Trusted Exchange Framework Task Force

Transcript
March 5, 2018
Virtual Meeting

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good afternoon. Welcome to the Trusted Exchange Framework Task Force. We will call the meeting to order starting with a roll call. Denise Webb?

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

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

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

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

Carolyn Peterson – Mayo Clinic Global Business Solutions – HITAC Committee Member
I'm here.

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

Aaron Miri – Imprivata – HITAC Committee Member
Here.

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

Designated Federal Officer

Okay. And John Kansky?

John Kansky – Indiana Health Information Exchange - HITAC Committee Member

Here.

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

Sheryl Turney? Do we have Sheryl on the line? Sasha TerMaat?

Unnamed

Sasha isn't here. I'm proxy testifying for her.

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

Okay. Thank you. Steve Ready? Is Steve on the line? Cynthia Fisher?

Cynthia Fisher – WaterRev, LLC – HITAC Committee Member

Yes, this is Cynthia.

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

Anil Jain? Do we have Anil on the line? Kate Goodrich? Andrew Prescott? David McCallie?

David McCallie – Cerner – Public Member

Here.

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

I believe Noam Arzt is on. He indicated his presence. And Grace Terrell?

Grace Terrell – Envision Genomics, Inc. – Public Member

Here.

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

Okay. And with that, I will turn it over to Denise and Arien.

Arien Malec – Change Healthcare – Co-chair

Okay. So, Denise is sunning it up in Mexico, but she is doing her duty joining from the hotel room. And then, we've got a big crowd in Las Vegas at HIMSS, as well as folks trying to get there. So, I apologize because I think we will have a rotating cast of characters through this meeting. But we're talking today about privacy and security. We're going to open it up, I believe, correct me if I've got this wrong, with the framing question, a sort of broader framing question, relating to the applicability of the TEFCA to a broad set of charges and then, dive into some of the issues related to privacy, security, identity proofing, authentication, and authorization. So, that is our agenda for today. This is the last of our big, substantive meetings prior to going dark for a week, writing some draft recommendations, and then, we will come back to review the draft recommendations for a week prior to the readout and report for approval to the final HIT advisory committee.

So, that's kind of where we are in the process. So, we got in, last week, to a really interesting set of discussions with regard to public health and push based use cases. There are a number of public commenters, for example, Direct Trust has made comments in this area, that they believe that the TEFCA should address push based use cases, as well as query based use cases. There's been some confusion related to ONC's choice of phrase single on ramp, with regard to the TEFCA. And that phrase has caused confusion relating to the set of use cases or interaction patterns, orchestration patterns, to use the language of the API task force that David and I co-chaired a while back, that the TEFCA addresses. I think, when reading the TEFCA, it's clear that the term single on ramp contemplated by TEFCA, in the context of the orchestration patterns that TEFCA contemplates, which are primarily query based access to the totality of patients' records across multiple settings of care, either brokered access.

That is finding the totality of the patients' locations of care and retrieving their records, regardless of what qualified health information network serves the end respondent. Directed access. That is point to point query that is looking up one specific location, again, regardless of which qualified health information network serves that location, as well as population level access. All of those orchestration patterns, if you will, are query based. They all involve looking up a set of patients' information either one by one or as a population and do not involve many of the additional kinds of information exchange that other health information networks provide. Those other kinds of information exchange include, for example, electronic prescribing transactions, direct messaging supplied by **HIIS** services, orders and results, including unsolicited results into EHRs as well as solicited orders and the corresponding result, as well as administrative transactions, such as eligibility, claims, remittance advice, and the variety of status information associated with those.

Given some of the confusions, and given some of the public comment, I think it would be useful for this task force to weigh in with regard to the question that we framed up this way. With regard to the single on ramp contemplated by TEFCA, should ONC's objective be to establish A) a single on ramp for all use cases or orchestration patterns that can be addressed through query based exchange, as implied by the interaction model from TEFCA but not explicitly stated; B) a single on ramp for all permitted purposes contemplated by TEFCA, whether query based, push based, or other. So, in A, we basically say, with regard to a qualified health information network, they're associated with query based exchange. And so, any of the permitted purposes that can be addressed through query based exchange are in the remit of the TEFCA. But other kinds of exchange that might be for those same permitted purposes are not. Under 2, we'd say that for all treatment based, all operations based, all payment based, and for all public health based permitted purposes, TEFCA would seek to establish a single on ramp.

The third variation is single on ramp for all clinical, HIN activities, including those provided by their actors. And I list a number of those here. A single on ramp for all EHI exchange, including political and administrative transactions, inclusive of single query, population query, push, ERX, lab orders, administrative transactions, and others not yet contemplated. So, this is the way I'm framing up, or we're framing up, this particular question. Given some of the issues involved, if people want to get put in the queue to answer this question, you can verbalize that, if you don't have easy access to the online tools. And, of course, David McCallie is our first member in the queue. But before we go to David, anybody else who wants to put their name in the queue and can't use the interactive features, please volunteer.

Mark Savage – UC San Francisco – Public Member
Arien, it's Mark. I'd like to, at the appropriate time. Thank you.

Arien Malec – Change Healthcare – Co-chair
Okay. I see David, Sheryl, Sasha, and Mark. And Noam, okay.

Tracy J. Williams
Tracy J. Williams.

Arien Malec – Change Healthcare – Co-chair
Okay. Great. So, David, let's go to you first.

David McCallie – Cerner – Public Member
Okay. I think the focus on national scale query based exchange, for the purposes of assembling a federated record, is the ideal starting point for TEFCA. And it should be limited to that, until enough experience is gained with that to expand it into other areas. In particular, it doesn't make a lot of sense for a voluntary network to try to take over established business models and established networks like E Prescribing or Direct Trust. That would be, I think, disruptive to the market in the extreme to have more than one way to do that. On the other hand, there really isn't a national way to do a federated query. So, TEFCA addresses that use case. I think that's an adequate starting point for it. And then, it can evolve from there, if enough good experience is gained. I also want to just – Arien, one little footnote.

We need to be careful that TEFCA isn't interpreted to disrupt existing query based models that might exist locally where you have an established relationship, for example, for fees to a population health service already. And, maybe over the long run, those would get replaced by TEFCA, if it provides a better or more comprehensive service. But I don't think we'd want institutions to think they have to turn off existing query based services simply because TEFCA is going to take on that for the federated national query.

Arien Malec – Change Healthcare – Co-chair
Thank you. Sheryl?

Sheryl Turney – Anthem Blue Cross Blue Shield – HITAC Committee Member
Thank you. Sheryl Turney. I agree with David pretty much everything that he just said. We were very concerned when we saw this at Anthem and in the payer community related to all of the existing connections that we have. And the technology and bandwidth required to bring on administrative claims, in the beginning, I think would be extremely difficult. And perhaps, we should take a measured approach to getting there. Also, we do have existing relationships with many HIEs that we hope will consider

participating in **[inaudible] [00:10:39]** in the future. And we wouldn't envision disrupting those vehicles of communication we have today, until such time as we agree to move them over related to how this single on ramp would work. So, we're hoping that this does provide the highway, if you will, for us to bring those exchanges into. And then, a time period by which we can appropriately switch over to them as it makes sense.

Arien Malec – Change Healthcare – Co-chair
Perfect. Thank you. Sasha or delegate thereof?

Sasha TerMaat – Epic – HITAC Committee Member
This is actually Sasha.

Arien Malec – Change Healthcare – Co-chair
Actual Sasha, excellent.

Sasha TerMaat – Epic – HITAC Committee Member
And thank you to John for shouting my name in the roll call. So, I agree with Sheryl and David's comments about not disrupting existing exchange no matter what mechanism it is, query based or otherwise. I think that's one of the key priorities folks are calling out. I also think this question needs a timeframe associated with it because, without a framing sort of chronology, it's kind of like how big do you want to dream. And that's a little bit of a false question. I think what we really need to focus ourselves on is what would we expect the RCE to embark upon first? Or how far would we expect the RCE to go with these use cases, in the three year contract? To me, prioritizing based on what you have as the first bullet, which I think Sheryl and David already endorsed, seems reasonable.

But I don't want us to swirl too much on what could be possible, if, practically speaking, we need to make a decision about what should happen in the short term.

Arien Malec – Change Healthcare – Co-chair
Thank you for that. Let's go to Mark.

Mark Savage – UC San Francisco – Public Member
So, I will put in a vote for push and pull as broadly as possible. I mentioned last time, we've got national programs, national imperatives that look at querying that also look at sending out information like referrals, like transitions of care. We talked about bidirectional exchange, patient submitted health data. I think we need to – that's where we need to be headed and as broadly as possible. So, I would understand, if there was a start with just the permitted uses, which is Bullet 2, if memory serves because I can't actually see any of the slides. But I think we're aiming to build something broader than just those use cases. And so, I think Bullet 4 is the one we should be aiming for, ultimately.

Arien Malec – Change Healthcare – Co-chair
Okay. Thank you. Noam?

Noam Arzt – HLN Consulting – Public Member
Yeah. I want to agree as well that I think pull and push both need to be on the table, if all of the permitted uses are to be considered. I think there is still a fair amount of momentum nationally, not perfectly, but a momentum around each. In general, I'm still uncomfortable with the whole on ramp metaphor. I'm

not quite sure what place the highway system in that metaphor actually means. Is that the physical network? How many sort of **ISO** layers up is the on ramp and the highway? So, I actually find the whole metaphor somewhat confusing. Thank you.

Arien Malec – Change Healthcare – Co-chair
Thank you. So, I would interpret the on ramp metaphor as saying that for every provider organization, they should have one point of contact with one organization for all of their exchange needs, with respect to whatever we believe is in order for TEFCA. At least, that's the way I'm interpreting the words single on ramp. I want to say, and just given the small sample size that we got through comment, I want to say that we have a majority opinion for, at least in the three year timeframe, concentrating on query based use cases, and a passionate minority opinion that leans more towards single on ramp for all EHI based exchange, including clinical administrative, both push and pull. I see Carolyn in the queue.

Carolyn Peterson – Mayo Clinic Global Business Solutions – HITAC Committee Member
Yes. I just wanted to note that I support the momentum behind Mark and Noam, in terms of both the push and pull. I think it's really critical for ensuring that consumers have that bidirectional data flow. And I'm sorry, if I just disrupted your **[inaudible] [00:15:51]** with passionate minority opinion.

Arien Malec – Change Healthcare – Co-chair
That's perfect. Denise, I see you've got your hand up.

Denise Webb – Marshfield Clinic Health System – Co-Chair
I just wanted to say that I agree with the summary that you made. I do think echoing Sasha's comments about what can we reasonably expect the RCD to work on in the first three years, I would say my preference and priority would be around the query based exchange and having a single on ramp to get to that modality because we do have other avenues for directed exchange. But I would like to, eventually, get to a single on ramp for all exchange.

Arien Malec – Change Healthcare – Co-chair
Okay. So, it sounds like there may be a consensus opinion that could emerge. I'm going to be very cautious about making that statement. And given some of the logistical challenges we have today, I'm not going to ask for a vote on that. What I'm going to do, in conjunction with Denise, is write up a what I believe to be a possible consensus based approach with a passionate minority language. And maybe write it up two different ways. And when it comes time to review the recommendations, we can have a formal vote on this matter to establish whether we have a majority with passionate minority and which side – I think that's going to be the case regardless of what we do. And I guess the question is which side is the minority side, and which side is the majority side. But I think, in either case, we're going to come up with a majority one side, passionate minority on the other side.

I think those are really important findings to give back to the full committee, as well as to ONC. Go ahead.

Cynthia Fisher – WaterRev, LLC – HITAC Committee Member
This is Cynthia Fisher. I'm sorry. I can't raise my hand because I'm in transit to an airport. I also support the bidirectional ability, which is important that I think it is addressed rather than starting with query.

And I do think it would be helpful, before you land on what majority or minority is is that it's clearly surveyed in advance of **[inaudible] [00:18:30]**.

Arien Malec – Change Healthcare – Co-chair
Thank you for that. So, just to be clear, my intent is to write it up both ways, and then, survey the full task force at a time when we're not all in transit and can more easily vote, so that we can establish which side the majority and which side the minority is on. But, again, I do think it's really important that whichever side we line up with that minority is going to be a passionate minority. And it sounds like we may be close to evenly split. And, again, I think that's a key finding that we want to contemplate. Noam, I saw you trying to get in. And David has got his hand up as well.

Noam Arzt – HLN Consulting – Public Member
Yeah. Just really quick. You said two different things. You talked about majority and minority, which I sort of get. But then, you threw in the word consensus. That's the word I'm more concerned about. Majority and minority doesn't mean there's consensus necessarily. So, I would suggest that the **[inaudible]**.

Arien Malec – Change Healthcare – Co-chair
Again, thank you for that. So, if we have, and it sounds like we may, if we have a relatively split opinion from the task force, we will not frame this up as consensus with passionate minority. We'll frame this up as fair majority, passionate minority and not try to frame it up as a consensus with a small but vocal minority. I do think that's an important consideration. And, again, how we frame that up I think will depend on how the voting proceeds. And we will make sure that the recommendations make it very clear the passion and the perspective on both sides of this. David?

David McCallie – Cerner – Public Member
Yeah. Just a compromised position that we discussed a little bit in the room here where we're together, and we're off on mute is that, if there were some selective push areas that are not addressed by any existing infrastructure or services that those might make the best place for the TEFCA over time to focus on first. So, start with the agreed upon query, federated query model, and then, consider expanding that for selected areas where there really isn't a good choice, say referral management with the 360X standards, maybe coordinating around that. So, there's an on ramp to the on ramp, if you would that is the possibility. Just don't jump in both feet.

Arien Malec – Change Healthcare – Co-chair
David, I frame that up as focused heavily on unmet needs, understanding that query based exchange is a current unmet need but not locking into other national priority unmet needs, with regard to the obligations of the RCE and the TEFCA.

David McCallie – Cerner – Public Member
That sounds good.

Arien Malec – Change Healthcare – Co-chair
Okay. I'm going to close this section, unless there's somebody who feels passionately that they want to get a word in and can't use the hand raising features. I'll wait two beats. Great. So, I think we've got a good sense. I think we've got some potential ways of framing this question. And we'll go, as I said, when

we open this up for review of recommendations, this will be an area that we'll explicitly open up for voting and amending to get the right sense of the group. And to Noam's point, I will not use the word consensus, unless we establish some position that attracts at least the super majority of the task force members. All right. Let's go to the next section. A whole bunch of really interesting questions here. I'm just going to read out and frame up some of these questions for folks who are in transit.

The first item is, I think, an item that anybody who has been involved here has faced, which is that, given that state law, with respect to requirements for, for example, either explicit collection of meaningful choice required of the patient prior to participation in electronic based exchange, particularly in electronic based exchange that involves look up of patient information and patient location information, so-called opt in dynamics. Or meaningful choice established to the patient with the ability to exclude the patient from indexes of patient information and location information, so-called opt out dynamics with other state laws that may be different from those two frames as well. So, for example, in some states, these dynamics involve not just the ability for the patient to register their choice.

And there are some states where, for example, it is per state law and regulation, not appropriate to even include to the patient in an electronic index, if the patient has indicated that they do not want to participate, which means that, somehow, you've got to be able to persist the information of that choice outside of the index and make sure that that persistence doesn't leak into the index somehow. A long way of saying, I think for anybody who has been in this area, there's a number of states that follow HIPAA as the law of the land. There are a number of states that go above and beyond HIPAA, with regard to treatment based exchange. The state law, with regard to HEMIT based use cases, with regard to operations-based use cases, with regard to other forms of exchange is not super well settled. The kinds of things that you can do under BAA, for example, under Population Health, may or may not conflict with state law regarding meaningful choice either prior to or subsequent to indexing a patient.

A long way of saying this area is super complicated. So, how can the TEFCA or the RCE appropriately address common obligations that occur – that provide national consensus, even in the face of variation of state law? No. 2, and I would frame this question as, given that congress still prohibits HHS, regardless of what may or may not be in HIPAA, given that congress, through its appropriately power still prohibits HHS from even engaging in research with regard to the establishment of a national patient identifier, with regard to patient matching, can you enable patient matching without creating a single patient identifier? And what recommendations might the RCE make with respect to interoperability or exchange of a single patient identifier?

With regard to Item No. 1, what recommendations do we have with regard to maintaining consents, revocation of consents, authorizations, establishment of choice, and other mechanisms for establishing the patients' participation, patients' meaningful participation either to be included or not included, in these forms of exchange. And do we have any expectations regarding educating patients on how their information may or may not be used, addressing issues like breach, and addressing common language. So, a set of really easy questions to answer. And, again, just given the set of people who are in transition, if you can use the hand raising features, please do so. And if you can't, vocalize in the next little bit, prior to going to people in the queue, and we'll enter your name in the queue. So, anybody who wants to be placed in the queue who hasn't already raised their hand, which right now is David, John, and Grace, if you're not David, John, Grace, and Carolyn, and you want to be in the queue, please vocalize now. Good. All right. So, we're going to go in order. David, John, Grace, and Carolyn. David, go ahead.

David McCallie – Cerner – Public Member

Yeah. Boy, we could spend the whole afternoon on any one of these questions. Just a quick replay of what we learned with Common Well in trying an opt out model and an opt in model. Initially, Common Well was an opt in model. And it didn't get a lot of uptake. We switched to an opt out model and got dramatically greater participation. I will clarify a really important point is the reason that we didn't get uptake with the opt in model wasn't that patients didn't want to share their data. It was that the offices couldn't take the time to explain it to the patients. So, they just skipped the whole process. When patients had it explained to them, they chose to opt in. But it's just too expensive and complicated to try to explain what's going on. So, we sort of reluctantly shifted to an opt out model and have had much, much greater useful sharing of the data, since that happened.

With respect to patient matching, I think that TEFCA should stay out of that space. And we continue to work on ways to improve the use of secondary identifiers, such as cell phone numbers, drivers license, etc., to link records together. Don't get embroiled in the politics of patient matching. On the consent question, I think the big issue there is there just are no standards for what consent needs to cover. And there aren't standards on how to capture it electronically. So, some of the requirements that the QHIN has to have on file, record of consent, and share with other QHINs seems to me to be really unworkable in the current state of the industry. We just don't have good tools to do that. And then, on the what to do about different state laws, what we do in Common Well is we, basically, just flow down that responsibility to the participant to ensure that nothing is shared that is illegal in that state. So, it's not the best solution.

But absent the ability to actually change the laws in the state, it's a workable solution. And provider groups have already implemented tools to manage what they're allowed to share within the state. And we just make sure they take that responsibility with respect to sharing across state lines. And then, finally, sorry for such a long answer, on the education, to me, the biggest need for education is on what happens at the – consumers need to understand that what happens to their data, when they take control of it themselves, and move it outside of the protections that are offered by HIPAA, there's nothing really to protect them from abuse of that data, other than FTC contract language, which is, obviously, really difficult to understand and enforce, if you're talking about things like click throughs. So, I think there's a whole lot of unanticipated, unintended, I'm sorry, a whole lot of unintended harm that could come, if a patient is naïve about what happens to their data, once they've accessed a copy and handed it off to a third party. Let the reader beware.

Arien Malec – Change Healthcare – Co-chair

Okay. I'm going to throw in a couple of editorials to David's editorials. 1) Is that the HIT Standards Committee and the HIT Policy Committee looked at these issues a number of times. And the general sense, from a variety of health information networks, is that, when choice is explained to patients, it doesn't matter which approach is chosen. Patients tend to register and opt in at about the 95 percent rate with about 5 percent being strong opt outers. But the choice of default, as David notes, does matter. And the administrative burden associated with collecting this information can meaningfully impede information exchange. So, again, the evidence is about 95 percent participation, about 5 percent strong, vocal decline to participate. But some significant affects, in terms of how you do it, in terms of level of participation.

2) This notion of deferring these obligations to the end participant and making sure that they hold by their obligations and not hold the RCE or the QHIN too close to the process has some precedence, ultimately, in how some of the E Prescribing standards work, in the sense that the E Prescribing standards

for, for example, query based access to medication records has a required field that's passed that indicates that there's been some affirmative collection of patient participation in that. But it leaves the details of how that's collected, how that's managed, and who gets involved in that process really to the end user through flow down terms that are on the HIT vendor. So, there appears to be some level of real world practice patterns that have been proven to scale, in these areas. And, again, just trying to provide some context for stuff that we've learned through a variety of **FACA** activities. John Kansky?

Aaron Miri – Imprivata – HITAC Committee Member
Actually, it's Aaron Miri. I'm stealing John's hand here. I'm sitting beside him.

Arien Malec – Change Healthcare – Co-chair
Okay. Good job.

Arien Malec – Change Healthcare – Co-chair
Thanks. All right. Arien, I think you mentioned, actually a point I was going to reference here is that I would recommend folks to visit one of the previous FACAs where we talked about this in detail, which is the API FACA, which wrapped up probably two falls ago now. We, actually, went into detail around the privacy and security component. I want to also bid that an item there that I think is important, which David touched upon, and you touched upon, which is informing consumer consent, and informing them up front of what's going to happen to their data. Something that's very important, especially from the developer side, is that if the patient hands you their data set, it is with expressed intent that they're giving you the data. However, what could be done with it may not be what the health systems had intended to. So, making sure the patient understands clearly, up front that your data can and will be used against you in a court of law is very important.

And it's very important, also, especially I put on my previous hat in the pediatric space, when it's a minor you're talking about, or there's a specific condition such as pregnancy or AIDS or things like that that you do not want to be put out there. So, I would really ask the committee to look back at the API FACA findings and what was ratified at the HIT Policy and Standards Committee as sort of the way to go forward. So, I agree with you there. On the item around patient matching, I totally agree with David. Stay out of that space. That is a hot button item. If anything, we could reference a patient matching strategy, at a very nebulous level. Say this helps inform that national strategy going forward, so we can get this done from a TEFCA perspective. But diving into that, it's just asking for it. And it's not worth it. It's just worth a squeeze. Last but not least, on this point, I think you hit the nail on the head that the privacy and security laws state to state and across the country vary widely.

I lived in a state, previously, in Texas, which had very argent, very breach notification laws that were above and beyond a lot of the states, which was great, if you're in the state of Texas. However, we had patients coming in from all over the country. The other point to this is that there are a lot of European citizens that end up in an Emergency Room. How does GDPR and others play to that? So, I would say we'd be very prescriptive about the way we go about this. Be cognizant and aware of the rules and the laws. And, at the same token, stay out of the hot button items.

Mark Savage – UC San Francisco – Public Member
Arien, it's Mark. If you can add me to the queue, and I have very little time. I may have to drop off.

Arien Malec – Change Healthcare – Co-chair

If you need to get in the queue, and you need to jump in the queue, let me know.

Mark Savage – UC San Francisco – Public Member
Okay. Can I just do that now because it may be 30 seconds?

Arien Malec – Change Healthcare – Co-chair
Go for it.

Mark Savage – UC San Francisco – Public Member
Okay. So, to keep it short, in general, on consents, I recommend the opt out approach that was teed up by the privacy and security tiger team. And we'll just leave it at that, without going into detail. And there's a lot of nuance. I'm happy to cover that, but I can't do it today.

Arien Malec – Change Healthcare – Co-chair
Okay. I'm going to – let's try to make sure that we get the recommendations of the API joint task force and some of the recommendations for the privacy and security tiger team. I do think there's a lot of art that's been out there and gone over and would be useful context for this task force, as well as for the advisory committee. Aaron, can you put your hand, or John, unless John wants to get back in, can you put John's hand down to keep things clean? And then, we're going to go to Grace.

Grace Terrell – Envision Genomics, Inc. – Public Member
Thank you. And I also would agree that the opt out approach has far more efficiency. But one of the things that I wanted to bring out in this discussion, as we're thinking about it, is what I'm learning in my new space in the genomic medicine world in that you don't just own your own genetic information. Your entire family does to the point that, from sequencing data, you can often identify information relative to other members of one's family who may or may not want to know that information or have that information shared. Sequencing is not considered PHI under HIPAA. It's more regulated through the GINA Act. But it is becoming an increasingly important area of privacy and security. And because it's not just a one to one connection between a patient and a query, but it impacts, potentially, other individuals within the family. It creates some complexity about the opt in/opt out that we may not be able to solve here. But we ought to be aware of it.

Arien Malec – Change Healthcare – Co-chair
Thank you for that perspective. Super useful. Let 's go to Carolyn.

Carolyn Peterson – Mayo Clinic Global Business Solutions – HITAC Committee Member
Two thoughts. First, with regard to the issue of educating patients, it strikes me that ONC has a role in setting out what information patients should be given, in terms of how their data will be used and protected. And it may be that there is some standard language that should be distributed by all of the QHINs and the RCE, in terms of educating people to keep all on the same page. One thing I noticed, looking at the key provisions, was that, in 6.1.3, there wasn't any mention of how individuals are notified when there's a data breach. And I think that's something that really needs to be involved, included in what we specify because it is really important for patients and consumers to know when those breaches have occurred. And, in practice now, we see quite a wide variation, in terms of when organizations share that information.

Sometimes, unfortunately, even if they do, and consumers and patients need to know that in a timely fashion. Thanks.

Arien Malec – Change Healthcare – Co-chair
Thank you for that. With regard to standardized language, I'd also like maybe ONC staff that we can put in some of the background or make sure we have in the recommendations as well pointers to the model privacy notice, as well as to the ONC playbook, both of which contain really useful background educational information. I tend to find that in areas where we're asking ONC to specific something, and when you provide more background, if you look at the past say seven to eight years of ONC well-funded activity, you find there's actually a wealth of information out there. But, sometimes, it's not as publicized or known by all participants as might need to. The model privacy notice does some thought about how to model the patient education, with regard to the language used in privacy notice, particularly for non HIPAA information exchange.

And the playbook has a really nice background on a whole bunch of issues, including choice and patient matching. Sheryl?

Sheryl Turney – Anthem Blue Cross Blue Shield – HITAC Committee Member
Hi. Sheryl Turney. I had a couple of comments on this one related to the privacy responsibilities. Our privacy legal folks are questioning, in the current rules of HIPAA, qualified entities have all of the responsibilities and, actually, suffer the penalties of the breach. In this design where there's qualified entities and non-qualified entities, it's not as clear what the roles and responsibilities would be related to a breach. So, we definitely wanted to see more detailed out on that aspect of it. And also, perhaps, even shifting more responsibility to the non-qualified entities in the event of a breach because we can't always be understanding what a bad actor, in this regard, is going to do. So, that's one comment. There were a couple of other comments related to patient privacy practices and what is anticipated. Maybe because I need to see a picture, the picture that I've put in my head, and maybe it's wrong, and if that's the case, please, you guys, tell me.

But most patients, in my opinion, are probably going to come into this QHIN either via a portal app developer or through an existing portal they already have, in my sense. And if that's the case, then, I do think there should be additional responsibilities on either the portal that the patient uses to A) have the education and the disclosures available, and have some of those disclosures hopefully go beyond the bounds of what they currently do today because some of the things that patients have said are I want to be able to give my data up for genetic research. And now, with the fact that maybe that's a family decision and not a personal one, but there's no place to record that today. What if you're an organ donor? Yes, it's on your license. But shouldn't it be part of your health records? Some of these other declarations that they would like to make related to their health record, how does that, basically, factor into who holds the data and who is responsible for transmitting that to the appropriate place, if it needs to happen?

And then, the third point that I wanted to make here on privacy was, obviously, I brought up, originally, a few days ago, the issue of the state rules, and the need for disclosure. So, even beyond what the state rules and regulations are that differ from federal regarding disclosures and privacy, there are instances when data is shared that these disclosures must go along with the data. And so, somewhere in the RCE's responsibilities, although I don't expect them to manage or monitor all of those, there needs to be some

language that indicates that the state rules that require that are being followed by the participants and the QHINs themselves because many of the states have rules regarding when disclosing X, you need to have this disclosure associated to it. And once it's out of the hands of the, again, qualified entity, then, how do we ensure that that disclosure happens as it needs to? Anyway, those are my three points.

Arien Malec – Change Healthcare – Co-chair

How to follow breach identification rules that are state by state. Just as I think a factual correction, and I'm not a lawyer here, but the obligations for breach notification and HIPAA are on the covered entity. But there are additional obligations that are under business associates through HIPAA as amended through the HITEC Act. And so, there are additional obligations on business associates with regard to breach notification. But a general business associate language is best when it clearly delineates breach notification requirements. And it seems pretty clear that part of the RCE's obligations needs to be to line out the breach notification obligations between the QHIN, the RCE, and the covered entities, the participants and end users, I guess, is the way the TEFCA describes it. Let's go on. We had so much fun on that page, let's go on to the next page.

We've got 10 minutes before we go to public comment. And then, we'll have another half an hour after that, which at which time, there may be some churn, depending on whether we have some overload in the conference room that's in Las Vegas at HIMSS. Let's talk about ID proofing. I'm going to distinguish, just because I've gone through this area a number of times, the somewhat related questions of identity proofing, authentication, and authorization and just define that ID proofing is the process by which you connect a purported human to the actual human. Authentication is the process by which you connect an individual's claims to be person X to the knowledge that they are person X. And authorization to be the process by which person X delegates or allows for certain activities to be performed that may be somewhat too vaguely stated.

So, just to give you an example, you walk into a bank. And you want to open up a bank account. The bank – nobody walks into banks anymore. We all do it online. The online process that people have, when they sign up for a bank account, verifies a couple of things. No. 1, usually verifies some aspect of control of email address, some aspect of control of knowledge of social security number. In some cases, it does what's called knowledge based authentication, which tests that person against established national databases, for example, for credit card header information or others, and some of the credit checking bureaus. So, those bureaus often have information that they use for credit checking that indicates that patients have had transaction X. And all of that information is used to verify that the person who wants to open up the bank account actually is the person who is authorized to open up the bank account and controls that information.

The second process is, when you log into the bank to access your record, the process by which the bank verifies that you are the person that you are, which might include user name and password. It might also include secondary checks like sending a one time code to the text message number on record, or the email address on record. And then, authorization is the process by which you say that an app that you control is allowed to pull information from your bank account or connect to your bank account to do certain things. Hopefully, that makes sense. With regard to the TEFCA, there are pointers to the new version of NIST obligations that no longer have the four factors to talk about specific requirements for identify proofing and authentication, with regard to the obligations of a QHIN and obligations for participants under the TEFCA. So, with that as the back drop, the questions are does ID proofing for

individuals strike the right balance between not being overly burdensome while being stringent enough to enable trust between entities?

Is a trusted referee or authoritative source a viable approach to supplement the ID proofing process for individuals? How can we clarify language relative to responsibility for ID proofing and authentication? Should TEFCA define provisions for expiration of tokens? So, again, just a little background. In the process of authorization, those authorizations are, generally, time bound and are associated with tokens that are used with respect to those authorizations. The matter of expiration of those tokens is a matter of policy. And that really determines when people have to reauthorize an application. So, to give, again, a real world example, maybe you use a box like a Roku box to watch streaming services. In some cases, those streaming services ask you to re-verify and reconnect to make sure that you still are the person that you say you are or that you're still authorized to have the streaming services. In many cases, those obligations are set by the end cable vendor or the end application that's providing the streaming services requiring you to go back and recheck. So, that's what's meant by token expiration.

And then, in what context should the TEFCA define certificate authority, including certificate policies and overall approach. So, with regard to some of the obligations for identity proofing, there are organizations that establish business level identity proofing and issue X.509 certificates as PKI, public key infrastructure, public/private keys that allow you to both encrypt information and traffic, but more importantly, verify that the two people who are trying to connect actually can match up and agree that they are the computers that are trying to connect. And those computers, in some cases, are associated to organizations. The organizations that issue certificates are called CAs. And the issuance and management of CA policy, certificate policy, is a pretty thorny area in security policy. So, with all of that trying to explain the questions, we're going to go to folks responding. And, as usual, David is first in the queue.

But I'll pause to see if anybody else wants to be put in the queue. And then, I'll see if anybody verbally wants to go in the queue, please do so.

Aaron Miri – Imprivata – HITAC Committee Member
Yes. Aaron Miri, please put me in the queue as well after David.

Arien Malec – Change Healthcare – Co-chair
Gotcha. David, go.

David McCallie – Cerner – Public Member
Yeah. Hi, it's David. I think a couple of high level comments. One is with respect to the language in the draft document around all of the details on security policy or security technology, I think there's far too many prescriptive details in the draft that should be left to the RCE to work out amongst the stakeholders. Set the high level principle, which is compliance with HIPAA, compliance with 2015 edition standards and so forth. But those details are too specific and only would refer to a couple of use cases. So, consistent with what we said earlier, leave the technology and architecture to the RCE to work out and stick to the policy requirements. 2) I think that there needs to be some notion of equivalent proxy for IDP and auth and auth, identity proofing and authorization.

And what I mean by that is, if a provider is accessing the system through an EHR that is invoking the APIs, and the provider has been thoroughly proofed sufficient to get access to the EHR data locally, then, they

shouldn't have to re-authenticate with a second factor to get to the QHINs. That, I think, would be an undue and unnecessary burden. And I would say the same for consumers. If the consumer is accessing the data through a portal where they have been identity proofed by a provider, and authentication is managed through the provider's portal strategy that should be sufficient, instead of requiring second factor every time they access the data. And then, third, on the token stuff, expiration tokens, I think that's just a detail that should be left to the use case and the RCE to figure out. token expirations make different – timing makes different constraints and different use cases.

And then, finally, on the certificate of authority, the biggest thing that ONC could do, if it was technically possible, or legally possible, and I'm guessing it might not be, is to try to make it easier for federal requirements for certificate of authorities to align with private sector requirements, without creating undue, expensive burdens that lift all of the private sector up to federal standards, which has been a problem in the past. It kind of creates a two-tier network that really is disruptive to the VA, in particular, where there's a lot of civilian access to the data that's needed.

Arien Malec – Change Healthcare – Co-chair
Great comments. The privacy and security tiger team addressed the first issue that David was mentioning regarding the mechanisms for ID proofing and authorization, with regard to connecting to your EHR and making sure that you don't establish additional burden. One of the ways that I conceptualized this is, if you're in a place where the provider is allowed to poke, prod, or do orders to poke, prod, or cut the patient, then, that's probably a high water bar mark enough. And we shouldn't put additional burdens on top. One of the visualizations I had on this is that, in some cases, getting into the OR and being gowned and garbed as a provider, if you can establish the computer itself is in the OR, you shouldn't require, for example, two factor authentication that's above and beyond what's already a pretty high level of ID proofing and authorization required to be on that OR and hold the scalpel. So, good comments by David. I think Aaron wanted to be in the queue. Go, Aaron.

Aaron Miri – Imprivata – HITAC Committee Member
Yes. So, really quick, I agree with David. There's a lot of items here to consider. 1) Again, I go back to what I said previously. Look at what we came up with the API FACA group. In general, though, I think we need to reference NIST standard as much as possible. The framework for 800.63.3 for levels of assurance really do go into specific detail about how to appropriately identify a person or an individual. As much as we can reference generally accepted frameworks like NIST would be preferable. 2) With tokens, I would say we stay out of that. Again, I agree with David on that that, if there is a way to do it on a national scale that would be great. It may be too tricky, especially given the disparity in state and federal laws there. 3) In terms of who is responsible for ID proofing, as much as we can empower the RCE to do that, the better.

I think they'll be in the best position to be able to understand what the needs are going forward there. And then, last but not least, just overall, from an ID proofing perspective, we don't want to make this thing too burdensome, otherwise, it won't get used. If you put a steep enough hill there, then, nobody will go up it. So, I think what's appropriate by the law, but above and beyond that, consumers are consumers. And if we want consumer participation, which, ultimately, will be the driver here, then, we have to make it doable. Thanks.

Arien Malec – Change Healthcare – Co-chair

I'm going to add, just because I always do this with regard to this topic, I'm pretty predictable here, that most of the ID proofing and authentication that is meaningful, in these contexts, is actually organizational and not individual. And, in many cases, we federate responsibility for individual identity proofing to an organization. So, putting specific obligations that go down to individual level identity proofing can be counterproductive, when, at the end of the day, what you really care about is the general hospital that's connecting to you really is general hospital. And that they have specific obligations that they've taken on relative to identity proofing authentication and authorization. And that they're practicing those under appropriate assertions and warrants established through contract.

So, to some extent, getting down to individual level authentication is counterproductive, unless you really, really, really need to go there because most of the obligations are inherent on the organization. And you want an organizational level identity proofing and authorization really well. And I guess the last editorial comment that I'll make is that, in the work that we did in Direct Trust, we found that EV, extended verification certificates, had really good policies for organizational identity vetting. But with regard to what David mentioned, in some cases, we had to go above and beyond, in order to meet DOD and VA requirements. And those burdens were incumbent on everybody who was engaged, even though, in some cases, the price of EV certs continues to drop over time. The special requirements that federal participants put on that go above and beyond, in some cases, not meaningful does create both a two tier network and creates an additional cost obligation. All right.

Thank you, Denise for reminding me because I was pontificating. We're at the top of the hour. We need to go to public comment.

Unnamed
Thanks, Arien. Operator, can you please open the line for public comment?

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

Unnamed
Thank you. And just as a reminder, we ask that you please keep your comments to no longer than three minutes. Operator, do we have any comments in the queue, at this time?

Operator
There are no comments in the queue, at this time.

Unnamed
Okay. If there are no comments in the queue, I will turn it over to Arien again.

Arien Malec – Change Healthcare – Co-chair
Great. Thank you. It sounds like we got some folks who are transitioning. Aaron, Sasha, David, and John are doing the room to room transition at HIMSS because we wanted to go to an extra half hour. So, we're going to take the next half hour, let me make sure I've got the time right. Yes. So, we do have another half hour reserved. We're going to go to the bottom of 12:30 Pacific, 3:30 Eastern, and go on to the next

question. All right. So, I'm going to introduce the topic of flow down provisions because it can be confusing for people. But it's proven to be a well established principle in information exchange. And the notion is that, in many cases, there's a set of indirect relationships to the ultimate folks who hold, for example, breach notification obligation who are the covered entities, or to the individuals participating in information exchange.

But, naturally, we have broader aggregators who bring together, for example, E Prescribing networks who then enroll health information technology vendors and pharmacy networks who then, individually connect provider organizations or pharmacies who might themselves be covered under entities under HIPAA. And because you've got a set of indirect relationships that occur between the organization that's facilitating exchange, or, in this case, an RCE that's creating blanket policies to organizations who themselves are facilitating exchange, and the ultimate covered entity or end user, participants or covered entities or end users, you create a notion of flow down terms, which are a set of obligations that each of the participants in a framework agree to flow down into their contracts with their participants with terms that require them to flow them down to the end organizations or end individuals who are legal authorized to enter into those contractual obligations.

So, as an example, it might be important, at the RCE level, for an organization to have certain protections with regard to breach notification. But it's at the individual organization level where those breach notification obligations come into force. And the way you do that is to have the RCE establish a blanket set of contractual agreements. Those contractual agreements include flow down provisions that the QHIN would sign onto. That QHIN would then, let's say they sign up health information technology vendors or developers, would flow those terms and the obligations to further flow those terms down to the health information technology developer who then, flow those terms down to the end covered entities who are the provider organizations they're signing up. And, in some cases, there's a secondary level or a tertiary or quaternary level of flow down terms that are established.

It seems a little convoluted. But, in practice, it's the only way to make sure that those obligations get where they're going to, without having the RCE individually onboard individual organizations. So, with all of that background, does the TEFCA establish appropriate participant and end user obligations, with respect to privacy and security, with respect to flow down provisions, and how can that be further clarified? And we're going to go see if there's any hands waved or other folks who want to go in the queue.

Unnamed
We do have the reference language on slides, if people want to see that.

Arien Malec – Change Healthcare – Co-chair
I think that might be useful. David?

David McCallie – Cerner – Public Member
I'm just raising my hand verbally.

Arien Malec – Change Healthcare – Co-chair
That's a surprise, man.

David McCallie – Cerner – Public Member

Do I get to go?

Arien Malec – Change Healthcare – Co-chair
David, go for it.

David McCallie – Cerner – Public Member
Okay. I'm, unfortunately, not looking at the slide anymore. But my generic comment would be it would be very helpful if the TEFCA language was focused on clarifying any differences or changes from existing law and policy, rather than reiterating parts of it and, in particular, going into details where it's not clear why the detail is being enumerated, since it looks like existing policy. For example, around HIPAA, security provisions. Is there a proposal to actually go beyond that, in some binding way? And if so, call that out. But otherwise, just point out that you have to be compliant. That would be helpful, I think.

Arien Malec – Change Healthcare – Co-chair
Okay. Other folks who want to get into the queue? Denise wants to get in.

Denise Webb – Marshfield Clinic Health System – Co-chair
Hello. On David's point, I just wanted to add to that that, as I was going through the TEFCA, I struggled with that in various places where isn't this already the law. So, I would concur with him where there's detail in the TEFCA that's already existing now, I think it should be taken out. We should just call out the exceptions and the differences.

Arien Malec – Change Healthcare – Co-chair
Okay. And, again, that's pretty consistent with many of the other recommendations that we've established relative to making sure that the ONC is establishing high level policy and not going into too much detail in areas where the RCE can take that detail on. And these cases of that policy, to the extent that it's well established, shouldn't be repeated in the TEFCA itself. Okay. I don't see any other hands being raised, although, it's hard for me to tell because we've got a file that's being uploaded that are the key provisions in the TEFCA. Here we go. So, these are the participant obligations. My recommendation here is, given that we don't have – I think we've got high level comments, and we don't have more detailed comments, why don't we just go on to the next item in the agenda. So, if we can go back to the agenda and display the next item. Good.

I think we've gotten through then, the key items here. Let me do, first, a call, since we have 12 more minutes, first, a call to see if there are any other key topics that we should have but have not yet talked about, with regard to the work of the task force. And this is sort of a last call to get information on prior to seeing drafted recommendations that we will have adequate time to review, critique, and get to closure on. But I want to make sure that there isn't something else that's been burning that we haven't talked about in the last four meetings. Sasha?

Sasha TerMaat – Epic – HITAC Committee Member
So, I was thinking about this the other day. And it struck me that we haven't talked about the sustainability of the structured exchange framework at all. And that seems like something that I know some of us were talking about during the public comment window. Is that something that there's interest among the task force in discussing? Aaron is nodding next to me.

Arien Malec – Change Healthcare – Co-chair

Good. And there's two levels of sustainability. Maybe I can frame up the questions. 1) Is I don't believe that ONC has announced a large pool of money that ONC is sitting on to fund, for example, the RCE. And I think public information, with regard to ONC's budget is pretty clear. So, there's some level to which the RCE may have a small amount of money to get some activities up and running. But that money is likely to be insufficient to even serve the initial RCE obligations, as well as to serve ongoing obligations. So, one question is relating to the RCE's sustainability, not just with regard to post three years, but maybe even with regard to activities for the first year. The second way that I've heard sustainability articulated is whether the obligations that the TEFCA establishes both for the RCE and, in particular, for the QHIN are such that many organizations that otherwise would want to participate and have a business model that allows for exchange might not want to participate.

And whether there are ways to relax those obligations and ways that establish the policy outcomes that ONC is seeking to establish, without artificially limiting the supply of actors who are willing to supply services. Sasha, do I have those two framed questions right? And are there other questions you'd want to add to that mix?

Sasha TerMaat – Epic – HITAC Committee Member

I think that's excellent finding. That covers my concern. I was just picturing, at some point, we're going to provide recommendations. And I don't want us to be in a position where we provide recommendations for something without having discussed if we think it is a viable solution to sustain itself. And if we don't have confidence that what we're going to recommend is going to be viable and sustainable, then, probably we should change our recommendation, based on the concurrence.

Arien Malec – Change Healthcare – Co-chair

Perfect.

Unnamed

Arien, I would add a friendly amendment to add some of the discussion about fee logic and restrictions. I think we touched on it but really not in depth like what you can and can't charge for and what kinds of constraints on how much you can charge. I think some of that is part of the sustainability discussion.

Arien Malec – Change Healthcare – Co-chair

Okay. Grace, I see you with your hand up.

Grace Terrell – Envision Genomics, Inc. – Public Member

Yeah. So, the metaphor discussion, earlier today, was interesting as I think it relates to the concept of sustainability because there was some question, which is why are we talking about this being a road or a confusion about the metaphor, as it related to that particular point. The whole time, I've been listening the past several sessions, I've been thinking of this within the context of sustainability as it relates to the question are we designing a utility. And so, as opposed to a metaphor related to a highway system, which, in every state, you've got tolls, you've got federal funding, you've got all sorts of other ways, and everybody uses it, but it's

based on the tax system. A utility also has a power grid throughout the US. There's certain standards that allow electricity, let's say, to be provided across a grid.

But it's based on the different business model, with respect to how it's paid for. So, anyway, within that context, we're thinking about sustainability. If this is a voluntary whatever, and it's always going to be dependent upon some sort of federal budgetary funding, that's a very, very different question and does speak to what we can design around that versus thinking about it as are we creating a utility, if you will, for information transfer throughout the healthcare industry in ways that will make it more efficient.

Arien Malec – Change Healthcare – Co-chair

That's a great framing. I'm going to go off on maybe a little bit of history, in this area. I won't spend too much time on it. But I would note that, in other areas, this notion between commercial actors that supply exchange information because they have a business reason to do so versus the regulated monopoly utility model versus the regulating duopoly or small set of actors model that we have in some state based energy markets. This debate has been going on in healthcare for a long time. I note that, in areas like credit card processing, **[inaudible] [01:12:47]** processing, ATM exchanges, and the like that there have been natural actors that have been consortia that have been created and facilitated exchange.

In some cases, the exchange services turned out to be so valuable that what started as consortia operating in a not for profit model ended up being very large for profit organizations. But organizations like Visa and Mastercard didn't start out that way. And, in fact, Visa started out as a not for profit. I'd also note that, in the history of information exchange in the country, we thought, for a long time, that we needed to have regulated monopolies and established state based information exchanges. And we've spent, as a country, a fair amount of money in that area on the order of maybe three-quarters of a billion dollars on standing up and state based exchanges in the utility model. And due to the sustainability issues we were just talking about, we haven't been able to get there to the level where those regulated utilities, regulated monopolies, actually had sufficient staying power to establish exchange. John, I see your hand is up.

John Kansky – Indiana Health Information Exchange – HITAC Committee Member

Yes. Thank you. It's actual John. So, if we assume that – on the question of sustaining this TEFCA ecosystem, the question of will it, ultimately, be sustainable. But there's also the question that, if we assume it is a sustainable will that means that sustaining be what we're expecting, will it be unintended consequences. For example, my view is that the QHINs appear to, if I'm interpreting and envisioning what ONC has articulate in this draft, the QHINs will have ample opportunity to engage in contracts with third parties, for example, those who engage consumers directly, or they can do it themselves. And I think there will be the potential for a transfer of billions of dollars of economic value from those who hold the data today to those who would hold the data in the future.

The intent, obviously, is to get consumers access to their data. I just think we need to be aware of how the market forces might play out, as this ecosystem seeks to sustain itself.

Arien Malec – Change Healthcare – Co-chair

Okay. And I assume that's related to some of the discussion we had about what QHINs are and aren't allowed to do with regard to data retention?

John Kansky – Indiana Health Information Exchange – HITAC Committee Member

Correct. Yes.

Arien Malec – Change Healthcare – Co-chair

Let's first frame up, with regard to the first framing that I did, the topic of the RCE and whether the obligations in the TEFCA, with regard to the RCE, are sufficient to allow – maybe the way to frame this up, and I think this is the way that TEFCA framed it up, is that the TEFCA had a desire that existing organizations with an established governance model might well jump into the fray with maybe a little bit of push and a little bit of funding to establish RCE governance but that it would be desirable to have organizations that already were established to serve this need as opposed to organizations newly forming to be an RCE. So, are there activities or language in the TEFCA that would inappropriately restrict established actors who have an existing governance model and an existing sustainability or membership model from serving the role of RCE?

Let me just frame that question up and see if we've got any opinions, with regard to that issue.

David McCallie – Cerner – Public Member

David will raise his hand verbally.

Arien Malec – Change Healthcare – Co-chair

Of course. Go for it.

David McCallie – Cerner – Public Member

Yeah. I think there's a reason to consider that the RCE logic and the QHIN logic might be different as the business constraints. The RCE is focused on governance and needs to have obsessively clear, transparent neutrality, which makes it difficult to envision a successful RCE that has strong ties to existing data holders, etc. On the other hand, the QHIN, since their primary purpose is to, essentially, guarantee that the data they do have access to is shared, under a common set of rules, it makes to me a lot of sense that they should be allowed to be connected to existing entities because, in a sense, that's their whole purpose is to share existing data. So, I think they're two different sets of rules. And the RCE should be studiously disconnected from those whom it governs.

Arien Malec – Change Healthcare – Co-chair

Let me just ask this question. Let's assume the RCE is a not for profit organization that has dues paying members. Who might be the dues paying members of the RCE? And would those dues that are paid be sufficient to establish the governance of that?

David McCallie – Cerner – Public Member

Yeah. So, if you're asking me, I'll answer. I would say it's the people who sign the agreement and agree to abide by it. It would be the QHINs, in the current structure, yeah. And they choose to pass costs downwards, obviously, to their members, as they're allowed to under the current graph. One would hope that the RCE isn't an insanely expensive organization.

Arien Malec – Change Healthcare – Co-chair
Two lawyers and an executive director?

David McCallie – Cerner – Public Member
Okay. Well, we're already at 350K.

Arien Malec – Change Healthcare – Co-chair
You wish. Exactly. Okay. Other comments on the RCE? I think we've head and already got comments on fee structures, with regard to the fee structure issues, potentially, being an impediment on the QHIN. Other issues that would drive away natural actors who might otherwise want to be QHINs in ways that aren't clearly tied to policy goals but may reduce the potential for QHINs to drive in and drive appropriate sustainability.

David McCallie – Cerner – Public Member
Well, the obvious, most powerful one is, if you can't do anything but be a QHIN, in other words, if you're not permitted to do anything else, then, it's a pretty limited set of actors who can take on that role. It's to impossible. It's what Common Well does, and it works fine. But it's pretty limited.

Arien Malec – Change Healthcare – Co-chair
And is this particularly with regard to the self-dealing obligations that we've previously talked about?

David McCallie – Cerner – Public Member
Yeah. And, again, as I have been drifting in these conversations, and I'll say I'm not completely comfortable with my drift, but drifting in the direction of saying the real obligation on a QHIN is that you share data that you have access to, whether that's data that you directly controlled as the provider or an HIE, or whether it's data that you control indirectly because a group of people have asked you to surface their data for them like Common Well does. Either way, the obligation on you is to share the data under their common agreement rules.

Arien Malec – Change Healthcare – Co-chair
And so, since this has become, at this point, a conversation between myself and David, I'm just going to pause to see of there are other folks who want to get in and provide comment. And, otherwise, I think I'm going to suggest that we close this out and talk about next steps.

Sasha TerMaat – Epic – HITAC Committee Member
So, this is Sasha. And I kind of raised the question slightly. I guess my thought is it's very clear to me how some of the things we're talking about require additional expense on the whole ecosystem. There's additional technical expense of connectivity brokers. There's additional legal expense of new

agreements between all of the participants. There might be new expense related to authentication expectations for systems and for users. And so, I can kind of start adding up, in my mind, how much would it cost to be a QHIN for a year. How much would it cost to onboard these many participants? How much would it cost, in terms of how much dues they have to pay the RCE? And then, I think the part that I'm less clear on is how will all of those expenses be born?

And we've talked a little bit about other models of funding that might be accessible to QHINs, if they're able to use the data for other purposes, or models that QHINs might charge their participants, if they're giving a service that is more convenient or worth more to their participants, than services that might already be in use today. But my gut sense is that the expenses we're adding are greater than the sort of advantages that are being put forth there. And if I'm the only one, I guess I could – Aaron and John are shaking their heads in agreement. So, I guess my concern is just that I feel that we either have to talk about how do we make the whole thing less expensive, so that it can be practical as a cost. Or if there are elements and ways to fund the framework, and all of the pieces of it that are missing, maybe I just need to sort of be enlightened to what those are and how they work, so that the advantages and the extra income that would come from it would accrue to the same sort of players who have to make those infrastructural investments. Does that make sense?

Arien Malec – Change Healthcare – Co-chair

That makes total sense. And to people who have followed some of my meandering thoughts, with regard to what 21st Century Cures obligations providers now have, there's a possibility that 21st Century Cures placed obligations on provider organizations to respond to access exchange and use data for all permitted purposes, which is a brand new obligation, with penalties associated with it that adhere to provider organizations. And if that's true, then, addressing the compliance burden associated with 21st Century Cures might be the business model that drives more people into the fold. I'm not sure that people have recognized that 21st Century Cures may or may not have had that obligation. If 21st Century Cures does not have that obligation, or if the obligation is just for treatment based use cases and some additional permitted purposes, then, the fee structure issues that we talked about might get in the way of establishing sustainability and governance.

So, there's, certainly, some thoughts that I've articulated in the past via Twitter and others. Given the time, we have four more minutes, we're going to talk about next steps. So, we're going to go dark and silent for a week. And we're going to put together the really incredibly helpful and articulate conversations that we've had over now eight hours of meetings and their transcripts. And we're going to summarize that into a few pages of recommendations to ONC. In my experience, that process is somewhat painful. And we're going to have to go through a process of reviewing those recommendations as a group. I'm going to take on the obligation of writing the recommendations. Denise is enjoying the sun in Mexico, so I'll be sending her drafts. But we're doing the first draft of this. But we're going to need a lot of thought and a lot of review. So, I'm going to try to make sure that the recommendations come out probably early on the weekend, on Friday or early on the weekend with adequate time for people to review.

As a request, if you have additional thought process, please send them to the email addresses that you see on screen. Myself, Denise, Zoe, and Lauren, and we'll make sure that gets into the drafting process. Otherwise, I'll try to get out the draft recommendations by Friday or early Saturday, so that they're available to this group to review. And I would expect us to spend a fair amount of time reviewing those recommendations and doing, in some cases, voting in areas where, as we previously discussed, that

we're split. So, that's the flow and sequence. If there are any questions about that, speak up. Otherwise, we have three more minutes, and we'll close out a little bit early. All right. With no other questions on the table, we're going to close a couple of minutes early. And, as I said, I see some recommendations coming down the pike towards the end of this week. Thanks so much. Bye.

[End of Audio]

Duration: 87 minutes