# Trusted Exchange Framework and Common Agreement Task Force

Transcript
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Virtual Meeting

## SPEAKERS

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

Hi, everyone. Welcome to the TEFCA task force. We have a full agenda today so we will dive right in. So far of the members, we have John Kansky, Arien Malec, Carolyn Petersen, Sheryl Turney, Sasha TerMaat, Cynthia Fisher, David McCallie, Mark Savage, and Grace Terrell. Are there any other members that have joined? Okay. We'll circle back a little bit later. At this point, I will turn it over to our co-chairs, John and Arien, to get us started.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Hello. Good afternoon or morning. Thanks for joining today. The plan is we're going to start off with an overview of the modalities from Alex Kontur for about 10 minutes to get that loaded in RAM. And then, we want to spend the rest of that hour working through any questions or discussion on modalities. And then, we're going to try to manage our time to pick up where we left off on the discussion matrix with individual access services. So, with that, Arien, any clarification or addition to that?

**Arien Malec - Change Healthcare - Co-Chair**

No. I think one of the things we discovered after the call yesterday is that there was the difference between the definition of directed exchange or targeted query and broadcast query. And then, specific sections that talk about the functional requirements. So, I think it's probably worthwhile to understand the functional requirements and then, now those interact with the definitions. So, we wanted to make sure that we got a good overview of those topics and then, to inform our discussion and recommendations.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Okay. Alex, fire when ready.

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**

All right. Real good. We'll get to the first slide. The first of the exchange modalities slides. Yes, thank you. Okay. So, as Arien mentioned, we did have a long conversation on the last task force meeting about the exchange modalities. But we didn't get into some of the sections of the MRTCs and/or QTF where some of the functional obligations for actually performing those modalities are written out and explained. So, we just wanted to cover those really quickly today just to give everybody a little bit of level setting and context about what we mean when we talk about query and broadcast delivery. Just as a reminder to everybody, the MRTCs and the QTF do include functional obligations that relate to intra QHIN behavior. So, again, that's the action that a QHIN takes to manage these things within its own network. But we have not dictated implementation.

So, we have not determined what a QHIN must implement or how it must implement these capabilities. The QTF is also a starting point to elicit feedback from the recognized coordinating entities. So, any of the standards that you see in there are not meant to be the final set of standards or specifications that this goes out with eventually. The RCE will have to take on the QTF and make changes as needed. Just at a very high-level kind of what is our intent for these exchange modalities, broadcast query is when you don't know where the

patient's data is and you're looking for all of the information about that patient that you can get. Targeted query is a more narrow use case. Either you know, generally, where you want to obtain data from or you specifically know a piece of data that you want and you know where it is.

Message delivery is for when you care about getting data to a known destination, even if you don't necessarily care about how it gets there. The language describing the obligations for the different entities under TEFCA, so QHIN's participants and participant members, is generally found in Sections 2.2.1 for QHINs, 7.1 for participants, and 8.1 for participant members. And so, a lot of what I'll cover comes from those sections. Next slide, please. I've also divided this up between the query functions and the message delivery functions. So, if we want to pause after the query sections just to talk about query, we can do that. If not, let me know and I can continue straight on to message delivery.

**Arien Malec - Change Healthcare - Co-Chair**

We should probably talk about query.

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**

I figured. All right. So, I started with the participant member first just because they have, I guess, the smallest set of obligations. However, you'll see that a lot of the language across all of the different entities is similar, if not the same. And so, for the most part, participant members have to do what participants in QHINs have to do. But because they're sort of the theoretical end of the chain, they just have a slightly lighter lift. So, we can break down query into, I guess, two components. Initiating a query and responding to a query. So, for a participant member to initiate a query, it has to be for one of the exchange purposes defined under TEFCA. And that query request has to be, or the query has to be consistent with applicable law.

The participant member can initiate a query on its own behalf. So, think of a provider at a provider organization who is looking for data. Or it can be on behalf of an individual user for individual access services. So, again, that's the use case of getting the patient their data, whether that's through a mobile application, a portal, what have you. In responding to a query, a participant member is required to provide all of the electronic health information in the current USCDI as long as that electronic health information is available, appropriate, and relevant to the specific exchange purpose, permitted under applicable law, and meets the minimum necessary requirements, which were imported from HIPAA. There is a little caveat here where if the participant member is only providing individual access services, they do not need to respond to queries for other services.

So, they would only have to respond to queries for individual access services. And, again, since the QTF does not dictate any of the intra network activities, it does not require participant members to implement any specific standards to handle query. Next slide, please. So, participant will look very much the same. To initiate a query, it must be for an exchange purpose and it must be consistent with applicable law. The participant can initiate a query on its own behalf in which case it must only look for the minimum necessary information on behalf of a participant member or on behalf of individual access services. When responding

to a query, a participant must request electronic health information from the folks lower down the chain. So, from any appropriate participant members. And then, it has to transmit those responses back up to the QHIN that asked it of information.

It also has to provide if it serves and maintains any electronic health information. It has to provide any or all electronic health information that it stores or maintains in the current USCDI. And, again, that's all electronic health information that is available, appropriate, and relevant to the specified exchange purpose, permitted under applicable law and meets the minimum necessary requirements. As with a participant member, if the participant is only providing individual access services, it does not need to respond to queries for other exchange purposes, only individual access services. And, again, like the participant member, it is not required to implement any specific standards under the QTF as currently drafted. Next slide, please. QHIN's, again, to initiate a query, it must be for an exchange purpose and consistent with applicable law.

The same language that you'll find in all of these cycles. It can be initiated by the QHIN on its own behalf in which case it must meet the minimum necessary requirements on behalf of a participant or on behalf of an individual user for individual access services. So, again, very similar to the participant members. When responding to a query, the QHIN must request electronic health information from lower down the chain. So, that's the participant, in this case, because that's who the QHIN has a relationship with and then, transmit any response it receives to the QHIN that initiated the query. If the QHIN stores or maintains electronic health information, it must provide all of that electronic health information under the current USCDI, again, if it's available, appropriate, and relevant, meets applicable law, and complies with the minimum necessary requirements.

The QHIN must also deliver the results. So, if the QHIN is broadcasting out, for example, and receives a bunch of information from different other QHINs, it must deliver those results back to the participant or individual user who initially requested the query. Next slide, please. On the technical side of things, we have proposed standards for when QHINs interact with another QHIN. So, again, this is the inter QHIN stuff that's in the QTF. IHEXUA profile, which uses SAML to convey the exchange purpose, IHEXCPD to do patient matching requests and response transactions, and IHEXCA for document discovery and retrieval requests and response transactions. There are also some functional requirements where we have not necessarily specified a particular standard.

For example, a QHIN has to be able to accurately resolve requests to match patient demographic information with patient identities under its domain. It must also be capable of locating the records for those patients, and some other functions as needed. In most cases, these are really to operationalize the IHE transactions in the event that the QHIN has implemented some other standard or specification within its network and, therefore, would need to kind of convert between standards. Also, some functional things like making sure that you're asking the appropriate QHIN the appropriate question. So, if it is a targeted query, you don't ask everybody. Obtaining patient demographic information from the query request, obtaining those query parameters and then, just processing all of these transactions.

And there are a few other things in the QTF but I didn't want to just list everything that was there. So, I think that covers, at a very high level, what has to happen for queries. So, I'll pause there and open up for discussion.

**Arien Malec - Change Healthcare - Co-Chair**

I've got a number of questions but I suspect that David will have his hand raised, which he does.

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

Sure. First off, that was an excellent summary. I really appreciated the clarity in that. One of the things that I think that some of us have gotten tripped up on is the use of the word broadcast, which the way you presented is a functional requirement. But some of us hear that as a technical means of achieving the functional requirement. So, maybe we should make a mental note to keep separate the notion that broadcast is describing a functional expectation that you go find the data elsewhere but it's not necessarily saying that the way to do that is to broadcast the query to everybody. I think some of us think that would not be scalable to broadcast the query to everybody. So, that's kind of Comment No. 1.

And Comment No. 2, again, sort of to help me clarify my own confusion is you have used the term record location to refer to intra QHIN requirements that the QHIN has to know where the data is. Some of us have used record location as an inter QHIN issue so that instead of having to "broadcast" to all QHINs, you would use record location knowledge to only request data from QHINs where you know that it has data where the QHINs know amongst themselves where the patient has data. So, I'm not offering a suggestion for how to change it but just to say clarifying the word broadcast as a functional requirement the way you're using it and the words record location service is an intra QHIN the way you're using it, even though I think some of us use it as an inter QHIN. I don't know. Does that make sense, Arien? I know you and I have thought about this a lot in prior –

**Arien Malec - Change Healthcare - Co-Chair**

Yeah. I have a whole bunch of queries – questions along the exact same lines. I want to go to Mark first because he's in the cue. And then, I'll jump in.

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

Thanks so much. Alex, I want to understand a little bit more about the electronic health information, the USCDI, the way your slides explain it, the requirement, maybe the limitation is the exchange of what's in the US Core Data for Interoperability, EHI, electronic health information, the way I use it is generally a broader term. I just want to make sure. This is a narrow scope to the US Core Data for Interoperability. That's a minimum requirement. Is that also a limit? Could somebody exchange more?

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**

Right. It is not a limit. It is only the minimum requirement. So, everybody is obligated to respond with this standardized data set. You do not have to respond with more but you can.

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

Okay. And is there – can you point me to where in the document is the encouragement to exchange more if you have it and can?

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**

I don't believe there's a specific place encouraging that unless you'd find some sort of language in like the test portion because these are contractual terms. We wouldn't want to necessary put encouraging language in. We certainly just want to talk about the obligations.

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

Okay. Thanks, Arien. I'd like to flag that as a small issue at some point.

**Arien Malec - Change Healthcare - Co-Chair**

And for me, this is also related to the relationship between the TEFCA and information blocking. So, under the TEFCA, I've got to potentially only respond with USCDI. And under information blocking, I have different obligations and aligning those, I think, would be interesting. So, I'm going to go back to this question. First of all, again, thank you for the overview. And I made the mistake of just looking at the definition of targeted exchange and broadcast exchange and didn't look at the functional requirements. And just as sort of a didactic or explanatory mechanism, I suspect, to David's point, that the terms are actually tripping people up because they map on their own expectation. But I do have a question about the actual terms.

So, my understanding, when I read the functional requirements, and I think if you can go back, maybe it's this one or the previous slide, if I look at the functional requirements, if I'm a QHIN who receives a request, it's my obligation to appropriately identify all of the sources of data that are responsive to that request. So, functionally, I either spray and pray or I have to implement a record locator service in order to meet the functional requirements. So, first of all, let me just pause and make sure that I've understood the functional requirements appropriately. If I'm a QHIN and you ask me for data about patient Joe Smith, and I say I don't know any data about patient Joe Smith but I don't have any functional means of identifying where Joe Smith's data might be in my domain then, I'm not actually responsive to the functional requirements of the QHIN. Do I understand that right?

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

Hey, Arien. It's Steve. I'm joining you all cameo for at least the next 40 minutes. So, this is an area where, given the stage of maturation of which we are along the way in terms of getting the RCE on board, I would say largely what you described seems fair. We've tried to allow for the QHINs to optimize their network and how they achieve the QHIN functions that we believe the QHIN needs to perform within their HINs perhaps with some guidance from the RCE et al in terms of overall network participation.

So, maybe getting back to your question, if I were a QHIN and you were a QHIN, if I received a request from you to find data on Alex, how I go about finding out who in my network has

Alex's data, I'm sure you and David and others have many different ideas about how that could be done most efficiently, we weren't, at this stage, ready to prescribe a particular one way that that be done. Maybe I'll pause there. Does that help answer your question?

**Arien Malec - Change Healthcare - Co-Chair**

I understand that. I'm really just looking at the functional requirements. You're not telling me how but if I don't have any means for identifying where Alex's data might be and I just respond no then, I'm not really a QHIN. At least functionally, as part of a QHIN, I've got to have the means to identify where Alex's data might be amongst my participant members and participants to do the job of a QHIN.

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

There's an alternative, I suppose, just to play it out in hypothetical would be that let's say that I'm more of a thinner client QHIN and I impose that obligation on my participants or I would say you three participants go find me this data. And maybe that's a hybrid between your spray and pray and having something more optimized in record locating.

**Arien Malec - Change Healthcare - Co-Chair**

Exactly. So, I'm not presupposing that a literal record locator is functionally required. But if I don't have a literal record locator, I do have to have the means to delegate that responsibility downwards whether that's through spray and pray or through, in your example, maybe I'm a federation of a bunch of local HIEs and I go ask the local HIEs. But if I don't do that activity then, I'm not meeting the functional requirements of a QHIN

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

Yeah. I think Alex and I are shaking our heads. That seems fair. And I think we are at the point where that kind of functional responsibility, let's call it, could be more prescriptive over time as the RCE comes on board and multiple other actors in the field get involved in what the MRTCs and QHIN technical framework requirements should be. Things could lean one way or the other or it could be more open-ended, as you described, so long as when you send me a query, I can respond back to you and you don't really care how I got it done under the hood.

**Arien Malec - Change Healthcare - Co-Chair**

Notwithstanding that I think the term targeted query and broadcast query are confusing as defined, I read an obligation under targeted query to go ask the QHINs that I believe have the patient's data. But I don't read an obligation to identify particularly the participant or participant member who does or doesn't have that data. Do I have that understood correctly? The definitional difference between targeted query and broadcast query in the MRTCs is that targeted query asks one or some subset of QHINs and broadcast query asks all QHINs. And then, it was just read to me that here record location, maybe it was different, but if I do a targeted query then, I've got to have the means of identifying which QHIN I go ask. As I said, I don't read the functional requirements to identify the participant or participant member. And maybe I've got that wrong.

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**

Right. So, in the short definition for these things, you won't see those functional requirements. But if you do look in the specific provisions that we just discussed in2.2.1 and 7.1, there is an obligation to request electronic health information from appropriate participants or participant members, whichever it is.

**Arien Malec - Change Healthcare - Co-Chair**

Okay. And, again, I think this is an area where I may be getting tripped up over the difference between targeted query and broadcast query. In a situation where – okay, anyway.

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

Maybe to help you out here, I think, as we've all experienced, there are only so many terms that exist in the universe unless you pride yourself on creating new acronyms for people to memorize. So, if broadcast query and targeted query don't work for folks, I would encourage you to use the words, not to say that you should not **[inaudible] [00:24:48]** this description. But I think, to your point, what you were getting at, Arien, when we consider targeted query, we are talking about that subset. And of that subset, you know who you want to ask data from them from which you want to ask data.

On the interactions that we would expect to occur from a broadcast query, it would be the I have a patient that's shown up and I don't know where their data is and I hope that the network can enlighten me, for lack of a better description.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

So, there are a couple of hands up but this is John. And I'm going to sneak in a quick question on this one so sorry if it's a dumb one. So, if a QHIN – I understand exactly what you just said, Steve. But if a QHIN gets a query from another QHIN, does it know if it's a broadcast query or a targeted query?

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

We're shaking our head no. Given how we relied on the IHE profiles, I do not believe there is any specific way to distinguish those in those transactions and, therefore, the QHIN is just responding to a query. And that's part of why you don't see these obligations broken out by targeted or broadcast. And you see where it's like appropriate or applicable.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

But a QHIN receiving a non – I sound like I'm answering my own question. If it's a query from somebody who knows where the data is, it's going to say hi, here's my query and I need data from Bob's Medical Center on this patient. And if it's a broadcast query, it's going to say hi, I just need information on this patient if you have it.

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

Yeah. So, the context may be implicit for the receiving QHIN of the query.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

So, you'll be able to infer – it's not different in that it's labeled broadcast or targeted. It's different in that one would be able to infer. Thank you.

**Arien Malec - Change Healthcare - Co-Chair**

Yeah. And I have a similar maybe last line of questioning before we go to the other folks who have patiently got their hands raised. Although, when I started, nobody had their hands raised. So, there is an intermediate mode that seems to me to be reasonable where I cache locations including separate network locations of data and I don't remember the actual specific participant or participant members. I just remember the QHINs that I'm supposed to go query and also remember the QHINs where I didn't get any data. And then, as an optimization method, I might go ask just those QHINs the next time for their data. And I think that's neither fish nor fowl in the definition that you've proposed.

By definition, it's not broadcast query because I'm not literally asking of the QHIN. But by definition, it's not targeted query because I don't identify the location of participant or participant members, to John's point.

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**

So, definitionally, targeted query – the complicating factor here is that we've got this sort of tree structure of networks. And if you look at sort of the space that we're playing in, we're really just talking about at the QHIN level in a lot of these cases. The targeted query definition has nothing to do with participants and participant members. It's, literally, asking a question of another QHIN. And then, that QHIN is obligated to go and do certain things to get the data from within its network from its participants and participant members. So, a broadcast query, I think, one of the things we're kind of dancing around here is not that every node in every network needs to be queried. It's that all of the QHINs need to be queried and then, they need to figure out where the appropriate data lies and get that back to the initiating QHIN.

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

Or just to piggyback on Alex's point and this is kind of where I think you're going, Arien, that there may be kind of a layer in the middle there where, over time, QHINs become more intelligent. And that would be a flexibility that I would say the RCE should discuss or would be in a position to hep orchestrate to determine that intermediate mode that you're discussing where I've done a thousand queries and I have a good sense of what the network topology looks like and that this is how I want to get the data back as efficiently as possible.

**Arien Malec - Change Healthcare - Co-Chair**

Okay. Thank you. Super helpful. Laura and then, David.

**Laura Conn - Centers for Disease Control and Prevention - Member**

Hi, it's Laura. Thanks. I just wanted to circle back just a minute. I'm sorry you jumped into this other topic. Back on the USCDI question of being minimum and just to ask a clarifying question based on the appropriate and applicable. At times, it might be less than the USCDI if the request didn't meet the minimum necessary or applicable law. Am I interpreting that correctly based on the language on the slides?

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**
Correct.

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

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**
And the language also accommodates, Laura, for instances where you don't have that data available generally depending on who the end point is.

**Arien Malec - Change Healthcare - Co-Chair**
Right. And I think Mark was asking the opposite of that question so I think these are important distinctions. I think Mark was asking the opposite of that question is that if I ask, for example, on behalf of a patient via patient access, almost by definition there's no minimum necessary. And the bound of data that I might be asking for might be broader than the USCDI. Likewise, if I ask for population health mechanism and social determinants of health or activities of daily living or otherwise are contained in unstructured documents, it might be appropriate for the respondent to surface up those unstructured documents. And Mark, I think, was asking whether that was permitted or allowed. And I think the answer is yes. And it's, actually, required relative to information blocking, which is, I think, maybe some of the recommendations we might want to consider. David?

**David McCallie, Jr. - Individual - Public Member**
Yeah. I've got a long list of things I'd love to talk about. I'll try to be parsimonious here. One high-level thing is I found it very useful in Alex's presentation to distinguish between inter and intra from QHIN responsibilities. And Arien, when you asked your question, it wasn't clear to me sometimes whether you were talking about inter or intra. So, that abstraction of the QHIN representing to the outside world a group of participants and their obligations to the outside world is useful. But we just should be careful to distinguish is this the QHIN responding to another QHIN or is this the QHIN acting on behalf of an internal obligation to its participants reaching outward? So, inter and intra is an important distinction to keep in mind there.

That's No. 1. And No. 2, I'm really happy to hear the notion of these abstractions are being deferred for technical details to the RCE. I think you can tell from the complexity of this conversation that that's the only way you're going to get a really robust implementation is to have stakeholders with deep understanding has out all of those gory details. So, I commend you on that. I think some of us have the concern that, and this is kind of my Point No. 3, that one of the ways the systems are being used today, at least in the company where I used to

work, is for every patient in let's take an ambulatory setting, before the patient shows up, a query is done to the network to fetch the federated record, which is then internally processed and matched against what's known about the patient in the local EHR. And then, the clinician gets a display of here is new stuff you may not know about.

Here's stuff that's happened since the last visit, however they want to pitch it. But the net is every patient encounter or at least a high percentage of patient encounters will, in fact, could, in fact, generate these queries that need to go to every other QHIN because you don't know where the patient has been since they were in last. You haven't even talked to the patient yet. This is all getting triggered in a midnight run based on the clinic schedule. So, the concern, from a technical point of view, about broadcast is that you could, in a sense, have every QHIN responding to every patient visit in the country every time a patient visit occurs. And that would get really difficult. I think, Arien, you calculated out some quadrillion transactions or something that that would result in.

So, I think that's why the concern is about this notion of broadcast, what do you mean. And you're not telling us how to solve that scaling problem but just that you need to solve it. The RCE needs to solve it.

**Arien Malec - Change Healthcare - Co-Chair**

Yeah. And by the way, just, David, to your first point, I get confused and got confused in Alex's presentation about whether participants and participant members are leaky out of the boundaries of the QHIN relative to targeted query or whether QHINs effectively provide an abstraction boundary that says you don't even know where what general hospital is. You just ask me and I go figure it out.

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

That's a hugely important distinction. I think, Steve, you know that care quality today to take one example of a targeted query implementation would bypass the QHIN because the address of the target is known from the dictionary, from the directory. So, this proposal that you've got on the table would change that and say you have to go through a QHIN. And I'm not sure that's a good idea. I don't know. I think that's a technical detail that's important but maybe beyond this conversation.

**Arien Malec - Change Healthcare - Co-Chair**

All right. I do not see any other folks with their hands raised. Let me see if I can pull the sense of the task force, which is I believe that there is a sense of relief relative to the MRTCs and the functional obligations and better understanding the functional obligations of QHINs. There is still some confusion relative to the obligations under "targeted query" and "broadcast query". In particular, how leaky the QHIN is relative to directory services and identifying participant members and participants' obligation under targeted query. And then, I think a general comment that it might be more useful to drop the distinction of targeted and broadcast and simply require a QHIN who is doing a query to query if the QHIN knows that – anyway.

I could drive some solutions but I won't. But there just may be some confusion around the

use of targeted query and broadcast query. And it might be better just to put the QHIN's functional requirements front and center and defer some of these distinctions as targeted broadcast when I query who I query at what time relative to QHIN status. So, I think that's the sense of the task force in terms of the reaction to the presentation and some of the questions associated with the presentation. I'm just going to pause to make sure that there aren't other – sorry. And then, I think there is – we had a reasonable discussion about USCDI, obligations to minimize data relative to USCDI, obligations to maximize data relative to USCDI, and the link between the TEF and information blocking, in particular, relative to obligations under USCDI.

So, I think those are the key discussion topics that might inform recommendations. I'm going to pause to make sure that I haven't missed anything. And on cue, there's David.

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

Yeah. I think this is a question that we touched on way back and I don't think it's a technical question but it's a policy question just to not forget about the asymmetry that is permitted for participants acting on behalf of individuals that they can query but don't have to respond. I think there are some open questions there that I would just cue up for downstream maybe that got mentioned briefly in Alex's presentation. Arien, does that make sense? We talked about, for example, if you were a PHR kind of service and you wanted to respond for certain kinds of direct treatment, were you allowed to? If you responded to some of them, do you have to respond to all of them? Is it legal to be a suck completely and never respond to anything but just consume? There were some of those questions I think we raised earlier.

**Arien Malec - Change Healthcare - Co-Chair**

Got it. Yeah, relative to participant and participant member obligations. I think we understand the QHINs are obligated to do all of the things.

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

Yeah. It's the IAS subset that –

**Arien Malec - Change Healthcare - Co-Chair**

Yeah. And the IAS subset, just to restate, is relative to participant and participant member obligations, not relevant to QHIN obligations because I think that's been a point that I've been confused on in the past. Okay.

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

Yeah. There's nothing that would stop a single participant QHIN from getting created under the current rules.

**Arien Malec - Change Healthcare - Co-Chair**

Yeah. But if you're a QHIN then, you're under the QHIN obligations and you're expected to respond to everything. Whereas if you're a participant or participant member, there's the – it would be funny, I think maybe your hypothesizing QHIN that's the outer boundary and a participant member that's the inner boundary. And the QHIN has to ask for everything and

the participant member, basically, doesn't respond to anything, except for IAS queries.

**David McCallie, Jr. - Individual - Public Member**
Right.

**Arien Malec - Change Healthcare - Co-Chair**
Yeah. We're hackers at heart and so, we're always thinking about how do you break the rules.

**David McCallie, Jr. - Individual - Public Member**
Speak for yourself.

**Arien Malec - Change Healthcare - Co-Chair**
Some of us are thinking constantly about how you break the rules. All right. I see no more questions in the cue so maybe, John, I get to delegate over to you and we get to deal with – I think we're going to IAS.

**John Kansky - Indiana Health Information Exchange - Co-Chair**
Message delivery.

**Arien Malec - Change Healthcare - Co-Chair**
Oh, we forgot message delivery. Of course. Let's talk about message delivery.

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**
All right. This should be pretty quick because, again, a lot of this is very similar to what we saw in the query side. Participant members to initiate message delivery, again, must be for an exchange purpose and consistent with applicable law. The participant member can initiate a message delivery on its own behalf in which case it must meet the minimum necessary requirements or on behalf of an individual user for individual access services. When delivering a message, the participant member must send the electronic health information to the appropriate individual user and must return an automated response to the participant. So, whether that is the response generated by the individual user or the participant member generating a response if the message was delivered to the participant member, that all has to flow back up to the participant.

We will note that the data being exchanged under message delivery is not limited to the USCDI data set. So, we were talking about all electronic health information in this case. And, again, participant members are not required to implement any specific standards under the QTF as it's currently written. Next slide. Participant, very similar to participant member, initiating a message delivery, again, must be for an exchange purpose and consistent with applicable law. The participant can initiate it on its own behalf meeting the minimum necessary obligations on behalf of a participant member or on behalf of an individual user for individual access services. The delivery response, again, sending the electronic health information to the appropriate entity, whether that's a participant member or individual user.

And then, returning those automated responses back up to the QHIN. Again, not required to implement any specific standards by the QTF. Next slide. QHINs, again, initiate delivery for an exchange purpose and consistent with applicable law. They can do it themselves, they can do it on behalf of a participant, or they can do it on behalf of an individual user. If they do it themselves, they have to meet the minimum necessary obligations. When they receive a request for message delivery, they have to send the electronic health information to the appropriate participant or individual user and return an automated response back to the QHIN that requested that delivery. They must also return automated responses that they've received to the participant or individual user that is the end of the chain, so to speak, for that message delivery just so that the participant and individual user would, for example, know that they're message has been received. Next slide.

So, on the technical side, again, we've got IHEXUA using SAML to convey exchange purpose. This is the inter QHIN activities. And IHEXCDR for the actual message delivery transactions. Internally, the QHIN functional requirements include patient identity resolution. I believe there is something in the XCDR or XCR spec, which it's based on that talks about patient matching the data that you're sending. And then, there are other functions, again, similar to operationalizing these IHE transactions, which is determining who you're going to send the message to, what other QHINs, actually obtaining the documents and metadata from the entity that's requesting you to send a message, and processing all of these transactions.

**Arien Malec - Change Healthcare - Co-Chair**

Before I let David in, I've got one question, which just relates to whether participants and participant members are leaky out of QHINs. And I think so far proposed they are not, which leads me to believe that I get a message as a QHIN from a participant or participant member, it's my responsibility to figure out the one and only one other QHIN that I should send that message to with any other metadata that I might have that might have some information on location it should be sent to. But I don't have any obligation to maintain that in any structured form. And then, the obligation of the receiving QHIN is to take a message delivery and figure out what to do with it where figuring out what to do with it involves, I think, sending it to the appropriate participant or participant member or I would assume also throwing my hands up and sending back that I can't deliver this message.

So, first off, this is where I get confused between the QHIN to QHIN boundary and the participant to participant boundary. Am I thinking about this the right way just thinking about QHINs as an abstraction that don't expose necessarily participants or participant members in a structured way and so, as a QHIN, when I get a message delivery message, I'm obligated to figure out what QHIN to send it to, send it to that QHIN and then, obligated to deliver the message receipt back and that's the extent of my obligations? Am I understanding that correctly? And then, as a receiver, I'm obligated to figure out which participant or participant member sent it down to and not necessarily bound by what was in the address or addressing information that I received. So, do I understand that correctly?

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

This is Steve. So, maybe I'll chime in here and Alex can always correct me. So, and this gets to perhaps you and David were having a mind meld on what you view as the type of leakage that's occurring, which might be helpful to clarify for everybody else. And I think you can tease that out in part as I react to your reactions, Arien. So, often when I torture Zoe and Alex about this, I write on my whiteboard who and how. And when you know who you want to send it to and how to send it, you don't need TEFCA, you don't need QHINs. And so, if you have an existing method that works for you to send data from Point A to Point B and you know how to do it and you know who to send it to then, you can use whatever you want.

If you choose, let's fast forward, and if all of this network infrastructure is fully created and operational, if you choose to use the QHIN exchange network as we kind of colloquially describe it because that's just part of your workflow and it's easier then, by all means, go ahead and do that. But in instances where you know who you want to send it to but you don't know how, that's where we envisioned at least one role for this QHIN to QHIN interaction to occur. And there are a lot of built-in functions that we already explored with query that would be reused to help QHINs process message delivery across. So, I don't know how to get to you the data that I want to send you, Arien, but I have a QHIN.

So, I'm going to send them the data and I'm going to say figure it out. Get this data over to Arien. Use the power of the network. Here's who I want you to send it to. Does that help?

**Arien Malec - Change Healthcare - Co-Chair**

Yeah. So, just to use an example, I might form a QHIN for the purposes of public health. And that QHIN might know all of the intricacies of how each state wants to receive its data. And the other QHIN that receives the message for public health says I'm just going to go send it over to the public health QHIN and let the public health QHIN figure it out.

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

Yeah. That would certainly be a plausible approach. You could definitely extrapolate your point to other scenarios as well. Yours is more kind of a specialized QHIN. But there could be other instances where let's say there's a – I'll pick them myself. Let's say there's a federal QHIN and everyone just knows if there's a federal agency that is the destination of your data then, all of the QHINs know to shoot it over to the federal QHIN and they'll figure it out.

**Arien Malec - Change Healthcare - Co-Chair**

Yeah. So, if I send a referral response report back to VA, I just go send it to VA and VA figures out where it goes. I'm struggling a little bit over the who and how. So, I think you said that the functional use case for message delivery is I know who but I don't know how. But I think I know who in the sense of what QHIN but I don't know who in the sense of what organization, at least not in a structured way. I might say this should go to Hospital XYZ but I don't have the web services endpoint that the actual who relative to technical delivery that's the –

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

Right. You as a sender wouldn't have all of that detail but you would say I'm referring this patient to cardiologist Dr. Joe. And I would send that up to my QHIN and then, my QHIN

would just take care of it for me. I'm sorry to make it so oversimplified. But I would give them the requisite addressing information for them to identify what QHIN Dr. Joe is a part of and then, my QHIN would get it to Dr. Joe's QHIN and Dr. Joe's QHIN would get him the data however that intra QHIN stuff works. And that would be not prescribed per se so they could use any type of transactional flow that they so choose to use.

**Arien Malec - Change Healthcare - Co-Chair**

Okay.

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

Let me jump in there because you moved my cheese a little bit. So, I know who I want to send the message to but I don't know how. So, I send it to my QHIN. But it turns out that the person that I want to send it to is not participating in the TEFCA ecosystem. That could happen, right?

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

Sure. And that would be unfortunate. That's certainly a risk with any network, right. There are people that weren't on Prodigy when I was on Prodigy and wanted to send an email to them on some other network for anyone who wants a tech throwback, Tech Throw Back Tuesday. But provided there is a sufficient amount of participation, our hope would be over time that would occur less frequently. But, certainly, there could be pockets of the US, let's say, that would not be part of it. And as I get back to earlier, there are certainly other transactional approaches that exist today to do – and I don't want folks to get hung up on message delivery and interpretation of what message is. It's like we could just call it data delivery. You know the destination that you want to send the data just like I want to send you a package.

I want to send Arien a package. Here is the information that I want to send to him. It could get put on the back of a bike courier and then, get tossed in a truck and then, get put on a plane and then, get put on the back of an alpaca and it makes it to Arien. I don't know how it got there but it did. And that's kind of the beauty of the network. I'm sorry I'm being a little colloquial but, hopefully, that helps with the conversation.

**Arien Malec - Change Healthcare - Co-Chair**

Got it. Okay. So, we've got David, Mark Roche, and Sasha who all have their hands up. And Sasha is asking the same question that I was going to ask in follow up so I will refrain from asking that in follow up, go through that in order. And I think we want to get to individual access at the top of the hour, which gives us four minutes to get through some of these questions, which I suspect we'll go a little bit over but we'll try to time limit and make sure that we do our usual go abroad before we go deep. This is our first pass deep. David.

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

So, I think it's well known that I think this is a disastrous part of the TEFCA proposal because we already have a network that accomplishes these goals, as well as these requirements,

would accomplish those goals. And so, I can go deep on that but we don't have time. But I will say NS Direct, obviously. So, if you substituted HISP for QHIN then, Direct meets all of these requirements today. And it's hard for me to see how this would be any better than what we have with Direct. And it's very easy for me to see how it could create chaos because or means and to the vendor community. If one has to offer both choices then, the vendors have to do the double work. And now, it's going to get really confusing as to how to get messages from one place to another.

And they'll probably just drop back to the good old fax machine because they understand how that works. A more subtle point, which may be a more relevant point both for direct and for this proposal is if you're going to send patient information to some other place, you better know where it's going and who is going to get it or you're in breach, which is a big deal. So, that means the directories that you will consult when you pick your target have to correspond to an entity prepared to receive the information. And if the entity is prepared to receive the information then, the directory can contain sufficient information to get it to them. That's how direct works. And the big problem with direct has been a lot of providers aren't willing to expose an inbox, an open-ended inbox, because they don't know what that will do to them, to their workflow, to the staff required to man it and distribute it internally and take responsibility for follow up, etc.

This doesn't solve that problem. You can't be in the directory unless you have a dedicated system prepared to respond to inbound patient information coming in. Otherwise, you're creating a breach opportunity every time somebody pushes up to the QHIN and says get it to employees. You have no idea where it will go. Sorry for the rant. I feel strongly about this one.

**Arien Malec - Change Healthcare - Co-Chair**

All right. We're going to go to Mark Roche and then, Sasha.

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

Hi. This may be in addition to the question that's just been asked. Does TEFCA plan to provide a centralized directory off all of the participating providers and healthcare institutions so that I'm a provider and practicing in Hospital A, I know which hospitals and providers are covered within TEFCA network and which ones are not?

**Arien Malec - Change Healthcare - Co-Chair**

I'm going to take a first pass response to that, which is the directory services are not one of the TEFCA obligations. There's no obligation, as far as I understand, for a QHIN to publish its own directory of endpoints, which is why I think this discussion of message delivery ends up being hey, other network, I'm getting you this thing and I'm giving you as much information as I've got. And it's your responsibility to deliver it to the end point. But we don't actually have a directory that exposes endpoints. I'm just going to pause there to make sure I understand that. And maybe, Sasha, I'll let you ask your question because I think it's a similar one.

**Sasha TerMaat - Epic - Member**

Yeah. So, I guess I was responding to some of the earlier descriptions about if you know who you want to send to but not how to send there then, presumably, you don't have something like a direct address. And I was just trying to understand if the necessary amount of information for addressing uniquely is something that is standardized or left to each QHIN to determine because I was trying to parse through how one QHIN would communicate with another with a non-standardized amount of information for uniquely identifying recipients.

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

This is Steve. Maybe I'll pick it up here. So, this is an area that was a change since the last – or I should say a transactional contact step changed since the last version of the TEFCA documents that we put out and that was in response to public comment. As David knows and all of you are well aware, ONC has been a participant, supporter, etc., of directly related transactions as part of certification. And all of that considered, we still received considerable feedback from a portion of the community that they didn't feel like the trusted exchange framework common agreement would sufficiently represent their interest if it didn't include some way of using the network to make point-to-point transactions a reality. And so, that was our interest in including that.

And there are some issues, as you all are rightfully pointing out, that will need to be solved both from a policy component aspect, which I would say is a little bit simpler than the query side. But on the technical side, to not make matters worse and I think there's definitely a value proposition question in perhaps a broader part of the community that you need to fully consider and be part of existing exchange mechanisms or the community that's putting forward the existing exchange mechanisms to better understand why the folks that wanted message delivery as part of this work, why their needs are currently unmet and that they suggested to us that it would be important to include in the QHIN technical framework and MRTCs.

But back to Sasha's point and I think it's piggybacking on Arien's, there are certainly a few other technical issues that would need to be resolved. And, again, not that we were deferring everything but we wanted to set up the structure and the skeleton for the RCE to take the subsequent feedback that we would receive during this time period and start to wrestle with how to either improve on existing services or make something that would work among QHINs that could be more specialized or solve particular use cases. Those are certain avenues that could still be pursued by the RCE.

**Arien Malec - Change Healthcare - Co-Chair**

Okay. David, one more question you get and then, we swap it over.

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

Just a suggestion to Steve and to the TEF team is independent of this workgroup, I think it would be a really good idea for you guys to talk to Scott Stuey or someone else who represents Direct Trust about some of the use cases that you're trying to address, the ones that came up because they've wrestled with all of those. And they can tell you what makes them hard or what the issues are. And, as usual, they aren't technical issues. They aren't

going to be solved by new technology. So, just be sure you get input from them. I assume you have already but I had a recent conversation with Scott about public health concern and Noam has agreed to meet with him and some of the Direct Trust members who are serving the public health entity in certain states to make sure they understand what is possible and doable with technologies that we have today. So, just be sure you get their input before you go into final mode.

**Steve Posnack – Office of the National Coordinator – Executive Director, Office of Technology**

Yeah, much appreciated, David. And I would ay you definitely touched on one stakeholder group that was more vocal than others about the need for message delivery to be part of this trusted exchange framework ecosystem.

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

Yeah. That is underway in public health for sure. And it may not be widely understood so it behooves to learn about it, I think.

**Arien Malec - Change Healthcare - Co-Chair**

All right. So, I'm going to turn us over to – yeah, go ahead.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Yeah, it's John. While we still have Steve and before he drops, I wanted to see if I could sneak in –

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**

He just left the room.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Is he gone?

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**

Yeah.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Dang, that guy is quick. So, maybe someone else from – it's not a Steve specific question. I was just going to put the hot lights on him for a second. And maybe somebody else from ONC can take this one. It gets to the broad question that we started with of the overall purpose and policy goals of TEFCA. So, I understood Steve to say, on the one hand, don't use the QHIN exchange network if you have another way to achieve your messaging goals. Are you talking specifically to a message transaction? I know who I want to send it to. I know how I can send it to them. I don't necessarily need to use my QHIN.

On the other hand, when I brought up a physician or a provider or whatever somewhere who might not be participating in the TEFCA ecosystem, his reaction was well, gosh, I hope there

aren't many people who aren't part of the TEFCA ecosystem. So, it's not necessarily a contradiction but I'm trying to develop my instincts on how we envision the QHIN exchange network being used when there are other means that exist in the world for just about all of these exchange purposes if anyone can comment.

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**

I think I would respond to that just by thinking about the congressionally mandated purpose behind this. So, that is focus really on this network to network level and being cognizant of the fact that there is a lot of stuff out there that currently works but that it still remains siloed. So, we don't want to necessarily disrupt what exists out there but we do want to make sure that what exists out there can talk to the other entities, organizations, groups that are trying to do the same thing. So, it's kind of walking a fine line where we want as many people to participate in the TEFCA as possible because we think that will get us to fuller at scale interoperability than if they didn't. But at the same time, we're not saying that TEFCA is the only mechanism through which all interoperability, health information technology transactions should be run.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Thanks. For the record, I'm struggling with developing my intuition because, on the one hand, it seems like ONC isn't trying to view TEFCA – I'm sorry the QHIN exchange network as the backup network. If you can't do it via what you usually do, try the QHIN. Yet, at the same time, I heard, and it seems appropriate, that we want the QHIN exchange network to not disrupt those means that exist today. So, I'm struggling to wrap my head around how that's going to play out in reality.

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**

And maybe a finer point to put on it is that you would, essentially, be using – that they would be well integrated and symbiotic, existing networks and the TEFCA network, so that you're not necessarily having to follow two different workflows depending on what you get back from one or the other. Rather networks join and TEFCA is as well enough aligned with their regular workflows and operations that it doesn't require them to do significantly more to be able to do TEFCA transactions as they do their regular business if that makes sense.

**Arien Malec - Change Healthcare - Co-Chair**

Yeah. So, I think this will form, potentially, part of the comments that we would offer up. I want to make sure that we get time to start IAS.

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

Hey, Zoe, do you mind zooming in on the document and making it a little larger, please.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Thank you. That was my question as well.

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

**Lead**
Is that better?

**John Kansky - Indiana Health Information Exchange - Co-Chair**
Yes. Okay. So, we are returning to, for those of you that have flipped at least once over the weekend or those who missed the last call, what we have in front of you is the matrix of questions or discussion items that we captured in previous calls. They are tiered and we're kind of in the home stretch of the top tier with individual access services. Let's see how far we can push through the bottom of the list today and capture notes and everybody can see what we're looking at. So, we're on IAS just looking at some of the things. The definition of IAS, it's in the beginning of the MRTCs on my copy, it's Page 35 but I know there is – anyway, it's in the list of definitions. And I was wondering if anybody recalls is there confusion over the definition of IAS?

I know there were certainly bullets a couple down lower where we want to talk about. Who has to respond to queries for IAS and then, I had some questions myself that came up earlier? I think David brought them up or someone did about IAS only providers. So, I'll take a breath. Does anyone have a specific question or topic about the definition of IAS that was up for discussion?

**Mark Savage - UCSF Center for Digital Health Innovation - Public Member**
This is Mark. I raised that the way it's defined, it limits everything about what the individual does to exercising a right to access under the HIPAA Privacy Rule or addressing that a copy be transmitted to a third party when there are a whole host of other purposes for which an individual might want to use a trusted exchange framework. Patient-generated health data was one of the examples that I mentioned. But shared care planning is something that the FHIR scale task force is also working on. Those are all things where patients are participating in doing things. It's not just about exercising your right to access a copy or to transmit a copy to somebody else. So, I framed it around the definition because the definition is actually what constricts the exchange purpose for both pushing and pulling.

**John Kansky - Indiana Health Information Exchange - Co-Chair**
So, you're suggesting there isn't ambiguity in the definition but you're suggesting that the definition constrains – you're pointing out that it leaves out certain potential, I guess, I'll say exchange purposes if that's not a misuse of the term for individuals.

**Mark Savage - UCSF Center for Digital Health Innovation - Public Member**
I don't remember if we got this clarity on the last call but it may be good to just ask and level set is that an intended constraint. That's the way I read it. If that's not intended then, it is an ambiguity. If it is intended then, it's not an ambiguity.

**John Kansky - Indiana Health Information Exchange - Co-Chair**
Got it.

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

**Lead**

Sure. In individual access services, the definition is specific to the right to access and obtain the copy and then, of course, to send it to a third party. But it is constricted to access and obtain.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Thank you. I've discovered it's impossible to facilitate these calls and take any notes whatsoever at the same time. So, I'm going to rely on others. So, the patient-generated healthcare data assured that IAS include the ability – we just answered that question, correct? That is not intended to be a part of the definition as written.

**Arien Malec - Change Healthcare - Co-Chair**

The way I think about it is IAS is access only and it's read only as defined.

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

So, this is Mark. I think there are some core use cases that actually go beyond that. And so, I'm raising the question because I think we're missing an opportunity if we keep it constrained the way it is currently, however you want to tee that up as a discussion topic.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Well, I think we're there now. So, you offered a couple of examples of use cases that appear to be outside of the definition. So, do you want to expound on that or is your suggestion that well, they shouldn't be?

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

I don't think something as basic as an individual participating in shared care planning should be outside the scope of TEFCA. So, we're designing something like that. As I said, I'm in the FAS task force. And I think we're building something that's not only for the present but also for the future. We should be building in some broader capability for patients and individuals than just exercising the right of access. We're building that in more broadly for providers and for payers. This is not a big on-ramp for some and a small on-ramp for others.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Not as someone who is not familiar with what shared care planning looks like or how it plays out. Are there obstacles to – given the exchange purposes and standards that we're proposing, is this a big step outside of the box that Mark is suggesting or is it imminently doable?

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

That's quite a range. I'd like to think it's imminently doable but I'm not sure about that.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

I don't know the answer. I don't see any hands up. Yes, I do. David McCallie. Thank you, David.

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

Yeah. You can count on me. So, first off, I understand Mark's concern that it might be too limited. On the other hand, I think that it would be a major hurdle and major success if TEFCA could fulfill the read only notion that is being described. And I would suggest walk first, run later. Presumably, the RCE, amongst the stakeholders could expand their capabilities over time. But this notion that an individual should have a simple way to accumulate all of their personal health data, all of their provider managed health data that the TEFCA could provide as envisioned here is a huge step forward compared to where we are today where you have to connect with each patient portal one by one by one and remember which ones you have and have massive numbers of passwords and all of that stuff. It just is too much friction for most consumers. So, I think this is really good. Go ahead, John. I'm sorry.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Yeah. I was just going to say if I take off my chair's hat and make my comment, I was going to say that that's pretty much how I would have summarized. This is great progress and a big leap forward. I can tell you that I learned during the information blocking task force that there are plenty of folks in Mark's camp as well.

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

Oh, yeah. I think Mark's goals are admirable. I think it's just extraordinarily complex to envision an entity that would take on that responsibility. I think it's way beyond what's being envisioned for the modestly funded RCE. But anyway, so be that as it may, I want to put two edge test cases on the table just to get, I think we've brought these up before, but to get reactions as to whether they would be allowed or not. And one IAS edge case would be a consume only participant, which is an entity that could recruit consumers and say give us your permission. We'll go gather all of your healthcare data and we'll monetize it with you or for you or we'll just monetize it and give you some freebie in exchange. And would that be allowed consume only?

I think the way it's currently written it would be. And then, sort of the inverse of that is health record bank model where an entity would join a network and say give us permission. We'll fetch all of your data. We'll organize it into a coherent medical record, de-dup it, give you the ability to annotate it, etc., and then, allow you to share it back with the same TEFCA network to other providers, which would now involve a limited subset of the permitted purposes that that node would want to be offering and would that be allowed. Sort of the consume only and monetize it is Case 1 and then, the health record bank is Case 2. Are those both permitted?

**John Kansky - Indiana Health Information Exchange - Co-Chair**

So, let's take it one at a time. Is there the opportunity – is it legal, is it kosher, is it okay for an IAS participant to only pull data and not respond to IAS queries? I wanted to say I thought that one was answered. And I thought that they had to respond for IAS. Can ONC help us out?

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

**Lead**
Yes, confirmed.

**John Kansky - Indiana Health Information Exchange - Co-Chair**
Okay. So, if you're IAS, you can be IAS only as a participant on the network but you have to respond as well as query is what you just said, Zoe, right?

**Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead**
Yes. And you have to respond with the data you have available.

**David McCallie, Jr. - Individual - Public Member**
But only to IAS, right?

**John Kansky - Indiana Health Information Exchange - Co-Chair**
Correct.

**Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead**
If you're only doing IAS services then, you only have to respond to IAS. But if you have other services and you're offering treatment and quality assessment and improvement then, you have to respond to all queries.

**David McCallie, Jr. - Individual - Public Member**
Yeah. So, that's kind of a no-op in a sense that if I'm an individual and I've granted this participant the ability to go fetch my entire record then, I'm the only one who could access somebody else to come and get it out of that participant. And I guess if I wanted to migrate my PHR to another vendor that would be a use case that would work. But it's pretty narrow. But anyway, the basic answer is yes, that's allowed sort of a consume only.

**John Kansky - Indiana Health Information Exchange - Co-Chair**
But I want to explore that. Let's not let go of that one just yet because I want to make sure I understand something. So, is it plausible that an app vendor who is a participant in the network, can they get that blanket – I'm thinking about the IAS, the limited rights that we have given the patient? Can that be sort of automated where the – is that allowable for the consumer to say to their chosen app vendor who is a participant on the network hey, I'll click this box that says you can go get any and all of my data that you can find because it's for this permitted exchange purpose? That seemed to be implied in David's example. And I'm wondering if there's anything that prevents that from happening.

**Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead**
I'm not sure I completely understand the distinction in the example but I believe that would be allowed. And then, if the individual or the service wanted to then take the data and allow

the patient to modify it or do something else with it, they would just need the patient to **[inaudible] [01:22:10]** receipt of the minute information. And then, they can do whatever they want with it. And then, the individual would be able to direct that that data be sent to a third party as part of the exchange purposes if they wanted to. Does that make sense?

**John Kansky - Indiana Health Information Exchange - Co-Chair**

It does and I'll be colloquial in the example of channeling my inner Steve Posnak. I guess, when I think of IAS, I think of there is this consumer and they're going to have an appointment with a specialist they've never seen before. So, they use their individual access services to pull their data from their primary care physician and they direct it to their specialist in preparation for that appointment. That seems super obvious. What I hadn't contemplated is I'm a consumer. I sign up with this app that sounds like a good place or a good app that has good functionality for me to access and control my data. But what really happens is that that service ends up just saying just give me your rights to shoot queries around the network and gather your data. It has to be, I understand, for exchange purposes that are permitted. So, I'm not sure whether what I'm suggesting is sensical or nonsensical.

**Arien Malec - Change Healthcare - Co-Chair**

No, it doesn't have to be – an exchange purpose is consumer says go get my record. That is the exchange purpose. You could give that third party app your proxy to go get your record and that's all they need. They can get all of your data. That's the whole point of IAS as I hear it, which is a good thing, I think.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

So, it doesn't have to be triggered by an encounter or a reason or anything?

**Arien Malec - Change Healthcare - Co-Chair**

No. And the concern that that raises – well, the good use case for that, the one that I think we all hope emerges is something like exactly your use case of pulling down your data, consolidating it into a record so that your specialist has a well-organized record to browse when they see you. That's the health record bank kind of model. The perverse case is let's say placement agency convinces you that if you give them access to your health data, they can convince employers that you're healthier than average and that you should go to the top of the job cue. Oh, and by the way, if your health data is not so good looking then, maybe you'll never get a job again. That would be also a permitted purpose because the consumer access permitted the data to flow.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Right. So, I guess we'll leave that example with – I think the free market economy is going to be as creative as possible with anything that turns out to be legal once this network exists is, I guess, how I would summarize it.

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

Yeah. But beware of the secondary unintended consequences when you enable something that was carefully managed before and you put a hole in the dike. You may not want the

flood.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

No, I completely understand. If I was creative enough to think of all of those use cases, I wouldn't have 10 startup companies but I don't. What about your health record bank example? Did we cover that?

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

So, let me just be very specific and I may be misremembering. But if you wanted to respond just for – you have this health record bank that you built with the consumer's permission and you wanted to be able to respond for direct treatment queries as if you were a legitimate provider under covered entity but you're not. You're a PHR building a health record bank. Are you allowed to do that? We understand you can consume the data but are you allowed to share it back just for direct treatment if that makes sense? Go ahead.

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

Right. Only if you're a covered entity or business associate with a relationship with that patient. But specifically for the treatment exchange purpose, it's limited to the HIPAA definition of treatment.

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

But would you have to be an actual covered entity? Let's just take the health record bank, an independent health record bank. It's not a covered entity today because it doesn't process payments. Would it be allowed to be on the network and fetch the data on behalf of the consumer and then, serve it back up to other providers in response to direct treatment queries with the consumer's permission, of course?

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

So, I think the answer is no unless it's the covered entity or the business associate operating on behalf of the covered entity.

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

So, I would suggest that we consider a recommendation that that use case should be supported. I think the health record bank model has a lot of potential. And this could be the technical trick that makes it possible. And where I'm headed or what I'm thinking of is there are companies out there now that work on specific complex diseases like inflammatory bowel disease or multiple sclerosis. And they have built tools to assemble an extremely useful summary view of the patients' medical problems, which is way beyond EHR vendors are offering because these things are highly specialized. And it would be really nice if they could plug into the network to fetch the data and then, serve it back up for the PCP and others because they've created this incredibly valuable summary of the patient's medical condition. That ought to be supported it would seem to me. So, maybe it is but I'd just like clarity.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

I see that we've captured that. It's my fault that we have a growing list of folks patiently with their hands up starting with it looks like Mark Roche is on top.

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

Sure. And I'm trying to understand the workflow. What is the process? How do you envision and whether you envision TEFCA soaring consents received from patients specifically pertaining to individual access services? Who should store that consent? And how is it delegated and maintained?

**John Kansky - Indiana Health Information Exchange - Co-Chair**

So, is that a question to ONC? I'm trying to think about that's different than meaningful choice in terms of how to constrain your data or is it?

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

It's an open-ended question. I guess it's for upper discussion. And I'm trying to get a better appreciation of the workflow. And if I as a patient request through TEFCA that my information be shared or that I get a consolidated view of all of the information wherever it's available, I'm trying to understand first where is my consent to share that data stored, whether the QHIN will store that or some other entity, or is it going to maintain within the institution that holds my record? And second, can I specific that only certain information within my health records such as medications and allergies could be shared but maybe not labs?

**John Kansky - Indiana Health Information Exchange - Co-Chair**

So, my understanding, I'll take a shot at stirring this pot a little bit, is in terms of meaningful choice, it's all or nothing in that a consumer can say no, don't share my data or do share my data but can't, at this point as drafted, be selective, as you suggested. What I'm struggling with is that's not the same as consent. And can someone from ONC – we're going to have – is consent even spoken to as a QHIN functionality?

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

Hey, John, yes. So, I would ask there are lots of different – the word consent can be kind of confusing and misleading. And as you were alluding to before, there are several different versions of consent or approval or meaningful choice within the TEFCA. So, rather than answering this specific question because I think that the answer varies, I would point folks to the applicable language in the MRTC. So, in Sections 6.1.4, 7.4, and 8.4, you have requirements. It says other legal requirements and that refers to one type of consent or approval. There are the meaningful choice provisions. There is also the consent or approval whatever you call it under the permitted in future uses section. That's 2.2.2, 7.2, and 8.2. And we can discuss those individual sections but that would be my recommendation.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Got it. Thank you. And not surprisingly, but you have an amazing command of this draft regulation. Okay. Going down the list, Mark Savage has a question and then, Cynthia.

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

So, several things. One is there are a couple of use cases that I didn't mention the first time that I'd just like to make sure that we're all thinking about. And I've picked ones that are sort of within the current legal structure. One is the patient's right to submit corrections and amendments under the Privacy Rule. So, people sometimes think we can't do patient generated health data. But that right of correction and amendment is a form of patient generated health data that I think we should be building for. The other is the precision medicine initiative. All of us, the individual participation in that to both contribute data and to get results, again, I think that's outside the definition of individual access services but it would seem to be a use case that we would want to be building for.

So, I wanted to add those to the list of things that I think are top of mind to consider here. The other thing I wanted to throw out is on the ONC NPRM, we're talking about EHI export, which goes well beyond the USCDI that we're only talking about USCDI here. And I'm a little curious about that. I don't know. It's not limited there but limited here. Why the difference? And to your point, John, as I understand it where the individual is using it to get data, what they're going to get is the USCDI. They're not going to get the designated record set back. So, I just wanted to throw those –

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Yeah. I thought I understood it in Alex's presentation, which that was something that I did not appreciate is that it's limited to USCDI, except for individual access services in which case it's not. Did I understand that correctly?

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

I sure hope so. That's not what I understood.

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**

A response to a query is limited to – I shouldn't say limited to because it's not a limit. The minimum obligation is to respond with all electronic health information in USCDI.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

And that applies to all exchange purposes including IAS.

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**

I believe that's correct.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Okay. So, Mark, you had it right, I had it wrong. Sorry to report, apparently.

**Arien Malec - Change Healthcare - Co-Chair**

Yeah. I think the editorial comment is that a minimum is not a limit. We're using limit in, I think, two different ways. There is what's the minimum that I need to do to meet my obligations under the TEFCA. That doesn't limit me to doing more than the TEFCA.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Certainly.

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

So, what I would want to then flag for, if we're sticking within this construct and not making a recommendation that goes beyond it, what I would want to flag for conversation is what can we say about encouraging people to go beyond that or a structure for doing that so that there is at least some dirt road on-ramp for some things.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Yeah. And we're capturing these comments. And I can't say what, at this stage, what might end up being in a set of draft recommendations for us to revisit until we get there. Cynthia has been patiently waiting.

**Cynthia Fisher - WaterRev, LLC - Member**

Thank you. This goes back a little bit to consent, and in the patient need for access to providing consent and to have various whole databases, have the comprehensive viewpoint into the patient, also in being able to pull that data. I do believe that it's really important that the patient clearly understands what the patient is consenting to. I think we had someone from ONC talk through various types of consent but I will tell you for a fact that some of the problems we're seeing with the certain EHR vendors and installations at least in the Boston market are that even in the EHR system, a patient cannot leave a screen or even get care unless they sign electronic iPad for consent. And the consent is merely a signature line where, even within urgent care or even within the hospital system themselves, they're not provided the written description of what they're consenting to.

We have various reports from various patients and families. We also see that what's being collected by the EHR vendors, even with adult children under the age of 26, in order to receive care, they have to complete a digital page, which includes alternative individuals to pay being the parents. And the parents' field of must fill also includes the parents' social security numbers including the financial payment for balance billing. And one has even refused care without that being complete. So, when we think about what's comprehensively being collected by certain providers and this being comprehensively linked to family members' credit cards and social security numbers, I think it's really important that we look at the future of big data and the future of the opacity of patients understanding what's being collected behind them and being able to have the ability to refuse to give financially identifiable information like social security numbers.

I just want to raise this issue because when we also look at the sharing of the data, we've talked before about provenance is, often times, it's so difficult for the patient to get access of their complete electronic health information. And we know it's being shared multiplicatively behind the scenes. It would be very prudent as we look at this umbrella in the TEFCA world to

give patients the ability to opt out, to actually see a trail, and to check out of it being included elsewhere. There are applications that we would want to allow innovative mobile apps like exist today like 360, Find My Friends, have the ability for a patient – if you look at the ability to time out access to information. It could be by the hour. It could be by the day. It could be by the week. But, ultimately, we would be best served if patients had control of who could see their data and who they want to share the data with rather than sort of a big brother approach and AI approach all behind the scenes.

But, ultimately, empowering the patient to control the privacy of their own care along with their secured relationship with their physicians. I just want to bring that up because I do believe that we need to look at the comprehensive use of this data and where the design can be problematic. Thank you.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Is there a specific shortcoming of as drafted or is that something you want to make sure ONC takes into consideration?

**Cynthia Fisher - WaterRev, LLC - Member**

Well, I think we really need to take into consideration the ability for patient control to privacy and access and the ability to utilize technologies where the sharing of the information could be timed out or denied by the patient and shared to the appropriate caregivers, which may vary based upon circumstances and locations. And I think we're best served if we flip this on its head and put the patient first. And so, I think if we look at this drafting, I think it behooves all of us because most come from a point of view whether it's a provider, insurer, or EHR vendor, I think really we need both 30,000 feet, flip it on its head, and take the position of the patient in the drafting.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Thank you. In an effort – we're coming up on public comment in about six minutes. So, let's see if we can finish out at least IAS. There's one that I believe came up on our very first or second call, which is who has to respond to queries for IAS. And this may be, if I'm remembering correctly, Noam Arzt's memorial question in that if I'm a participant that uses a QHIN of choice and from that QHIN comes a request for an individual's access to their information, who has to respond to that. And the example that was given was, I believe, a public health authority. And I'm not sure if we clarified and do I even have the right scenario.

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

Noam is not on the call but I recall his concern was about whether public health would be obligated to respond. And his concern was that many public health entities aren't prepared to do so. That seems like a slippery slope to me because there are probably a bunch of small EHRs that can't respond either. Does that mean they can't be EHRs anymore?

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Fair point. Let's explore that. Thank you. So, if it's against the local – I'm sorry. If it's against state law for a public health authority to disclose that information then, they don't disclose

it. But if there is no law saying that they mustn't, are they required to respond to IAS queries?

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

**John Kansky - Indiana Health Information Exchange - Co-Chair**
So, we answered that one earlier and the answer is yes, they are. Question mark.

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**
Yeah, that's the intent.

**John Kansky - Indiana Health Information Exchange - Co-Chair**
Okay. That does sound like it's going to be hard knowing what we know about local health departments, etc. There were also some questions, let me flip a couple of pages here, about did we address a question must an IAS only participant respond to all IAS queries and the answer was yes. May IAS only participants respond to other exchange purposes. And I guess the answer would be then they're not an IAS only participant. So, any clarification from ONC? If you're IAS only and you somehow made the world know that that's what you are, you can't optionally respond to other exchange purposes?

**Alex Kontur - Office of the National Coordinator for Health Information Technology - SME**
Correct.

**Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead**
Well, I think if you're a HIPAA covered under your business associate then, you can respond. You're just not required by the terms of the contracts to respond.

**Arien Malec - Change Healthcare - Co-Chair**
Yeah. So, the example of a health record bank that David keeps bringing up, the purpose is to hold data on behalf of the consumer. What I'm understanding is that they could be an IAS only responder but they couldn't go one step beyond that and respond, for example, for treatment because, if they did that then, they'd be not an IAS only responder.

**John Kansky - Indiana Health Information Exchange - Co-Chair**
I'm going to have to think about that one but for now, it seems to make sense.

**David McCallie, Jr. - Individual - Public Member**
This is David. I think that's – I have that as a concern that would limit a very useful kind of participant.

**Arien Malec - Change Healthcare - Co-Chair**
And as a consumer, I'd love to be able to delegate my iPhone that stores data on my behalf

and actually allows me really reasonable controls over what app can access what for what purposes. I'd love to be able to delegate that app to have Apple respond for me I certain circumstances but not all. But it doesn't sound like that would be permitted because I'd be, in that case, not an IAS only responder. I would want to if I tiptoed over the line and I responded for a best treatment purpose, suddenly I'd be in the all or nothing or all or limited.

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

And I would point out the logical inconsistency of that. You have the right to ask for everything but no right to share it back. That doesn't seem to make sense.

**Arien Malec - Change Healthcare - Co-Chair**

Well, as an individual, I have the right to access for everything so that's fine.

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

Right. That works. It's the other way that it doesn't work.

**Arien Malec - Change Healthcare - Co-Chair**

Yeah.

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

I want to be able to share it back. It's the PGHD but, in this case, I'm just talking about existing provider authored data that you want to clean up, summarize, organize to be useful for downstream providers. You should be able to share that back in some easy way. You can always send it in a direct message or whatever. There are other ways to do it but it would be nice if it was naturally on the network.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

So, just interrupting, sorry. Before we go to public comment, I just wanted to ask have we finished the IAS category or were there other write in candidates that folks wanted to bring up for discussion? And then, we'll go to public comment and circle back.

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

This is Mark. The only thing I can think of that may come up is if we think that we want to write recommendations around particularly important use cases but not for all use cases. So, I don't know if you want to categorize the use cases that I've brought up that I think are more central than others or whether you want to wait until we are discussing recommendations. That's all I can think of at the moment.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Thanks. I would say the way I was thinking about that was that you've made a good point that there are use cases that we should consider. And you've offered some examples, which is really helpful. Let's see how that comes out in draft recommendations if it does and we'll debate it then. With that, can we go to public comment?

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

Thanks, John. We'll just get the number pulled up here. Sorry, my computer froze so I may be a little bit delayed.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

It actually is displayed.

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

Okay. So, operator, can we please open the public lines?

**Operator**

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

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

And do we have any comments in the cue?

**Operator**

Not at this time.

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

Okay. We'll check back on the comments before we adjourn. John?

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Yes. Hey, Arien, can we sneak in one more section, which only has one question and it happens to be a question that I kind of championed? And it seems like it's a less than eight minute discussion to knock that one off.

**Arien Malec - Change Healthcare - Co-Chair**

Oh, famous last words.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

I'm tempting fate. We could take a shot at it and you can make fun of me if I turn out to be wrong. How about that?

**Arien Malec - Change Healthcare - Co-Chair**

Sounds good. That sounds super fair.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Okay. So, this gets to Section 2.2.2 on permitted and future uses. And what I understood it to say and Zoe can laugh at me when I botch this, is that you can't do anything that's not for one of the exchange purposes, except the following. And where I got wrapped up was the very last thing it says is you can do anything that the individual who is the subject of the data specifically says that you can do. So, I'm like, okay, if it's not on the permitted purposes list, I can ask the individual. And if they say yes, you can do that and it meets all of the requirements of the authorization then, I'm good. However, the point right before that in the list implies it says that as otherwise permitted by applicable law meaning I can do anything that is not against the law.

So, what I was trying to clarify, I read that as, and I'm not going a particularly articulate job of saying so, is I can do anything – once we have the data that's been accumulated through normal exchange purposes, one of the things that I can do is anything that's not against the law. And another thing that I can do is anything that the individual says I can do. So, is that right or do I need to reframe that question in a much more intelligible way?

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

That's right, except I don't know that I would phrase it as anything that's not against the law so much as anything that's explicitly permitted by applicable law. So, the example or, I guess, the intent behind that section is HIPAA permits all of treatment payment and operations. So, if you're covered under your business associate then, you would be able to use, disclose, aggregate, etc., for all of the treatment, payment, and operations.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Yeah. I think the go-to example here was research. And I should have come up with an additional one that was maybe not so safe but the research example was some research you can't use the patient's data without their specific authorization. But some research can be conducted if it's deidentified data and there's an IRB, etc. So, I read this to say one of the permitted purposes for a QHIN is to use research as long as it doesn't require individual authorization. Is that a fair example?

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

This is Kathryn. I was going to say the only thing I would add to that is to the extent the requirements under HIPAA to use the information for research are met just like you just outlined. If it went through an IRB if it's deidentified, things like that because that's, I think, what the intent of applicable law would be.

**Arien Malec - Change Healthcare - Co-Chair**

And then, John, I've got some other examples for you that are non-research. If I wanted to donate my data, I'll use sort of farious and nefarious. I've always been troubled that farious isn't a word. So, if I wanted to donate my data as a patient with a rare disease, in order to maximize treatment algorithms, I'm not sure if it's a research use or an operations use, but I

could do so. If I was a patient aggregating a company that had a business model of selling data to pharma companies what would be an example of something that is permitted that would require specific authorization in order to do so. So, it's a wide range of activities that are not prohibited that are permitted under applicable law but are not one of the safe weighing activities under HIPAA.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

I guess what's helping me in this is that, and the authors from ONC are going to say duh, John, that's what it says, so I'm a QHIN. I've accumulated this data. I'm asking myself what can I do with it without breaking any rules. It's the same things that you can do with it under HIPAA or any other applicable law that goes beyond HIPAA . If those restrictions do not apply then, it's permitted is what I'm hearing.

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

Yes.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Okay.

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

I think the applicable law has to apply to the entity that's in question.

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

Another way of saying it maybe is that TEF doesn't change any of the fundamental rules regarding what you can and can't do with patient data. It just says specific things of what you can use this network for.

**Arien Malec - Change Healthcare - Co-Chair**

Yeah. Or to not **[inaudible] [01:57:32]**.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

We just have a minute so I'm pushing my luck. But there seems to be this feeling evolving that a QHIN is a thankless job nobody would want. And it seems to me that there may be some clever things that QHINs are going to be able to do to have business models to support their business.

**Arien Malec - Change Healthcare - Co-Chair**

Yeah. The way I'd put your answer, John is that a QHIN is the outer boundary. So, if you take IHE as a QHIN is the outer boundary of IHIE. TEFCA says nothing about the inner boundary, except in response to cross QHIN exchange.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Right. Okay.

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

It doesn't create any new permissions that didn't exist before.

**Arien Malec - Change Healthcare - Co-Chair**

Or new restrictions that didn't exist before, except with respect to CommonWell or Care Quality or what have you querying IHIE.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Got it.

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

Another way of saying it is those entities could continue to exist and totally ignore TEFCA and nothing in their world would change.

**Arien Malec - Change Healthcare - Co-Chair**

Right.

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

TEFCA hasn't changed any fundamental rules about data.

**Arien Malec - Change Healthcare - Co-Chair**

Right. It's intending to enable – I guess my point is that the outer boundary is what it's intended to enable, which is cross-network exchange and then, certain obligations that are associated with cross-network exchange but it has nothing to say about intranet work exchange. It has nothing to say about, in general – it's a floor on the cross-network exchange but it doesn't have anything to say about other things that go beyond that as long as they're explicitly authorized.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

This is helping with my instincts.

**Arien Malec - Change Healthcare - Co-Chair**

Right. And we're definitely over time now. Thanks, all.

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

And really quickly, our next meeting isn't until next Monday, June 3.

**Arien Malec - Change Healthcare - Co-Chair**

A little bit of a rest.

**John Kansky - Indiana Health Information Exchange - Co-Chair**

Okay. Thanks very much.