Trusted Exchange Framework Task Force

Transcript
March 14, 2018
Virtual Meeting

Operator
All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Hello, and good afternoon, everyone. Welcome to the Trust Exchange Framework Task Force. We will call the meeting to order starting with a roll call. Denise Webb?

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

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

Arien Malec – Change Healthcare – Co-Chair
Hello.

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? Is Aaron on yet? We'll circle back. John Kansky? Is John on? Sheryl Turney? Sasha

TerMaat?

Sasha TerMaat – Epic – HITAC Committee Member
Present.

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

Steve Ready – Norton HealthCare – HITAC Committee Member
Present.
Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Cynthia Fisher? Not yet. Anil Jain? Kate Goodrich? Kate? Andy Truscott? No Andy. 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.

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
And Grace Terrell?

Grace Terrell – Envision Genomics, Inc. – Public Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
All right. Just enough for a quorum. I'll hand it over to Denise and Arien.

Sheryl Turney – Anthem Blue Cross Blue Shield – HITAC Committee Member
Yes, hi. This is Sheryl Turney. I'm on also.

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

John Kansky – Indiana Health Information Exchange – HITAC Committee Member
Kansky is here, too.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Great. Thank you, guys. Anyone else?

Arien Malec – Change Healthcare – Co-Chair
Anil is waiting for the conference line in the chat.

Anil Jain – IBM Watson – HITAC Committee Member
I'm on now. Thanks, guys.

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

Arien Malec – Change Healthcare – Co-Chair
So, we have more than a quorum. So, we've gotten a lot of really helpful feedback so far on the draft recommendations. A lot of really good substantive comment, which is why the draft recommendations were draft. We're going to have to do a few rapid turns of the discussion, as you saw, based on the last meeting. We did a fairly rapid turn of editorial changes. We've gotten some more feedback inbound, and we're likely to do probably a few more turns before it comes time to submit the final recommendations. I really appreciate the level of rigor and attention people have paid to the recommendations and to the substantive comments people have made so far. We have a lot of work to do this week, in order to prepare for the final presentation for next week.

Unless Denise objects, I think it would be best to go to the place we stopped last time and just go through the detailed review of requirements or of recommendations and go through the same process and try to do one pass through the whole document before we go back and address some of the changes that we've made or some of the other suggestions that have come inbound. Denise, if you've got other alternatives or other approaches, I'm certainly happy to go along with that.

Denise Webb – Marshfield Clinic Health System – Co-Chair

No, I'm good with that.

Arien Malec – Change Healthcare – Co-Chair
Yeah. All right.

Denise Webb – Marshfield Clinic Health System – Co-Chair
I agree with that.

Unnamed
Arien, can I jump in with a quick question?

Arien Malec – Change Healthcare – Co-Chair
Sure.

Unnamed
How important is it to get feedback back to you guys in writing, sort of interlineating in the draft compared to the phone call? I haven't sent anything in writing. I'm just listening to you, and I'm wondering if I should be erring on the side of getting it in writing, too, rather than – in addition to participating on the phone calls.

Arien Malec – Change Healthcare – Co-Chair
I think it is helpful to do both. I'd also say that, just given the timeframe, there's only so much input that we can reasonably take in. Hopefully, you've seen that the drafting that we did after the last meeting addressed many of the verbal comments. So, I don't think there's any need to repeat comments followed up in writing, if you've already made them verbally in the task force. Clearly, if you feel, on reading the edits, that you've got something that you feel very strongly about that hasn't been addressed, feel free to follow up in writing. At the end of the day, we're trying to create consensus-based requirements, which means there may be some areas that one person or another feels very strongly about that may not make it into the final draft.

In other cases, there may be something that people feel very strongly about that we can make some appropriate tweaks to the language to address. But I'd say try to make them verbally here. We'll make sure that we accommodate them in the draft. We'll try to make sure that we flip drafts quickly. And if you find something that you feel very strongly about that we haven't addressed, please make a comment via email as quickly as possible, so we can address it.

Unnamed
Thanks.

Arien Malec – Change Healthcare – Co-Chair
All right. I think we were most of the way through the RCE language, if I remember the last time.

Denise Webb – Marshfield Clinic Health System – Co-Chair
Yeah. We stopped on the recommendation that started with ONC should require the RCE as it

works on standards, implementation, guidance, profiles, and other enabling materials make such material open to the public without restrictions. And I think we ended with that recommendation.

Arien Malec – Change Healthcare – Co-Chair

I think that's right.

Denise Webb – Marshfield Clinic Health System – Co-Chair

We stopped there. And we were about to go into the prelude to the next recommendation.

Arien Malec – Change Healthcare – Co-Chair

Thank you for that. So, if we go down a couple more pages.

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

Arien, this is Lauren. For those that are viewing the document on Adobe, there is a way to expand that main window. I know it's a little bit hard to see. It's a little small.

Arien Malec – Change Healthcare – Co-Chair

Yeah. That little arrow that looks like it means compress everything, but it actually means expand everything. It's right next to the stop sharing window, if you have that, or to the left of the pod options, if you have that as well.

David McCallie – Cerner – Public Member

Arien, it's David. Before we jump into the new stuff, on the RCE page, the bottom of Page 6, when I was looking over it, I had a couple of –

Arien Malec – Change Healthcare – Co-Chair

Can you go back up one to the bottom of Page 6? Perfect.

David McCallie – Cerner – Public Member

And there were just questions. The first one is, in the recommendation paragraph in the middle there, it said the RCE should represent a broad range of provider perspectives. Do we want to include a broader range than just providers? Would payers and aggregators like registries also merit inclusion there? Or does your sense of the world provider include that?

Arien Malec – Change Healthcare – Co-Chair

It would not include that. So, I think it's something we should discuss. The logic behind this, and the logic behind my understanding of the discussion that we had on this, is that the 21st Century Cures obligations, in the legislative text, are on provider organizations. There are other stakeholders who are interested stakeholders but don't have the same information blocking obligations placed on them. So, on the other hand, serving a range of health information stakeholders, including public health and payers, generally, is a good thing. And then, on the

third hand, I'm obviously running out of hands, if you build a governing structure that includes everybody in healthcare, you end up building an unmanageable governance structure.

Sasha TerMaat – Epic – HITAC Committee Member

This is Sasha. Could we maybe talk about that at a higher level because I saw, in several of the recommendations, the kind of I guess underlying assumption that providers must participate in the Trusted Exchange Framework, or they would be considered information blocking. But that isn't something that we've had a lot of opportunity to discuss. And I guess my feeling was more that the Trusted Exchange Framework should be such a competitive offering, as far as exchange, that people would voluntarily participate. And it wouldn't be an obligation, if there were other sufficient methods to exchange.

Arien Malec – Change Healthcare – Co-Chair

I just saw your comments come in.

Sasha TerMaat – Epic – HITAC Committee Member

Yeah. No, and they were just before the meeting.

Arien Malec – Change Healthcare – Co-Chair

Yeah. So, hopefully, I didn't say anywhere in the document – hopefully, the current draft of the document does not say anywhere in it any implication that participation in a **QHIN** or the task would be a requirement. 1) The ONC has yet to put out even draft regulatory enablement for any of the information blocking provisions under 21st Century Cures. 2) I think, Sasha, as you noted in your email, the TEF is supposed to be a voluntary set of activities. And, in many ways, ONC, because it's voluntary, is able to use a different set of regulatory or nonregulatory tools than ONC would if it were nonvoluntary activity. That being said, we can take this out.

But that being said, I think a number of commenters have presumed that – and maybe read between the lines in the 21st Century Cures language, have presumed that there's an implied, if not an implied safe harbor, at least an implied presumption that you're doing the right thing, if you're participating via through a QHIN via the TEF with regard to information blocking. And, again, if people feel like that's too far a line to step, I'm quite happy to –

Sasha TerMaat – Epic – HITAC Committee Member

I feel like we have a responsibility on us to make the Trusted Exchange Framework on us and the RCE and ONC and QHIN, but to make the Trusted Exchange Framework a viable option that people would see it as the best way to exchange information. And I actually kind of feel like it will be a distorting factor, if there are other regulatory penalties that make it kind of seen as the only way. That sort of messes with some of the other assumptions we've made about how would we measure success. If you say you have to participate in this, and then, we say we're successful because everyone participated, we've kind of – I think we need different success metrics, if that's the underlying assumption. So, I guess I'd like to certify that we have a voluntary participation underlying assumption. And we could still say here that we think provider stakeholders are maybe worthy of a special call out in RCE governance.

But I think I would propose, I guess, to the group that we underline that we're framing all of our assumptions around the expectation that it is voluntary to participate.

Arien Malec – Change Healthcare – Co-Chair

I'm seeing a lot of hands up. This is a really important topic to discuss. We'll go to Noam, Anil, Mark, and David. David so quickly put his hand up.

Noam Arzt – HLN Consulting – Public Member

I'll pass for now. My comment isn't about this point, and I don't want to disrupt the conversation. But please, come back to me.

Arien Malec – Change Healthcare – Co-Chair

We'll do. Anil?

Anil Jain – IBM Watson – HITAC Committee Member

Yeah. I think my comment has to do with some of your – there is a line blurring between providers and payers. And I think, if you think about why we're all doing this, it's to handle some of the biggest challenges around value-based care and population health. And so, rather than – I heard some verbiage about focusing on the provider and staying with the provider, when it comes to information blocking. I think it's really anyone that is participating in some sort of accountable care. And so, as providers take on risk, they are, in some ways, becoming the plan or becoming the payer. And payers who are now aggregated provider relationships in an ACO structure are taking it on as well.

So, I don't have the best language in how to represent that. But I think we're missing something, if we just focus on the provider, in the context of what we just discussed.

Arien Malec – Change Healthcare – Co-Chair

So, Anil, the only counterpoint that I would have to that, and just interested in your thoughts, is that, if you read the 21st Century Cures Act, it is very clear that the only two entities that are subject to information blocking penalties are HIT vendors and providers. And so, a payer could choose to keep data – to refuse to share data for a variety of purposes and suffer no penalties associated with those activities. Whereas a provider or a health IT vendor is subject to penalties under 21st Century Cures. To some extent, they've got a bigger interest in – they've got more skin in the game to making sure that there's at least ready-made pathways for information exchange.

Anil Jain – IBM Watson – HITAC Committee Member

Understood. I do think that I see providers having relationships with payers where the payers themselves are the HIT vendor sort of deployment vehicle, or the ones who are actually supplying the technical solutions. So, they're creating relationships to extend, for example, the large EHR vendors, or committee based EHR vendors, to the **ACOs**. We're not losing sight of the fact that, in any kind of population health or value-based care, simply having the EMR vendor and the provider have free flow of information across the "provider" ecosystem isn't going to

be enough to actually solve the problem we're trying to solve here.

Arien Malec – Change Healthcare – Co-Chair

No, I completely agree with that. And it's a great point. Mark?

Mark Savage – UC San Francisco – Public Member

I'm going to go back to the starting point for this thread about how broadly defined participation and just providers and patients. I'd say that I hear you, Arien, that 21st Century Cures talks about information blocking and some context of users. But looking at it positively, affirmatively, the Trusted Exchange Framework is supposed to serve a broader range of stakeholders. And I think that's where we – we ought to think about this more as coalition building, getting the essential people to the table, letting them know that they have something to contribute because they are users, stakeholders. And I think we should use that broader range. So, I'd look at the users that are mentioned in the draft and in the user guide and think of it that way. The question about voluntary, I know that, generally, it's not.

But I just want to also note that, in the provision in Cures, which says that federal agencies can require the use of it, so, I'd just throw that out there to make sure that we had that in mind, as we're talking that we're not saying anything here that actually suggests we're going against what 21st Century Cures is saying, although we can make sense to frame our thinking about it as a voluntary structure.

Arien Malec – Change Healthcare – Co-Chair

I'm going to defer to ONC on this. But my understanding is that, if a federal agency made an activity nonvoluntary and required for participation, they would, typically, have to do that through contract or through rule making, as opposed to through broad obligations on provider organizations.

Mark Savage – UC San Francisco – Public Member

And that's what 21st Century Cure says in contracts.

Arien Malec – Change Healthcare – Co-Chair

Yeah. David?

David McCallie – Cerner – Public Member

Yeah. I think that this conversation would make a lot more sense, if we had the data blocking rule available, so that we could tie the two together. So, in some sense, ideally, we could come back and revisit this, at some point, after we have the data blocking rule. But we don't. So, given that we have to operate under the assumption that we don't know what the connection between the TEFCA and data blocking is, I would propose maybe that the concept here be stakeholders associated with the permitted purposes, which is to say, if the permitted purposes are narrow, the stakeholders are a narrower group. But if the permitted purposes and use cases, to use their language, are broader, then, the stakeholders would e broader. For example, there's no mention of computer input or payer input.

Arien Malec – Change Healthcare – Co-Chair

Well, there definitely is, or there should be, and apologies if there isn't, there definitely is a note that the governance should include the patient perspective, if by consumer, you mean consumer apps and the like.

David McCallie – Cerner – Public Member

I meant, well, patient is probably close enough to –

Arien Malec – Change Healthcare – Co-Chair

So, providers and patients are explicitly called out. How do people feel about David's suggested amendment, which I find kind of elegant?

Mark Savage – UC San Francisco – Public Member

This is Mark. I think it makes sense, at an operational level. But we're talking about, as I understand it, the issue of governance. And so, I think, at a governance level, you don't have sort of a sliding scale, depending on how narrow or broad the permitted purpose is. You include the key groups for representation, so they're available. So, for example, a lot of stuff with tech innovators, it seems like technology developers and payers in public health ought to be mentioned as well.

David McCallie – Cerner – Public Member

And that was my point that, to the degree that there's a clarification around the permitted purposes during the first three years of the RCE's funding by ONC, the appropriate stakeholders should be represented in the RCE. And we don't quite know what that list is. We've proposed a narrowing of the focus, from the broad list of everything you could do with a single on ramp. What I'm suggesting is stakeholders that reflect the permitted purposes and use cases that are expected during the first three years could be represented. Admittedly, it's deferring a little bit but connecting it to the goals.

Arien Malec – Change Healthcare – Co-Chair

So, the other way of managing this is – anyway, we can also talk about broad range of perspectives. So, the concerns that were reflected, in this recommendation, were the concerns that, historically, when governance organizations have been formed, they tend to over sample from particular areas. Particularly, when you look at representation for provider organizations. It tends to be the largest provider organizations that have the institutional means to participate. And unless you guard against that oversampling, you tend to get over representation. I'm also a little worried about making recommendations that, effectively, require ungovernable governance because you've got so many stakeholder perspectives that are represented on a governance structure.

And I understand there are different governance structures that may be not the same as a board structure. But you're, basically, asking the RCE to do so much and adjudicate so much that the organization becomes, effectively, ungovernable.

David McCallie – Cerner – Public Member

Arien, my point is though, if you expect participation from a particular segment of the industry,

and they have no representation, the participation is going to be unlikely.

Arien Malec – Change Healthcare – Co-Chair

David, I like your formulation. But I'm not hearing a lot of broad agreement for the formulation. What I'd recommend is that we keep moving –

Unnamed

Could you repeat what he said?

Arien Malec – Change Healthcare – Co-Chair

Yes. So, David's recommendation is that the stakeholders who share obligations under permitted purposes, for the TEF, be the ones represented in the governance in the RCE.

David McCallie – Cerner – Public Member

This is David. And it could be maybe better structured away from the permitted purpose angle and just say stakeholders drawn from groups expected to participate in the exchange of data using the TEF. Whatever the permitted purpose is. So, in other words, if there are no – I'll just say, if there are no payer exchanges contemplated, if, at some point, it just doesn't appear that that's where it's going to go, then, that group doesn't need the representation. On the other hand, if payers are expected to play a large role, in exchange of data, using the use cases around population health queries then, they should be a part of the governance. So, stakeholders reflecting actual use of the network or continued use of the network.

Arien Malec – Change Healthcare – Co-Chair

I'm going to suggest, just in the interest of time, that we try to do a breadth first search first and note that there is some clean up of this language that is desired, and that we try to collect alternatives to this. At the end, if we can't get an agreed on alternative, we can get fuzzier because you can always get fuzzier. Let's go to the next page.

Noam Arzt – HLN Consulting – Public Member

I'm sorry, Arien. If we could just come back to where I started within the –

Arien Malec – Change Healthcare – Co-Chair

Oh, sure. Please. Apologies. Go for it.

Noam Arzt – HLN Consulting – Public Member

And so, if we could go back a page. I think, actually, in the end, it becomes relevant from the conversation we just had. I'll try to make this point quickly. I'm concerned about the little, two lined paragraph smack in the middle of this page, which talks about – it says the task force believes the likely sustainability model for the RCE is through dues. And then, there's, essentially, a governance comment about oversight. So, I'll say two things. First, just like we think it's presumptuous to recommend, within, any of these documents, a particular technical architecture or standard, I believe it is also presumptuous to say that we believe that any particular sustainability model is what will or should happen because, in fact, it's up to the RCEs

to propose something. So, I would suggest that we strike these two lines entirely.

I don't think it takes away from anything we're trying to say. And to link to the previous point, I'm, therefore, confused about this whole conversation about governance of the RCE, governance within the RCE. So, here, these two lines seem to say that it's the paying members who have oversight role. Is that a gloss for governance? I don't know. And yet, we were talking just before. Well, no, it's the impacted stakeholders who have some governance. So, I find all of this confusing and, in some ways, perhaps, conflicting.

Arien Malec – Change Healthcare – Co-Chair

Yeah. So, just one key point. So, Noam, I think we got your comments via email. I agree with you that, at this stage, it's probably inappropriate for us to say that the sustainability model is through X. So, I have no issues with striking that. That did come out as task force discussion. I do think there's a general principle. And the oversight role is fiduciary oversight. I think there's a general principle that organizations that are paying dues to an organization should have at least some say in how the money is spent. So, that's the only commentary there is that that clause is and is intended to be restricted to fiduciary oversight making sure that organizations aren't contributing money and then, having money spent in ways that they don't agree with seems to be bad governance.

Noam Arzt – HLN Consulting – Public Member

Except that just because organizations are "paying" doesn't mean that it's "dues". So, in fact, I could see an RCE that that requires payment, but that payment isn't dues and doesn't bring up fiduciary responsibility.

Arien Malec – Change Healthcare – Co-Chair

It's totally fair, and I completely agree that we should not assume that the governance of the RCE will be structured in any one particular way. I'd recommend that we keep going. We got through the recommendations on standards implementation, guidance profiles as open, and we didn't see any comment on that. So, let's try to keep going and spend the next half hour getting through a good chunk of in a breadth first search, a good chunk of the information in front of us.

Noam Arzt – HLN Consulting – Public Member

Arien, this is Noam. I had sent you a comment within that section as well, right? And someone made earlier reference, this whole notion of judging the RCE primarily based on outcomes that it may or may not be able to control. I don't know that I agree with that. I don't know that I don't, but I don't know that I do.

Arien Malec – Change Healthcare – Co-Chair

Noam, we talked about, in the beginning of the meeting, a desire to get through these recommendations going through the full set of recommendations first, and then, coming back and looping back to information that we've already covered. So, just in the interest of time, I'd like us to be able to stick to that. We will have ample opportunity for people to come back and re-comment on the revised language after we've gotten through the full document.

Noam Arzt – HLN Consulting – Public Member

Okay, sorry.

Arien Malec – Change Healthcare – Co-Chair

Nope, thanks. Next page. There we go. And sorry, Noam, you're right. This is, actually, the recommendation that we're commenting on. So, the task force did discuss how we should judge the success or failure of the RCE. And it was, at least my understanding of the belief of the task force, that we should judge the RCE primarily on outcomes based measures and the real world success of interoperability enabled by the RCE's activities secondarily through satisfaction measures and process based measures should be viewed as leading indicators. So, we also noted that the effort, outcome, satisfaction, and process measures should be defined with the end in mind and working backwards to satisfy between constraints of realism and policy urgency.

So, the recommendation here is ONC should develop a set of outcome based measures and associated milestones, based on the expected patient and provider real world experiences enabled through the tests and associated RCE activities. The RCE should define a set of satisfaction, user experience, and process measures metrics linked to the outcomes measures. Measures and milestones should be defined from the perspective of the desired real world goals executed to be achieved by the end of Year 3. And then, work backwards to interim goals, balancing realism and urgency. Outcomes, measures, and milestones should be set based on high priority use cases and forward reference of the task force recommendations and permitted uses. So, at this point, sorry, Noam, I think Noam does want to be in the queue. But we've got Mark, Noam, and John as in the queue to comment on this recommendation. Mark, go ahead.

Mark Savage – UC San Francisco – Public Member

So, this is a comment here, but at some other places, too. Because the word realism, because we're trying to push the envelope, I worry that that holds us back a little bit and want to suggest feasibility instead of realism. And I understand the focus on Year 3. But I think any strategic governance entity is going to be looking beyond Year 3, as it's trying to stack up what's the best way to do things. So, I would, perhaps – what occurred to me is, from the perspective of the policy imperatives and real world goals, recognizing that not all might be achieved by the end of Year 3.

Arien Malec – Change Healthcare – Co-Chair

So, my understanding is the way this comment was framed was around the milestones for the first three years, keeping in mind that that's the timeframe it contemplated and a task at which the RCE would be re-selected. Maybe we'll go to Zoe to make sure we got that right. That was the thought process behind three years.

Zoe

Yes, that's correct. That is correct, yes.

Mark Savage – UC San Francisco – Public Member

So, maybe there is some thinking, when we have more time, to be done between whether to use goals or milestones there. Is it the milestones that are expected to be achieved by the end of Year 3 rather than the goals?

Arien Malec – Change Healthcare – Co-Chair

That's fair. So, there should be some level of forward looking approach. But I do think the language here was noted that you would judge the success. And mindful of Noam's defense here, the notion is that you would judge the success of the RCE at that three year period. Not just on meeting process measures and secondary milestones, but also what was happening at the end of that three year period. Thank you. So, next in the queue is Noam. Then, we have John and Anil.

Noam Arzt – HLN Consulting – Public Member

Yeah. So, I guess I sort of said what I had to say, mostly. So, I am concerned. So, we're in a section about the RCE. For instance, if I look at the very last line of this recommendation smack in the middle of the page, the outcome measures and milestones, though it doesn't say it explicitly in this sentence, are of the RCE, right, not of Trusted Exchange? Right? I just want to make sure I'm reading this the way you intended it.

Arien Malec – Change Healthcare – Co-Chair

Yes, you are. So, the thought process here, which I believe, and, again, if the task force generally believes very differently, the thought process that's leading to this language is that, if we had an RCE that hid all of its process milestones, but we weren't seeing real world interoperability, there could be a variety of reasons for that failure. But you wouldn't tend to judge the RCE as being incredibly successful, at that stage. And, again, very mindful that there may be other contributing factors to failure to achieve real world interoperability. It does seem appropriate to tie the RCE to the national outcome, as opposed to tying the RCE to process based measures that they can meet without meeting the national outcome. That's at least the way I understood the conversation of the task force. Why don't we go to Anil?

Noam Arzt – HLN Consulting – Public Member

The only thing I added that seems to me like we're setting up the RCE to hold the bag. And that's all that I'll say. Something goes south, it's all the RCE's fault.

Arien Malec – Change Healthcare – Co-Chair

All right, John?

John Kansky – Indiana Health Information Exchange – HITAC Committee Member

Sure. I'll try to be brief. So, it's clearly the easiest thing for us to recommend that outcomes measures are used to measure the RCE's success because that sounds right. As somebody who has been forced to think long and hard about what an outcomes measure is for health information exchange by one's board, I can tell you that it's really hard to define outcomes measures for health information exchange that, as someone mentioned earlier, can legitimately be attributed to the RCE, depending on maybe someone has an example for me. But if you go so far as to say outcomes measures like reduced re-admissions or reduced repeat tests, there

are so many variables between the RCE and that outcome, as that's not a really good measure. If you start counting transactions that the RCE has enabled, I think that's a process measure.

Arien Malec – Change Healthcare – Co-Chair

Okay. That's completely fair. And this may just be drafting issues when, in the discussion that led to this drafting, I believe the discussion of outcome was associated with the real world exchange activities. So, you might consider, from a health outcomes perspective, that to be a process measure from an RCE perspective, that's an outcome measure. So, if participants in exchange are actually exchanging information, that would be the level of RCE success criteria that would be contemplated. I agree that there's a set of health outcomes that are associated with that that could be very well beyond the ability of the RCE to achieve.

John Kansky – Indiana Health Information Exchange – HITAC Committee Member

So, maybe we just need another sentence or two to make that recommendation clear.

Arien Malec – Change Healthcare – Co-Chair

Cool. Thank you. That's super useful feedback. Mark?

Mark Savage – UC San Francisco – Public Member

I was just going to put it in the comment. The National Quality Forums Interoperability Measurement Framework talks about outcomes. So, not the only source, but we do have some work that's already been done by the range of stakeholders.

Arien Malec – Change Healthcare – Co-Chair

Relating to exchange activities, or relating to the –

Mark Savage – UC San Francisco – Public Member

Interoperability.

Arien Malec – Change Healthcare – Co-Chair

Okay.

Mark Savage – UC San Francisco – Public Member

Which includes exchange.

Arien Malec – Change Healthcare – Co-Chair

Yeah. So, we should be explicit. We're talking about measures of interoperability, not measures of clinical outcomes associated with interoperability.

Mark Savage – UC San Francisco – Public Member

Correct.

Arien Malec – Change Healthcare – Co-Chair

Okay. Thank you. All right. Let's go on to qualified health information networks. So, we spent a good amount of time discussing the notion of participant neutral. And we discussed, in our general, overarching comments, that we desire ONC to be more explicit about policy goals. We have a specific recommendation relating to participant neutral. So, 1) ONC should clarify the policy intent and the meaning of participant neutral and revise the definition of associated qualification criteria for QHINs to better reflect the policy intent. ONC should define a policy goal that the overall ecosystem of QHINs is neutral and accessible to all parties. ONC should use more neutral definitions that do not prevent data holders from offering QHIN services.

And if ONC desires stronger, more restrictive participant neutral language, ONC should continue the various ways that perspective QHINs may structure business entities to address possible restrictions. So, that last sentence is related to the comment that it's, generally, feasible to take one business entity and structure it differently so that sub business entities, or not for profit entities, that use services end up being the business entity that's associated with the exchange activity. And, in particular, the commentary around this noted that many of the real world exchanges that people associate or attribute to a specific vendor are, in fact, not for profit organizations that are governed and managed by provider organizations that use particular health information technology or a set of exchange services. So, thoughts, comments on this recommendation?

And I will go back and forth between screen sharing and looking at the participant list. I don't see anybody whose hand is up. Does that indicate – Sasha's hand is up. Anybody else? Okay. We'll go the Sasha.

Sasha TerMaat – Epic – HITAC Committee Member

Thanks, Arien. And I think the recommendation is well stated and reflects the conversation. And I emailed this, so maybe folks will have a chance to look offline also. But the preamble language here about speculating about why ONC did this, I guess I'd vote to just take that out of our letter. We didn't get that specifically from ONC. And I don't know that it is agreed upon by everyone. And it probably doesn't need to be there.

Unnamed

Which line were you referring to, Sasha, which sentence?

Arien Malec – Change Healthcare – Co-Chair

Speculate the intent.

Sasha TerMaat – Epic – HITAC Committee Member

To speculate the intent.

Arien Malec – Change Healthcare – Co-Chair

This is the royal we in this case, so apologies for that.

Sasha TerMaat – Epic – HITAC Committee Member

I don't think we need that paragraph, and I think we could just take it out and go to the next

part about we want ONC to clarify the underlying policy goals, and that leads into our recommendation about policy intent.

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

Unnamed
I'm sorry, but which paragraph are we talking about striking? I'm still not there.

Arien Malec – Change Healthcare – Co-Chair
The paragraph on the top of Page 8 that starts "We speculate the intent of the language is to ensure."

Unnamed
Just that paragraph?

Arien Malec – Change Healthcare – Co-Chair
Just that paragraph.

Unnamed
Okay, thank you.

Arien Malec – Change Healthcare – Co-Chair
We got Mark and John in the queue.

Mark Savage – UC San Francisco – Public Member
So, this is Mark. Conceptual because I don't have an answer, but the sentence that says let the RCE and QHINs work out the operational details on the broker model, I think that seems right, from sort of a general operational perspective. At the same time, I worry about how long that could take. We need to move quickly. And I want to lift up the possible delay and timing issues. And I don't have any answers. But I just lift that up as something for us to be thinking about.

Arien Malec – Change Healthcare – Co-Chair
So, just to be clear, this is the next recommendation. So, we'll get there in just a second. But maybe we want to talk about clear time frames associated with that.

Mark Savage – UC San Francisco – Public Member
Okay. Sorry, I –

Arien Malec – Change Healthcare – Co-Chair
No problem. John?

John Kansky – Indiana Health Information Exchange – HITAC Committee Member
Real quick, just trying to follow along with the editing as referring to how we tee this up with

the taking out of the paragraph on speculation, which I think I agree with. My concern was that, when we stated, by the way, which is something I vehemently agree with, when we stated that we didn't really understand why ONC wanted to limit the who could be a QHIN, I think they perceived that they have answered that question. And so, I didn't want us to imply, in a way that was confusing to ONC, that no, you haven't because it's more that we haven't understood the answer, if that's fair.

Arien Malec – Change Healthcare – Co-Chair

Yeah. I'd also note that, if you look at the way this is defined, the definition of participant neutral is, literally, in the definition section. So, it's not – anyway, it's fair to say we didn't understand the answer. I think, in this case, it's also fair to say it's not clear that there was a lot of language around it just because of where it occurred.

John Kansky – Indiana Health Information Exchange – HITAC Committee Member

So, as long as the way that it's written reflects that. I just wanted to say that out loud. Thanks.

Arien Malec – Change Healthcare – Co-Chair

That's totally fair.

David McCallie – Cerner – Public Member

Arien, it's David, and –

Arien Malec – Change Healthcare – Co-Chair

David, your hand is in the queue, and you're making your comment.

David McCallie – Cerner – Public Member

Good. That's why I raised it, after the fact raising. We're both asking for increased clarity around participant neutral. But aren't we also suggesting considering a broader ranger of choices than what it appears they intended to communicate?

Arien Malec – Change Healthcare – Co-Chair

Yeah. So, the recommendation here is 1) Sub Recommendation 1 is ONC should clarify the policy intent and revise the definition of associated qualification QHINs to better reflect the policy intent. 2) ONC should define a policy goal that the overall ecosystem of QHINs is neutral and accessible to all parties, which I think reflects the commentary that we had around that. 3) ONC should use more neutral definitions that you not prevent data holders from offering QHIN services. And 4) just a note that, if they want something stronger, ONC should consider the various ways that business units might be structured to address. Is there something you think is missing from those four sub recommendations?

I think the drafting intent was that the third, effectively, bullet here, ONC should use more neutral definitions to not prevent data holders from offering QHIN services was intended to address that this may be over rotated on a particular solution rather than addressing the policy goal.

David McCallie – Cerner – Public Member

Yeah. I just want to make sure that we're not talking merely about clarification. We had opinions about what participant neutral could mean, and we should capture those.

Arien Malec – Change Healthcare – Co-Chair

Yes. So, I believe the opinion here is captured in the mix of the second and the third bullet. And if it's not, I think we're absolutely open for additional drafting to reflect the task force's perspective here.

David McCallie – Cerner – Public Member

Okay. And I'll take a look at it, when we get the next version of edits, and see if I feel comfortable with it. My version is a little out of sync with yours.

Arien Malec – Change Healthcare – Co-Chair

Okay. I don't think anybody else's hand is in the queue. Good. All right. Next is ONC should define – so, this is separating the definition of the broker model from the TEF itself. And so, generally consistent with our recommendations that ONC defined functional requirements, specifically for the broker model. We believe that ONC should define functional requirements and let the RCE and QHINs work it out. I think it was John who commented that we should define clear and urgent milestones to that working it out, so not open ended, three year long working it out. And so, I think we need to make that editorial comment, but the recommendation here is ONC should define a set of functional requirements, document the outcomes of using a QHIN from the perspective of provider patient.

For example, ONC might define a functional requirement that a provider or patient should receive all known locations where patients' data might be found and the content of data to be found at those locations, regardless of the technology vendor or QHIN used by the end location of data. So, I'm going to pause there and see if that recommendation appropriately addresses the task force's perspectives here. I see David with his hand up. I'll wait two beats. Go, David.

David McCallie – Cerner – Public Member

I think that that recommendation does capture it, if you kind of know what we talked about. I'm not sure a naïve reader would understand that. So, I might argue for a slightly more explicit example of a potential functional requirement. I submitted some possible thoughts in the email I sent you guys yesterday. But I'm happy to walk through them. It's just being a little bit more concrete. I think you captured the truth there, it's just subtext almost.

Arien Malec – Change Healthcare – Co-Chair

Yeah. So, without objection, we'll look at David's comments and see if we can insert them in appropriately. And then, we'll definitely go back to the full task force to make sure that we've captured the intent of the task force appropriately. Hearing no objection.

David McCallie – Cerner – Public Member

And we'd have to revise them if we didn't. I just was whipping off some examples of something that was slightly more explicit. And, again, to be taken just as example, not anything other than

think about it this way.

Arien Malec – Change Healthcare – Co-Chair
Okay. Now, the easy topic of fees.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Arien, I think we have to pause for public comment.

Arien Malec – Change Healthcare – Co-Chair
Okay. Let's do that.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Operator, can we please open the lines?

Operator
Thank you. If you would like to make a public comment, please press Star 1 on your telephone key pad. A confirmation tone will indicate your line is in the queue. You may press Star 2, if you 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 start keys.

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

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

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Thank you. Hand it back to Arien.

Arien Malec – Change Healthcare – Co-Chair
All right. Fees. The simple topic of fees. Can we go back to the document?

Unnamed
Arien, I have a prolegomena question about fees. Would you mind explaining what you mean by common carrier requirements because you referenced that numerous times without ever defining what it means?

Arien Malec – Change Healthcare – Co-Chair

Sure. So, common carrier is definitely a term of art in, effectively, network neutrality spaces. The simplest analogy is that we establish a highway system. But with respect to – and that highway system may have restrictions on, for example, weight or load that might be carried on the highway system but doesn't restrict the kinds of commercial activities that take place on the road or highway. So, you couldn't establish, in a common carrier approach, that a particular kind of commerce has one cost to use the roadway system and another kind of commerce has a different cost to use the roadway system. And individual traffic has a third fee structure to use the system. We have a system where everybody can use it. In the internet space, there's been, obviously, a robust and vigorous debate about whether common carrier requirements should be applied to ISPs and other people who are carrying traffic.

And, in particular, Netflix, which bears the bill for bandwidth on its end should also bear the bill for bandwidth on the consumer end, such that there's a varying level of quality of service and associated pricing associated with carrying particular kinds of traffic on the network. With regard to the definition in the TEFCA, the net of the pricing rules establish that 1) RCEs have a duty – sorry, QHINs have a duty and obligation to respond for permitted purposes under the TEF. And 2) any fee structures they have have to be cost based and not activity based. And the net of those creates, effectively, common carrier like requirements. So, that's the background for the shorthand of common carrier.

Unnamed

But it specifically calls out different fee structures for different use cases, no charge for individual access, etc. So, it struck me as not being common carrier. I'm not sure it adds to the –

Arien Malec – Change Healthcare – Co-Chair

Okay. That's fine.

Unnamed

It may be one of those terms that people read in too many things.

Arien Malec – Change Healthcare – Co-Chair

That's fine. I think, in particular, the intent here was to note that there are cases where, right now, there are participants who pay for access. Who under the TEF and under the set of permitted purposes would no longer have to or be able to – the QHINs would no longer be able to charge for those forms of access. And some of the examples that are provided here are payers who request data and chart abstraction for HEDIS measurement or for risk adjustment. Often times, payers are willing to pay for access. SSA is famously willing to pay for electronic access for adjudication. And under the rules established here, the QHIN would no longer be able to charge for that access, except on a cost-plus basis. So, super happy to avoid the term common carrier and just describe it more functionally.

Unnamed

Yeah. I think that might help us, although it doesn't make the problem any easier.

Arien Malec – Change Healthcare – Co-Chair

That's fine. Sasha, you have a hand up.

Sasha TerMaat – Epic – HITAC Committee Member

Yeah. So, just because I think this is a really complicated area, and I was maybe trying to digest it the same way David did. So, there's two types of fees mentioned in the TEF, as I understand it. One is about how QHINs might charge for their services. For example, if a network charged its participants a participation fee, and the other is how QHINs might charge each other, which is the one that's restricted to being cost based specifically. Neither of those – both of those apply to the QHINs. Would a model between end points still not be able to have monetary compensation? I guess I'm asking a question. If SSA isn't end point but participates through a QHIN, and a provider organization is an end point and participates through a QHIN, is the compensation SSA might offer the provider organization for that exchange even relevant to these provisions about what QHINs can and can't charge?

Arien Malec – Change Healthcare – Co-Chair

That's a really good question. And this may not have been commentary in the task force, and I apologize if it was not commentary in the task force. Some of the commentary that I have participated in and seen on this topic notes that, and I'll pick on SSA because I think SSA is the least likely to do activities like this, so we'll pick on SSA deliberately. If SSA established – if there were a federal QHIN, for example, a QHIN that was attached to federal participants, that QHIN might establish a zero based cost structure with SSA. And SSA could ask for data for disability determination through its local QHIN, could make requests to provider organizations. And those provider organizations would be obligated to respond independent of fee structure because of a permitted purpose.

And the QHIN would be obligated to respond for that permitted purpose. And based on the cost plus language would be limited to what they charge. If you look at real world activities for SSA, often times, SSA desires to mediate through exchange participants, rather than contract directly with the provider organization. And they're perfectly happy to pay for an exchange participant who them splits the C with the provider organization. So, that's the thought process that led into some of this discussion.

Sasha TerMaat – Epic – HITAC Committee Member

Okay. That's helpful. So, are we making a recommendation here about how QHINs charge their participants, about how QHINs charge each other, or both?

Arien Malec – Change Healthcare – Co-Chair

Yeah. So, this is a super complicated area. And we don't have much time to discuss it. We probably should start the next discussion talking about this. Some of the thought process that goes into this is that there's an overlap between 21st Century Cures' obligations on provider organizations for information blocking and the fee structure requirements in the TEF that overlap in interesting and complicated ways. So, if you read the 21st Century Cures, and if ONC, through rule making, establishes an interpretation of 21st Century Cures that obligates providers to respond in all cases for permitted purposes, then, you get to a world very quickly where the combination of that duty to respond and the fee structure language on QHINs pushes the cost for a variety of purposes that currently are being paid for by the end actors who are getting the

data onto the providers who are supplying the data.

And the SSA case kind of worked out that we just did is one of those risk adjudication and HEDIS measurement on payers is another one where you could end up flipping the market for fee structures, if you don't align the fee language and the duty to respond language or the information blocking language in the right way. It's complicated. And I realize this may be my thought process and not the thought process of the task force. Maybe I'll better gloss this or work out this example. And then, we can discuss it and make recommendations as a task force on the next task force call.

Sasha TerMaat – Epic – HITAC Committee Member

Arien, I know you've mentioned a few times the information blocking provisions about providers and HIT developers. There is also a provision around health information networks, which is, of course, broadly defined by the Trusted Exchange Framework, might be worth thinking about how that would also influence.

Arien Malec – Change Healthcare – Co-Chair

Yeah. And let's talk about it next time. John, I see your hand is up. But we are out of time. So, when we get to the next Friday call, we'll have ample time to address these issues.

John Kansky – Indiana Health Information Exchange – HITAC Committee Member

And I'll endeavor to put my thought in an email before I forget it.

Arien Malec – Change Healthcare – Co-Chair

Excellent. Thank you. Thanks everybody.

Unnamed

Noam asked for clarification on the meeting schedule for next week, Arien. He needs it in email. Never mind. Someone needs to send it to him in an email. He's offline.

Arien Malec – Change Healthcare – Co-Chair

Okay. Maybe Lauren can help there.

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

Sure. Okay.

Arien Malec – Change Healthcare – Co-Chair

Thanks, all. Bye.

[End of Audio]

Duration: 60 minutes