



Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

January 19, 2022, 11:00 a.m. – 2:30 p.m. ET

VIRTUAL



Speakers

Name	Organization	Role
Aaron Miri	Baptist Health	Co-Chair
Denise Webb	Individual	Co-Chair
Medell Briggs-Malonson	UCLA Health	Member
Hans Buitendijk	Cerner	Member
Steven Eichner	Texas Department of State Health Services	Member
Cynthia A. Fisher	PatientRightsAdvocate.org	Member
Lisa Frey	St. Elizabeth Healthcare	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Valerie Grey	New York eHealth Collaborative	Member
Steven Hester	Norton Healthcare	Member
Jim Jirjis	HCA Healthcare	Member
John Kansky	Indiana Health Information Exchange	Member
Kensaku Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Hung S. Luu	Children's Health	Member
Arien Malec	Change Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Aaron Neinstein	UCSF Health	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Brett Oliver	Baptist Health	Member
James Pantelas	Individual	Member
Raj Ratwani	MedStar Health	Member
Abby Sears	OCHIN	Member
Alexis Snyder	Individual	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Anthem, Inc.	Member
Thomas Cantilina	Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
Ram Iyer	Food and Drug Administration	Federal Representative





Jonathan Nebeker	Department of Veterans Health Affairs	Federal Representative
Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Micky Tripathi	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Sweeney Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Mariann Yeager	The Sequoia Project	Presenter
Alan Swenson	Carequality	Presenter
Elizabeth Holland	Centers for Medicare and Medicaid Services	Presenter





Call to Order/Roll Call (00:00:00)

Mike Berry

Hello everyone and thank you for joining the January 2022 HITAC meeting. I am Mike Berry. I'm with ONC and we are very happy to have you with us today. As a reminder, your feedback is always welcome, which can be typed in the chat feature to everyone throughout the meeting or it could be made verbally during the public comment period that is scheduled at about 2:15 Eastern Time this afternoon. Let's get started with our meeting. First, I would like to welcome ONC's executive leadership team to the meeting. And with us today is our national coordinator, Micky Tripathi, Steve Posnack, deputy national coordinator, Elise Sweeney Anthony, the executive director of the Office of Policy, and Avinash Shanbhag, the executive director of the Office of Technology. I will now call the meeting to order and begin roll call with the HITAC members with the federal agency representatives of the HITAC. When I call your name, please indicate your presence and please state if you have any conflicts of interest. Let's start with the co-chairs. Aaron Miri.

Aaron Miri

Good morning. No conflicts of interest.

Mike Berry

Denise Webb.

Denise Webb

Good morning and I do not have any conflicts of interest.

Mike Berry

Medell Briggs-Malonson.

Medell Briggs-Malonson

Good morning. I do not have any conflicts of interest.

Mike Berry

Hans Buitendijk.

Hans Buitendijk

Good morning. No conflicts of interest.

Mike Berry

Thomas Cantilina. Steven Eichner.

Steven Eichner

Good morning. No conflicts of interest. Present.

Mike Berry

Cynthia Fisher.





Cynthia Fisher

Good morning. I have no conflict of interest.

Mike Berry

Lisa Frey.

Lisa Frey

Good morning. No conflicts of interest.

Mike Berry

Raj Godavarthi.

Rajesh Godavarthi

Good morning, no conflicts of interest.

Mike Berry

Valerie Grey.

Valerie Grey

Good morning. No conflicts of interest.

Mike Berry

Adi Gundlapalli.

Adi Gundlapalli

Good morning, no conflicts.

Mike Berry

Steven Hester.

Steven Hester

Good morning. Present, no conflicts.

Mike Berry

Ram Iyer. Jim Jirjis. John Kansky.

John Kansky

Good morning. I have no conflicts but I do want to note that I also serve on the board of the Sequoia Project.

Mike Berry

Ken Kawamoto.

Ken Kawamoto

Good morning. Just a few for me. I report honorary consulting, sponsored research, licensing, or co-development in the past year with Hitachi, Pfizer, and RTI, UCSF, Indiana University, **[inaudible]**





[00:02:41], MD Aware, and ONC through Security Risk Solutions. I also have helped develop a number of health IT tools, which we are commercializing to enable a wider impact. Thanks.

Mike Berry

Thank you. Steven Lane.

Steven Lane

Good morning. I have no conflicts, but like John Kansky, I serve on the board of the Sequoia Project.

Mike Berry

Leslie Lenert.

Leslie Lenert

Good morning. No conflicts.

Mike Berry

Hung Luu.

Hung Luu

Good morning. No conflicts.

Mike Berry

Arien Malec.

Arien Malec

Good morning. No conflicts.

Mike Berry

Clem McDonald.

Clem McDonald

I have no conflicts.

Mike Berry

Jonathan Nebeker.

Jonathan Nebeker

I have no conflicts.

Mike Berry

Aaron Neinstein.

Aaron Neinstein

Good morning. Reporting consulting fees over the past year with Eli Lilly, Roche, Medtronic, and Intuity Medical.





Mike Berry

Eliei Oliveira.

Eliei Oliveira

Good morning. I am the tech lead on two ONC funded projects to the Dell Medical School.

Mike Berry

Brett Oliver.

Brett Oliver

Good morning. No conflicts.

Mike Berry

James Pantelas.

James Pantelas

Good morning. No conflicts.

Mike Berry

Raj Ratwani.

Raj Ratwani

Good morning. Med Star Health is the recipient of an ONC LEAP Award that is currently active. Thank you.

Mike Berry

Michelle Schreiber.

Alex Mugge

This is Alex Mugge for Michelle Schreiber representing the Medicare CMS. No conflicts.

Mike Berry

Abby Sears.

Abby Sears

Good morning. One of the members of the OCHIN team is on the board of the Sequoia Project.

Mike Berry

Alexis Snyder.

Alexis Snyder

Good morning. No conflicts.

Mike Berry

Phil Southerland.





Fillipe Southerland

Good morning. No conflicts.

Mike Berry

Ram Sriram.

Ram Sriram

Good morning. No conflicts.

Mike Berry

And Sheryl Turney.

Sheryl Turney

Good morning, no conflicts.

Mike Berry

Great. Thank you so much, everyone. I appreciate that. And now, please join me in welcoming Micky Tripathi for his welcoming remarks. Micky.

Micky Tripathi

Great. Thank you so much. Can you hear me okay? Let's do a sound check.

Mike Berry

Yes.

Welcome Remarks Interoperability Standards Workgroup, and e-Prior Authorization RFI Task Force (00:04:51)

Micky Tripathi

Great, thanks. Welcome everyone. Our first meeting of the year I am delighted to be here. We have got a really busy meeting today and there is a ton of really exciting activity going on at ONC that I want to share first before I turn it over to Denise and Aaron. First, I want to welcome all of our HITAC members and federal representatives today and congratulate eight new members on their recent appointments to the HITAC for a three-year term. We very much look forward to our new members joining us here on the HITAC and helping us think through all of the exciting interoperability and health IT issues that are here before us. Please join me in welcoming Medell Briggs-Malonson, Hans Buitendijk, Steve Eichner, Raj Godavarthi, Hung Luu, Aaron Neinstein, Eliel Oliveira, and Fil Southerland. Welcome all of you and thank you so much for committing your time and your experience and expertise to HITAC.

We also have a federal representative, Tom Cantilina, who is representing the DOD on HITAC and we want to thank James Ellzy for all of his time and effort on HITAC for the past couple of years. We're looking forward to learning from each of you and appreciate your service on HITAC this year and going forward. I want to talk about some ONC program updates just to highlight a few things that have been going on. You may have seen that yesterday the Sequoia Project who is the TEFCA recognized coordinating entity





released the first version of the TEFCA common agreement and QHIN technical framework for operationalization. That's quite a word. And we're extremely excited about that. It is years of hard work as all of you appreciate, tremendous feedback and engagement from HITAC as well in helping us shape that. And we're just delighted to be able to work with Sequoia to release that. And we have later today Mariann on the Sequoia team will be spending more dedicated time to that.

The only thing I'll add to that is that, as many of you know, Nationwide Health Information Network has been part of the ONC vision since our founding in 2004. We are particularly excited about being able to be at this point in our health IT and interoperability journey. And we very much look forward to working with the Sequoia Project and with the entire industry on moving this forward. This morning, you may have also seen in the spirit of no rest for the weary, we released the Draft USCDI Version 3. That is out for public comment through April 30. That contains data classes and elements from the USCDI Version 1 and Version 2, along with the proposed data classes for inclusion in Version 3. We will be charging the HITAC to review the draft and provide recommendations, which we will talk about in a little while. Last week, we released the 2022 Interoperability Standards Advisory reference edition.

There are some notable updates to that, including improvements to COVID-19 reporting, laboratory categorization, e-prescribing updates, FHIR for public health reporting, and increased support for SDOH and health equity as well. I very much look forward to you reviewing that and your comments. Also, in the long list of things, ONC released the Project USA, which I always want to call Project USAT, but Project USA technical specification the final Version 1.0. I think that came out last week. You may have seen that release. That completed a one-year goal that we had and accomplished to coordinate the creation of a healthcare specification that could be used across the industry for representing patient home addresses and mailing addresses. This new specification will advance the healthcare industry's proficiency in recording and managing accurate and consistently formatted patient addresses and support more efficient patient matching and record linkage.

I think it is a surprise to many the representation of addresses is such a big issue. But I think for all of you who have been deeply steeped in this, you know it really is a big issue. And this is a real great forward step in being able to have greater consistency around that to help with patient matching interoperability in general. The last thing I will mention is we expect to release an e-prior auth request for information. And if that's released, ONC we will solicit public comments, including HITAC feedback on how the health IT certification program can incorporate standards and certification criteria related to electronic prior authorization. As many of you may know, e-prior auth is a very complex set of issues There is a lot of heterogeneity out on the market with respect to workflows.

There is a lot of change going on with respect to standards that derive from 1996 HIPAA legislation and emerging standards and new standards such as FHIR. We very much welcome this release, which we expect it well but it is not done until it is done. We very much welcome industry feedback on how we should be thinking about, in partnership with CMS, all of those dynamics as we think about moving forward with much better approaches and electronic approaches for prior authorization. Let me now turn to the HITAC in particular. We have two subcommittees that are related to these rollouts. Specifically, the draft USCDI Version 3 and the e-prior auth RFI. We have two subcommittees that we want to go over the charges for those subcommittees as they can help support these important pieces of work. The first is the interoperability standards workgroup and I think we have got some slides here.





I will not read each slide but the overall overarching charge for interoperability standards work group is to review and provide recommendations on the draft USCDI Version 3 and other standards. Certainly, what we have talked about from the beginning is evaluating the draft USCDI Version 3 as well as opportunities to update the ONC interoperability standards, which is also out and we have some due dates there as well. I think also now that TEFCA is released, there may be opportunities for that work group to help us in thinking about standards and components related to the support of TEFCA as well. That could be something that comes on the agenda as well as we move forward. Next slide, please. Here is the roster. I want to thank in advance Steven Lane and Arien Malec for co-chairing and all of you for your participation in that work group. Next slide, please. Next is the electronic prior auth RFI task force.

So, we are issuing a request for information as you may have seen in the unified agenda that was published by OMB to seek input regarding electronic prior auth. We are requesting comments on how the ONC certification program could incorporate standards and certification criteria related to electronic prior auth. As you may know, the certification coupled with program requirements from CMS are work, hand, and glove to help us move forward with standards based interoperability in a wide variety of areas. And so, e-prior auth is an important part of that consideration. The task force charge would be to provide input and recommendations in response to that RFI and to do that in the early March timeframe, March 10, 2022. Next slide, please. Let me thank in advance Sheryl and Tammy for co-chairing that and also thank the other members of the task force for your help with this.

Next slide, please. In terms of the next steps, you can see here the interoperability standards work group is going to meet on January 25. I think we've got a TBD on the electronic prior auth RFI until we have officially released the RFI, again, assuming that we do. But it is on the unified agenda and we have every expectation of releasing that. As always, contact Mike Berry if you have any questions on this. He will very quickly get to an answer. Let me now just skip ahead to a couple of other comments here. One final ONC update to note, we have adjusted the ONC annual meeting format to provide more space for all of us to address the ongoing needs related to the pandemic. The new dates and activities will be on February 2 and 3, we are going to have a number of education sessions and office hours to learn about information sharing, USCDI, and many, many other topics.

Stay tuned on the ONC and HealthIT.gov website for the agendas for that. For those who are participating, thank you for your participation on those. That will be February 2 and February 3. We are going to have what is the annual meeting on April 13 and April 14. And that will be the more standard panel sessions, exhibit hall, and networking. We very much look forward to engaging with all of you in both of these activities. Let me close here by marking that this is going to be a big year for health IT and interoperability. Information blocking provisions, as many of you may know, of the 21st Century Cures Act went into effect on April 5, 2021. We have been receiving complaints through our portal over that time period. And we will be sharing information on the numbers of complaints received over that time period very soon.

The expected beginning of enforcement by the Office of Inspector General of the information blocking provisions of the 21st Century Cures Act is expected to happen this year. You couple that with the requirement to make available all electronic health information beginning later in the year. That is not just the elements of the USCDI. All of that together will make information sharing a priority across the industry in 2022. Coupled with that though, we are also doing things to make things easier to share information. So, what are those things? EHR certification rules requiring FHIR API's, both individual and bulk in deployed systems by the end of 2022 for any use desired by provider and according to business and contract terms





are going to help fulfil the 21st Century Cures requirement for access for APIs “without special effort.” And then, of course, we have TEFCA, which we announced yesterday. And that gives us a framework for network interoperability to come together.

It includes the FHIR roadmap, which anticipates the proliferation of FHIR API’s starting this year and lays out the approach for network infrastructure to supplement the IHE based exchange and categorize adoption of FHIR based exchange through standalone API’s and networks. Obviously, everything I just said is a high-level summary. Please go to our website where you will find the actual rule, the education materials, the FAQ’s, and other details. But I just wanted to mark that there is a lot happening in 2022. I really think we are going to make a small dent in the universe of healthcare interoperability with all of these things that we’re going to be moving forward on in 2022. Many, many more details to come as the year unfolds and I want to thank HITAC in advance for everything you have done but also in advance for your engagement and advice in what is going to be a really exciting year for all of us going forward. So, thank you, again. And let me turn it over to Aaron and Denise or their opening remarks.

Opening Remarks, Review of Agenda and Approval of November 10, 2021 Meeting Minutes (00:17:07)

Aaron Miri

Thank you, Micky. Denise, would you like to open up?

Denise Webb

You go ahead, Aaron. And I’ll go next and do the review of the agenda.

Aaron Miri

Will do. First, let me say congratulations to all of you, all of the new members who have joined the committee. Welcome to the HITAC family. Congratulations to the ONC. What a phenomenal progress. It has been really exciting and it has kept me up late every night reading all the bulletins and all of the announcements. So, it’s really, really good. And to give you some real-world anecdotes, we are in the process of major electronic medical records switch. Literally, we are having the conversation about standardizing United States postal address within the record as we migrate records from our seven different EMR’s down to one. And that specification, actually, helped shape the conversation. Already, I can tell you firsthand with my chief digital officer hat on, it is making a difference in translating. Thank you for the work that’s going on there. Denise?

Denise Webb

Great. I want to welcome everyone to our new year. And I especially want to welcome our nine new members on the committee. We have a full committee and a very large committee now. And I’m looking forward to working with all of you on all the initiatives that you just heard about. I’m especially excited about the release of TEFCA, since I’ve been involved in health information exchange for 16 years now. I have been waiting for us to move forward with nationwide interoperability. It’s really exciting to be part of this and to be involved in the work. I want to note that in the chat, ONC did include some links to TEFCA and the e-prior auth RFI in the unified agenda as well as a 2022 ISA reference edition. So, those things are available in the chat if you didn’t see that.





We've got a full agenda today And I would like to quickly review our agenda. And then, I am going to turn it over to Aaron to call for a motion to vote on our meeting minutes from December. So, we are first going to hear from Mike Berry, our designated federal officer, on our final work plan for 2022. And he is going to be seeking input from all of us. Then, we will get a TEFCA update from Mariann Yeager, the CEO of the Sequoia Project and the RCE lead and her team. We'll take a short break for 15 minutes and then, we will come back and hear from Elizabeth Holland who was with CMS on the promoting interoperability program update. And then, Aaron Miri will tell us about what is happening with the HITAC Annual Report Workgroup as we close out our annual report work and deliver that to congress. And I believe we will be voting on that in our next meeting.

And then finally, we will have public comment and any final remarks and adjournment. So, Aaron, if you could get our meetings approved that would be great.

Aaron Miri

No problem. Hopefully, you all received the meeting minutes and had a chance to look it over from our December meeting. May I get a motion to approve please?

Ken Kawamoto

This is Ken with a motion.

Aaron Miri

Can I get a second?

James Pantelas

Jim Pantelas, second.

Aaron Miri

Thank you. All those in favor, please signal by saying aye.

Group

Aye.

Aaron Miri

Any opposed say nay? Any abstentions?

Hans Buitendijk

Abstention, Hans.

Steven Eichner

Abstention, Steve Eichner.

Aaron Miri

Noted Hans, Steve. Got both abstentions. The meeting minutes, therefore, are passed. Denise?

Denise Webb





We will transition to Mike and if you will handle all the comments and questions for Mike's presentation, which will be great.

Aaron Miri

Just to point clarify, that was November, not December. It all blends for me in the holiday timeframe. That was November meeting minutes, not December meeting minutes. Just for the record, sorry about that.

Denise Webb

I said that, sorry. I thought it was December. It all blurs together.

HITAC CY22 Final Work Plan (00:22:04)

Mike Berry

Well, thank you Aaron and Denise. Hi, everyone. Mike Berry, I am back to talk about the HITAC work plan. And this work plan we presented to the HITAC at our November 10 meeting. It was slightly revised based on your comments. As you know, your comments are very important and we wanted to incorporate those comments and show you some changes that we made since last time. The first thing I want to point out was, basically, in orange are a couple of things that we added. And this is the notice of proposed rulemaking for this year that was listed in the unified agenda. So, we are going to have a task force to look at that NPRM when it is released. The unified agenda does list July through September public comment period. So, I plugged that timeframe into the work plan. However, it could shift based on when the NPRM is, actually, released.

So, that is something that we could all look forward to. Also, the health equity by design hearing is not in orange, but we are planning to hold that hearing in March. So, this will take place of the March HITAC meeting in addition to I should say because you probably will have some agenda items that are regular HITAC items and we will get through those. And then, we will transition to the hearing. As you saw from the hearing for 2021, it was mostly all day. And so, even though we have scheduled a 10:00 to 3:00 Eastern Time slot for the HITAC, just be prepared that it could be extended. We are working on the agenda and building that out and will be presenting that in March. As Micky mentioned, we are anticipating an e-prior authorization request for information task force. And I plugged in the dates January through March to present recommendations at the March 10 HITAC meeting. And this is all conditional on the RFI, actually, being released. These are two items that are listed in the unified agenda that we wanted to also include in the HITAC's work plan.

So, that is all the changes for that page for now. If we can shift to the next slide. These are the additional topics that we talked about. We got a lot of feedback from the HITAC on these topics to refine them a little more. You'll notice in orange the refinements that we've made based on your feedback. I don't need to read through these. I just want to show you what we've incorporated into the work plan. And as I mentioned in November, these additional topics are things that could potentially turn into taskforces if we believe it is needed. Or it could be focused discussions during HITAC meetings. We are likely not going to get to all of these. There are two pages of them. But we will work through these and talk about them in future HITAC meetings as appropriate. Next slide?

Here is the second page with additional highlighted sub bullets that the HITAC recommended that we incorporate. I'll give you a moment to read through that and then, I will turn it back to Aaron and Denise to





see if anyone has any specific feedbacks on these pages. We can toggle back and forth between the pages as necessary. So, Aaron and Denise, I will turn it back to you to open up discussion.

Aaron Miri

If any of you have any questions, let's go ahead and have you use the hand raising function or if you are on the phone, I think everyone is dialed in via Zoom but if you are on the phone, if you can speak up. We will be looking for your hand raise. Okay. I see Steven Eichner.

Steven Eichner

Yes, thank you. We notice that the public health task force was grayed out on the calendar. Should we expect information on that at some point in the future?

Mike Berry

Yes. We did not put in a date for that yet. We are still working through that. In November, Steve, I know you weren't on the HITAC at that time, but we discussed holding a task force related to public health and/or also having some feedback sessions. I know, of course, public health data systems task force last year focused on providing recommendations related to the executive order related to COVID-19 response. And so, that executive order work group may need some clarification items as part of their work. So, that could be a feedback sessions. There could be new topics. But we are planning that. We just don't have a date. There will be a date announced in the future, however.

Steven Eichner

Wonderful, yes, because it certainly crosses over in some areas looking at SDOH, health equity, and those components. We want to make sure we do everything we can to support the efforts on the public health side.

Aaron Miri

Doctor Lane?

Steven Lane

Thank you. Just a comment on the closed-loop referrals. I think this group in the past has been educated regarding the 360X standard protocol, which is now just about ready to go live in production. A number of people on this committee have been involved in its development and advancement. And that might be something that we want to come back and revisit during the course of the year if we are going to be looking at closed loop.

Aaron Miri

Great suggestion. Other hands raised? Clem?

Clem McDonald

I was muted. I hadn't been aware of something called transition from USCDI to full scope of EHI definition. I can picture what that might be but could you elaborate on that in the last item on the last bullet?

Aaron Miri

Mike, is that for ONC?





Clem McDonald

Well, it's for whatever. You've got a slide up there.

Denise Webb

I know what that is.

Aaron Miri

Go ahead, Denise. That would be good.

Denise Webb

So, this is a transition that providers have shared the USCDI data elements up until October 5. That is under the content and manner exception. The definition of EHI is constrained to the USCDI data elements. But on October 6, that definition is restored to the full scope EHI of as defined in the regulation in the final rule. And at that point, providers are going to need to respond to requests for all EHI. Of course, they have the exceptions.

Clem McDonald

This is October of this year 2022?

Denise Webb

That's correct.

Aaron Miri

I see Elise with her hand race. Maybe we can let Lisa chime in if we don't mind. Just that way, we get some clarify.

Denise Webb

Sure.

Elise Sweeney Anthony

Hi everyone, Elise Sweeney Anthony, executive director of policy here at ONC. I think Denise did a great job. I want to also add in that it's not just providers. The transition from the data represented by the USCDI to the full scope of EHI is the part of information blocking regulations. Therefore, it applies to all actors that are covered. Just as a note to folks as well as they are thinking about that, that would be health information networks and exchanges, healthcare providers, as well as developers and certified health IT.

Denise Webb

Thank you, Elise, for that clarification. I had my provider hat on.

Elise Sweeney Anthony

Absolutely. That's what we're here for.

Clem McDonald





Could ask one more question? Does that mean all the work with USCDI goes away in this very ill-defined or does it get carried into that new thing?

Elise Sweeney Anthony

I can jump in again on that, and Avinash maybe on the line as well. Avinash leads our technology team. The USCDI is a standard that is developed by ONC. That continues to be extremely important in a number of different aspects of what ONC does, including under the certification program but also in terms of TEFCA, which is trusted exchange framework and common agreement. The reference to the information blocking electronic health information definition starts with the data represented in the USCDI. But over time, we recognize the additional information needs to be supported under the information blocking regulations. So, giving the initial timeframe of the USCDI, the data represented in the USCDI being used allows for transition from those who are stakeholders as well as covered actors as we move towards the full scope of the EHI definition, which as Denise noted is October 6.

Aaron Miri

All right. Next on the list is Mr. Jim Jirjis.

Jim Jirjis

Quick comment about the last one and I have an endorsement. Clem, to me, it seems like the FHIR API's and what we exchange with national exchanges that USCDI is what will continue to be used. In addition, in October, when people request full EHI, you may need to be able to fulfill it, but it may not be through the same mechanism because the EHI is a lot huger. We may be regularly exchanging with apps and commonwealth for example, USCDI. On any given day, somebody may contact us and want full EHI, in which case, we can figure out how to fulfil that through other needs if needed. The performance is a pretty big issue there, right?

Clem McDonald

Thanks a lot. That helps!

Jim Jirjis

I wanted to endorse something on the prior slide. And that is when we had our discussions last year about the app economy, to really get a meaningful place where apps are powerful and the paradigm shifts from solely the EHR with a full apps that are read only, this notion of the writeback is something that would require rulemaking to make happen because I'm not sure the industry is just going to invite that. I want to endorse if we are going to have a mature app economy, that writeback is really important for us to work on.

Aaron Miri

Yeah. And all kinds of digital therapies at that. Not just apps, but any kind of patient generated health apps, anything at all and what that looks like. You're absolutely right.

Jim Jirjis

Accurately put. Thank you.

Aaron Miri

Good points. Next up on the list, Ken Kawamoto.





Ken Kawamoto

Thanks. I think this is a great list. Let me lower my hand. Just a thought here. I do really support getting the electronic data extract and using FHIR for it where we can and aligning it with things like US Core. One thought as we implemented all of these is we tend to focus on support for something being binary. It's either supported or not supported. If we address something saying US Core, we say it is done and we move on often times. I think there are, certainly, important gaps in terms of things that aren't supported like orders, for example. If you look at the data and say, "You should order something," while the US Core does not include how to make sure that everything has been ordered, for example, of what you just recommended.

But there are also other aspects even when it is supported such as value sets that are represented as extensible and specified. So, if there is a mapping concept, it should be used. Yet, there are, certainly, major EHR vendors that do not support that, which means the intent of the profiles are not supported. There are also things like query parameters and performance where even if something is supported, it can take 30 seconds to pull the data the way it is worded in the EHR, which may work in some use cases. But in many use cases, having a doctor wait 30 seconds to pull up the patient's past medications is really unacceptable. So, I think having a bit more nuanced look and thinking beyond do we support this data and do we support it in a way that is, actually, useful at the point of care I think is important. Thanks.

Aaron Miri

Great point. That translates to the bedside manners. Good point. All right, Steve Eichner.

Steven Eichner

Thank you, Aaron. There are a couple of points I would like to raise. One, looking at the bidirectional exchange of data with public health, we need to instate policy and law in that framework as well and not necessarily focus on exchange through HIE's or HINS. It is something we should be able to support and investigate. Secondly, looking at the other slide where we had discussion of patient access to data, there also needs to be patient rule and regulating access and controlling access to data because as our data framework becomes more complex, who is managing data sharing on behalf of the patient or what role the patient has in managing with whom their data may be shared is going to become more critical as we are looking at electronic profiles of individuals becoming much more sophisticated. Kind of a financial profile of knowing what I bought at the grocery store last week. We are getting sophisticated enough on the technology framework that my health profile can be assembled from a bunch of different pieces.

It would be useful and informative for patients, not only to understand with whom their data is shared, but to be able to have a voice in where and when their data is shared.

Aaron Miri

Yes. The notion of granular consent, which I know that there has been a lot of work done even in prior years. That's a great point ensuring that people have a say. Good. Raj.

Raj Godavarthi

Could you go back to the previous slide? I would like to acknowledge the intersection of clinical and administrative data. There is a huge burden, especially in the example of prior authorization between patient and providers and, especially for the patient care. You see the time limit times between previous to 14 days.





It is really something we need to get a handle on. As you have more chronic diseases and more patient reading up on these things, anything we can do in this area would help to improve the patient care.

Aaron Miri

Good points. Doctor Briggs?

Medell Briggs-Malonson

Thank you so much. One additional comment, especially looking at the slide with SDOH data. Since we are moving towards really focusing on health equity by design, you really can't achieve health equity without making sure that SDOH data is clearly defined because there are various different types of social and structural political determinants. I would underscore that this SDOH data and really making sure that we have clear definitions and understanding of the different forms of SDOH data is critical for all that we are going to be doing in terms of thinking of health equity, in terms of our infrastructure design, as well as moving forward with other interoperability. So, I just wanted to highlight that important piece as well.

Aaron Miri

That's great. I would also encourage you to look at some of the prior USCDI and other work group dialogue and discussion. It has been very spirited amongst members exactly to your points of trying to put definition around what it is SDOH, what attributes, what variables, what are the standards around it particularly given how it's a big spectrum. So, great points. Is it Hung Luu, is that right?

Hung Luu

Yes. This is Hung Luu and if you go to the next slide under intersection of research and health IT, one issue we have been grappling with is that is much easier now to move data between institutions. There is data now residing in or at least accessible in our EHR from other institutions that the patient has received care. I think the one thing that needs to be clarified is what are the implications for IRB permission in terms of if they commission or a researcher obtains an IRB from the home institution and then, performs research that includes data from other institutions gathered through that method. Maybe this question has already been answered in terms of if it is there in the EHR, it is part of that EHR. I do not think it is clear to everyone. I think that needs to be clarified.

Aaron Miri

Great points. We had a lot of discussion around research and conversations and even international standards and data and privacy and cyber security standards. Great points. We can definitely double click on that. Denise?

Denise Webb

I just wanted to provide some information for new committee members related to Raj's comments on the intersection of clinical and administrative data and challenges with prior authorization. Many of us participated on that task force. We had quite a bit of discussion on prior authorization. And Sheryl Turney was the co-chair of the ICAD and now will be the co-chair of the e-prior auth RFI task force if that RFI is released. And I think there is a lot of information that can be carried over from the ICAD task force into the e-prior auth RFI task force that would be pertinent and relevant.

Aaron Miri





Good points, Denise. Clem McDonald?

Clem McDonald

In the context of research, we have been trying to convert a huge file of research data to FHIR. An issue that comes up is they create these structures that are de-identified. They have sequential time order data and everybody invents a totally different way to distinguish Day 1 from Day 2. There needs to be attention to this. There is never going to be communication among researchers. I mean, the inventiveness is impressive and how many different ways they can do it.

Aaron Miri

Got it. Great points, great points. We're running a bit close to time here. Are there any last questions from folks? We have a couple of minutes left on this section. We have a hand raised I believe. Clem, did you mean to put your hand back up?

Clem McDonald

I'm trying to lower it.

Aaron Miri

No problem. That pesky technology. All right. What else have we got? Anybody else? I'll add a quick comment here and then, we can move on to the next section. I do want to say the annual work group, I would encourage you to look at that. We will talk about that in detail this afternoon. It is also your opportunity to layer in other topics with more granularity. We are looking at all types of data and it ends up in our report back to congress, which we have to write annually and to give them a spectrum and lay of the land of what did we do, what did we work on, what are we proposing, what we should think about. Interestingly, public health was on there before even the recent COVID crisis a lot of it due to the vaping crisis that was there beforehand, and so forth, and so on. All of you can remember Ebola, Zika, all the ones we've dealt with in most recent memory. So, please look at that and insert your comments and questions. We take every bit into consideration of that. Again, we'll talk more about that this afternoon.

But that is another form of vehicle for you to lay out your wishes and your experiences, which we so desperately need. With that, and I am not seeing any other hands raised, I believe we can go to the next section which is the TEFCA update with Mariann Yeager. I want to say upfront congratulations. That is a long road to drive. Excellent job. And we're so excited across the industry to see the announcement just yesterday. So, congrats, Mariann.

TEFCA Update (00:43:40)

Mariann Yeager

Thank you, Aaron and Denise and to Micky and the ONC leadership team and committee for inviting us to talk with you today. It is a real honor to be with you to share the progress of our work on TEFCA working with ONC and, of course, Sequoia is truly honored to serve as the recognized coordinating entity. Joining me as Alan Swenson. He is the executive director of Carequality. And he and his team are really going to be the ones who operationalize what we released yesterday, of course, in coordination with Sequoia and the ONC team and I just want to call that out. If you go to the next slide, I think we have the requisite disclaimer that we're here today in our capacity in working with ONC under a cooperative agreement.





All of the funding to date has been provided by ONC. We are presenting the information. As we know, we are not representing the government per se or presenting any official position of HHS. Next, I'd like to talk about what we will cover today. We'll cover in the next slide the information at a high level and provide an overview of TEFCA, the respective components, and highlighting those, which were released yesterday. We will dive a little bit into the exchange purposes and how they work. That has been a really important focus area because that was where we received a lot of feedback from stakeholders. We want to highlight privacy and security requirements and then, really turning our attention to how does one become a QHIN and when are we going to operationalize this. Actually, I want to leave plenty of time for the committee to pose questions.

So, let's go next and we will talk a bit more about TEFCA and you can advance to the next slide as well. Of course, we are working with ONC to implement a very important aspect of the 21st Century Cures Act. Congress directed ONC to develop or support a trusted exchange framework and common agreement to facilitate exchange between health information networks. We have been working in earnest with ONC since we were selected in working through that and, again, showcasing the byproduct of that to you all today. So, let's go to the next slide. The goals here have been a little refined. And the first is really to have a foundation, a floor that supports nationwide interoperability that establishes common rules of the road for policy and technology. The second goal is to really make sure it is simpler for organizations to connect and to connect for a multitude of purposes.

So, that multipurpose connection has tremendous need and value. So, we don't necessarily need a dedicated network for patient care and a separate one for population health and another one to generate healthcare value but to make it simpler for organizations to connect for all those purposes. And, importantly, to allow each of us as individuals to gather our own healthcare information. We will be over time assessing how we are accomplishing those goals. But more specifically, there are tremendous benefits that TEFCA enables and really by providing a trusted way to connect to sources of information across the nation, again, to allow us as individuals to use our platform of choice, to get access to our own information from TEFCA connected sources.

For healthcare providers and health systems, I think the most mature capability that exists on the market today is around treatment and care coordination and population health. Importantly, looking at public health, certainly, in light of the current pandemic and future emergencies. TEFCA will provide tremendous benefit to make it simpler and easier for public health officials to get access to information to improve quality, reduce costs, and improve response efforts. Payers, this is an area where the private sector has really tried to make strides in enabling bringing payers into the existing information exchange ecosystem. It occurs in some cases, not more universally. But, again, payers would have value to be able to access information they need for care management, to support value based care models and peer to peer exchange. We know that there was already existing infrastructure that many providers and organizations are already connected to health information networks.

And the value here is that we want to build upon existing infrastructure and not replace but build and layer upon that to make it easier for those networks to access information to connect with others that might not be in necessarily their region or domain. Technology developers, again, enablers of connectivity and technology. This should make it easier for them to have scalable ways of supporting that connectivity and really allow them to focus on innovation. We have heard a lot over time and there still remains a keen





interest on how do we leverage TEFCA to support research. And there is just tremendous opportunity to improve quality, reduce costs, and expand participation in clinical research. Those are just some of the benefits through the lens of those who would have the recipients and be able to access information.

Let's go on to the next slide. So, how does all this work? ONC really sets the policy direction and is responsible for certain governance requirements. There are inherently governmental functions that ONC can't delegate to anyone else. And since this is a government endorsed approach, having ONC really leading this has really been essential. The RCE has been delegated certain responsibilities, will provide oversight of QHIN's, will support a governance approach for QHIN's and, of course, facilitating the work in developing the requirements and the components we will talk about here, as well as operationalizing them. The QHIN's are really the networks that opt to seek designation as a formally qualified health information network. They agree to abide by the foundational policy and technical requirements. And they agree to directly connect with each other to facilitate nationwide interoperability. I want to point out here that the idea is not to replicate the current network topology.

QHIN's are really more aggregators of connectivity, they represent in and of themselves, other connected participants and sub participants, some of which could actually be networks in their own right. If you think of qualified health information networks, these are the Uber nodes. These are high-performing, highly reliable, high-security networks that, again, agree to abide by terms in how they connect to each other. There is a great deal of flexibility and opportunity for innovation in a way in which a QHIN connects to its participants. Alan will get into a little bit more on that when we talk about the technical requirements and QHIN technical framework. Let's keep progressing. So, what are the components of TEFCA? If you go to the next slide, I just want to highlight what we released and what the building blocks of this are. The trusted exchange framework, which will be the slides they released today that was really yesterday. So, the trusted exchange framework, I would think of these as the nonbinding principles for exchange.

Think of these as the north star principles that ONC believes are in the public interest. The comment that was released yesterday, the common agreement is a legal agreement. There were seven operating procedures that accompany the common agreement that further spell out the RCE and QHIN's would implement those. The QHIN technical framework Version 1 was also released yesterday along with a FHIR roadmap, which was a draft put forward for input. We will be publishing a QHIN onboarding process and designation standard operating procedure and an application that's in the works for undergoing review with ONC. When that is ready, we will release that as well. Metrics, those are spelled out of what we will be collecting minimally as in the QHIN technical framework. But, obviously, until QHIN's go live, we can gather metrics at that point. We also published a number of standard operating procedures outlining how governance will work. We'll talk a bit about that.

There was a lot of work in flight. We had a skinny down set of artifacts that we thought we would be ready to release. We were really delighted based upon a lot of support, fantastic feedback, and just an incredible ONC, RCE team that we were able to deliver quite a bit more than we were anticipating. Again, getting these out is the first part of an important milestone in operationalizing this. If you go to the next slide, I'll talk just high-level. Again, the trusted exchange framework are the nonbinding set of principles and foundation for policies and practice around information sharing among networks. There seems to be a lot of broad industry alignment of these. ONC has done a lot of work overtime on principles for governance. You can see the fall and the categories here represented on the slide. It's really building up that guardrail so to





speak, which helped set the tone for common agreement. At this point, I think we can go to the next slide. I'm going to turn it over to my colleague, Alan Swenson and he will tell us a bit more about each of the more detailed outlets.

Alan Swenson

Hi everyone, glad to be here. And we did go through quite a bit of this yesterday as well, so some of you probably were participating in that. And there will be many more webinars to come over the next few months as we get into more details on this. The common agreement is the first primary document that Mariann referenced was released officially yesterday. It's a quite lengthy document, legal document, the contractual terms that all QHIN's will agree to. It's contractual terms between the QHIN and the RCE. This is, essentially, the rules of the road for participation for being QHIN and defines all of the legal requirements pointing to also some of these other documents, the standard operating procedures that we will get into some of the details of which ones specifically were released yesterday and more to come and also the QHIN technical framework, the QTF.

So, the common agreement is the document that QHIN's will sign to become a QHIN and binds them to the terms of common agreement as well as the terms of those other incorporated SOP's and QTF and other documents as appropriate. This is the common agreement meaning that every QHIN will sign the same document ensuring that everyone knows what everyone else has agreed to for consistent and common participation among all of the QHIN's who are participating. Let's move to the next slide.

Within the common agreement, again as I said, this is the agreement that QHIN's will sign. There are some requirements that QHIN's will flow down to their participants and participants down to their sub participants. Again, that is to ensure that everyone is participating in the same way, is bound to the same rules and requirements. You can see some of those required flow down categories listed here on this slide. And as everybody takes a look, I'm sure, at the actual text of the common agreement, you will see these are bolded, called out, required flow downs. So, it is very clear to a QHIN who signs the common agreement which of the requirements in the common agreement are or include a required flow down that they need to incorporate into their participant agreements.

The participants need to incorporate into their agreements down the chain, again, to ensure that everyone is participating at the same level and following the same rules of the road for that participation. Next slide, please. Standard operating procedures, there were seven of those that were released yesterday. There are others that are definitely in the work. I think we will talk about some of those that are still to come, I think, in some of the later slides such as some of the onboarding and designation and some additional things that will be coming. But these are some of the primary ones that were needed on Day 1. And so, these were all released with the common agreement yesterday. As far as your reading material, these are only five or six pages each so not a whole lot of addition to the sixty some odd page common agreement. Still a good amount of material there and lots of, again, requirements of what QHIN's will be required to do setting up how the advisory groups and governing council and the whole process of governing future changes to the common agreement and to these SOP's, handling of disputes, conflict of interest, security.

And we will talk about some of that here in the later slides as well. But lots of great content and requirements, lots of legal terms that the QHIN's will agree to, again, to ensure consistency across what the QHIN's do and how they manage things within their own network. Let's go to the next slide please. And then, we have





the QHIN technical framework, the QTF. This one is largely a technical implementation guide. Again, it goes along with the common agreement. And this provides the technical terms that QHIN's will be required to satisfy in order to be a QHIN, ensuring consistency so that any QHIN, as a QHIN moves into production, receives designation from RCE is immediately able to communicate technically with all other QHIN's without any additional pre-coordination or testing or, hopefully, any troubleshooting or anything. It all just magically works. For those familiar with the Carequality process, I think we will get into some of the onboarding and designation here in a few slides.

But it will look very similar to what we've proven out in the Carequality for implementers moving to production today. And so, the QTF defines all of those technical requirements. It is a very technical document. It points to some specific industry standards that are used and then, puts additional constraints and requirements on top of those standards to ensure that everyone is actually using them the same way consistently. It does also include a number of flow down requirements to participants and sub participants such as areas like auditing and things like that where we want to ensure that things flow down not just to the QHIN level but down the chain to the participants and sub participants. Next slide please. We are starting off with two exchange modalities. These were in the draft that were released over the summer and so these should both be familiar with everyone who has been following along this whole time.

We have QHIN query and QHIN message delivery. These are often referred to as push and pull. The query flow uses three IHE transactions to ask for patient information, retrieve patient information from wherever that patient information is housed. Message delivery is a push, a single transaction to send patient information such as in the case of a referral or electronic case report to public health or whatever the scenario may be where information needs to be pushed from one source to another. One of the documents that was released yesterday as well is the user guide. And it, actually, gives some example scenarios using both of these across multiple different types of permitted purposes for the exchange purposes. We will get into some of that later but there is some great detail in that user guide as well. And so, both of these transactions, the standards that they point to are defined in the QTF along with all of the additional constraints and requirements to ensure that everybody is doing both of these in a consistent manner.

Next slide please. Lastly, as far as some of the technical pieces here, we also released the FHIR roadmap yesterday. This is an exciting one. There has been a lot of interest and excitement around FHIR and the direction that things are going and lots of questions, previously, around what is TEFCA going to do with FHIR. So, along with the common agreement, SOP's, QTF, we released the FHIR roadmap, which details three planned or proposed stages for how FHIR can be used even today under common agreement and QTF Version 1. And what we plan to do moving forward over the next three years with additional stages to add additional FHIR functionality into this exchange among QHIN's through TEFCA. A lot of great detail there.

The main immediate take away you will see in the FHIR roadmap is initial coordination and work with some work groups, industry workgroups to pull together the folks who really know what is needed, the direction FHIR is going, to take some of the work that FAST and others have already been doing with operationalizing FHIR at scale, and plan out do these stages make sense, what does moving to Stage 2 really look like, what does moving to Stage 3 really look like and get industry consensus on that as we build out the next iteration of the common agreement and the QTF to incorporate those requirements and move us down the line toward full FHIR integration. So, there are some great graphics and details in that. I've already seen a





lot of people pulling out some of the graphics on Twitter and sharing thoughts on it. So, definitely take a look at the FHIR roadmap as well. I will turn it back over to you, Mariann Yeager. One more.

Then, back to you after this one. The last piece, and I mentioned this one a little bit before, we have another SOP coming for onboarding and designation. It's the onboarding and designation SOP. It will define the process for onboarding and getting to designation. Within the common agreement, you will see today that there are number of eligibility criteria that are defined in the common agreement. If you are a potential QHIN or considering becoming a QHIN, you're absolutely going to want to take a look at those eligibility criteria. Those are going to be the first determining things for you to be a QHIN. And there may be organizations that, yes, it makes sense. Or others will say we, certainly, want to participate but maybe it makes more sense for us to be a participant within a QHIN versus becoming a full QHIN ourselves. **[Inaudible]** **[01:02:33]** awaiting applications to become a QHIN based on those eligibility criteria.

The testing and ongoing process for nonproduction before we begin production. Again, this will be very familiar to those who have gone through some of this process and are familiar with Carequality. Some of the nonproduction testing process before moving into production and all of that will be defined within the onboarding and designation SOP for how a QHIN achieves that final designation as a QHIN to move into production exchange. If we go to the next slide that brings us back to Mariann.

Mariann Yeager

Yes. The common agreement does put forward how governance will be structured. So, the approach is really a participatory representative governance model where QHIN's, participants, and sub participants have the opportunity to engage. The role of the governing council will be to review amendments to the common agreement, the QHIN technical framework, SOP's, and new artifacts as well that may come out of that. They will serve as a resource to us as the RCE and really have an opportunity to vet and provide input and really providing feedback and input to the RCE as well, in addition to all of the stakeholder feedback we receive. They also serve a formal oversight role in serving as a point of coordination to resolve disputes. They are involved, for instance, also in addressing security incidents.

The way the governing council will have representation from QHIN, there will also be an opportunity for QHIN's who are not elected to the governing council to have a voice through a QHIN caucus. So, all QHIN's have the opportunity and will be consulted, for instance, when changes come about or if there are new standard operating procedures or new FHIR implementation guide, etc. Similarly, there will be a caucus of participants and sub participants who have an opportunity to also provide input. And they'll have a certain number of elected seats on the governing council as well. The governing council has the authority to convene advisory groups around particular topic groups of interest and engage subject matter experts even outside of the QHIN and participant/sub participant community and see that as an opportunity, again, to be informed. We're anticipating there are going to be some really detailed technical and policy issues that may require some unique subject matter expertise.

So, having the governing council have some opportunity to engage in that way is important. There is another group that's not necessarily reflected here, which is the cybersecurity council. They will look at the security of TEFCA itself, which is the network of accepted QHIN's. Particularly, since this is part of the critical infrastructure for the US, it will be really important to have a keen eye on that. That group will be chaired by the RCE cyber security officers. Recognizing it is going to take a while to really get production ramped up,





not a while but a short period of time that there is going to be a transitional council that will serve during the first year. Their role is to have oversight processes in place out of the gate as soon as information begins exchange. And then, they will turn their attention to standing at the governing council and the respective caucuses and processes around that. ONC oversees our work under the cooperative agreement and making sure we fulfil our obligations to follow governance in accordance with the common agreement. I think we go to the next slide.

What we want to do now is talk a little bit about the exchange purposes and how they work. There are six exchange purpose that are identified in the common agreement. These represent the reasons for information can be shared from QHIN to QHIN. Only these six exchange purposes are authorized under the common agreement. The first two represent, not the first two in the list, treatment and individual access services are required responses. What that means is that if you are a QHIN, participant, or sub participant and you receive a request for information for treatment purposes and for individual access services then, you are, essentially, required to respond. There are some caveats around there and appropriate exceptions under applicable law, etc. But that is really the expectation. We recognize that there is some need for further clarity around that. I would say the ability to exchange for treatment-based purposes today is supported quite expansively in the US.

But still, there may be some clarifications around there in terms of treatment relationship, etc., and similarly for individual access services. We will be pulling that standard operating procedure together. We'll get input and then, make that available to QHIN's for adoption. The other four exchange purposes are contemplated. They are in the common agreement. But what we heard very clearly from stakeholders was that these are not as mature. And it was going to require further clarification, specificity, and also possibly changes to participant agreements and sub participants agreements and other things. So, rather than excluding potentially a large set of organizations participating in TEFCA, let's give time and really be thoughtful about what those additional expeditions are. This is an area where the Carequality community has done a lot of focus. I think Alan can probably speak to some of the specifics around that.

The great thing is, again, TEFCA is intended to be multipurpose, multi-use, and expand over time. We do have the flexibility in working with the ONC and through change management processes to add additional processes over time and also be clear about whether they require with responses or not. Alan, do you want to add any color to this? This is a really important area.

Alan Swenson

Yeah, it definitely is. For those of you who have been involved with the work of Carequality, most of the definitions for exchange purposes are very similar if not the same as they are defined in Carequality. There are a couple of them that have some differences that were modified here. For a large part, these are mirroring what we do in Carequality today. In Carequality, all of these exchange purposes are used to some extent though treatment is primarily what is used today because of some concerns that have been raised and issues that we are working there with the others. We are, actually, starting work right now with a big focus on healthcare operations and payment. We have done a lot of work with public health over the course of the past couple of years due to the pandemic. Lots of great lessons learned there. As Mariann said, we heard a lot of feedback around some of those concerns and need for additional clarification around when we say everyone has to exchange for the purpose of healthcare operations, what does that really mean?





Who can ask for healthcare operations data? When you respond, what are you responding with for healthcare operations? That is a pretty broadly defined term under HIPAA. We are working through a lot of that in Carequality and I think a lot of those lessons learned will be incorporated here along with feedback from the industry as we create some of these TEFCA implementation guides for the use of these other exchange purposes.

Mariann Yeager

Great. If we go to the next slide, I think what we want to do is to provide more clarity around the definitions of the exchange purposes. This is an area, again, there was pretty strong support for having a level playing field between those entities subject to HIPAA and those not. So, the treatment of payment in healthcare operations generally have the same meaning as they do under the HIPAA privacy rule and they apply to all information exchanged under TEFCA with the purview of this is a common agreement regardless of whether the parties involved are covered entities or business associates. And that was an area we received a lot of feedback. Again, this is an area that's breaking new ground. So, it was important to have that common denominator set of expectations. Public health includes requests for uses and disclosures of information by public health authorities.

Again, these have to be consistent with HIPAA privacy and applicable law. Government benefits determination supports agencies that need information to determine whether if someone qualifies for non-health government benefits. A good example there, of course, is social security determination purposes. And then, it also anticipates the use of consumer facing apps or platforms that enable individuals to get access to their information. So, for the purpose of requesting that information, that is what's called individual access services. So, Alan, I think you had mentioned and I think we had a question from Jim and others about the implementation guide and unpacking what is healthcare operations, specifically, because it is so expansive from a definition perspective that what we found in the real world, getting folks to agree to exchange, to any operational purpose is a really difficult thing to do.

So, we want to be thoughtful about it, have some concrete examples and expectations of what could be requested for recognizing it is something we will build over time but we have got to start and be thoughtful, and super practical really to make strides in that respect. I think if we go to the next slide, I'm going to do a high level here. And then, Alan, I know we talked about this, actually, with the team this morning about there has been some confusion about individual access services. So, when we talk about individual access services or IAS, we're talking about the purpose for which information is being exchanged. And this is an individual that wants to exercise the right to access. They have a direct relationship with someone along the chain that can act on their behalf and facilitate request. And then, those that have information about the individual are required to release that for that purpose for that individual's right to access. So, that is where the required to respond comes into play.

Does that mean everyone in the chain has to be an IAS provider? No. Those who wish to offer services to individuals and provide a platform or an application to individuals to access their information can opt to do so. So, that is something that a QHIN participant or sub participant can determine. So, that's not a requirement. But Alan, I'm going to pause there and if you want to add color to that. And I think I'm turning it over to you next.

Alan Swenson





Yeah, I think so. So, I can certainly start here. As you said, there has certainly been some confusion and some clarification asked for along what IAS means. As Mariann was saying, there are really two pieces to it. And the confusion comes because we use the same term for both pieces of it. There is IAS as an individual asking for their own information and it is an exchange purpose with the requester of their information. IAS is also the services provided by a QHIN, participant, or sub participant to enable the individual to access their own information. And so, the required to respond piece is when a patient makes a request, an individual makes a request and that request is sent for the exchange purpose of individual access services, meaning it is coming from the individual themselves requesting their own information. That is a required response.

Everyone else who participates whether they offer IAS services themselves, which we'll get to in a second, or not is required to respond to an individual's request for information. Now, offering IAS services is when a participant, for example, has a patient portal and they add functionality into their patient portal to make so that the patient, not only can see their own information, but can also do requests out to others through TEFCA exchange or through TEFCA to pull in that additional information from other places that have that information. That would be that participant or sub participant, potentially, offering IAS services to enable the patient to make those individual requests. So, offering of IAS services is optional. QHIN's, participants, sub participants, anyone can make apps or portals or whatever available to individuals, to consumers to do those requests. That is optional.

But once a patient has that access and makes that request, it is required to respond. If we move to the next slide, there may be some questions come in on that one and we can come back to it. But let's move on to privacy and security. So, if we go to the next slide here, there are a number of privacy and security requirements in the common agreement that apply to QHIN's and also flow down to participants and sub participants. It is expected, as it says here on the slide, that most entities are likely going to be, at least initially with the initial exchange purposes, are likely going to be HIPAA covered entities or business associates of covered entities. And so, they are already going to be required to comply with HIPAA privacy and security requirements.

The common agreement does put in place requirements as required flow down for the participants and sub participants that those who are non-HIPAA covered entities are still required to follow a number of outlines using entire section of the common agreement that outlines a number of HIPAA provisions, that are required to be complied. And those non-HIPAA covered entities are still required to follow those provisions as if they were covered entities. So, if you are a non-HIPAA covered entity or if you are a health information exchange that has non-HIPAA covered entities as participants and we will be updating agreements for them to participant, I absolutely want to make sure you understand those required flow downs, those provisions from HIPAA that will apply to everyone regardless of whether you are actually a HIPAA covered entity or not. And that is to ensure strong privacy through all exchange as well as security through all exchange, with everyone complying to the same requirements, again, whether you are actually a HIPAA covered entity or not.

If we move to the next slide, the security pieces of it, similarly, there are security requirements that apply to QHIN's across the board, to participants and sub participants. There is one of those SOP's that was released yesterday is the QHIN security requirements for the protection of TEFCA information. A big, long title but it goes into all of the additional beyond what is in the common agreement. Some of the additional





specific security requirements that are sub bullet if you're with third-party certification, security assessments, having a chief information security officer, cyber risk coverage. Actually, there is an entirely separate. Another one of the seven is the cyber security SOP. So, both of those pieces across those two SOPs in particular are lots of strong security protections put in place that apply largely at the QHIN level but do have a number flow down to participants and sub participants as well, again, to ensure that we have complete privacy and security of all this information being exchanged across all of the levels of QHIN's, participants, sub participants through the whole chain.

Let's move on to the next slide. And one more here please. Thank you. That brings us back to the application onboarding process. And I touched on this a little bit previously with one of the other slides. We have an onboarding and designation SOP and a QHIN application that goes along with it. Those are coming shortly, being finalized currently. And that is going to define this whole process and so as you see on the slide, there are number of educational opportunities coming up, a number of scheduled webinars all available for registration with more to be added. But many of them are available for registration today on the RCE website. So, if you are not already registered for those, there is an overview of the common agreement and overview of the QTF, a deep dive into the common agreement, lots of webinars. Like I said, we have more to be added for educational opportunities.

The common agreement includes eligibility criteria to become a QHIN with more detail on those eligibility criteria to be included in that onboarding and designation SOP along with the application that asks for specific assertions and evidence and answers to questions to ensure that you actually meet those eligibility criteria. So, both the application and the onboarding and designation SOP will be coming shortly. And then, there will be a designated point of contact as a potential QHIN is going through that application onboarding process to get to designation. Next slide please. A little more detail here on that application process. Again, this will be detailed in that soon to come onboarding designation SOP. But for those, again, familiar with the Carequality process, this will largely look familiar. Some additions and changes here. But the prospective QHIN will sign the common agreement and submit application. And that application will be reviewed by the RCE.

If the application is accepted then, the onboarding and designation SOP defines the whole process and required timelines of everything that happens from there. There is a technical testing process. Ultimately, the QHIN who gets through or potential QHIN who gets through that lumbering process has their common agreement countersigned, receives designation from the RCE as a QHIN and moves into production where the final steps in the onboarding designation process is some production validation to ensure that immediately they can properly communicate with all of the other QHIN's are already in production. And then, there is ongoing monitoring and things from there that are defined in some of the metrics that will be coming along with the QTF. It includes a number of in production metrics already for QHIN's to report on a monthly and quarterly basis. If you go to the next slide, I think, Mariann that is back to you.

Mariann Yeager

It is. If you go to the next slide, how and when will TEFCA be operationalized? We released the initial set of artifacts yesterday. We want to wait at least 90 days so we can do education and outreach and help those who are interested in becoming QHIN's understand why and what are the requirements and expectations, what are we going to be looking for in terms of documentation and evidence of that. And then, we will be onboarding the initial set of QHIN's this year. Now, we are anticipating it is going to be a pretty





straightforward process and there may be some back and forth. And so, we are just speculating that we will need a minimum of that period of time. It really depends, of course, on who the initial set of applicants are in terms of their capabilities and whether they have done this sort of thing before and preparedness and testing, and all of that.

Someone, actually, asked yesterday. So, it is a one time or staged time periods where the applications will be open. We have this initial time period. We will accept applications on a rolling basis thereafter. But because the first group of QHIN's really are interdependent on one another to satisfy part or some of the requirements for designation, they have to do partner testing in a test environment and partner testing in production environment. We really want to have that initial group really announced together. And then, we will add and designate QHIN's on an ongoing basis. So, again, the transitional council will operate within the first 12 months of the first group of QHIN's going into production. And then, they will work in earnest to establish the longer term governance approach. Let's go to the next slide. We are doing a lot more education and outreach. You can see the link to the resources. We have webinars coming up including deep dives. And, of course, we are happy to take comments and questions from the committee here today. Thank you.

Denise Webb

Thank you, Mariann and Alan. I do know we have some questions. A number of people put questions in the chat. But I would encourage you to raise your hand and ask a question. We are going to start with Jim Jirjis.

Jim Jirjis

I had two or three questions all in the same theme. So, traditionally, we are going through this right now. As we connect to HIE's or now the national exchanges, there is often paper. ISA's [inaudible] [01:23:55], etc. And there is often a redlining that goes back and forth. And we are starting to experience that now. What we are seeing is that language that protects the exchange capping their liability, etc. But one of the questions I have is A) will there be standard paper that people will be expected to be used. And if so, balancing liability indemnification for the various participants versus the exchanges. I have a lot of questions around that. And then, similarly, how will we monitor whether or not folks are claiming permitted use but actually violating?

Mariann Yeager

Okay. Those are great questions. On the standard paper, I would say is really the QHIN to QHIN agreement and that the RCE signs. So, that is a common agreement. There is not going to be any redlining there because redlining means we have to take it through governance and, ultimately, ONC approval and governance process approval. There are required flow down provisions. The language is provided in the common agreement itself. Folks have asked whether we should provide a template or example of an addendum that could be implemented. We opted to not prescribe that approach here for TEFCA because we know that there are existing network and participation agreements that may include these types of provisions already. So, rather than having to reinvent the wheel and creating burden by adding more paper into the process. The issue of liability is addressed in the common agreement. And there is some discretion in terms of the terms in a participation agreement between a QHIN and its participants that are really outside the purview of what we are talking about here. It will be interesting if there is an interest in expanding that further. In terms of monitoring whether folks are complying with the exchange purposes, which is something





that we have to think about how we would monitor. We, typically, and I think Alan can speak to this and his experience with Carequality, hear about it through issues and concerns that are raised. And there are other types of behaviors that can indicate that. For instance, if there is a big, huge jump in a particular end-user requesting information for a certain exchange purpose. But that is something we are really interested in hearing more on.

Jim Jirjis

One last comment and I'll be quiet. I think because this whole TEFCA infrastructure is yielding a bunch of QHINs that are coming out of it, there will be a certain power the QHIN's have, especially as we start incentivizing people to connect to national exchanges. And it may be worth addressing the QHIN to provider protections to make sure that both the participant provider as well as the QHIN have language that appropriately protects each of the participants. Otherwise you end up with asymmetric power.

Mariann Yeager

Like pushing the liability down to providers do you mean?

Jim Jirjis

We are starting to see that, which is why I bring it up.

Mariann Yeager

Thank you, Jim. That is on our radar. We are going to have to pay careful attention to that. It's really great feedback.

Denise Webb

All right. Thank you, Jim. Aaron Miri, you're next.

Aaron Miri

Great presentation, you both. Thank you for that. A quick question for you, actually, two questions on the same topic. Have we worked through the challenge with appropriate and precise patient identification on the TEFCA itself so that as we traverse QHIN to QHIN, that data across and it really is validated? This is truly Aaron's record. We are struggling with it right now in Florida. We see several million patients a year. We share a lot of patience with Southern Georgia. It's amazing how the same individual that goes across state lines that's only 20 or so miles away and the record looks totally different just because of data entries. So, I would say that's No. 1. And then, similarly, as it relates to a lot of folks coming here to seek treatment from overseas. But yet they then have other international type GDPR type provisions but we have forgotten others. How is TEFCA going to be addressing those both as they similarly intersect?

Mariann Yeager

Alan, do you want to start with the first one?

Alan Swenson

Yeah. It's definitely a complicated issue, as you definitely know. And something in the Carequality side of things, we have been working on trying to improve demographic-based patient matching for a while. Part of the problem is that there isn't an industry standard or a way that everyone does it. A lot of vendors view it, either EHR vendors or even EMPI providing vendors [inaudible] [01:28:48] of how they manage





demographic based matching algorithms and things. And a lot of hesitancy in the past to share that and make improvements across the board. Now, with that said, we do call out in the QTF that there will be additional work with the QHIN community to improve some of the patient matching recommendations and requirements. We did put into place some requirements to, hopefully, help with some initial improvements, such as we require performance already in QTF Version 1 with the USA standard. The project USA standard just came out last week from ONC.

So, we were ensured going through drafting that that will be published before QTF is published so that we could point to it. And it all worked out nicely with the timing. That was published and then, we published the QTF and we did point to it. So, QHIN's are going to have requirements to convert things to, if not already coming from, their participants in that format to match the project USA standards. And that is to make it so that we at least have consistency in the information that is shared. Now, how an organization in data entry is not something that we really get into as far as best practices and things. In the Carequality world, we have been doing a lot of work with HEMA, for example, has done some great work recently with best practices for data entry and how to collect patient demographics using certain ID's to get the information from so that it's consistent. I think there is a lot of work that still needs to be done with all of that in the industry as a whole.

And now having this TEFCA infrastructure in place with QHIN's to come and participants and sub participants being able to leverage that to make some of these improvements, I think, will be a big, necessary focus.

Mariann Yeager

So, Aaron, for your second question, for people from overseas seeking treatment in the US, how do GDPR and other rules potentially apply, the way the common agreement treats this is once TEFCA information is received and incorporated into the recipient's system of record then, it ceases becoming TEFCA information and it is subject to the body of laws, for instance, your organization would be subject to. So, to the extent that you have to meet these additional obligations for privacy or security or state laws or others that would apply.

Aaron Miri

Got it. It's what Jim Jirjis was just saying how if there is a trickle down stream effect. Got it. Thank you.

Mariann Yeager

Yeah. Sure thing

Aaron Miri

Denise, I think you are muted if you were saying something.

Denise Webb

Sheryl Turney is next. Sorry.

Sheryl Turney

Thank you. The questions I had around TEFCA really relate to, and I put them in the chat as well so you can go back and look at those but really are the concerns that have been raised by many, not just us,





regarding patient access and the lack of a standard consent model. And I understand in terms of the way you are positioning it is if there is individual access provided. But when you couple the issues with member matching and without having that standard consent model, what are the assurances that patients have that their data is going to be protected and secure, especially in light of that most HIE's don't provide capability for patients in their geographic area with the data they collect to even consent to their data being used and shared in this way. And then, there is the element of third parties and researchers using the data with the patients not giving specific consent because many think if they de-identify the data then, they are able to use it based on the provisions that are based in HIPAA.

So, I would like to hear some discussion around those topics.

Mariann Yeager

Maybe I can get us started. This is an area where we will have more discussion in terms of what the expectations are for IAS providers around obligations for consent and future uses and all that. It will be touched on in the common agreement overview webinar on January 26 in a deep dive. I do not know that we will have enough time to get into that topic to do that topic any justice. But there was considerable discussion on that. Alan, do you want to add some commentary on that?

Alan Swenson

Yeah. I'll just add that this is definitely something that was contemplated and considered about what needs to be included for individual protections. Obviously, the privacy and security requirements that we require everyone to be compliant with from HIPAA whether you are covered as an entity or not, helped with some of that. In the common agreement, you will definitely want to take a look, the whole document, obviously, has a whole lot of related content in it. But Section 10 in particular is an entire section. It is multiple pages long of all the requirements that apply specifically to an organization that offers individual access services. It has requirements around individual rights to control of their data, deletion of their data, consent requirements, privacy and security notice requirements that an IAS provider is required to provide to the individual clearly defining what is going to be done with their data, how that IAS service provider will use their data, etc.

Again, whether that IAS provider is a HIPAA covered entity or not, all of these requirements will apply. So, whether this is a patient portal from a provider office or a patient app, they are going to have to comply with all of the same requirements to ensure some of these privacy protections for the individuals that use the services.

Mariann Yeager

This is one of the areas, too, Sheryl, to your point that we heard a lot of feedback and even in our own experience about the need to bridge the gaps in policy, existing law to really support this.

Sheryl Turney

I can say that I think there are some unanticipated events that could occur that make this very challenging. And I would say one that we often see this as a payer, and I am sure we are not the only ones to see it, but you take the example of someone sharing data and submitting a claim for the incorrect member. That data, when they make a claim and it's incorrect and it's for the wrong member, maybe there is another member with the same name, they have to then back that data out. An individual even seeing that type of information





in this type of framework are going to see the data that was incorrectly submitted and the back out. And that is still going to share somebody else's with an individual that should not be seeing it.

So, I just think there are so many aspects that have not yet been considered in this framework that many of us that are already in HIE's have experienced that we need to anticipate those in advance of providing that access.

Denise Webb

Thank you, Sheryl. The next question is from Eliel Oliveira.

Eliel Oliveira

Thanks, Denise. I want to build upon Aaron Miri's last question on identity and matching. Aaron, great seeing you again. To be fair, this was not a question that I came up with. It was from Senator and Dr. Cassidy back in Louisiana asking what happens when someone shows up at an Emergency Room or EMS truck whether they are homeless or do not have any ID and they are unconscious? How do you get that person linked to their data so that you can treat them appropriately? I understand this is nothing compared to what we are dealing with right now just solving the problem of matching. But if there is no answer to it, I would suggest that is maybe something to consider in the next generation of TEFCA.

Alan Swenson

Yeah. That's definitely an important topic. Thanks for the question. Again, I think that goes to some of the work Carequality has been doing and some of the guidance from HEMA that came out along with some of the project USA specifications recently. There is not really a great answer. If the patient is homeless or unconscious and does not have ID on them, how do you find their information? You probably cannot unless you know enough about the patient's demographics to make that match. Some of that is based on how demographics based matching algorithms work and what number of demographics and which demographics are required to make that match. There are definitely some improvements that could be made there and recommendations, again, specifically around homeless patients and things who otherwise, you know the demographics but they just don't have a physical address or a consistent physical address and how to handle that.

There are definitely some improvements across the board in data entry is where all of that starts, obviously, but once it is entered into a system, how do you match that across system? I think there is a place for TEFCA to help push some of that forward as we have QHIN's participating and able to engage in some of that discussion. Some of it is also a much larger industry discussion than just how do you match the patient, but how do you even document the patient in the first place.

Denise Webb

Our next question is from Steven Eichner.

Steven Eichner

Good morning. I have two questions. One is looking at the advisory groups and the advisory panels, how are those going to be configured or set up initially? And what are the focus areas? And secondly, I know there is an opportunity to push data across the network but it may not be supported by all providers. Does





the provider directly ensue information about whether a particular participant can receive a message? Or do we need another method for determining that? Thanks.

Mariann Yeager

Thank you, Steve. The advisory panels, there is not a specific set of focus areas or composition requirements set forth just yet. We need really need that structured and established as we get governance. We need QHIN's in production. We need to have real-world activities going on. And then organically, we are anticipating that there is going to be a need to engage subject matter experts to inform this work, and of course, other stakeholders maximizing transparency and all of this of course. So, I would say it is not predefined as we speak but it gives flexibility to the RCE, to ONC, and the governance process as a whole. In terms of pushing data and whether or not all providers have the ability to receive push messages, Alan, would you like to speak to that one?

Alan Swenson

Yeah. And the intention is that there will be information in the directory. The directory will include information about QHIN's, who their participants, who their sub participants are, etc., including the methods of exchange available whether someone can receive a push message, including the exchange purposes that a provider organization or anyone else that is a sub participant down the chain, the appropriate exchange purposes for which they would ever request information so that that can be verified that this organization should never be requesting for payment, for example. If they try to send a request for payment, it will is not even going to go through because they should only ever be requesting for the purpose of treatment or whatever that scenario looks like. So, that information is intended to be in the directory so that it's there and available.

And I heard part of the question about the provider's ability to receive certain types of information. There is not, in all cases, we certainly point to certain specifications with CCDA, and USCDI for coding for the content that is exchanged. There are some allowances for other forms of content. If the issue is a specific type of information or type of content being received by a provider, the expectation detailed in the QTF is that a provider would have in place some sort of agreement with its QHIN or its participant, whatever up the chain looks like, for any data conversion or conversion between types of documents if it can only receive certain types of documents and not others.

Denise Webb

It looks like that was our last question. We are just about at the end of our time. I do want to thank you very much Mariann and Alan for your presentation today and for taking all of our questions. There are some additional questions in the chat, which will go into the minutes that you will be able to access. So, we will go ahead and take a 15 minute break. Please stay logged in. We will stop the recording during the break. But the audio is live just to let everybody know. We will see you back in 15 minutes.

Mariann Yeager

Thank you.

Denise Webb

Thank you.

Mike Berry





All right. It looks like we are all set to go. Welcome back, everyone from our short break. We are ready to resume the remainder of our agenda today. I would like to turn it over to Denise to get us started.

Denise Webb

Great. Aaron Miri had to step away will return to report out on the Annual Report Workgroup.

Mike Berry

I think you might be on mute.

Denise Webb

Oh, no.

Elizabeth Holland

I hear her.

Denise Webb

Can everybody hear me?

Mike Berry

We are still not hearing you.

Elizabeth Holland

We can hear you. Maybe Michael should check his speakers.

Denise Webb

Everyone else can hear me.

Mike Berry

I am sorry, Denise. It would help if I had my earbuds in. My apologies.

Promoting Interoperability Program Update (01:44:20)

Denise Webb

All right. So, our next presenter is from CMS, Elizabeth Holland. And she is going to talk to us today about the promoting interoperability program and give us an update on the program under Medicare. So, let me turn it over to Elizabeth.

Elizabeth Holland

Hello and thank you for having me. I'm going to talk today about the CMS requirements in 2022 for eligible clinicians, eligible hospitals, and critical access hospitals for requirements to participate in the promoting interoperability program and promoting interoperability performance category. Next slide, please. This is just my scary slide. Next slide, please.

You may remember that in the American Recovery and Reinvestment Act of 2009, it created the HITAC Act, which created ONC officially and also created the Medicare and Medicaid electronic health record incentive programs. That, essentially, paid incentive dollars to eligible professionals, eligible hospitals to





adopt, implement, and upgrade certified EHR technology and to demonstrate meaningful use. The programs span Medicare and Medicaid and all of those clinician types. As we move forward with the program, we went through stages. Each stage built on the stage before it. We no longer now had stages but we continue to build on the program and try to push people to use EHR's in more meaningful ways. Next slide, please. So, as an update, the Medicare incentives ended in 2016 with the exception of eligible hospitals in Puerto Rico. They were never eligible for the original program but congress changed the law after we had finished paying all of the Medicare incentives and added in the Puerto Rico hospitals.

There have been downward payment adjustments, which started in 2015. Medicare Access and CHIP Reauthorization Act of 2015 was passed and ended the Medicare EHR program for eligible professionals did not affect the Medicaid programs. We renamed the program so it is not the EHR incentive program anymore. We renamed it as promoting interoperability in 2018. And just past year, the Medicaid incentives ended. Next slide, please. So, under MACRA, the law required that there be a merit based incentive payment system as well as advanced alternative payment models. I'm mainly going to stick on the MIPS side because that is where the eligible clinicians are. Through this program, all Medicare clinicians can earn payment adjustments be that a positive payment adjustment, neutral payment adjustment, or downward payment adjustment. Next slide, please.

So, to report from MIPS, there are four performance categories, quality, cost, improvement activities, and promoting interoperability. What essentially MIPS did was bring together several existing programs into one umbrella. They quality had been known as QRS before and promoting interoperability was the EHR incentive program. Again, we are just talking about MIPS eligible clinicians who were before known as Medicare eligible professionals. To earn a score under MIPS, we allocate 100 points to each of the performance categories. And since the inception of the program, promoting interoperability has been 25% of the MIPS score. The breakout between quality and cost has changed over the years, quality originally being much higher than it is. Now, it has leveled out between them.

Next slide, please. So, the requirements for 2022 are, as I mentioned, 25% of your MIPS score. You still have a 90 day performance period but it is a minimum performance period. So, you can pick anything from 90 days up to the full calendar year. We tend to use performance-based scoring at the individual measurement level, although we do have several yes/no measures. And we require the use of either 2015 edition certified EHR technology, the 2015 edition Cures update, or a combination of both of them. Next slide, please. These are measures now for 2022. You may notice if you are familiar with the EHR incentive program that some of these look very familiar. ePrescribing has been a measure ever since the beginning of the program. We have a newer measure, the query of the prescription drug monitoring program measure, which is a yes/no measure. And it is worth 10 bonus points.

We have health information exchange where we have two older measures that have been around for quite a while. And then, in the last two years, we introduced this health information bidirectional exchange measure, which is also a yes/no measure. We have provider to patient exchange and public health and clinical data exchange. We changed our policy for public health and clinical data exchange last year so the beginning of 2022. It used to be that you had a choice of any of these. You could report any two of the public health measures. Now, we work very closely with the Centers for Disease Control and Prevention and we are requiring both the immunization registry reporting and electronic case reporting. That really





grew out of the pandemic. We still have other measures under public health that you can report on but they are worth bonus points. Next slide, please.

So, in addition to the measures that you must report, in reporting the measures, you must either have a one in your numerator to fulfill the measure or test to a yes if it is a yes/no measure or claim an applicable exclusion. And each measure has exclusions that you may be able to qualify for. You also have to provide your CMS certification ID so we know what EHR accommodation you are using. We have information blocking attestation. That is what it used to be called. But now, you are attesting that you do not take actions to limit or restrict the compatibility of certified EHR technology. There is an ONC direct review attestation, security risk analysis, which has also been around since the beginning of the program. And we added a safer guide measure this past year as well. Next slide, please. So, the scoring is weighted at 25% of the MIPS score. And you could earn a maximum score of 100.

So, if you earn the maximum score in each of the required measures that would equal 100. But if on some of the measures you score lower, you still have the opportunity to earn back those points by submitting the bonus measures to get your score up as close to 25. So, we add the points, multiply by 0.25 and that gives the number of points that goes for your final score. So, the final score, when we add up the categories depending on where you fall, you would earn negative, neutral, or positive payment adjustment. And that is to all of your Medicare physician fee schedule payments. So, if you have a high Medicare volume, this could have a very high impact on your practice. I believe in 2022, the adjustments can be up to plus or minus nine percent. Next slide, please. Now, we are switching to the eligible hospitals or critical access hospitals. We have tried to very hard to align the promoting interoperability performance category with the interoperability program.

They both have a performance period of a minimum of 90 days. There is still performance-based scoring and the certification requirements are the same. Next slide, please. And this is where it differs just a bit. The electronic prescribing the measures are the same. For health information exchanges, it is the same. And provider patient exchange is the same. One of the differences is in public health. Here, we are requiring that hospitals report on all four of these measures. Again, this is an agreement that we worked out and proposed with consultation and with the Centers for Disease Control and Prevention. These are very important to getting information and helping us through the pandemic. So, on the clinician side, you saw that we were requiring two measures here but it is actually four measures. Again, there are still bonus points available. Next slide. So, for the promoting interoperability program, things are little different. We still add up the measures to reach a score. But for hospitals, there is no way to achieve a positive payment adjustment.

All you would get if you do not earn minimum threshold of 60 points is if you don't do that and you don't qualify for a hardship exception, you would earn a negative payment adjustment. So, for 2022 we had to increase the threshold. We are trying to push people to score better. Next slide. Again, this is very much in line with what we require for clinicians with a couple of differences. The main difference here is on the clinicians side, we have the requirement to just attest to reviewing the high-priority safer guide. But for hospitals, we want them to review all nine safer guides. I neglected to mention on the clinicians side, and our policy is the same on the hospital side, the safer guides are a new measure. And for the first year, we established that you needed to attest to this measure either yes or no and either of those would be





considered an acceptable response. And they are not scored. That is to give people a chance to come up to speed and make sure they can familiarize themselves with these guides.

Another difference for the promoting interoperability program is that hospitals at cause must submit clinical quality measures. Next slide. So, the requirements for clinical quality measures is you must report on three self-selected ECQM's and the safe use of opioids [inaudible] [01:57:21] measure. And a change here is for ECQM's. And all of these ECQM requirements align with those requirements under the hospital and patient quality reporting program. So, they are beginning to lengthen the amount of time that data needs to be collected and reported. So, now for ECQM's, you need to report on three self-selected quarters. And for the other measures for the promoting interoperability program, it is still just 90 days. Next slide. And just to give you an idea of which measures you can choose from, again, the safe use of opioids is required and them, you would choose any three. Next slide.

That brings me to the end of my presentation. If you have additional questions on promoting interoperability performance category, you visit the first link for the promoting interoperability program. You can visit the second link or you can, certainly, feel free to reach out to me. Thank you very much.

Denise Webb

Thank you, Elizabeth. Just for clarification, the clinicians have the four categories, which includes clinical quality measures, correct?

Elizabeth Holland

Qualities in that, yes.

Denise Webb

And I know you showed some of the choices for the hospitals. But is there also a specific set of measures and a number of those that have to be selected and sent as an electronic CQM for the clinicians as well?

Elizabeth Holland

Electronic quality measures are not required for clinicians. There certainly electronic quality measures that they can choose from when submitting their quality measures. But they do not have to be electronic. We are moving towards more digital measures in the future but there is a lot more choice under policy.

Denise Webb

Do the clinicians have three quarters?

Elizabeth Holland

For quality, it is a whole year. They have to do a whole year for quality.

Denise Webb

Oh, a whole year, okay.

Elizabeth Holland

Quality and cost categories are both a full year. Improvement activities and promoting interpretability performance category are both 90 days currently.





Denise Webb

Thank you. I appreciate that clarification. It looks like, Clem McDonald, you're up next for a question.

Clem McDonald

So, a couple of things. I was at all of those meetings when they first decided how to do quality measures. A peculiar thing happened is that, although it was proposed that simpler rules would be provided, some of the big hospital systems wanted to have every tiny detail in the rule so they would get as high of a score as they could. So, I hear you talk about just digital rules. Some of CMS's more recent rules were things like percentage returns to the hospital with pneumonia or things that are very computable and very easy to understand. Is this what you meant by going towards the digital ones?

Elizabeth Holland

For hospitals, the requirement is for promoting interoperability program that the measures must be computed in the certified EHR technology. So, we are limited to those ECQM's because that was included in the HITAC law. We do not have that kind of restriction on the clinician side. In the quality category, there are many different kinds of CQM's. And under the hospital IQR program, there are many different kinds of ECQM's available.

Clem McDonald

Maybe I'm not characterizing these correctly. The initial set we're saying like the breast-feeding one I thought was kind of a peculiar one because it had a condition that you should be required to follow this rule if you have herpes simplex on your breast. No mention about the hand or any of the other places you can touch her baby with. And they are in the hospital for like 12 hours on average. So, that one seemed kind of silly. But mostly, they are just fixed measures about easy to measure things that do not require a lot of extra data collection. Are these and one of these sets? Or am I categorizing them right?

Elizabeth Holland

I think there are many choices in the IQR set. And some are chart ups or active measures and some are hybrid measures getting data from multiple sources. I know for the promoting interoperability performance category, there are over 100 that you can choose from so there is a wide range.

Denise Webb

The next question is from Les Lenert.

Leslie Lenert

I had a question about the eCR category for credit for interoperability. So, that's the electronic case reporting. What are the criteria required for the certification of this? Is it only eCR for COVID-19? Or do you have to comprehensively provide eCR data for all of the notifiable conditions for the state in which the health facility is in?

Elizabeth Holland

We have not specified that. We are just say it is for electronic case reporting. We do know while some EHR's are certified for the function of eCR, many are not. So, we did add an additional exclusion so that if your EHR isn't certified for that functionality in 2022 only, you can claim that exclusion.





Leslie Lenert

Okay.

Denise Webb

Our next question is from Steven Eichner.

Steven Eichner:

Your last response helped answer part of my question. What standards should providers use to exchange information for eCR?

Elizabeth Holland

It is specified. We work very closely with ONC on these measures. And they provide the information on the standards and certification requirements. I don't know if anyone from ONC can directly address that.

Avinash Shanbhag

This is Avinash Shanbhag from ONC. Can you guys hear me?

Denise Webb

Yes, Avinash.

Avinash Shanbhag

Oh, great. I can give you a quick response. Again, right now, over 35 certification requirements for electronic case reporting is really functional requirement in terms of exchange. In terms of data, there is, obviously, the requirement to have them coded with, I believe, ICD-10 codes. But in terms of exchange information guides, it is still a functional requirement just to clarify that. I know we looked at recently some of the work that has happened in the CDC area around eCR. Now, we [inaudible] [02:05:26] EICR and other information guides but currently as defined in certification, it is a functional requirement.

Steven Eichner

I guess as a follow up to that, what can be done to help accelerate that so that providers can take advantage of technology as fast as possible to evolve paper reporting and improve the quality and timeliness of data being received by public health?

Avinash Shanbhag

This is Avinash. I don't mind jumping in. I can start and then invite others to chime in, especially from CMS. There are quite a few areas that that CDC has promoted in terms of making these reports be efficiently exchanged. So, ideally what would be useful is for industry and [inaudible] [02:06:31] and focus [inaudible] [02:06:38] on the ground understanding on which standards actually work and should be kind of promoted. Again, working within the community, working with what works would be substantially beneficial for us to look at. And, again, things are much better as [inaudible] [02:07:07]. And we see a lot of flexibility that we are given in terms of allowing some of these newer technologies that are using the latest FHIR based standards to be eligible to be considered to be certified for [inaudible] [02:07:27]. So, it is flexibility but having industry [inaudible] [02:07:33] certainly makes it easier for both the senders and receivers.





Steven Eichner

I'm sure public health at large would be happy to support in any way that it can helping providers move to electronic reporting as quickly as possible for everyone's advantage.

Denise Webb

All right. Les Lenert, you are up again.

Leslie Lenert

I just wanted to clarify was this the eCR you are talking about or electronic lab reporting? eCR has a very specific architecture, a CCD document structure. And when I say architecture, you, actually, submit the CCD to a screening entity with forwarding to public health. Is CMS requiring this entire production chain to be in place to be certified in this area? Or, as I said, is it something that is more related to working with vendors? The vendors have a key role in this. Yes, there are triggers for the eCR reporting that only the vendor can implement. But there is a lot of infrastructure in between and really much more architecture than most systems with a centralized screening tool fielded by APHL and then, forwarding to public health departments that doesn't really reflect most of the standards that we've seen at ONC.

Elizabeth Holland

CMS is only requiring the vendors to be certified and to get that particular eCR module certified. To my understanding, many of them have the modules but they have never bothered to get the eCR portion of it certified. And so, since they already have the capability, they just need to go through the certification process. From the time that we proposed this last spring to the time of the final rule, the number of vendors being certified skyrocketed.

Leslie Lenert

I think what you are describing is actually from the time you proposed this to the final rule, what we saw was a large number of vendors supporting eCR for COVID-19. And that is very different than broadly supporting the architecture proposed under eCR along with a subscription to different definitions of triggers and things. So, I think this is an area where we can really use some additional investigation and discussion from the HITAC to see what we can do to move the innovative work with eCR forward.

Denise Webb

Thank you, Les. Dr. Lane, you're next.

Steven Lane

I certainly want to echo all of the comments that support the more rapid advancement of eCR to a named standard and requiring that of the EHR vendors. It sounds like there is a path to getting there. It just may take us another year or two. The other point that I wanted to make about eCR is that we should looking for opportunities to require collaboration from the public health entities who are now going to be receiving this data electronically. It is critically important that they are able to receive that, integrate that into their systems, and turn around and tell us providers that we can stop reporting using other parallel processes. In our state in California, that's been a real challenge two years into the pandemic now where still we have not been given leave to stop manual reporting, even when we are sending in data by eCR.





Denise Webb

Excellent point, Steve. We have a couple minutes if there is maybe one more question. I don't see any hands up. If not, thank you, Elizabeth, for presenting to us today and giving us this update. Very much appreciated.

Elizabeth Holland

Thank you.

Denise Webb

And we have one final topic before public comment. I will turn it over to Aaron to give us an update on the Annual Report Workgroup's activities.

HITAC Annual Report Workgroup Update (02:12:45)

Aaron Miri

Normally, for the HITAC members and others who have been on this journey with us for a while, you would see up here with me my co-chair, Carolyn Petersen, but her HITAC term ended. So, with it, we are wishing her the best and thinking of her. So, I will be presenting the conclusion for this year. Hopefully, many of your smiling faces will join me on a journey next year. So, we'll be at full strength. Let's go into it please. Next slide. What I will go through today is the work group scope, membership, schedule and next steps, and a discussion of the HITAC annual report for FY' 21. It is more of a cross walk section. The actual report is pretty lengthy and has a lot of good details and data in it. But we'll go through the executive summary and then, we can always double click if we need to. Next slide.

Our kind of scope here, especially for the new members or new folks. The work group will perform, contribute, and review the draft and final versions of the reports as submitted to the secretary of HHS and congress each year. It really helps us track our progress. And it is amazing when we kind of look back in time and see how much has been done over the past few years. So, specific charges, we need to provide specific feedback on the content of the report, as required by 21st Century Cures, including an analysis of the HITAC progress. Assessment of health IT infrastructure and advancements in the target areas, analysis of existing gaps in policies and resources for target areas, and ideas for potential HITAC activities to address identified gaps. What is important to note is we don't want to speculate or comment on things that are not final or are maybe sort of out there and being talked about or whatever. We try to keep the report to things that are salient.

Case in point, when TEFCA was first announced, we tried to make sure the actual rule was finalized before we commented on it into the report. We try to make sure timing is appropriate and that we are commenting on things that are definitely solidified versus is just still being an idea that has come into maturation. Next slide. This is the work group membership right now of folks are there right now with Dr. Jirjis, Dr. Lane, and Dr. Oliver, three esteemed colleagues. Again, other colleagues have come and gone so I would be remiss. Of course, our phenomenal ONC team who was there with us side by side in the trenches, specifically, Michelle Murray. Thank you for all of your work. It is just amazing how much you get done for us. So, thank you for that, Michelle. Next slide. All right, meeting schedule and next steps. Next slide.

Basically, we are here today to talk about the draft for the FY21 annual report. There will be time for you to look again at that after this call and after this discussion. I do hope you are able to come to this meeting





with some ideas. For the new folks who joined, I remember when I first joined, although we did not have a report group that year, it was a little daunting to get caught up to speed of how HITAC works. So, I would encourage you if you haven't read the report, read the report and get comments back to us ASAP via email so we can look at it and talk about it. Of course, in February or March timeframe, somewhere in there, we will transmit the reports to Dr. Tripathi for review and consideration. Next slide. We're going to review reports and suggest some edits if any. We will approve the revised report and then, we will be transmitting that final report and then, send it onward appropriately to Congress. So, let's go through. If you will pull up the crosswalk for me please. There we go. Let's go to the crosswalk if you don't mind.

So, this is a lot of words and a lot of sections. And I don't want to just regurgitate to you and go boring Aaron. So, let's talk about it in sort of abstract here. We're going to go into the meat of issue. So, what I want to ask you to do it is we are going to go section by section. If you have questions or comments on a grouping within the section, I will pause at the end of that section and look for hands and then, we will go to the next section. And I will try to keep us on time. Again, a lot of these come from you all, especially existing HITAC members, the public, others that have weighed in. We have looked at it. We have had great debate about a lot of these things and discussions. Obviously, in the first section here with public health, we know what the issue is here. We have got to be able to allow for clinical population data reporting, improvement of data quality, etc.

The opportunity is to get immediate bidirectional interoperability. The word bidirectional, I appreciate Dr. Lane and others that have really made sure that that was a key, fundamental focus for this. So, we tried to make sure those are in our recommendations everywhere making sure that bidirectional data flow is there. And then, of course, providing what we believe the activity should be is providing guidance for operationalizing standards, addressing implementation variation, convening more listening session. We did last year, which was very, very successful. And then, assessing the public health activities and systems to understand what is needed to better help public health data systems. I'm sure as my friend Steve Eichner can say when I was in Texas, there is a lot of opportunity there to really become more concise and trying to get away from the reliance of fax machines.

And that next section down there on the same topic, you have got incentivizing and funding. There needs to be an incentivize and funding structure that aligns for **[inaudible] [02:17:55]** public health data sharing and really encouraging folks to be able to share that data. So, the opportunities are aligning incentives and funding structures across clinical and public health data systems, more data collections needed by public health organizations to support situational awareness and health equity. Health equity is a big, big, big component of this. We have to get better about that data and that granularity. Of course, reducing silos in data exchange by exploring the roles of HIE's and promoting interoperability of public health and clinical data systems. I only wish we had HIE's run as well as Mr. Kansky's and others across the country that do a great job of leading this. How can we really help promote that kind of forward thinking and leadership to get this going?

So, activities there are to explore ways that the ONC health IT certification program can support data exchange between public health organizations and all of the stakeholders across the continuum of care.. Explore how the ONC health IT certification can be aligned other public health certification programs such as the electronic laboratory reporting certification and certified immunization registries receiving data from certified EHR's. And then, of course, partner with NCVHS to identify barriers to potential opportunities for





public health use of HIE's where affordable and available. I really appreciate, again, the listening session last spring really helped highlight this and really understanding just the number of disparate data sets that need to be interlinked. Next section if you scroll down. There are a few more here. And like I said, after this public health section is over, I will stop and we can take questions on this in aggregate. So eCR, that is what we have been talking about today.

We have got to get better about electronic case reporting. Again, there is so much reliance on fax machines as we saw even in Austin, Texas where I came from where that tripped up a lot of things. Key opportunities, expand the adaption and support of eCR and integration by public health authorities, healthcare providers, and health IT developers. Encourage public health authorities to respond more fully to healthcare providers upon receipt of a report about a reportable disease and health IT developers to enhance such capabilities. And, of course, the recommended HITAC activities. Learn about the experience of government agencies like the CDC and state health agencies and departments and developing tools, sharing data for eCR, assessing what gaps remain. Again, going back to that spring listening session, we heard about the state of Louisiana doing some phenomenal work and sharing public health data. Really forward thinking and leading the country. How do we learn more about that?

Collaborating and convening groups across federal, state, tribal, local, territorial governments to encourage both adoption and advancement of the technology and bidirectional data. Again, there is that word bidirectional. So again, it is a partnership listening and trying to figure out where all of those gaps are or potential opportunities that we can overcome with standard development and collaboration. On the next one with ELR, electronic laboratory reporting, again, the lack of the use of standards. It creates a barrier. We set up two CLEA certified labs at UT. It was very interesting. The standards don't always match what you're doing or what you're transmitting, especially when you're processing as many PCR samples as we were. So, how do we get a better use of terminology, standards, and electronic laboratory reporting? How do we ensure standardization?

Our HITAC activity recommendation is encouraging the ONC to work with the CDC, public health entities, support organizations, etc., to standardize technical capabilities and facilitate laboratory results data collection. And then, of course, the sharing of such across all of the various domains. The next one there was syndromic surveillance, of course. This is all about making sure you are monitoring cohorts of patients and really increased sharing of information would improve that tremendously. How do we encourage the opportunity? How do we encourage public health authorities to provide that timely POP health level syndromic surveillance information back to healthcare providers and patients to support responding to public health threats? This is our activity that we're recommending. Identify existing data sharing methods like the CDC's Health Alert Network and best practices for federal, state, tribal, local, etc. Public health authorities to share real-time POP health syndromic surveillance data with healthcare providers and with patients.

How do we get that early warning radar system out there so folks know what is going on and how to react, and how to respond? Transparency through data. The second to last, the information exchange to facilitate care and monitoring of patients with long COVID. This is becoming a major issue. So, the gap there is identification of patients with long COVID, which is not straightforward. As a result, POP health level analysis of this condition has been challenging. It has been. So, the key opportunity there is to improve the clinical documentation standards for patients with long COVID and as a blueprint for other conditions. Our





activity we are recommending here is to explore the data needs of existing programs for documenting long COVID cases among patients of populations, including standards, registries, and electronic patient reported outcomes. This also goes back to looking at social determinants of health that were mentioned earlier and so forth and so on.

How does all of that play together? And last in the section before we do a round of questions, is the public health workforce recruitment and training, a credit to the ONC with \$80 million they were able to distribute and really additional things that are coming out the pipe that's going to help in long run? The key gap there has been public health departments struggle to attract, train, retrain public health professionals. Finding contact tracers is next to impossible. Key opportunities, improve public health information, technology, workforce, resources, and capacity. I think if we opened folks' eyes to the difference they can make, which is part of what those training programs were about and they are going to applaud HHS for doing, it's going to help. An activity that we're recommending here is to adjust ways to attract, train, and retrain public health professionals with skills in public health informatics, data science, health IT, in addition to that ONC public health training program I mentioned earlier.

I just went through that like Speedy Gonzalez. So, if I can help answer any questions or take any questions here, please raise your hand. Steve Eichner is first in the cue.

Steven Eichner

Thank you so much. And I do want to give a reminder that you are allowed to submit written comments as well.

Aaron Miri

Yes.

Steven Eichner

Thank you and thank you for providing the overview. I do think one of the challenges with things that we need to add on to the discussion of components is looking at policy changes. One of the things I think is relevant is that a lot of the data collected by public health may be collected by the disclosures but is received by a system that is not necessarily part of a HIPAA covered service on the public health side. And that may impact the ability to re-share that information. In a similar vein, I don't want to leave out patients, privileges, and access to their own information and their rules of responsibilities in sharing information with other providers. That ties into public health reporting in terms of looking at patient privacy and patient rights and understanding when and for what purposes the patient's data is being shared. It may be different with sharing it as a public health entity for one purpose but not necessarily re-shared for other external purposes.

And that is something that we need to figure out how to best do and how to leverage technology for that advantage. The other point is looking at the public health work force with not only training but looking at retention. It is one thing to hire someone to get them well trained. Being able to retain them in the work force is also a vital component.

Aaron Miri

Great points, great points. Mr. Kansky?





John Kansky

My feedback, which I will commit to putting in writing for you is on the very first row, public health data systems infrastructure. I will try and state this concisely. None of us, I suspect, would argue that the public health reporting infrastructure did not exist and it was demonstrated during the pandemic response that the data that was submitted we had challenges with quality and completeness. So, we acknowledge in the current draft here that we need to do better by improving the linkage between providers and electronic health records and the public health system to make that a part of the infrastructure. I also think there is an emerging consideration of the approach of using statewide health data utilities. For example, in some states that would be a health information exchange as the infrastructure that accomplishes the same thing. So, in my experience in national interoperability, often the answer to which one is both, I would suggest and we acknowledge in the very next row that we should look at the role of health information exchanges in supporting public health need for information.

I just think there is a bullet missing from that first row. Thank you.

Aaron Miri

Good observation. Clem?

Clem McDonald

I would like to support what John just said but there are two things. One of them is the long COVID, that is not really mostly a technical issue. We have been looking at it in Medicare and one thing we noticed is the definitions are really tough if users do not define that they say this is long COVID. That we can maybe encourage more of. But the other thing is we did not see a whole lot of difference between long COVID and long influenza. I think these are very wooly subjects in what you need. You're going to need infectious disease and clinical experts more than technical information experts. So, I do not know if this is the perfect subject for our particular committee. It is a tough problem and it may not be way different from just long after any virus infection. The other thing is the very top one, there is a lot of emphasis on, if you go back up, there was the word about the constraint. Let's see here.

It was really structuring on what is allowed to be sent that is the minimum necessary. And that is tricky. Clearly, we want to follow all of the rules but it is tricky because when you have text information being sent around, you do not computable you know what is in it. So, if you just exclude all text information, you're blowing away some things that public health needs. So, I think the excessive emphasis on the minimum necessary may actually impede the public health aspect of all of this if we are not careful.

Aaron Miri

Good points.

Clem McDonald

We don't always what's necessary.

Aaron Miri

That was a good point. Maybe we can expand upon it a little bit. Okay. If there are no other questions on this section, let's move to the next section to keep time please. We should be at interoperability next. Yes. Patient matching. It has already come up a couple of times today. So, the issue there is patient matching





when sharing data needs to be improved. It's an issue. We heard it from the TEFCA conversation. We have heard these questions of how is it going to be done. The opportunity there is to address the alignment of incentives and certification programs across domains, to encourage the ecosystem-based approach to improve patient matching. And the, of course, this helps public health from that. So, the activity that we are recommending there is to find a core standard set of data elements to support patient matching across healthcare and public healthcare systems, including demographic information.

I think we heard Mariann mention HEMA and other organizations that have done some phenomenal work and really detailing this out. I put the report that came out from the GAO, HHS has done work in the past with fellows. I think we can really get to the meat of this and provide some guidance in the industry perhaps to consider an adoption, especially as the QHIN TEFCA has stood up. The next item here is information blocking. Information blocking interferes with seamless and secure access of exchange. We know that. And so, following the publication of the ONC Cures Act final rule, assess how the information blocking has, actually, been going. I can tell you firsthand that there is not all happy campers across the way about this across the domain, patients and providers both. So, how do we get clarity and get everybody to be good with patients to have their information when they want it, how they want it, and where they want it?

What we are recommending as HITAC is to really convene a listening session to establish the measures and the impact of information blocking requirements across the ONC Cures Act final rule, across the entire industry in conjunction with the ONC's measurement efforts. We want to make sure that we actually know that we are getting the goal and we are getting the progress, and that there is true transparent information sharing without delay, which is important thing. On the exchange for data for transitions of care that issue is the poor exchange of information during transitions of care increases the likelihood of poor outcome. If I go from surgery to recovery and then, recovery to home, that is very different care settings, very different care plans, very different types of treatment options and other things that are available to you. So, the opportunity is the exchange of data for both transitions of care between institutions and transfer levels of care between floors or units.

So, if I'm going from LTAC to home or hospital to rehab or whatever as well as between units and levels of care, it needs stronger standards. And I appreciate Dr. Lenert as he has been very vocal on this and has some great research and work around it. Investigating and documenting the requirements for improving the exchange of data during transitions and transfer levels of care, particularly around standards to improve coordination of care. Basically, developing set standards that we can recommend as being things to adopt, items to adopt, processes to adopt to start standardizing this across the industry. Let's keep going. Three more items here for this area. Increased health equity across populations, locations, and situations, again, that data collection. The gap is ensuring that health equity includes healthcare, i.e., the tracking and sharing of health information to support both health and healthcare equity initiatives. The opportunity there is more industry standards supporting the collection of health equity data on elements that can be agreed upon.

When you set up a vaccine, you would be amazed, especially when you're trying to do it equitably, how many data elements are just not standard available but you start collecting, which we turned to Red Cap to be able to collect on our patients so that we could do this in a very equitable way and help respond. And then, of course, the recommended activities here. Convening a listening session to identify barriers and opportunities related to standards for consistent collection of health equity data elements. Again, trying to understand what are all of the missing pieces and items that we need to make sure that we are leading in





a much more equitable manner. Again, going back to the next topic here, increase health equity across populations, locations, and situations reducing algorithm bias. Efforts are needed to better understand and reduce racial and ethnic biases in algorithms. This is a big issue right now with artificial intelligence, algorithms, and machine learning depending on the data sets. So, the opportunity there is screen healthcare and public health data systems for bias in algorithms to improve data used for decision making.

Of course, the recommended activity here is convene another listening session to understand this better, to identify sources of algorithmic bias in healthcare and public health data systems as well as potential solutions so we better understand the magnitude, the scope of and the depth of the problems. Is it a standards issue? Is it a technology issue? Is it a data availability issue? What is it? And then, of course, the last topic here in this item. Interoperability standards prior use. It's closed loop referrals. The gap there is there is a lack of cross organization support for closed loop referrals. The opportunity there is to explore the opportunities to advance standards to prove this. And then, of course, what we're recommending as our activity on this item is to review the recent and planned activities of CMS and payers regarding standards needed for closed loop referrals and prior authorizations.

So, really beginning to start to peel back the onion on these very complex issues that have been plaguing us for some time. Questions on this section for interoperability? I see Mr. Arien Malec with his hand up first.

Arien Malec

Thank you. On the topic of patient matching, I think this is, actually, an area where we already have a core standard set of data elements, both in trying in USCDI, as well as the USAT or a standard for address information. And I wonder whether the recommendation here might, at this point, be more tailored towards governance for data collection, particularly data collection at registration and other work flows where patient information is collected such that it can be more adequately matched. Other areas that might help here are more routine verification for higher assurance patient identity and using additional factors for patient information matching. I guess my observation here is that in all of the work that I have done on patient matching and on patient matching algorithms, at the end of the day, I can algorithmically tune. We have got pretty decent open-source documentation, publicly available documentation of linking.

There is some work that I can in the large to tune and optimize matching at high scale. At the end of the day, I am always going to be limited to the quality and the provenance of the data I am using in order to drive additional matching factors. So, an opportunity potentially to hone in on, not just the data that is being exchanged and standards for the data that is being exchanged, but also hone in on standards for governance, provenance, and work flows associated with collecting good patient information at the source. Thank you.

Aaron Miri

Good points, Arien. Thank you very much. No other questions in this section. Again, you can respond with written comment back to Michelle. I think she put it in the chat window. Try to get it to her within a week. It definitely can be considered by the 26th. The next section here is privacy and security. The first there is the public opinion about impact of the use of health IT and privacy and security of data. I think we're seeing this everywhere. So, the issue is does public opinion data already exist that encapsulates user and consumer opinions of certain uses of health information technology, aka contact tracing, ransomware malware attacks? So, the opportunity there is to review and research these use cases and peer reviewed literature.





What we're recommending though is to really assess what's going on right now with public sentiment there. Assess recent literature and suggest areas for more investigation of consumer impact of uses of health IT. You saw folks completely abandon contact tracing apps because of fears of privacy. Completely understandable.

So, how do we better learn what the source root of that is so that way during the next pandemic, we are better equipped? And then, that next section there, alignment of innovation and regulation of privacy and security of data. That issue there of innovation sometimes gets ahead of the regulatory environment, which stifles innovation sadly. So, how do we align the health IT industry to accelerate innovation in areas where existing regulations are in place? And then, I give ONC a lot of credit. Years ago, with a lot of the tiger teams, they try to put out information to say this is how HIPAA, actually, applies the developers. So, we stopped the inadvertent culmination of the wrong information out there. So, how do we do more of it? How do we learn about the federal regulatory activities for all of the agencies of health IT innovation and assess to fit in any gaps and suggest, of course, any course of action from the heels of that? So, how do we do more of that across all domains?

For those two section areas before I go to the next target area, any questions? Patient access information. So, safety impacted mobile health apps. I think we talked about this in the prior section today as well. So, as third-party apps continue to be introduced, the concern about the clinical accuracy of these apps of potential patient harm. Our opportunity there is to support initiatives that review and rank the validity and safety of mobile health applications. There was some great work that was done by ONC there and even started with the chapel way back here in the day. So, it's continued. And then, of course, support, awareness, and education for patients regarding digital therapeutics, leveraging alerts and patient portals, and helping to really spearhead this, the tip of the spear, to keep people safe. And then, of course, the activity we are saying is to define updates to past ONC patient access guides and educational materials needed since the start of the pandemic.

If you recall, about 2016 timeframe or 2017, there was a great patient education site that was put up by ONC. I'm sure it has been updated many times. So, how do we continue to updated that and add more resources to it? And the next section there is the increased health equity. Again, this is very important to us across populations, locations, and situations. So, it's accessibility to health IT making sure that it is successful to all and democratize that information. So, the pandemic has highlighted the ongoing digital divide regarding access to health IT by consumers for purposes of testing vaccine appointment booking, etc. These are just examples. The opportunity there is to learn more about the barriers that populations are experiencing, inequities, and inform mitigation intervention activities and actions to ensure that such information is available to patients as they access other relevant protected health information.

So, what we're recommending are a few things, actually. Explore the barriers of delivery of relevant public health API's, patient portals, mobile device applications, etc. Locate and compile a catalog of efforts across federal agencies to learn from and collaborate with the, aka the FTC, CDC, and others. Discuss patient facing third party apps used to access provider EHR's via API's and public health data systems. And, of course, discuss large scale patient data captured via apps such as the National Institute of Health, All of Us program, things like that. Keep scrolling please. So, for that section, patient access and information, any items there or questions or comments? So, as I said earlier, there is an entire report. This is the executive summary. It was important to put a summary out there of this stuff. But there is an entire giant report,





including user stories and whatnot that try to in plain English explain to folks that are not in our industry just how important and what it would look like if we got some of this right and, more importantly, why we're doing it and recommending what we're recommending.

To the degree of it, I really encourage you to please provide feedback, provide comments. If there are other comments anybody wants to make, please speak up now. Otherwise, please email them in. We will look at them. Try to get them in to us by the 26th and we will definitely look at how we can incorporate an act or at least table it for next year if it is more pertinent for that. No comment goes unheard. Questions, comments, concerns?

Denise Webb

If there are not any other questions or comments on the annual report, we have a few minutes before going to public comment. We can open up the floor to the committee for questions or other general comments that anyone would like to make.

Aaron Miri

What I appreciate about this committee, especially for the new folks that are joining, is the balance between pragmatism and innovation and pushing the envelope. And so, there are no bad comments is my point to you. So, please be creative if there are technologies we should consider. It may be on a future roadmap, which you will see in there what things we are considering maybe like median term out, artificial intelligence, things like that, quantum computing. I like that stuff being a digital nativist. But we have to be pragmatic as well. So, what makes most relevancy right now in the immediate, obviously, public health issues? Awesome.

Denise Webb

Well, if there are no further questions or comments, do you want to go to public comment early?

Mike Berry

I just wanted to check to see if there were any parts of the slide deck that you wanted to go back to?

Aaron Miri

I think we are okay. I really do.

Public Comment (02:43:55)

Mike Berry

Okay. That sounds good. We can skip to public comment. We are a little bit ahead of schedule but that is okay. If you are not ready to give your public comment, you can submit it to our contractor ONC-HITAC@accelsolutionsllc.com.

To make a comment, please use the hand raise function. If you are on the phone only, press*9 to raise your hand. Once called upon, press*6 to mute or unmute your line. All other comments will be limited to three minutes. I will check to see if we have any public comments. I see the first person is Bob Brown.

Bob Brown





Thank you very much. My name is Bob Brown and I wanted to highlight a submission to the committee concerning how IT supports healthcare and interoperability. Our submission is via the meeting's public chat function and includes our contact information. Thank you.

Mike Berry

Thank you. I do not see any other public comments but I will ask our Accel team if they see anything that I do not just to make sure.

Accel

There are no further comments.

Mike Berry

Thank you. I just want to note that our next HITAC meeting is going to be on February 17. So, we hope that you can join us for that. Of course, all of our materials presented today are on HealthIT.gov. You can just Google the HITAC calendar and pull it up that way. Go to today's meeting date and you will all of the materials there, including the draft annual report that Aaron just reviewed with everybody. With that, I will turn it back to Denise and Aaron.

Final Remarks and Adjourn (02:45:57)

Aaron Miri

Denise, do you want to start?

Denise Webb

Well, again, I want to welcome all of our new committee members. Hopefully, you got a nice preview of the work ahead of us and have some ideas about maybe some of the work groups or task forces that you would like to participate on. I do want to remind everybody to provide their written comments. Please read the annual report draft and provide your written comments by January 26 to the ONC-HITAC@accelsolutionsllc.com address. That would be appreciated, I am sure, by Aaron and the rest of his teammates. We are off to a good start. The race has begun to get a lot of work done this year. So, I am looking forward to working with all of you. And until next time, I am going to turn it over to Aaron for his comment.

Aaron Miri

Yeah. We'll close it out here. Thank you all. Welcome, again, to all of the new folks and all of the new faces. We really appreciate the engagement, especially from the new members. Thank you for that. That is exactly what we look for is that really robust, spirited, meaty dialogue so we can get into the meat of this. The more we can surface what's really going on where the rubber meets the road and the friction that exists between systems and whatever are the legacy issues, the faster we can get over them and really shine a light on it. I appreciate ONC leadership for empowering us to go tackle these bold issues and seeing what clever ways we can try to create solutions. And then, I also, again, appreciate this entire committee. And Denise, thank you for your leadership. This is going to be a great year, especially with all of you. And together, we are going to make some really, really good things happen. So, thank you for that. Be safe. Stay safe and be well. Bye, all.

