



# Transcript

## HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

October 13, 2021, 10:00 a.m. – 1:00 p.m. ET

VIRTUAL



# Speakers

Name	Organization	Role
<b>Aaron Miri</b>	<b>Baptist Health</b>	<b>Co-Chair</b>
<b>Denise Webb</b>	<b>Indiana Hemophilia and Thrombosis Center</b>	<b>Co-Chair</b>
Michael Adcock	Magnolia Health	Member
Cynthia Fisher	PatientRightsAdvocate.org	Member
Lisa Frey	St. Elizabeth Healthcare	Member
Valerie Grey	New York eHealth Collaborative	Member
Steven Hester	Norton Healthcare	Member
Jim Jirjis	HCA Healthcare	Member
John Kansky	Indiana Health Information Exchange	Member
Kensaku Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Arien Malec	Change Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Individual	Member
James Pantelas	Individual	Member
Carolyn Petersen	Individual	Member
Raj Ratwani	MedStar Health	Member
Abby Sears	OCHIN	Member
Alexis Snyder	Individual	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem, Inc.	Member
Robert Wah	Individual	Member
James Ellzy	Defense Health Agency, Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
Ram Iyer	Food and Drug Administration	Federal Representative
Jonathan Nebeker	Department of Veterans Health Affairs	Federal Representative





Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Micky Tripathi	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Sweeney-Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Mariann Yeager	The Sequoia Project	Presenter
Alan Swenson	Carequality	Presenter
Steve Gravely	Gravely Group	Presenter





## Call to Order/Roll Call (00:00:00)

### **Operator**

All lines are now bridged.

### **Mike Berry**

Great. Thank you very much. And hello, everyone and thank you for joining the October HITAC meeting. I'm Mike Berry with ONC. And we are really excited to have you with us today. As a reminder, we welcome your feedback, which can be typed in the chat feature throughout the meeting or it could be made verbally during the public comment period that is scheduled at approximately 12:30 Eastern Time this afternoon. First, I would like to welcome ONC's executive leadership team to the meeting. And with us today is our National Coordinator, Micky Tripathi, Steve Posnack, our Deputy National Coordinator, Elise Sweeney-Anthony, the Executive Director of the Office of Policy, and Avinash Shanbhag, the Executive Director of the Office of Technology. I will now call the meeting to order and begin roll call of the HITAC members along with the federal agency representatives of the HITAC. And I'll start with our co-chairs. Aaron Miri.

### **Aaron Miri**

Good morning.

### **Mike Berry**

Denise Webb.

### **Denise Webb**

Good morning.

### **Mike Berry**

Michael Adcock. James Ellzy. Cynthia Fischer. Lisa Frey.

### **Lisa Frey**

Good morning.

### **Mike Berry**

Lisa, I think you might need to put it on mute because we're getting an echo. Thank you. Valerie Grey.

### **Valerie Grey**

Good morning.

### **Mike Berry**

Adi Gundlapalli.

### **Adi Gundlapalli**

Good morning. Thank you.

### **Mike Berry**

Steven Hester.





**Steven Hester**

Good morning.

**Mike Berry**

Ram Iyer. Jim Jirjis. John Kansky.

**John Kansky**

Good morning.

**Mike Berry**

Ken Kawamoto.

**Ken Kawamoto**

Good morning.

**Mike Berry**

Steven Lane.

**Steven Lane**

Good morning.

**Mike Berry**

Leslie Lenert. Arien Malec.

**Arien Malec**

Good morning.

**Mike Berry**

Clem McDonald. Elaine Hunolt who is sitting in for Jonathan Nebeker, Elaine. Brett Oliver.

**Brett Oliver**

Good morning.

**Mike Berry**

Terry O'Malley.

**Terrance O'Malley**

Good morning.

**Mike Berry**

James Pantelas.

**James Pantelas**

Good morning.





**Mike Berry**

Carolyn Petersen.

**Carolyn Petersen**

Good morning.

**Mike Berry**

Raj Ratwani. Michelle Schreiber.

**Michelle Schreiber**

Good morning.

**Mike Berry**

Abby Sears is absent today. Alexis Snyder.

**Alexis Snyder**

Good morning.

**Mike Berry**

Ram Sriram.

**Ram Sriram**

Good morning.

**Mike Berry**

Sasha TerMaat.

**Sasha TerMaat**

Good morning.

**Mike Berry**

Andrew Truscott.

**Andrew Truscott**

Good morning.

**Mike Berry**

Sheryl Turney.

**Sheryl Turney**

Good morning.

**Mike Berry**

And Robert Wah.





**Robert Wah**

Present. Good morning, everyone.

**Mike Berry**

Great. Thank you very much, everyone. And now, please join me in welcoming Micky Tripathi for his opening remarks. Micky.

**Micky Tripathi**

Can you hear me okay?

**Mike Berry**

Yes.

**Welcome Remarks (00:03:23)**

**Micky Tripathi**

Excellent. Okay. I figured out the technology. Good morning, everyone. And thank you so much for joining. I'm just really, really excited to be here today because we've got a special meeting focused on TEFCA, the trusted exchange framework and common agreement. It's been almost five years since passage of the 21<sup>st</sup> Century Cures Act. They called on ONC to develop a trusted exchange framework, including a common agreement among health information networks nationally. When I took office in January, somewhat halting progress was being made on it. And it had been almost two years since release of any key artifacts and no timelines had been set either externally or internally for what would be implemented and when. A key question, at that point, of course, was does it still make sense to move forward with this model as we've all been engaged in this for a while. After some examination, I believe and very firmly believe and ONC firmly believes that the answer is a resounding yes.

And why is that you may ask because we have nationwide networks today. Won't they just take care of it is one question that we get sometimes. The other set of questions we often get is well, we have FHIR API's. Won't they make networks obsolete anyway? So, why all the focus on this? Let me just discuss each of those things in turn. One is we do, indeed, have networks. And they've made tremendous progress. I, myself, was directly involved in them at the local, state, and national levels for the last 20 years and can certainly attest to the great work that they've done and they continue to do. I will also say though that their progress is slow due to the difficulties of getting market consensus in a really fragmented market of competitive actors. They've done very well in creating the policy and technical foundation for providers to exchange data for treatment purposes. But last mile implementation remains really think and really spotty. I think any one of us who goes to get care has the experience that most frontline providers and staff aren't even aware of these network capabilities by and large.

And the organization instinct is still fax, paper, flash drives, and CD ROM's. And that's the low hanging fruit. Extending these networks to include other important healthcare stakeholders like individual patients, for example, health insurers, public health agencies, and research safety surveillance has made relatively little material progress due to conflicting competitive pressures of the various healthcare stakeholders and legal regulatory issues that are really difficult to navigate with a market only process. So, and now, let's just speak about FHIR API's for a second and the future relevance of networks. I think the answer there isn't an "or" meaning FHIR API's or networks, it's an "and". It's both meaning that FHIR API's are going to exist in the





wild and they will continue to flourish in the wild. And they're going to be great. They're already starting to be great and they're going to be even greater for focused exchange and richer interoperability patterns and unique data requirements like FHIR hooks and smarter FHIR apps and FHIR questionnaires and lots of great use cases there that we want to be able to continue to push on and promote.

Networks, however, are going to continue to serve the more backend purpose of high volume, high reliability B to B exchange of standardized information. They provide transparent scalable governance and contracting, clear rules of the road, shared services like security, endpoint directories, record location, a variety of things that networks provide that are different in nature but still equally important. So, we don't know how interoperability is going to unfold over the next five years any more than we did five years ago. And it's important that we push on all options so that we don't cut off innovation and to preserve a fair and competitive playing field. With all of that in mind, we're really excited to finally bring this to reality. And what you're going to see here is the result of considerable refinements to greatly increase the odds of success. So, first in July, we announced the timeline that hadn't been announced before. TEFCA backed exchange is going to be available for participation in the first quarter of 2022.

That's important for internal accountability to keep us all focused on the government side to meet our obligations and our responsibility to the market. And it's also important for the market to know so that all of you in the market can set your expectations accordingly and decide what it is you want to do to make the investments that you want to make as you think about where you want your network base interoperability to go. We've more directly aligned TEFCA to complement the market and to help it get past obstacles but not to replace it or stifle what's going on in the market today. And this is everything for explicitly alignment it with HIPAA and applicable law so that we're not creating confusion by creating a separate set of rules to beginning with the standards used in the market today to meet the market where it is and not expecting a huge leap forward that can create a considerable gap with where the market is today and where TEFCA base exchange might lead us.

So, we have also though included a FHIR roadmap. And that's going to be a part of what we deliver. Previous versions of TEFCA and all of these artifacts were completely silent on FHIR. We're now going to include a FHIR roadmap that will set high level expectations for the incorporation of FHIR based exchange. Of course, nationwide and state regional HIE's are already on this path. But each is doing it in relative isolation. So, there is a lot of activity in each of these networks but it's relatively uncoordinated. And so, forward progress directionally but not a lot of orchestration or coordination. So, what we're hoping is that the FHIR roadmap is going to be the opportunity for us to get nationwide coordination for a full nationwide picture of FHIR based network exchange. Another aspect of the refinements we've made is we're giving more operational leeway to our private sector and nonprofit partner, the Sequoia Project.

The federal government has a really important role to play in providing a north star for nationwide interoperability to bring these networks together and have them pointed in the same direction and provide that degree of consistency across them and in setting hard policy guard rails that are important to the public interest and ongoing oversight to continue to assert the public interest as we think about nationwide interoperability. But the federal government also has an equally important role to play in getting out of the way in areas where we don't have the expertise, the experience, or the management structures or management agility to provide day to day management and day to day operational roles for something as fast moving and as continually evolving as network-based exchange in healthcare. Finally, and somewhat







more behind the scenes but equally important is that we've been working really hard to get federal partner participation, which really could be a critical driver of adoption.

I'm please to say that we've got dedicated discussions underway with many of our federal partners, including CMS and CDC, for example, and that's just an example. Though I certainly can't promise anything, I certainly don't want to promise anything on anyone's behalf there, I will say that we've got a level of really no kidding, strategic, and programmatic interest from those agencies that's unlike anything we've had in the past. So, a lot of hope that we've got a lot of things going in the right direction now that can help us all move forward. So, we've done a ton of work to get this back on track over the last few months and to fulfill the important goals laid out in the 21<sup>st</sup> Century Cures Act. And what you're going to see this morning is the fruits of those efforts, which reflect not only hard work by the Sequoia Project and the ONC staff but considerable stakeholder feedback over the last few months and, indeed, over many years, let alone the last several months and federal partner input as well.

One final point I want to make on TEFCA is that we should recognize that this is going to continue to evolve. In the Common Agreement that the Sequoia Project is going to describe to you and the associated policies and procedures that derive from it are going to have to adapt to changes in the market on an ongoing basis. The most important thing we can do from the federal government side is to set up the very good starting point and then, transparent, trustworthy processes to build and adapt from there. So, I very much look forward to the discussion. I want to thank in advance the Sequoia Project team. That's Mariann, Alan, Steve, Cait, Chantal, and very much thank you in advance for your partnership and for the presentation today. One other thing before I leave is I just wanted to flag a couple of items for your awareness.

We're really excited to begin our work with the awardees of the Public Health Informatics and Technology Workforce Development Program where we awarded \$73 million to strengthen US public health information technology efforts, improve COVID-19 data collection, increase representation of underrepresented communities with the public health IT workforce. We did make that announcement of 10 collaborations, minority serving institutions and collaborations that we're going to be formally kicking off next week. The other thing I just wanted to flag for all of you is I hope all of you saw an important new blog post that came out last Friday about ONC's work on our new initiative called the USCDI Plus. This initiative is developed to support the identification and establishment of domain or program specific data sets that will operate as extensions to the existing USCDI. It's a service the ONC is providing to our federal partners who have a need to establish, harmonize, and advance the use of interoperable data sets that extend beyond the core data and USCDI in order to meet agency specific programmatic requirements.

And I'm pleased to announce that CMS and CDC are our first partners. And we've got a ton of great work on the ground going on with both of them right now to get that up and running. And we'll add more domains once we've got the program more firmly established. We'll continue to use similar processes of the USCDI and we'll, certainly, leverage the HITAC and the USCDI task force going forward to provide critical input on that. As I said, we're just getting started so more to come as we figure out the right timing and the right ways to be able to get that engagement. But I assure you, that will definitely be a part of this going forward. So, let me, again, thank the RCE team for joining us today. And I really look forward to hearing the HITAC committee's feedback on the key elements of the Common Agreement of QTF. Thanks to the entire community for your important contribution to ONC's work. And let me turn it over now to Aaron and Denise for their opening remarks.





## Remarks, Review of Agenda and Approval of September 9, 2021 Meeting Minutes (00:13:49)

### Denise Webb

Thank you, Micky. And good morning to the entire committee. We are really looking forward to hearing about all of the good work and the culmination of the work that the RCE has completed and to have some dialogue on that. And I want to welcome Mariann and Alan and Steve. Thank you for being here today to present to us and give us an opportunity to provide some feedback. Aaron, I'll turn it over to you for any remarks.

### Aaron Miri

Absolutely. So, good morning, everybody. Thanks very much. Micky, thank you for those comments. Kudos to the entire ONC team. I think the entire community recognizes the phenomenal pace you guys are going at and some of the work that's being done there. So, thank you for that. All of the HITAC members, several of you I've interacted with over the past month on numerous different initiatives. Kudos to you and your locale areas and the work you're doing to really benefit all of healthcare. It's just an amazing committee. So, today is a pretty packed agenda. I know that Denise is going to go through that with you in a bit. And then, we'll do an approval of minutes and whatnot. But Denise, I'll turn it back to you so we can get going on the agenda.

### Denise Webb

All right. So, for the agenda, we really do have single focus today and it is the trusted exchange framework and common agreement. And so, Mariann and her team are representing the recognized coordinating entity is going to go over the key elements of the Common Agreement. And I know many of you all probably participated in a number of meetings. I know I did while I was able to. And she'll talk about that first. And we will have an opportunity to have some discussion and take a very short break so everybody can grab a coffee or go to the restroom. And then, we are going to hear about the key elements of the qualified health information network technical framework, or the QTF and then, have some discussion on that. And, of course, we hope we have comments from the public. We'll have time for public comment and then, our final remarks and adjournment. So, if we can get started with approval of the minutes, Aaron, if you want to take that.

### Aaron Miri

Yeah. Let's do it. So, if you all have seen the minutes from last meeting, we're going to go ahead and call a vote on approval. May I have a motion please?

### Andrew Truscott

Truscott moves.

### Aaron Miri

Do we have a second?

### Jim Jirjis





Second, Jim Jirjis.

**Aaron Miri**

All right. All of those in favor, please signify by saying aye.

**Group**

Aye.

**Aaron Miri**

All those opposed say nay. And any abstentions? Okay. The minutes are approved from the previous meeting. Denise, before we get going, let me make a quick announcement about the Annual Report Workgroup if you would. So, really quickly, I just want to give a quick update here. Again, today is really about the phenomenal work the Sequoia Project and others are doing and hearing some of those details. But on the Annual Report Workgroup, quick updates for this HITAC to know, Dr. Jim Jirjis and Dr. Steven Lane have joined us. We had a phenomenal discussion, I think, last week. All of the days are kind of blending for me right now. But it was phenomenal. We went through it. Good work there. We are firming that up. We continue to discuss any of the gaps and challenges and opportunities for HITAC activities for inclusion.

Again, I encourage you to please send us email, let us know if you have thoughts or things that are coming up, especially as you are going about your day that you think are relevant for the report. And then, we'll be bringing a draft report to this full committee for consideration early in the winter of '22 to really work through the meat and potatoes of this and get it to goal. So, just some quick updates for you for the Annual Report Workgroup. I couldn't do this without my partner in crime, Carolyn Petersen. She's phenomenal co-chair for the committee. And I thank her and I thank Michelle and the entire ONC team for the great work they're doing there. So, I think you all will be pleased with what you see here in the very near future. Okay. So, with that, I guess, Denise, I'm going to go ahead and introduce our first guests here to keep us on time. So, we're going to begin by speaking with Mariann Yeager and understanding more about what's going on there from the RCE world. So, Mariann, welcome to the HITAC And look forward to turning the floor to you.

**Trusted Exchange Framework and Common Agreement (TEFCA) Recognized  
Coordinating Entity (RCE) (00:18:27)**

**Mariann Yeager**

Well, thank you all very much for inviting us. Let me adjust my camera a little bit. So, thank you all for the opportunity to be able to share our progress with the HITAC. As you know, there's a lot of work underway. If you go to the next slide, we'll share the requisite disclaimer that we are here presenting information that we've been facilitating through a cooperative agreement with ONC in our role as the recognized coordinating entity. So, nothing that we're sharing is really an official position of the government. Go to the next slide. We'll talk a little bit about what we're going to cover today. We're very eager to hear feedback from this very experienced group and are very interested in all stakeholder viewpoints. We would like to cover certain aspects of the Common Agreement here. There is not really sufficient time to cover all of it. And similarly, with the QHIN technical framework and, obviously, we really want to get your insights into this important work and, of course, from all stakeholders.





We also shared the elements of the Common Agreement as the summary of the key terms and the draft eligibility criteria for QHIN's as well as five documents that look at TEFCA from the viewpoint of various stakeholders. So, we'll try to be brief in our comments so we have ample time for discussion. So, next I think you all have already introduced the team. But if you go to the next slide, Alan Swenson heads up Carequality. He's also been on point, not only in forming and providing great insights into the work on a common agreement but also lead on the QHIN technical framework. And it will be Alan and his team that work with organizations who wish to be QHIN's through the application, onboarding, and designation process. We have two expert legal folks on the team, Steve Gravely, and Cait Riccobono from the Gravely Group. And they've been on point working with the ONC team and our team on the Common Agreement and the accompanying standard operating procedures. And Chantal Worzala who has been heading up stakeholder engagement for us.

So, next I wanted to do a quick level set on the Cures Act and TEFCA just as sort of context for those who may not have been following it as intensely. So, on the next slide, why do we need the trusted exchange framework and common agreement? Well, the TEFCA came about to address a complex ecosystem where organizations today often have to join multiple health information networks to access the information that they need for treatment and other purposes. And TEFCA really aims to simplify this by enabling organizations to select a home network in that they can use that as their connection point to interconnect and exchange information with others who participate in different health information networks. So, TEFCA is a government endorsed approach for network to network information sharing. And in that respect, it really provides a unique opportunity for government and the private sector to work closely together to adopt the policies, legal terms and implementation level requirements to enable health information networks to interconnect more readily without substantial additional effort.

So, next Cures Act became law in December of 2016. And it required ONC to develop or support trusted exchange framework and common agreement. ONC opted to develop the framework with the intent of leveraging existing efforts to advance the aims of the Cures Act. And the Cures Act permits ONC to also support existing frameworks as well. The time line Micky had mentioned on the next slide, there we go, when he got engaged and was briefed, we really met as a collective team and realized that we have a tremendous opportunity with TEFCA. But time is of the essence in order for this effort to have relevance and realized that there is an opportunity to accelerate and bring this program to market in Q1 of 2022. So we're really working and getting input right now on the draft of the Common Agreement and the QHIN technical framework, which is an implementation guide. We're working very closely iteratively with the ONC team to refine those documents.

We're in the process of enlisting input on the Common Agreement elements. We'll be collecting input, obviously, through public webinars as well as through stakeholder input process through which we're collecting comments through October 21. And then, really we'll publish or release the first version of the Common Agreement and the QTF in Q1. These are really living documents. Micky mentioned it, but I really want to emphasize that we know that we are going to learn a lot and that there are a lot of nuances that we need to get more experience with this particular approach that we are going to be modifying it over time. So, we may not be able to incorporate and deal with every single solitary issue between now and the end of the year but we'll continue to iterate on it, again, through an open, transparent governance process. And





then, of course, throughout 2022, onboard QHIN's that, hopefully, have information being exchanged as soon as next year.

Really just to reiterate, the goals of TEFCA are to establish a floor for interoperability to simplified nationwide connectivity and, importantly, provide a mechanism and infrastructure, a back bone, if you will, so individuals can more readily gather their own information. So, next there are many benefits to TEFCA. For consumers, it provides an opportunity to look at and share records across providers, for instance, rather than via each provider portal. Providers and health systems have the ability to get a 360-degree view of patient care, which is crucial for care delivery, care coordination, management, and value-based care, and having a single on-ramp or a simplified on ramp to include public health reporting, frankly, creates efficiencies as well.

For state programs and public health, there's richer data creates better health metrics and the potential for more timely and complete reporting and efficiencies in program reporting management. Payers will be able to look beyond claim data and have a fuller picture of enrollee health to support care management, value-based care and other initiatives. Beyond that, there are significant system-wide efficiencies and synergies from having full participation in a nationwide exchange platform. And there's a public benefit to this. And having a government endorsed method for information sharing not only engenders trust, but it provides unifying framework for trusted exchange that can support a multitude of purposes. So, rather than having an approach that's geared just towards treatment, it's multipurpose, multi-use, multi-use case extensive over time and technology agnostic. The overall hope is that we'll simplify how information is exchanged and continue to evolve as the back bone for the U.S. If we go next to the value proposition for TEFCA, we have published these.

The fact sheets are now on the RCE website. We conducted interviews with more than 100 subject matter experts from 5 different stakeholder communities and wanted to understand the value proposition, the opportunity for nationwide exchange and a more universal interoperability from their particular perspective. And you can see here it's plans, government, public health, healthcare providers, health information networks and consumers importantly. How will TEFCA work? So, ONC designated a private sector organization, the Sequoia Project, to oversee and govern QHIN to QHIN exchange. We serve that role as the recognized coordinating entity. We were designated as such in 2019. Since then, we have been working with ONC to develop the agreement and implementation guide that networks who wish to be designated as TEFCA qualified would adopt. And if they're successful in demonstrating their ability to meet the expectations, they would be qualified health information networks or QHINs. So, we facilitate the process for verifying that those who apply function as a QHIN and meet the requirements and designate them as such.

By becoming a QHIN, QHINs agree to share information with other QHINs according to the Common Agreement. This is the agreement that the QHIN and the RCE sign. It puts forward the terms and conditions for exchanging information. And by extension, they also agree to comply with the implementation guide, which we call the QHIN technical framework. And that specifies the technical functions and technical requirements. Once QHINs are designated and live, we as the RCE oversee QHIN to QHIN exchange to assure ongoing compliance with the requirements. And then, there are certain expectations the QHINs themselves are expected to pass along to organizations or individuals who connect to that QHIN. These are called QHIN participants. And there could be others that connect to those organizations called





subparticipants. Examples of participants could be government agencies, HIEs, healthcare providers, health plans, public health.

Subparticipants could be providers or others who connect their HIEs, for instance. And then, importantly, individuals would also be able to connect either directly to a HIN or through an app or platform of their choice to access their information. Again, next, just to summarize our role, we're working to develop, update, and maintain the Common Agreement, working to revise and refine the QHIN technical framework, maintain that over time. It's really important for us to convene and get input through public stakeholder feedback meetings. We do those on a monthly basis and have done a lot of extensive outreach and will continue to do so. And then, to operationally identify, monitor, support the QHIN process and maintain for adjudicating non-compliance and governance around that. And we also have to find a way to make this effort sustainable. So, that's some background on our work as RCE and what we're really ramped up to do. I would like, at this point, to turn it over to Steve Gravely who is going to walk you through elements of the Common Agreement. Steve.

### **Steve Gravely**

Thank you, Mariann. I was trying to get off mute. Hello, everyone. Most of you I know. It's nice to be talking to you again. For those of you who I haven't had the privilege of meeting, I'm Steve Gravely, with Gravely Group, legal counsel to Sequoia. And I have the immense privilege of leading the team from a contract perspective in terms of the Common Agreement. We are going to walk through this pretty briskly because we want to be able to have a dialogue with you about your questions. My apologies if I'm moving fast. Next slide. We'd like to think of the Common Agreement as an organic tool. And there are many elements to that organic tool. There's the Common Agreement itself, which is a contract, but that's really just the tip of the iceberg. The Common Agreement, like many contracts, tries to clearly express rights and responsibilities of the parties to the Common Agreement. But then, there's a lot more to the relationship and to making all of this work than simply the legally binding contract.

There are these other extremely important elements that work with the Common Agreement itself. There are standard operating procedures that go into specific detail about a variety of important topics. Perhaps security of information, or how does an organization become a QHIN, or mechanics of the governing body, things like that. Then, there is the QHIN technical framework that Alan Swenson will talk about in a few minutes. There is the whole onboarding process from application through evaluation, vetting and then, ultimately, designation of the organization as a QHIN. And then, in the near future, which is really exciting to be able to say now, but in the near future, in the first quarter of '22, once this exchange framework is operational, there will be operating metrics that will be collected. And those are an important part of the elements because they will allow RCE and ONC to really evaluate what's happening, how is it happening, and identifying any issues that need intervention.

And then last but absolutely not least is the governing approach to this entire what I call an ecosystem. And the governance structure is codified in the Common Agreement and the SOP. But the governing approach really transcends that. And that's why it's an important element, because governance, in our view, effective governance is essential, I should say, in order to support the evolution and operation of the framework, provide order and stability and predictability, but not bog the network down. And that's a challenge sometimes in and of itself. So, that's why we list governing approach as an element of the TEFCA. Next slide, please. So I've just realized my camera wasn't





on and I apologize for that. You were spared looking at me for a few minutes. All right. Let's walk through these elements one by one.

The Common Agreement. Well, that will establish the legal infrastructure for the exchange of information among the participants, the QHINs, their participants, their subparticipants. That will all be codified in a legal document that every QHIN, qualified health information network, will sign with the RCE. Right now, that's Sequoia. But there will be an RCE and this will be a two-party agreement between each QHIN and the RCE. So, at a very simplistic level, the Common Agreement is a contract and that's really, really important because of all the legal significance that attends contracts in American common law and statutory law established over the last several hundred years. Now, some provisions of the Common Agreement are between the RCE and the QHIN. Other provisions of the Common Agreement, the QHIN is required to flow down to its participants and then, they are required to flow those down to their subparticipants.

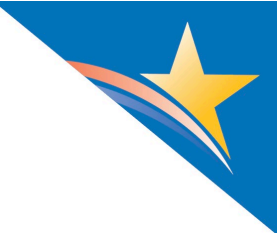
And we anticipate that we will very clearly label the required flow downs in the body of the document so that there's absolute transparency to everyone around what has to be flowed down by a QHIN to its participants and then, on to their subparticipants. The Common Agreement will incorporate by reference two other elements: The QHIN technical framework and the standard operating procedures. So, they become part of the body of the Common Agreement, although they are distinct elements themselves. We do that, obviously, to assure enforceability and to not have to create multiple repetitive documents to leverage what's in the Common Agreement to allow the RCE to enforce provisions in the technical framework and the SOPs. Not a unique model, a model with which I'm sure every one of you is familiar. As Mariann said and I certainly want to reiterate, this is an iterative process.

Micky indicated that this is something on which ONC has been working for years, something that the RCE and ONC have been working together on for over two years. And all along the way, we've emphasized the importance of feedback from all interested parties and trying to not just sit back and be passive but to be active and soliciting feedback. So, certainly today, we welcome feedback from the HITAC. Next slide, please. So, now what I'm going to do is dive into a few core concepts that are in the Common Agreement. We have neither the time, nor probably is there the need to show a table of contents and work through every single section. We would be here all day and I'm sure you guys would appreciate that, but that's not our mission this morning. Our mission instead is to focus on a few core concepts that we want to dialogue with the HITAC about. The first one is cooperation and non-discrimination.

Micky alluded to this, as did Mariann, in describing where are we today with our existing infrastructure that supports the exchange of health information. And so, the Common Agreement, I'm not going to comment on that because I'm sure you all have your own view and we've already discussed it earlier, the Common Agreement intends to clearly specify what is expected of a QHIN, its participants, and that participant's subparticipants in order to ensure that everyone is rowing in the same direction, which sounds simple, but we all know it isn't. We all know it doesn't always happen by accident. So, how do we do that? How do we take that goal and then translate it into a contract? We're proposing to do that by focusing on specific types of activity making it clear that there's an expectation that the QHIN and their participants and subparticipants will timely respond to inquiries.

This includes responding to queries for TEFCA information. In other words, the nugget of gold that





a query is seeking to get about me as a patient. Sure, it includes that, but it's much more than that. It includes inquiries about is there a problem on your end, or QHIN A says, "I'm experiencing the following; does anyone have any insight? Is it my problem or is there something going on?" And you can imagine an infinite number of variations on that example. Cooperation includes responding to those inquiries. Saying to QHINs these are important, these are your exchange partners, and these queries deserve priority. Yes, everyone's busy. Yes, everyone is short staffed. We all get that. But these must be given priority. Unfortunately, that doesn't happen all the time today. On the other side, there's an affirmative obligation to push out information if you're a QHIN or a participant or subparticipant about problems on your end and once you become aware of them.

So, let your peers know, "Hey, I'm having a problem." And again, that doesn't always happen today for a variety of reasons. The next part of cooperation is when there are issues, and there certainly will be issues, that QHINs and on down the line, I'm not going to repeat it every single time, that they're expected to support each other, to provide resources, to provide assistance, to provide information, to make time on the calendar, to support each other in working the problem and resolving the issues. And then, last but certainly not least, something has to be last on every list, but it's very important, an affirmative obligation to engage in information sharing with your peers about cybersecurity risks. And we could talk for hours just about this topic. But we all understand that that threat matrix continues to evolve. We understand that this information is desirable and sought after.

So, the ONC and the RCE envision a very robust cybersecurity information sharing framework that will help to reduce the threat that we all know is there. So, those are some expectations about cooperation. Let's now turn it around and look at non-discrimination. What we are going to say in the Common Agreement is very clearly that a QHIN and its participants and its subparticipants are going to be prohibited from limiting interoperability with any other QHIN participants, subparticipants, or with any individual in a discriminatory manner. And the agreement will go into some detail describing what that is. The essence here is that you're treating similarly situated organizations or individuals in a different way without a valid reason. And I know that sounds a little bit like a variation of the golden rule, but that's how we're approaching this idea of non-discrimination.

It's not that you won't set limits on certain types of activities, but they have to be done in a consistent, fair, equitable way that has to be a rational basis for them. They have to further add an acceptable purpose. And that's a concept that the Carequality framework has operated for many years and has been a guiding principle of the Carequality framework, which has served as a bit of a model for the Common Agreement. And these are foundational values for what we're doing here. Next slide. Next concept. Exchange purposes. Every network has to have a set of rules that explains what you can use the network for. That's what exchange purposes are in the Common Agreement. They go by different names in different networks. We call them exchange purposes. At this time, we plan to start with six, the six that are on the right-hand column of the slide. Treatment, payment, healthcare operations, public health, benefits determination, and what we're calling individual access services.

I'm going to unpack these in the next slide, but this is our starting point, and I want to emphasize starting point. The Common Agreement will, specifically, recognize the ability to add additional exchange purposes over time through the change management process that is addressed in the Common Agreement and standard operating procedure. And the expectation is that there will be other exchange purposes in the future. And we envision that process as both a bottom up and a







top-down process, meaning that the stakeholder community at large that is involved in exchange will have suggestions, ideas, requests about new exchange purposes. But ONC as well, being at the forefront of advancing interoperability, will also have ideas and suggestions for additional exchange purposes. And those are not mutually exclusive by any means. So, we're looking at this very holistically as a bottom up, top-down dynamic that will, at least I think ultimately, lead to traditional exchange purposes.

This last bullet is really important. QHINs will be required under the Common Agreement to support all exchange purposes. That is absolutely not the case today. And I'm not saying that in a critical or derogatory way at all. We simply know that there are many networks that are treatment only. There are many other networks that purport to support a number of exchange purposes but are de facto exchange only. The Common Agreement will require as a term of the contract that QHINs will support all exchange purposes. That's a real advancement and elevation however you want to describe it. A great example where ONC is using the Common Agreement to advance interoperability. Next slide. So let's unpack these exchange purposes really quickly. Treatment, payment and healthcare operations.

Those are generally going to match the HIPAA processing role definitions. I say generally, because, obviously, the HIPAA privacy rule applies to covered entities and their business associates. We're leveraging HIPAA to a large extent. But we're making it clear that the definitions and other provisions of the privacy rule and the security rule apply not only to covered entities and business associates, but also to every QHIN participant and subparticipant, whether they are a covered entity under HIPAA or business associate or not. So, we're adopting these definitions and requirements and then having them apply in most cases to everyone in the ecosystem. Public health exchange purpose, again, looks to HIPAA for the definition of public health authority, which as you know is extremely broad. It includes both governmental, federal, state, local, tribal, governmental instrumentalities, agencies, or even contractors acting under the authority of the government.

It's a very broad definition. And this exchange purpose includes requests for uses and disclosures of information by public health authorities. Benefits determination is similarly broad. It supports any government agency that is seeking information in order to make some type of determination as to whether a person qualifies for benefits. Social Security Administration is the go to example, but absolutely it doesn't end there. So, that's another very broad exchange purpose. The other thing that is a bit different with Common Agreement is that it is anticipating the proliferation of consumer facing applications. And Micky alluded to this. I think we all agree we'll continue to see it. These apps helping individuals obtain access to their information, use their information, decide how to disclose their information. And we're calling this individual access services. That's the exchange purpose that we're calling it.

And so, this exchange purpose will support individuals obtaining access through a consumer facing app or some other type of platform, we're trying to be as broad as we can there, to obtain their own information to the extent that that's permitted by applicable law from anyone in the network. So, that's a really exciting exchange purpose. Now, I'm going to unpack IAS in a minute. One wrinkle about that, there are some exceptions. Remember a moment ago, I said that QHINs, participants, and subparticipants had to support every exchange purpose. And that is a true statement. But for IAS, there are some exceptions and we'll unpack those in a couple slides. Next slide, please. All right. Let's talk about privacy. And to avoid confusion, I have a privacy slide and a security slide that talk about the entire ecosystem. But then, when we get to individual access services, you'll see





privacy and security slides that build on these two.

So I wanted to unpack that now. This is for everybody. We anticipate that most of the connected entities, maybe not QHINs, but certainly participants or subparticipants are likely going to be either covered entities or business associates of covered entities. And, therefore, they are already in compliance with the HIPAA privacy and security requirements. That's a working assumption. But we are not relying upon that. The Common Agreement then says that if you're a healthcare provider that is not subject to HIPAA because you're not engaged in standard transactions, and there certainly are some out there today then, you are expected to protect TEFCA information, TI, TEFCA information, that is individually identifiable the same way that a HIPAA covered entity would protect EPHI. So, in other words, we are not saying that you're subject to HIPAA. We don't have that authority. We're saying that as a matter of contract, you will treat TEFCA information the following way.

The following way is exactly the way HIPAA covered entities or business associates treat EPHI. That's a perfectly accepted legal mechanism. It's enforceable and that will be what non-HIPAA healthcare providers are expected to do. The other question is what about other non-HIPAA entities, organizations that aren't healthcare providers that aren't subject to HIPAA, IAS providers come to mind, of course, but there are others. How should they protect the privacy of TEFCA? Our plan is to, in most cases, continue to apply the privacy rule paradigm. IAS is a bit of a special case, which we'll talk about, but in most cases apply the privacy rule paradigm to these non-HIPAA entities. We expect to have a section of the Common Agreement that will be very granular, very specific based on the assumption that if you're a non-HIPAA entity, you may not be very familiar with the privacy rule.

So, saying that you're subject to the privacy rule might not be good enough. We probably need to tell you here are the provisions that you're subject to and here is where to find them. A little bit of bread crumb but probably not too much detail. Probably necessary detail. Next slide. So, how about security? Well, QHINs, and this is where we are intentionally differentiating between QHINs on the one hand and their participants and subparticipants on the other. QHINs will be held to a really high bar. A couple of elements of that bar, but certainly not all of them, is a requirement that every QHIN have third-party certification by an industry recognized cybersecurity framework. It should be high trust. It should be someone else. But it's a third-party certification that is recognized as an authority on this. In addition to that, QHINs must undergo annual security assessments. That goes beyond your certification.

For those of you who are certified, you know that, typically, high trust certification requires not annual assessments but biannual or triannual. We're layering on top a requirement for annual assessments. And there are some other requirements. They have to have a chief information security officer. They have to also do other types of activities in their reporting requirements. So, QHINs are being held to a high bar. There are also specific flow downs to participants and subparticipants, which establish as a minimum/floor that all participants and subparticipants must comply with the HIPAA security rule, whether you're a covered entity or business associate or not. So that is, again, a contractual standard where we are leveraging the security rule very intentionally. We also plan to have pretty strict security incident notifications involving QHIN to QHIN exchange. And again, it doesn't matter whether you're subject to the breach notification rule under HIPAA or not.





You will be subject contractually to these security incident notifications. If you think about the Common Agreement, it's an agreement between the RCE and the QHIN. So, it's a two-party agreement. But in that two-party agreement, we are imposing obligations on the QHIN to report to the RCE, also to report to their fellow QHINs with whom they don't have a contract but it's a term of the contract with the RCE that they report notifications to their fellow QHINs. And then, there are also flow down provisions to that QHIN's participants and subparticipants. We've really spent a lot of time thinking about this in an effort to try to avoid duplication of existing notification requirements and not to create conflicts between what someone already has to do and what we're asking them to do under the Common Agreement.

And then the RCE will stand up and support a cybersecurity council that is composed of representatives from the participating QHINs as well as the RCE CISO and other RCE representatives. And that council will focus exclusively on cybersecurity issues that affect the network. So, that's part of the ongoing infrastructure. Next slide, please. Now, I want to pivot to what can QHINs, participants, and subparticipants do with the interoperability. We framed this by looking at types of activity. Requests, uses, disclosures, and responses. So, requests will be transmitted by the QHIN's connectivity services that it maintains with its participants and subparticipants. And the QHIN is required to transmit that request in a manner that is consistent with the QTF that Alan will talk about in a moment. That's pretty standard, I think. Now, we are putting limits, though, on who can make certain types of requests.

For example, if you're going to transmit a request for treatment that request has to be made by someone who is authorized to engage in treatment. I couldn't initiate a query for treatment. So, that's a simplistic but accurate example of a more complicated idea that we are putting controls on how requests are initiated because they have to tie to the requester's underlying ability to support that request. This is something that's pretty commonly known today and seems to work more or less. Now, when we think about uses and disclosures, and those are the HIPAA framework terms, right, so use relates to the internal use of TEFCA information by a QHIN or a participant or subparticipant. Disclosure, obviously, is sharing that with someone else. That's how we're using those terms. The use and disclosure of TEFCA information by a QHIN, participant, or subparticipant will adhere to the Common Agreement privacy and security requirements as well as any privacy notices that either HIPAA requires, state law requires, federal law requires, tribal law requires.

So, those are cumulative, not mutually exclusive. So, QHINs, participants, and subparticipants are permitted to use TEFCA information. They're permitted to disclose TEFCA information. But they must do so in accordance with the Common Agreement and the privacy and security requirements that we just talked about as well as any other applicable law, specifically, requiring privacy notices but any other applicable law. So, then responses is a little bit more complex, I guess. The general rule is that a QHIN and/or its participants and subparticipants will be required to respond to a request for certain types of health information for any exchange purpose. What does that mean? Well, if providing the requested information would violate applicable law, that should be federal, state, tribal, local in some cases, and not just statutory but regulatory as well, if providing that information would cause a QHIN participant or subparticipant to violate applicable law then, they are not required to do that, of course.

In addition, there are six specific exceptions to this duty to respond if you will where a response is permitted but not contractually required. And those include a public health agency is permitted to respond to a request for TEFCA information, but it's not required to. An individual access services





provider, an app or a platform that supports individual consumer, as it's sometimes referred to, access for their information. If they receive a request, they're permitted to respond to that request, assuming they have the requisite authority from their individual customer whose information is being disclosed. They're permitted to respond but they are not required to. Let's go to the next slide. There are six specific exceptions to this broad duty to respond rule. And I've highlighted the two that we think are the most noteworthy.

Now, let's pivot again. I hope I'm not making your head spin and I'm also trying to be respectful of the time. We want to pivot now to how do you become a QHIN. So, the Common Agreement will articulate five specific criteria. At least that's our current thinking, five specific criteria that one must meet in order to be designated by the RCE as a QHIN. Then, there will be a standard operating procedure that will talk about the entire process from application to designation. And part of that will be the eligibility criteria unpacked. So, again, you're all familiar with this. A contract says you must do the following, one, two, three, more details in the attached. Sometimes the attached is an exhibit. Sometimes the attached is a terms of use. Sometimes the attached is a user manual. In our case, the attached would be standard operating procedures where we will unpack in great detail what these mean. And I'm going to walk through these real quickly.

Now, so a QHIN has to meet these criteria as a threshold matter in order to be designated. But then, it doesn't stop there. The QHIN has to report to the RCE on an ongoing basis about how it's meeting its obligations. And so, when we're looking at someone who wants to become a QHIN, the RCE has to evaluate is this organization capable of supporting the high expectations and legal requirements in the Common Agreement, the SOPs, and the QTF. And part of that has to do with what are they doing now. And part of that has to do with what is their track record of doing these things in the past. So, what we're thinking about doing is you have to demonstrate that you have the capability to support the exchange purposes. You also have to show that you have a track record over the past 12 months of having engaged in substantially similar activities so that the RCE can see, oh, yes, you can actually do this. I'm going to pause. I see Aaron has popped up on the screen. Hopefully, I haven't done anything bad.

**Aaron Miri**

I appreciate it. You've done a great job. It's a very complicated and multifaceted entity and set up and so forth. So, I really appreciate it. I do want to keep it to time and I know there are several slides left. Maybe we could hit the real high-level, 50,000-foot on each of them and come back after to make sure we stay to calendar. Will that work for you?

**Steve Gravely**

Absolutely, Aaron. Thank you. I'm sorry.

**Aaron Miri**

Go for it, Steve. No, no. It's quite all right.

**Steve Gravely**

I get a little carried away. Okay, next slide. So, these are the five criteria. These two, you must be a U.S. entity, that's a defined term. And you must be able to exchange required information. And that's the are you able to do it. Let's go to the next slide. This is the more complicated one. But this is where I was talking about where you have to demonstrate that you can do this, right? And we've picked the 12 calendar months as a marker. No magic in that. But then, we've also indicated that





the RCE can consider other evidence because we don't want to keep people out unfairly. So, we have the ability to designate someone on a provisional basis. Maybe they have been doing something for eight months or 9 months. So, that's what this very long paragraph says. Next slide. Then, the applicant has to show that they have the resources in place. Not just the technology, but also the personnel, the governance, the legal and other infrastructure necessary to support a high volume, high quality network.

And then, last but not least, they have the ability functionally and technically to comply with the QTF, which Alan is going to unpack. Next slide. Real quick, on insurance. This is something we're discussing real time with ONC and others. We are going to require some evidence that a QHIN have either insurance or sufficient reserves to cover the liability. Next slide. I'm going to defer this for Alan. Let's go to the next slide. IAS, well, we've already talked about that probably more than I should have. Let's just skip on. Again, I did mention there were some additional privacy and security requirements. If we have time, we can unpack that. Next slide. Fees, and I believe this is my last one. We at ONC are very committed to not erecting barriers to exchange. And, therefore, QHINs will not be able to charge fees to other QHINs to exchange information. Now, QHINs can charge their own customer fees. We are not trying to blow up an economic system. But they aren't able to charge other QHINs fees to exchange information. With that, I think that's it for me. Next slide.

Again, my apologies to the group and to Alan. I will now stand down.

**Aaron Miri**

All good. I appreciate that. All right. Let's see here. That's the last slide for the Common Agreement. It's time for Q&A, I believe. So, with that, HITAC members, I know we're a couple minutes over, but I appreciate Steve doing that expedited review at the very end. Hopefully, you folks read ahead and we can now open up for questions. I would encourage you to please use the hand raise function as we do for these things and we can get into it. All right. First up, I see Mr. John Kansky.

**John Kansky**

Thanks, Aaron. Hey, can Steve comment on what constrains the reuse of data accumulated or received through TEFCA transactions? What constrains QHINs, IAS providers, or participants in terms of reuse of TEFCA data? Thank you.

**Aaron Miri**

You may be muted, Steve.

**Steve Gravely**

Sorry, Aaron, I was. That would be applicable law, John. Whatever that entity is subject to. And then, in the case of IAS providers, they are going to have terms of use with their customers that probably restrict them as well. But the construct really is applicable law.

**John Kansky**

That is to say if they get data and it's legal for them to use the data for that purpose and they haven't agreed to constrain it otherwise in a contract, they can reuse the data?

**Steve Gravely**

Yeah, that would be accurate.





**John Kansky**

Thanks.

**Aaron Miri**

Thank you very much. Next in queue, Arien Malec.

**Arien Malec**

I want to jump in and remind people that in most cases, a QHIN is going to a BAA. There are, obviously, cases of non-HIPAA covered entities but your typical QHIN is going to also be a business associate covered and constrained by a BAA that obligates them to data use under the business associate agreement. And, again, I think that's the right balance of law that the QHIN operate on behalf of the participants that it connects. And I think we've gotten ourselves into trouble by trying to apply other participants' obligations on all of the participants in the network. And in this case, I think we're setting an appropriate balance. I also want to remind; I saw a number of comments go through the chat in the chat. I want to remind people that constraining behavior through contract law is what makes the world go round.

The cases where federal enforcement is required other than the usual remedies that are associated with contract law, the cases where there are federal agencies who directly apply enforcement such as OCR or FTC, are few and far between. And in almost all cases, it's contract law that makes the world go round. So, grounding legal agreements in contract law is a very appropriate thing to be doing. And then, the notion of a flow down term is a very common framework in health information exchange, in broad health information exchange networks. And almost every participant in the U.S. healthcare system is subject to a flow down term of some shape or form, whether it's for e-prescribing or clearinghouses or participation in a national network or HIE. And it seems to just work. I just want to commend the work in grounding, just taking advantage of all the constructs that we've worked out over the literal decades of doing this to put together a pretty quick pragmatic, contractual framework. Thank you.

**Aaron Miri**

Thank you. All right. Next in queue is Mr. Jim Jirjis.

**Jim Jirjis**

Thank you so much for the presentation. That was really informative and I appreciate you taking the time. I have three questions I put in the post but I'm going to ask one verbally here. We understand that the six exchange purposes that govern instances of health exchange, we kind of get that. How does that work, for example, if somebody, a participant or somebody, tries to make a request, how does the filler of the request, the QHIN or others, is there information requirements that validate the purpose of the request, or is that just sort of -- how is that enforced and executed upon?

**Steve Gravely**

Thanks, Jim. Great question, which I'm going to defer to Alan or Mariann because that type of thing is addressed in the QTF, I believe.

**Mariann Yeager**

I'll start and Alan maybe can weigh in. So, it's part of the assertions that accompany the message. And then, the agreement itself, I think, requires accurate assertions. And I don't know, Alan, do you





want to defer that to the QTF discussion or address it now?

**Alan Swenson**

We can certainly get into more of the details when we get into some of the QTF stuff. It is the contractual piece defining the exchange purposes, as Steve explained. And so, you're required to use the exchange purpose as appropriate to the request. And then, within the actual message itself, there is an assertion, a SAML assertion that indicates who the request is from, details of the request including that exchange purpose to allow the responding side to make an appropriate determination based on those details of what they will respond with.

**Jim Jirjis**

Those will be published, those detail requirements for each of the six regions, what data is required?

**Alan Swenson**

Yes, those are details as to definitions of each exchange purpose. Those are defined in the Common Agreement.

**Aaron Miri**

And for clarity, this is Aaron, I just want to make sure, those permissible-type activities, also I would take it there's going to be the other side of it, which is common impermissible, AKA data harvesting and things, correct? So, you'll be very clear and explicit about that.

**Mariann Yeager**

Yeah. The prohibited purposes are not laid out.

**Steve Gravely**

Go ahead, Mariann

**Mariann Yeager**

Go ahead. It's multifaceted. I'll let you take this one.

**Steve Gravely**

The simple answer is not really simple is that instead of listing what you can't use the interoperability for, we identify what you can use it for. And that's exchange purposes in conformance with the SOPs and the QTF. So, if it's not a permitted exchange purpose then, you cannot do it. And so, that's fairly typical. So, I'll stop there.

**Aaron Miri**

I appreciate that. I would give some credit to ONC here as they put out their FAQs recently about information blocking, which helped clear a lot of questions that are very common in the marketplace with some very plain English. I would encourage you to think about doing some similar. I agree it's not exhaustive and you can't quite clearly think of every permissible way somebody might do something we haven't thought of before. I understand that. But just some of the common plain English items may get us over the line in terms of adoption and any hesitations around that. Just food for thought. That was a good question. Okay. Next in queue, I see Sasha TerMaat.

**Sasha TerMaat**

Thanks. I was wondering, as we expand from some of the more commonly adapted purposes to all





of the proposed ones, what will be the plan for making sure that we have the supporting tools ready, like implementation guides, so that the roll out implementation of some of the purposes that might be less common across the industry can be efficient?

**Mariann Yeager**

This is Mariann. I think that the initial version of the QTF does not lay out the specifics around all of that. We are hearing from stakeholders that there would be an interest and value in unpacking that further. I'll defer to Alan, since that's really related to the QTF itself and the other exchange purposes, Alan.

**Alan Swenson**

Yeah, we'll definitely talk more about that in the QTF. In general, yes, the QTF itself is the implementation guide that defines the constraints for how to use any of the connectivity services for exchange. It does not necessarily get into specifics of differences from one exchange purpose to another. So, there may be additional work there as things are needed, if needed. But it is, as Steve explained, required that each of the exchange purposes are, essentially, equal in required response following the implementation guide conformance requirements of the QTF.

**Aaron Miri**

Okay. All right. So, the next in queue, I see Andy Truscott and John Kansky. Andy.

**Andrew Truscott**

Thank you so much. Thank you, team. It's been a very informative presentation. Thank you very much for the obvious level of effort even put into the thinking and for articulating it more succinctly what's a fairly complicated series of issues. I have got four points to make. Some of these are questions and couple are more statements. The first is I thought I just heard when we were talking about expressions around exemptions that this would be a SAML assertion as opposed to anything in [inaudible] [01:21:43] etc. Was that correct? If that was correct, have we considered a broader set of implementations to enable more [inaudible] [01:21:56] integration with existing HIEs and exchanges, etc.?

**Alan Swenson**

That is correct. We'll get into some of the further details in the QTF review. All of the exchange in the initial Version 1 are IHE profiles using SAML assertions. OAuth would come in as we move to FHIR in a future version.

**Andrew Truscott**

Okay. That would be interesting to hear the ONC feedback if we're constraining to only IHE profiles. That would be very interesting to hear more detail around that. Secondly, the white listing approach I personally believe that black listing as well would be pragmatic and sensible. I would provide more direct instruction and clarification around permissive uses. Thirdly, there needs to be some kind of implementation part here for existing exchanges. Not everybody uses IHE profiles to that particular point you just made. And that incremental approach, how are we going to support that? How are we going to, yeah, support is the word, both financially but also with, as Sasha was just saying, implementation guides, etc.? Better understanding around that would be very useful.

Certainly, some of the implications of the mandates, which you're defining here appear to, actually, fundamentally change some of the technical characteristics of some of the exchanges to, actually,







make them more processes of data. And understanding the intended and unintended consequences of that, I think, will be particularly useful. And lastly, I think there's a lot of lessons to learn both from previous activity here in the U.S. but also with global activity. And I think some of the constraints that we seem to be facing upon this in the mandates up front, we could learn from how that has promoted or prevented adoption elsewhere. Thanks very much again.

**Alan Swenson**

Yeah. This is Alan. The third point that you raised, we'll definitely get into in review of the QTF. I don't think we need to say anything further on that one. We will look at where the IHE profiles are, specifically, required and other forms of connectivity will be used down the chain. We'll get into that in the QTF review.

**Aaron Miri**

Wonderful. I like Andy's idea of learning from our global partners. That's an excellent suggestion. Next in queue, Mr. John Kansky.

**John Kansky**

Thanks, Aaron. I think this is the best place to make this comment and I want it to be clear that I think the RCE is doing a great job and that explanation was super helpful. This comment is, I guess, directed at the ONC. I wanted to draw some attention to something that I don't hear us talking a lot about going all the way back to 21<sup>st</sup> Century Cures and the instruction to avoid disruption of existing exchange. My perspective is that my organization and other HIEs nationally are expecting to adapt to this and find our place in the new ecosystem. However, I did want to share that early empirical feedback I'm getting from our customers or from the field is that TEFCA, my version, puts its thumb on the scale strongly in favor of EHR supported networks over agnostic health information exchanges. So, I would ask ONC to consider gathering some input from the field, specifically, to make sure that the roll out and roles of TEFCA are in compliance with that aspect of 21<sup>st</sup> Century Cures. Thanks.

**Aaron Miri**

Good point, John. I can tell you that on the provider side we absolutely do get a lot of interesting noise from the field that has conflicting signals. I think that's a very relevant and salient point to look at and get more data and evidence of the point of it. Hopefully, combined with the good work Sequoia Project is doing and others are doing, folks are better educated about what's required. And we can chalk it up to misinformation or miseducation on the roll out. We have got about four minutes left to break. Any other questions? Any hands? Any other comments folks want to ask? Mariann, maybe this one's for you. This is on the top of my mind. You alluded to it earlier. I think it's a wonderful job that Sequoia does. You've got information blocking boot camp that was really helpful and really widely acclaimed cross the industry. You mentioned something about a certification process here as well in other trainings.

Is there anything further you're able to speak towards in terms of general education either on the provider side or on the potential cooperative partner side?

**Mariann Yeager**

Do you mean around TEFCA, specifically, education?

**Aaron Miri**





Yes, ma'am.

**Mariann Yeager**

Yes. So, we have stakeholder engagement and education strategy that we're working on in preparation for the roll out. And that would include public sessions, of course, and then targeted by the stakeholder groups. Of particular note is the importance of having clarity for consumers in terms of what this means for them and what this enables them to do in terms of their information. So we, as part of our planned activities, develop a strategy, again, with ONC. So, we will be doing a lot of education. I anticipate there will probably be some technical assistance we'll have to provide, particularly for networks that want to go through the onboarding process.

There will be probably a rigorous vetting of the applicants themselves in terms of making sure that they have the characteristics and can meet the criteria particularly around governance, which is really important, and that they have the capability to support that and then, possibly likely technical testing. But yes, stakeholder education on this is going to be key for success and is really beyond having QHINs on board, but that there's interest in participating in this method of exchange for sure.

**Aaron Miri**

Wonderful. Wonderful. I like the fact that patient education, I'm sure, we have some phenomenal patient advocates on the HITAC. I'm sure that made them perk up and listen in closely. That's really good focus on making sure the consumer is educated on how to access your information is important. So, that's good. HITAC, I think we are at time for break. Mariann and Steve, I want to applaud both of you. That was a lot of information to get through in little over an hour. Thank you for doing that. We definitely look forward to the second half of the presentation here. So, HITAC members, you have until 11:35 Eastern time, a little bit over five minutes, maybe five minutes straight up now. Go stretch, grab a water, and we'll see you back in five minutes.

**[Break]**

**Operator**

All lines are now bridged.

**Mike Berry**

Thank you very much and welcome back from our very short break to the October HITAC meeting. And I will turn it over right away to Aaron and Denise to kick us off for the second portion of the RCE presentation today.

**Denise Webb**

All right. So, we are going to launch into the second half of the presentation from the RCE and they are going to cover the QHIN technical framework and I think I'm turning over the mic to Alan, I believe. Take it away, Alan.

**Aaron Miri**

Alan, you may be on mute if you were talking.

**Alan Swenson**

There we go. After a year and a half of this, you think we could figure out how to not double mute everything. Hopefully you can hear me now.





**Aaron Miri**

Yes we can, thank you.

**Alan Swenson**

Perfect, thank you. Yeah, thanks, everybody. We are going to jump into the QHIN technical framework, the QTF. I think most acronyms we use have been defined at this point but I'll try to define any as they come up, at least the first time. I know we like to use a lot of acronyms, QTF being one of my favorite kinds of acronyms. It's an acronym embedded into another acronym. To know what QTF means, you have to know what QHIN means. QHIN are the qualified health information networks. It's important for the name here, again, we'll get into some further details. But this is the QHIN technical framework. If we jump to the next slide, we'll look at some of what's included in here. This is really getting back to one of the earlier questions. This is the implementation guide. For those who are familiar with Carequality's query-based documentation information guide, this will feel very similar to you with some additional pieces as we get into some of the additional forms of exchange this also includes.

But this details the technical specifications and other requirements, specifically, for QHINs to accomplish exchange. So, again, that's important getting back to some of the earlier questions about IHE profiles and where things apply, who things apply to, etc. This really is about QHINs and what QHINs are required to do. There are a few technical requirements that do flow down to participants and subparticipants, such as some of the auditing requirements and handling of patient demographics and returned data and things like that. But for the most part, the QHIN technical framework defines and is specifically limited to defining requirements to the QHINs. So, let's jump to the next slide here and some of what is included in that. So, the QHIN technical framework, the goal is really to build from current capabilities that exist in the industry today. Starting with known standards that are widely used and then, looking toward the future of additional approaches.

That gets into, again, one of the previous questions around current use of IHE profiles, some of the things we'll talk about in the next few slides coming into the future with FHIR-based exchange. But we're starting with standards widely used in networks and frameworks today, specifically, for there on the left, patient discovery, document query and message delivery are the main flows that we'll be talking about here. There are a number of functions and technology that are outlined in each of the bullets here. If you had a chance to review the QTF, it's a quick, exciting read. If you haven't read it yet, I definitely recommend you go take a look at it. I know many of you did submit feedback so thank you for having taken a look at that already. Each of the bullets here lines up with sections throughout the QTF. Each of these having specific constraints and conformance statements throughout them defining how all of these are used.

Certificates and will handling of mutual TLS, communication between servers for health education, etc. Authorization and exchange purposes gets back to some of the definitions of those exchange purposes are contained in the Common Agreement itself. But the QTF then, puts requirements around how those are asserted. Again, that's looking at the SAML token that's in the actual IHE profile message. There are a few pieces here that I do want to, specifically, spend a minute talking about. We didn't get into a whole lot of the discussion previously with directory services. The directory services has really two pieces here. There is the contractual piece and then, there are some of the technical requirements, the technical pieces.





The contractual piece that we largely skipped over in discussion of the Common Agreement really just gets into the requirements for handling of the directory service, what you're allowed to do with the information that comes from the directory, prohibiting it being used for marketing purposes, with some exceptions. And so, there are some details around confidentiality of information that is contained within the RCE directory service. That directory, ultimately, is on the technical side. What we are talking about here is a FHIR R4 organization and endpoint directory. Again, for those familiar with the Carequality framework today, this will feel very familiar to what you already know and use there.

This will define the relationship between QHINs, their participants, their subparticipants, sub-subparticipants, all the way down the chain, including connectivity endpoint information, details about organizations that are participating, and the OIDs, home community IDs, etc., so a request can be both targeted to a specific organization where information needs to be from and be able to chain that up to who the QHIN is, as well as being able to audit who a request, specifically, came from when you are responding to a request from someone else. So, there would be multiple ways to initiate a query. Again, we'll get into that a little bit here in the actual flow in a couple of slides. But the directory allows for both targeting to, potentially, a QHIN, to multiple QHINs, or even to participants and subparticipants within a QHIN based on the structure of those QHINs and how that is defined and chained together within the directory.

Patient identity resolution is a topic that also has some requirements in the QTF. I know that is a topic of discussion that has been had here in the HITAC previously. There are many national discussions going on as well around patient identity resolution, demographics-based matching. There are requirements around demographic information that must be sent when sending a request in order to ensure that the responding side has the appropriate ability to make a patient match based on the demographic information that is included in the request that comes across to them. We do not today define a baseline for patient matching algorithms. There is not an industry standard for that today although there are a number of efforts going on on that front including information matching, demographics based matching workgroup through Carequality that is ongoing currently looking for recommendations.

I know this is a topic that's come up in many past webinars and I believe is something we likely would be looking at future improvements, coordination, work with the community on how to improve some of the demographics-based patient matching. Again, there are some specific constraints around information that must be sent in order to ensure the best matching possible. But really, the matching is then left to the responding organization and their patient matching algorithms to make an appropriate determination if they know the patient that the information is being requested for. Again, I mentioned auditing does have some flow down, participants and subparticipants some requirements and the flow down as well for auditing. Let's move to the next slide here. Again, I mentioned there are multiple pieces to the exchange here. Really, it's broken down into two exchange modalities.

Those exchange modalities being query and message delivery. Those are sometimes referred to as push and pull in the industry. They often are used complementary to each other. Query being the ability to ask for information. I'm seeing the patient for the first time and I need to go get information from wherever it is. Or the patient was recently discharged from the hospital. I need to get additional discharge information from the hospital. I can send a query and ask for specific information to be returned. Message delivery is a proactive push of information. I am sending a





referral or discharging the patient from the hospital and need to send discharge information, sending an electronic case report for public health, etc., where I am proactively sending information that I know is going to be needed rather than waiting for the other side to come ask for it. The two are, again, widely used in the industry together today.

And so, it makes a lot of sense to include both of them together as the initial phase of TEFCA-based exchange. Let's jump to the next slide. This gets into a bit of the diagram of the exchange and also shows in the middle here some of the actual exchange profiles that we are requiring. Now, the important point here, again, is that that middle column that shows IHE, XCPD, XCA query, XCA retrieve and then, XCDR for the four steps of exchange or the four flows or pieces of the exchange, those are only required QHIN to QHIN. So, what the QTF defines is the method that QHINs communicate between each other to ensure that we have consistency from one QHIN to another, and that the QHINs are able to successfully communicate. For the technical connectivity steps, the QTF does not define how a QHIN must communicate with its participants or participants with their subparticipants, etc., on down the chain.

So, a participant who is connected to their QHIN could be leveraging really any other method of connectivity. It could be an XDF connection. It could be proprietary APIs. It could even be FHIR APIs. It could be any other number of standards that could be used. So, that goes back to one of the previous questions around just what is already supported and other methods of exchange. The IHE profiles that are required here are QHIN to QHIN. Anything else could really be used QHINs down the line. I expect that will probably be a point of differentiation between QHINs. It's very likely there will be some QHINs that say we are going to make this easy and require that our participants send messages to us with XCPD, XCA and XCDR so that we don't have to translate anything. We just pass the message through. There will, certainly, be other QHINs who will expect to be connecting the types of participants who don't support those standards today. And they may have a set of proprietary APIs or may use other industry standards.

If this were an HIE, for example, that's using other industry standards already, they can continue to use whatever other method down to their participant and then, the QHIN would be responsible for handling the translation from whatever method of connectivity their participants got the message up to the QHIN to the appropriate XCPD, XCA or XCDR message when sending it across to the other QHIN. So, the way that the flows work, I think, most are probably familiar with both of these flows at least to some extent, but starting with the query, the query is a three-step process. So, it starts on the left side of the diagram here with the query source requesting information from someone who exists in the directory. That message iterates up through any number of hops. Subparticipants to participants up to QHIN, again, using any method of connectivity as allowed by each hop along the chain gets up to the QHIN.

And the QHIN would convert that initial message, this is a patient discovery, to an XCPD. So, this is requesting do you know this patient based on the provided demographics. That query could be sent as a targeted query. If the query source knows, specifically, who they need information from that could be targeted in the directory to a specific organization to send the request to. If this is an Emergency Room visit and don't know where the patient has information, a PCP seeing a patient for the first time and wants to gather anything that's available outside that could be more of a broad query where the QHIN would send the query on to all other QHINs and ask each QHIN if they know the patient. So, both of those methods of targeting or more broadcast type query would both be allowed, the QHIN leveraging information in the directory to determine the appropriate route to send





those. The receiving QHIN, at this point, with the patient discovery query, is going to determine if they know who the patient is based on a few potential options.

These are detailed in the QTF for those who have taken a look. The QHIN, I would expect that many will have either a record locator service or master patient index at the QHIN level to be able to determine if and which of their participants or subparticipants know the patient because the QHIN already knows that. It would also be allowed for the QHIN to federate that query down to their participants and down the chain if the QHIN doesn't know who the patients are, asking each participant or, potentially, subparticipant to make that determination on their own and return the response back up to the QHIN, who would then aggregate those responses to pass back to the initiating QHIN and down the chain back to the query source. Once a patient match has been found, the response to that query is either no, I don't know who this patient is or yes, I do, and here's the patient's identifier.

The follow-up query is the XCA query for this patient identifier that the query source knows what documents are available for this patient. The response to that comes back as here is a list of available documents. The subsequent query is XCA retrieve where, for one or more documents in the provided list, I would like to retrieve, download those specific documents. Those three steps usually are pretty back-to-back to back in many scenarios for the query flow. The message delivery flow is the final listed on the slide here. That is the XCDR standard. Again, the important piece is that XCDR is what's required QHIN to QHIN. This could be an XDFF push, an ITI41 connection. It could be even other forms of direct messaging or proprietary APIs, FHIR, etc., to get from the initiating source, the message source, up to their QHIN. The QHIN converts it to an IHE XCDR message to the responding QHIN who then, passes it down the chain to the ultimate responding source, the end destination.

In that one there is an acknowledgment that comes back. But otherwise, it is a one step process. Back to one of the questions from the previous discussion. In the query flow, it's left to the responding source to determine the appropriate response to each query. So, along this whole chain, information from the query source is sent along with the SAML token of the request so the responding source can determine from the directory who is this organization, who is the user or the system that initiated the query, what is the purpose for the request looking at the exchange purposes. And using that information, the responding source can make an appropriate determination of whether they are allowed to respond with information or if there are additional consents or authorization requirements needed and what information is appropriate to respond with.

In the case that additional information or consent information, specifically, is needed, there is the ability detailed in the QTF for the responding source or for the query source even to assert a consent that has been collected or that is needed. So, the query source could assert in their query that they do have an additional patient consent form on file that it's known as instance access consent policy. There are a number of methods that that can be sent. But, typically, that would be a document that the responding source could, actually, go get and hold in their system to have that patient consent on file in order to make an appropriate release. I think the only other piece I would call out on this slide just because of some of the previous questions is, again, just highlighting the QHINs are these super notes that are managing the connectivity in the middle.

Participants and subparticipants could really be any types of organizations that meet the definitions





to participate, including individuals themselves through individual access services. So, I think it was one of the previous questions about the role of HIEs and Mariann touched on this a little bit in the overview, but an HIE, there may be some HIEs where it's appropriate for them to become a QHIN and they may desire that functionality. Others could be a participant within a QHIN or even, potentially, a subparticipant. Really, at the participant and subparticipant level, the difference is just who they have a relationship with, whether that's directly with the QHIN or if they are below a participant of a QHIN.

For a provider organization, there will certainly be some provider organizations that are participants directly underneath the QHIN. There will be others that are subparticipants beneath a participant of a QHIN. It shouldn't really make much of a difference as far as any sort of technical requirements or what they have access to. That's more just contractual of how far down the chain it is to their connection back up to the QHIN. Let's jump to the next slide. I was looking to see if any additional questions have come in. I think this is the last major slide here. It's just the discussion on FHIR. Again, all of the current proposed exchanges are using IHE profiles. We acknowledge that FHIR is important, that organizations are supporting FHIR. There are requirements such as in certification requirements and others that are requiring move for support of FHIR. However, there are a number of concerns currently with how FHIR would work in this QHIN to QHIN exchange model.

Handling security with this multi-hop exchange, OAuth, in this multi-hop exchange, that's not really how it's designed. Routing of [inaudible] [01:56:43] transactions over multi-hop. There are certainly some things going on in the industry with FAST and others addressing some of the concerns. And so, the plan is that with the final version, released version, Q1 2022 of the QTF, we will also be releasing a FHIR roadmap showing the plan for getting to the inclusion of FHIR-based exchange in this framework. We are definitely looking for feedback on that from all of you. We've received some great feedback already in some of the QTF comments and feedback that we received and expect that there will probably be additional work collecting feedback and working with the industry as we plan out how to eventually get to the inclusion of FHIR within the ecosystem. Next slide, please. I believe that is it. And Mariann, I think we're back over to you.

### **Mariann Yeager**

Thank you very much. I think, at this point, we wanted to highlight how we are collecting feedback. If you go to the next slide, I'll cover that in a little bit more detail. We have a webinar series for the sessions that have already taken place. You'll find the materials and the recordings posted. The next one is taking place tomorrow where we are going to go through a deep dive in the QHIN designation and eligibility criteria. This is really important and we really want to make sure that stakeholders both understand it and then, provide input. We will be collecting input on our website until October 21. You can see there's a form there. It's a lot easier for us if people use the form to submit the comments. But we will collect them through our email as well if that's preferred. It's helpful for us because it puts it in a structured format.

All feedback that is submitted to us will be publicly available. So, just make sure there's not confidential information included in that. I know that some folks had asked if they could submit feedback after October 21. We will continuously collect feedback. I think we've said numerous times, these are living documents. We are going to learn and they're going to morph. We really need to get this initial version out there so we can get this program launched and get things started so we can get the governance process structured and, of course, all of the other opportunities for input. If you're not able to provide feedback before October 21, don't worry. Still submit it. We still





process and assimilate everything. I think with that, we're opening it up for further comments and discussions.

**Denise Webb**

All right. So, we do have some questions. I know there were a few questions in the chat. We'll start with Arien though. He has his hand up. And thank you very much, Mariann and Alan.

**Arien Malec**

Hey, thanks to all the presenters, Mariann, Alan, and Steven. One question and then, I'll make an editorial comment on SOAP versus FHIR to lead us off. This has been an ongoing healthcare industry island issue where many of the standards we use for information exchange are from a technology perspective and just look at what is standard in technology are a little bit off in a Legacy island. It's down to things like what programming language can I use or can I use .NET Core as opposed to something that has simplified operations in a cloud environment versus having to use the full Legacy .NET stack. And it's because the SOAP specs and the U.S. Star specs are used in environments in industry that are Legacy environments. So, you pull them out when you need them but they are not generally batteries included with the programming languages of our choosing.

So, my plea would be to quickly work through the technology issues related to using OAuth transactions in multi-hop environments. There's nothing inherent in REST technology or inherent in OAuth or JWTs or anything like that that makes them inapplicable to multi-hops. So, it's implausible that that's a blocking issue. It is possible we need some work and we need to put together some profiles and do some testing. So, I completely acknowledge that. But I just would encourage participants to put a more aggressive timeline for healthcare to join the rest of technology. That's the editorial comment. So, the question is I'm a little lost on the record locator service flow. When the receiving QHIN does not have the ability to respond with a record locator and multi-tasks in their network, whose responsibility is it to assemble the resulting information?

I was good with you in the description all the way to the end where it seemed like the requesting QHIN had the obligation to assemble all the information back into a combined query response. My perspective is that it really should be the receiving QHIN's obligation to solve for its local deployment model, figure out how to query all its subparticipants and then, respond back with a singular query response that's inclusive of all of its member organizations. I wonder if you could address that.

**Alan Swenson**

Yeah, absolutely. That's a great question. The answer is it depends on the flow and who is being queried. So, the initiating QHIN, if they're only sending a query to one other QHIN that one other QHIN, again, depending how targeted the query is, may be responding back with a patient identifier for one of its participants or subparticipants, in which case no aggregation of response is even needed. It just passes straight back through. If the responding QHIN is doing the look up of all of its participants, subparticipants, and finds multiple of its own participants and subparticipants who know the patient then, the responding QHIN would need to aggregate all of those into a single response back to the initiating QHIN.

**Arien Malec**

Perfect thank you.







**Alan Swenson**

In that case it would still be a single response. Now, however, if the initiating QHIN is from a single query of its participant querying multiple QHINs and multiple outside QHINs know the patient then, the initiating QHIN is receiving multiple responses that it would aggregate back into a single response down to its participants.

**Arien Malec**

Thank you. That makes perfect sense. Thank you for that clarification.

**Denise Webb**

Thank you, Arien. Jim, I know you had a question in the chat. Did you want to ask your question?

**Jim Jirjis**

Yeah. I understand that information carried in that message includes reason, one of the six covered reasons, and other information about the specific requests. That will all be spelled out? Is that correct? And if we're a recipient, let's say, and there's a requester that works through the QHINs, is it us just taking it on faith that they're good actors and that somebody claiming to have an operations or treatment reason actually does? I mean, how is it enforced if there are bad actors who are connecting and requesting information claiming to be one of the six approved uses, but we, the recipients, have no way of actually vetting that?

**Alan Swenson**

Yeah, I think there are a couple of pieces to that question, and Steve or Mariann may want to jump in on that as well as far as some of the enforcement. The first part of the question is yes, it's largely is trust. These are contractual terms, as Steve explained previously. There are specific requirements from the Common Agreement that are clearly called out as being flow down terms to participants and subparticipants, including the appropriate use of exchange purposes. When a query comes through, the responding side is able to trust because it has agreed to the same terms as everyone else that this is a legitimate querying organization and the purpose being asserted is legitimate for the request. They can then use that information to make a determination of response, again, trusting the outside source of the request without necessarily otherwise having any relationship, work with, or knowing anything about the source of the request.

As far as non-compliance or issues, there is a governing body that would be overseeing some of that. There is a dispute resolution process that is defined for handling issues that do arise. But it is largely based on trust in the shared Common Agreement and the terms of flow down.

**Jim Jirjis**

Is that something that will there be fines or termination or legal action if there is someone found to be in violation?

**Mariann Yeager**

This is Mariann. The process would be facilitated through a dispute resolution process and there would be a panel that would hear, oversee, and address the matter. Then, the repercussions, if it's not resolved is suspension or termination. Steve, anything else you want to add in terms of enforcement?

**Steve Gravely**





No, that's it.

**Jim Jirjis**

Obviously, if there was misuse of it, the OIG might be involved, I'm guessing. I just have one other quick question. And that is we heard in the news, for example, the Health Gorilla is now announcing they're connecting to eHealth exchange. I'm curious, with the networks if these third-party app developers with FHIR, RESTful APIs and OAuth, too, will they be able to connect to QHINs? And if so, am I reading by your deck that you're still trying to figure out the OAuth Q piece in the multiple hop situation?

**Mariann Yeager**

I was going to address the business side first and then, if you want to address the OAuth, or do you want to address about OAuth first? O was just going to mention the other part of it.

**Alan Swenson**

I was going to say the OAuth piece, again, would primarily come in with an eventual move to or addition of FHIR-based exchange. If an individual participant of a QHIN is using FHIR-based exchange for their connectivity to the QHIN that would be perfectly acceptable in this initial version as long as the QHIN is able to handle that incoming information and translate it into the appropriate IHE profile with the required SAML information.

**Jim Jirjis**

My understanding of OAuth 2 and tell me if I'm being remedial here, is that there's an authentication with the application but then, there is also an authentication with the source, right? How does that work when a third-party app may be trying to get information on behalf of a patient from an HCA or Vanderbilt? They really aren't able to authenticated. Or will the exchange facilitate that authentication to the source system?

**Alan Swenson**

There would not be an authentication all the way to the source system today. Again, that's the piece that would require the multi-hop of the OAuth flow through the QHINs and is one of the considerations that we need to determine how to appropriately handle with the FHIR roadmap. The initial phase would require the sending of the SAML assertion in an IHE profile. It would not be using an OAuth authentication flow in the initial phase. That certainly could be used within a QHIN, but you wouldn't be able to authenticate all the way to the participant of another QHIN today.

**Jim Jirjis**

So, if Health Gorilla, for example, had FHIR-based capabilities and was wanting to connect through a QHIN, in fact, they would be able to do so without the patient having to do the step of OAuth 2 in the initial iteration.

**Alan Swenson**

Yeah. So, an organization like Health Gorilla or others that use FHIR as the method to connect to their gateway, they could continue to use whatever method they want, whether they were to become a QHIN themselves or to connect to another QHIN as a participant. And they would just need to handle appropriate translation, which, again, many of these networks already do today when they're exchanging through Carequality or Health Exchange, Common Well, etc., handling whatever method of connectivity comes from their customers and translating it to the appropriate





standard for the network they're exchanging across.

**Jim Jirjis**

Thank you.

**Denise Webb**

All right. I don't see any other hands up from committee members. Are there other questions? If there aren't any other questions on the QHIN technical framework, how about any questions, in general, about the entire presentation from Mariann, Steven and Alan?

**Aaron Miri**

While the HITAC members are considering that, I want to, again, give major credit to Mariann and team and larger team for their great work. This is not easy stuff. But wow! Great job!

**Denise Webb**

It doesn't look like we have any other questions. So, I might ask ONC if we're able to go to public comment early. And while we're looking at that, are there any final words that you all have, Mariann, Steve and Alan, that you want to share with the committee?

**Mariann Yeager**

Certainly. I'll just start and say thank you all so much for your kind words of support and for the very thoughtful questions and comments. We just really welcome the opportunity to hear from you and certainly open to any other feedback.

**Denise Webb**

Well, thank you. And we appreciate all the work that you have done and the great stakeholder engagement that has occurred over the several months now. It's been excellent. All right. Mike, can we go to public comment?

**Public Comment (02:13:22)**

**Mike Berry**

Yes, we can. Operator, can we open up the line for public comments?

**Operator**

Yes, if you would like to make a comment, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press star 2 if you would like to remove your line from the queue. And for participants using speaker equipment it may be necessary to pick up the handset before pressing the star keys. One moment while we poll for comments.

**Mike Berry**

And while we're waiting, I just want to remind everyone that our next HITAC meeting will be held on November 10. If anyone still needs today's presentation materials, they can be found on our website at healthIT.gov. Operator, do we have any public comments?

**Operator**

There are no comments at this time.





**Mike Berry**

All right. Thank you. Denise, Aaron?

**Denise Webb**

All right. Any other feedback from the committee? I'm sure everybody would love to have time back in their schedule.

**Aaron Miri**

It looks like Dr. Lane has a question.

**Steven Lane**

Yeah, I wasn't able to follow kind of all the chat that Dr. Wah was offering about another topic. I just didn't know if since we have a little time, maybe we could give Robert the floor so he could provide the update he was trying to provide there.

**Aaron Miri**

I apologize. I was moderating and not reading the chat.

**Steven Lane**

Exactly, right. I think a lot of us were focused on the presentation.

**Denise Webb**

Most of us were following the topic today, so we didn't see that.

**Aaron Miri**

Yeah. Let's clear the topic first. Let's make one more time. I would say, Denise, one more pass with the committee since we have Mariann and the team here to give the floor to our guests if they have anything. I don't see any other hands raised.

**Denise Webb**

Nothing on public comments.

**Aaron Miri**

Okay. No comments, all right.

**Robert Wah**

This is Robert. I don't know if you want to use this time. I don't mean to jump in, but that's fine.

**Aaron Miri**

That's fine. If you would keep it quick and brief, I would appreciate that. Let's get this going.

**Robert Wah**

Absolutely. And I appreciate the opportunity and, Steve, thanks for highlighting this. Just to give HITAC an update on what's happening with smart health cards, I think it is pertinent to our discussions about data interoperability and how we can move health data more efficiently. I've talked about this many times in my role as chair of the commons project and also as a member of the vaccine credential initiative, VCI. Almost 150 million citizens now have access to getting a smart health card to demonstrate and contain their vaccine status. It's now many states are allowing





access to their state IASs with this. Health systems are using their EHR platform like Cerner and **[inaudible] [02:16:53]** health to create an issue of smart health cards and all major pharmacies are as well. I just wanted to update the group on that and also alert them to an event we are going to be hosting on October 28.

We're calling it the global forum. We already have Secretary Leavitt and Andy Slavitt lined up as speakers for that. It will be 10:00 a.m. to noon Eastern time on October 28. The link for that registration will be live tomorrow on VCI.org. I thought it was good for the committee to know about this. I talked about the fact that beyond the vaccination use case, smart health cards are secure digital envelopes that healthcare information can be put in that is privacy protecting, individually controlled, and non-tamperable. We could think about other use cases besides the vaccination considerable. That I think is pretty exciting for the use of health card. But the entire ecosystem has been built. We've informed issuers to issue them. The commons project created a verifier app that's free in the app store so you can scan a QR code that comes out of a smart health card. We have also created the common trust network, which is a registry of trusted issuers because without a registry of trusted issuers, obviously, the whole system doesn't work. We've tried to create the entire ecosystem to make these smart health cards work in the current environment.

And as we see more mandates for vaccination status to be demonstrated, whether going into a bar or employment, back to work, we think all of these are going to drive demand for a non-tamperable privacy protecting, individually controlled way to demonstrate your vaccine status. That's a summary quickly as fast as I can do it, I think. But thanks for the opportunity.

**Aaron Miri**

Wonderful, Robert. Thank you. I appreciate it, Dr. Wah. Okay. I think that is it. We did give folks also a chance if they had any more questions for Mariann and the team. I don't see that. Denise, I guess if everybody is in agreement, should we say our final parting words?

**Final Remarks (02:19:08)**

**Denise Webb**

Yes. Thank you, again, to our presenters from the RCE. We really appreciate your time and excellent presentations. And now, we all have a lot of things to think about and give you potential feedback through your public feedback forums. So, thank you so much and I wish our entire committee and our ONC team a good rest of their day.

**Aaron Miri**

Absolutely. And so I echo that. Thank you, again, to Mariann, to Dr. Tripathi, and the whole ONC team for great work. I would say from looking in from the provider lens, TEFCA cannot come soon enough so whenever that materializes. But with great respect and kudos, echoing what John Kansky said and others that we have a phenomenal existing HIE infrastructure in the country. Seeing that work together symbiotically and work together with the TEFCA construct will be critical. And I look forward to seeing that and really making patient information flow. So, with that, have a great afternoon. Be safe, please, and take care.

**Adjourn (02:20:28)**

