Trusted Exchange Framework Task Force

Transcript
March 12, 2018
Virtual Meeting

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
All right, perfect. Good afternoon, everyone, and welcome to the Trusted Exchange Framework Taskforce meeting. We will call the meeting to order starting with role call. For those members that are planning to join us on Wednesday the 14th, in addition to indicating your presence on today's call, can you also just provide a verbal yes or no if you are available and planning to attend on the 14th, starting with Denise Webb.

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

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

Arien Malec – Change Healthcare – Co-Chair
I'm here, and yes.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Carolyn Peterson? Maybe Carolyn's not on yet. Aaron Miri?

Aaron Miri – Imprivata – HITAC Committee Member
I'm present and yes, I intend to attend.

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

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
I'm here, and I missed the other question.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Are you available on the 14th for the optional call?

John Kansky – Indiana Health Information Exchange - HITAC Committee Member
I'll check and put it in the chat.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sure. Sheryl Turney?

Sheryl Turney – Anthem Blue Cross Blue Shield – HITAC Committee Member
Sheryl Turney is present, and I am available on the 14th.

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

Sasha TerMaat – Epic – HITAC Committee Member
Present, and yes.

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

Steve Ready – Norton HealthCare – HITAC Committee Member
Present, and yes.

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

Linda
This is Linda, her assistant. I'm dialing in on her behalf. And she unfortunately is not available on Wednesday.

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

Anil Jain – IBM Watson – HITAC Committee Member
I'm here, and yes.

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

Okay. Kate Goodrich? Is she not on? Andrew **Trescott**? Do we have Andy on? I know he said he may have some issues dialing in today. David McCallie?

David McCallie – Cerner – Public Member
Present, and yes for Wednesday.

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

Mark Savage – UC San Francisco – Public Member
Here, and yes on the 14th.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. And I do believe that both Noam Arzt and Grace will not be available to join us today, so with that, I will turn it back to Denise and Arien.

Arien Malec – Change Healthcare – Co-Chair
All right. Good morning or afternoon, as the case may be, depending on whether you're on the right side of the country or the wrong side of the country. And we tried – I apologize. We tried to line everything up to get the draft recommendations either on Friday or over the weekend, but due to travel and the weekend schedules, we weren't able to get all of the reviews done. So, apologies for that. I think we're gonna start first by going – because I think everyone's fairly well-prepped for the voting for how we think about the single on-ramp. I think we will first go to lining up the single on-ramp, and then start reviewing the recommendations recommendation by recommendation. Actually, let's go through in order, because the first set of recommendations should get us through the notion of single on-ramp. So, why don't –

Male Speaker 1
Are we looking at the Word document? Is that our –

Arien Malec – Change Healthcare – Co-Chair
Yeah, we're looking at the Word document. Follow along at home. Let's go to the next page. All right. So, we first put together a set of overarching recommendations that didn't follow the narrative and timeline of the questions we were asked to respond to. And the first of those overarching regulations generally is the recommendation for clarity on policy goals. The first of those recommendations is the recommendation that ONC should clearly define policy goals expressed as a clear statement of outcomes ONC wishes to or wants to enable, or outcomes ONC wants to prevent in areas where ONC believes defining or prescribing particular implementation policy is critical to national success. We recommend ONC first define the overall policy goals. So, generally reflecting the frequent feedback – easy for me to say – from the taskforce that ONC, in the TEF, would often go to a detailed description of how without first describing the policy goals and the what that ONC intended to enable in ways that sometimes made it difficult for us to make alternative recommendations for policy enablement that met equivalent goals.

I guess we'll pause there and see if there's any – if this recommendation makes sense to the taskforce, if there's any comment from the recommendation.

Male Speaker 1
I think it's good.

David McCallie – Cerner – Public Member
David says it's good.

Arien Malec – Change Healthcare – Co-Chair
I don't see any hands up, so without objection – yeah, go ahead.

Male Speaker 1
Arien, so this is not an objection, but just as I was reading this, I flashed that the converse is sometimes true as well, that there's some detailed discussion of why in principle, but lack of clarity or specificity about how. And I'm thinking in particular about individual access. So, it's not meant to take away from what's written here, but it sometimes goes both ways.

Arien Malec – Change Healthcare – Co-Chair
We do – so, we try, in the recommendations, in areas where we agree with the overall policy goal, but note that we don't have the enabling standards or policy recommendations. We do try to make those comments. So, as we get to those areas, make sure that we've appropriately framed up any obstacles where the what is clear but the how isn't. Let's make sure that we've appropriately framed up those areas.

Male Speaker 1
Okay.

Arien Malec – Change Healthcare – Co-Chair
Second recommendation is responding to, for example, some of the commentary that the TEF made very detailed recommendations in areas where there may be appropriate guidance otherwise. So, as examples, there might well be appropriate guidance in **NIST** documentation, where what may be duplicative documentation in the TEF. And so, the general sense of the recommendation is in those areas, ONC would be better framed – if ONC desires and believes that it's appropriate to make highly detailed recommendations, ONC would be better served by pointing to NIST or appropriate or other documentation that provides the appropriate policy claims. And I won't go through and read all of the recommendations, but that's the general sense of it. And we do note that in the end, that a lot of the examples where ONC has pointed to a very detailed recommendation, in later recommendations, we are recommending that many of those detailed recommendations would be more appropriately detailed at the RCE and enabling implementation guidance level.

Aaron Miri – Imprivata – HITAC Committee Member
This is Aaron. I agree.

David McCallie – Cerner – Public Member

David. I agree as well. I think some of those could fall under recommendation number one, in a sense. In other words, if the policy goal is to achieve a certain level of cybersecurity, then specify what the policy is rather than recite the particular – in this recommendation.

Arien Malec – Change Healthcare – Co-Chair

You'll see in the second section that we generally make that recommendation as well. By the way, we haven't talked about process. We're going through what may be your first detailed read of this document in this meeting. I would highly recommend folks to do a detailed read. I did a day-long session in a hotel writing the 12 pages of this. Denise did a lovely job, after she came back from Mexico, of correcting many of my writing and drafting issues. But this could use many more sets of eyes on it. So, I would highly encourage people, if they have editorial – so, editing comments, please read with review comments on and send us any of those editing comments. If you have substantive comments, I think it would be appropriate to send those via email so that we can review them in Wednesday's and Friday's call, and try to craft appropriate language. But if you have areas where you want to suggest ways of making this language clearer, I definitely would recommend that and would welcome that. All right.

Male Speaker 1
Arien?

Arien Malec – Change Healthcare – Co-Chair
Yup?

Male Speaker 1
Before you dive back in, one suggestion in the next draft is maybe number these so we can refer to them by number, just for linking.

Arien Malec – Change Healthcare – Co-Chair
I agree with you. There's a level of fighting with Microsoft Word that is sometimes nice to do at the end of the process as opposed to the beginning of the process.

Male Speaker 1
Okay. I've been there.

Male Speaker 2
And Arien, I just want to throw out a thank you to both of you for all the work to get us where we are today. And I was gonna say that back when you said you were aiming for Friday, and we got it this morning. But to both, all the work over the weekend, even, thank you.

Arien Malec – Change Healthcare – Co-Chair
Yup, I appreciate it.

Denise Webb – Marshfield Clinic Health System – Co-Chair
Thanks. And I apologize. I'm the one that held it up because I was flying around. It wasn't until I got on an airplane Saturday night that I was able to start working on it.

Arien Malec – Change Healthcare – Co-Chair
Yikes.

Male Speaker 2
No worries, just a thank you.

Arien Malec – Change Healthcare – Co-Chair
It was not the best – the overall schedule was not the best timing for this. Okay. So, next major heading is division of responsibility. And this is the major section where we make recommendations to the effect that ONC would be better served by defining the overall policy goals and deferring many of the operating details to the RCE in conjunction with the qualified health information networks, SBOS, and the like. So, if we go down to the next page.

Male
Read what's at the top of the page. I'm not tracking online. If you could just say the page that starts with . . .

Arien Malec – Change Healthcare – Co-Chair
The page that starts with "These cycles of trial testing and feedback and revision." We point to the API certification requirements.

Male Speaker 1
Got it.

Arien Malec – Change Healthcare – Co-Chair
And the fairly successful API functional requirements that led to a fairly rapid cycle of revision trial testing, feedback, and revision. And so, then the first recommendations is ONC and the Trust Exchange Framework should define policy outcomes and function requirements, and to the extent possible, refrain from naming particular standards or particular implementation mechanisms. Instead, ONC should charge the RCE in conjunction with the QHINs to evolve through clear milestones involving real world production use, feedback, and refinement towards naming standards, implementation guides, and enabling policies meeting the broad policy goals and functional requirements defined by ONC. If stakeholders do not make clear progress towards defined policy outcomes, ONC should retain the policy levers sufficient to name and direct standards, implementation guides, and enabling policies and other mechanisms to address market failure. So, I'm gonna pause there.

Denise Webb – Marshfield Clinic Health System – Co-Chair
We'll make sure we add page numbers, too.

Arien Malec – Change Healthcare – Co-Chair
Yeah. We actually do have page numbers. I think ONC staff did that on Monday, so we really appreciate that.

Denise Webb – Marshfield Clinic Health System – Co-Chair
Oh good.

Arien Malec – Change Healthcare – Co-Chair
Yeah.

Male Speaker 1
Yeah, not on my copy.

Denise Webb – Marshfield Clinic Health System – Co-Chair
Yeah. The one I'm tracking doesn't have any.

Arien Malec – Change Healthcare – Co-Chair
Yeah. We'll get there.

David McCallie – Cerner – Public Member
Arien?

Arien Malec – Change Healthcare – Co-Chair
Yeah.

David McCallie – Cerner – Public Member
It's David, and this is out of sequence, but I don't want to forget it if I don't mention it now, which is it seems like there's another – you're focusing on one very important high-level goal around the difference between policy goals and technology implementations. And we're diving into that. There seems to be another high-level policy thing or high-level goal that we touched on a number of times, which is sort of the notion of incremental expansion of permitted purposes and use cases, or modularity, or something. Is that addressed elsewhere?

Arien Malec – Change Healthcare – Co-Chair
We do get to that. Yeah, we do get to that, because that was one of the –

Denise Webb – Marshfield Clinic Health System – Co-Chair
He got that.

Arien Malec – Change Healthcare – Co-Chair
Detailed requests that we had, which is in the permitted purposes section.

David McCallie – Cerner – Public Member
Okay, good. I just want to make sure we get that.

Arien Malec – Change Healthcare – Co-Chair
Yeah, exactly. This first section is all the stuff that we responded to, even though we weren't asked to. So, ONC should, in areas of broader concern, clearly document key policies outcomes, including those for market or ecosystem development, and establish clear checkpoints for evaluating whether additional restrictions on the QHINs or RSCs need to be established. As examples, see the **test** requirements on QHIN participant neutrality. So, this basically says, if there are – and **[inaudible] [00:15:20]** neutrality was

one of the areas that the group had a lot of feedback on. But if there are areas where ONC has concerns about the evolution of the market, and those concerns aren't based on – are based on fears that the market will develop in way X versus way Y, that ONC should establish milestones. Say, we expect the market to develop in this way, establish market milestones for evaluation, and then use those milestones to course correct and provide interventions if necessary. I'm not sure if that voiceover is clearer than the text that I wrote, but that was the intent of the text.

Male Speaker 1

The voiceover actually helps.

Male Speaker 2

Yeah, and it might not be a bad idea to put an example like that indented underneath this. So, for example, set a milestone assessing participation by small providers, you know?

Arien Malec – Change Healthcare – Co-Chair

Yup, perfect.

Male Speaker 1

Greater than 80 percent small providers participation, something like that, where you give an example of what you mean.

Arien Malec – Change Healthcare – Co-Chair

Perfect.

Male Speaker 1

And maybe to generalize, this is a recommendation not just about establishing outcomes, but also metrics over the three years, or whatever the timeframe is.

Arien Malec – Change Healthcare – Co-Chair

We do have sections describing metrics, but definitely, we can talk about market ecosystem development or metrics. We can include that revision. Okay. Next recommendation. ONC should work closely with the RCE and coordinate with other federal actors in areas where policy clarification or coordinated federal action are critical enablers in QHIN success. For example, past actions of ONC and HHSOCR have been incredibly helpful in providing guidance in interpretation of HIPAA in multiple areas, coordinating and harmonizing federal information security and identity assurance requirements to commercial standards will be important to enable broad adoption of interoperability by federal actors.

So, this is a statement saying that in some cases, ONC has a key role to play in streamlining areas of policy. And we're making recommendations that ONC actually actively engage in those areas, where ONC can either make critical guidance relating to federal policy, or make critical guidance relating to federal actors in areas that help the

RCE engage and not have to solve problems, particularly on the RCE. So, another way of framing this recommendation is, there's a set of activities that the RCE can't do that ONC can do relating to providing guidance in matters of federal policy, both national guidance relating to HIPAA as well as guidance relating to federal actors.

Aaron Miri – Imprivata – HITAC Committee Member

Hey, Arien, this is Aaron Miri. A couple things here. One, I would say potentially, I like this paragraph. Maybe add something about states, so it's not just harmonizing federal information security, but federal and state information security. And not just identity assurance, but also privacy, right? So, I think just to be very clear, there are a number of discrepancies when you look at the state and federal from that aspect of things. Again, we could reference some of the work that was done by a previous taskforce. And again, to your point, they're brought up here, how to go through and deal with HIPAA. Case in point, the API taskforce, OCR and ONC brought up that sheet of how does a developer deal with EPHI, right? So, maybe you could reference one of those documents as an example.

Arien Malec – Change Healthcare – Co-Chair

Yes. We definitely do recommend those documents in the recommendations. We can make another reference there. I'd note that OCR made a really helpful guidance on form and format. I'm not sure I talked about the guidance on form and format. I think I intended to. So, we can make that example of the form and format guidance with respect to APIs.

Aaron Miri – Imprivata – HITAC Committee Member

Yup, perfect.

David McCallie – Cerner – Public Member

Arien, it's David. And I say this slightly in jest, but actually, I'm a little but unsure. The difference between subregulatory and guidance. Is there enough of a difference to warrant mentioning the notion of subregulatory advice?

Arien Malec – Change Healthcare – Co-Chair

I try to stay away from those areas. And any area where I've got to get schooled on regulatory policy, I try to stay away from those areas. Generally, my understanding is subregulatory is activities that are contemplated in regulation, whereas guidance is interpretive information that isn't clearly stated in regulation that needs to be done as a separate regulatory process, that we could say subregulatory and guidance. I don't think it would hurt us to be able to do that.

Male Speaker 1

I had the same –

David McCallie – Cerner – Public Member

And then, I would throw out –

Male Speaker 1
Oh, sorry.

David McCallie – Cerner – Public Member
Just add two other work phrases, safe harbor and moral equivalent of safe harbor.

Arien Malec – Change Healthcare – Co-Chair
Yeah. Moral equivalent of safe harbor.

David McCallie – Cerner – Public Member
Yup.

Genevieve
Hey. Hi, this is Genevieve. Just one note on the subregulatory and the guidance. I think the lines between that are actually much, much greyer than perhaps you would think they are. And because of some executive orders and things like that, I would be quite cautious about using that kind of language.

Arien Malec – Change Healthcare – Co-Chair
Yeah. That's why I try to stay away from those areas.

Genevieve
Yeah. And just one other note that I'm gonna toss in there because I can. I'm just gonna take my ONC purview. On this recommendation in particular, just keep in mind the things over which ONC has authority versus even our other federal partners have authority. So, particularly when I hear things like state law variation mentioned, please just keep in mind that we don't have an awful lot we can do there. We've had previous efforts, like the one with **NJMA** that tried to focus on that. And so, in the effort to get recommendations that we can really sink our teeth into, just keep that in mind.

Denise Webb – Marshfield Clinic Health System – Co-Chair
Thanks, Genevieve. I was gonna say that myself.

Arien Malec – Change Healthcare – Co-Chair
Yeah. And I tend to use the word "coordinate" because it is the Office of National Coordination. It's clearly in the purview of ONC to coordinate. Just to be clear, it's not in the purview of ONC. It's a direct, for example, OCR policy or CMS policy, or etc., etc., etc. But ONC has in the past been incredibly helpful in working with OCR or working with CMS to make sure that the broader policy goals are met. And Genevieve, I completely agree with you that ONC's also tried pretty hard with states, to limited success. All right, next page. Yeah, go ahead.

Male

It would be possible, perhaps, to include recommendations on how to deal with state variations. If it's a given fact that you can't change, then you can have policy they can deal with.

Arien Malec – Change Healthcare – Co-Chair

I think we do have recommendations in those areas that contemplate that there's broad areas of state policy. I think the position that ONC is often in is that ONC can't make a statement that says that you can avoid, for example, Minnesota's requirements on requiring state-based accreditation for a health information network, because ONC's not in a position to provide any guidance related to any area of state law or regulation.

Male Speaker 1

But you could have a policy that suggests nodes that have legal standing in particular states must follow state rules, and the TEFCA must be able to deal with that. In other words –

Arien Malec – Change Healthcare – Co-Chair

So, I do think we make some of those recommendations, yes. So, I do think we make some of those recommendations relating to, for example, consent. And when we get to that section, if there's other feedback that you have there, let's make sure that we get that appropriately captured.

All right. Now the fun one. Single on-ramp. So, our general recommendation with respect to the term "single on-ramp" is on page four. So, this is in the section "Defining Single On-Ramp." The general purpose recommendation is, ONC should clearly define the role of the QHIN relative to existing forms of exchange, and more clearly define the objectives and scope of "a single on-ramp" with respect to the types and capabilities of exchange anticipated to be provided through that single on-ramp. Then we describe that there were two broad positions, one that basically says, this stuff's complicated enough that we should focus; and the other that says, this stuff is important enough that we should actually swing and make a big dent.

And then we go down and define three subflavors of recommendations that we will tag with either majority and passionate minority, or plurality and minority, passionate minority, with respect to these. And it would be nice if we could eliminate at least one of these through some kind of consensus-based process. So, let me define the three flavors of recommendation. On the bottom on page four. Recommendation: ONC should clearly define the on-ramp provided by QHINs to be for query-based exchange and access to EHR. ONC should clearly document that only a subset of – here we go to the next page – the needs of defined permitted purposes will be served the QHINs, with other needs satisfied by the other HIN. So, that's basically the pure play query option. Option two, ONC should clearly define the on-ramp provided by QHINs to serve underserved, high priority EHI exchange needs, regardless of exchange modality. In particular, QHINs should serve needs for public health and coordinated referrals, as well as query-based exchange, even when those needs require unidirectional and bidirectional push exchange. So, that's focused mostly on query, but also going to other

areas that are underserved relative to national priorities. And the third one is another pure play.

ONC should clearly define the on-ramp provided by QHINs to be for all forms of EHI exchange, including but not limited to query-based exchange and push-based exchange models, including push to public health, electronic orders results, electronic prescribing, administrative transactions. Who forgot to mention direct? Oddly, I forgot to mention that.

Male Speaker 1
I wonder why.

Arien Malec – Change Healthcare – Co-Chair
And administrative transactions. Now, there are some forms of exchange, this may be an on-ramp only and for other forms of exchange, maybe **we'd** exchange solutions. So –

Female Speaker 1
Arien, instead direct a push model, though?

Arien Malec – Change Healthcare – Co-Chair
Direct is a push model.

Female Speaker 1
Yeah, because I think we capture it when we say –

Arien Malec – Change Healthcare – Co-Chair
Push-based exchange model.

Female Speaker 1
[Crosstalk] [00:26:58] of exchange and push-based exchange models. And then you give example of push, which could be direct to public health, or . . .

Arien Malec – Change Healthcare – Co-Chair
Yeah.

Female Speaker 1
Yeah. Because I think you had direct in there, and it didn't – it wasn't flowing, and I suggested a change, and you made the change and took "direct" out.

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

Male Speaker 1

And Arien, are you intending on purpose for these to be so hard-edged? For example, recommendation number one is you could say start with **career**-based exchange, expand based on –

Arien Malec – Change Healthcare – Co-Chair

Yeah, I think if we go back up, we're framing this around – can you go back up one page? So, we're framing – you'll note the sentence "With particular respect to the role of QHIN over the next three-year period." And it might be worthwhile better defining that these types of definitions are really with respect to that three-year period, and to contemplate that beyond the three-year period, I don't think anybody in the taskforce was opposed to expanding or broadening the forms of exchange contemplated by the QHINs. This is really around what's the type priority and where do you focus over the next three years. So, we'll make sure to add that.

Denise Webb – Marshfield Clinic Health System – Co-Chair

We could put that in the beginning of the recommendation, that for the first three-year period that ONC should focus the definition of on-ramp. Something like that.

Male Speaker 1

Yup, that would help. Because people will read – they'll scroll down and read the recommendations only.

Arien Malec – Change Healthcare – Co-Chair

Correct, yes. And not read any of the regulatory guidance text.

Male Speaker 1

The **[inaudible] [00:28:56]**, yeah.

Arien Malec – Change Healthcare – Co-Chair

Yeah, exactly. Okay. This is the point where – oh, Sheryl's got her hand up.

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

Thank you, David. I do agree that we should talk about having a minimum set, but not specifically what else should be included, because we certainly don't want to limit QHIN's ability to do more. And at the end of the day, we are trying to spur innovation. So, if a QHIN is going to be established and may build in the capabilities to do the queries as well as the push model or the direct model, we certainly wouldn't want that to stand in anybody's way.

Arien Malec – Change Healthcare – Co-Chair

Good point.

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

Yeah. And also, especially as I'm still a little bit unclear on how a patient interacts in this

network, because my understanding, most of the HIEs don't have any patient interaction. So, certainly that innovation's gonna require potentially something different than what we're currently contemplating.

Arien Malec – Change Healthcare – Co-Chair

Perfect. Okay, so let me redact what I said. The two comments that I'm hearing. Number one is we need to be more explicit about we're talking about focus areas for the first three-year period. Secondly, we want to note that we're not precluding the QHIN from taking on other activities, but that these recommendations are really around what the minimums are for the QHIN.

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

Right. So, like setting the floor.

Arien Malec – Change Healthcare – Co-Chair

Exactly.

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

Perfect.

Arien Malec – Change Healthcare – Co-Chair

Okiedoke. Any other comments on the frame first before we start to assess where folks line up? And I think we know that, for example, Noam's not on, but we'll count his vote for option three. I want to be fair to him, that I think his opinion is fairly clear. Mark, you have your hand up?

Mark Savage – UC San Francisco – Public Member

I do. I think this is a framing question, but you tell me if it belongs in the specifics. Any further elaboration about what you mean about – in the option two, serving underserved, high priority exchange needs. How does one decide whether – how does our recommendations frame what falls on which side of that line as a minimum?

Arien Malec – Change Healthcare – Co-Chair

Yeah. So, it's a really good question. This was somewhat hand-waving. But it was intended to follow some of the dialogue that we had, where I think many people acknowledged that information exchange for coordinated referrals or information exchange for public health was underserved, and that it might be appropriate for QHINs to take on the role of being a single on-ramp for those organizations. In terms of what the criteria are for defining high priority underserved, frankly, beyond coming up with the language or the equivalent language of high priority underserved, I'm not sure that I have any particular opinion about how to define that. But I think there's a sort of obscenity definition version of this that I think everyone might acknowledge that administrative transactions are pretty well served.

There's a lot of evidence around unsolicited results, for example, getting into EHRs.

There's a fair market around HISPs where it's not clear that adding other market actors to HISPs would change the dynamics considerably. And then I think there are other areas that are less well served. And I think the critical question about that is, what's the overlap between national priority and not as well served? I'll go back to my earlier admission that it's basically hand-waving.

Mark Savage – UC San Francisco – Public Member

Okay. Thank you.

Male Speaker 1

Arien, another framing question. I mean, an alternate way to think about this might be to prioritize the permitted purposes and use cases. And then say, these are the sequence that the group thinks should be addressed at whatever pace they can get to. And knowing that in the first three years, you're not gonna get terribly deep into that list, but you at least have the prioritization.

Arien Malec – Change Healthcare – Co-Chair

We do make recommendations later on, or we make draft recommendations later on relative to prioritizing permitted purposes. But the problem with that when I was putting together some the verbiage here is that to say that public health is a high priority permitted purpose doesn't address the question of exchange modality.

Male Speaker 1

Well, but you could break it out. You could say, support public healthy query for immunization status via the federated query, high priority. Push of notice of communicable diseases, low priority. **[Crosstalk] [00:34:34]**

Arien Malec – Change Healthcare – Co-Chair

Yeah. I don't think we'll be in a position to be able to make those detailed recommendations. But it's definitely one way to frame it.

Denise Webb – Marshfield Clinic Health System – Co-Chair

I think the RCE might really have to have that – look through that.

Arien Malec – Change Healthcare – Co-Chair

We've got two other hands in the queue, so I want to make sure that we prioritize people who are quietly raising their hand. John, and then Sasha, and then Mark again.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member

Thanks, this is John. And just because it sounds like we're headed for a vote, I don't want to belabor this, but I also don't want to not understand. If I characterize recommendation one as focus on, at least start with query, meaning limit, and the number three, the Noam option, is kitchen sink, then is number two kind of in the middle in terms of acknowledging unidirectional/bidirectional push exchange as an

additional thing you need to be capable of, and pointing those – or selecting high priority stuff to be named? I mean, it's sort of in between?

Arien Malec – Change Healthcare – Co-Chair

Yeah. So, again, number one, let's acknowledge that I think the sense of the taskforce, unless there's violent objection to this, is that we're talking about three-year priority and floor, not long-term priority and limitations. But I think you've got the sense right, that option one is three-year priority, set the floor at addressing query-based exchange versus three-year priority, set the floor on query-based exchange and other high priority use cases to be named, including the two examples, public health and coordinated referral.

John Kansky – Indiana Health Information Exchange - HITAC Committee Member

Thank you.

Arien Malec – Change Healthcare – Co-Chair

Thank you. Sasha.

Male Speaker 1

So, my concern – oh, sorry. Go ahead, Sasha.

Sasha TerMaat – Epic – HITAC Committee Member

Oh. So, this is Sasha. And perhaps my question will be partially addressed later in the document as well. But while I'm a strong, I guess, believer that we have to very judiciously prioritize work for the next three years and won't be able to accomplish all of our ambitions in that time, I'm also wondering how this ties into the conversation we started on our previous call about sustainability. Because I think that for some stakeholders in the trusted exchange framework, one of the sort of return on investment goals they would have would be to access the single on-ramp concept in some sense, and be able to eliminate other streams of interoperability that currently exist in favor of sort of prioritizing this investment in their technology and in their exchange systems. And so, is there a separate conversation about sustainability that I should sort of save that thought for and keep prioritization here?

Arien Malec – Change Healthcare – Co-Chair

I think it's a really good callout. And again, I would point back to the notion that what we're acknowledging, and we'll make sure the language is clear in each of these options, is that we're really talking about a three-year priority and floor, and acknowledging – and we should put some framework language in that acknowledges that EHR developers and QHINs may well be able to serve broader market needs by establishing a true single on-ramp. There are discussions of sustainability that do not currently go to the level of detail that you're talking about. So, I don't want to – I think it's harder to say that that question is not addressed currently in the set of recommendations around the document itself.

Sasha TerMaat – Epic – HITAC Committee Member

Maybe a placeholder for us to further discuss. I do think if we were making a set of discussions, we would want to feel that the recommendations we put forward will lead to a sustainable model.

Arien Malec – Change Healthcare – Co-Chair

Yeah. So, what I'm hearing very clearly is we need to make it clear – I've just used clear twice. What I'm hearing is that we need to make it very clear that our recommendations are with respect to priority and floor, and that we do not intend to limit options for EHR developers or for QHINs that wish to establish single on-ramps for other exchange modalities, regardless of which of these options we select.

Male Speaker 1

Limit the QHINs or RCE.

Arien Malec – Change Healthcare – Co-Chair

Yeah, that's right. Mark, and then Carolyn. And then we gotta go to vote because We don't have much time.

Mark Savage – UC San Francisco – Public Member

Just checking my current understanding of the draft, the draft from ONC. There is no prioritization of permitted purposes, right? They're all six just laid out there.

Arien Malec – Change Healthcare – Co-Chair

Yeah.

Mark Savage – UC San Francisco – Public Member

It wouldn't be stacked. Okay. Thank you.

Arien Malec – Change Healthcare – Co-Chair

Yeah. And we're making recommendations for prioritization of permitted purposes. The current –

Mark Savage – UC San Francisco – Public Member

Okay. I haven't gotten that far in your draft, but I'll look forward to seeing that.

Arien Malec – Change Healthcare – Co-Chair

Okay.

Mark Savage – UC San Francisco – Public Member

Thank you.

Arien Malec – Change Healthcare – Co-Chair

Yup. And then Carolyn.

Carolyn Peterson – Mayo Clinic Global Business Solutions – HITAC Committee Member

Thanks, Arien. My question about clarification has to do with requests initiated by patients and this question of bidirectional. I see bidirectional in the second but not in the first or the third, and I didn't really see initiated queries anyplace. Can you clarify which would go where?

Arien Malec – Change Healthcare – Co-Chair

Yeah. So, the definition of bidirectional in that case was bidirectional push. So, that was really specific to the notion of, for example, a coordinated referral, where you might push one direction and then get a push back. Definitely, we make a recommendation in this current draft recommending the role of the patient and the individual, as well as the role of the individual as a query – a source of data, as well as the patient as a query initiator. So, that notion of bidirectional is not limited here. This is really around focusing on query versus focusing on push. And as a subset of focusing on querying and push, the notion that you might want to focus on orchestrated push or bidirectional push.

Carolyn Peterson – Mayo Clinic Global Business Solutions – HITAC Committee Member

All right, thank you.

Arien Malec – Change Healthcare – Co-Chair

Yup. All right. Mark?

Mark Savage – UC San Francisco – Public Member

Arien, just more specifically on that question, does this address at any point patient-generated health data as one bidirectional use case?

Arien Malec – Change Healthcare – Co-Chair

It does. I have to admit that I did not use the word patient-generated health data in the draft. But we do have language relating to patients as a source of data. And when we get to that section, let's make sure that we get the comment in that we need to clearly indicate the sense of the taskforce that patient-generated health data should be a query source. All right. Let's – gosh, how should we do the voting? How many people – we have 31 participants, but not all 31 are authorized to vote. Gosh.

Denise Webb – Marshfield Clinic Health System – Co-Chair

We can just do each option and raise a hand.

Arien Malec – Change Healthcare – Co-Chair

Yeah, okay. Let's do it that way.

Mark Savage – UC San Francisco – Public Member
Or a role-call, and just ask one, two, or three.

Arien Malec – Change Healthcare – Co-Chair
Yeah, let's do it that way. Thank you, yes. Lauren, can we do a role call, and then we'll treat Noam as voting for option three? But otherwise, do a role call and have respondents say one, two, or three. Thank you, Mark, that's super helpful.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. We'll just start here at the top, starting with Denise.

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

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

Arien Malec – Change Healthcare – Co-Chair
One.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Carolyn? Carolyn, option one, two, or three?

Carolyn Peterson – Mayo Clinic Global Business Solutions – HITAC Committee Member
Oh, sorry. Option two, please.

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

Aaron Miri – Imprivata – HITAC Committee Member
Option one, please.

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

John Kansky – Indiana Health Information Exchange - HITAC Committee Member

One.

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

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

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

Sasha TerMaat – Epic – HITAC Committee Member
One.

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

Steve Ready – Norton HealthCare – HITAC Committee Member
One, please.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Cynthia? Do we have Cynthia on the line? Oh, I think her admin. We'll come back to Cynthia. Anil?

Anil Jain – IBM Watson – HITAC Committee Member
Option one, please.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. And Kate is absent. Just checking in, did Andrew dial in, by chance? No Andrew? David?

David McCallie – Cerner – Public Member
One, please.

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

Mark Savage – UC San Francisco – Public Member
Three.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. And we have Noam as a three, and we don't have Grace on the line. Okay.

Arien Malec – Change Healthcare – Co-Chair
Okay. Let's get additional votes from folks who weren't able to attend. So, before we prematurely declare a majority opinion, I think it's important to make sure that we get the full sense of the taskforce.

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

Denise Webb – Marshfield Clinic Health System – Co-Chair
So, what is your total for each option now?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Let's see. For the ones, one, two, three, four, five, six, seven. We have eight ones. One, two, and three threes.

Arien Malec – Change Healthcare – Co-Chair
And how many members of the taskforce are there?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Total or on the call today?

Arien Malec – Change Healthcare – Co-Chair
Total.

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

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
16.

Arien Malec – Change Healthcare – Co-Chair
Okay. So, I think we're –

Denise Webb – Marshfield Clinic Health System – Co-Chair

We have four more votes.

Male Speaker 1

Four to go.

Arien Malec – Change Healthcare – Co-Chair

Yeah. Okay. So, we don't yet have a 50 percent plus one, but we're pretty close, with four more votes to go. Okay, good. Well, we've got a few more minutes, so why don't we go until – Lauren, with your permission, go until 11:55? Okay? Let's go down to the next page. All right. Now, we start our recommendations relating to the recognized coordinating entity. There's a lot here. So, number one is we note that the taskforce believes ONC should defer and assign many of the operating decisions that need **[inaudible] [00:45:50]** guidance for overall architecture and orchestration standards, interoperability guidance profiles and metrics to the RCE, working in conjunction with the QHINs. Accordingly, the RCE should have strong capabilities in healthcare interoperability. The taskforce believes the RCE should be broadly trusted, above reproach, transparent, and open.

The governance of the RCE should represent a broad range of perspectives, including the patient, and not be overly weighted towards large health systems, federal providers, users of particular health IT and a particular QHIN or set of QHINs, and should have sufficient protection against activities that would lead to or be perceived as leading to conflict. At the same time, the taskforce believes the likely sustainability model for the RCE is through dues paid by the QHINs, who should therefore have a fiduciary oversight role for the RCE. The taskforce believes the RCE role may not match exactly any of the existing governance actors, and that the RCE selected by ONC may represent a merged or reconfigured version of one or more established actors. I want to just pause there. That's not recommendation, it's surrounding text, but there's a lot there, so I just want to see if there's any feedback. Mark, is that your hand up from previously, or is that your hand up on this stuff?

Mark Savage – UC San Francisco – Public Member

Oh. No, I do have a comment here, but what you're seeing is a raised hand from previously. What I would say is I like this sense of things, and I think in addition, we have support in the analysis – what webinar was it? Maybe it was the first one in July, where looking at many of the different existing structures and finding that they covered some but not everything, and sort of the compare and contrast. I think that's –

Arien Malec – Change Healthcare – Co-Chair

That's the intent of – yeah, that's the intent of this last sentence here, that the RCE role may not match exactly any of the existing governance actors, and the RCE selected by the ONC may represent a merged or reconfigured version of one or more of the established actors. It's clearly not our role to select the RCE, not is it, I think, our role to point out any particular RCE actors and make commentary on them. But I do think it

represents the sense of the taskforce that – it wasn't the sense of the taskforce that this was a gimme, and that it might be helpful for the RCEs to skate to where the puck's going.

Mark Savage – UC San Francisco – Public Member

Agreed. I just wanted to lift that gap analysis up, because I think it's pretty important.

Arien Malec – Change Healthcare – Co-Chair

Okay. Fair point. Okay. The recommendation here is ONC should establish eligibility criteria for the RCE, requiring **[inaudible] [00:48:32]** status, a clear sustainability model, and a governance model that balances responsibility between the national interests and the dues-paying members of the RCE. The governance model for the RCE should represent a broad range of providers' perspectives, keeping in mind the definition of provider relevant to the 21st Century Cures Act is broad and expansive, as well as the patient perspective. The governance model for the RCE should deliver transparency, protect against governance or board configurations and operating models that could lead – next page – lead to or be perceived as leading to conflict. And particularly, the RCE governance should not be weighted towards or against particular segments of the provider community, e.g., large or federal providers, health IT vendors, particular QHINs, etc.

Aaron Miri – Imprivata – HITAC Committee Member

Arien, this is Aaron. Question for you. Is there somebody we could reference at the federal government? Maybe there's a sector that's already doing something very similar? I'm thinking of like **ARIN** or some other group out there that's not-for-profit that holds sort of that collective status that you just referenced as an example?

Arien Malec – Change Healthcare – Co-Chair

Yeah. I don't think it's appropriate, so my stance would be I do not think it would be appropriate to call out particular RCE actors. I think the sense, from what I've heard from the community, is that many community members, frankly, have their favorites that they lean to. And I think it would be inappropriate for the taskforce to make particular recommendations in this area. If the taskforce believes that it would be appropriate to name a range of actors that are out there, and that that would be helpful for ONC, I'm willing to bend. I'm pretty sure that ONC knows who the actors are right now and doesn't –

Aaron Miri – Imprivata – HITAC Committee Member

Sure. Sorry. My question – I'm sorry, maybe I didn't – I wasn't clear. I meant outside of healthcare, for something totally separate, in terms of governance. So, you're talking about a makeup of multi-constituents, multi-stakeholders from a governance perspective. I mean, are there other groups outside of healthcare that have nothing to do with this, but maybe serve as a model to look at it and frame – again, I didn't mean to say so-and-so's the best in the world.

Arien Malec – Change Healthcare – Co-Chair

Got it. Understood. Okay, thank you. Yes, if there are good examples – if there are good examples for that that people could submit, maybe we can take that up next time.

Male Speaker 1

I was looking and didn't find any obvious examples, but I'm sure I didn't look far enough. NTSB was one that kind of sort of –

Aaron Miri – Imprivata – HITAC Committee Member

Yeah, like that, right.

Arien Malec – Change Healthcare – Co-Chair

NTSB's a good one.

Male Speaker 1

Except it's part of **FAA**, I believe.

Male Speaker 2

Yeah, it is.

Male Speaker 1

UL Laboratories.

Arien Malec – Change Healthcare – Co-Chair

UL's a good one. Yeah. Yeah. All right. Any other comments on this section before we go into the next recommendation? I think that – let's just say the next recommendation, see if there's major conflict here. So, [inaudible] [00:51:38] requirement of the RCE is it works on standards implementations guidance profiles and other enabling material to make such material open to the public without restrictions on use or reuse except as necessary to reinforce certification marks or other proof of QHIN compliance with RCE-defined requirements. So, basically, this is responding to some of the taskforce commentary that the work of the RCE should be open. In some cases, it's important to maintain trademarks or branding marks for certification, so you can only carry this mark if you accord with blablabla. But to any other extent possible, any of the material should be open content licensed and be broadly available. And I'll just pause to see if this is an objectionable point. It does reflect some of the commentary the taskforce had.

David McCallie – Cerner – Public Member

Arien, it's David. I certainly don't have any objection to that point, but on the prior topic, I noticed there's no commentary about the integration between RCE and ONC. And is it worth mentioning that? For example, should RCE automatically include ONC? Gosh, ONC in its governance structure or something like that, or is that just – that's maybe way outside our scope?

Arien Malec – Change Healthcare – Co-Chair

I would think that's way outside our scope, unless we think it's super important to say either ONC should or ONC shouldn't.

David McCallie – Cerner – Public Member

Yeah. Well, I think it's a should, so.

Arien Malec – Change Healthcare – Co-Chair

I think it's a should as well, so.

Arien Malec – Change Healthcare – Co-Chair

Yeah. All right.

David McCallie – Cerner – Public Member

Maybe including ONC reputation or something like that in that list of stakeholders.

Arien Malec – Change Healthcare – Co-Chair

I'll make that edit. Okay. Let's go to public comment.

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

Okay, thanks, Arien. Operator, can you please open the public line?

Operator

Certainly. If you would 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, and you may press *2 if you'd like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the * keys. Again, that is *1.

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

Thank you. And as a reminder, we ask all public comments to be kept to no longer than three minutes. Operator, do we have any comments in the queue at this point?

Operator

None at this time.

Arien Malec – Change Healthcare – Co-Chair

Awesome. So, we've got a Wednesday call and then a Friday call. I'd ask taskforce members, please feel free to, as you read the document, submit editorial – sorry, submit editing comments, misplaced periods, commas, language that's unclear via

revision and track changes. Submit substantive comment via email comment so that we can consolidate it and address it during the next taskforce meetings. And we've got two more to go. We're actually making reasonable headway through the recommendations, so I'm cautiously optimistic that we're gonna be able to make it all the way through to have a finalized set of recommendations. I'd note that it is important for us to have a finalized set of recommendations for the HITAC meeting because ONC does need time to respond to our recommendations and incorporate them or not appropriately into the next revision of the task. So, we might feel like that we've got is impossible. At the same time, I think there's a lot of benefits for putting up the best recommendations that we can and helping to inform ONC's decision-making. So, with that, we'll maybe end a little bit early and come back fresh and energized for Wednesday and Friday. And again, the more people read the documents ahead of time and provide meta-commentary, including some of the stuff that we've already gone over, the more helpful it will be.

I'll try to take these recommendations and put out another draft, putting it past Denise and ONC staff first before we go out to the full taskforce. So, if possible, we'll get another version out that hopefully responds to the sense of the taskforce in this meeting. And then, Lauren, I think we're gonna ask the members of the taskforce who weren't on and whose votes weren't recorded what their votes are. Is that right?

Denise Webb – Marshfield Clinic Health System – Co-Chair
And Arien, this is Denise. And just one comment to the taskforce. I wouldn't wait for the next draft before you start working on your comments.

Arien Malec – Change Healthcare – Co-Chair
Please.

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

Arien Malec – Change Healthcare – Co-Chair
Yeah. Vote early and often.

Male Speaker 1
Sorry, thank you.

Arien Malec – Change Healthcare – Co-Chair
Thank you so much.

Male Speaker 1
Thanks very much.

Female Speaker 1

Thank you.

Arien Malec – Change Healthcare – Co-Chair
Bye-bye.

[End of Audio]

Duration: 57 minutes