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

Trusted Exchange Framework Task Force

Transcript
March 16, 2018
Virtual Meeting

Meeting Transcript

Operator
Thank you. All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Good afternoon, everyone, and happy Friday. Welcome to the Trusted Exchange Framework Taskforce. We'll call the meeting to order and start with a role call. Do we have Denise Webb on the line? No Denise yet? Arien?

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

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Aaron Miri? No Aaron. 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? No Steve yet. 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
Great. Anil Jain?

Anil Jain – IBM Watson – HITAC Committee Member

Yup, I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Kate Goodrich? No Kate. Andy **Truscott**?

Andy Truscott
Here.

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

David McCallie – Cerner – Public Member
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, thanks.

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

<u>Noam Arzt – HLN Consulting – Public Member</u>
Here.

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

<u>Grace Terrell – Envision Genomics, Inc. – Public Member</u>
Here.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer</u>
Okay, thanks. Arien, I will hand it over to you.

<u>Arien Malec – Change Healthcare – Co-Chair</u>
Okay. I'd just note that Sheryl says she's on via the chat. I'm not sure if she was registered as being on. We're in the last stages of the race here. Many of us feel tired of this activity, but we've got a little bit more to go. We want to finalize the recommendations on Monday so that we can send them to the full advisory committee. For today, my goal would be for us to touch all of the recommendations that we have yet to have discussed. We've been sending updates fairly frequently with drafting edits that have come out of previous taskforce discussions. I think it's useful for us to get through all the recommendations, and Monday, looking at the final recommendations and make sure that it really accounts for all of the taskforce deliberation. I propose that given we had a fair discussion of fees, and the interaction between fees and obligation to respond, that we start with that section on the QHIN obligations and read the actual recommendation, and then keep going through the actual recommendations to try to make sure that we touch all of the recommendations in this meeting. So, if we could move –

<u>Male Speaker 1</u>
Arien?

<u>Arien Malec – Change Healthcare – Co-Chair</u>
Yeah.

<u>Male Speaker 1</u>
I don't know if others are having this, but I'm still waiting for the web portion to launch. I may be the only one.

<u>Arien Malec – Change Healthcare – Co-Chair</u>
Okay. I can see it, I think.

Male Speaker 1
Well, just keep going, especially if I'm the only one.

Male Speaker 2
Yeah, mine's coming up. I can see it.

Arien Malec – Change Healthcare – Co-Chair
Yeah, so I think we're going to be – I think we did this one. By the way, did we have a final – Lauren, do we have a final vote for the majority/minority discussion? I think it was pretty close.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yes, we do. Let me pull that up. We had a total of eight for option one. Two for option two, and five for option three.

Arien Malec – Change Healthcare – Co-Chair
Okay. So, what I think we can is that given the 16 members of the taskforce, we can say that we had an even 50 percent, or half the members preferred option one, and there was strong and passionate support for both of the other options. We won't read that out as a consensus, and we will be sure to register that the draft language already does register the notion of a passionate minority opinion. We'll make sure that the final language reflects the strong beliefs on both sides of this.

I think we addressed both of these items. And then we go on to fees. So, you can see the updates that we did to address some of the discussion last time relating to, first of all, the use of common carrier in all of those areas. And please note if there's any areas that we missed. We tried to talk about – rather than common carrier, we tried to talk about the combination of zero or cost basis inter-QHIN fee structures and obligation or duty to respond. Based on some of Sasha's comments, we tried to better make it clear that the fee structure obligations were not on the QHIN to participant fees, but really on the inter-QHIN fees. And so, we tried to make it very clear that that's what we're talking about. And then we also tried to make it very clear that because, really, the TEF is voluntary – TEF participation and QHIN participation is voluntary, that the goal here is for provider organizations and other organizations to actively participate in exchange enabled by the TEF. And so, I tried to make sure that we weren't implying that the TEF and participation in QHINs was or considered to be a mandatory activity, or were required to, for example, mitigate responsibilities related to information blocking. So, it's a lot of complex language here. Would love the taskforce to make sure that it actually represents the thoughts of the taskforce and that the language makes sense.

So, if we go to the recommendation, one page down. So, it says "ONC should establish through the TEF the combination of zero cost basis QHIN to QHIN fee requirements with a duty to respond by QHIN's participants and end users only on QHIN intermediate exchange that is required for all providers, and ideally for uses that are reciprocal in nature, where both sides of the exchange equally benefit or are equally likely to query and respond. ONC should understand that the zero cost basis QHIN to QHIN fee structures, combined with duty to respond for inner purposes will significantly shape market dynamics." So, that's the suggested recommendations text net of all of the discussion. I'm just gonna pause. I see David, Noam, and John in the queue. We'll wait a couple more beats and we'll go to David.

David McCallie – Cerner – Public Member

Yeah. I'm a little bit – getting a little sluggish here on the screen, so I'm running behind and I've got interference. Hang on, let me mute it. Okay. So, I haven't had a chance to digest this in detail. But I wonder, is there any point in mentioning or discussing the notion of setting a fee cap or even specifying a fee that the inter-QHINS –

Arien Malec – Change Healthcare – Co-Chair
Yeah, that's a later recommendation.

David McCallie – Cerner – Public Member
Okay. Because I know that in some other federal mediated interchanges, like under **CK**, **both satellites**, etc., they do it that way.

Arien Malec – Change Healthcare – Co-Chair
Yeah. You'll see that is later – the next recommendation, actually.

David McCallie – Cerner – Public Member
Is the document that was sent earlier today the one that's on the screen or are they divergent?

Arien Malec – Change Healthcare – Co-Chair
It should be the same.

David McCallie – Cerner – Public Member
Okay. I must have the wrong one. Sorry.

Arien Malec – Change Healthcare – Co-Chair
Okay. Yup. Noam?

Noam Arzt – HLN Consulting – Public Member
Yeah, just a very minor nit. When you have in the text QHIN-QHIN, but when you say that, you say QHIN to QHIN, I would suggest you actually write that out. It's a bit ambiguous to put the dashes there. Because in fact, you even said it the way you meant it.

Arien Malec – Change Healthcare – Co-Chair
Yup. So, we could say QHIN to QHIN, or we could say inter-QHIN exchange, or maybe QHIN to QHIN exchange is better.

Noam Arzt – HLN Consulting – Public Member
Yeah. Whatever you mean it to be, but write it out as clearly as you can so that it's clear.

Arien Malec – Change Healthcare – Co-Chair
Totally fair. Yup. Thank you. All right, John.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
A comment and a question. The comment is that when I read the sort of preamble before the recommendation, I wasn't sure it sounded scary enough. What do I mean by –

Arien Malec – Change Healthcare – Co-Chair

Because I tried to tone it down a little bit.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
Yeah. I read it and I thought that the microeconomic hobbyist within ONC might shrug their shoulders and say, okay, so it's gonna disrupt business models a little bit. That doesn't sound so bad. So, I thought – I don't know if anxample at some point in the preamble might be helpful to make sure we make the point.

Arien Malec – Change Healthcare – Co-Chair
Thank you. So, that was the intent of "reduce the incentive for provider and QHIN participation in the TEF." It might be stronger to say that the combination of zero to no cost fee structures, duty to respond, and the opportunity for payers and disability determination or claims determination organizations to do, effectively, free queries or very low cost queries. The strongest thing we can say is that based on the fee structure, based on this combination of obligations, most providers and QHINs that would otherwise want to participate in the TEF will decide not to participate in the TEF. I guess they're not QHINs by definition. But most QHINs and HINs will decide not to participate in the TEF. I think it will be the kind of scariest language, and if there's a perspective that that's appropriate to say, I'm more than happy to say that.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
Yeah, I think, John, something that needs to come through in general is that – and it's specific to this area, but I think also overall – is that if the general step up to be in the ecosystem is too high, there's gonna be a lot of people trying like crazy not to participate in the ecosystem, or wanting to and not being able to. So, that's just a general theme that I think needs to come through.

Arien Malec – Change Healthcare – Co-Chair
Totally fair.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
And my quick question was, I wanted to make sure I understood the first paragraph of the recommendation. Are you saying that ONC needs to be careful that these sort of price controls apply only to QHIN to QHIN transactions so that downstream relationships are not screwed up?

Arien Malec – Change Healthcare – Co-Chair
Yeah. So, let me give a gloss on the first sentence. And every time I have to give a gloss, it's a good indication that the language does not adequately convey the intent. Now, the intent also may be wrong, but it's bad if the language isn't clear. And the preamble text tries to go through an explanation of this. But treatment-based use cases are cases where both parties to the exchange, because they're all providing treatment, are generally equally likely to be queriers and respondents, and generally equally likely to generate value from their participation in the QHIN, particularly in the area where the 21st Century Cures language quite clearly places information blocking penalties on not participating in treatment-based exchange. So, there are a set of cases where the incentive to participate is reciprocal and common. And in those areas, a uniform fee structure for QHIN to QHIN exchange makes sense. And the analogy here is that banks that put together – even though ATM fees are not uniform, they're as close to uniform as you're gonna get. The bank with the largest ATM network has done most of the work in establishing the network and has more uses of the network. And so, there's a reciprocity in terms of the inter-ATM fee structures that are applied at that level that don't either – that don't

discriminate against or bias towards network of one particular size or another, or actors of one particular type or the other, because there's reciprocity and equal likelihood to participate in exchange of that type, which is very different from areas where value on one side versus the other is – there's more value on one side of the exchange versus the other or dramatically more actors on one side of the exchange versus the other. So, the intent of the first thing is we should – the uniform cost QHIN to QHIN fee structure approach should be reserved for exchanges that are both reciprocal and common obligation, like treatment. And I'll just pause there and see if that makes sense, John, to you or to others.

Mark Savage – UC San Francisco – Public Member
Arien, this is Mark. Maybe – go ahead.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
No, go ahead, Mark.

Arien Malec – Change Healthcare – Co-Chair
Mark, you're also next in the queue, so.

Mark Savage – UC San Francisco – Public Member
Okay. So, this is a question I had, and it may get to what you're asking right now, which is that so, the reciprocal use and what was meant by that particular language, because two things. One is, we've got what are identified as six permitted purposes, but you could think of them as uses as well; and then three uses, which you could also call means or methods. Anyway, they're already spelled out, so I wondered, what's the effect of a qualifier here that says uses that are reciprocal? And the second thought I had on that particular language is what is reciprocal may not be at the same time, right? You may have a referral, for example, and that's happened one way. But everybody's referring to everybody, so it is at some larger level reciprocal, but maybe not in a particular instance. And so, if somebody is really parsing out the language, I just got stuck on that word "reciprocal" and what it meant.

Arien Malec – Change Healthcare – Co-Chair
I'm more than happy – if the intent of the language makes sense, I'm more than happy to accept cleanup help for it. And a referral, as you say, is not reciprocal in the sense that it's happening at the same time. But it's equally likely that the cardiac specialist and the primary care provider will participate in exchange, and both of them have common obligations relative to 21st Century Cures. And those are exactly the areas where I think ONC's fear is that QHINs could establish toll gates or monopoly activities where there's an obligation to participate and an obligation to query, but where if you let inter-QHIN fees vary dramatically, that QHINs could take that as a monopoly rent-seeking activity. That's my read of the policy concern. And so, the intent here is to say, let's be really clear about the criteria by which you should apply this mechanism to address that policy concern.

Mark Savage – UC San Francisco – Public Member
If this helps, I just wondered if you could put the period after "for all providers". "Required for all providers." And just delete the rest of it.

Male
But isn't the whole point they're not all the same? Some of these use cases are not equal. They are not

equal. I think that's the case for it.

Arien Malec – Change Healthcare – Co-Chair
I'm gonna enforce – maybe we'll get to free-flowing discussion, but I'm gonna enforce trying to get us through the list of people who want to be on the queue. So, Mark, if you could put your hand down, unless you've got more to say here, we'll go to Sasha.

Mark Savage – UC San Francisco – Public Member
Nope, no more.

Arien Malec – Change Healthcare – Co-Chair
Andy, David – cool. David, and then back to John. Sasha, go.

Sasha TerMaat – Epic – HITAC Committee Member

So, I share the concerns expressed in both of these recommendations, and I think we can get the words missing correct to express them. The first, of course, trying to avoid scenarios where current structures like with the SSA are disrupted, and the second recommendation, trying to still provide an incentive to QHINs to be effective, efficient in how they provide services, which is not necessarily there if they have to base it on attributed costs. The third sort of cost disruption that I'm seeing, or fee disruption from this model, is that those requesting information should be incentivized somehow to the same type of efficiencies. So, QHINs would want to be efficient in how they serve up data and reward it if they achieve it. But requestors who invest R&D in efficiency in terms of not sloppy programming that just refreshes data all the time unnecessarily but is intelligent about how far to search for the data and how frequently to do seem like they should also be sort of incentivized because that will reduce the overall cost of the network as a whole. And I'm not seeing sort of that other sort of avoidance of cost-shifting in either of the recommendations. I'm wondering if there's room for maybe a third point.

Arien Malec – Change Healthcare – Co-Chair
Yeah. Sasha, I get the point you're making. I wonder whether those are cases that are best dealt between the QHIN and the participant, because the QHIN is in those cases going to get hit with the QHIN to QHIN fees and is likely to pass those on to the participant. And those would be cases where the QHIN would want to work with their participants to make sure that their programming is appropriate in ways that minimize noisy or chatty queries. So, that's the first thought that I have, is that –

Sasha TerMaat – Epic – HITAC Committee Member

I think that's fine, as long as all of the exchanges were sort of reciprocal and equally weighted. If some of them are free, then that disrupts that balance.

Arien Malec – Change Healthcare – Co-Chair
Gotcha. Okay. Well-stated. Thank you. Got it.

Sasha TerMaat – Epic – HITAC Committee Member

But yes, it'd be the only connection there. If they were all equally weighted and reciprocal, then I think yes, it could just be between QHINs and participants. But if some of these exchanges are given to sort

of free inter-QHIN cost, then that disrupts the market of incentivizing the requestors in those cases.

Arien Malec – Change Healthcare – Co-Chair
Gotcha. Thank you. I'm just writing it down in ways that hopefully I can interpret my own writing. Okay. Andy, and then David, and then back to John.

Andy Truscott
Okay, thanks. Just quickly, I think we've beaten this one into the right direction to submission on this recommendation. Just responding to your gloss around equally likely to query and respond. I'm not sure that we should – there were many, many factors that sit outside what the fee structure is, about the likelihood of query and response. I'll be tempted to potentially suggest we say "and are equally capable of query or response," or and/or response. Something like that, so we're not actually trying to determine a whole bunch of other factors which set outside of the QHIN or QHIN **[crosstalk] [00:22:13]**.

Arien Malec – Change Healthcare – Co-Chair
I'm leaning towards – I think it was John's idea, or maybe it was Mark's idea, that we just end the sentence at "required for all providers," or end the sentence at "uses that are reciprocal," or "uses that are common" and leave off the detail because it sounds like the detail ends up driving as much confusion as it tries to clarify. But again –

Andy Truscott
Yeah, but the detail is helpful because it does address, actually, that part of 21st Century Cures about information block. So, the detail is useful, and I would say we need to keep it. We need to wordsmith it, but we should keep it.

Arien Malec – Change Healthcare – Co-Chair
Maybe "equally likely to participate."

Andy Truscott
That's fine. I'd be good with that. Also, I have a hang-up on the word "ideally" earlier in that sentence, because it's like, well, do you want them to or do you not?

Arien Malec – Change Healthcare – Co-Chair
Yeah. Totally fair.

Andy Truscott
Well, ideally. But maybe just say not ideally. Say, "And for uses that are reciprocal in nature where both sides of the exchange equally benefit and are equally capable of participation."

Arien Malec – Change Healthcare – Co-Chair
Yup. Perfect. I like it.

Andy Truscott
That work for you? Okay, good. Cool.

Arien Malec – Change Healthcare – Co-Chair
Thank you. Unless other folks have – somebody else may have the dramatic rewriting that really makes

the intent clear. David.

David McCallie – Cerner – Public Member
Yeah. A couple of slightly unrelated things. First, with respect to Sasha's comment about not encouraging sloppy programming, just the obvious assertion that the architecture that's settled upon by the QHINs ought to minimize the need for sloppy programming. In other words, we should work really hard to remove the chattiness of the network by appropriate use of record locator services and caching and other tools like that, rather than depending upon cost incentives to try to improve architecture.

Arien Malec – Change Healthcare – Co-Chair
We do actually make that comment and make that recommendation in the section where we talk about the record locator model, which is previous.

David McCallie – Cerner – Public Member
Yeah, I agree. I just want to – it's too late by the time people have written sloppy code.

Arien Malec – Change Healthcare – Co-Chair
Yeah. I think Sasha's points also are true, which is that the right way to address this is at the interaction model or the orchestration model, and then secondarily, we should recognize that people who've got an effectively free intra-QHIN or QHIN to QHIN exchange don't have the same incentives as folks who have a fee structure to, even within the constraints provided, appropriately use those constraints.

David McCallie – Cerner – Public Member
Yeah, which raises my next point, which is ONC should be very clear about what their goals are. And I would want to know more about why some of them are mandated to be free. I think that's just so potentially distorting because of that the likelihood that somebody will try to game the system, that what is the goal?

Arien Malec – Change Healthcare – Co-Chair
We could recommend – so, just to think out loud, we could recommend that the zero cost basis be reserved only for – and to our subsequent comments, only for true individual access.

David McCallie – Cerner – Public Member
Yeah, so I think we touched on that earlier. I would certainly agree that we'd be pretty precise about what that means. Individual acting on their own behalf, not in proxy to an aggregator, etc.

Arien Malec – Change Healthcare – Co-Chair
Yup, exactly.

David McCallie – Cerner – Public Member
And then the final comment was the one I blurted in on earlier out of turn, and I apologize for that. But I think it's now self-evident from the subsequent discussion, but that we're sort of saying not all use cases are equal from a fee point of view. So, just make that really clear, that some use cases may have different rules around how fees are determined than others. So, reciprocal exchange is not the same as a one-way consume only exchange, etc.

Arien Malec – Change Healthcare – Co-Chair
Yeah. And maybe I just feel like I beat that one to death in all the previous language, but it's worthwhile putting it maybe in the recommendation more explicitly that fee structures that don't do this or cases that don't do this will need different fee structures.

David McCallie – Cerner – Public Member
Right, right. Well, we had had a little bit of discussion about why was reciprocity in this at all. And I'm saying because it's different.

Arien Malec – Change Healthcare – Co-Chair
Yeah. So, what do people think about – is their objection to removing the zero cost language relative to the – or keeping the zero cost language only for the true individual access? Making a recommendation to keep the zero cost requirement only for true individual access?

David McCallie – Cerner – Public Member
Agree.

Female Speaker 1
Agree.

Female Speaker 2
I agree.

Male Speaker 1
I'm okay with that.

Arien Malec – Change Healthcare – Co-Chair
Okay. I'm hearing a voice affirmation. Is there significant objection? Is there objection? Okay. In the presence of voice affirmation and the absence of objection, we're gonna include that. Senate rules. John and then Andy back in the queue.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
So, this is John. No argument with any of the appropriately detailed issues we're discussing here. And feel free to parking lot me if this is out of sequence, and it may be based on a misunderstanding. But I have some concerns about overarching QHIN economics that go something like this. You point out that certain things are at cost by definition. Certain things are forced to be zero, which don't cost zero; therefore, the QHIN has to make money in some other way. We all acknowledge that. A couple of calls ago, there seemed to be some degree of surprise and concern, including me, in the realization that QHINs, through the permitted purposes, could accumulate and retain all the data, and therefore, there was nothing in my understanding preventing them from leveraging that data to not make thousands of dollars that they need to sustain themselves, but to make hundreds of millions of dollars based on the kind of tsunami of data that would be shifting from its current holders to retain in QHINs. Is that a misconception on my part, number one? Number two, if it's not, is that a concern or a tsunami that we need to point out?

Arien Malec – Change Healthcare – Co-Chair
Can we talk about that after we get through this fee structure discussion? I think it's an important

point. I sent you an email response back to your concerns, and I think it's probably worthwhile making sure that the back and forth get turfed to the full taskforce. So, thanks for brining that up.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
Whenever it fits, yeah. Thank you.

Arien Malec – Change Healthcare – Co-Chair
But let's get through this second recommendation and then explicitly bring that back in. Andy. Actually, I'm gonna skip over you, Andy, for one second and go to Genevieve, because I see she's in the queue, and I want to make sure that – I'm sure she's got an important perspective on this stuff that we haven't considered.

Genevieve
Yeah, thanks, Arien. Can you hear me okay?

Arien Malec – Change Healthcare – Co-Chair
Yeah, good.

Genevieve
Okay. So, just one note on the **[inaudible] [00:30:01]** access. Can you make sure if you put that into a recommendation that you define what you mean by that and you define it within the realm of OCR guidance on individual access?

Arien Malec – Change Healthcare – Co-Chair
Yup. Great comments, both. I think in the permitted purposes, we tried to go to some level of detail about defining what we mean. And I think the note to follow all the guidelines under HIPAA is appropriate. Okay, Andy, sorry to jump over you. Back to you.

Andy Truscott
Just quickly. This is one thing to what David and Sasha were saying, that my belief that what we're trying to do here is define a pattern and a function, not the actual technology solution. If a QHIN has some kind of legacy platform that is running quite nicely that's not efficient, it is sloppy programming. And all of our customers are happy to run that way. We shouldn't be telling them they can't, should we?

Arien Malec – Change Healthcare – Co-Chair
You'll see in the –

Andy Truscott
The preferred way of working, but not mandated.

Arien Malec – Change Healthcare – Co-Chair
Yeah, thank you. So, you'll see in the next recommendation some glossed text and some recommendations that are attempting to provide the appropriate incentive for people. So, this is something that Sasha I think very appropriately brought up. It's useful to provide the incentive for good actors in ways that tend to drive costs down over time, as opposed to allowing fee structures that disadvantage good actors and advantage bad actors. And I think the concern that we have right now,

or the concern the text reflects right now is a concern that the fee structure as it stands does the opposite of what we would want to be intended. So, maybe when we get to that section, we can bring that point back up.

Andy Truscott
Yes. I'm not gonna go on today. Let's just make sure we don't disincentivize existing HINs.

Arien Malec – Change Healthcare – Co-Chair
Yup. Great.

Female
Yes, just a quick comment. As we've been talking about the cost and the fees, we're thinking about it almost exclusively within the context of the cost of moving the information and sharing the information. It would seem to me that one of the things that's not being thought about in all this really is the actual storage of information that for individual organizations is the ongoing cost. And there may be an interesting problem that if things are too free to essentially request and obtain information from one source through the information highway that we're creating here, there can be some incentives that essentially is risk-taking in a different sort of way, where people are just getting access to information when they need it without having to have the storage cost as part of what they have in their own call structure. So, as we're thinking about the way to sort of set fees or the way to think about the incentives for that, one of the things that probably needs to be taken into account is the problem with easy access to information that someone else has the cost of actually storing.

Arien Malec – Change Healthcare – Co-Chair
So, I think maybe when we get to the issue that John is raising, we also bring that point back up.

Female
Okay.

Arien Malec – Change Healthcare – Co-Chair
I think in general, most of that is a QHIN to participant obligation that I think the TEF very appropriately stays out of. But clearly, there are economic issues relating to acquiring and storing large amounts of data, and there are unintended consequences for making it really easy to do that, particularly for things for images and the like. So, it's definitely an important consideration. David, and then we're gonna go on to the next recommendation and also go on to the issue that John raises.

David McCallie – Cerner – Public Member
Yeah. I'm worried about another odd edge case that occurs to me, and maybe it's a footnote somewhere. But we haven't talked a whole lot about targeted queries. It seems to be envisioned in TEF that they would still be allowed, and that would be, in my understanding, a participant to participant query that essentially bypasses a QHIN. It would be possible if that ends up being lower-cost than the QHIN-mediated queries to imagine a misbehaving provider who just sends out thousands of targeted queries for a low cost or zero cost, conceivably bypasses the QHIN entirely, thus sort of defeating the whole purpose of having the QHIN as a record locator and **caching** layer.

Arien Malec – Change Healthcare – Co-Chair
So, I don't see that the TEF – the way I read the TEF is that the TEF contemplates the targeted query is part of the QHIN's obligations. And I think the TEF is effectively silent at what provider organizations

might do on their own accord.

David McCallie – Cerner – Public Member
But don't you see this is a threat to the QHIN model if it is structured in such a way that it's cheaper to broadcast – to blast out – I'll try to avoid the "broadcast" word – to blast out thousands of directed queries, targeted queries?

Arien Malec – Change Healthcare – Co-Chair
If you've got language that you would suggest that would mitigate against that –

David McCallie – Cerner – Public Member
Well, the draft is very fuzzy about what a targeted query is allowed to do, so I'm just raising the question that it does have this. It's listed as a legitimate type of query. It doesn't define it very well. I'm not sure what the language is, but I think it could be an edge case that if the network costs are non-zero or significant, let's just say, then it could get exploited that way.

Arien Malec – Change Healthcare – Co-Chair
Yup.

David McCallie – Cerner – Public Member
It happens today.

Arien Malec – Change Healthcare – Co-Chair
It does. So, at this point, I'm gonna acknowledge your concern and encourage you to submit language that addresses those concerns in ways that maybe change the text.

David McCallie – Cerner – Public Member
Thanks.

Arien Malec – Change Healthcare – Co-Chair
All right. This is a trick that I learned from Brian Bellendorf. His response to any Apache should do X is patches welcome. So, the next section addresses some of the concerns that we've been discussing relating to the unintended consequences of the attributed cost formula on punishing the innocent and rewarding the wicked. So, the example that's provided is if one QHIN invests R&D capital to projects that make their services more efficient, because their attributed costs go down, they can't recoup any of that improvement through increased margin, whereas the organization that codes sloppy, loose, and fast reduces overall R&D expense, has an inefficient, relatively inefficient query, but also has higher attributed cost. And the net of that is to reduce incentives to improve efficiency. And so, the two recommendations that we're making, number one is that the inter-QHIN, or QHIN to QHIN, to Noam's previous suggestion, the QHIN to QHIN should be uniform, and that the **RCE** might want to contemplate reverse auction or other kinds of mechanisms that have been used in the past to reduce – to encourage fee structures to reduce over time.

So, the recommendation is ONC should provide the RCE the authority to employ mechanisms to ensure QHIN to QHIN fees are uniform for like services, and should encourage the RCE to adopt mechanisms such as auctions that prevent against inappropriate price increases and provide incentives to QHINs to reduce cost structure for QHIN to QHIN exchange over time. And as I read it again, and the first

sentence actually isn't saying what I think it intends to say, which is that ONC should ensure that QHIN to QHIN fees are uniform for like services. And I think we want to make that change. So, I see David in the queue. We'll see if other folks want to join in the discussion as well. Go, David.

David McCallie – Cerner – Public Member
Yeah. So, I hadn't thought about this a lot, but my concern here is that if you specify uniform fees but don't have some kind of requirement as a part of the common agreement for service level agreements, that you then incentivize sloppy behavior in the other direction, which is to say I'll just build a QHIN that's really sluggish and slow because it's underpowered. So, you've got a constraint from both sides.

Arien Malec – Change Healthcare – Co-Chair
Okay.

David McCallie – Cerner – Public Member
So, maybe in the context level of minimum service level agreements, QHIN to QHIN behavior.

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

David McCallie – Cerner – Public Member
About the RCE, I mean, again, a body of stakeholders, figure out what works.

Arien Malec – Change Healthcare – Co-Chair
Yup. Good point. Other commenters? Okiedoke. We're gonna go onto John's concerns. So, John, I'm gonna replay the discussion that we had via email and then let you comment to see if I've got it wrong. So, one of the RCE to QHIN common agreement restrictions that was established in the TEF prevents the RCE from establishing through common language activities that limit or prohibit the QHIN from providing a variety of services, including de-identification and aggregation services. And John's concern is that this creates an incentive on QHIN actors to be data accumulators, and to monetize the increased interoperability enabled through the TEF to create business models that involve, for example, selling data to a variety of organizations to improve sales and marketing. The read that I had on the same language was that what ONC was doing was making those decisions a covered entity to business associate agreement conversation and not an RCE conversation.

And I noted a couple of examples that currently exist. For example, in care quality, as I noted to join, care quality prevents the Indiana Health Information Exchange from persisting links that are gleaned from doing appropriate queries, so that the subsequent queries are more efficient or provide a better experience for end users because of the restrictions that care quality has on the exchange participants that are different from the restrictions that apply to covered entities. And it actually prevents covered entities from asking their HIN provider to perform certain services or make certain services more efficient over time. I think we need to acknowledge that covered entities under HIPAA are free themselves to do de-identification and aggregation, and are also free to assign the obligation to business associates to do that. And as I noted in my response, it's not clear to me how you design language that prevents activities that people think are inappropriate without also inadvertently preventing activities that people would consider to be highly appropriate. And I gave as examples of both of those the notion of selling data to enable or improve pharmaceutical sales and marketing, and selling data or using data to improve precision medicine or clinical trials recruitment.

I'm gonna go first – I know David's hand's in the queue, but I'm gonna go first to John, because he's the person who raised the issue, and I want to make sure that I'm fairly representing his concerns. And then maybe we can talk about whether there's language that we can or could propose to address those concerns. John, go ahead.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
Thanks. So, I'll try to be brief and boil it down. Nothing that conflicts with what you just said, just maybe a slightly different version of the story. If it's true that TEFCA will compel current holders of data to share their data through QHINs, and if it's true that QHINs can aggregate the data, and if it's true that QHINs must find business models to more than cover their costs, and there's nothing preventing them from those business models, what prevents, for example, the following scenario? Apple, which has a huge national platform, creates a means for anyone with an iPhone to pull down and use, in good ways, their patient data. And what prevents, while the QHINs cannot charge each other money for patient access, and perhaps the patients themselves can't be charged, the value of that platform would probably run into the billions of dollars to Apple or whoever is the successful monopoly or oligopoly. Is that a likely scenario, or is there something in TEFCA preventing that? And if it is a likely scenario, is ONC thinking, well, that's exactly what we want, or does anyone see a problem or concern?

Arien Malec – Change Healthcare – Co-Chair
Okay. Really well stated. So, John, just to underscore what you're saying, is that because QHINs have to establish a sustainability model, and because we're increasing the amount and volume of exchange, there is essentially a push on provider organizations to cover their costs of exchange by allowing QHINs to take on a set of obligations that they might not otherwise take on. I'm trying to be very deliberate in these discussions because they're public, not to call out any particular organizations. So, I think it would be helpful, except in cases where there's actual examples that have been well articulated and well discussed. So, I think it would be helpful to talk about consumer organizations that have strong platforms and the like. But David.

David McCallie – Cerner – Public Member
Yeah. Boy, what an insanely complicated topic. I don't even know how to think through clear points. But let me reiterate something I heard Genevieve say in one of our earlier calls in response to the subject when it first came up, which is that a QHIN would not be able to do queries on its own behalf other than for permitted purposes. So, a QHIN who wants to become a population health entity couldn't just instantiate itself and start blasting out queries to go out to a multi-hundred million patient database because that's not a permitted purpose. The individual acting through a QHIN that was just raised is a permitted purpose, so I think that's a very real concern, and I think it warrants special attention. We certainly raised it in its response, that exact use case, so it is a concern. And I don't have a great solution for it other than some clarity around what does it mean for an individual to act on their own behalf? Maybe that's done through a portal or something. It could be scoped into a specific way that an individual can act on their own behalf.

But the broader question I wanted to raise or suggest is that I think it makes sense to allow the QHINs to persist data only for purposes necessary to efficiently run the network, which would hopefully cover the case of something like persisting record locator data, so that you don't have the issue of unnecessary broadcasts, but not persisting data for other purposes. An abstraction around QHINs.

Arien Malec – Change Healthcare – Co-Chair
Yes. The issue there is that you get into really weird situations where – I'll pick on – maybe I won't pick on IHIE again. So, let's imagine a large regional information exchange that provides a whole set of value added services for research and for process improvement and quality improvement in its region. What you're doing in that case is you're preventing a whole range of activities from that actor as a sideswipe from that restriction, or you're forming that entity to kind of create two sub-entities, one that performs value added activities and the other that performs pure exchange services. And you're sort of complicating the architecture to address legal language. And again, I don't think these issues are theoretical. I think they're very practical, and I think they're examples of organizations that are extant right now that are doing a range of activities on behalf of their provider organizations under business associate agreements that the participants and the HIN believes is appropriate. John, let's go to you.

David McCallie – Cerner – Public Member
Well, Arien, let me just respond to you.

Arien Malec – Change Healthcare – Co-Chair
Yeah, go for it.

David McCallie – Cerner – Public Member
Because I think that that puts us in a sort of an either/or debate. Either on one extreme, you have a very pure definition of QHINs that's artificially restricted around these notions of fair play, or on the other side, you say anybody can become a QHIN as long as you follow the common agreement with respect to responding to queries. And I think where we're gonna get into trouble is if we try to split something in the middle and allow halfway pregnant QHINs or something. And I'm perfectly happy to make the argument that anybody should be a QHIN as long as they respond to certain agreements around responding to queries about patients for permitted purposes. And then you get out of the worry about whether the QHIN's accumulating data or not. A large provider organization could become a QHIN. Why not? So, I think it's gonna be either/or. Where we're gonna get into trouble is if we try to live in the middle ground. Either it's really pure or it's anybody.

Arien Malec – Change Healthcare – Co-Chair
I'm trying to think of how to draft language at this point, and it might be possible to draft language that's a recommendation, but it may well be possible to draft language that expresses a set of concerns that the taskforce is driving. John, I saw you with your hand up, and then you put your hand down, and then you put your hand back up. I want to make sure that . . .

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
Yeah. I was kind of gonna say what I think you just said, which is that – just verifying, is it within our scope to call this out as something we want to make sure ONC acknowledges and is thinking about? And it may not be a recommendation. But if it's within our scope, I think pointing out that, hey, we thought about this, and it seems like there's something to be concerned about.

Arien Malec – Change Healthcare – Co-Chair
Yeah. It's essentially a recommendation that acknowledges that we didn't find a clean answer for it, but asked ONC just to take additional thought in addressing.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
Well, and while I'm sure they thought it through, it's sort of making sure that they have.

Arien Malec – Change Healthcare – Co-Chair
Yeah, that's right. Sheryl, Sasha, and let's let Genevieve get her comment in.

Genevieve
That's so kind, Arien, thanks. So, it's a slight bit of a question on this. Is the concern, and just to make sure I'm voicing it correctly, the concern is that the QHIN can amass data that they can then sell for whatever purpose they want? And the follow-up question is, if that is the concern, are they not bound under HIPAA because they are in effect business associates to those HIPAA terms? And if they are not bound by HIPAA because we are concerned because there could be QHIN that's serving non-covered entities, are there simply some HIPAA term around resell of data that we could include in the Trusted Exchange Framework that if you are abiding by the common agreement, you have to follow those terms whether you're a covered entity or not? And I know that was like three questions.

Arien Malec – Change Healthcare – Co-Chair
Yeah, three questions. So, Genevieve, first of all, let me repeat John's formulation of the concern. So, let's take as an example a large consumer electronics organization that has palm top or desktop presence with a large number of consumers. And let's further suppose that that organization facilitates individual access in ways that also allow that organization to amass large amounts of data for a variety of purposes, many of which will be in the benefit of the public and the benefit of the patient. The concern at that level is that that organization could also use that data in ways that actors might not want them to do too or might look askance at.

And then with regard to binding, maybe your suggestion is non-covered entities should be bound to at least HIPAA terms relating to constraints on de-identification and aggregation, although as everyone knows, HIPAA doesn't have any – basically forces you to go through a process to make sure that when you de-identify data, it's actually de-identified, it doesn't have any restrictions on your ability to sell de-identified data. It does obviously have restrictions on your ability to sell PHI. So, maybe the suggestion is that non-covered entities should be bound by terms that are equivalent to HIPAA in terms of their obligation under the TEF.

Genevieve
Yeah, I'm not necessarily saying that. I think as you guys are thinking through it, that's perhaps another way to think about it, to say that some of the way we were thinking about it internally.

Arien Malec – Change Healthcare – Co-Chair
Got it.

Genevieve
So, that might be a way you guys could come up with a recommendation that might actually deal with the issue at hand.

Arien Malec – Change Healthcare – Co-Chair
That brief discussion caused four hands to raise. So, I'm gonna try to drain the queue at this point and then move on to additional recommendations. And at this stage, I think I'm open for people – definitely, I'm open for people to suggest language. I'm thinking that the out here is for us to present

the sense of the taskforce that this is a tentative area that needs addressing, and encourage ONC to apply some deep thought in this area, and maybe be more precise about some of the nature of the concerns that we have and get at some of the complexity of the non-covered entities. And Genevieve, definitely appreciate that ONC's already been thinking in these areas and is most likely way ahead of us in the taskforce in thinking about these areas. Sheryl, Sasha, John, and David, and then we're gonna go to the next set of recommendations.

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

Okay, so this is Sheryl. Thank you. I actually have a couple points. I was a little confused by someone's previous comment about the QHIN aggregating data, because the way I read the framework, I read it from the perspective that the QHIN must allow participants to exchange aggregated data. But I didn't see anywhere in there where it allowed the QHIN to aggregate data. So, that was kind of a question. I was just wondering where that interpretation sort of came from. If we extend to the point where we're assuming that the QHIN has the right to aggregate data, again though, I would make the point that that really, even as part of the participation agreement, shouldn't be allowed unless there was a business agreement in place between the two parties. And I don't think just the participation agreement and being part of the QHIN should allow an entity to aggregate data.

And then to the other point that was brought up relative to a large consumer organization amassing data, that is a concern for many of the participants on a QHIN. And I know, taking an example of a health payer might have a ULA agreement in place that prevents that aggregation in other types of uses. But we would agree that having perhaps part of the participation agreement QHIN require that both covered and non-covered entities both be bound by the parameters of HIPAA would be appropriate, because it solves a lot of other sort of nebulous situations that we've been talking about relative to trading information with non-covered entities, especially in light of who's required to report if a breach is encountered on the non-covered entity side and who's under HIPAA, then potentially at risk for any fines or lawsuits following along that line.

Arien Malec – Change Healthcare – Co-Chair
Yeah. So, the language in question – so, thanks for those questions. The language is question is 2.1 and 2.2.

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

Yeah, and I'm reading it right here, and it was confusing about the QHIN being able to aggregate data, only being able to exchange aggregated data by participants.

Arien Malec – Change Healthcare – Co-Chair
Yeah. So, 2.2 says, "Once the HR is shared with another qualified HIN, the receiving QHIN may exchange or **chain**, use and disclose only to perform functions in connection with the permitted purposes in accordance with the common agreement and the qualified HIN's network or as otherwise permitted by applicable law." And it's that last clause that would allow, depending on how you interpret it – that last clause that would allow other activities that the covered entity could delegate to the QHIN under their business associate agreement. Anyway. Complex, really complex topic. Sasha, John, and David. And as I said, then we're gonna go into the next set of recommendations.

Sasha TerMaat – Epic – HITAC Committee Member

I support raising this as an issue in our feedback to ONC. I think that some of the ways it happens today with business associate agreements are not going to be as applicable in the model envisioned by the Trusted Exchange Framework because many or all the QHINs might have access to data, but the covered entity business associate agreement might only be between one QHIN and one participant.

Arien Malec – Change Healthcare – Co-Chair
Fair point. Genevieve, and then John and David.

Genevieve
Oh, I didn't raise my hand again, sorry. I need to lower my hand.

Arien Malec – Change Healthcare – Co-Chair
John.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
John's turn. It's sort of responding to Genevieve's request for clarification about what we meant. I just wanted to say that not talking about – John is not trying to say something as simple as worrying about QHINs selling data. I think there's ample opportunity to monetize a giant pile of data, which is perfectly admissible under HIPAA, whether that data is identified or not. And then a separate but also attempt at clarifying comment is that if I have to express my concern in just one half of a sentence, I'd say this regulation moves as mountain of data from where it's currently held, potentially through the QHINs, and that data can be leveraged economically to the tune of god knows how much money. And so, it's usually bad in a free market for a regulation to move that much economic value from one sector to another. So, just making sure we're thinking about what we're doing.

Arien Malec – Change Healthcare – Co-Chair
David, I saw you take your hand down. Did you want to?

David McCallie – Cerner – Public Member
No, it's because I got kicked off, so I'll put it back up when you're ready.

Arien Malec – Change Healthcare – Co-Chair
Cool. Now you can take it down.

David McCallie – Cerner – Public Member
Okay. So, this is a point of, again, watching out for an edge case, which is that this individual access aggregation on a consumer device, I'll just point out that even if the consumer device company does not itself aggregate the data, the fact that the consumer device company's platform allows for app developers to have access to billions of downloaded records does effectively aggregate the data. So, it is an indirect aggregation that's gonna be really hard to tease apart. It'll happen, and it's just something that, as per the previous comment, we just have to be aware of, that those are consequences of doing something like this. Maybe intended, maybe not. ONC needs to be clear about whether they're comfortable with those kinds of outcomes.

Arien Malec – Change Healthcare – Co-Chair
Just to be fair to consumer companies who make devices and whose name may or may not be related to fruit, at least some platforms both encrypt information on the device and require authorization for

app developers to be able to access that information. That doesn't mean that all developers of applications which follow the same rules or that any developer who currently follows that rule couldn't change their rules and their technology enablement.

David McCallie – Cerner – Public Member
Or even if they kept those rules in place, that's still gonna allow for immense aggregation.

Arien Malec – Change Healthcare – Co-Chair
Sure.

David McCallie – Cerner – Public Member
Because they have to make it attractive.

Arien Malec – Change Healthcare – Co-Chair
Let's get permitted uses and disclosures. And there is obviously a whole lot to discuss here. So, the first topic is relating to many of the conversations we've had around individual access. The notion is the taskforce believes individual access should be cleanly separated from aggregator-based access for the purposes of fee restriction, the duty to respond. So, actually, we already said that relative to fee restrictions. Note that TEF acknowledges patients have the right to donate or otherwise use their data if they choose, which may involve actors that are not governed by HIPAA but would be subject to FTC regulations. So, recommendation: ONC should clearly define individual access, such as aggregator-based access on behalf of the individuals differentiated from the individual acting on their own. Fee restrictions, duty to respond should be restricted to the case where the patient is requesting access to supply data to an application or utility that the patient manages, and subsequently, data donation should be optional under the patient's control.

So, this is an attempt to, following the taskforce's discussions, appropriately define the term "individual access." To Genevieve's point, we should also make it clear that individual access is as defined under HIPAA. Mark, I see you've got your hand up, and then other folks who want to weigh in, feel free to put your hands up as well.

Mark Savage – UC San Francisco – Public Member
Yes, thanks. So, on the first recommendation, I know we tend to use acronyms as a shorthand, but I think it's important to focus on access and use. And here, I'm looking at whoever is requesting access. I actually find the construct from the meaningful use rule, if you download or transmit or share to an entity or an application to be useful language. Just to broaden access to thinking broadly about the ranges of ways that individuals will be using the information and can use it under the HIPAA rules.

Arien Malec – Change Healthcare – Co-Chair
Yeah. So, the drafted intent is intended to follow HIPAA and define it in terms of access. And access really implies the transfer of information to the individual directly to the individual to do whatever the individual chooses to do with that information. Maybe again, to Genevieve's point, we can make it clear that that's what we mean when we talk about individual access.

Mark Savage – UC San Francisco – Public Member
And it is HIPAA already.

Arien Malec – Change Healthcare – Co-Chair
Yup.

Genevieve
Well, Arien, the one reason I bring that up is when you look at the individual access under the OCR guidance, it specifically talks about third party applications or people or groups that an individual gets no rights to. So, that's –

Arien Malec – Change Healthcare – Co-Chair
Yeah. Thank you, Genevieve. And that's the intent of the clause, "where the patient is checking access to supply data to an application or utility that the patient manages." So, acknowledging that we're not really talking about cases where the patient themselves is coding to the QHIN API requirements. The most likely access scenarios are patient delegated access to an application, that the key bit is that the patient's access is under their control, and that the intent is for HIPAA access and not for subsequent data donation or other activities.

Male
So then, Arien, does the situation follow where the patient directs the patient's provider to send her information to another provider for a second opinion or something like that?

Arien Malec – Change Healthcare – Co-Chair
That's treatment, isn't it?

Male
Yes, but isn't this – that's why I'm thinking of access as having a broader range. I'm not sure why this recommendation is so limited.

Arien Malec – Change Healthcare – Co-Chair
Again, because it's really trying to follow the HIPAA Act, the definition of HIPAA access relative to other things that are under the patient's direction, but would fall under, for example, treatment purposes or payment purposes.

Male Speaker 1
And it is called out in the draft, so we're not inventing a new –

Arien Malec – Change Healthcare – Co-Chair
Exactly. David, you've got your hand up.

David McCallie – Cerner – Public Member
I'll just say that I'm still confused, but I will try to resolve that off the queue.

Arien Malec – Change Healthcare – Co-Chair
Okay. I see Denise is on as well.

Denise Webb – Marshfield Clinic Health System – Co-Chair
Hi. Well, I think also, we wanted to clarify too that the patient under individual access is essentially an end user too, but they're not obligated to donate their data such as a health system would be, because the flow down requirements. They're not a business associate. You can't flow down those

requirements to them.

Arien Malec – Change Healthcare – Co-Chair
That's the next recommendation actually in the –

Denise Webb – Marshfield Clinic Health System – Co-Chair
Right. But we do talk about is not obligated to donate. But the other thing is on that point about having your information sent over to somebody you're going to see, there's two ways under HIPAA that can't be done. It can be done through a HIPAA release, where they ask for that information to be sent for treatment purposes. But I've found as a patient, it's sometimes easier under the individual access to say I want my information sent over here and direct it instead of authorize it, if you're following me.

Arien Malec – Change Healthcare – Co-Chair
I am. I'm just trying to follow the – in both of those cases, the authorization's under HIPAA?

Denise Webb – Marshfield Clinic Health System – Co-Chair
Right. We should probably just add that, under HIPAA.

Arien Malec – Change Healthcare – Co-Chair
In only the case where the patient is acting as the HIU, one where the patient's actually expressing their HIPAA access rights and then subsequently directing the patient to flow to another provider is where individual HIPAA access rights come into play. In all the cases where the patient asks or directs their provider to go do something with the data, that's either treatment, payment, or individual authorization under HIPAA, which are different clauses and different use cases under HIPAA.

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

Arien Malec – Change Healthcare – Co-Chair
David, I saw you put your hand up and put your hand down.

David McCallie – Cerner – Public Member
Yeah, **on hold**.

Arien Malec – Change Healthcare – Co-Chair
Okay. I'd like to go the next recommendation, which kind of follows on this one. ONC should make it clear the duty to respond is on providers, not individuals. Individual controlled services should be able to make data available for query through a health record, bank, or similar structure, but should not be required to do so. And should they make data available, the choice of response should be up to the patient. So, basically saying that this duty to respond should not be implied to flow down to the patient. And I think the TEF right now is somewhat ambiguous about that. I don't hear any objection to that one.

Mark Savage – UC San Francisco – Public Member
Mark, with a question. Is there a duty as well for QHINs and HINs?

Arien Malec – Change Healthcare – Co-Chair
The duty to respond language is an obligation on the QHIN, as well as through flow down terms on

participants and end users. So, the way that the TEF is written, there's a duty to respond for purposes permitted under the TEF is queried. And because patients are considered end users, you could follow down that logic and make that logic imply the patients have a duty to respond. But I think we're clearly saying the patients don't.

Mark Savage – UC San Francisco – Public Member
Right.

Genevieve
I agree patients shouldn't have to respond, but given there are participants besides providers and individuals envisioned, can we just clarify the first sentence to say that individuals **wouldn't** respond, and it's not solely providers who would?

Arien Malec – Change Healthcare – Co-Chair
You're right. You're absolutely right. And I will admit that when I read that sentence, I went, oops. Okay. It really should be written in terms of QHINs, participants, and end users, and that we're clearly noting that individuals are –

Male
But not individuals.

Arien Malec – Change Healthcare – Co-Chair
Should not be end users as defined on the duty to respond terms. Yup. Okay. So, second recommendation. Explanatory texts, policies, and standards to **[inaudible] [01:12:59]** access have been developed and are in moderate scale use. So, this is really relating to some of the ecosystems that have been developed around Smart on Fire. However, individual access to broad scale cross-provider query uses are under active pilot and policy requirements and standards enablement. For example, the format and meaning of OAuth2 requests in a patient request use have not been established, and so our recommendation is ONC should task the RCE to test and evolve standards and policies sufficient to enable broad scale individual access. Standards should align with the policy and security requirements established for individual access.

And as I'm reading this, by the way, it really should be the RCE to work with standards development organizations and similar organizations, as opposed to task the RCE to test and evolve standards, because that's really not the RCE's role.

Male
Right. Thank you.

Arien Malec – Change Healthcare – Co-Chair
David.

David McCallie – Cerner – Public Member
Yeah. It makes sense to me, but I would wish this was expressed more in terms of goals. Is the goal to make it easier for an individual to delegate access and not need a portal? I mean, I think it's all good and true and I like it, but I'm not sure what goal we're trying to achieve here.

Arien Malec – Change Healthcare – Co-Chair

Thank you. So, I'm gonna tie this back to the taskforce discussion that we had where we acknowledged that in the case of a portal pulling from a single EHR or of an app pulling through a portal delegated access to a single EHR, the patient already has delegated access to a portal, and that portal has already gone through forms of individual identity assurance and authorization sufficient for that particular portal access. As you extend it beyond multiple settings of care, the discussion was how would we trust – in what circumstances would a respondent trust that the patient has been individually identity-proofed and individually authenticated sufficient to be sure that that patient actually is the end user in question? And I think there's an assertion or a perspective that maybe portal access should be sufficient, but it's not clear that policy has been established sufficiently that makes that statement a no brainer.

David McCallie – Cerner – Public Member
So, we could conceivably recommend that a starting point would be that individuals requesting access to their federated record go through a portal account where they have been sufficiently identity-proofed and then explore broader access patterns as experience is gained.

Arien Malec – Change Healthcare – Co-Chair
Well, that would be maybe too directive to the RCE. I'll try to do another draft of the language here. Would definitely recommend or encourage help if there's an alternative way of expressing this.

David McCallie – Cerner – Public Member
Yeah. I mean, I'm concerned about the notion that – I think the naive notion that a number of people have that if you have formal identity proofing through third party identity proofing services, that that's sufficient information to match you to your clinical records. That's typically not the case.

Arien Malec – Change Healthcare – Co-Chair
Exactly. That's really what the recommendation is intending to express, is that this is not a slam dunk because it's not clear that we've solved the individual identity assurance and authentication problem sufficient for broad scale query.

David McCallie – Cerner – Public Member
So, maybe we could put a consider, starting with portal-based access, given that that has done on mapping too of medical identity, and then the QHINs have broadened that to link to other records. I mean, the record-linking capability of the QHIN is what makes it useful.

Arien Malec – Change Healthcare – Co-Chair
Yeah. So, Genevieve and Aaron?

Genevieve
No, it makes perfect sense. I just want to know, if you take a look at section six of the draft Trusted Exchange Framework, it does require the use of the Smart on Fire guide for basically individual access, which does use the portal credentials. So, just note that that is actually in there.

David McCallie – Cerner – Public Member
And that makes great sense, Genevieve. That works well if it's a portal that the patient has an account that they've been authenticated into. It might not work for a QHIN because they won't have a portal as a QHIN.

Arien Malec – Change Healthcare – Co-Chair
Right.

David McCallie – Cerner – Public Member
That was a concern I had about that.

Arien Malec – Change Healthcare – Co-Chair
Aaron.

Aaron Miri – Imprivata – HITAC Committee Member

Hey, this is Aaron Miri. So, I would agree with the comment of assertion and validation needing, and that portal access is not sufficient enough, especially the linked records. However, that being said and done, NIST has done a fantastic job of really going through and figuring out how you determine different levels of assurance, whether it's a biometric or whatever else. So, to the point made earlier that perhaps you could reference or guide the RCE to look at NIST standards, especially around 863-3. That may be helpful in pointing people towards something that is a nationally recognized standard to identify and validate a person or individual.

Arien Malec – Change Healthcare – Co-Chair
Yeah. So, Aaron, just to be a little more explicit, as far as I know, the Smart on Fire – I know this to be true – the current Smart on Fire implementation guide does not carry information that would allow a respondent to look at the OL2-delegated authority and verify whether any particular identity assurance standard had been followed or not. So, that's kind of the issue, is you get a request for data and you look at it, and it's individual access, and you don't have any way of looking at that and saying, do I trust the method of individual access that's been performed, or do I know the level of individual access that's been performed?

Aaron Miri – Imprivata – HITAC Committee Member
And that's my worry, is that if you look at it as an unintended consequence of a potential breach, because if you don't validate who is accessing –

Arien Malec – Change Healthcare – Co-Chair
Correct. Exactly. And that's exactly the concern that's expressed. Noam.

Noam Arzt – HLN Consulting – Public Member
Yes. I'm just noting that we're quickly running out of time.

Arien Malec – Change Healthcare – Co-Chair
I know.

Noam Arzt – HLN Consulting – Public Member
We haven't quite finished, so could you say again sort of what our plan is for finishing this up? My concern being that I have an issue that's not in the draft, so I want to make sure we have a chance to raise issues that have been missed.

Arien Malec – Change Healthcare – Co-Chair
So, my hope, my naive hope was to get through the rest of the recommendations in this call. We are not going to be able to do that. I think it would be appropriate, and Noam, I was definitely thinking of you as I was watching the clock go through. We're actually pretty close. And we really do have only a few more recommendations to get through, so I'm pretty confident that we can get through the rest of the recommendations early in the next call and get information through. Noam, I'd love for you to spend the rest of the time that we have until public comment to talk about public health, as well as any other areas that aren't in the current draft.

Noam Arzt – HLN Consulting – Public Member
Yeah, thanks. That's really my main concern. So, in some ways, it goes back to what you started the call with, this sort of majority/minority thing on the – I guess – what was that? On the single on-ramp, right? That's where we sort of included our conversation about query, push, etc. So, given the ambiguity of that section, meaning that we didn't come to a consensus, we're left in a position where we really haven't made a statement about whether the public health permitted use is in fact served by the TEFCA draft or not. And I've maintained from the start that without the inclusion of this push capability, that public health isn't well served. So, if we're gonna leave the single on-ramp somewhat ambiguous, I feel that we need to make some statement about whether public health is being well served by this or not.

Arien Malec – Change Healthcare – Co-Chair
Yes. I definitely acknowledge that. We do, in the next section that we're just about to discuss, say – and you may disagree with this – other permitted uses and disclosures of a pilot-based use are only through a proprietary exchange. The taskforce believes these uses require active production testing and refinement prior to broad scale use and subsequent recommendation. So, it covers public health sort of through sleight or under a broad rubric. If you've got text that you'd like to propose for a recommendation to the full taskforce, I don't think there's any objection to including it. In the discussion in the taskforce, I think many people noted that because many of the public health use cases are either established through meaningful use or subject to significant local variation, state and local variation – I say local, mindful in California, we have I think five or six different immunization registries that all follow different proprietary formats. It's not clear that there is a ready-made go do this. Even if we said pushes in, it's not clear that there's a ready-made go do this that we can point to that says every QHIN must support X.

Noam Arzt – HLN Consulting – Public Member
I can propose some language for discussion if you will provide some time on Monday to discuss it.

Arien Malec – Change Healthcare – Co-Chair
Sure. I'd love to go to John and to Mark, but we first need to go to public comment.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
We do. Operator, can you please open the line for public comments?

Operator
Sure. If you'd like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press *2 if you would like to

remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the * keys.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
And do we have comments in the queue at this time?

Operator
There are no comments at this time.

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

Arien Malec – Change Healthcare – Co-Chair
All right. Let's go to Mark, and then let's go to the next recommendation that I just briefly referred to.

Mark Savage – UC San Francisco – Public Member
Well, it is on the next recommendation.

Arien Malec – Change Healthcare – Co-Chair
Perfect.

Mark Savage – UC San Francisco – Public Member
I think the stacking, the different priorities of some permitted uses and holding others for later or in advance, or whatever the right word is, doesn't really address the public health needs, because I think the definition of public health, among other things, goes back to the HIPAA definition. These are all current uses, current permitted purposes. And I must have missed the conversation where the taskforce was talking about sort of ranking these, because it's not clear to me.

Arien Malec – Change Healthcare – Co-Chair
Yeah. To be clear, Mark, the proposal is not that they be ranked or that one is more or less important. The discussion is that with regard to broad national scale uses, we have some areas that have established use and established patterns of use, particularly treatment. We have some like SSA disability determination that do have established use, but have some areas that are problematic with regard to the USCDI. And then the statement here is that the other permitted purposes – we're not making a statement as a taskforce whether we think they should be prioritized earlier or later. We're making a statement as a taskforce that acknowledges that the level of production testing relative to national scale use has not been established, and we're recommending that they be prototyped, established in use. We do later on in text, or the text later on does go through some level of detail regarding payment-based use cases and population health-based use cases that acknowledge specific issues that are at play there. But I just want to clarify that the intent here is not that the taskforce is saying we think treatment and individual access should be first because they're better. We're saying that treatment and individual access are closer to national scale, and therefore should be the early term priorities as we work out the patterns for use for other permitted purposes. I just want to see if that alleviates your concern. It might not.

Mark Savage – UC San Francisco – Public Member
No, it doesn't. But in the interest of time, I'll save it for Monday.

Arien Malec – Change Healthcare – Co-Chair
Okay. David? One minute.

David McCallie – Cerner – Public Member
I'll put my hand down. I've forgotten what it was.

Arien Malec – Change Healthcare – Co-Chair
Okay. All right. So, on Monday, we have half an hour. We've gotta get through all the rest of the recommendations and finalize the recommendation text. So, please, I will do another turn of the – Denise and I will do another turn of the draft, and we will get out the text by – I understand that it's the weekend, but we'd really appreciate folks to read the final or the near final draft text to make sure that we're prepared on Monday to get through the rest of the items and finalize the discussion. And Noam, and maybe Mark, if you've got proposed language that addresses your concern around some of these topics, definitely would love to hear it and have it expressed to the full taskforce.

Noam Arzt – HLN Consulting – Public Member
Yeah, I'll get to that this afternoon, because my afternoon is earlier than your afternoon.

Mark Savage – UC San Francisco – Public Member
Awesome. I'll work on that too.

Arien Malec – Change Healthcare – Co-Chair
Yup. Thank you. All right, Lauren, over to you. I think we're done.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
All righty, thank you so much. We will adjourn, and we'll talk again on Monday.

Arien Malec – Change Healthcare – Co-Chair
Thanks, all.

Male
Thanks, everybody.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you, everyone.

Female
Thank you.

[End of Audio]

Duration: 90 minutes