, I'll ask if anyone else has an opinion. Did that question make sense, or do I need to restate it?

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
Can you try that one more time? Yes, can you resay it one more time?

John Kansky – Indiana Health Information Exchange – Co-Chair
Sure. So the definition of HIN that emerged, or the opinions and recommendations that emerged from the info blocking task force defined HINs very broadly. And it kind of went out of its way not to leave any organizations out that might fit that definition. So if we went to apply the definition of HIN broadly when we consider organizations that can be QHINs. And I'm quoting, HIN already operates a network as eligibility for QHIN, is it problematic in any way that the definition of HIN is very broad, given that the RCE is going to vetting applications for the organization's ability to be successful and meet the other criteria.

Arien Malec – Change Healthcare – Co-Chair
Yes, and maybe to add another wrinkle to that is – so there is a set of additional tests, but is the intent, and maybe this is an ONC question. Is the intent that any HIN that is a HIN by the information blocking definition, a HIN that meets the funnel for the four tests that are provided here?

John Kansky – Indiana Health Information Exchange – Co-Chair
Is there any ONC guidance on that point?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Could you just repeat the question?

Arien Malec – Change Healthcare – Co-Chair
Yes. The question is, the information blocking NPRM has a definition for HIN that is very broad and very expansive. This definition has an additional four tests that serve as qualifiers for HINs. Is the intent that any HIN that meets the HIN under the Cures NPRM test is a HIN at the top of this funnel that then is further qualified by the four additional tests? Or are there additional definitions that are implied before these four additional tests?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
The former. Any HIN per the HIN definition in the NPRM, and then, plus these four additional tests.

Arien Malec – Change Healthcare – Co-Chair
Yes. And one other question, I know that David has his hand up, but I'm just going to take a co-chair prerogative question. What is the definition of – does live clinical environment imply that the transactions are for clinical purposeless?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
So, what I'll say about the clinical environment, and again, tying back to the policy goals of maximizing efficiency and minimizing failure. Is that we wanted to ensure that those organizations that are going to be designated as QHINs that they are not just in the planning stages or still beta testing. That they've actually exchanged data in a live environment.

Arien Malec – Change Healthcare – Co-Chair

Got it. Let me pose another boundary question test. I run and operate a clearinghouse that does large volumes of live exchange. I believe I am a HIN for purposes of the Cures and PRM test currently. Am I – do I meet the live clinical environment test under subpart II? And you don't need to answer, I think it may be a boundary question. Your answer may be clearly yes, or it may be a boundary question test.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
I'll say, yes, I'm not going to comment on specific examples.

Arien Malec – Change Healthcare – Co-Chair
Okay. David and Aaron have their hands up, John.

John Kansky – Indiana Health Information Exchange – Co-Chair
Hey, and I think I just cracked the code. I can see raised hands.

Arien Malec – Change Healthcare – Co-Chair
Oh, good.

David McCallie, Jr. – Individual – Public Member
So, David here again. Another boundary test. As I read the document, it sounded like it would be possible for a QHIN to perform individual access services only. I think I understood it to be that way. And if that were correct, boundary test would that allow a Facebook or an Apple or a Google to become a QHIN? And if not, why not? What would reject them? Just add that to the list of boundary tests if you would.

John Kansky – Indiana Health Information Exchange – Co-Chair
Thank you. And Aaron, you have hand raised?

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
Yes. And then, one question for me, and this ties back to the information blocking task force. If a HIN becomes a QHIN, let's assume that it's a vendor. Let's assume that it is a certified health IT vendor that is now also operating as a QHIN, and they suddenly are found to be committing information blocking, bad actor activities and they are decertified. Do they lose their QHIN status and therefore participation in the overall environment or – I forget the acronym, the whole environment?

Michael Berry – Office of the National Coordinator for Health Information Technology – SME
This is Mike. Do you want me to – I can at least say a few things to that.

John Kansky – Indiana Health Information Exchange – Co-Chair
Yes, please.

Michael Berry – Office of the National Coordinator for Health Information Technology – SME
That question is good in terms of there are multiple jurisdictions there on that one. So you would have the program, and you would have OIG both having jurisdiction there. So the ONC under the certification program, ONG under their civil money penalties. So, we talk in our rule about how we would coordinate and all that. And the resolution of that, and I think you're getting to the point, that if they were found to have been info blocking, what would be the resolution?

That is still to be determined, right? So it could be civil money penalties plus decertification or banning from the program. The product may not get decertified, so we have to be clear about that.

And then, TEFCA's separate participation which is governed by contracts. And the RCE would still have to do the common agreement in whether there are – you know, what are bad behaviors and what are the consequences for bad behaviors. So not probably the full answer that you want, but to show you how there is an interplay there on various jurisdictions and so forth.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
Super helpful. Thank you.

John Kansky – Indiana Health Information Exchange – Co-Chair
Thank you. Other hands raised? No. So, are there – can I poke the group a little bit on are there any questions or comments on definitions on the slide – if we can go back to slide 23. Are there any questions about other definitions that ONC is looking for, comment on the application, the cohort, designation onboarding, provisional QHIN? Are those things generally clear? They were to me, but I want to make sure that there aren't other smart folks out there that had comments.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
This is Aaron. I would say one thing, and I don't want to jump ahead, because I think it's going to be its own discussion. I would be very curious if there is a definition slide that then ties up to an expected liability or ramifications of liability for receiving one of these designees. Case in point, I'm just making this up, but if you become a QHIN, you're identified as that, does that increase your exposure for liability and/or what is recourse around that?

And I know we have a privacy and security discussion coming up in the future, but to me, I think a definition page with those matchings up would help all of us understand the gravity of some of these definitions.

John Kansky – Indiana Health Information Exchange – Co-Chair
And just to demonstrate, I would agree with you. Not trying to go down that rabbit hole, but an example, and maybe there already is an answer, is that for example, identify proofing that is done a participant member or participant level, can a QHIN accept that identify and are they liable if it's wrong, for example.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
Yes. Or a consent or whatever else. Exactly.

John Kansky – Indiana Health Information Exchange – Co-Chair
Or whatever else. Yes, exactly. And I think we have a call for that when we get to privacy requirements later on the work plan.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
Yes, I can't wait. I love it. I can't wait.

John Kansky – Indiana Health Information Exchange – Co-Chair
Duly warned, okay thanks. David, I think you have your hand up as well.

David McCallie, Jr. – Individual – Public Member
Yes, just a general comment on the onboarding process. It makes sense to me the way it is described in terms of cohorts and provisional statuses and all that. But it strikes me as maybe overly prescriptive in that the RCE could define a process that worked for the RCE as long as some high-level conditions are met. That may have to do more with who can qualify to be a QHIN and who can't and some of these liability questions that have raised and relationship to the NPRM information blocking. Those would seem to be more useful areas to go deep than to specify the onboarding process overly. **[Inaudible – crosstalk] [01:33:29]**.

Arien Malec – Change Healthcare – Co-Chair
I think a bigger question, especially for ONC was what was the intent behind creating the notion of a cohort.

David McCallie, Jr. – Individual – Public Member
Yes. Why so much granularity

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yes, we wanted to ensure, again, going back to this efficiency and failure as goals, we really wanted to make sure that there were proper support and technical assistance for that overall onboarding and implementation process to become a QHIN. And so, when we brought in that definition of QHIN to allow for more actors to apply. And felt that by adding that cohort period where ideally, you are in a cohort with other similar organizations, that you might be able to share best practices or learn from. And that also that the RCE would be available during that time to provide technical assistance or support if needed.

John Kansky – Indiana Health Information Exchange – Co-Chair
And if the RCE in their judgment said you know what? This requirement for a cohort is really unhelpful. Will they have the latitude to change that or would we have to put that in the form of a recommendation?

Arien Malec – Change Healthcare – Co-Chair
I'll put it another way, is a cohort of one legally permissible?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yes, so to answer, Arien, your question, yes. There is no language precluding a cohort of one. To the first question, I might have Mike answer this a little bit deeper. But we have, in the NOFO there is some latitude to modify the application and cohort process with ONC approval. Mike, do you have anything else to add.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
Right. And of course, the RCU will be evaluating the program and holding public listening sessions to get an understanding of outreach. And will work with ONC to make any revisions as needed throughout the cooperative agreement process.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Exactly. And that being said though, a comment in this area is certainly within scope and welcome.

Michael Berry – Office of the National Coordinator for Health Information Technology – SME

Again, this is Mike, I will just add one more thing to the idea of this cohort. Because as you saw, it says a group of one or more. But it was also to ensure like fairness in the process so that there wasn't one QHIN ahead of the game. You know, you wouldn't get into a situation where like, oh I applied the day before you, and somehow you hit the market first and you hit the market first gives you some sort of advantage. So, it was an idea to make sure there was a fairness and level playing field as well.

John Kansky – Indiana Health Information Exchange – Co-Chair
And I just may have read too much into this. I also assumed there was a bit of Alexander Graham Bell principle that if you were the first person with a phone, you needed somebody to call. Did I read too much into that?

Michael Berry – Office of the National Coordinator for Health Information Technology – SME
Yes. I think that's fair too, yes.

John Kansky – Indiana Health Information Exchange – Co-Chair
Okay. So any other questions or comments regarding the process, designation, onboarding, the definitions that apply there? We are coming up on the public comment, but we have about another six minutes.

David McCallie, Jr. – Individual – Public Member
This is David. Again, sort of trying to do some boundary testing. As I recall in the original TEFCA One proposal, there were some rules about that you couldn't become a QHIN if you also aggregated data for other purposes. In other words, you monetized the data in some other way. That seems to be gone. And I think that was one of our recommendations, maybe even at the task force level. But I just want to be clear on that that a QHIN can be in the data business for other reasons and not be disqualified as long as they meet these other requirements of minimum requirements. Is that correct?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Correct, yes. That's confirmed.

David McCallie, Jr. – Individual – Public Member
Okay.

John Kansky – Indiana Health Information Exchange – Co-Chair
And I'd like to probe that. There is a disqualifying affiliation between QHIN and RCE. Is there any guidance you can give on the word affiliation in that context? How affiliated can an RCE and a QHIN be before they're too affiliated?

Michael Berry – Office of the National Coordinator for Health Information Technology – SME
Yes, we actually received several questions through the TEFCA NOFO mailbox on this topic. And we have prepared a response that will be posted tomorrow. So, until it becomes an official response, we will just have to let it wait until tomorrow. But if you go on to the TEFCA NOFA FAQ page, you will find the answer to that question.

Arien Malec – Change Healthcare – Co-Chair
How exciting.

John Kansky – Indiana Health Information Exchange – Co-Chair

Got it.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
Can I ask a question, this is Aaron, I have my hand raised? So I just want to make sure I understand David's question and the response from ONC on it correctly. So if a QHIN, if I'm getting this right, and as part of an RCE is then using the overall data deidentified, aggregating it, and then choosing to monetize it in some which way, say selling it so – I'm going to make this up. A pharmaceutical company for trending analysis. They are allowed to take the overall data across the networks, even if I never explicitly allowed for that as part of the overall agreement. I'm trying to make sure that folks are allowed to monetize the data, even if de-identified, that's shared over the overall environment. Did I hear that right?

John Kansky – Indiana Health Information Exchange – Co-Chair
That's not what I'm hearing implied. I would assume that any actions would need to be under a BAA or other agreement. That we're not creating a restriction on who can be a QHIN based on other activities that that organization may do.

David McCallie, Jr. – Individual – Public Member
Yes, this is David. That was the spirit of my question. So that if an entity that currently monetizes data through some existing legal process wants to become a QHIN, they could do so, as long as they operate the QHIN part of their business under the QHIN rules. In other words, they couldn't fetch data for non-permitted purposes, even though they might like to for the rest of their business. They would be prevented from breaking those rules, but they still could become a QHIN. That would be the way I read the current law, anyway, the current proposal.

John Kansky – Indiana Health Information Exchange – Co-Chair
Yes, and I believe that's a 2.2.2 question, and we have time to discuss that next week, but I'm intensely interested in understanding the answer to that. So can somebody summarize, because I think I got lost as it went by? So what are we saying is…?

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
Yes, so this is Aaron. So my question, my question was, and I think is what David was saying, is can a participatory QHIN, right. A QHIN that is identified. If they are looking at and they are part of this overall environment of data sharing, Can they take that data and do other activities with it such as deidentify and sell it, resell, as just an example. And other activities. Maybe research, maybe R&D development, anything else, or their expressed uses that are permissible and not permissible.

Arien Malec – Change Healthcare – Co-Chair
Yes. So I would comment that I think we are getting confused between selection criteria, that is who is allowed to become a QHIN, and permitted activities as part of the activities of being a QHIN. And then, what is permissible to negotiate as part of the data use agreement.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
I think it's one and the same, Arien. This is Aaron. I think actually if there are certain activities stated up front, that it may exclude you.

Arien Malec – Change Healthcare – Co-Chair

I don't understand that. So if I have a part of my business that does activity X, and another part of my business that does activity Y, I'm not presuming that all participants in activity Y thereby participate in activity X.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
No, but there may be – and I'm just making this up now because I think it's up for us to talk about. There needs to be an implied or an expressed, some sort of I shall not do bad behavior, much like we did with information blocking. So there may need to activities or stuff you state you will not do as part of the overall network. Again, all up for debate. I'm just saying there may need some rules of the road here.

John Kansky – Indiana Health Information Exchange – Co-Chair
And this clearly gets into the 2.2.2 permitted and future uses of EHIs. I see your point, Aaron. But we're absolutely going to get into that.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
Cool. Thank you.

David McCallie, Jr. – Individual – Public Member
And again, this is David. Again, it comes back to sort of who cannot become a QHIN? What would prevent you from becoming a QHIN? Some examples of that would be interesting if there are any.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
Yes. Agreed.

John Kansky – Indiana Health Information Exchange – Co-Chair
No hands raised, and we are about at public comment. Any guidance from ONC on whether we want to take that break now?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sure. Why don't we do that because we pulled up the numbers? So, operator, can you open the public line?

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

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

Operator
No comments at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. We will check back before we adjourn, but I'll hand it back to John.

John Kansky – Indiana Health Information Exchange – Co-Chair
Thank you. So Arien, Zoe, is there areas that you can think of that we want specifically to probe that we didn't get covered?

Arien Malec – Change Healthcare – Co-Chair
I feel like other activities will end up opening large cans of worms.

John Kansky – Indiana Health Information Exchange – Co-Chair
Agreed.

David McCallie, Jr. – Individual – Public Member
Or cans of large worms?

Arien Malec – Change Healthcare – Co-Chair
Yes. Well, large cans of large worms.

John Kansky – Indiana Health Information Exchange – Co-Chair
Zoe, are you comfortable with the stuff that we got put in the ONC basket today?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yes. Yes, no I think this is a great discussion. It looks like we might have one public comment coming in. But otherwise, I think if we want to end early, that's fine with me.

Arien Malec – Change Healthcare – Co-Chair
Yes, and I see Chris has his hand raised and had previously had his hand raised and was redirected for public comment, so I think we kind of – I don't know if he's on the phone or if he needs to redial through.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Operator, do we have Chris on the phone?

Operator
Let me check for you now. Chris Baumgartner? Is that correct?

Arien Malec – Change Healthcare – Co-Chair
Yes.

Operator
Yes, he is on the phone. I can open his line for public comment.

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

Operator
You are welcome. We have a public comment from Chris Baumgardner.

John Kansky – Indiana Health Information Exchange – Co-Chair
Go ahead, Chris.

Chris Baumgartner – Washington State Department of Health – Public Commenter
Hello. Can you hear me okay?

John Kansky – Indiana Health Information Exchange – Co-Chair
Yes.

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

Chris Baumgartner – Washington State Department of Health – Public Commenter
Okay, great. This is Chris Baumgardner. I'm with the Washington State Department of Health. And I have been trying to really follow how these, the notes proposed rulemaking as well TEFCA draft 2.0 would impact public health. And I have two kinds of key things I threw into the chat/public comment window there, that kind of have my head spinning. One is, would public health as a participating entity be required to respond to an individual access service request? It's not that we wouldn't necessarily want to, but some of our laws and our rules may not allow for it. And frankly, our resourcing may not allow for it.

A great example, immunization registry. If we had individual access request, you know, hey I want all of my immunization records, I'm not sure we would have the capacity to make that happen through the trusted exchange framework given our resourcing.

Another key concern is while it does define public health in the TEFCA and seems to cite the fact that we are not a covered entity or business associate. But that we are a health oversight entity, the minimum necessary requirements applying to all participants has me concerned, but because it looks like it's then trying to put covered entity requirements back on to public health if we are participating in the TEFCA. So those are my two comments/concerns/questions.

John Kansky – Indiana Health Information Exchange – Co-Chair
I'm going to for help from ONC on anybody that wants to feedback on Chris's comments/questions/concerns.

Arien Malec – Change Healthcare – Co-Chair
This is a point of order. Public comment is really useful. If we can provide on the spot Responses that can sometimes be helpful. But you know, the rule of public comment is to provide members of the public the opportunity to have input in the process. And so there is no specific need to reply to each and every public comment.

Chris Baumgartner – Washington State Department of Health – Public Commenter
Got it. Thank you.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
And that's all right. I can give a couple of fact-based answers to that question if that's okay. So first I would say, looking at the definition of public health, it references the HIPAA rules it also references any other applicable law. And there is a – if you look the definitions of common agreement, participant QHIN agreement, and participant member agreement, you will find a list of precedents in there in the case of any conflicts or inconsistencies between the common agreement and applicable law.

The second fact-based answer that I will give is that as it is written today, immunization registries or any public health entity would be required to respond for individual access services.

John Kansky – Indiana Health Information Exchange – Co-Chair
Any other public comments?

Operator
No additional comments at this time.

John Kansky – Indiana Health Information Exchange – Co-Chair
With that, Zoe, I'm happy to give people 10 minutes back.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Fantastic. Let's just quickly go over the homework for the 5/14 call. Just come in prepared to discuss the exchange purposes, modalities, EHI reciprocity, and permitted and future uses of EHI. So these are the recommend definitions, go ahead.

Arien Malec – Change Healthcare – Co-Chair
I would also recommend reading the QTF.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yes. I would definitely take a look at the entirety of the QTF. Give it a good read. And we will be concentrating on this topic both for the 5/14 call and the call that we have after that. So we should have a total of two and a half hours on this topic.

John Kansky – Indiana Health Information Exchange – Co-Chair
Oh, boy. So, thanks to everyone for their attention and participation. Very much appreciated. And we will talk to you on the 14th.

Arien Malec – Change Healthcare – Co-Chair
Have a good one.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Thanks.

John Kansky – Indiana Health Information Exchange – Co-Chair
Thanks, everybody.

David McCallie, Jr. – Individual – Public Member
Have a great weekend.

John Kansky – Indiana Health Information Exchange – Co-Chair
Bye.