Health Information Technology Advisory Committee

Transcript
March 21, 2018
Virtual Meeting

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
No Andy yet? Anil Jain?

Anil K. Jain, IBM Watson Health, HITAC Member
I'm here.

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

Arien Malec, RelayHealth, HITAC Member
Good morning.

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

Brad Gescheider, PatientsLikeMe
Good morning.

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

Brett Oliver, Baptist Health
Hi, good morning.

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

Christina Caraballo?

Christina Caraballo, Get Real Health
Good morning, I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Clem McDonald? No Clem yet? And Cynthia Fisher, I believe she's going to be late as well. Denise Webb?

Denise Webb, Marshfield Clinic Health System
Present.

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

Denni McColm, Citizens Memorial Healthcare
Present.

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

John Kansky, Indiana Health Information Exchange
Hi, I'm here.

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

Kensaku Kawamoto, University of Utah Health
Good morning.

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

Leslie Lenert, Medical University of South Carolina, HITAC Member
I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Michael Adcock? No Michael yet? Patrick Soon-Shiong? No Patrick yet? Raj Ratwani? No Raj –

Raj Ratwani, MedStar Health
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Oh, good morning, Raj.

Raj Ratwani, MedStar Health
Oh, I'm here. Good morning.

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

Sasha TerMaat, Epic
Good morning.

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

Sheryl Turney, Anthem Blue Cross Blue Shield
Good morning.

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

Steve L. Ready, Norton Healthcare
Present.

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

Steven Lane, Sutter Health, HITAC Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Terry O'Malley?

Terrence O'Malley, Massachusetts General Hospital

Here.

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

Tina Esposito, Advocate Health Care, HITAC Member
I'm here.

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

Valerie Gray
Good morning. Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning. And our federal representatives? Do we have **Chesley** Richards on the line? Not yet? Okay. Goodrich? Lauren Thompson?

Lauren Thompson
I am here.

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

Ram Shiram?
I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning. And from the ONC team, beside myself, we have our National Coordinator, Dr. Don Ruker, Genevieve Morris, Jon White, Elise Anthony, Steve Posnack and Seth Pazinski. We have a full agenda today. We have quite a bit to go through, so I want to think everyone for your time in joining us today. I hope that the weather does not interrupt your plans too much. And with that, I will turn it over to our National Coordinator, Dr. Rucker.

Don Rucker, M.D., National Coordinator for Health Information Technology
Thanks, Lauren. Hi, everybody. I want to echo Lauren's hopes that the weather is not too interruptive for folks. Before we get into today's thing, I just wanted to make sure everybody knew about the initiative that we are doing at HHS and CMS on MyHealthEData, So, MyHealthEData, all one word. And Blue Button 2.0. So, we're building on the work of ONC and CMS and all the prior ONC coordinators in the past in – next steps in getting data out. So, CMS is

going to be releasing Medicare claims data. And what's different about Blue Button 2.0 is it's going to be using the OpenAPI FHIR protocol as well as OAuth 2.0. And I think we'll be the first of a number of efforts there, with the ultimate goal of getting everything on people's smartphones, and in control.

As you probably have heard, a lot of interest from the White House. Jared Kushner joined CMA in announcing this in Las Vegas. And Secretary Azar has obviously made a number of comments – in his very short tenure as Secretary so far, has made a number of statements about interoperability. Really getting to the work of the High Tech Committee. So, that's exciting. I think, today, we're going to have a brief update on the USCDI – from the USCDI task force. And they spent more time on the Trusted Exchange Framework task force. And having been on these kinds of committees and subcommittees, I just want to thank everybody who's worked – I've read the stuff that you've put out so far, and there is a lot of work and thought and great ideas in things that we need to do next steps on together in there. And I just wanted to thank people. So with that, I will turn it over, I believe, to Carolyn.

Carolyn Petersen, Mayo Clinic
Yes, thanks, Don. Our first agenda item this morning has to do with reviewing the agenda and the approval of minutes. Dr. Rucker just went through what we'll be covering today, the brief update on the US Core Data for Interoperability task force update, and then getting into talking about the Trusted Exchange Framework draft recommendations and voting on that. First, we need to approve the minutes. Do I have a motion?

Male Speaker 1
Motion.

Carolyn Petersen, Mayo Clinic
And do I have a second?

Male Speaker 2
Second.

Carolyn Petersen, Mayo Clinic
Thank you. All those in favor of approving the minutes from our February meeting, would you please acknowledge that by saying, "Aye?"

Female Speaker 1
Aye

Male Speaker 3
Aye

Several Male and Female Speakers
Aye

Carolyn Petersen, Mayo Clinic

And anyone opposed to approving the minutes from the February meeting, would you please so signify by saying, "No?" And anyone who wishes to abstain from the approving the minutes, please note that now. Thank you. We have approved the February minutes, and we should be ready to go with our next update.

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

Thank you, Carolyn. Before we move on to the USCDI update, I just want to do a quick audio check. Do we have Robert on the line yet? And Robert if – are you able to hear us? Okay. We'll circle back to that. Apologies about that. I will turn it over to Christina and Terry.

Terrence O'Malley, Massachusetts General Hospital, HITAC Member

Thanks very much. This is Terry O'Malley. Christina and I want to thank you for the opportunity to present our new draft – draft recommendation. We'll go through this 13-slide deck quickly in order to leave as much time as possible for your comments. And we especially value comments that suggest alternative directions. So, next slide please.

This is the outline of our presentation. We will show you the members of the task force, review the charge, and get to our recommendations. We'd also like to thank the task force members. Next slide, please. Who are the following – and they hail from a wide variety of backgrounds and interests. And they provided a very spirited discussion, which we have tried to distill. Next slide, please.

Our charge, as taken from the USCDI draft – we're going to focus really on the four specific charges. How to get stakeholder feedback, proposed stages for draft data class promotion with objective criteria, how and by how much to expand the USCDI and the frequency of publication. We're going to concentrate on the proposed stages for data class promotion, which were the subject of extensive discussion, and touched only briefly on the other charges, which need a lot more discussion before we can present the consensus. So, the next slide, please.

Here are the proposed categories, three old and three new. This is an expanded maturation model for data classes with six, rather than three, stages as originally proposed. And in this presentation, each stage has its own slide, and each slide is formatted in a similar way. There'll be the principal purpose of the stage, kind of what it does, what is needed for entry into the stage, what happens in the middle, and what it takes to get to the next stage. So, we focused mostly on the inputs and outputs of each stage. Much of our work over the next month will be to add clarity around what happens within each stage to produce required output. So, next slide, please.

Since spring training for baseball is underway, I thought it was really time for a baseball analogy. And these categories roughly align with tryouts in stage one, making this team in stage two, and the batter's box in stage three, at the plate and getting a hit in four, and the USCDI has the opportunity for an illustrious career, culminating in stage six, which is the data class **[inaudible][00:09:29]**. So, we'll start with proposed status. We felt that any stakeholders should

have barrier-free access to proposed data elements or classes with specific value to them. No restrictions based on who can propose, or what they propose. The purpose of this stage is to give every stakeholder a voice, and not just those with the loudest voices. The data class gets in because somebody proposes it. Then, there's a process that we have yet to fully identify, in which data elements or classes proposed by different stakeholders are aggregated to create a data set with a value to a wider group of stakeholders. The value of the whole, we hope, would be greater than the sum of its parts. And the net value of this data set, we'll have to figure out how to estimate its value based on the coast and value to each of its stakeholders. The data sets and preliminary data classes get out of this stage when there is apparent net value based on any number of measures: cost efficiency, improved quality of safety, value to a government priority, value to society. You make it out of the tryouts when a coach appreciates your value. Next slide, please.

This starts the next stage. The purpose of this stage is to get to a much more tightly specified data class after demonstrating value. So, content, definitions, substitution where appropriate of previously standardized data elements. The work in this stage is meant to balance parsimony with yet, the broadest use possible. And this process is intended to create a data set with broad value and clear specifications, which becomes an official data class with the addition of use cases. And at this stage, it's basically made the team, and it's ready for limited testing in stage three. Next slide, please.

The emerging status. So, emerging status puts the data class on the radar. It's now ready for testing and further specification in limited settings. And testing will likely lead to further adjustments and additional clarity – semantic interoperability, harmonization occur here, the data class also undergoes a final sort of net value assessment. "Do the benefits still outweigh the costs now that we have a better idea of what the costs are?" The data class emerges to candidate when it has sufficient value and adequately specified, so the interoperability can be supported. It will emerge ready for commercial deployment and testing. Next slide, please.

So, the candidate status means that the data class is ready for testing at scale. And that testing in a commercial enterprise can and will occur. In this stage, the barriers to wide scale deployment are identified and mitigated. And what remains after the conclusion of this stage is deployment at scale. Next slide, please.

So finally, we get to USCDI. So, the difference – one of the difference with this model is that we don't think the USCDI is the end of the line. So, the purpose of the USCDI is to highlight the data class and take deployment to scale across the country, using all of the policy levers available. So, admission to the USCDI alerts industry that this data class has reached priority status and will advance. Called out by CMS, HHS, and anyone else who has a lever to pull. And data classes will get out of USCDI only when they've achieved nationwide deployment and ease of access. And at this point, the data class can retire to the Hall of Fame, having achieved everything expected of it. So, that concludes our flyover of the stages – and fortunately, the strained baseball analogy as well. So, I'll make a few high-level points about the other parts of the charge, and then ask you for your comments. Next slide, please.

So, one of our charges was about expansion. One of the things that's become apparent to us is

that each of these charges requires a fairly complex dynamic to reconcile, often, conflicting goals of the stakeholders. The benefits of interoperability are not shared equally, and nor are the costs. And it's a delicate balance. And we'll try to dissect that in the next few weeks. There will likely have to be regulatory body oversight to push this process forward. And the main difference between our recommendation and the USCDI draft is that we see expansion as being driven by the pace at which data classes can complete this process, rather than by some predetermined timeline. We expect that some of the draft data classes will move through these stages faster than others. Next slide, please.

The frequency of publication. We like the idea of an annual publication of the data classes that have achieved stages three to five, coordinated really with the ISA. And also, periodic announcements as the data class reaches the next USCDI stage. As the NCVHS comment letter that we just received stated, "It may take a while before industry can settle into a yearly rhythm of updates. But we should probably start. It's not likely that there will be a high volume in the first year. But it could ramp up fairly quickly." And finally, the last slide, please.

Process for stakeholder feedback. We believe that public comment is critical at as many stages as possible. Details to be completed. So, over the next month, the task force is going to focus on an objective process to estimate cost and value, to combine proposed data elements and the data classes with the broadest possible value, and to accelerate data classes through these stages as quickly as possible. I'm sure we'll also touch on potential roles for ONC, beyond that of convener. So Christina, do you have something to add before responding to comments?

Christina Caraballo, Get Real Health

Nope. Thanks, Terry, for the concise yet very informative overview of the work that the task force has done to date. I'd say let's go ahead and open it up for comments from the committee, so we can get closer to our grand plan.

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

So, we do – this is Lauren. We have about 10 minutes or so for any questions or comments of the USCDI task force team. If there are no initial thoughts or questions, you can always send something offline to an email, to either Christina or Terry. And, I see Denise. Do you have a comment?

Denise Webb, Marshfield Clinic Health System, HITAC Member

Yes. Because we, as a TEF task force, talked about the intersection between what the recommendations that we're making and for the task with the USCDI – I mean, I think it's really important that -- as we were going over stage one, the proposed status for this USCDI process – that I think the relevance for the alignment to the permitted purposes and uses that are in the task – have to be an important criteria. So, there's gotta be a balancing between the task and the USCDI, because they really work hand-in-hand, I guess is what I'm trying to say. That's my comment. Thank you.

Terrence O'Malley, Massachusetts General Hospital, HITAC Member

This is Terry. If I could respond to that. It's absolutely essential, and it just occurred to me

having read the TEF comments that I'm wondering if we might propose sort of shared use cases as sort of the initial trial balloons. If we can get a data class that's really ready to roll, and use that as a test case for testing the interoperability. Just a thought.

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

Okay. I see Denni, and then Leslie.

Denni McColm, Citizens Memorial Healthcare

Yes, this is Denny. I just wondered if the committee was planning to take the currently proposed data elements in the USCDI, and put a pile of them through this process of assessing their value and see how they all come out? Just a thought.

Christina Caraballo, Get Real Health

This is Christina. We did an exercise with the task force that each of our members took a data class and went through kind of a high-level process. We have not gone through each of the data classes in the USCDI. I think we viewed them as already existing. So, it hasn't been on our charge to actually take a look at those specific data classes. Terry, would you add to that comment at all?

Terrence O'Malley, Massachusetts General Hospital, HITAC Member

Yeah. I think that's fair. We focused mostly on the process. But, I think in the next four weeks that's a very useful exercise to see the – sort of take these through the process and see where they all end up. I think some of them are going to end up ready to be candidates, and others are going to need a little bit more work to get it in process.

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

Okay, Leslie?

Leslie Lenert, Medical University of South Carolina, HITAC Member

Yeah, so just to follow up on that question. Does the task force – how long does the task force think it will take to get a set of fundamental recommendations to stage four in this framework?

Christina Caraballo, Get Real Health

We've really designed the framework so that there is no set timeline to actually get to USCDI. I think we're looking at aligning it, as we have said in the expansion process with the ISA and looking at how we align with the TEF. But, it really is dependent on the data classes progressing through the categories or stages that we've defined. And it's not necessarily a set number that will make it to the USCDI on any regular basis. It's as ready.

Terrence O'Malley, Massachusetts General Hospital, HITAC Member

And I think I can see a slide in next month's presentation that lays that out.

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

Okay. Seeing no other comments – oh, sorry. Arien?

Arien Malec, RelayHealth, HITAC Member

Just quick question for you. And I echo the comments about the importance here of interlacing this work with the TEFCA work that we're doing. Question for you, on stage five of the USCDI, it's the slide 10 of the presentation, there's a comment there that, of course the QHINs and participants are required to update their technology. You know, one of the comments – and I don't want to jump ahead to the TEF discussion – that we always talked about was basically the cost of doing business and the cost of decision points of what it would take for, in this case, QHIN's or others to update respective technology, and for providers to update their technology. Well, one of the criteria in an upcoming presentation on USCDI – start looking at that, and coming up with a rubric, per se, of what the cost would be to discuss a potential class and including that. Because again, the cost of interlacing some of this could be quite high depending on the technology stack and what not.

Christina Caraballo, Get Real Health

This is Christina. And that's an excellent point, and something that's actually come up a lot within in our task force calls. It's part of that net value that Terry was discussing earlier, and we're hoping to get into a little more detail. But the cost and – just the level of effort of getting the QHINs to be able to support the data classes is very high on our criteria of what needs to be evaluated.

Arien Malec, RelayHealth, HITAC Member

Excellent, thank you.

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

Okay. I see no other comments or questions at this time. Terry and Christina, I want to thank you for your work so far. It looks like we will be hearing a lot more from this team next month, about this time. And at this time, I will turn it over to Robert Wah to just provide some high-level framing for the process before we dive into the Trusted Exchange Framework recommendations. We will also hear from Arien and Denise for additional context. And then, they will guide us through the discussion. So, I will turn it over to Robert. Are you on the line Robert?

Robert Wah, DXC Technology, HITAC Co-Chair

Yes, can you hear me?

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

We can now. Thank you.

Robert Wah, DXC Technology, HITAC Co-Chair

Okay. Thanks, Lauren. And let me just start by saying thank you to Carolyn, my co-chair, who has stepped up as I have had more connection difficulties than I expected for the last meeting and for this one as well. I'm currently overseas, and getting connected into this website and the phone simultaneously has been more of a challenge than I expected. But anyway, thank you again for that introduction, Lauren. When we discuss this next section, we thought it would be good to just give a little background on how we plan to handle these large volume of recommendations that are before you from the task force. And also, want to thank the task force for their extremely rapid evolving of these recommendations. It's a lot of work. And I think everybody recognizes that, but I wanted to acknowledge it again, as has been already stated.

The way we thought we would do this is, we've grouped it into five areas. There's an overarching set of recommendations, and then there are sub groupings – I think four sub-groupings of recommendations below that. And we thought for efficiency, what we would do is use those five groupings to review the recommendations from the task force. And when we complete these discussions, then we will have a vote on the entire set of recommendations. And so as we go through the groupings, if you have specific comments about one of the recommendations within the grouping, it would be appropriate to then bring that up. We will allow one last final chance, if somebody has a specific comment about a specific recommendation after we've heard all five groups, we'll entertain that as well. But our ultimate goal would be to then vote as a – on the entire group recommendations, rather than take each individual recommendation for voting. I hope that is clear to everybody. But we thought that that would be the most time efficient way to do this, and yet allow us to have a good discussion about the entire group of recommendations. But when we have this large number of recommendations, we thought it would be more effective and efficient to go through them as bundles. So, if nobody has any comments about that, I will turn it over to Arien to then start the discussion. Again, first with the overarching charge into the four sub-groups. Arien?

Denise Webb, Marshfield Clinic Health System, HITAC Member

Hello, this is Denise. And I'm going to get us started on this. Arien and I have split duties on reading this presentation. And so, I want to thank our task force. We have 16 members – I don't have a slide for that. In fact, if we could go to the next slide, please.

And we have been very busy over the last four weeks. I believe we've had about eight meetings and 10 1/2 hours in-session together, as well as a lot of work behind the scenes. And I especially want to thank my fellow co-chair, Arien, because he did a lion's share of the work on the drafting for us. We are going to go over the five groupings that we worked on to address the overarching charge that was given to us as a task force to develop and advance recommendations on part A and B of the TEF. Our detailed charge included four areas: the recognized coordinating entity and eligibility requirements; the definition and requirements of qualified HINs, and making further clarifying recommendations on eligibility requirements; permitted uses and disclosures and feedback that we have as a task force and further recommendations; and then finally, privacy and security. We did, as a task force, have quite a bit of discussion that resulted in overarching comments and recommendations on the TEF. And these overarching comments and recommendations, Arien will be going over, that are around three particular areas concerning clarity of goals, vision of responsibilities, and discussion on the single on-ramp. And so, Arien and I will be tag teaming. And he's going to start off with the

overarching comments.

Arien Malec, RelayHealth, HITAC Member

Thank you, Denise. So actually before I begin, I had an event yesterday that reminded us why – or reminded me – why this task force and the TEF charge exists. This incident yesterday has informed – the kind of incident that has informed many of our work to improve interoperability nationwide. But my son has a genetic disorder that causes, among other things, seizures. He was going for a walk and had a seizure, fell and banged up his knee and his face pretty badly. So, we ended up going to the urgent care clinic to have his knee X-rayed to see if he required more substantive follow-up. And in that process, his complete medical record and his complete medication record exists in our local Children's Hospital. Both the Children's Hospital and the urgent care clinic have an EHR – that's a meaningful use certified EHR. And yet, we were forced to go through the laborious process of explaining his complex medication history. And quite obviously, this is a fairly inefficient state of, and an unsafe state, of affairs. We can achieve much lower cost, higher quality care if the digital health infrastructure that we have created is able to exchange information as a matter of course. So with that, let's go to the next slide.

As Denise noted, in our deliberations we were asked to go through a number of questions. And in our deliberations, we also came up with a number of additional overarching comments. The recommendations letter that we sent to the full committee – and should be available in the public website shortly – goes through a fair amount of detail and background for each of these recommendations. But we're just going to dive into each of the overarching recommendations. So for the first one, the task force struggled a couple of times with areas where the current TEF draft dives into a fair amount of detail relating enablements for policy goals, but doesn't spend as much time describing the policy goals. And so, one of our overarching recommendations amounts to first, that the ONC, in the TEF, should clearly define the policy goals, expressed as clear statements of outcomes, ONC, which wants to enable our outcomes, ONC wants to prevent. And in cases where ONC does go into a level of detail, they should first describe the high-level policy goals that back that level of detail. And in general, that articulation of high-level policy goals helps reviewers and helps implementers make sure that we're implementing the high-level policy goals appropriately as we work the framework through the process. That's really the net of recommendation number one.

Recommendation number two, in some cases we found that ONC was duplicating information in the TEF that existed in other areas. So for example, there were specific discussions on hashing algorithms, key links, and the like, where appropriate pointers to NIST and other documentation would have been helpful. And our recommendation there is that in those areas where there's existing policy documentation that describes some of the detail that may be required, that ONC and the TEF should point to that policy documentation, as opposed to duplicating that information in the TEF itself. In general, you'll see another one of our overarching recommendations – or, actually our recommendations for the RCE – recommends that ONC change the balance of detailed recommendations in favor of having the RCE. in conjunction with the QHINs, work out those recommendations. So in many cases, this level of detailed recommendation, overall we'd recommend that ONC defer to a ton of implementation. But in some cases, there may be some critical areas of national priority that ONC believes should be specifically described in the TEF. And in those cases, where there's existing policy documentation, it's better for the TEF to point to that existing policy

documentation, as opposed to duplicating the information in the TEF. As I think people recognize, NIST, for example, takes their documentation through multiple cycles of revision, and those kinds of indirections help provide appropriate context, and make sure that policy recommendations keep up to date with, for example, changes in cyber security. We're going to go to the next slide.

There's obviously a lot of words on these slides. So in general, we recommend – and we pointed to the fairly successful success case – that's a little duplicative – we pointed to the success case of the functional certification for API requirements. I'm going to remind the committee that when it came time for meaningful use stage three and MIPs, that we knew as a policy goal that we wanted to evolve nationwide interoperability towards APIs as a matter of course. And as Dr. Rucker noted, the Blue Button 2.0 work that CMS has engaged in to make Medicare claims data available to patients through OAuth 2.0, OpenID Connect, and FIHR, is an enablement of that work. At the time, when ONC was contemplating the type of standards and certification criteria to put in to back that move towards APIs, we hadn't yet gone through the level of detailed specification for OAuth 2.0, OpenID Connect, and FIHR. And ONC chose to put together functional requirements for the workings of the API without defining the specifics for the standard certification behind the API. And that high-level policy goal enabled a set of public and private sector actors, including HL7 and the Argonaut project, as well as member organizations of the Argonaut project to prototype work-through standards, work-through implementation guidance, drive that implementation guidance to real-world enablements, and rollout successful standard spaced APIs that met the functional certification requirements in the real world at a much more rapid pace than locking those API requirements into certification would have enabled.

In general, we recommend – in recommendation number three – that ONC take that stance with regard to the TEF. We believe that there's a fair amount of work to go through to enable nationwide interoperability for the variety of use cases and permitted purposes described in the TEF. And that level of functional requirement and clear milestones and dates certain, provides the implementation community a good target to shoot for, a good timeline to shoot for, without overly constraining innovation, or making it difficult to rapidly evolve through implementation, feedback, and practice. So, that's the net of recommendation number three.

We note that there are some areas in recommendation number four – we note there are some areas where ONC has fairly clearly in the TEF been concerned that the market may evolve in ways that are disadvantageous for certain classes of providers. So to give an example – even though this isn't stated in the TEF, and this may just be, represent my interpretation of how ONC was looking in the TEF – there are smaller provider organizations that may use EHRs, innovative EHRs. And there may be a level of concern that interoperability will be available mainly for large, fully integrated delivery systems, and not as much towards smaller, innovative practices, such as the urgent care clinic that I went to yesterday. In those cases, where there are key policy goals that ONC is pointing to and concerns, rather than define specific policy enablements, we feel it should be a better practice for ONC to define clear expectations, expressed in terms of functional outcomes. And then, define clear milestones to evaluate those expectations, and reserve policy tools in order to drive the right level of action at a subsequent date. We note, in both recommendation three and in recommendation number four, that ONC does retain all of the policy levers sufficient to name standard implementation guidance, and

other particulars relating to those areas. And allowing the market to evolve towards a clear, functional statement of policy outcomes, gives the market and the market actors the best tools to do that kind of rapid evolution. But if we see market failure, if we see failure to align around an ecosystem that provides the public benefit that ONC is seeking, ONC should and can retain all of the tools necessary subsequently to define tighter and more specific recommendations and requirements.

Recommendation number five is that ONC should work closely with the RCE, and coordinate with other federal actors in areas where policy clarification or coordinated federal action are critical enablements – ah, enablers – and we point to two areas here where this kind of close coordination has been incredibly helpful. One is the ongoing set of activities that ONC engages in with HHSOCR, where ONC, in conjunction with OCR, has clarified HIPAA in a number of very important areas. As a particular example, ONC's clarification with HHSOCR around the form and format requirements already existent for HIPAA, allowed and clarified policy with regard to API-based access. Effectively, what OCR did was name standards based, API-based access **[inaudible][00:41:37]** format that is readily deliverable to patients. And based on already existing HIPAA guidance associate with readily available forms and formats, there's a sufficient policy enablement for patients to use the apps of their choice in order to connect to those APIs. That kind of work, particularly as we extend the permitted purposes under the TEF into areas such as payment, healthcare operations for quality improvement, and the like, that level of close coordination with ONC and OCR will help clarify a number of policy requirements. Likewise, ONC collaboration with CMS relating to close connection of the TEF and ACO and other kinds of value-based care activities will be very helpful.

And finally in the area of federal coordination, as we see DOD, VA, HIS, and SSA engage – among other federal actors – in the TEF, harmonization of standards, particularly relating to privacy and security, is incredibly helpful. A number of task force members noted that in some cases, we try to drive commercially appropriate standards for privacy and security up to the level of federal actors. And while it's important in the overall healthcare ecosystem to improve the level of privacy and security and enablement, in some cases we drive literally the requirements in that area up to the level that's required for, for example, nuclear safety. And it may be more appropriate to encourage federal actors to acknowledge that, for example, veterans and service members engage in care both in the community, as well as in federal settings. And make sure that we have a privacy and security policy framework that's harmonized across both of those settings, and moves as much towards raising the bar of the commercial settings as it does also towards harmonizing federal standards with those commercial settings. And make sure that we're not driving everything towards, literally, nuclear safety standards. Do we have one more set of overarching recommendations? Go to the next slide.

Denise Webb, Marshfield Clinic Health System, HITAC Member
Yup. Single on-ramp.

Arien Malec, RelayHealth, HITAC Member
Yeah. Single on-ramp. Okay. This is a fun one. So, the task force found that the term "single on-ramp," that was used multiple time in the TEF, caused a fair amount of confusion. The term

single on-ramp was used – is used fairly aspirationally. But the enablement in the TEF is primarily around query-based exchange, in particular to brokered, query-based exchange. And a number of task force members who were looking for the TEF to address specific concerns relating to public health, for example, patient-generated health data, and other key areas of national policy, felt that the single on-ramp underlined in the TEF should also be for push-based exchange that is necessary for public health, for example, in the area of reportable labs or in reportable diseases, as well as in bilateral or coordinated push transactions that might be necessary for coordinated referral transactions. Other members felt that the TEF had appropriately defined the term "single on-ramp" relative to query-based exchange because – under the belief that there is a fairly complicated set of work that we're going to be going through in order to drive universal adoption of query-based exchange and its appropriate focus there. So, we characterize this as narrow focus versus broad focus. In general, our recommendation is that ONC should clearly define the role of QHINs, as well as the RCE, relative to existing forms of exchange. And narrow the scope of what's defined as a single on-ramp with respect to the types and capabilities of exchange anticipated. Beyond that recommendation, we were not able to achieve unanimity. In fact, we were fairly evenly split between the narrow focus and broad focus goals. And so, we articulated a set of possibilities for ONC to contemplate, without recommending either one. And noting that the task force was effectively 50-50 split between narrow focus and broad focus. If we go to the next slide –

Narrow focus would ask the ONC to clearly define the floor capability for the on-ramp, provided by QHINs to be for query-based exchange and access DHI. In all of these cases, where there's some subset of needs contemplated under the TEF, we also want to make it clear that QHINs may provide that this is a floor, and the QHINs may provide more forms of exchange. And that evolving towards a true, single on-ramp, may be a useful policy goal. So, we don't want to imply or have policy constraints that prohibit QHINs from offering additional services, or from EHRs to connecting to QHINs to offer a broad range of services. We also noted that 50 percent of the task force aligned around one of what we're calling 7B and 7C. Even though there is some level of alignment towards 7B versus 7C, we don't want this to be taken to look at a plurality for 7A, relative to 7B. The distinction between 7B is 7B really defines the term "single on-ramp" holistically, relative to all forms of exchange, really wanting to establish a true, single on-ramp for multiple forms of exchange, whereas 7C really aligns around a single on-ramp that is specific to national priority goals over the next three-year period. That's an important distinction, by the way. The task force noted that although aspirationally, we might want to get to a single on-ramp -- even for the folks who advocated for a narrow focus, the real discussion of the task force was over the three-year period for evaluation in the RCE, established by ONC. And so, all of these recommendations should be taken with respect to a three-year period. So, I believe that is the last of our overarching recommendations. Can we go into the next slide?

Denise Webb, Marshfield Clinic Health System, HITAC Member
We have one more.

Arien Malec, RelayHealth, HITAC Member
One more. Great.

Denise Webb, Marshfield Clinic Health System, HITAC Member

We have number eight, depending on what we **[inaudible][00:49:15]**.

Arien Malec, RelayHealth, HITAC Member

So – thank you. Yeah. That's exactly right. So, if we choose a broad and expansive definition of – or a broad definition of single on-ramp, we also recommend that the ONC work with the RCE to establish standards and capabilities for push-based transactions, in particular for public health exchange, for coordinated referrals, and for supply of patient data, patient PGHD and to EHRs. So, now that does actually conclude the first eight recommendations, the first eight of, I believe, 26 recommendations that we're offering under this recommendation letter, and concludes our discussion of the overarching recommendations. So just to give a summary of our overarching recommendations, number one is more specificity – in general, more specificity around policy goals, an approach that ONC adopts to define policy goals and milestones and dates certain for achievement of those policy goals while letting the actors involved in information exchange work out the details. And better definition, better coordination with federal actors, and better definition of the term "single on-ramp." So at that, Robert, we turn it back over to you to allow the community to deliberate the overarching recommendations.

Robert Wah, DXC Technology, HITAC Co-Chair

Thanks, Arien and Denise, both. Yeah. So, you can see the challenge that we have with a large number of recommendations, and we appreciate the task force's work here, and the Chair's, in trying to get this in a way in which we can manage our comments. I also want to comment that the other challenge we have is to run the committee meeting. And because we have a large public audience as well, and there's various modalities in which the public will have an opportunity to comment on our work, I want to make sure I clarify our process for that. So, your Chairs have planned that we would allow the task force Chairs to give a summary of each of these bundles of recommendations as a prelude to the discussion by the committee on each bundle of recommendations. There is time scheduled at the end of our discussions, as a committee, for public comment. And so, I would ask the patience of the public members that are participating in the meeting to hold their comments until that section. I see that some people are making comments in the chat line, and we will try to add those back into the discussion at the appropriate time. But if I miss one or two, please, as the public, please feel free to remind me that were those other comments.

I will also say that we are trying to time box this a little bit. As you can see on the agenda, we scheduled the bulk of the meeting for this section. But as you can imagine, this large number of recommendations will take a while to go through. So, Lauren has volunteered to be the timekeeper on this. We will roughly try to stay to that, recognizing there may be some variability between the bundles. So, some bundles may take a little longer to discuss than others. And so, overall, we would like to stay within our time that we have scheduled for the entire issue. But we'll have some flexibility within each bundle. So with that, we will open it up to the committee to comment on the bundle of overarching recommendations that Arien just presented.

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

Thanks, Robert. And I see Steven, you are first in the queue with a comment.

Steven Lane, Sutter Health, HITAC Member

Yeah. This is Steven Lane. I just wanted to go on record as really giving great appreciation to the group that has developed this recommendation. This clearly was a lot of work, and they were very clear. And I just wanted to thank you for that. I also wanted to say that under recommendation six, I think it's very helpful to call out that differentiation between the narrow focus, which I think was reflected in the draft TEF, and the broader focus, which I know that I raised during our first meeting – discussion of this. And I think attempting to look at this holistically with the broad focus is really going to benefit us in the long term, even thought it does mean a bit more work up front.

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

Thank you, Steven.

Steven Lane, Sutter Health, HITAC Member

Thank you.

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

Any other comments or questions on the overarching recommendations?

Arien Malec, RelayHealth, HITAC Member

Our general theory is to overwhelm the committee with words **[laughter]**.

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

Aaron, I see you have a comment.

Aaron Miri, Imprivata, HITAC Member

Yes, I do. This is Aaron Miri, Imprivata, HITAC Member. First of all, I appreciate everybody on the committee that served together to pull this together. This is a fantastic body of work done in a very short time period. And I've served on other **[inaudible][00:54:35]** before that had a much longer runway, so I appreciate everybody and the diligence on this. And great job, Arien and Denise, pulling this together.

So, sort of comment I want to stress and really focus on, especially around recommendation five with the information security, privacy and identity insurance. I think we talked about it enough as a task force, but I want to stress as a larger groups that harmonizing and making sure that we point towards understood, such as NIST or other guidelines, is critical. And I think all of us came from different perspectives of our career and experiences where one group was speaking English, one groups was speaking Greek, and the two couldn't talk. So, making sure that we all align, and making sure that we continue to stress leveraging those generally accepted criteria and frameworks is critically important. Those are my comments.

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

Thank you. Christina, you're next.

Christina Caraballo, Get Real Health, HITAC Member

Thank you. I would like to echo that this is a great presentation. Thank you so much. And I was thinking of the USCDI under recommendation three, and the fact that you guys had recommended that there should be a refrain from naming particular standards. One thing under recommendation three that we could do is possibly point to the interoperability standards advisory and the USCDI to address this area as well for the more specifics.

Arien Malec, RelayHealth, HITAC Member

I want to point out that later in our recommendations relating to permitted uses and disclosures, we recommend that ONC and the RCE elaborate the USCDI with regard to the priorities established for each of the permitted purposes. So, I think pointing at the ISA, as well as the USCDI, I think is an important callout.

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

Thanks, Arien.

Christina Caraballo, Get Real Health, HITAC Member

Well, and I can –

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

Oh, sorry. Go ahead, Christina.

Christina Caraballo, Get Real Health, HITAC Member

Nope, go ahead. Terry's probably going to say what I'm going to say **[laughter]**.

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

I think I see Ken next in the queue?

Kensaku Kawamoto, University of Utah Health, HITAC Member

Sure. Thanks for the really detailed recommendations. Could you comment a little bit on – and sorry if I've missed it – on the balance between doing the wide-based search and the inevitable probably misidentification of someone else's records that's going to happen? And how that's being considered?

Arien Malec, RelayHealth, HITAC Member

So, is this with regard to query-based exchange over the QHINs and the possibility of **[crosstalk]**?

Kensaku Kawamoto, University of Utah Health, HITAC Member

Yeah. Just the notion that if you're searching throughout the whole nation, if you're a – if you don't have a name like mine, which there still might be, but if you had a fairly usual name, there's a decent chance that the algorithm will pick you up someone else's record and pull it in.

Arien Malec, RelayHealth, HITAC Member

Yeah. So, the committee did not consider that particular item. There is the possibility, in any form of health information exchange, the possibility of accidental disclosure of information. In general, HIPAA does accommodate for accidental or incidental notifications, particularly in cases where the person to whom the information was disclosed follows appropriate procedures regarding data deletion. And there's a specific notice in HIPAA regarding – more specific language in HIPAA regarding the responsibility or, in some cases, the ability to address that throughout without going through a breach notification process. There are areas where, and again, this is probably secondary to our recommendation of ONC and OCR collaboration, there are areas that I think would be helpful for ONC and OCR to work out, regarding for example, looking up a patient's information in an index, and getting the wrong patient prior to actually pulling down the patient's information, where I believe that that falls under the incidental disclosure language in HIPAA. But it's not explicitly a permitted purpose, either. Just as a reminder, the permitted purpose, for example, for treatment requires that you are actually treating the patient. And in this case, you're looking up the wrong patient's information. So, establishing some level of policy guidance regarding these kinds of of inevitable incidental disclosures, I think would be very helpful for the community. But I do think that is sort of secondary to our overall requirement that ONC work with OCR to work out many of the policy details.

Kensaku Kawamoto, University of Utah Health, HITAC Member

Yeah. That sounds great. And I think beyond the disclosure, just if you could think through how to minimize the chances that somebody will trust the information that gets pulled in and make a decision that leads to patient harm. Which, I'm going to just venture a guess it will happen, and someone will get harmed, someone might die, but being explicit about – but maybe in the overall scheme of things, the benefits from all the number of people who will get better care, who will prevent adverse events is worth it. But I think being a little bit – I guess, acknowledging of the fact that there will be harm that comes from accidental data handling, and providers just trusting that information. I think it would be useful to think through how to really minimize that cost, and/or to try to have mechanisms to prevent it. So, the notion that when you're looking at the data, it's more obvious when it may be, for example – it could be as simple as you're talking to the patient, and see **[inaudible] [01:01:02]** data that came from these particular health systems – "Have you received care?" – kind of thing, where – but anyway, it just seems like it's inevitable something will happen, if we're not careful about it.

Arien Malec, RelayHealth, HITAC Member

So in general, our recommendations do address those areas, but recommend that the RC and QHINs work out the details locally. With regard to some of the broad national priorities, we definitely do recommend that ONC work with OCR, particularly to work out some of the issues relating to breach. I think relating to liability, I'm not sure that ONC or OCR could appropriately

address liability concerns relating to information exchange. But you know, it might be possible to contemplate some language that we might want to put into the recommendations. In general, I feel somewhat uncomfortable making specific recommendations in this area. Because the task force didn't explicitly – wasn't asked to, and didn't explicitly address – that particular concern.

Kensaku Kawamoto, University of Utah Health, HITAC Member

Yeah, no. Fair enough, maybe for the ONC folks. Yeah. I think the benefits definitely outweigh the costs. But there will be costs, so mitigating it as much -- mitigating it as much as possible would be great.

Arien Malec, RelayHealth, HITAC Member

Thank you.

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

Thanks, Ken and Arien. So, we'll try to take one more comment from Terry, then I think we'll need to move on to the RCE portion of the recommendations. Terry?

Terrence O'Malley, Massachusetts General Hospital, HITAC Member

Thanks again. And great job hacking your way through a really thick jungle. It's some great clarity here. One of the ways, just following up on the last comment, you might want to think about a data class that specifically addresses unique individual identification as sort of the priority to run through the USCDI process. It seems to me to be sort of a fundamental cog in this whole machine, and would appreciate any thoughts on that.

Arien Malec, RelayHealth, HITAC Member

Yeah. That's exactly what I was pointing at in that there is, in HIPAA – it's one of the odd areas in HIPAA – where HIPAA allows data to be used for treatment if it is, in fact, the same patient. But there's no explicit handling in the HIPAA rags for looking patient demographic information and selecting the right patient, except insofar as there is specific language in HIPAA relating to these kinds of incidental and non-harmful disclosures. So, it would be really helpful for OCR and ONC to help clarify the process in looking up a demographic index – the demographics of patients to find the right patient, to minimize some of the downstream risk of disclosure and risk of harm.

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

Okay. Ken, if I can come back to your comment? Or do you still have your hand raised from previously?

Kensaku Kawamoto, University of Utah Health, HITAC Member

No, you can come back.

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

Designated Federal Officer

Great. So, I think I'm going to hand it over to Denise now for the RCE.

Denise Webb, Marshfield Clinic Health System, HITAC Member

Great. Thank you. In the area of the recognized coordinating entity, we are advancing three recommendations on the RCE, which address particular eligibility requirements for the RCE, and how the ONC should judge the success or failure of the RCE and what milestones might be considered. So to summarize, on recommendation nine and ten, I'll first note that, just as we talked about in the overarching recommendations, that the task force believed that ONC should assign a number of the operating decisions and a lot of the detailed guidance, the overall architecture and orchestration of standards, etc., to the RCE, working in conjunction with the QHINs. And then given that, obviously the RCE should have strong capabilities in healthcare interoperability. We believe that the RCE should be broadly trusted, be above approach, transparent, and open. That the governance should represent a broad range of perspectives, and that it not be overly weighted to any particular group, such as large health systems, federal providers, a particular QHIN, etc. And should have sufficient protections against activities that might lead to, or be perceived as leading to, conflicts of interest. We also acknowledge that the RCE role might not match exactly any of the existing interoperability governance actors. And that the RCE, selected by ONC, might represent a merge or reconfigured version of one or more established actors. And we also suggest that ONC may wish to look at successful governance models from outside of healthcare, such as the NTSB or the National Lab. So, that summarizes recommendations nine and ten. And if we can go to the next slide for recommendation 11.

We did discuss how ONC should judge the success or failure of the RCE, and what milestones might be considered. And generally speaking, we thought that the RCE should be judged primarily based on outcome-based measures. For example, those set forth in the impact domain or subdomains of the National Quality Forums Interoperability Measurement Framework, and then actual real world success of interoperability. We noted that this is a voluntary framework and that the TEF and the RCE will really be judged based on how successful this is for providers and patients to adopt and receive services through the QHIN that address the policy goals that are in the 21st Century Cures Act.

Some secondary measures that we thought should be satisfied were are around satisfaction or survey-based measures, measuring the perception of the user experience with interoperability, primarily of patients and providers, and secondarily of health IT developers and QHINs. And that basically summarizes recommendation 11. So, I think I'm catching us up on time here. Those are the three recommendations that the task force had on the RCE eligibility criteria. I'll turn it over for comments now for this grouping. To Robert – I think Robert, your hand was up?

Robert Wah, DXC Technology, HITAC Co-Chair

Thank you, Denise. And we'll – I think we have Lauren keeping track of the hands raised.

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

I'm sorry, I don't see any hands raised at this time. Do we have any comments or questions or

thoughts for recommendations nine through eleven?

Female Speaker 2
Not as a controversial topic, I don't think **[laughter]**.

Robert Wah, DXC Technology, HITAC Co-Chair
That's why I said I think there's going to be some variation across the bundles, but – we want to make sure that we have it.

Denise Webb, Marshfield Clinic Health System, HITAC Member
Yeah. This one is a little more straightforward I think.

Robert Wah, DXC Technology, HITAC Co-Chair
But at the same time, we want to make sure we have an opportunity for all the recommendations to have an opportunity to be fully discussed. I think the best outcome is when we have every perspective possible expressed on this. But we want to do it in a time-efficient way. So.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yup. And we can always come back at the end, as you mentioned. But I do see one comment from Aaron so far?

Aaron Miri, Imprivata, HITAC Member
Yup. Aaron Miri, Imprivata, HITAC Member here. So, quick comment. I want to add maybe a little bit more color into your recommendation 11. You know, the task force, we did spend quite some time just throwing around use cases and ideas of specific measurements. I think that I do want to stress that's very important for there to be very clear and defined measurement on success criteria for the RCE. Case in point, it could even lead towards the earlier question on this call about, "Did we accurately identify the people accessing or traversing the system? Did the RCE do their job effectively and identifying folks?" That can be a measurement criteria just a brainstorm. Those types of things can help really alleviate any concerns or help mitigate any of those risks that were brought up earlier. So, I just want to point that out that recommendation 11 can really be meaty and really help prove the meat in the sauce.

Denise Webb, Marshfield Clinic Health System, HITAC Member
Aaron, thank you for providing that example. That's a really good one.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
And Tina, I see you have a comment?

Tina Esposito, Advocate Health Care, HITAC Member
So, I think recommendation 11 is fantastic. And I applaud the group for identifying the need to

ensure that we are quantitatively sort of measuring success. And this may come later, but the comment I would have is that there should be some thought or some discussion around how will those measurements be used to assess performance, sort of both at the ONC level – I agree with the process metrics for an RCE, so that they're clear that they need to measure their performance. But I guess just one step further in terms of how will that be used then to assess sort of the election of the RCE, if you will, and how we will use that – or how will that be used to insure that outcomes are being achieved?

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

Thank you, Tina. I'm seeing no other comments at this time. Denise and Arien, are we okay to proceed to the QHIN portion of the recommendations?

Arien Malec, RelayHealth, HITAC Member

Let's do it.

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

Okay.

Arien Malec, RelayHealth, HITAC Member

Alright. So, for the QHIN section, number one, there was – just for people who are following along at home – there was a definition of "participant neutrality" that was stated in the definition of a QHIN, literally in the definition section. And the task force spent a fair amount of time discussing the language and the enablement for participant neutrality, and consistent with the rest of our recommendations, we recommend that ONC clarify the policy intent relating to the specific definition of participant neutral. We generally recommend that ONC define a policy goal that the overall ecosystem of QHINs is neutral and accessible to all parties. But that ONC should use more neutral definitions, and not prevent data holders from offering QHIN services. So, the specific detailed definition of participant neutral was defined as prohibiting a QHIN from serving data relating to itself. And we felt that there would be a number of potential QHIN actors who are also potential data holders. And that defining the QHIN in that way could potentially limit the number of, or types of, organizations that might want to offer services.

We also noted that in many cases, some of the surmised concerns that ONC was trying to mitigate actually could be fairly trivially stepped aside, based on that particular definition. In that, for example, some of the information exchanges offered in conjunction with vertically integrated health information technology systems are, in fact, run by not-for-profit organizations that are run by the providers who use a particular information technology system, and are not run by the information technology vendor themselves. So, we would – if ONC has a particular concern relating to the participant neutral language, ONC might consider the various ways the perspective QHINs might structure their activities to address those possible restrictions. So, that's the intent of recommendation number 12. We had a lot of discussion relating to the broker model. And this is in general, following our general recommendation that ONC establish the policy, and allow the RCE and QHINs to work out the details of the technology enablement house. So, if we go to the next page.

ONC should define a set of functional requirements documenting the outcomes using the QHIN from the perspective of a provider or patient. For example, ONC might define a functional requirement that a provider or patient should receive all known locations, or a patient's data that might be found in the content of data to be found at those locations. Regardless, the technology vendor or QHIN used by the end location of data. So, that's a proposed, and again, a proposed functional definition of the broker language that addresses or sidesteps some of the particulars in how the broker might be constituted or some of the details associated with the activities of the broker. That definition would allow for multiple configurations of a model for achieving the outcome. So for example, one could cache or remember locations across multiple invocations, or have QHINs that share data on location between themselves in the same way that, for example, the DNS system does. But again, the general recommendation is rather than define the specific functions of a broker model, define the policy requirements for what should happen and let the RCE and QHINs work out the how.

There's a fair background in the document relating to QHIN fees. Some of the background for the fee structure discussions is that the task force discussed the notion of either free, or cost basis, fee structures for QHIN-to-QHIN exchanges, combined with the TEF language that establishes a duty to respond for permitted purposes and some consequence for unintended – for some risk of unintended consequences for that activity. So for example, there are a number of business cases that drive interoperability needs. As one example, that's quite public and well-established, SSA finds that electronic adjudication of disability determination is much cheaper and more effective for taxpayers than retrieval of paper-based charts, chart abstraction, and paper-data handling relating to the information required for the disability determination. And so, based on the value that SSA receives from that work, SSA is, in fact, willing to pay for electronic retrieval of information associated with a disability determination. Or I believe the fee structure is $15 a chart, or $15 a disability determination. These kinds of business models provide an effective business model for information exchange, both from the provider and from the qualified information networks that serve them. Based on the TEF language for duty to respond and the QHIN-to-QHIN fee structure, we noted that, for example, a federal QHIN, a QHIN that served federal actors, that made a disability determination request based on the TEF language would both, based on the duty to respond, require actors to submit data. And also based on the TEF, in this case, zero-cost QHIN-to-QHIN exchange, have no additional fee structure charged from the federal QHIN to – or from the QHIN that was doing the response. And what effectively that does is it makes SSA's fees in that case, effectively optional in the sense that we have force-duty to respond, and driven the cost down to a zero-dollar cost basis. So, in those areas the task force was concerned that we're essentially undermining the business case for exchange, and undermining a variety of potential use cases for exchange, where the benefit should be associated, or could be associated, with the fee structure that might drive more optimal configurations of value. So, we'll go to the next slide.

Number one is ONC should establish, through the TEF, the combination of zero or cost basis QHIN-to-QHIN fee requirements with the duty to respond by QHINs. Participants and end users only **[laughter]** – on QHIN intermediate access, it's required by all – sorry, I think we got a little bit of – oh, there we go – respond by QHINs, participants, and end users only on QHIN intermediate access, it's required by all participants and end users, and for users that are reciprocal, where both sides of the exchange benefit and participate. ONC should understand

that zero or cost basis QHIN-to-QHIN fee structures, combined with duty to respond for permitted purposes, will significantly shape market dynamics and increase the incentives for organizations to opt out of participation in the TEF. So, there's a gloss on that clause. If an organization would be effectively forced to exchange information based on the combination of zero or cost basis QHIN-to-QHIN fee structures, and the duty to respond established under the TEF, they have an incentive actually not to participate in the TEF, in the sense that they could separately contract with SSA, and get a $15 per case, or separately contract with a Medicare Advantage payer and get potentially a fee structure for risk adjudication or for HEDIS measurement. In all of those, the SSA pricing structure's fairly well established in regulation. And it's a regulatory work by the SSA. The notion of a payer-based fee structure for Medicare Advantage risk adjudication or HEDIS measurement is also a well-established pricing structure in the industry. So, if you force duty to respond and force a cost basis or zero-cost fee structure, you're effectively providing incentive for provider organizations to opt out of QHIN intermediate exchange, and TEF intermediate exchange, and separately contract for exchange, which sort of undermines the case for the TEF and QHINs in general.

We also noted that some of the details here are little complicated, because they're driven by ultimately what ONC and HHF determine is Congress's intent in some of the language associated with information blocking. And so this notion of duty to respond under information blocking requirements needs to closely track the duty to respond established in the TEF. And right now, we weren't in a position to determine whether the duty to respond established in the TEF actually tracked the duty to respond associated with information blocking. So, a pretty complex and meaty set of recommendations. And it's quite possible we'll have some comment in that area.

We talked about the 5attributed cost calculation that's associated for fee structures. And we noted that based on the way that attributed costs are calculated, it's quite possible to undermine the incentive for improving QHIN operations over time. So, some of the examples that we gave is that if I spend, as a QHIN, R&D dollars to improve efficiency, I actually – because I've lowered the cost basis for exchange, I don't have any means for capturing the improved efficiency that I have relative to other QHINs. And the bad actor QHIN, who spends – who kind of does their activities cheap and dirty, and doesn't spend as much R&D, in fact, because their cost structure is higher, has no incentive to reduce their cost structure over time. And so, you've effectively got a mechanism that drives QHIN exchange to the highest, rather than the lowest, cost structure. So, on the next slide –

We recommend that ONC provide the RCE the authority to employ mechanisms to ensure QHIN-to-QHIN fees are uniform for like services and like performance SLAs. So, here basically you would establish, for example for treatment-based use cases with a particular SLA, so for example, five seconds to pull a case for treatment, you'd establish a common fee structure. And that common fee structure would provide incentives for QHINs over time to improve performance and improve operations so that they can effectively beat that cost structure, and reap the benefits from beating that cost structure.

We also noted in the second clause, the second part of the recommendations, that the RCE should adopt mechanisms. And we point, for example, to reverse auctions as a possible mechanism that we don't want to overly constrain what mechanisms are adopted that prevent

against inappropriate price increases, and provide appropriate incentives for QHINs to reduce cost structure for QHIN-to-QHIN exchange over time. So for example, these kinds of reverse auction structures have been used by the FTC relating to bandwidth auctions. And the basic notion is you bid out a QHIN-to-QHIN fee structure, and you pick a mechanism to pick a QHIN-to-QHIN fee structure. And if all the QHINs improve their performance and you rebid, you're actually driving the cost for QHIN-to-QHIN fee structures down over time, while providing incentives for QHINs to beat that structure and improve profitability. We also noted that the presence of zero-based QHIN-to-QHIN fee structures decreased incentives on participants and end users to develop and use those services efficiently. So, as a note, the public health, the SSA, or other disability determination or benefits determination use cases, as well as individual access use cases, were noted at a zero-based fee structure. And our recommendation is to reserve the zero-base QHIN-to-QHIN fee structure solely for true individual access. And when we get down to permitted uses and disclosures, we make additional comments related to individual access. Do we have another recommendation under qualified health information networks?

Denise Webb, Marshfield Clinic Health System, HITAC Member

Nope. That was our last.

Arien Malec, RelayHealth, HITAC Member

Let's go back up. So, those are our recommendations relating to our charge for qualified health information networks. And I'll turn it back to Robert for discussion.

Robert Wah, DXC Technology, HITAC Co-Chair

Thank you, Arien. Again, another bundle that we have been presented. I'll open the floor for the committee to comment and respond.

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

And I see Ken, you have a comment?

Kensaku Kawamoto, University of Utah Health, HITAC Member

Yeah, hi. I found the recommendations for what can the US, I guess it's here and later on as well, US core data set group include – were there anything in this set of work where you found there was any particular recommendations for the other work group here in this set of recommendations?

Arien Malec, RelayHealth, HITAC Member

We do, in the permitted uses and disclosures, make recommendations for tracking USCDI relative to the specific-use cases associate with permitted uses and disclosures. So, when we get to that section, you'll see that recommendation.

Denise Webb, Marshfield Clinic Health System, HITAC Member

Yeah. We have something very specific on that.

Kensaku Kawamoto, University of Utah Health, HITAC Member
Okay.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Any other comments or questions?

Robert Wah, DXC Technology, HITAC Co-Chair
While we wait –

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Oh, I'm sorry. Go ahead, Robert.

Robert Wah, DXC Technology, HITAC Co-Chair
I was just going to say while we're waiting for people to raise their hand, I just wanted to take a moment to say in the public comment area of the application we're using, I've noted that there are good comments. And we appreciate that. And I want to encourage people to use that. I think I also want to make sure that people know that the public comments that are put in the chat line do become part of the public record of this meeting. And so, some of the comments are questions and some of the comments are just not **[call cuts out]** – but some comments consist of questions, and some consist of comments. And I wanted all the people that are putting those in the chat section, that they will be included in the record of this meeting. For purposes of making this whole meeting work right, I think it would be best, if possible, if you have a question or something that you would like feedback on directly from the task force Chairs to use the public comment period at the end of the meeting, to use that period to forward that question. If you have a comment that you want added to the record, you can do so in the chat area of the application. And I just wanted to clarify that for the people that are using the chat area. That's how we plan to use that input source.

Denise Webb, Marshfield Clinic Health System, HITAC Member
Robert, this is Denise. Can I make a point of order?

Robert Wah, DXC Technology, HITAC Co-Chair
Sure.

Denise Webb, Marshfield Clinic Health System, HITAC Member
I just want to make sure that all the committee members, if you have comments and questions, it is best if you verbalize those because we are going to take a vote at the end of this. And if there's some concerns a committee member has, or some suggested revision that they think needs to be made before they're willing to vote favorably on the recommendations, it would be best if that was brought up verbally rather than in the chat.

Robert Wah, DXC Technology, HITAC Co-Chair

Yes, thank you, Denise. That's absolutely right. For the committee members, this is our opportunity to have a full discussion of the recommendations that are being put forward by your task force. As you know, our process is that we expect the task force to take the deep dive into these issues, but ultimately it is the committee's work to then approve the recommendations that come from the task force. And so, this is our opportunity as a committee to fully air our questions, comments, and issues about those things that the task force has put before us. So, yeah. I'll echo Denise's comment that this is our time to fully discuss these recommendations. And to remind the committee that our plan is, at the end of discussing these five areas or bundles, we will plan to have a vote on the entire set of recommendations from the task force.

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

Alright. So, let's call for comments or questions from this last bunch of recommendations before we move on to permitted uses and disclosures? And perhaps the lack of comments are a testament to the good work of the task force. And so, with that I think I'm going to turn –

Arien Malec, RelayHealth, HITAC Member

One can only hope **[laughter]**.

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

Okay. Back to you, Denise, for the next bunch. Correct?

Denise Webb, Marshfield Clinic Health System, HITAC Member

Alright. Thank you. This next grouping has several recommendations, and I'll ask my fellow co-chair to please not feel amiss to jump in if I fail to emphasize something I should, because this gets into some pretty deep areas. So, this next grouping is around the permitted uses and disclosures, and the actual exchange modality use cases, specifically broadcast query, targeted query, and population-based query. So, ONC did ask us to provide feedback and recommendations on these areas. And we have, as a task force, eight recommendations to advance here. The first two recommendations are around individual – excuse me, the first three recommendations are around the individual access permitted purpose. And then, there is a recommendation around permitted uses and disclosures that are beyond individual access and treatment. We have a general recommendation around the alignment of USCDI with these permitted purposes and use cases. A recommendation which I believe Arien sufficiently went into previously on a discussion of QHINs related to the fee structure for FSA disability determination. And then, we have a recommendation related to payment permitted purpose and population-based core use.

So, let me see if I can step through this and provide you a summary for these groupings within this category. And I will note that on the slides that there is a bit of the summary of our discussion and preamble that is not actually part of the specific recommendation. So, starting with the first three recommendations around individual access. As a task force, we strongly endorse the requirement for individual access. But we also noted this is an emerging space, and in a lot of cases, policies and standards requirements are not clearly established. And we do

believe that individual access as defined in HIPAA needs to be cleanly separated, where it's individual access with an individually controlled account, needs to be cleanly separated and clarified from aggregated-based access, which would be done as a secondary purpose via a proxy through an individual access request, particularly as it relates to fee restrictions and duty to respond.

So, the first recommendation is around ONC clearly defining access consistent with HIPAA, as I noted, and making that differentiation between aggregator-based access. And that fee restrictions and duty to respond should be restricted to the case where the patient is requesting access to view, download and use, or transmit data, to an entity or application or utility that the patient manages. And also, that subsequent data donations should be optional and under the patient's control. That the patient itself does not have, **[inaudible][01:35:06]** down requirements, a duty to respond.

The second recommendation is around that, to make it clear, that the duty to respond is an obligation of the other participants and end users, not an obligation of individuals. But that does not preclude the patient who has control of their data to make their data available if they so choose.

Recommendation 19 discusses that ONC should ensure that stakeholders – and we're talking about the RCE and standard solvent organizations and so forth – test and evolve standards and guidance and profiles, and accompanying policies that's sufficient to enable broad-scale individual access. Because as we noted earlier, there is not a lot of policy in standards requirements that **[inaudible]** established for this permitted purpose. Alright. So, that – those are the three recommendations around the individual access permitted purpose. Okay.

On the next recommendation, the task force endorses the requirement for treatment-based access and acknowledges that it's a well-accepted area, and has many examples that are working well in practice. But we did note that there's other permitted uses and disclosures that have only had pilot-based use, or use through a proprietary exchange model. And we do believe that these uses beyond treatment require some active production testing and refinement prior to broad-scale use. And so, that's the nature of our recommendation 20. That while there is a lot of broad-scale testing and production use for treatment purposes, that these other purposes aren't necessarily at the same level of maturity. But, we would not want to preclude the QHINs, the HINs, or the participants from enabling the other permitted uses. Hopefully, I got that right. Arien **[laughter]**? As I said to you –

Arien Malec, RelayHealth, HITAC Member

Yup.

Denise Webb, Marshfield Clinic Health System, HITAC Member

Chime in if – okay. Recommendation 21, so let's see. What slide are we on? I apologize, my computer screen just went blank. But we should be – we can stay on slide number 16. That's the preamble to our next recommendation, recommendation 21. There was a lot of discussion around the fact that in order to enable some of the use cases for these permitted purposes, that there needed to be maturity around the standards and for the data model, and that the

USCDI, while it's outside our scope and charter for our task force, we did note that what is occurring in the USCDI had to evolve in close coordination and collaboration with what's required in the TEF, in terms of duty to respond after permitted uses and disclosures. And we did note as a task force that in some cases, the data classes are not yet available, or not complete. So for instance, so the Social Security Administration disability determination use case, there are data elements that they need that are beyond the class of data that's available in the USCDI. And then, we also noted in other cases, view the minimum necessary requirements in terms of providing data. So for instance, public health has the authority to have data, certain classes of data, there are some data classes that provide a lot more than what they're permitted to have. And so, thus we advanced this recommendation that ONC work closely with the stakeholders to align USCDI to the particular needs of each permitted purpose, both to address additional data needed and to minimize data provided for the particular use case as the law permits.

Recommendation 22, I believe Arien has sufficiently covered that earlier, but this relates to the fee structure and the potential for fee disparities. And that ONC should work with stakeholders to resolve the fee disparities for the disability determination use case. We also noted here, for purposes of use beyond individual access and treatment, to see our previous comments related to the QHIN fee structures for some of our concerns related to duty to respond and a zero or cost basis QHIN-to-QHIN fee requirements.

The next recommendation, recommendation 23, we're still on slide 17. We thought as a task force, that the payment permitted purpose as defined in the TEF documents was too broad to really be useful, and that payment-based uses and use cases include several types of data and scenarios such as claims attachment, medical necessity, utilization management as listed on the side here. We also noted that – and this relates to recommendation 24 – that with population-level queries, there are population-level queries that are related through a provider-based population-level query, and a payer-based query. And that in the particular case of the payer-based queries, there is a lot of complexity related to member filtering. And actually, matching up members with particular providers with particular payers. And I know just from personal experience, like seeing this in the HIE when we wanted to a patient activity report for the health plan organization to let them know when a patient has been admitted to the hospital that's one of their members, that there's a lot of complexity in getting that all lined up, that you're not giving them information for someone who that is not presently one of their members.

So, recommendation 23, on the next slide, slide 18. We are recommending that ONC clearly define some purposes of use under the broad payment permitted purpose, or define the policy objective. And that really ONC should work with RCE to establish an **[inaudible]**, including working on standards and policy – implementation guidance and policy guidance for each of the permitted purposes for which there is a duty to respond.

Now, our last recommendation – I think it's our last one here – yup, in this area – relates to the discussion around population-based query, modality, or use. So, provider-based HIPAA operations is probably a lot clearer and easier, or not really easy, but less complex for the provider scenario, and their ability to do data aggregation across several covered entities for quality measurement, or for ACO purposes. But when we get into the payer-based population query, or population-based query by other actors other than payers, this is not necessarily

ready for scale. So, recommendation 24 recommends that ONC should work with the standards development organizations and the public, private stakeholders, to define **[inaudible]**, and get feedback and refined standards for population-based queries for provider-oriented value-based care uses. And then, should work with OCR and other stakeholders to align standards with policy requirements to ensure the standards can be used in practice. And that we are also recommending that ONC delay implementation of these use cases until appropriate testing can be performed. And that is the last recommendation under permitted uses and disclosures. And I'll turn it over to you, Robert, and Lauren to facilitate comments.

Robert Wah, DXC Technology, HITAC Co-Chair

Thanks Denise. And Lauren, I think you already have somebody with their hand up?

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

Yup. We do. Steven? And then, Leslie.

Steven Lane, Sutter Health, HITAC Member

Yes. I just wanted to applaud the recommendation for a go-slow approach to payer-based access. We, within our organization, heard a lot of concerns about this and a real sense that this needs to be done in a very deliberative way, as you say, with the input of groups that have put a lot of thought into this. I, again, wanted to applaud that.

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

Thanks, Steven. Leslie?

Leslie Lenert, Medical University of South Carolina, HITAC Member

The introduction to the Trusted Exchange Framework called out specifically use of the infrastructure for research. And I've noticed that there is not a specific comment on, or text in the section here on, use of the network for research. Did you all discuss this? And is there any plan for a recommendation that would support the use of the network for research-related queries that are approved by human subjects and other appropriate methodology.

Denise Webb, Marshfield Clinic Health System, HITAC Member

I'll respond first, and then I'll let others – Arien or others on the task force jump in. But I do know around the population-based queries, I believe we had talked about some of those other actors in a population-based query, possibly would be research. And that a lot of that hasn't been workout and defined. And then, I think we also acknowledged that under individual access, that patients are permitted to send their data to whomever or whatever they would like to. And that may facilitate the needs of research.

Arien Malec, RelayHealth, HITAC Member

I agree with both of those. I'd also note that the task force charge did not ask us to address research needs with regard to the TEF, nor was research one of the explicitly permitted purposes established in the TEF. So, I think it's fair to say that it's a great point, but the task

force wasn't asked and didn't do any specific deliberation in that area.

Leslie Lenert, Medical University of South Carolina, HITAC Member
I'd just like to add that it is explicitly called out on page three of the TEF, where we envision – we seek, the vision we seek is to achieve a system where individuals are – it goes on – and that we're – have public health agencies and researchers can rapidly learn, develop, and deliver cutting-edge treatments by having secure, appropriate access to electronic health information. So, this is part of the introductory framework of the TEF. But, it never really found its way into the authorized uses of it. And I think it should explicitly be called out as an authorized use, research as an authorized use of the national network.

Genevieve Morris, Principal Deputy National Coordinator for Health Information Technology
Hi, this is Genevieve. Just one comment on that. The section that you read from the introduction is the ultimate vision of where we're heading to. In the draft, we did not suggest research as an explicit permitted purpose, because we wanted to get feedback on whether the industry was ready for that. We did receive a number of comments during the public comment period on it, so we are working through all of those right now.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thanks, Genevieve. Any other comments or questions?

Genevieve Morris, Principal Deputy National Coordinator for Health Information Technology
Lauren, this is Genevieve. Am I allowed to ask a question?

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

Genevieve Morris, Principal Deputy National Coordinator for Health Information Technology
So, I just didn't know – Arien and Denise, if you guys could address when you read through recommendation 20, it seemed to indicate that the initial permitted purposes should be treatment and individual access only. However, because the rest are untested and not ready for – I'm going to say "primetime." But then, recommendation 21 you indicate that the SSA, in particular the benefits determination use case is fairly well tested, and you applauded its inclusion in the permitted purposes, which seems like a perceived conflict to me between those two recommendations. And so, I didn't know if you could clarify a little bit what you all are recommending as sort of the initial set of permitted purposes that would be included?

Arien Malec, RelayHealth, HITAC Member
The issue there is relative to the USCDI. And we had – an earlier draft made explicit USCDI links to the SSA case, and then we decided to combine the USCDI comments into an overall USCDI recommendation. But the task force members noted that the permitted purpose is well established and well aligned, but that the consolidated, the current consolidated CDA and current USCDS, core clinical data set, or whatever it is – is insufficient for the SSA use case. So,

that's really where the issue lies in most cases. People who respond to the SSA disability determination do so using the SSA's CDA guide that calls for additional information over and above the consolidated CDA.

Genevieve Morris, Principal Deputy National Coordinator for Health Information Technology
Okay. So, is the ultimate recommendation there that the benefits determination not be included as a permitted purpose because the minimum USCDI requirement doesn't meet all of their needs? Is that what you guys are recommending?

Arien Malec, RelayHealth, HITAC Member
Yeah. So in general, we're not making accommodations about prioritizing permitted purposes. We're making more explicit recommendations that certain permitted purposes have all of the technology enablement available to go. And in other cases, we're making recommendations that there are some specifics that need to get worked out. But I think in the SSA case, it's a fair summary of the task force recommendations that we'd say that the permitted purpose is worked out, the technology enablement is worked out, but that the USCDI needs to be aligned to make sure that the data is available for SSA.

Genevieve Morris, Principal Deputy National Coordinator for Health Information Technology
Okay. Thanks, that was helpful clarification. Thank you.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. I'm seeing no other comments or questions, and it looks like we're doing pretty good on time here. How about we transition to privacy and security for our last set of recommendations?

Arien Malec, RelayHealth, HITAC Member
Alright. I think it's our last two recommendations. So, we had a fair amount of discussion relating to the notion of individual consent or what the privacy and security **[inaudible]** team, previously called meaningful choice, and that the general recommendation, or the general discussion, is that I think there's a number of people who have been hoping for some superset of individual choice requirements that would meet or satisfy the needs of all states and localities. It was the task force's belief that there is no one universal superset of, "Just do this," and you're covered in every locality. Nor is it possible for ONC or OCR to establish such a need, because state law and local regulation may change.

In general, we noted that the best practice in this area is to push the obligation to achieve meaningful choice down to, as close as possible, the patient. And allow that information to flow up appropriately. So in some cases, the obligations available to meet state law or to meet local regulations or to meet institutional guidance, are best addressed by the provider organizations that are registering and onboarding patients. We generally found that if you ask patients and collect meaningful choice, you tend to get about a 95 percent response rate, favorable in a fervent five percent response rate that's unfavorable. And a number of actors noted that they started with requiring opt-in semantics, and realized the administrative burden for those opt-in

semantics was higher than the benefit warranted. So in general, recommendation 25 is ONC should not demand universal requirements to collect **[inaudible]** or individual consent for HIPAA permitted purposes. ONC should assign requirements necessary to the RCE to address, which should consider successful implementations that allow flowing or signings requirements to the organizations, for example provider organizations that are closest to the patient, and to obligations established under state and local law and regulation. That's recommendation 25.

Recommendation 26 related to the request to consider specific patient matching and linking requirements, as well as patient education and rights and responsibilities, particularly for the patient application side of HIPAA FTC legal boundary. In the discussion note for the task force, we noted there's a fair amount of information that's available already. And that we felt that it was appropriate for ONC to provide existing background to RCE, but not otherwise constrain requirements for patient education and patient matching. So, I guess the summary of this is we feel like there's a lot out there. There's no magic. I think some people are looking for ONC to provide, again, the magic patient linking bullet, silver bullet, that solves all patient linking problems. Our general recommendation is ONC should make all the information that it has available to the RCE, but not lock down specific requirements, either for patient education or for patient matching, as specific obligations to RCEs or to the QHINs. ONC, HHS, OCR, and other relevant actors should establish appropriate guidance interpretive the background regarding the rights of patients, with respect to patient-generated health data that flows to covered entities or other actors participating in the exchange, including through the TEF and QHINs.

We had a fair amount of discussion toward the end of our deliberation around some questions like, "What happens when a patient makes data available? It flows into a provider organization, and then what happens to it? And can it then flow through the TEF, and for the QHIN?" We noted that we didn't really have the time or the expertise in the committee to deliberate on all of those discussions, and those areas punted to HHS. And so, generally, ONC and HHS, OCR to address some of those. I note that there's been a number of really helpful reports including the ONC Playbook. Good, interpretive guidance for HIPAA, both published by ONC as well as published by HHS OCR. And with regard to the obligations and issues relating to non-HIPAA covered entities, in particular to the sets of consumer applications that are covered under FTC regulation, there's been a number of really important reports and white papers that ONC's published in this area that provide helpful guidance and context in those areas. So that I believe covers the sum total of the 26 recommendations that we made in this recommendation letter. So, maybe we go to – back to you, Robert, for committee or task force comment – sorry, committee comment relating to these last two recommendations. And then, back to overall committee comment relating to the overall recommendations letter.

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

And I see we have Ken in the queue with a comment?

Kensaku Kawamoto, University of Utah Health, HITAC Member

Okay. Thank you. With regard to recommendation number 25, are you – can you clarify a little bit about how the – when you say the practices have already been defined, can you clarify that a little bit more? And comment also on whether, in a national sort of sense, it may be difficult if

different groups are using different – regions are using different approaches towards – say, making sure it's the same patient?

Arien Malec, RelayHealth, HITAC Member

So, the – when I say the practices have been defined, what we're saying here is that there is an established practice, and we see this for example in e-prescribing networks, we see this in existing work from CommonWell, from national HIEs that operate across state boundaries. And the success practice in this area is a – you might want to call it a coordinated punt, which establishes through flow-down language the obligation on provider organizations to appropriately follow state and local regulations regarding supplying and authorizing patients for index and for data retrieval. As a sort of editorial note here, there isn't a universal – even a universal opt-in language. There are some states that, for example, if a patient opts out, actually require that the patient's data be expunged from the index. So, you can't even maintain in the index the notion that patient opted out. In other localities, opt out means the patient's data can be included in the index, but the patient must be noted as having opted out of, for example, treatment-based exchange. So, there's really no universal way of establishing – so that the intent of this recommendation is to note, there's no universal way of establishing some uniform set of requirements that meet the needs of every state and locality. And instead, what we recommend to the RCE is to establish appropriate flow-down terms to assign this authority, or assign responsibility down to the locality and to the provider organizations responsible for meeting its obligations under state and local law. So, hopefully that's –

Kensaku Kawamoto, University of Utah Health, HITAC Member

Just to clarify, the federal government and ONC HHS do not have authority to define something standard? Is that the case?

Arien Malec, RelayHealth, HITAC Member

Yeah. So, ONC – so I'm going to – if Elise is on, maybe she can correct me on this – but HIPAA establishes what is, in effect, a national floor for patient privacy for, for example, electronic health information and PHI. But HIPAA acknowledges the rights of states to go above that floor. And HHS, OCR, and other federal agencies have no authority to establish a ceiling for activity in this area. So, all that HHS OCR is authorized to do is clarify and interpret the national floor established by HIPAA. But, there's really no way for any federal actor to limit the activities of state and localities, unless they conflict with that national floor. I'm going to see if Elise is on, or anybody else from the policy office who can clarify my comments?

Genevieve Morris, Principal Deputy National Coordinator for Health Information Technology

This is Genevieve. I know I'm not Elise **[laughter]**. But that is accurate. Where the state law is a higher bar than HIPAA, HIPAA says that you can't overrule it. If the state has a lower bar than HIPAA, then HIPAA is the floor that you have to meet. So, we do not have authority to implement either consent or opt-in, opt-out laws that are universal across all states, and always to be followed. Though, we certainly do have some leeway around standards for exchanging that consent information.

Kensaku Kawamoto, University of Utah Health, HITAC Member

Okay. Thank you.

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

Thanks, Genevieve. And I see we have another comment from Aaron Miri, Imprivata, HITAC Member?

Aaron Miri, Imprivata, HITAC Member

Yes. Thank you. I just want to provide a little bit of coloring on recommendation 25. And for folks that maybe, like me, really dig into the weeds of the private security side of things. What we're asking for a lot of these things is some more clarification, and really continuing on the great work that ONC and OCR did in previous working FACAs and others of identifying the various use cases, and where the overlap is with HIPAA or FTC, or whatnot. Case in point, FTC wouldn't have jurisdiction over a not-for-profit – it really is on the for-profit side, versus maybe HIPAA would be. And so, I would point people that are really looking at this stuff, to look at maybe the API FACA from April 2016, and how each use case for exchanging data was laid out and what it falls under from a jurisdiction perspective. So, those are the kinds of real-world applicability use cases we're looking for, and we recommend further development on. Because this can get very, very difficult and very tricky depending on the use case and the circumstance.

The other comment I want to make is on recommendation 26, regarding the individual identity assurance, and basically the cyphers and whatnot. It is -- this is another one of those items that really, I said earlier, pointing to sort of those universal frameworks it's very important that everybody align to, so that everybody is following the rules of the road together. So, thank you.

Arien Malec, RelayHealth, HITAC Member

Yeah. I'd note in this area that we have I think 18 pages overall of recommendations, and there's a lot of interpretive detail behind each of the recommendations that we're offering here. And then, in our references section, we point, for example, to the approved FACA recommendations relating to the API task force that Aaron just noted, as well as to the ONC playbook. So, there's an ever-expanding circle of guidance here. And in some cases, the issue is pointing to it and finding it, not its existence in the first place. But there's a lot to read here.

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

Okay. Any other thoughts, comments, questions about privacy and security? I think – and Ken, is that another comment?

Kensaku Kawamoto, University of Utah Health, HITAC Member

Yeah. Just a quick one. If you had ideas for other data points that could be pulled that would help with this area from the US core data set, I think that would be useful. Just one thing, I know I was talking to someone who had an idea was, for example, our credit reports know where we've lived, or at least pretty accurately in my experience, where we've lived in our lifetime. That kind of information I think could be useful to say, "Hey, you know, we just matched data from a state that we have no indication you've ever lived there. Unless you were there on vacation, and happened to be hospitalized. That's a highly unusual place for you to have record?" Probably not right here, but if you have recommendations on what other data

points might be potentially feasible to pull into use to help with this data matching, I think – and because I think there's a lot of focus, appropriately, for getting data, but I think it would be good to make sure we don't accidentally pull the wrong people's data and for providers to not make wrong decisions based on inappropriate data.

Arien Malec, RelayHealth, HITAC Member

Yeah. We didn't explicitly discuss that in the task force. I would point to the ONC playbook as providing appropriate background relative, for example, to best practices for data handling that enable appropriate patient matching, and also point out that the ONC has done some challenges relating to data matching. There was a report that ONC – a multi-day session – that ONCE did on data matching, patient matching, and patient matching and linking, and a report out that ONC commissioned in that area. So, there's actually a fair amount of information relating to those topics that if you dig around HealthIT.gov, you'll actually find a ton of information there. As I've commented to ONC in the past, sometimes the challenge isn't that ONC hasn't done the work. It's that there's so much work that's been done that it's actually now a cataloguing and an indexing problem.

Kensaku Kawamoto, University of Utah Health, HITAC Member

Yeah. Okay. Thank you.

Arien Malec, RelayHealth, HITAC Member

Yup. Thank you.

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

Okay. Seeing no other comments, Robert I will turn it back to you. I believe we want to do just another call to address any and all recommendations at this point? Did we lose Robert? Okay. I know he was having an issue with his phone. So, I will just poll the members again just to see if there's any recommendation you'd like to revisit. All of the 26, or any other thoughts or edits or recommendations for the task force to consider before we move to a vote? And I see Ken, and then Sasha, and then Christina.

Kensaku Kawamoto, University of Utah Health, HITAC Member

Okay. Thanks – and sorry for multiple comments. I really like the initial comments around making the functional requirements clearer, not necessarily what the nitty-gritty details of how you get to it. And one suggestion there, maybe just completely related to this, in the area of this matching, I think it might be useful to say, "What is the recommendation and expectation from the government and from this committee etc. on how accurate it should be?" I can imagine something like, "Hey, we expect that if you do a random sampling of your patients and you're matching – you won't accidentally match the wrong patient. That only happened one out of 100 patients, or one out of 1,000 patients." I assume there are some thoughts on how often that kind of thing should be happening? And I think getting – I don't know if you can put it down on paper, but I think getting some sort of sense of what is that expectation functionally, I think would be useful to know that, "Oh yeah, the expectation is 99 percent of the time we'll be right. And that's worth it even if you're wrong one percent of the time, and that kind of thing."

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

Thanks, Ken. Sasha?

Sasha TerMaat, Epic, HITAC Member

Hello, this is Sasha. And I wanted to, I guess, thank you again, Denise and Arien, for leading the task force through all of this material. I know from participating that there was certainly a lot to cover. And as is noted at the bottom of slide 36 here, there were many other things that we might have discussed within the task force, and didn't have a chance because of the directives provided by ONC and the time constraints of already meeting a great deal over the last month. One area that I think we should at least note that we did not discuss within the task force, before we take a vote, is sort of potential different alternatives to the model proposed in the Trusted Exchange Framework draft. So, there was not conversation about alternatives to an RCE structure with qualifying health information networks, or comparisons of other possibilities that might have been implemented under the language in 21st Century Cures. Some of that, I think there's openness in the language in 21st Century Cures that might have permitted other things, but that was not something that we had the opportunity to address.

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

Thank you, Sasha. We will note that. Christina?

Christina Caraballo, Get Real Health, HITAC Member

Yes. Thank you. In your recommendations, you've pointed out that the framework highlights individual access as a principal, but does not specify how patients and other individuals participate fully and equally to access the information. I would like to suggest that we recommend that when the QHINs are established, ONC ensures that there is a dedicated QHIN that focuses solely on patients and individual access to their health information. And provides that educational resources for patients to better understand what is in their health records, and get that access. So basically, a QHIN that doesn't have patient access as part of what it does, but really focuses on individuals as their main group that they're advocating for in the larger ecosystem.

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

Thank you, Christina. Steven, I saw your hand. Did you mean to put it back down?

Steven Lane, Sutter Health, HITAC Member

Yeah. That's fine. Thanks.

Arien Malec, RelayHealth, HITAC Member

I want to point out with regard to the patient and the individual access, the current recommendations don't go exactly in that direction. Instead, that they recommend that the RCE fully establish – that the RCE represent the patient point of view and the patient perspective, and that there be an established patient representative on the RCE to make sure that the

overall ecosystem is responsive to the needs of patients as well as multiple provider organizations. So, I think those comments are captured in the task force recommendations. Just not that specific enablement.

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

Thanks, Arien. Okay. Now Steven?

Steven Lane, Sutter Health, HITAC Member

Yeah. I just wanted to follow on to Christina's comment. And I think that patient access will end up coming through multiple QHINs. And that they should all, or as far as possible, be sensitive to that use case. I also imagine that there will end up being potentially more than one that may have, as its primary focus, the patient access use case. I think the market will drive that.

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

Thank you, Steven. Let me just do a quick audio check. Do we have Robert back on the line yet? Okay. Seeing no other comments or questions, Carolyn, I'm going to turn it over to you to walk us through the voting. And just as a reminder, we are voting on the full set of recommendations, all 26. And I'll just check one more time, do we have Robert yet? Okay. Carolyn, let's turn it over to you.

Carolyn Petersen, Mayo Clinic, HITAC Co-Chair

Thanks, Lauren. So, we need a motion of recommendation to accept the bylines as they are. Do we have that? Or recommendations for changes?

Male Speaker 4

Recommended.

Carolyn Petersen, Mayo Clinic, HITAC Co-Chair

So, we have a recommendation to accept the recommendations proposed by the TEF task force? Do we have a second?

Male Speaker 5

Second.

Female Speaker 3

Second.

Carolyn Petersen, Mayo Clinic, HITAC Co-Chair

Those in favor?

Several Male and Female Speakers

Aye.

Carolyn Petersen, Mayo Clinic, HITAC Co-Chair

Those who oppose? **[Silence].** Those who abstain? **[Silence].** Okay, the vote is now closed. We have a clear number of votes in favor of the motion. Hand it back to you, Lauren.

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

Thank you, Carolyn. And thanks again to everyone for the thoughtful comments and questions in response to the task force. So, we will finalize the recommendations from the committee to the National Coordinator here at ONC. And we will confirm that with the members offline after the meeting. Any other outstanding thoughts or comments or questions before we go to public comment? **[Silence.]** Hearing none. Operator, can you please open the line for public comment?

Operator

Yes. Thank you. If you would like to make a public comment, please press star one on your telephone keypad, and a confirmation tone will indicate that your comment line is in the question queue. You may press star two to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys to make your comment.

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

Thank you. And just as a reminder, we will ask everyone to limit their comments to no more than three minutes. Operator, do we have any public comments in the queue at this time?

Operator

No public comments at this time.

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

Okay. We'll give it another 30 seconds. And then we'll check back to see if there are any public comments. In the meantime, I will just remind everyone that our next meeting will be April 18. That is an in-person meeting here in D.C. Just a note to the committee and the public as well, we have a location change in the hotel. You can find that information on our website. For the public as well as the members, you should have received that information yesterday. The USCDI task force will continue to meet over the next several weeks, and we are looking to see their final recommendations, final draft recommendations I should say at the April meeting as well. So, continued discussion for both relating to USCDI and agenda and materials will be sent closer to that meeting. I will check back in. Operator, do we have any public comments at this time?

Operator

Yes, we do. We have a public comment from Erin Richardson with Federation of American Hospitals.

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

Erin Richardson, Federation of American Hospitals – Public Comment– Public Comment
Hi, can everyone hear me?

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

Erin Richardson, Federation of American Hospitals Okay. Great. I will keep this short and sweet. Thank you very much for allowing us to listen to today. It was very interesting to see your recommendations. I think one recommendation that the Federation put forth to ONC, and continues to have based on the number of recommendations you all have here, it seems that there's a lot of outstanding issues and a lot of outstanding questions, and kind of core questions that go to the heart of the TEF, and it working for everyone involved. And I think we would really like to see a second round or a second draft before this goes final. So that these things can be addressed, and people can see the various changes before it moves into the final form.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you, Erin. Operator, do we have another comment?

Operator
Yes, we have a comment from Leslie Kelly Hall with Health Direct.

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

Leslie Kelly Hall, Health Direct
Hi, Leslie Kelly Hall from Health Direct. Thank you for allowing me to speak. Hi, guys. So, I would like to echo Christina's comments about having really defined patient advocacy and sponsorship throughout this work. Because there isn't a natural sponsor for patients, either in terms of influence or commercial sponsorship, to advocate for particular standards or interoperability. So, I encourage ONC to take on that role. And further, as a former CIO, when I provided 12 years of access to patient record, including open notes, the calls to the physicians went up about 30 percent in one week's time. And the burden was overwhelming, as providers tried to explain with the records meant. When connecting patient education, the calls went down 12 percent from the original point of non-access. And so, this is an important – to have ability for patients to understand their care that they're having. And access without explanation just puts continued burden on physicians. So, thank you for allowing me to comment.

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

Designated Federal Officer
Thank you, Leslie. Operator, do we have another comment?

Operator
No comments at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. I just want to circle back. Were there any high tech members who did not announce themselves at the top of the call? Do we have Clem, Cynthia, Michael, or Patrick on the line? Chesley or Kate Goodrich? Okay. With that, we will adjourn. Again, I want to thank all the members for their time and efforts, especially the TEF task force. And we will talk again next month. Thank you, everyone.

Male Speaker 6
Thank you.

Male Speaker 7
Thanks.

Male Speaker 8
Thank you. Have a good one.

Female Speaker 4
Thank you.

Female Speaker 5
Take care.

[End of Audio]

Duration: 142 minutes