Trusted Exchange Framework Task Force

Transcript February 20, 2018 Virtual Meeting

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

Hello, and welcome, everyone. Good morning or good afternoon, depending on where you are located. We would like to welcome you to the Trusted Exchange Framework Task Force of the Health Information Technology Advisory Committee. Today's meeting will be led by our co-chairs, Arien Malec and Denise Webb. I will start the meeting with an official roll call. Arien Malec?

<u>Arien Malec – Change Healthcare – Co-Chair</u> I'm here.

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

Denise Webb?

Denise Webb – Marshfield Clinic Health System – Co-Chair Here.

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

Carolyn Peterson. Carolyn? We may have to circle back. Aaron Miri? John Kansky?

John Kansky – Indiana Health Information Exchange - HITAC Committee Member I am here.

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

Sheryl Turney?

Sheryl Turney – Anthem Blue Cross Blue Shield - HITAC Committee Member

Here.

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

Sasha TerMaat?

<u> Sasha TerMaat – Epic - HITAC Committee Member</u>

Hello.

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

Steve Ready? Steve Ready? Cynthia Fisher? Anil Jain? Kate Goodrich? David McCallie?

David McCallie – Cerner – Public Member

Here.

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

Thank you. Mark Savage? Mark? Noam Arzt?

Noam Arzt – HLN Consulting – Public Member

I'm here. Good morning.

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

Hello. And, Grace Terrell?

Grace Terrell – Envision Genomics, Inc. – Public Member

Here.

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

Thank you. Just a reminder to everyone, we will do a brief introduction of all of the task force members shortly. Since this is a virtual meeting, if you would like to ask a question or make a comment, in the upper panel near the left center, you can ask to raise your hand using the

hand raise icon, and one of the chairs or myself will call on you for comment. With that, I will turn it over to Arien Malec and Denise Webb.

Arien Malec – Change Healthcare – Co-Chair

Hey, everybody. Welcome to the Trusted Exchange Framework Task Force. This is one of those items where we are being tasked by the Health IT Advisory Committee to provide recommendations first through HITAC, and then ultimately through ONC on the Trusted Exchange Framework. As I think everybody recognizes, the Trusted Exchange Framework was called out by Congress in 21st Century Cures as a key component of ONC's mission to enable a broader information exchange and mitigate perceptions of information blocking from both provider organizations and Health IT vendors.

We have a pretty steep work plan ahead of us. Even though it is not Christmas, the mantra "office of no Christmas" still applies. We have two meetings a week through a marathon. We have one week where we'll have only one meeting, where we will draft up some recommendations, and then we will go back to two meetings a week in order to finalize the recommendations. This is an important activity because the work we are doing will lay the groundwork for ONC's adoption and implementation of the Trusted Exchange Framework for the nation. The work that we do right now is incredibly impactful on the future of the Health Information Exchange Ecosystem and the future of healthcare and health delivery in this country. I think we have got a very talented and engaged task force, and I look forward to the long and grueling hours we will put into doing this work. With that, I am going to turn it over to Denise for additional comments.

Denise Webb – Marshfield Clinic Health System – Co-Chair

Thank you, Arien. I want to thank all of you for contributing your time to work with Arien and I on this important work. I have been involved in this world of health information exchange for several years and I am looking forward to us making marked progress in the next years to come, with this work we're doing on the Trusted Exchange Framework. So, we have the opportunity to shape what comes out and make recommendations to the committee, and eventually to the ONC. I look forward to working with all of you. Again, I thank you for your time and your commitment to this.

Arien Malec – Change Healthcare – Co-Chair

Why don't we do a brief round of introductions? If you could, just state your name and the organization for which you work. You don't need lengthy comments or --

Unidentified Speaker

Arien, we've lost you.

Arien Malec – Change Healthcare – Co-Chair

There we go. Why don't we have Lauren walk us through a round of introductions? If you could, just state your name and the organization you represent. There is no need for lengthy directions or bios. We have a ton of work to do today and over the next short amount of

time. So, we would appreciate if you could keep the hellos to the minimum, just so we can recognize people's voices on the phone.

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

Why don't we start with Carolyn, and then we can follow the order that's on the screen?

Carolyn Peterson – Mayo Clinic Global Business Solutions - HITAC Committee Member

This is Carolyn Peterson. In my day job, I work for Mayo Clinic. But, I am actually on the committee as an independent patient advocate, being a 35-year cancer survivor.

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

I believe Aaron is absent. John?

John Kansky – Indiana Health Information Exchange - HITAC Committee Member

I am John Kansky with the Indiana Health Information Exchange.

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

Great. Sheryl?

Sheryl Turney – Anthem Blue Cross Blue Shield - HITAC Committee Member

Hi, I'm Sheryl Turney and I am with Anthem Blue Cross Blue Shield.

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

Thank you. Sasha?

Sasha TerMaat – Epic - HITAC Committee Member

Hello. This is Sasha TerMaat with Epic and the Electronic Health Records Association.

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

Great. And, just checking again, has Steve Ready joined? No? Okay. Has Cynthia Fisher joined? Not yet? Anil Jain? I see Anil is on Adobe, but maybe we will circle back. Kate Goodrich? David McCallie?

David McCallie – Cerner – Public Member

Hi. Good afternoon. David McCallie. I am the Senior Vice President at Cerner. I have been there for 25 years.

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

Thank you. Mark Savage?

Mark Savage – UC San Francisco – Public Member

Hi. I'm Mark Savage. I am at UC San Francisco's Center for Digital Health Innovation.

Arien Malec – Change Healthcare – Co-Chair

And some of you may know Mark for his much more famous wife. I want to point out that Mark has some connection to ONC through Lucia Savage, who used to be Chief Privacy Officer for ONC.

Mark Savage – UC San Francisco – Public Member

Always glad to give a twofer.

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

And Noam Arzt?

Noam Arzt – HLN Consulting – Public Member

Hi. I'm Noam Arzt and I'm the president of HLN Consulting.

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

Okay. And Grace Terrell.

Grace Terrell – Envision Genomics, Inc. – Public Member

Hi. It's Grace Terrell. I am the CEO of Envision Genomics, which is a precision medicine company, as well as a practicing general internist at part of the Wake Forest Baptist Health System.

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

Great. I will turn this over to Denise or Arien.

Arien Malec – Change Healthcare – Co-Chair

Again, I just welcome, everybody. Thanks for your participation. Thanks for your time. We're going to be asking a lot of you over the next month. Let's go to the agenda. Let's go to the charge. So, our goal as a task force is to provide comment on the draft Trusted Exchange Framework that ONC has put out. In particular, to make recommendations on Part A and Part B. And, in particular, for people who have read the Trusted Exchange Framework, Part B is the substantive. Part A sets up policy goals and Part B sets out much of the substantive mechanics. So, we are going to be doing a fair amount of work on Part B, in particular, commenting on the recommendations relative to the RCE. Also, particularly, commenting on the eligibility requirements for the RCE, recommendations for the eligibility requirements for the RCE, necommendations and disclosures, and recommendations relative to privacy and security.

If there are other topics that we want to get into, I think we can add those. We just need to make sure we are getting through these as well. Some of us have been through a bunch of this stuff before, so there is some danger to getting super detailed and just following the logic of the recommendations. I would encourage people, if they have higher order comments or higher order activities that we might want to put comment on come to an agreement on, we should add those to the agenda. But, again, it's subject to the notion that we need to get through these four key charges. I am going to pause and see if there are any questions relative to the charges that we are being asked to get through.

David McCallie – Cerner – Public Member

Arien, this is David. Go ahead.

Arien Malec – Change Healthcare – Co-Chair

I am surprised to hear you make some comments.

David McCallie – Cerner – Public Member

No, I have a question for you, actually. Are there parallel work groups or task forces addressing other aspects that we should be prepared to stay away from? I don't know what else is being done.

Arien Malec – Change Healthcare – Co-Chair

That is a great question. I was going to jump in and acknowledge that the time clock for public comment for the task has expired, or it is about to expire, and acknowledge that ONC has given this task force a longer time clock to make recommendations, acknowledging that the HITAC took some time to get up and running. Number two, I acknowledge that, in my experience, really good substantive recommendations from the task force have historically held a lot of weight with ONC because we can be, in some cases, more thoughtful and represent a wider range of interests than the broad set of public comment. But, I'd also say that ONC is free to disregard our comment. It is going to be looking at the balance of both

the public comment and our comment. Number three, there is a parallel task force to go over the USCDS. What do we call it these days?

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

The USCDI. The U.S. Core Data for Interoperability.

Arien Malec – Change Healthcare – Co-Chair

Thank you. So, there is a parallel task force to go over the USCDI. And, unless we think we have something really important to say, we should let that task force do their job relative to USCDI and confine our comments primarily to the task.

David McCallie – Cerner – Public Member

Thanks.

Arien Malec – Change Healthcare – Co-Chair

Other questions on the charge?

Cynthia Fisher – WaterRev, LLC – HITAC Committee Member

Arien?

Arien Malec – Change Healthcare – Co-Chair

Yeah?

Cynthia Fisher – WaterRev, LLC – HITAC Committee Member

This is Cynthia Fisher. The call center had me on mute. I didn't know if you knew I was on the call, so I just dialed back in.

<u>Arien Malec – Change Healthcare – Co-Chair</u> Oh, thank you.

Cynthia Fisher – WaterRev, LLC – HITAC Committee Member

I've been on the call. Thanks.

Denise Webb – Marshfield Clinic Health System – Co-Chair

So, Arien, I think Zoe is going to launch into her presentation.

Arien Malec – Change Healthcare – Co-Chair

Perfect.

Denise Webb – Marshfield Clinic Health System – Co-Chair

And then, we can let her get through her presentation and see if there are any questions from the task force members after that.

Arien Malec – Change Healthcare – Co-Chair

Absolutely.

Zoe Barber – Special Assistant, Principal Deputy National Coordinator for Health IT, ONC – U.S. Department of Health and Human Services, Office of the National Coordinator for Health IT

Thank you guys so much. I name is Zoe Barber and I am the ONC Staff Lead for the Trusted Exchange Framework Task Force. I am also Special Assistant to Principal Deputy National Coordinator Genevieve Morris and have been working closely with her over the past year to develop the draft document that we are going to be discussing today.

As Arien mentioned, we are here to develop an advanced recommendation on the Trusted Exchange Framework and we are going to be looking specifically at four main topic areas – the RCE, the qualified HINS, permitted uses and disclosures, and privacy and security. So, I am going to go into more detail on all of these four areas and talk a little bit about the areas in the document that align to these four topics.

What is the draft Trusted Exchange Framework? As many of you know, the language in 21st Century Cures tells us to either develop or support a draft Trusted Exchange Framework and a common agreement. What we have released, on January 5th, was just the Trusted Exchange Framework. That is what we will be providing our recommendations on. We then plan to work with an external entity, a recognized coordinating entity, which we will talk about in more detail in a few minutes. That will develop the final Trusted Exchange Framework, including the common agreement, which will be published in the Federal Register by the end of the year.

So, the draft Framework is divided into two sections. The first is Part A, which are the principles for Trusted Exchange. These are the overarching principles and guidelines, the rules of the road if you will, for engendering trust among health information networks nationally. They are divided into six principles that also align to the terms and conditions in Part B.

The first principle is standardization. This is referring to adhering to federally and industry recognized standards. And, in Part B, we have included a number of requirements about how qualified health information networks must connect to each other, including requirements around use of a connectivity broker and having the ability to exchange all of the data in the USCDI.

The second principle is around transparency. This refers to the need to conduct all exchange openly and transparently. Principle three is cooperation and nondiscrimination. This really refers to the fact that we do not want any organizations limiting the exchange of data to

another organization based on competitive purposes. We have included a number of provisions within Part B to address that.

The next principle is security and patient safety. We have a number of privacy and security provisions in Part B, and we are going to get into more detailed discussions about that over the course of the next month. The next principle is access. This refers to the ability for a patient and their caregiver to be able to access their own data regardless of where they went for care or even if they remember the doctor they saw. We have addressed this in a number of ways in Part B, including the inclusion of the individual acts of use case.

The last principle is data driven accountability. This is a goal that came out of 21st Century Cures, focusing around the ability for a provider to query for multiple patient records at one time in a single transaction to support population health level services.

The next section is Part B, and these are the minimum required terms and conditions for Trusted Exchange. These are the actual legal contractual language that we are going to be working to incorporate into the final common agreement we develop with the recognized coordinating entity. It is important to note that Part B is not a full end-to-end agreement, and it focuses on the variation, or the divergence, across some of the health information networks that are operating today that are currently inhibiting the flow of information.

ONC gathered input from a number of stakeholders and we heard from them where the gaps were in the market where we needed to set up some standards and rules for allowing data to be exchanged.

Briefly, I will go through the five goals of the Trusted Exchange Framework. Goal one is to build on and extend existing work done in the industry. We felt that there was a lot of work being done in the industry now around participation agreements and exchange. We did not want to trounce on the good work being done, but rather fill in the gaps where things have not been working. Again, we met with a number of stakeholders and what we tried to hit the right balance between not being too prescriptive, but still minimizing some of that variation that prohibits data from flowing today.

Goal two is to provide a single on-ramp to interoperability for all. Here, we're talking about allowing all types of providers to sign on to any health information network of their choice and receive all the information on a patient, regardless of where that patient went for care. We heard from multiple stakeholders that currently, they are forced to enter into multiple point-to-point agreements or connect to multiple point-to-point interfaces. That can be extremely costly and complex in order for them to access all of the data that needs to be exchanged. It is our goal to provide a way for everyone to connect to the exchange network of their choice, and then that becomes a gateway to all of the other networks that may have information pertinent to the care of that individual or population.

Goal three is to be scalable to support the entire nation. Having a system that can be used, regardless of what kind of healthcare stakeholder you are and where you are located. Goal four is to build a competitive marketplace, allowing all to compete on data services. This gets to the need to transition the marketplace from competing on the actual exchange of data and data hoarding to competing on the actual add services that can be performed on top of the data itself. We believe that, by easing the flow of information across the market, we will allow for some new innovative technologies to enter the marketplace, including maybe things like apps that will allow data to be accessed by patients, at their fingertips.

Finally, goal five is achieving long-term sustainability. We believe this framework, by laying out some of the base requirements for exchanging data and allowing for variation on a broader set of use cases, will promote long-term sustainability.

These are some of the stakeholders that can use the Trusted Exchange Framework. We try to structure the framework in a way that would be as inclusive as possible and allow all different types of healthcare stakeholders across the continuum to participate. Here, you'll see we included health information networks, health information exchanges, public health, payers, technology developers, providers, individuals – again, going back to that individual acts of use case – and federal agencies. We had a number of meetings with our federal partners to make sure that the terms and conditions of the tasks are working for them and enabling them to exchange data.

How will the Trusted Exchange Framework work? The first two things we are going to cover are the RECE and qualified HINs. This is just a brief snapshot of what the entire structure will look like. We are going to break down each of these components.

First, we are going to discuss the Recognized Coordinating Entity. This goes back to that language in the Cures Act, that ONC either develop or support a Trusted Exchange Framework. We feel that there are a number of existing entities today that have already been doing work similar to this, and they are well conditioned to act as this external entity to operationalize the framework and to act as the governance and enforcement body who can provide day-to-day oversight, management, and enforcement of the qualified HINs.

ONC plans to work collaboratively with the RCE, via a cooperative agreement, to develop that full common agreement that qualified HINs will have to adopt. And then, also, to continuously update the framework as needed with new technologies or new use cases, and stay involved in the implementation of the task throughout the cooperative agreement.

Here are some details on our plans for awarding this entity. We are planning on releasing this funding opportunity for a single – that is one single – entity to be the RCE. It will be a multiyear cooperative agreement. We are hoping to release this by April and then award an organization by August. Then, ideally, we will hit the ground running and develop and finalize that common agreement, so it can be published by the end of the year.

Our first discussion on Friday is going to center around the requirements for the RCE, specifically talking about some of the eligibility requirements, what their roles and responsibilities might be in relation to working with ONC, and also monitoring the qualified HINs. What kinds of metrics and milestones are we going to want to use to measure the success of the RCE and the qualified HINs?

Some things to think about in regard to the RCE is that, due to the tight turnaround on the timeline for the cooperative agreement, and also based on our goal for building off existing work done in the marketplace, we are looking for an organization that has existing experience building multi stakeholder collaborations. Maybe this is someone who is currently operating across state lines and has a nationwide footprint already. Possibly, it is an entity already has in place a multi-stakeholder board or legal counsel, such that, when they are awarded in August, they will be able to hit the ground running and get started writing the common agreement.

Next, we will talk about the Qualified Health Information Network. This is saying that the Trusted Exchange Framework aims to create a technical and governance infrastructure that

connects health information networks through a core of qualified health information networks.

Here, we have a definition of a health information network. This definition is in your materials and you can take a look at it on your own. These are the details for what a qualified health information network must be. Qualified health information networks are a subset of that larger population of health information networks. So, they have to meet these additional capabilities that need to be supported on top of what a health information network has to have. Our intention is to have a small number of qualified teams that are connecting directly to each other and can act as the gateway, or facilitators, of exchange for the rest of their exchange participants.

In order to be a qualified HIN, you have to meet all the requirements of the HINs. But, additionally, you should be able to locate and transmit PHI between multiple persons or entities electronically, have mechanisms in place to impose the minimum core obligations, and to audit participants' compliance. And then, you have to have in control a connectivity broker service. We will discuss the capabilities and requirements around this connectivity broker service more. Essentially, two HINs will be connecting to each other through this service, which will include the ability to send and receive broadcasts and directed queries through a master patient index and a record locator service. They will also be responsible for returning data to a requesting qualified HIN from across all of the QHIN's participants and end users in a single transaction.

The key here is that the qualified HIN must be able to support that broadcast query use case. We believe, in order to do that and promote scalability, you are going to need a small number of these qualified HIN connection points at the top. The next area of definition that we will look at is the participant neutral requirements. Currently, in the draft document, we talk about participant neutral, in that none of the exchanges of electronic health information, by or on behalf of the qualified HIN, can actually include the qualified HIN itself as one of the parties exchanging data.

Again, the overall goal is to keep the total number of qualified HINs small in order to best promote that broadcast query use case and to promote scalability. When we are looking at these two definitions, with the connectivity broker service in the participant neutral requirement, we are going to make sure that we are hitting the right chord and that these definitions are getting to our intended goal of having that small number of qualified HINs that can connect to each other and support broadcast queries.

I'm going to talk a little bit about the structure of a qualified health information network. Here, you can see how you have your qualified HIN at the top and they connect to other qualified HINs via their connectivity broker. And then, within the qualified HIN, they have their own participants and end users. Here's a good example of how this might work. Let's say we have a qualified HIN that is made up of a number of Health IT developers. So, that may include an EHR vendor, a population health or analytics vendor, and maybe even a consumer app or a patient portal app. In that case, some of the end users may be an individual provider or hospital, or even an individual consumer who may be using that patient portal app.

So, the way the exchange of data would work is that the end user -- in this example, the consumer -- would query their vendor for information and then that participant would query the qualified HIN. The qualified HIN would then send a broadcast query to all of the other qualified HINs, using their connectivity broker service and the standards that are enumerated

in the task. The qualified HINs would then query their own participants and their own end users, using whatever their agreed-upon internal standards are to see if they have the information.

The qualified HIN would then send a note back to the initiating qualified HIN saying we either do have your data or do not have your data. Then the initiating qualified HIN would say please send me the data. And then, the responding qualified HIN would have to consolidate all of the data from all of their participants and end users and send that response back to the initiating qualified HIN in a single transaction.

At that point, the initiating qualified HIN can then send that data back down to their participants and end users, using whatever the agreed-upon standards, policies, and procedures are that they have within the qualified HIN.

Something to note here is that we tried to not specify any of the internal infrastructure or technology requirements of the qualified HINs themselves. We are trying to leave open enough flexibility for the QHINs to develop their own business models and allow for them to perform the value add services and serve the stakeholders that they want to directly serve. But, at the same time, the qualified HINs will be responsible for responding to all six of the permitted purposes.

Just bringing it all back together again, you see we have that RCE umbrella organization at the top, who is performing that oversight and governance for the QHINs. QHINs are connecting directly to each other through that connectivity broker service, and through standards that we have specifically laid out in the Trusted Exchange Framework. Then, you will see how they are passing that data back down to their participants and end users.

Next, we will talk about some of the use cases that are covered under the Trusted Exchange Framework, and the permitted purposes. Some of the usual suspects are treatment, payment, and healthcare operations, as defined in HIPAA. We have also included permitted purposes here for public health, benefits determination, and individual access. I will note that the benefits determination permitted purpose is specifically for non-healthcare related benefits. This is something that, after conversations with our federal partners, including the Social Security Administration, we added this permitted purpose specifically to serve their population for when they have to make Social Security or disability benefits.

We have received some comments that the public health use case may not be fleshed out enough. So, we are looking to see what other requirements we might have to put in to flesh out that use case further. Then, on the individual access use case, we want to make sure that we are hitting the goal and intent of the 21st Century Cures Act.

So, the three use cases we have laid out in the Trusted Exchange Framework are broadcast query, directed query, and population level data. One thing to note here is that qualified HINs are welcome to have other agreements with other qualified HINs and other organizations for use cases outside of these three cases, as long as they are not conflicting with the terms of the task, we have said there is no limitation on agreements you can have on top of these use cases.

The first use case is this broadcast query use case, and this goes back to what we were talking about with the connectivity broker service. This is the ability to request data on a patient from multiple endpoints, in a single query, without knowing where the data resides. It supports situations where you don't know where you are pulling the data from. This is particularly important for the individual access use case because, as a patient or a caregiver, I

may not remember who all my doctors are, and I certainly may not remember where they are located, especially if I travel around and move a lot. Having the option of being able to do a broadcast query, where I can pull data from across the continuum using a single network and have it returned to me no matter where I went for care, is going to be important for my ability to engage in my own care and also to act as a caregiver to my family members.

The directed query use case is something that is probably familiar to all of us for situations where you do know where the specific health information resides. And then, finally, the population level data use case. This is a future use case. It's something that is still in development. But, ideally, this would allow a patient representative to query for all patients in a panel at the same time rather than having to request each record individually. This will support population health services and quality measurement, risk analysis, etc.

Some questions we may want to consider when we are discussing the use cases and the permitted purposes are, again, some ways to further flesh out that public health and individual access permitted purposes, making sure that we are striking the right note with the broadcast query and the capabilities around that. And, are there ways to support additional permitted purposes or use cases that we did not include, such as research.

The U.S. Core Data for Interoperability – as Arien mentioned at the beginning of the call, we are not directly going to be talking about the USCDI. There is another task force group that is going to be focused solely on the USCDI. However, we will be getting into it a little bit, just in the way that it affects some of the other topic areas we are going to be focusing on. So, specifically how some of the mandatory updating of the USCDI may affect the qualified HINs.

Finally, our last topic area is privacy and security. So, we worked very closely in collaboration with NIST, which was something that was mandated in the 21st Century Cures Act to make sure that we were setting a minimum bar for ID proofing and authentication. A major issue that we have heard from the industry is that not everyone is identity proofing consumers at the same level. Some are setting the bar too high and others are setting the bar too low. This is inhibiting data exchange. In our conversations with NIST, we tried to set a minimum ground of ID proofing, to where people can be comfortable treating the patients, but are also not setting the bar too high so that no one can meet the requirements.

We have set the bar here at the new IAL2 requirements. These are the new NIST requirements that have been transitioned from the old level of assurance standards. We are going to be hitting IAL2 for both end users and participants.

We are aware that IAL2 might be a high bar for individuals, so we have added a couple of exceptions specifically for individuals, to hopefully allow for them to meet the identity proofing requirements without too much burden. The first is, we are allowing for practice staff, for example, to act as a trusted referee and as authoritative source. This is where they can use personal knowledge of the individual to enroll a patient. The other exception is an antecedent event. So, staff may also act as an authoritative source and use other identification that was maybe collected during an antecedent or prior event to verify the identity of the patient.

We are heavily monitoring some of the industry initiatives that are out there right now, like the care and help lines, to see what they are going to come up with around ID proofing and consent. And we are hopeful that as we get towards the final, there will be some new policies and standards that we can bake in and might make this even easier. We are looking for feedback from you guys, also, on how we can make the ID proofing easier for patients so that we are not creating a barrier.

Similar to the identity proofing requirements, we have also set requirements for authentication, again using the new NIST standards. Specifically, we set the requirement at AAL2, with requirements for support of SAL2 or SAL3. A qualified HIN would require a two-factor authentication for this use case.

So, we are going to be going through each of those topic areas. As you can see, we have a tight schedule. Arien, I don't know if you want me to hand it back to you to go through the work plan in more detail?

Arien Malec – Change Healthcare – Co-Chair

No. Why don't you go to the work plan and then we can do the follow-up questions?

Zoe Barber – Special Assistant, Principal Deputy National Coordinator for Health IT, ONC – U.S. Department of Health and Human Services, Office of the National Coordinator for Health IT

Okay. Perfect. So, on our meeting on February 23rd, we are going to get into some of those questions about the recognized coordinating entity, their eligibility requirements, what milestones they might want to hit over the course of the three-year period, and what some of the metrics and milestones are that should be for measuring success and compliance. Then, on Monday, the 26th, we will get into the requirements and definitions of a qualified health information network. Again, we will get into that connectivity broker service, the definition of participant neutral, the next definition of a connectivity broker, and some of the requirements that we have around qualified HINs having to share their fee schedules and participation agreements.

March 2nd, we will get into our discussion on permitted uses and disclosures, so again going through the six permitted uses and the three use cases we have discussed. Then, on March 5th, we will be hitting our topic area of privacy and security and going into more detail there. At that time, we will also begin drafting recommendations and spend that week beginning March 5th drafting recommendations. We won't have a meeting on March 9th.

Then, starting March 12th, we will be reviewing those recommendations, finalizing those recommendations, and then ideally sending the final recommendations to the full committee on the 19th and presenting on the 21st. It's a pretty tight schedule, but I have faith that we can get everything done.

Arien Malec – Change Healthcare – Co-Chair

As an editorial for folks who have been through task force approaches before, this is incredibly ambitious. This will require a huge amount of work -- probably both work on the meetings as well as work off-line. Because of the time urgency of this and because of the need for ONC to respond to our recommendations and incorporate them into the final iteration of the test, we need to adhere to this schedule. I apologize in advance for this death march approach, but I am confident that, with this group, we can get through it.

Mark Savage – UC San Francisco – Public Member

Arien, this is Mark. Can I ask a quick question?

Arien Malec – Change Healthcare – Co-Chair

Please.

Mark Savage – UC San Francisco – Public Member

Just to check to make sure that folks, in designing the workplan, reflected that March 5-9 is HINs?

Arien Malec – Change Healthcare – Co-Chair

Yes, it's one of the reasons that we did no meeting on March 9th. March 5th, we might want to consider doubling up on the 2nd if we find we can't have a large number of people on the 5th. So, I ask if we can stick to this work plan, that would be great. But, if we have a large number of people who will be out of pocket on the 5th, then we might need to find additional time on the week of the 26th to go through the privacy and security recommendations.

We are going to need some time to draft recommendations. I think, for anybody who has been through this before, you think you have captured what you thought through, until it comes time to draft the final recommendations. Then, you realize there is a lot more ambiguity than the discussion got through. So, I think it is important to have a good long time to go through the draft recommendations and get them tightened up. It's not ideal from a timing consideration, and if we need to double up on the 2nd, or find some more time on that week, I think we would all be open to doing that. It would be ideal if we could stick to this plan.

Mark Savage – UC San Francisco – Public Member

Is there any chance of finding a room at HINs on the 5th for those of us who might be there? Perhaps we can do the best of both worlds.

Arien Malec – Change Healthcare – Co-Chair

Interesting idea.

Denise Webb – Marshfield Clinic Health System – Co-Chair

That is a good suggestion for the attendees at HINs. That is the first day, so there is the preconference workshop that day. I am hoping that folks can make themselves available. I am actually going to be in Mexico, but will call in.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member

Arien, this is John Kansky. I am currently on the HINs board. So, if you need somebody to score a room on the 5th, let me know.

Arien Malec – Change Healthcare – Co-Chair

That would be awesome. If you could do that, I think that would be incredibly useful.

Mark Savage – UC San Francisco – Public Member

But, it needs to be a room with dial out. We want to be fair to those who are not in the room. Which, I won't be.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member

Sure. So, can anybody give me feedback on how many people we expect to be on site, so I know how big a room with the phone I need?

Arien Malec – Change Healthcare – Co-Chair

Just to keep things sensible for you, why don't we send that information to Lauren and then have her consolidate it and send it to you?

John Kansky – Indiana Health Information Exchange - HITAC Committee Member

Perfect. Yes, thank you.

Arien Malec – Change Healthcare – Co-Chair

I think we have five more minutes before we go to public comments and close out the meeting. So, are there any broad questions about the charge remit or work plan?

Sheryl Turney – Anthem Blue Cross Blue Shield - HITAC Committee Member

This is Sheryl Turney. I have a question. Because of the way this advises ONC, is there going to be any advisement that goes back to Congress? Would we see mandates coming out of this? I am asking because it does seem that, for some of the qualified HIN standards and requirements, it might be beneficial to mandate some aspects of this. Is that within the realm of recommendations that we have?

Arien Malec – Change Healthcare – Co-Chair

Our charge is to the National Coordinator. So, the HIT Advisory Committee advises the National Coordinator. I think it is appropriate, if we find it compelling enough, to recommend that the National Coordinator follow-up with Congress and consider making recommendations, but I think that is outside of our charge relative to what our goal is. Lauren, do you have any comments there?

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

No, Arien. I think you captured it. I would just clarify that, within our recommendations to the National Coordinator, we could also recommend that they be escalated to the secretary of HHS.

Arien Malec – Change Healthcare – Co-Chair

In an editorial comment, I would say that Congress mandating standards in law is probably a bad idea.

Sasha TerMaat – Epic - HITAC Committee Member

This is Sasha. I just have a logistical question. Given the scope of our work, and the expectation that some of it will happen not during our meetings, what is the best way for us to be communicating and working in a synchronized fashion, not during these calls? Will we have specific assignments, processes for capturing feedback off-line?

Arien Malec – Change Healthcare – Co-Chair

I am going to defer to Lauren on this. I have done in the past small sub work groups, in order to keep things on pace. So, I would say, as we discover areas where as a sub group wants to go off and do some additional work, I definitely encourage that. And then, typically, the least common denominator here is sending Word documents via email, which for those of us who are used to more collaborative tools is somewhat unsatisfying. I don't know, Lauren, if our contract facilitator has any additional tools at our disposal.

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

We can take that off-line to see what collaborative tools we have online for the group, but you are correct in that we can certainly establish sub work groups of the Task Force. We can also just set up an email distribution for the group, for quick communication. We can follow up on unofficial collaborative platforms.

Arien Malec – Change Healthcare – Co-Chair

Lauren, it would be helpful if we could just send to the committee members a list of committee members, key staff, and associated email addresses. We can use that as a handy reference for doing email-based communication. But, it would be nice if there were more group chat-like or – I won't use the S-word, but similar tools that allow us to do social collaboration. Those kinds of tools can be useful in working through things like this, as well as wikis.

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

Yep, we'll definitely --

Unidentified Speaker

I think in task forces, in the past, we have used Google Docs. I'm not sure if that's approved.

Arien Malec – Change Healthcare – Co-Chair

I think we just did it sort of ad hoc, and we did not ask anybody, which is sometimes a useful way to go.

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

Yeah. And we can circle back with our IT team, just to make sure we have the appropriate parameters on our end set into place.

Arien Malec – Change Healthcare – Co-Chair

And Lauren will keep us honest relative to our obligations under the FACA rules.

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

Absolutely. I have just about nine minutes before 3:00. Are there any last-minute questions or comments before we go to the public comment period? Okay. Hearing none, Operator, can you please open the line for public comments?

Operator

Certainly. Ladies and gentlemen, if you would like to ask a question at this time, please press star-one on your telephone keypad. The confirmation tone will indicate that your line is in the question queue. You may press star-two if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star key. Again, that is star-one to ask a question at this time. We will hold for just a few moments to see if there are any questions.

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

Thank you.

Operator

Again, that is star-one to ask a question at this time. It seems that we have no questions over the phone.

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

Okay, thank you. With a few minutes left, Arien and Denise, I will hand it back to you to see if you would like to utilize the last eight minutes or so. Do you have any other comments or questions?

Arien Malec – Change Healthcare – Co-Chair

Denise, over to you.

Denise Webb – Marshfield Clinic Health System – Co-Chair

I think it would be helpful if Zoe could indicate to the members of the Task Force what the process will be for the next couple of meetings and what they can expect to see in preparation.

Zoe Barber – Special Assistant, Principal Deputy National Coordinator for Health IT, ONC – U.S. Department of Health and Human Services, Office of the National Coordinator for Health IT

Absolutely. I think Denise, Arien, and I might want to talk about this in more detail about specifically how we will go through the discussions. I think, for the meeting on Friday, with the recognized coordinating entity, we will draft a bunch of various discussion questions that we can go through. And I would encourage folks to take a look at the requirements for the RCE, and that is before Part A of the draft document, under the section "How Will It Work." That has a lengthy description of the RCE. For the following meetings, I would encourage folks to look at the portions of the draft document that align with the topic we will be discussing that day. We have included a draft of the full document in your materials also, if you need any help finding anything.

Arien Malec – Change Healthcare – Co-Chair

One other thing I think would be useful, is to review the actual 21st Century Cures legislative text. I want to acknowledge that, in some cases – for example, permitted uses and disclosures -- will be in a somewhat odd area, where I think people who followed me on Twitter will recognize that I have been somewhat obsessed by what Congress actually intended in some of their language on these topics.

But, I think it is useful to ground our work in what the legislative text actually says. Because, in some cases in the past, I know that folks have been critical of ONC for going in Direction X versus Direction Y, not to recognize that Direction X was mandated by Congress. Secondly, to acknowledge we are going to get into some areas where there will be additional clarifications that will come out via rulemaking, via the Imperium which I believe was slated for April -- at least tentatively on the OMB work plan. In those areas, we are going to have to do our best, recognizing that in some areas, there may be additional work going on at ONC relative to rulemaking that will clarify what we are doing.

Zoe Barber – Special Assistant, Principal Deputy National Coordinator for Health IT, ONC – U.S. Department of Health and Human Services, Office of the National Coordinator for Health IT

Great. Thank you, Arien. That is a good point. For the members, we can get you copies of that legislation if you do not have a readily available.

Arien Malec – Change Healthcare – Co-Chair

Yeah. Maybe some excerpted copies that are relevant for the test and permitted purposes.

<u>Zoe Barber – Special Assistant, Principal Deputy National Coordinator for Health IT, ONC –</u> <u>U.S. Department of Health and Human Services, Office of the National Coordinator for</u> <u>Health IT</u>

Sure.

Denise Webb – Marshfield Clinic Health System – Co-Chair

That would be very helpful.

Grace Terrell – Envision Genomics, Inc. – Public Member

This is Grace, Terrell. I just had another question, as you all were talking. It appears I'm going to miss one meeting -- it happens to be the one on Friday – for previously scheduled things. Is there going to be the possibility of having access to the material of a meeting that we missed? As I am looking here, watching the dialogue be typed, how can we do that in a way so that we are able to keep up with pieces of the dialogue that we may unnecessarily miss?

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

So, this is Lauren. Both the meeting transcript and the meeting summary will be available on healthit.gov. We can send you the specific list under the full FACA schedule. Shortly after the meeting, the transcripts will be there. And, a few days after that, the meeting summary.

Arien Malec – Change Healthcare – Co-Chair

And, as we have draft recommendations, and we will send those draft recommendations to the full Task Force. So, even if you miss a session and you have some comment, being able to provide editorial comments or others on the recommendations will be a second pass at that topic. Rest assured, you won't have just one pass. You can have multiple. If you do miss a meeting, I encourage people to send their thoughts pre-meeting. If there are particular topics of concern or questions you want to ask, it's a useful practice to be able to send those pre-meeting and we will get them discussed during the meeting itself.

Denise Webb – Marshfield Clinic Health System – Co-Chair

Thank you for saying that, Arien. I was just going to suggest that to Grace since she can't be with us on Friday. If she has input – we definitely want to get everyone's input.

Arien Malec – Change Healthcare – Co-Chair

Absolutely.

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

Okay, any other last comments or questions?

Arien Malec – Change Healthcare – Co-Chair

This will be the easiest meeting in a sequence. It only gets harder from here.

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

Okay, I would like to thank everyone for their time today and we will adjourn now.

[Event concluded]