Health Information Technology Advisory Committee
Office of the National Coordinator for Health Information Technology

Trusted Exchange Framework Task Force

Transcript
March 2, 2018
Virtual Meeting

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

Thank you. Hello, and welcome to the TEF Exchange Framework taskforce meeting. Happy Friday. We will call the meeting to order, starting with a roll call. Denise Webb?

Denise Webb - Marshfield Clinic Health System - Co-Chair

Present.

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

Arien Malec?

Arien Malec - Change Healthcare - Co-Chair

I'm here.

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

Carolyn Petersen?

Carolyn Petersen - Mayo Clinic Global Business Solutions - HITAC Committee Member

Present.

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

Aaron Miri? We don't have Aaron on the line? John Kansky?

John Kansky - Indiana Health Information Exchange - HITAC Committee Member

I’m here.

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

Sheryl Turney?

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

I’m here.

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

Sasha TerMaat?

Sasha TerMaat - Epic - HITAC Committee Member

Hello.

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

Steve Ready? Do we have Steve on the line? Cynthia Fisher?

Cynthia Fisher - WaterRev, LLC - HITAC Committee Member

Yes, I’m here.

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

Anil Jain?

Anil Jain - IBM Watson - HITAC Committee Member

I’m here.

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

Kate Goodrich? Is Kate on the line? David McCallie?

David McCallie - Cerner - Public Member

I’m here.

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

Mark Savage?

Mark Savage - UC San Francisco - Public Member

Here.

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

Noam Arzt?

Noam Arzt - HLN Consulting - Public Member

I'm here.

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

Grace Terrell?

Grace Terrell - Envision Genomics, Inc. - Public Member

Here.

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

We'll circle back for those that were not on quite yet. Denise and Arien, I turn it over to you.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Okay. Great. Welcome, everyone. First of all, before we go into our charge for today, I just want to let everybody know that we added 30 minutes to the call today and on Monday given the amount of discussion and the tight timeline we're on to put our recommendations together. But everyone does not need to feel obligated to stay on if you are not able to.

So, if you have to drop off, what we're going to do is do the public comment right before 3:00 Eastern time and then we'll continue our discussion for those of you who can stay on the call. We'll do the same thing on Monday. And we've also added an optional meeting for March 14th in case we need to have that meeting. I might have to join Sasha at EPIC because we're going to be at EPIC all day that day.

Then the other thing I want to mention is that we do have an additional new member on our taskforce, Andy Trescott. I don't know that he's able to join today, but he will also be a part of our taskforce. So, jumping right in to our order of business today – of our four charges, we're on number three here on permitted uses and disclosures. So, that's going to be our topic today. If we can go to the next slide…

This is how we're going to go to go through this discussion today. We are going to talk about what enhancements or clarifications the taskforce recommends for the permitted purposes and we will go over each of those on the slide here, then we'll go into the use cases around population-level data and broadcast undirected queries.

And then the last two areas that we need to cover are around enhancements or clarifications for the data reciprocity aggregation and future uses in terms of the requirements being placed on the **[inaudible] [00:03:031]** and then we'll talk about participant and end user obligations. Alright, next slide, please.

Alright. Getting into the permitted purposes, the first one we're going to the permitted purposes, the first one we're going to talk about is around individual access. As I think many of you know, under HIPAA, individuals have a right of access to their health information to access it, exchange it, and use it or have a qualified representative do that for them, and that's to send their healthcare information and direct it to any place that they choose to direct it.

So, you'll see here on the slide – let's start with a discussion around this permitted purpose and whether the taskforce members have input as to whether this needs to be clarified. Are there enhancements in the TEF that you think are needed? It looks like I already have hands up. David McCallie, your hand is up first.

David McCallie - Cerner - Public Member

Thanks, Denise. First, I think I'm going to reflect a little bit of what we discussed in our internal discussions here at Cerner about this and what I've heard other people discuss. A couple of things – one, we think in general, it's a great idea. It's a right and a capability to pull your federated record together as an individual. It makes a ton off sense. So, we're highly supportive of the idea.

A couple of things that we would like clarification about, though – one is respect to who is or is not obligated to do the response. It sounded at some points like the QHIN would be expected to have consumer-facing capabilities native to its own offerings. In other places, it sounded like it would be something that could be an option for a QHIN but could be delegated to a QHIN's participants.

We'd prefer the latter – make it an optional thing for a QHIN so that a QHIN doesn't necessarily have to encumber itself with the complexity and cost of having direct-to-consumer-facing capabilities, particularly if its members already have that through their portals or other offerings. So, that was clarification number one.

Clarification number two was is ONC willing – or maybe the RCE should be designated – the choice or the discussion about willing to make a distinction between an individual operating on their own behalf versus an aggregator off individuals operating on behalf of the aggregation of individuals. We think that there should be a distinction between those two, in particular, the notion around fee requirement, that individual access be a no-charge access. We don't think that should apply to aggregators of individuals who might bring millions of individual queries to the network. So, I'll stop there.

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

This is Sheryl Turney and I agree with the comments that were just made. We also were questioning the individual access because it did appear as if some parts of the comments, there would be the opportunity for portal app developers for participants. That's part of the innovation component. So, that seems to be more in line with the way this QHIN design appears to be developing. I'm not the expert in the technical architecture component of it, but through the use of APIs and other things, that seems to be what the words are trying to say. So, clarification on that, I agree.

We also agree about the fee structure comment, but then we have another comment. We typically as a payer get hit from external queries from some of the partners that our patients will want to work with, like Fidelity or Quicken or someone like that. So, how, in this scenario – and I couldn't really figure it out based on what I was reading here – would the participants be verified and validated if there were a portal or individual portal, app developers provided access on this network – how do you validate who is a trusted one and who is a Russian spy? I don't know how that typically works.

Our folks who looked at the security aspect of it couldn't really find that in the meat of the trusted framework either. We have actually been penetrated – not penetrated, but his by external entities outside the country. We would certainly want to make sure the security and privacy protocols would prevent any of that. It seems as though there is a lot of discussion about the QHINs and the QHINs hooking up to one another and all of those being validated and verified, but what about all the participants on the QHIN. That would be my question there. And then how do we know that the validation process **[inaudible] [00:09:40]**.

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

Can we ask everyone to mute your lines please if you're not speaking?

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

So, in today's world, some of these individuals are giving their credentials to screen-scraping capabilities. So, you don't know if those screen scrapers have gotten those credentials with permission or with not permission because there is no way to know that. So, with this arrangement, there's an API. To me, that would mean that there would be some trusted partner, trusted verification process. It was not clear to me in the material where that really resides. So, maybe I'm missing it. If I am, those that are more educated about these things can please fill those gaps. Those were questions on this piece.

Denise Webb - Marshfield Clinic Health System - Co-Chair

So, Grace, I think on Monday, we're going to have further discussion on the privacy and security aspects of the TEF. I definitely think your concerns do fall in that realm on how we're going to identity-proof folks. I think David’s point about this nuance between whether the QHIN is obligated to respond for this particular permitted purpose or has the option to delegate it is an important discussion.

I know in the CARIN Alliance, we actually got in quite a bit of discussion about an end user and actually distinguishing between an end user that’s a health system that uses a particular EHR product and the end user being the individual or an individual’s designated third-party app. I do see Mark was in the queue next and then Arien.

Mark Savage - UC San Francisco - Public Member

Thanks.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Mark?

Mark Savage - UC San Francisco - Public Member

So, I too found some ambiguity around individual access. I’ll describe it in a different way than, say, David or Sheryl described it. I think the principle is pretty clear and so is the ONC’s user guide, that patients, caregivers, authorized representatives, and family members are supposed to be able to use the Trusted Exchange Framework for access, just like the other stakeholders. But I’m having a lot of trouble finding in Part B how that actually operates. I think there’s some important clarification to happen.

The definition of rights on the screen is all good. But what’s the operational side of those rights? How do we make sure that patients, family, and caregivers are actually able to get access to their information and that they will actually get the information as is their right?

There may be a very simple answer to this. There’s a definition of an end user which mentions an individual, but it’s a lowercase I. There was a lot of attention paid to defining terms with uppercase. So, maybe it’s as simple as making sure that we all understand that individuals are end users and therefore, that’s one way that they get into this onramp.

At the moment, it’s not clear to me whether and how this happens. There’s that sentence in one of the later slides, 7.1, about, “Notwithstanding the foregoing, a qualified HIN shall not be required to include individuals as participants or end users.” So, that’s just an example of my lack of certainty about this important question.

Denise Webb - Marshfield Clinic Health System - Co-Chair

I think that’s really a good point because there’s also a concern about the blowdown requirements of business associate agreements and things and you’re not going to slow down those to an individual or a third-party app that the individual chooses.

Mark Savage - UC San Francisco - Public Member

Right.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Arien?

Arien Malec - Change Healthcare - Co-Chair

Yeah. I just want to endorse many of the comments that have already been made and also point out that the enabling standards – I think this is an area where I think everyone endorses the notion of the permitted purpose. I think there's some really good question about how we distinguish individual access on behalf of the patient versus on behalf of an actor that may themselves be acting on behalf of the patient and in which cases are those deemed individual patient access requirements versus aggregator access requirements.

And then I also want to acknowledge that there's a standards to policy overlap here that a number of the commenters have noted. In particular, I'm not aware of readymade standards that allow for the request to carry both the notion that this is individual access and the purpose of use and also carry contextual information on the level of identity proofing. I think much of the comment has been related to the notion of the prior identity proofing and the level of obligation that the responder has to trust that the request is appropriately and duly made on behalf of the patient.

So, I just want to acknowledge that this is a use case that everybody wants to support but also recognize that there is some heavy lifting with regards to standards and implementation that needs to go along with this area that is not readymade and frankly, not fit for purpose at the moment. It's going to require some active investigation.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Zoe, can you pull up the next slide or whomever is controlling the slides? I just realized I have these printed out too, but these are areas that we were touching on as well around the obligation to respond, that obligation being on the QHIN and individual requests for no data exchange. So, if people have comments on these areas as well in terms of clarification, I certainly welcome people to give their contribution.

David McCallie - Cerner - Public Member

This is David. I wanted to just add one notion on the tail end of Arien's comment, if I may. One of the thoughts we've had, at least in the early going of this, maybe before some of the identity proofing is as robust and complete and comprehensive as this document seems to suggest – one way to know who the individuals are is to have them go through a provider portal because the providers will have typically identity proofed and authenticated them with a lot of care since they are providing medical care for them.

That may be one way to jump start things, to make it easy for an individual to get access to their federated record by going through a portal where, in a sense, the portal is vouching that they've been identity proofed. Again, maybe that's really from Monday's conversation, but I think that's a way we can get started with this. And then – oh, go ahead. I'm sorry.

Denise Webb - Marshfield Clinic Health System - Co-Chair

I was just going to say I might agree that that is a way to get started, but we really do want to have consumers be able to identify apps and have the machine to machine where the individual doesn't have to go log in to their portal except for maybe once to authenticate the app or validate that they give consent for that app to have their information.

David McCallie - Cerner - Public Member

The app can authenticate against the portal as the Apple does, for example. It does it once and then remembers the token from that point forward.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Okay. That makes sense.

David McCallie - Cerner - Public Member

That would be completely consistent with what I was talking about. It's really about the identity proofing and leveraging that the provider will have done that. The document makes some great statements about that. The draft has some exceptions specifically to account for providers doing the proofing. I think that was a really smart addition to the document.

I wanted to shift, though, on the individual access point here on the new slide, 6.1.1 or, actually, 7.1. I was surprised that the obligation to respond to query polls was couched in the context of individuals. It seems to me that that's the core principle of the whole darn thing. What makes a QHIN a QHIN or the common agreements common agreements is that you are, in fact, obligated to respond for queries, assuming its permitted purpose and you're authorized to do so. That's not limited to individuals. That applies to all the use cases. So, why was this carved out under individuals? I was very surprised by that?

Denise Webb - Marshfield Clinic Health System - Co-Chair

That's definitely a good point. Arien?

Arien Malec - Change Healthcare - Co-Chair

Yes?

Denise Webb - Marshfield Clinic Health System - Co-Chair

Your hand is up?

Arien Malec - Change Healthcare - Co-Chair

No. We already addressed it. I just didn’t take it down.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Mark, your hand is up?

Mark Savage - UC San Francisco - Public Member

Yes. I’m wondering if this is an appropriate time to hear, perhaps, from ONC about how individual access is supposed to work under the Trusted Exchange Framework and also to hear the answer on Arien’s question just so that we – it’s ambiguous to some of us. Maybe there is an explanation that helps us proceed.

Zoe - Unspecified Organization and Role

Sure. Hi, this is Zoe. That was a great point on the 7.1 provision there. I will say I think this was meant to be a clarification and a reinforcement that we are requiring reciprocity for all permitted purposes. So, even if you are a qualified HIN and you’ve said before that we’re trying to not dictate the internal business model and structures of the qualified HINs, so, what we’re saying here is essentially that you don’t need to be directly serving or even indirectly serving consumers if that’s not the business model that is intended.

However, you still would have to respond to queries from other QHINs that are serving those individuals or whoever is requesting it. What has been pointed out, that would also apply to the other permitted purposes as well.

Mark Savage - UC San Francisco - Public Member

So, Zoe, under the structure of this framework, how do individuals get access to their information? What’s the operational approach?

Zoe - Unspecified Organization and Role

So, I’ll do my best. I guess depending on what QHIN they were a part of, it would vary, I guess, depending on the type of business model and the structure of the QHIN, whether it would be an end user or a participant or, like other people have mention, if they were going through a third-party app or through a designated caregiver. But it would essentially follow the same structure of the individual or their caregiver or the app query and up to the QHIN to receive information.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Carolyn’s hand is up.

Carolyn Petersen - Mayo Clinic Global Business Solutions - HITAC Committee Member

Thanks, Denise.

Denise Webb - Marshfield Clinic Health System - Co-Chair

You're up.

Carolyn Petersen - Mayo Clinic Global Business Solutions - HITAC Committee Member

My question is in response to the comment that was made, two comments previously talking about how if it's not the QHIN's business model to respond to individual requests then they don't have to. If we're saying that QHINs can opt out of dealing with individual requests, then what are we doing to ensure that there is, in fact, a mechanism for consumers? In theory, if all of them opt out of consumer requests or you wind up with maybe just one, then don't consumers have to be part of multiple of QHINs or don't they wind up having their data flowing through multiple outlets to deal with organizational requests as well as their own?

David McCallie - Cerner - Public Member

This is David. The way I framed my question, I didn't mean to imply that a QHIN could opt to not respond at all. It's just that they could conceivably opt to delegate it through their participants. It's an open debating point. I'm not sure that's the right way to do it. For QHINs to all have consumer-facing capabilities direct increases complexity and cost and may, in fact, not work for the purposes of engaging patients to be more engaged in their care process because you would be bypassing the care process. So, it wasn't that they could get out of it. It's just that they could proxy it through the participants.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Well, the other point on that is that participants and end users like a health system, they're obligated under HIPAA to allow the individual to have their information. So, if they're an end user of a health information network that's part of a QHIN, then that would be along that model that you talked about, David, of being delegated. That's where there would be the insurance that they would get their information if the QHINs themselves are not serving individuals directly, I would think.

Arien Malec - Change Healthcare - Co-Chair

I just want to acknowledge that we're a half an hour in.

Denise Webb - Marshfield Clinic Health System - Co-Chair

I was just going to say that. So, just to summarize, it sounds like the taskforce overall is in support of this use case – excuse me, this permitted purpose, but it does require a little bit more clarity. So, we'll look to capture those points in our recommendations.

Before we leave this slide, I did want to make one comment on an individual's request for no data exchange. I don't know if this just needs some clarification, but under the TPO, treatment payment operations, it seems that there are provisions in HIPAA where an individual, if they pay cash for their care or their encounter, they can request that that be restricted.

But because the networks are operating as business associates to covered entities, I would think that they are just an extension, then, of the health system, of their participants and end users. I didn't know that the individual could actually restrict their data from being exchanged that way under treatment payment and operations – so, just a comment. If we could go to the next slide…

Alright. Let's talk about public health as a permitted purpose. I know on the last call, Noam had some specific comments around the public health access to information and getting information that they need under the law. So, Noam, I see your hand is up.

Noam Arzt - HLN Consulting - Public Member

Yeah. So, what's interesting about this are a couple of things. Just to be succinct – it's great that public health is a permitted purpose, wonderful. The problem is there is nothing else in TEFCA that enables the way public health works. Broadcast query, even direct query, simply does not satisfy the public health permitted use.

So, I hope the answer isn't to then remove the public health permitted use because it doesn't fit the model of what TEFCA's operational description is. It should be to improve TEFCA so that it can handle the things that public health needs, which is primarily a strong and clear push method of sending data into public health.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Just to add on your comments, Noam, because I did work in public health – one of the complicating factors for health systems is having all of these various interfaces and things to satisfy the public health reporting requirements. I think that to be able to have one onramp that satisfies the push and the pull would be desirable. At least from a health system perspective. I'm going to have to mute because it's getting noisy. I have David – no, let's see… No hands up – oh, Arien, your hand is up.

Arien Malec - Change Healthcare - Co-Chair

Yeah. I think it's really important – this is a comment that I made at the HITAC meeting where TEFCA was discussed. I think ONC inadvertently caused some confusion when the TEFCA referred to the notion of a single onramp. But elsewhere and in the comments to HITAC, ONC acknowledged that there a variety of HINs that are well-established or are fulfilling particular missions that were not the coverage area for a qualified health information network.

My personal opinion here is that it is simplest to think of the QHIN as a single onramp for query-based exchange to the totality of a patient's health information regardless of where it exists across the continuum and to make it clear that the public health use cases that are being addressed here are secondary to that overall policy goal and acknowledge that there are multiple public health uses cases for which the qualified health information network will not be a single onramp.

If you don't do that and you attempt to truly create a single onramp, then you're asking the QHIN to subsume the duties of a direct HISP, of a state HIE, or state immunization registry connectivity point to subsume the activities of an orders and results distribution network, to subsume the activities of an electronic prescribing network, maybe even to subsume the activities of an administrative claims and eligibility network. I don't think that's desirable. I think that's inappropriate.

So, my recommendation here is that ONC firmly establish the policy goal for the qualified health information network as being particular to the needs of query-based exchange to the totality of a patient's health information across multiple settings of care and then to the extent that we're talking about particular use cases, we're inherently bracketing those use cases or subsetting those case cases to the subset that is applicable.

It's not clear to me that there are zero public health needs for query-based exchange. For example, if we have an emergent outbreak, it may be useful to do query-based exchange to enable decision support, for example, for an emergent disease. So, it's not clear to me that there are zero use cases for query-based exchange. Those in general are my recommendations.

Noam Arzt - HLN Consulting - Public Member

And I guess I respectfully but somewhat forcefully disagree. I think to simplify what you're saying, then, the activities under TEFCA, which become our sort of de facto national paradigm for interoperability, become just query-based exchange. Then, in fact, my original fear that public health as a permitted use and use case will essentially be pushed aside. I think that would be a shame for a QHIN to take on the responsibilities that you talk about that are essentially the responsibilities that a lot of HIEs in fact do take on. Our world and our needs, I believe, are simply too complex and important to limit this to query-based exchange. I don't know what others think. I'd be curious to hear.

David McCallie - Cerner - Public Member

This is David. I'm going to jump in line and just make a quick comment in that I think regardless of the answer to that question, I think we should acknowledge up front or I would request that ONC acknowledge up front that not all of these permitted purposes are equally easy to do or equally well-understood and that whatever we take as an approach going forward, we do it in a modular fashion, sequentially addressing the high yield, easy, well understood things first and then having sufficient time and debate to solve for the harder use cases, which I agree, public health is a harder one.

Noam Arzt - HLN Consulting - Public Member

I believe actually the opposite is true. I believe the public health use case is well-entrenched, easy to understand and well-developed. It's broadcast query that doesn't work.

David McCallie - Cerner - Public Member

Noam, in our experience, every state is different. Every single state is different with what they want us to do with public health. I'd say it's very complicated.

Noam Arzt - HLN Consulting - Public Member

That's a slightly different issue. I understand what you're saying. And part of that difference is a reflection of differences in state, local, and tribal laws, which will affect broadcast query as well.

David McCallie - Cerner - Public Member

Agreed, although we sort of figured out broadcast in those jurisdictions, mostly. Most states we figured it out. Public health is not so far along.

Denise Webb - Marshfield Clinic Health System - Co-Chair

So, Noam, do you have some specific recommendations around what that would look like relative to what you would want to see in the TEF?

Noam Arzt - HLN Consulting - Public Member

I think that the operational mechanism, if they stay in the TEFCA itself – that's a whole other question, right? I have a lot of serious questions about whether a trust agreement should have an architecture built into it. But let's put that aside for a second. If the public health permitted use stays, there ought to then be reflected in the TEFCA a way to do it and broadcast query isn't the way.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Okay, noted.

Arien Malec - Change Healthcare - Co-Chair

Sorry, this is Arien. I just want to acknowledge that this question is essentially at the heart of TEFCA. What are the bounds of the obligations of the QHIN? And in particular, do we treat the aspirational notion of a single onramp as meaning a single onramp for all forms of exchange, which, to my mind, would include a broad range of categories that are not contemplated in the TEFCA? I enumerated a number of them. Is it query-based exchange or broadcast query-based exchange or is it broadcast query-based exchange with a couple of exceptions?

I note that a number of organizations including DirectTrust have argued for TEFCA to include directed exchange or direct-based exchange mechanisms in the TEFCA. I worry that the notion of a single onramp actually is maybe counter to what folks are looking for because it really forces the qualified health information networks to subsume a whole lot of well-established economic activity that is fully inflight and also to David's point, to subsume a set of activity that hasn't been addressed because it is god-awful complicated not from an exchange perspective, but because of variation and heterogeneity of the local connectivity points.

But I want to acknowledge these are really central questions and we probably shouldn't be coming at it from public health backwards. We should probably be coming at it from what are the obligations of a qualified health information network forward.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Yeah. And what is the real notion of a single onramp? That does steer people in different directions, I think. Any other discussions? We do need to keep moving on. Let's move on to the next slide. Alright. The next is around permitted purposes for benefits determination. Any clarification or enhancements needed for this?

David McCallie - Cerner - Public Member

This is – oh, I need to raise my hand. Sorry.

Denise Webb - Marshfield Clinic Health System - Co-Chair

That's okay. Go ahead.

David McCallie - Cerner - Public Member

It's David. So, we've had many discussions at CommonWell with the Social Security Administration. I believe Care Quality has had similar discussions about this use case. So, I think it's reasonable well-understood from entities that have tried to implement query-based full. The challenge so far has been that the amount of data needed for the benefit determination is typically much greater than what current EHR gateways are serving up. They need a much deeper dive into the record, essentially almost a **[inaudible] [00:39:13]** completeness.

That's been a challenge for the vendors. I think that would continue to be a challenge. It would be data that goes way outside the USCDI, for example. So, even though I think it makes great sense as a taxpayer to enable this kind of capability and maybe someone who someday would need to avail of those services, I do think there are a bunch of technical challenges and it goes way outside USCDI. So, it's a little bit inconsistent with the requirement that QHINs be focused on USCDI, I think.

Arien Malec - Change Healthcare - Co-Chair

Lauren, given the background noise, would you mind taking over the queue management duties? Or I can take them over.

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

Sure. That's okay. I see Mark with a hand up.

Mark Savage - UC San Francisco - Public Member

Yes. There's a question about the definition here, which has a determination by federal or state agency. I was talking with some physicians here at UCSF yesterday who talk about trying to take the clinical data and they're looking at benefits data and insurance information data to try to pick what's the best medication to prescribe. It would seem like there are others besides federal or state agencies that would be using this permitted purpose, at least in a generic sense. So, I'm just wondering why it's limited to federal or state agency in the definition.

Arien Malec - Change Healthcare - Co-Chair

And I withdraw my comment because that was the same comment that I was going to make.

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

Do you want to take that question or do you want to come back?

Zoe - Unspecified Organization and Role

I can try to take that question. I think that we had several conversations with Social Security Administration and other federal agencies, which is sort of, as you guys know, where we came up with this. I think we're trying to maybe crawl before we walk a little bit here and kind of ease into this. But if you guys have suggestions for if there are other agencies or other types of organizations who would be using this, it would be very helpful to know that. This is something that I think could potentially evolve, along with the RCE. So, those comments would be great.

I also wanted to touch on the last comment that was made about there being more information or more data than is currently included in the USCDI that needs to be changed and just remind everybody that we're trying to set a minimum floor here and that we can always do more on top of that. Also, the USCDI is designed to expand over time. So, again, specific feedback on what kind of data classes or data elements that we can include in the USCDI in the future to support this permitted purpose would also be helpful.

Mark Savage - UC San Francisco - Public Member

If I can just jump in with one further thought, then, on my earlier comment. I have not done this crosswalk myself, but I think we should make sure that having a definition that's limited to federal or state agencies does not have the inadvertent effect of squashing uses by others in the Trusted Exchange Framework. Sometimes that happens when you define things more narrowly than the world is trying to operate. So, it's something to check.

David McCallie - Cerner - Public Member

David – I want to add one other technical constraint as to why this is a slightly more complex use case than the reciprocal treatment use case. That is that the consent process for these disability determinations is very different. It's outside of HIPAA and requires special forms, at least for the Social Security work. I assume states are likewise. So, the system has to be prepared to deal with that complexity or to trust that the channel from those agencies will warrant upfront that they have obtained consent and documented it properly, etc. It's just one more twist that makes it not so straightforward.

We've been trying to help Social Security with this at CommonWell for a couple of years and it's just been really hard work. We haven't made near as much progress as we would have like to have made. I think that's true for Care Quality as well. It's harder than it looks.

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

Okay. Just to circle back – Anil, I saw your hand go up and down a couple times. Was there…?

Anil Jain - IBM Watson - HITAC Committee Member

Yeah. I guess if you wait long enough, it gets answered, right? So, I had some questions that were very similar. Not to tie up any more time, I think this is a complicated are and I'm good right now.

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

Okay. Thank you. So, any other last-minute thoughts or comments on the benefits determination? If not, I think we can move to the next slide.

Arien Malec - Change Healthcare - Co-Chair

Maybe I'll just frame this up since Denise is dealing with background noise. We went to some specific areas for permitted purposes. I want to acknowledge that while there's been a fair amount of prior art relative to treatment-based use cases, payment and healthcare operations are fairly broad use cases. Under payment, for example, would include such activities as utilization management, medical necessity checking, and prior authorization checking. Any other activity that might be addressed through a medical attachment on a claim could also be addressed as a payment-based use case.

In addition, in payment, there is a broad set of use cases related to quality measurement for payment as well as risk adjudication and risk management for payment. So, for example, an MA plan that needs to query for the appropriate risk determination for RAF optimization or RAF scoring for a patient under Medicare MA plan risk-based payment, that would be a payment-based permitted purpose.

Under healthcare operations, based on the definition of healthcare operations that allows for information exchange across multiple sites, most of these are related to quality management, quality measurement and physician measurement or physician performance measurement, the broad variety of cases that might be contemplated in an ACO or other value-based care strategies.

So, I just want to acknowledge that there is a broad range of use cases once you exit the key portion of TPO into PO. Something that sounds fairly clear like payment ends up having a wide variety of subset use cases and permitted purposes that fall under the boundary. So, I wanted to provide context for people regarding that case.

I see David, you've got a green checkbox. I'm not sure if that means your hand is up or if you've selected the wrong dialogue box.

David McCallie - Cerner - Public Member

Well, my hand is up.

Arien Malec - Change Healthcare - Co-Chair

Yeah, got it. I see Sheryl and Grace also in the queue. So, we'll go in that order.

Denise Webb - Marshfield Clinic Health System - Co-Chair

So, I think that framing, Arien, was quite useful and it's a good context for my comment, which is that, again, we understand, I think, reasonably well the notion of reciprocal exchange for treatment purposes, where you have two systems that agree to share data back and forth under the treatment mandate of HIPAA.

The asymmetries that start to come in when you introduce the broader use cases I think will put some stresses on what we know how to make work. So, for example, if you had a QHIN that represents payers and the only thing that QHIN does is query for patient data but doesn't provide any data in return – the best I can tell, that's not part of USCDI payer data – then I think that will put stresses on the system. It may be something that can be worked out, but it goes beyond what I think we have a lot of experience with today.

So, it's a caution, really. How do we try to maximize the reciprocity of the relationships and make sure that the USCDI minimums cover reciprocal useful information back and forth? Claims data is useful in a population health system, for example.

Arien Malec - Change Healthcare - Co-Chair

As an editorial comment – I made this comment previously – I'm going to take a bit of Chair's prerogative and not that the definition in 21st Century Cures relative to permitted purposes is, to my mind, ambiguous. Maybe to ONC's mind, it is not ambiguous. But the ambiguity or lack of ambiguity is going to get resolved through a rule-making process. So, we're in the position of somewhat speculating at the intent of 21st Century Cures regarding the definition of interoperability and the definition of information blocking.

Under one read of 21st Century Cures, 21st Century Cures has obligated all provider organizations, which is a fairly wide term in general to all permitted purposes to respond to information requests for all permitted purposes, which put a non-reciprocal obligation on providers relative to all of these cases, regardless of whether providers think it's fair or not.

On other readings of 21st Century Cures, there's some discretion that's allowed by ONC and HHS to define the permitted purposes under 21st Century Cures. In those cases, looking at items such as reciprocity may well be appropriate. So, I apologize for the Chair's privilege there. We're going to go to Grace.

Grace Terrell - Envision Genomics, Inc. - Public Member

Thank you. So, as I'm looking at the very broad category of treatment, payment, and healthcare operations. I am thinking about the fact that we've talked about quality measures previously today as well as on earlier days. This is actually the place and space, if you put those three things together, where we could potentially really get to outcomes versus process measure within the context that not only has public health and population health implications, but implications for individuals themselves.

So, as we're thinking about permitted purposes, growing a ring around the fact that treatment, payment, and healthcare operations really is the place and space where we can, for the first time, possibly get at outcomes measures ought to really inform the way we think about the architecture and structure.

Arien Malec - Change Healthcare - Co-Chair

Thank you for that. Perhaps we should – sorry, Sheryl, go ahead.

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

We can move to the next slide.

Arien Malec - Change Healthcare - Co-Chair

Okay. Oh, boy. And with regard to operations, we get to population-level data. I think many people have acknowledged that the operations use cases that are most applicable also require access to population-level data to be most effective. Again, as an editorial comment, at CommonWell, we've contemplated solving these cases as a one-by-one query and it is incredibly inefficient to be able to do that.

At the same time, if you don't address some level of population-level data, it's not clear how the QHIN can be useful with regard to operations-based use cases. On the other hand, this is a brand new usage model relative to the needs of the country solved in this way. I see that David has his hand up. Anybody else, put your hand up if you want to make comments in this area. David, go.

David McCallie - Cerner - Public Member

Okay. I'm going to just enumerate a number of concerns that we have with this one. I want to assert I think it's good idea in the long run, but I don't think it's very well-thought through, given the number of unknowns in the current draft. So, this is one of those permitted purposes that I would push out to a future date pending a lot more review and piloting and experimenting amongst the stakeholders. So, just high-level, here are some of the concerns.

One is the notion of the proposed standard being worked on by HL7 around so-called flat FHIR or bulk data FHIR is extremely green, no experience with it yet. It will take quite some time to work that out. Number two, that standard is based on an asynchronous fetch later approach that's used by websites that want to enable the download of massive amounts of data. It's not a good fit for the query broker model being described here. So, I think it may be that the QHINs have some role to play in discovery where the patient data lives, but they may not be the channel through which the data should be brokered back.

Number three, the definition of a member is not the same as an MPI definition of the person. In the work that we've done with payers, we have quite a bit of challenging work to decide what data is qualified by membership for what periods of time. It's not necessarily all data for all time. It can gated by the duration of the engagement with the plan. That needs to be thought out. Anyway, I'll stop there. That's enough. I just think there are a lot of challenges here. It's a good use case. But let's take it carefully and pilot it, not expect to turn it on quickly.

Arien Malec - Change Healthcare - Co-Chair

As an editorial pile on on David's comments, I'd note that the two operations use cases that allow for a cross-covered entity exchange also require that there be a common patient population, which is why these population-level filters are so important, but also require some level of adjudication to make sure that both parties agree that that's the appropriate common patient population set. Denise?

Denise Webb - Marshfield Clinic Health System - Co-Chair

Yeah. I'd echo that. That was one of my concerns. The other is around this whole notion of a minimum necessary in HIPAA. I know there seems to be what I would consider some inconsistency, where in parts of the TEF it says that the QHIN must return all available information on the particular individual that the query is being done about. And if we have a group of individuals under this sort of use case, I don't see that they would be entitled to get all information, yet the QHIN has said they must respond with all available information on the patient. Maybe I'm just misunderstanding that, but I know this has come up in a few conversations at our health system.

Arien Malec - Change Healthcare - Co-Chair

Yeah. Lauren, I think we need to go to public comment. We're overdue.

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

We have another two minutes, but we can pause now and go to public comment. Does that work?

Arien Malec - Change Healthcare - Co-Chair

Yeah.

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

Operator, can you please open the line for public comment.

Operator

Certainly. If you'd like to make a comment at this time, please press star-one on your telephone keypad. The confirmation tone will indicate that your line is in the queue. You may press star-two to remove your comment from the queue. Again, that is star-one to make a comment at this time.

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

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

Operator

We have none at this time.

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

Okay.

Arien Malec - Change Healthcare - Co-Chair

We've been so thorough.

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

Okay. One last check – any other comments? If not, we'll hand it back to Arien and Denise. Operator, any other comments?

Operator

None of the phone.

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

Okay. Thank you.

Arien Malec - Change Healthcare - Co-Chair

One of the notes that I have here is that with a number of these use cases, the feedback from this group has been we endorse the notion, but reflect that the level of standards maturity and practice maturity is not sufficient to enable the particular use case. Is that a fair reflection both of the comments for population level data query as well as individual access-based data query?

Denise Webb - Marshfield Clinic Health System - Co-Chair

Yes.

Mark Savage - UC San Francisco - Public Member

This is Mark. I'd say that in some cases, it's also just the operational clarity, how it works. It may not be a standards issue. It may be it's just not clear what's intended.

Arien Malec - Change Healthcare - Co-Chair

Yeah. That's also fair. And then I think also makes sense as a meta-comment for the payment-based use cases. My reflection – I may be completely mistaken on this – is that there is a fair amount of standards-based ART for treatment-based query-based access for some emerging ART for individual access, but very much emerging, ART that SSA has done for benefits determination – there are a lot of individual one-off activities relating to population-level query that tends to be somewhat bespoke and emerging.

And then for payment-based use cases, again, there's a range of options that feel to me, at least based on the experience that I know in this area, that also feel to me like somewhat bespoke and one-off activities to be able to address risk adjudication, HEDIS measurements, chart abstraction, utilization management, and prior authorization medical necessity checking. I'm not aware of well-defined standards-based scaled or moderately scaled activities that exist in all those areas.

David McCallie - Cerner - Public Member

But those, Arien, it might make sense if we were to evolve into the broad notion of population support to pick a few of those, set some expectations, profiles in FHIR, or whatever it takes, a CDA template or whatever, and start with some very specific use cases like that. Rather than from going from zero to all data dumped, go by way of a specific set of step stone use cases that are of known value and that we all have to do anyway.

Arien Malec - Change Healthcare - Co-Chair

With regard to payment, I've made a number of assertions – I want to actually reflect those back out to the group – that to me, it makes sense to break payment down to a variety of subset use cases. I've acknowledged some use cases for PA and medical necessity checking, some use cases for utilization management, some use cases for risk determination, and some use cases for HEDIS measurement. There may well be others.

But does that approach of breaking the payment-based use cases down to appropriate use cases that are being handled today through a mix of mostly proprietary means, in some cases chart pulls and chart abstraction, that we take those use cases and break them down one by one? Does that make sense as an overall approach and does the enumeration that I just made make sense as an appropriate enumeration or are there other cases for payer-based use cases that I've missed?

David McCallie - Cerner - Public Member

There is this Da Vince Group that's getting fired up to do some of that work in the FHIR space. I don't know how their breakdown lines up with the ones you enumerated. But I suspect there is some overlap.

Denise Webb - Marshfield Clinic Health System - Co-Chair

So, Arien, as it relates to the TEF – in fact, as I'm looking at the slide that says use case around population-level data – to me, population-level data is not a use case. It's a type of query to satisfy a particular use case. So, I think that distinction needs to be made because otherwise, it is the broad ocean instead of saying we need to have the capability for population-level data queries, but they need to be constrained to the particular use cases.

Arien Malec - Change Healthcare - Co-Chair

Right.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Does that make sense?

Arien Malec - Change Healthcare - Co-Chair

That makes complete sense. In the ontology that I'm just throwing out there, the ad hoc ontology or the ad hoc folksonomy that I'm throwing out there, I'd look at population-level data to address definition one, definition two operations use cases. That is quality measurement and physician measurement, as well as risk determination and HEDIS measurement for payer-based use cases would be the four that, to me, sort of scream out for population-level data feeds, whereas many of the rest of those use cases can be addressed through individual-level data needs.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Does Grace have her hand up? I see a green checkbox.

Grace Terrell - Envision Genomics, Inc. - Public Member

No.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Okay. I wasn't sure if you were trying to raise your hand, Grace. Sorry.

Arien Malec - Change Healthcare - Co-Chair

So, may we go to the next slide? So, this isn't really a use case.

David McCallie - Cerner - Public Member

Yay.

Arien Malec - Change Healthcare - Co-Chair

I'm somewhat responding to David's public chat here, but I agree with the comment. Population health and broadcast and directed queries are more of an operational model more than they are a use case. But here, we're looking at the distinction between a broadcast and narrowcast. Let's define this maybe more in operational and outcomes terms that in one mode, we are asking for all known locations across multiple QHINs for the sum totality of data or locations of data known about a patient and the sum totality of the data known about the patient.

In other modalities, we're asking aa specific location for a specific patient and returning back just the data that matches that patient at that location. So, that's the general definition. I see David and Noam have their hands up. So, we'll go to David first. I wonder if David is benefitting from being first in the alphabet here.

David McCallie - Cerner - Public Member

Tell your parents name your children with an A so that they come to the top. Put a tilde in front. So, I've twisted myself in knots to try to figure out a simple way to describe how these structures ought to be presented. I think they're trying to capture some very important thoughts, but I think it's misleading or at least confusing.

It seems to me there are two broad-spectrum use cases just like Arien said. One is the directed-style query, where the provider or the querier knows exactly where the data is that he or she needs and they go ask for it and they get it back. I think some rules should apply to that in terms of if you're operating under the common agreement, obligatory response, etc. But you can imagine somebody just needs the results of a scan that was done and they know where it was done and when it was done and they just need the results.

And then there's the broader query, where you're essentially trying to create a federated record and you don't know where the activity is or you don't know what activity is out there. So, you're asking essentially for a lot of it. The architecture to accomplish the latter could involve this notion of distributed record locator services that are obligated to query each other, but there are a lot of other ways to do that as well, including, for example, distributing ADT information to all of the QHINs so they all know where all the data is and don't have to talk to each other.

Or you could have a master record locator service that everyone shares. You could even do it with a blockchain, dare I say it. So, I would say focus on the two functional descriptions, the ability to go directly to a provider or to a source for knowledge you know about and the ability to go broadly to fetch federated records. And then it lets the RCE figure out the best technical architecture to make that happen. So, too many words, but these aren't – I'll stop there.

Arien Malec - Change Healthcare - Co-Chair

Good. What I'm hearing, David, you say is number one, you're endorsing the notion that there's a distinction between broadcast or give me all the information known for a patient versus directed, give me just the information at this one location. You don't believe they're use cases. You believe they're modalities of exchange, but they're useful ones. And number three, you're recommending that ONC articulate this in policy and functional terms and defer the implementation of this to the RCE in consultation with the qualified health information networks.

David McCallie - Cerner - Public Member

Yes.

Arien Malec - Change Healthcare - Co-Chair

Is that a fair summary?

David McCallie - Cerner - Public Member

Yeah, well said. In particular, the phrase broadcast is the one that gives me a little bit of nervousness because that implies a technical approach literally spraying out queries, which may not make any sense at scale.

Arien Malec - Change Healthcare - Co-Chair

We should describe it in functional terms, that is, that I want to know all the locations of records for this patient, regardless of what qualified health information network serves the end responder and then I want to pull that information, again, regardless of health information technology or responder independent of the underlying architecture or approach that's required to get there.

David McCallie - Cerner - Public Member

Yes.

Arien Malec - Change Healthcare - Co-Chair

Alright. Noam, Mark, and Sasha…

Noam Arzt - HLN Consulting - Public Member

Yeah. Just a fairly minor comment, but also about languages – the phrase that continues to bother me is directed query and not its definition, actually. I agree with what was just said. But this material should be consumable by a less nuanced reader than the rest of us. For better or worse, the term direct many associate with the direct protocol. Not at all what is meant here, but to a casual, less nuanced reader, there is room for confusion here. I've suggested that maybe a targeted query would be a more descriptive and without the use of what has essentially become almost a reserve term, which direct directed – it's confusing.

Arien Malec - Change Healthcare - Co-Chair

I did too good a job of branding. We've also used point to point for this purpose as well. Let's go to Mark and then Sasha.

Mark Savage - UC San Francisco - Public Member

Yeah. I just wanted to lift up the point that was raised in an earlier call about push and where that fit. I didn't mention this back then, but the examples of referrals and transitions of care and the electronic exchange, it's an important question.

Arien Malec - Change Healthcare - Co-Chair

Maybe if we have time at the end, we can go back to this question because it is a foundational question. We can survey defense of the taskforce. It occurs to me that right now, the taskforce is split. I'm not sure if it's a passionate minority split or if it's a 50/50 split or how that split works out. Let's go to Sasha.

Sasha TerMaat - Epic - HITAC Committee Member

Thanks. So, I wanted to, I guess, agree with David's point about I think it will be most effective to specify the desired outcome and not be – the specific technical architecture that we want to use and leave that specification to the RCE as we investigate what the best way to achieve it would be.

Also, I think it would be advantageous to think of this as more of a spectrum of outcome flavors rather than as two choices because you could have scenarios where the two endpoints are well-known. You could have scenarios where you are able to cast a small net based on some things that are known based on a specific location. There could be scenarios where casting a net that is as broad as the entire network could be the most appropriate response. So, I don't think we have two flavors here. I think we actually have a spectrum of ways that you might cast that net in that way.

Arien Malec - Change Healthcare - Co-Chair

Very helpful. Thank you. Denise?

Denise Webb - Marshfield Clinic Health System - Co-Chair

I just wanted to jump in. I don't know if everybody can stay on right to the end. We wanted to remind folks of the homework and the areas to review for Monday's call on privacy and security are on the second to last slide. So, make sure to take a look at that. Thank you for putting that up there.

Arien Malec - Change Healthcare - Co-Chair

Yeah. Thank you.

Denise Webb - Marshfield Clinic Health System - Co-Chair

I just wanted to make that announcement. We can continue on. We probably should hit the last two areas, Arien, before we get to the end of our call.

Arien Malec - Change Healthcare - Co-Chair

We should hit the last two areas and if possible, reserve some time to discuss the boundaries of the qualified health information network. Let's go back up – one down. Wow. A bunch of easy topics. So, this was discussed previously with regard to the topic of individual access, but the notion is that qualified HINs must support permitted purpose regardless of whether they themselves facilitate that permitted purpose for their members. They must submit queries for that permitted purpose when they are requested to do so.

So, we discussed this topic with regard to individual access. We should also note that it applies to the broader set of use cases. If David doesn't get to his comment, I've got some comments in this area, but I'll go at the end of the queue.

Second is the notion of limits on aggregation. This gets at in some cases, the notion that an intermediary wants to restrict the use of data for downstream providers in ways that make uses very difficult for those downstream providers – I read this as language trying to create effectively an even playing field or what I've called in the past common carrier requirements for the qualified health information networks to be neutral and common carriers.

Then the notion that the receiving HIN may retain, exchange, use, and disclose only in conjunction with permitted purposes and in conjunction with the common agreement and participant agreement, applicable law, or BAAs.

So, a bunch of stuff here, but turning it over to David first…

David McCallie - Cerner - Public Member

Yeah. I'm going to mostly just ask for clarity in the next version of this on the meaning of the word reciprocity in 5.1 and the meaning of aggregation in 2.1. I don't see that 5.1 is talking about reciprocity at all. So, I'm puzzled as to what it means there. Then in number two on aggregation, I was really thrown off by that. I think what it means is aggregation as in bundling the responses that it might have accumulated in performing a query, but I initially read it as aggregating as in storing and building into a database. I assume it's the former. You can't limit what gets bundled up. You can't filter, really. So, it's not so much about limits on aggregation as limits on filtering.

Arien Malec - Change Healthcare - Co-Chair

That would be useful for ONC to clarify because every time I hear the word aggregation, my mind immediately goes to the definition under HIPAA.

David McCallie - Cerner - Public Member

That's my question or concern is let's get clarity on that one.

Zoe - Unspecified Organization and Role

This is Zoe. I would say it's the latter. It means aggregating, so you can do things like store data and do quality measurements.

David McCallie - Cerner - Public Member

So, you're saying that's not allowed to aggregate or you may aggregate as much as you want? Is this about the QHIN or the participant?

Arien Malec - Change Healthcare - Co-Chair

This is about the participants.

David McCallie - Cerner - Public Member

Oh, this is about participants.

Arien Malec - Change Healthcare - Co-Chair

What I read this as – and Zoe, please clarify – is that a QHIN can't restrict its participants as well as transitive participants for how they may aggregate data with regard to quality measurement or other activities that are otherwise allowed to a covered entity under HIPAA. Zoe, do I have that right?

Zoe - Unspecified Organization and Role

Yeah, Arien. That sounds right. So, if there is language that we need to clarify here, then we should definitely talk about that.

David McCallie - Cerner - Public Member

One question to ask in that context is is there any circumstance under which a QHIN is allowed to accumulate EHAI clinical data other than as required for audit purposes and things like that.

Arien Malec - Change Healthcare - Co-Chair

That's what I read 2.2 to say is, "The qualified health information may exchange, retain, use, disclosure electronic health to perform functions in conjunction with the permitted purpose in accordance with the common agreement and the participant agreements."

David McCallie - Cerner - Public Member

So, retain – does that mean a QHIN can build up a database, a CDR?

Arien Malec - Change Healthcare - Co-Chair

In connection with the permitted purposes in accordance with the common agreements and participant agreements and otherwise permitted by applicable law. So, I read that as yes, except with respect to any restrictions that are supplied by the common agreement and the participant agreements.

David McCallie - Cerner - Public Member

That seems huge. It's very much different from the way services like CommonWell operate today, where nothing is accumulated.

Arien Malec - Change Healthcare - Co-Chair

Zoe, would you read this as allowing if the query was done for quality measurement, would you see this allowing the QHIN to also do the physical quality measurement, the adjudication of a clinical quality measure, or am I overly broadly reading that language?

Zoe - Unspecified Organization and Role

I would say yes, they could if they wanted to, but that would be a business choice.

David McCallie - Cerner - Public Member

Can a QHIN go and query the other QHINs on its own purpose or is it only allowed to accumulate as a side effect of one of its participants asking for data to flow through it. If so, then the QHINs will immediately become master databases of everybody's record in about however long it takes to issue all the queries.

Arien Malec - Change Healthcare - Co-Chair

It would have to be secondary to a permitted purpose and, "I want all your data," is not a permitted purpose. "I want the data for this ACO on behalf of this provider," is a permitted purpose if that's one of the permitted purposes that's allowed under the agreements.

David McCallie - Cerner - Public Member

Yeah. This opens the door for the QHINs to become massive databases. That may or not be the intended consequence.

Arien Malec - Change Healthcare - Co-Chair

Sheryl, I see you have your hand up.

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

Yes, thank you. I have a comment about that as well. That would be definitely of concern, of course, for the payer community because at the end of the day, under the rules that we all follow, which obviously HIPAA is number one, and then we have many state rules and regulations as well in terms of the sharing of the data, but we also have our clients that we have to address. So, I'm a little bit curious because we have the same concern.

Certainly, a QHIN becoming a large data aggregator is an issue. Then if there is a secondary or unintended use of the data, that would be another issue. But we have in some of our arrangements – and I don't know how this would be handled – limitations on what data we can share for some of our ASO clients, for instance. I don't know how all of that would really be worked out with some of these rules because we're under an obligation from a contractual perspective as well.

So, in the ASO arrangement, where they are considered under a health plan, they have the right to dictate to us as their administrator how to handle some of that data. So, I think that's still an open issue that needs to be discussed and sort of figured out.

Arien Malec - Change Healthcare - Co-Chair

Yeah. That's, by the way, a really interesting case that I've seen in a variety of other circumstances in cases where HIPAA or the QHIN rules allow what a specific business associate agreement prohibits, you may put the responder or the QHIN in an odd place with regard to meeting its obligations under one versus the other.

I see no other hands up. So, we're going to go to the next slide. So, 9.1.1 is that the participants have to supply all the data classes in the then current USCDI and must respond. Zoe, can you provide me a distinction between participant and end user?

Zoe - Unspecified Organization and Role

Yeah, absolutely. In the structure that we envision, you have the QHIN at the top. The participants are the direct members of the QHIN and then the end user. So, it makes the case where a QHIN is made up of several different electronic health record vendors. Maybe the participant is the hospital and then the end user is the actual provider or maybe it's the patient. So, in section nine are the slow provisions for the participants in section ten.

Arien Malec - Change Healthcare - Co-Chair

Got it. Okay. Basically, this is making sure that even the QHIN does reciprocity, that the end notes also have to establish that level of reciprocity, that they have an obligation to respond or duty to respond.

Zoe - Unspecified Organization and Role

Exactly.

Mark Savage - UC San Francisco - Public Member

This is Mark. Can I just jump in and confirm, Zoe, that patients, individuals are end users?

Zoe - Unspecified Organization and Role

They could be depending on the structure of the qualified health information network and who they serve.

Mark Savage - UC San Francisco - Public Member

Okay.

Denise Webb - Marshfield Clinic Health System - Co-Chair

How would they respond to a query, then? If you call them individual end users, an individual is not going to respond to a query.

Zoe - Unspecified Organization and Role

There could be a caregiver on behalf of an individual or perhaps talking about a third-party app or a patient portal.

Denise Webb - Marshfield Clinic Health System - Co-Chair

It says, though, that each end user shall respond to queries and polls. So, with reciprocity, if the end user has to respond – it just doesn't make sense. An end user that is an individual would haven't data that you would be querying from them unless it's their data off of their Fitbit or whatever.

Arien Malec - Change Healthcare - Co-Chair

Right. I see David and Carolyn have a comment. Maybe we'll open next call with a specific – I'm going to frame up a question for next call that I'd like people to be prepared to answer with regard to the definition of the obligations for the single onramp for a QHIN because I don't think we're going to get to it today.

Denise, David, and Carolyn – Denise, you already got in. So, David and Carolyn – David is first and then Carolyn is second, so it is actually hand-waving order. That's useful.

David McCallie - Cerner - Public Member

Good or bad. My only comment is that the clarification needs to apply to make sure that the query poll obligation applies to targeted as well as any other kind of query. We've got multiple types running around in the document. So, just make sure there's something different about the query types.

And I would say the query inbound might be very targeted and specific and say, "I just need a CT scan report," at which point, I would hope it would be perfectly legal to just respond with the CT scan. Or it might say, "I need the full record," in which case, you would respond with the full record. So, decouple the requested purpose of the query, but you must respond one way or the other, just meet the purpose. And next is Carolyn…

Carolyn Petersen - Mayo Clinic Global Business Solutions - HITAC Committee Member

Thanks, Arien. Just to respond to Denise's comment a minute ago about **[inaudible] [01:25:13]** and patients being end users and perhaps needing to respond to queries – given the increasing use of patient-reported outcomes measures, remote sensors in the home, and other kinds of uses of patient-generated health data, while I think that's not one of the primary use cases or events we'd expect to happen, I would be very concerned about ruling out the possibility of that being a need, given the evolving structure of clinical trials, the use of telemedicine to perform treatments and other thins and just a general increase of patient involvement in their own care. I think we definitely don't want to exclude that.

Arien Malec - Change Healthcare - Co-Chair

Carolyn, I didn't hear Denise's comments as intending to exclude patients. I think what Denise was questioning is if a patient is an end user and there's a request to respond, do they have the same obligations to respond that a provider organization does? How far do those obligations to respond follow?

Does it require every patient to have a PHR or a home record bank that's the aggregation of their records and to respond to each and every request for a variety of purposes or do they have special rights and obligations with regard to response. I don't think anybody is questioning whether they have the ability to respond. I think the question is whether they have the same obligations to respond that provider organizations do.

Denise Webb - Marshfield Clinic Health System - Co-Chair

I think we need to define two kinds of end users. There's the end user provider organization and then there's the individual. I was reacting to the word "shall," "shall respond." Shall means it's mandatory that they have to respond. So, I don't think we would make a patient respond.

Carolyn Petersen - Mayo Clinic Global Business Solutions - HITAC Committee Member

I agree that it would not necessarily be our expectation to do that across all patients in all situations. However, there may be interactions between patients and providers in which patients agree to take on those responsibilities as a part of being able to access interventions in certain ways or to access certain types of services.

Denise Webb - Marshfield Clinic Health System - Co-Chair

I totally agree.

Arien Malec - Change Healthcare - Co-Chair

I don't hear a disagreement here.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Like a third-party app, maybe, that the patient uses to send their patient-generated through. That app would respond on behalf of the patients to send that data.

Arien Malec - Change Healthcare - Co-Chair

So, with one minute left, again, I want to remind this group about the homework. I'm going to add a homework item from the group. I'm going to frame a question relating to the intent and purpose of a single onramp and see if we can solicit both the range of perspectives and the passion associated with that range of perspectives and see if we have a majority position, a plurality of positions, and a majority with a very passionate minority. I think that's it. Denise, anything else?

Denise Webb - Marshfield Clinic Health System - Co-Chair

I just want to thank everybody for helping me out. I know I was supposed to be leading the entire call, but it got a little difficult with the noise around here.

Arien Malec - Change Healthcare - Co-Chair

Yeah. We've all got each other's backs.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Thank you. I appreciate it.

Arien Malec - Change Healthcare - Co-Chair

Next call from HIMS, for those of you who are from HIMS, we've got a lot to discuss. So, this was our next big push and we should be able to get through most of this and get to the fun art of writing comments, writing recommendations, and then reviewing those recommendations, which is, I've got to tell you, from past experience, both painful and incredibly rewarding. So, thanks, all.

Denise Webb - Marshfield Clinic Health System - Co-Chair

Alright. Thank you.

[End of Audio]

Duration: 90 minutes