

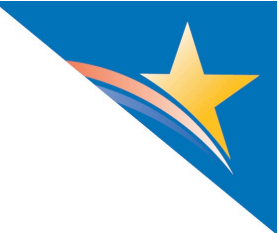


# Transcript

## HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

May 18, 2022, 10:00 a.m. – 12:30 p.m. ET

VIRTUAL



# Speakers

Name	Organization	Role
<b>Aaron Miri</b>	<b>Baptist Health</b>	<b>Co-Chair</b>
<b>Denise Webb</b>	<b>Individual</b>	<b>Co-Chair</b>
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
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
Ryan Argentieri	Office of the National Coordinator for Health Information Technology	Deputy Director, Office of Technology
Mariann Yeager	The Sequoia Project	Presenter
Zoe Barber	The Sequoia Project	Presenter
Chantal Worzala	Alazro Consulting	Presenter
Joel Andress	Centers for Medicare and Medicaid Services	Presenter
Kyle Cobb	Office of the National Coordinator for Health Information Technology	Presenter





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

### **Michael Berry**

And, good morning, everyone. I am Mike Berry with ONC, and I would like to welcome you and thank you for joining the May 2022 HITAC meeting. We are always very pleased that you can be with us. As a reminder, your feedback is welcomed, which can be typed in the chat feature throughout the meeting, or can be made verbally during the public comment period that is scheduled at about 12:15 Eastern Time this afternoon. So, 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 Steve Posnack, the 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 of our HITAC members along with the federal agency representatives of the HITAC. So, when I call your name, please indicate that you are here, and I will start with our cochairs. Aaron Miri?

### **Aaron Miri**

Good morning.

### **Michael Berry**

Denise Webb?

### **Denise Webb**

Good morning.

### **Michael Berry**

Medell Briggs-Malonson?

### **Medell Briggs-Malonson**

Good morning.

### **Michael Berry**

Hans Buitendijk?

### **Hans Buitendijk**

Good morning.

### **Michael Berry**

Thomas Cantilina? Steven Eichner?

### **Steven Eichner**

Good morning.

### **Michael Berry**

Cynthia Fisher? Lisa Frey?

### **Lisa Frey**





Good morning.

**Michael Berry**

Raj Godavarthi?

**Rajesh Godavarthi**

Good morning.

**Michael Berry**

Valerie Grey will not be with us today. Sanjeev Tandon?

**Sanjeev Tandon**

Good morning.

**Michael Berry**

Steven Hester?

**Steven Hester**

Good morning.

**Michael Berry**

Ram Iyer? Jim Jirjis?

**Jim Jirjis**

Here.

**Michael Berry**

And, we have a new federal representative, Meredith Josephs. John Kansky?

**John Kansky**

Good morning.

**Michael Berry**

Ken Kawamoto? Steven Lane?

**Steven Lane**

Good morning.

**Michael Berry**

Leslie Lenert? Hung Luu?

**Hung S. Luu**

Good morning.

**Michael Berry**





Arien Malec? Clem McDonald? Jonathan Nebeker?

**Jonathan Nebeker**

Good morning, folks.

**Clem McDonald**

I am here.

**Michael Berry**

Thank you, Clem. Aaron Neinstein?

**Aaron Neinstein**

Hi, good morning.

**Michael Berry**

Eliel Oliveira? Brett Oliver?

**Brett Oliver**

Good morning.

**Michael Berry**

James Pantelas? Raj Ratwani?

**Raj Ratwani**

Good morning.

**Michael Berry**

Michelle Schreiber?

**Michelle Schreiber**

Good morning.

**Michael Berry**

Abby Sears?

**Abby Sears**

Good morning.

**Michael Berry**

Alexis Snyder?

**Alexis Snyder**

Good morning.

**Michael Berry**





Fil Southerland?

**Fillipe Southerland**

Good morning.

**Michael Berry**

Ram Sriram? And, Sheryl Turney?

**Sheryl Turney**

Good morning.

**Michael Berry**

Good morning to everyone, and thank you so much, and now, please join me in welcoming Steve Posnack for his opening remarks. Steve?

**Welcome Remarks (00:02:50)**

**Steve Posnack**

All right, thanks, Mike. Mike always does such a great intro. If you would like to book him for conferences, narrator gigs, voicemail records, or other cameos, I only take an eight percent cut. So, good morning. Thank you, everyone, for joining HITAC today. It is one of those rare spring moments in the D.C. area, and like you may recall from school, I would really like to say I am really tempted to tell everyone we are taking class outside, and then we are going to have a heat wave this weekend, so, what can you?

As Mike alluded, we have a new federal representative on the HITAC. I would like to welcome our rep from the FEHRM, the Federal Electronic Health Record Modernization Office, Dr. Meredith Josephs, who is the Chief Medical and Informatics Officer with the FEHRM and will be serving as its representative, so we look forward to her contributions. For those of you who attended the annual ONC meeting, I want to thank you, and including our HITAC members who participated. We had a great turnout, many insightful presentations and presenters, discussed health IT, health equity, public health, patient access, and overall electronic health information exchange, and so, again, we cannot do those types of events without you, so we really appreciate you lending your time and expertise to the ONC annual meeting and any future engagements that we may have, which we definitely have some coming up toward the latter half of the year. You will be able to access and you can access all of the recorded sessions and presentation materials on HealthIT.gov.

I also just wanted to look back at the past couple weeks. We had Public Service Recognition Week, and again, I want to extend my thanks to all of the folks at ONC in particular. I am biased, but if you do have a chance to thank a fed or other public servants, please go ahead and do so. And, in that same regard, ONC also celebrated its 18th birthday, if you can believe it, as of last month, April 27th, and as many of you know, the HITAC happens to be Advisory Committee Version 4 for ONC during this period, so here is hoping that the fourth time is the charm. We love HITAC, and it has been working pretty great for us.

So, with that said, the ONC buzz blog has really been running hot in the past couple of weeks. I want to thank our staff, who are churning those out and putting them through the communications pipeline. Yesterday, we put out an update on the FIT program and public health informatics workforce-related issues. We introduced LEIDOS as the new ONC-authorized testing lab, so, a certification program. Even though it





may just seem like it is chugging along, it still has changes over time, so I would encourage you to check that out. We have put out a blog post on the STAR HIE program and updates, and then, on Monday, we jointly published a post from us and the Sequoia Project on TEFCA updates related to schedule for the standard operating procedures, which is my well-placed segue to say that we have asked Mariann Yeager here today from the Sequoia Project, who is leading testing implementation, to give you all an update on our progress since launching it earlier this year.

So, in closing, I just want to thank everybody again for taking time out of your day to be part of HITAC and for joining us, and with that, I will turn it back over to Aaron and Denise to get through the formal parts of today's agenda. Over to you.

### **Opening Remarks, Review of Agenda and Approval of April 13, 2022 Meeting Minutes (00:06:23)**

#### **Denise Webb**

All right. Thank you, Steve and the whole ONC team, for all of your great updates and for the excellent annual meeting program. I did get to participate in a few of those sessions. So, we have some good presentations today. We will not be voting on anything. I welcome our committee back for our monthly meeting. And, I do not know if Dr. Meredith Josephs has joined yet, but if she has, I want to give her a warm welcome for joining our committee. I am sure she will find it very valuable. And, with that, I am going to turn this over to Aaron for his remarks, and he will go over the agenda and get our vote on last month's meeting minutes.

#### **Aaron Miri**

Absolutely. So, welcome, everybody, to this month's meeting. As Denise was saying, welcome to today's meeting, and I love Steve's opening comments there. We are 18 years old. That is fantastic. So, it is all real from this point forward, as I guess we usually tell 18-year-olds on their birthday, so, get ready to pay your taxes and now be an adult, so, there we go. Anyways, welcome to the meeting. We are going to go through today's agenda and take a vote on last month's meeting minutes, but let's go through the agenda first.

So, obviously, we just had remarks. First will be the Interoperability Standards Workgroup Update, led by Dr. Lane and Arien Malec, then we are going to go through our TEFCA update led by Mariann Yeager and her team, then we are going to do a CMS quality initiative and ONC UCSDCI Plus quality domain update, then we are going to go to public comment at 12:15-ish, and then final remarks and adjourn, so it should be a quick meeting today, but meaty nonetheless and well worth the engagement. So, let's take a vote on last month's meeting minutes. Hopefully, you got them in your email and you have had a chance to review. So, can I get a motion to approve?

#### **Medell Briggs-Malonson**

This is Medell Briggs. So moved.

#### **Aaron Miri**

Thank you. May I have a second?

#### **Sheryl Turney**







Sheryl Turney, second.

**Aaron Miri**

Thank you. All those in favor of approving last month's meeting minutes, please signify by saying aye.

**Several Speakers**

Aye.

**Aaron Miri**

Any opposed, say nay. And, any abstentions? All righty, then. I think we have approved the meeting minutes from last week, and Denise, I will turn it back to you.

**Denise Webb**

All right. So, we are ready to get started with our agenda, and our first presentation will be from Steven Lane and Arien Malec, our workgroup cochairs for the Interoperability Standards Workgroup, so I will turn it over to you, Steven.

**Interoperability Standards Workgroup Update (00:09:11)**

**Steven Lane**

Wonderful. Thank you so much, and good morning, everyone. Thanks again for the opportunity to come and present a brief update on the work of our Interoperability Standards Workgroup. We can go ahead to the next slide. So, we are just going to talk a little bit about what the HITAC charged our workgroup with doing, we are going to remind you of the HITAC priority use cases that have been identified that have really been the principal focus and target of our workgroup's work, go over our membership, talk a little bit about the focus we have had, the meetings we have carried out, and the remaining work before us, so this is really just a brief update along the path. Next slide.

So, this was the charge that the workgroup received. You will recall that there had been prior task forces over the past few years that we have all had the chance to participate in. This year, we came together as a single workgroup to evaluate both the draft USCDI Version 3, and you heard our recommendations about that last month, and now, we are involved in our second charge, which is looking at the ISA and providing input to that and improvements that can be made along the way. I will just remind you that the ISA has been with us for quite some time. It was first published in 2015. It has been updated continuously ever since then with a reference edition being published each year, and the ISA really is the tool that the ONC uses to identify and evaluate the maturity of health IT standards that are used across the industry to support interoperability nationwide, so it really is the catalog of what is out there and its state of adoption, and then we reference that when we put together the USCDI each year. Next slide.

So, these are the HITAC priority uses of health IT. I believe these were identified initially as we started the HITAC some years back, and I believe they have evolved just a bit over time, but we are looking specifically at the uses of technology to support public health, clearly a big focus now with the continuing pandemic, interoperability writ large across the industry with multiple stakeholders, privacy and security, and patient access. So, much of the work we have done, both with regard to developing recommendations for the USCDI and now the ISA, is really focused on these areas, not to say that our group does not come up with additional ideas that we want to comment on as well. Next slide.





So, this is the roster. It has not changed substantially. A number of you have been quite involved, and we have really had great input also from members of the public. We have had a whole host of meetings and presentations, and Arien, are you on? He is not, okay. So, let's go ahead to the next slide and talk just a little bit. One of the things that we did do is we have interacted substantially with the ONC team that is supporting the workgroup and asked them to provide input in terms of their priorities. We started with a set of topics and areas of focus that came to us from last year's Interoperability Standards Priorities Taskforce, so we inherited a number of items from prior work, and then the ONC helped us by identifying these as areas in which they were particularly interested in receiving input.

So, lab orders and results has been a hot topic in our workgroups for a number of years, SDOH is obviously increasingly important, though actually, it has always been important, but there is increasing awareness of its importance in terms of health IT standards, patient access, electronic case reporting, and interoperability standards advisory enhancements. Whenever you work with a system such as the ISA that has been around as long as it has, each year, you look at it with fresh eyes and you can see opportunities to improve it, so we are digging in there and making some structural suggestions as well. Next slide.

So, these have been a series of presentations that we have had to the workgroup from subject matter experts in these specific topic areas. We have dug deep into lab data standards to look at how that has evolved and how our recommendations in that area can evolve with it to move us towards more specific interoperability, semantic interoperability of laboratory data. We had the Gravity Project back to update us on the work that they have been doing with HL7 in the space of social determinants of health and got a lot of useful input there. We have been digging into the electronic case reporting standards and seeing how those are evolving very actively this year and provide an opportunity for the ISA to be updated to reflect the latest standards, and hopefully to see some advancement in terms of requiring the use of those standards going forward.

And then, there has been a strong interest in looking at the technology solutions that are available to support individuals in exercising their rights to request corrections to their records that are granted under HIPAA. This has been a patient right for many, many years, but there really have not been technical standards to support that. HL7 Patient Empowerment Workgroup has been doing a lot of work in this area, and they have educated us and will be bringing forward some recommendations related to that. So, a great example of real public engagement in the work of the HITAC to bring forward these new opportunities. Next slide.

So, we have just a few meetings left before we return to you next month with a full set of recommendations. We will probably come back with maybe 20 or so recommendations with a number of subtopics within them, so I think we will have a robust set of recommendations for you to consider next month, and I think that is the end of the presentation, if you want to go to the next slide. I am happy to take any questions that you may have about the work of our workgroup.

**Aaron Miri**

Fantastic. So, for HITAC panelists, please signify by raising your hand if you have a question, and I will call upon you in the chat window. Let's see who had their coffee this morning and is ready to ask Dr. Lane some questions.





**Denise Webb**

I think they are letting you off easy today, Steven.

**Steven Lane**

That is okay. We are expecting a lively discussion next month when we come back with some of the meat on these bones, so we will look forward to that, and again, just a huge thanks to the members of the HITAC and the public who have been participating in this work, some just very actively with a lot of useful input, so we are most appreciative.

**Aaron Miri**

Okay. Well, then, I think if there are no questions from the HITAC, we will move on. We will be a little head of schedule here, then. All right. So, Denise, should we go to the next one?

**Denise Webb**

Yeah. So, next we have the TEFCA update, which I think we are all anxious to hear where we are at with, so I will turn it over to Mariann Yeager, and she has a couple of her folks with her that she will introduce.

**Michael Berry**

I am not sure if Mariann has joined us yet. Zoe and Chantal, are you able to kick us off while we wait for Mariann?

**Denise Webb**

Are they on?

**TEFCA Update (00:18:09)**

**Chantal Worzala**

I was being very good about muting myself. This is Chantal Worzala. I am a consultant to the Sequoia Project on their RCE work. I will go ahead and get us started. Mariann is just finishing up a presentation with the DOD, so she will be joining as soon as she can, but why don't I go ahead and get us started so that we can keep the ball moving? So, I am very pleased to come back and share an update of where the RCE is in really operationalizing TEFCA, and I really want to give a shoutout to our partners at ONC, who have really helped move all of this forward, thinking through the policy issues that are really very important from the federal government level, and as Steve noted, there was a blog released earlier this week bringing forward the timeline to really lay out the detailed operational policies that will guide our nationwide exchange infrastructure.

So, on the next slide, this is just the requisite disclaimer that the Sequoia Project is doing this work under a cooperative agreement with the federal government. Next slide. And, what we are doing here is presenting what was in the Common Agreement Version 1, our QTF, and the SOPs released on January 18. This is not a legal document, although we try to be very accurate, and now that I have gone through the disclaimers, I am going to go ahead and hand it back over to Mariann to do the meat of the presentation.

**Mariann Yeager**

Thank you, Chantal, for pinch-hitting. I was detained on another panel, so, thank you all very much for inviting us here today. So, what we are going to talk about, if you go to the next slide, is we want to provide





a brief context about TEFCA for those who do not think about it every single day like we do, share more about the components and the timeline, and then we are going to share some of the late-breaking news from this week, where we will talk about the status of the standard operating procedures and the release schedule, and then I will turn it over to Zoe and Chantal, who will walk through the draft standard operating procedures that we released earlier this week.

So, if we go on to the next slide, again, for those of you who do not think about TEFCA day in and day out, this really came about as a result of 21st Century CURES Act. They directed ONC to develop or support TEFCA, and really, ONC serves to define the overall policy direction. There are certainly some inherently governmental functions that they have to retain with respect to governance, just ultimately approving common agreement and changes to it, etc. We were really honored to have been selected as the RCE, recognized coordinating entity, in August of 2019, so we are in year three of our cooperative agreement, with year four starting in August of this year, and in our role, we are helping ONC develop the components to operationalize TEFCA. We will serve an operational role, working to onboard and designate QHINs, and then support the governance approach for QHIN-to-QHIN exchange.

The heart of TEFCA is really those networks that want to seek a special governmental status as a TEFCA qualified health information network, and really, TEFCA puts forward the expectations that QHINs have to meet to be designated as such and to exchange information with each other directly, to basically support a nationwide backbone, and each QHIN network itself connects its own respective set of participants and sub-participants, and there are flow-down obligations that go along with that.

So, that is really some background on TEFCA. If you go to the next slide, there are seven components. There is the trusted exchange framework, which is the policy parameters that really underpin TEFCA, and then memorialized in agreement. The common agreement is the single contract that all QHINs have to sign, along with the RCE. It points to other operational details that are memorialized in standard operating procedures. It also points to an implementation guide that QHINs have to support called the QHIN technical framework. And also, just this week, we put forward more details on a QHIN onboarding and designation process that is in draft form and a draft application, and then, once this operational, then QHINs will actually be expected to report certain metrics and abide by the governance approach that, again, have all been memorialized. So, we really can check all seven boxes, and of course, we will continue to evolve those over time.

So, if you go to the next, when we think about the timeline to operationalize TEFCA, I also wanted to take stock at the progress that we have made and really just point to how much this has accelerated over the past three years, and in particular over the past year or so with the leadership of our national coordinator, Micky. So, we think about harkening back to 2009, HITAC really spoke to the need for a nationwide health information technology infrastructure, and in December 2016, again, 21st Century CURES Act was passed. Fast forward a little over a year, and in January 2018, ONC released the draft trusted exchange framework, and then, fast forward about 15 months, when ONC released Draft 2 of the TEF and a set of minimum required terms and conditions, which were key elements of what was intended to be part of the common agreement.

In late August of 2019, we were selected the recognized coordinating entity, had to get up to speed very quickly, and of course, having a decade of experience working on frameworks and trust agreements, we





really hit the ground running with our ONC team, and over the next 18 months between 2020 and 2021, we really actively engaged stakeholders, formed a common agreement workgroup, and really worked closely with our ONC colleagues to inform the draft versions of the common agreement and QTF, which were published in August of 2021.

With Micky's leadership, you are going to start seeing the timeframes go from years to months, and now weeks, and so, four and a half months after that, we published the first version of the common agreement and the QHIN technical framework on later materials. Just a handful of months after that, on May 16th of this year, we released the draft QHIN application and additional standard operating procedures, and then, over the next several weeks and months, we are going to publish additional artifacts, so we will need to launch the program and open up the application process for candidate QHINs in late summer/early fall.

You can see that we are nearing operational timeframe, and fast forwarding ahead, we will continue to support additional use cases, onboard QHINs, establish governance, and really begin that rollout in earnest in 2023, also recognizing that in August of 2023 is technically the end of our term under the cooperative agreement with ONC, but there is no shortage of work, certainly, to continue, so we are really excited about that opportunity. So, if we go to the next slide, I think this is where I turn it over to Zoe. Oh, actually, I am going to cover this, excuse me. I was going to pass it off to Zoe, and I am supposed to cover the SOP status and release schedule.

So, if you go to the next slide, one of the things that we really appreciate in working with our colleagues at ONC is it is not just an aspirational goal. We come up with plans, and we deliver on it together as a team, and so, the timeline I shared is just really a statement and a testimony to the commitment that we have as an RCE team. Certainly, with the ONC team, we are really working under a cooperative agreement and brought on the inside of a governmental process, which is such a unique opportunity to channel everything we have learned and experienced over the past 10 years to really bring in perspectives from many different stakeholders, and we really see that, again, with Micky's leadership and the leadership of the ONC team, we have been able to make great progress.

So, we did publish seven SOPs in January. I think there should be another bullet between dispute resolution and governing council. Three were related to governance approaches. There was conflict of interest, dispute resolution, which is ever important, and then two related to security around cyber insurance and QHIN security.

We were really delighted on Monday of this week to put forward two draft SOPs, one related to onboarding and designation of QHINs and the accompanying application as well as a draft standard operating procedure on the types of entities that can participate in TEFCA. We are seeking feedback on those three artifacts. We also published an updated SOP related to the QHIN security requirements to protect TEFCA information, and this was updated to address how the process for selecting third-party certifications will work, as well as publishing the first certification that we will recognize, just acknowledging that there will be others that we will approve over time.

So, if you go to the next slide, this is the list of SOPs in our schedule. Again, this is a work plan. We have a work plan, and we are delivering on it. We track progress; we work with the ONC team literally every single day hand in hand. So, you can see that we have two coming forward in June, and the first seven or





eight on this list are really needed for launch. So, again, we were going to see progress here in weeks and a handful of months, and then we are basically open for business as soon as these other exchange purpose implementation SOPs are published. So, in June, we will publish two more.

The exchange purposes SOP will spell out how the treatment in individual access services which require responses, so QHINs and participants basically have to respond to requests where they have information on that individual and where they are permitted to release it. Then, in July, we will release the final version of the types of entities that can participate in TEFCA, followed quickly in August by the actual updated QHIN onboarding and designation SOP and the application, as well as several other SOPs which have not been submitted/released in draft form yet, but that will, and that is around foreign ownership in more details to implement the individual access service use case specifically around the security expectations, the privacy and security notice, and then the exchange purpose implementation SOP.

And then, following that, you will see a series of SOPs that we will continue to release. I do want to call out that there are two additional exchange purpose implementation standardized operating procedures that need to be specified. We heard from stakeholders very clearly that we need more implementation-level details in order to support payment and healthcare operations. We all recognize that there is a pretty massive set of workflows that can be supported, and so, we felt that it was important to really respond to that and have thoughtful implementation details to support that, as well as public health and government benefits determination.

I also want to note that the private sector has really been trying in earnest for several years to come up with a way to support payment and health through operations, and it has just been really difficult to move the market with the private sector pursuing that alone. So, the benefit of having government leadership to advance that will help us accelerate it. So, again, here are in May of 2022. To have an operational implementation guide that we believe is market ready and that we have assurance it will be adopted is just a number of months away, so again, we really believe that having ONC leadership and working side by side with them has been an accelerant. So, with that, I do think at this point, it is ready to turn it over to Zoe go into a little bit more detail on these SOPs. Zoe?

**Zoe Barber**

Hi, everyone. Thank you so much, Mariann. I am going to talk through the next two documents and then turn it over to Chantal. So, first, I will talk about the draft types of entities that can be a participant or sub-participant in TEFCA. Go to the next slide. Great. So, as the title of this SOP illustrates, the purpose of this SOP is to clarify the types of entities that are entitled to request information under one or more of the exchange purposes, and to clarify, these are the types of entities that can participate in TEFCA. And, the primary condition for this definition is that in order to participate as a participant or sub-participant in TEFCA, you have to be the type of organization that is entitled to request information under one or more of the exchange purposes.

And so, as we have talked about in the past, the first version of the common agreement authorizes six exchange purposes, and those are treatment, payment, healthcare operations, individual access services, government benefits determination, and public health. And, as the TEFCA evolves and grows, it is likely that that list of authorized exchange purposes will expand, and so too will the types of entities that can participate in TEFCA.







But, that said, this is a fairly comprehensive list, and the majority of organizations that do want to participate will find themselves fitting under one or more of these categories, particularly under the category of covered entity or business associate. But, of course, this SOP is open for feedback, so we are accepting public input, and we would welcome public input from the HITAC, whether on this call or in writing, and so, please let us know if we have hit the mark on this definition or if we are missing something. Next slide.

Okay, next, I am going to talk about the draft QHIN application. Go to the next slide. First, I am going to tee up the application process, and this slide really covers everything from pre-application all the way through the QHIN onboarding and designation process. So, the first step in the process is for prospective QHINs to really educate themselves on what is required when they join the TEFCA network, so, attending all of our many webinars and educational sessions and reviewing the common agreement, the QTF, and the SOPs, and we actually ask for prospective QHINs to let the RCE know their intention to apply prior to actually submitting the application package, so that way, we have some time to work with them and to make sure that they have everything needed to go through the application process in length.

Next, we will provide the application package, and a prospective QHIN actually signs the common agreement ahead of time, and then submits the application package. The RCE will then work hand in hand with that applicant every step of the way to make sure that we have all of the documents that are needed to ensure that we have a complete application. This is really meant to be a collaborative mutual process, really trying to help that applicant move through the steps smoothly.

We will make an eligibility determination once we have a complete application, and then, once an application has been accepted, the prospective QHIN will begin the onboarding process, which could take up to 12 months, so the onboarding process does include an initial round of testing, which includes some manual testing as well as preproduction testing with other designated QHINs or applicant QHINs if there are no designated QHINs, and prospective QHINs have 12 months to work through this process, and again, this will be a very collaborative process where we will be working with the prospective QHINs every step of the way to make sure everything is going smoothly and to give them as much support as possible.

And then, once the testing process has been completed successfully and all of the onboarding requirements are met, the RCE then countersigns the common agreement and actually designates the QHIN. We also will provide notice of that designation to both the applicant and to ONC in writing. And then, just a couple more steps, actually. Once an applicant is designated and becomes a QHIN, they will be added to the RCE directory, and then, at that point, there is a final stage of postproduction testing that will occur within the first 30 days to really make sure that the QHIN is up and running.

So, if you go to the next slide, the actual application itself is really intended to provide the recognized coordinating entity with the information that we need to determine whether a prospective QHIN has the ability to meet its obligations and responsibilities under the common agreement. Becoming a QHIN is not something to be taken lightly.

It is an enormous responsibility, and there needs to be the appropriate amount of resources and infrastructure to ensure that the QHIN can manage the large volume of transactions that will take place on a day-to-day basis, and also to ensure that there is appropriate trust and reliability within the network, and





that is why the application and onboarding process is so involved and so collaborative and there is so much testing, because we really want to make sure that when these QHINs go into production that they are then not going to fail and potentially derail the entire network, so we want to make sure that we are doing the work ahead of time to prevent any kinds of failures or delays down the line. So, the application is really designed to ensure and to allow the applicant to demonstrate their readiness to join that community of trust and to manage that enormous responsibility.

And, of course, the application does include a fair amount of confidential information that QHINs will have to submit, and that will be treated as confidential information, and the RCE is working on a process right now to make sure that all of those documents can be uploaded to our website in a secure fashion. Next slide. Great, and now I will hand it off to Chantal for the onboarding and designation SOP. Thank you.

### **Chantal Worzala**

All right, thank you, Zoe. On the next slide, the onboarding and designation SOP covers in great detail the steps that Zoe just went over, and really, the goal here is to make sure that there are no surprises in the process and to lay out something that is fair and workable, and ultimately results in successful exchange in production. So, this process is in the SOP in draft form, and so, we really are looking for feedback, particularly on the timelines that are laid out for the various steps in the process.

This slide has the eligibility requirements that are derived from the common agreement. I will simply add to what Zoe said, that in addition to designation as a QHIN, there is also the possibility to be given a provisional QHIN status. I know that is something that the HITAC discussed last time we were here, and so, I just wanted to circle back and confirm that that is part of the process.

On the next slide, the SOP has four sections, and it pretty much goes through what you would expect. What do you have to do to become designated as QHIN, including the application process, the testing process, and then the designation? And so, again, if there are prospective QHINs out there...well, we know there are prospective QHINs out there, but we are very much looking for your feedback to make sure this is a workable process for both sides, the RCE and those who are applying.

On the next slide, there is an updated SOP. This is final. It is not out for comment, it is an update of what was released in January with respect to QHIN security for the protection of TEFCA information. On the next slide, the goal here is to make sure that this nationwide health information exchange infrastructure is indeed as secure as it can be because of course, healthcare is part of our nation's critical infrastructure. And so, we have updated the SOP to include a list of approved QHIN cybersecurity certifications, and if you go to the next slide, you will see that we now have a link on our website where you can find the list of currently approved certification. We have also added very specific requirements for the scope of both the third-party certifications and the annual technical requirements, and we do want to note that if there is a certification body that believes they meet the requirements and they would like to be considered to be added to the list of approved certification, they can request approval from the RCE. So, with that, I will go ahead and hand it back to Mariann.

### **Mariann Yeager**

Thank you, Chantal. I think we wanted to just do a quick recap, if we wanted to move to the next slide. So, again, we published the release schedule in conjunction with the ONC on Monday, so that is available, and







of the SOPs we put forward, we are opening up two of them for input. To be honest, the QHIN onboarding and designation standard operating procedure and application are really largely geared toward QHINs, so we are expecting to hear from candidate QHINs that are interested, but of course, we will always take feedback from others, and we are definitely interested in getting feedback on the types of organizations that can be participants and sub-participants, which, again, are largely geared toward interpreting the exchange purposes. We are very much looking forward to receiving feedback on our monthly calls, and as we move forward with working on the payment and healthcare operations implementation standard or operating procedure, we will really be engaging input from subject matter experts, and also having dedicated calls where we will delve into those details as well.

We have worked on an approach and a work plan to implement the FHIR roadmap, so, stay tuned. We will have more information on that forthcoming, and really, again, we look forward to any insights and feedback from this group. With that, we can go to the next slide. And, here are links to all of these resources. We will have a webinar, and on May 25th, we will actually do a drill-down into more detail on the application and onboarding designation process itself. There is a lot of detail there. There is some complexity. And so, since that serves as the gating mechanism for organizations that seek QHIN status, we obviously want to make sure there is ample opportunity to understand it, and then elicit feedback proactively. So, with that, I think we will open it up to discussion with the committee.

#### **Denise Webb**

Thank you, Mariann, Zoe, and Chantal for all of that great information, and I also want to mention that Mike and Chantal did put some links in that, first for the meeting materials for today, and then others for the RCE resources. So, we do have a couple hands up, and I have a question too, but I will wait for my question, and I will start with Steven. Please, Dr. Lane.

#### **Steven Lane**

Thank you so much, Denise, and thank you, Mariann and team, for a great presentation. I want to remind the HITAC that I serve as the chair of the Care Quality Steering Committee and the immediate past chair of the Sequoia Project, so I have had kind of a ringside seat as this TEFCA work has moved forward, and it has really been exciting. I have not been actually on the team, but have certainly gotten updates along the way, and as I said, the team has been doing great work. I want to remind everyone that TEFCA really builds on the vision that was first put forward in the HITECH Act way back in 2009 to establish a nationwide health information exchange infrastructure that we have all been working very hard on here within the HITAC, and many of us were here when ONC began this work back in 2016 and put forward their policy framework, and then, in 2019, when the Sequoia Project was selected to serve as the RCE. And, since then, and especially under Micky's leadership, we have seen this incredible acceleration of the progress, to the point where we can actually anticipate operationalization of this in this year.

But, what I can see is that the success of this, since it really is still a voluntary framework for nationwide interoperability, it is really going to require ongoing collaboration across the public and private sector, and across the multiple federal agencies, and that we are really going to need to see widespread participation if we are going to build the case for TEFCA adoption and realize its potential benefits. So, one thing that is worth noting is that CMS, which, of course, is the largest healthcare payer in the country, has specifically asked for public feedback on advancing TEFCA participation through their many programs, and I just wanted to really encourage everybody as much as possible to consider commenting on that and





encouraging CMS to really participate and engage, and to provide opportunities to support TEFCA-based exchange through their programs because I think that is going to be central to the ongoing success of this. So, thanks again.

**Denise Webb**

Thank you, Dr. Lane. I appreciate that encouragement and extra information. Our next question is from Jim Jirjis.

**Jim Jirjis**

Hey, Mariann. Thank you so much for the hard work and the presentation. Boy, we are getting close. The question I had was if it is not too early, can you give us a little insight into the reason an HIE or other entity might want to become a QHIN instead of connecting to a QHIN, and what are the types of organizations and how many are there that are raising their hands to go through the process? What is the nature of such organizations?

**Mariann Yeager**

It is interesting because over time, there are different groups that have reached out to us and expressed interest in becoming a QHIN, and I usually turn it back around to them and ask, "Why would you want to be a QHIN?", so I have gotten some interesting perspectives on that from them. I think the onboarding and designation SOP is really, really important because I think that lays out pretty clearly what the expectations are at an operational level from a governance perspective. It is more than just technical capabilities. There is a role for all.

My sense is that the groups that already have these competencies as part of their business probably will find it is not as big a leap to seek QHIN status versus those that maybe serve in a technology-enabling role or in a facilitative role. You really have to have all of the above. So, what we are seeing is that there is an interest in why there is a lot of value in having a government-designated status. That is very appealing, and we have heard that time and again. We have seen that they see this as an opportunity to participate in supporting traditional use cases beyond treatment-based exchange. The private sector has done a phenomenal job in advancing treatment-based exchange, and I think we have talked about this before, and Micky has even stated that. It is becoming far more ubiquitous to support treatment-based exchange, but the private sector has not been able to really move the needle in supporting payment, and healthcare operations, and having a single nationwide approach or consistent nationwide approach to support certain public health use cases, and that is a tremendous, tremendous opportunity, and we are just seeing that there is a really strong interest from a number of groups to participate in that.

Ultimately, they need to go through an evaluation. Should they seek to be a QHIN? Do they have the processing capacity, the security, the resources, the ability to process high volumes of transactions as one of the nationwide nodes in this nationwide network of networks, or is it more appropriate for them, and better, and a better fit to participate in a particular QHIN? So, I think it is really evaluating options, and we hope that with this additional information, those who are considering QHIN status will do the due diligence. Please do that before applying. The last thing we want is for an organization to submit an application without having really fully understood what the expectations are, without thinking about the resource requirements and expectations, and we will work very collaboratively with them, but the last thing we want to do is deny someone becoming a QHIN because they did not even do the due diligence before applying.





In terms of how many, anecdotally, we have an idea of those who have expressed interest, but we will not really know until they reach out to us and indicate and express their interest in seeking QHIN status, and until they submit the application itself, but there is a healthy interest, I will say that, and from a pretty diverse group.

**Denise Webb**

So, Mariann, related to Jim's question, I had a similar question, but it was around individual access services. I know that some of the health information exchanges, the state-level exchanges such as in New York, are actually going to be offering individual access services and, in fact, are requiring their participants within their statewide exchange to provide individual access services to any of their providers' patients that are participating so that they can get their data that is held in the state exchange. Who do you envision or what types of entities do you envision outside of these HIEs that might come in and want to offer individual access services as a QHIN? I think I remember that anybody that is an eligible participant has to comply with the HIPAA requirements, even if they are not a covered entity. Is that correct?

**Mariann Yeager**

So, there are a couple things to unpack there. One is every QHIN has to support all of the exchange purposes. Technically, there are responses that are required for individual access requests, so that is correct. The expectations for someone that provides an individual with the capability, such as a platform or app, for instance, to request and gather their health information is subject to an additional set of requirements. There are expectations around privacy and security, there are expectations around notice, and other expectations as well. The gap we were able to address around privacy and security is really important to note because we are assuming that most QHINs and participants and sub-participants are likely subject to HIPAA. For the most part, they are probably other covered entities or business associates in their own right.

However, there are healthcare providers that do not participate in administrative transactions and may not be subject to HIPAA. There could also be these individual access service providers that may themselves not be subject to HIPAA in any respect, and what we heard from stakeholders pretty clearly, which has been an issue that we have observed in the private sector that we facilitated at first, is that there is an interest in having a bar that is consistent across the board for all actors regardless of whether they are really subject to the HIPAA rules or not, and so, there are provisions that do put forward an expectation that if you are not directly subject to HIPAA, you have to comply as if you were, and there are certain requirements linked to that, so that addressed a pretty big gap that we saw as an impediment, and of course, when we put forward the additional standard operating procedures around individual access to services, there will be more detail to unpack around how that will play out.

**Denise Webb**

Yeah, and what I meant to say is that these other entities might not want to be a QHIN, but they would be an eligible participant or sub-participant.

**Mariann Yeager**

Right, exactly. We are thinking for the most part that that is the role they will play as a participant, largely as a sub-participant.





**Denise Webb**

Well, I think that provides a lot of assurance, especially for a number of CIOs from the healthcare entities, because they have been very concerned about the individual access services and commercial entities providing those services not being subject to HIPAA, but if they are going to participate in this exchange network, they are going to have to comply with that, so that is reassuring.

**Mariann Yeager**

The other thing to note, too, which has come up a lot on that is who is going to vet these app providers? Well, if a QHIN connects an IAS provider as a participant to their network, then they are obligated to make sure that their participants comply appropriately, and so, we do not know what sort of vetting they might do of an IAS provider, but there are specific expectations around identity proofing and privacy security notice, all those things, and so, there will be accountability in governance to reinforce that as well.

**Denise Webb**

Great, thank you. So, are there any other questions from our committee members? I do not see any hands up. No? All right, well, thank you, Mariann, Zoe, and Chantal. We really appreciate the information, and we look forward to more updates in the future.

**Mariann Yeager**

Thank you.

**Denise Webb**

All right. So now, we are going to transition to Joel and Kyle to give us a CMS quality initiative and USCDI Plus quality domain update.

**CMS Quality Initiative and ONC USCDI+ Quality Domain (00:55:21)**

**Kyle Cobb**

Hi. That is a tongue twister, isn't it? Hi, this is Kyle Cobb, and, Joel? Maybe you are on mute.

**Joel Andress**

Sorry about that.

**Denise Webb**

There he is.

**Joel Andress**

Good morning, everybody. Thank you for having us.

**Kyle Cobb**

Okay. Well, shall we get started, Joel? Let's look at this. By way of introduction, Joel and I have been working on this project for the last year, and it has been moving along somewhat slowly, but we have been getting all of our ducks in a row to really get to work pretty soon, we hope, and we presented this presentation that we are going to walk through today at HIMSS, and we have also shared it with some other





groups over the last few months, really just walking through what we are doing specifically around ONC's USCDI work and USCDI Plus work and how it relates to CMS's quality initiatives.

So, with that, maybe we could go to the next slide. So, like I said, the learning objectives are to really look at how we are coordinating and how we see this project as being rooted with these data elements and how they inform the new quality measurement paradigm, and then, finally, how USCDI really becomes the underpinning of that. Next slide. Over to you for this one, Joel.

### **Joel Andress**

All right, thanks, Kyle. So, in thinking about how we are going to engage with everybody else from our little corner of quality measurement with the broader community pushing for interoperability and data exchange, we kept coming back to this concept of the learning health system. It is not, of course, unique to us in any way, shape, or form. This graphic was adapted from one that the CDC had itself adapted from a graphic of the learning health system from an HL7 CQNI workgroup.

The concept that we want to pursue, which I think this reflects pretty well, is that we want the data requirements, the administrative burden associated with quality reporting, and the byproduct of those requirements, that is, the data, to be integrated within the rest of the healthcare data system, and this is reflect in the concept of a learning healthcare system because the greater part of the work is about setting up the infrastructure within the systems that capture data, that report data, that transmit data between different points in the healthcare system, such as payers, providers, patients, and others, and ensures that they follow a set of common standards, but also share a set of common expectations about what data are required, and by building this, you have not only the underlying infrastructure the data are able to pass through, but you also have an understanding of what data should be traveling through that infrastructure, and ensuring that the data that are being captured are able to support the various use cases that we can identify within the learning health system. We must adhere to some of the larger and more well-known functions.

There are others, and some functions, of course, that we could get into for quite a bit of time, but the problem that we have had with quality measures for a long time has been that we are seen as an adjunct or an add-on to the healthcare information system. That is, we are an additional administrative burden that is done in addition to providing care for patients, and the goal of what we are going to be talking about today is moving to a state where quality measurement is a byproduct of the provision of care and input into developing our understanding about care, and to ultimately improve the care that is being provided to our patients.

I think much of our work for this past year has been focused on establishing a pathway to build out commonly accepted standards of data formatting for data elements that are required across the series of use cases within the healthcare system and ensuring that we have a method for collaborating both partners in the quality measurement space, but also across use cases for the learning health system to ensure that the data elements are compatible across that full spectrum. We expect that is going to be a very long and iterative process at the end of the day, but I think the encouraging thing that we have seen in pursuing this work with Kyle and her team at ONC has been that there **[inaudible] [01:30:30]** in pursuing this because as we are able to build out this infrastructure from the quality measurement space, that, in turn, puts that infrastructure to work for all of the other use cases for the data that we need to collect. The trick is ensuring





that what we are asking people to collect will be useful for all of those needs, and that is where the need for collaboration really kicks into high gear. Kyle, I think I am turning it back to you now.

**Kyle Cobb**

Okay. Thanks, Joel. I think the trick of data standardization is really key. Actually, let's go to the next slide, and we can talk more generally about some of the standards that underpin this work and that, quite frankly, make it possible. So, just a little bit of history before we go into the standards, but the CURES Act adopted USCDI Version 1 as a standard, which really has made this baseline for all the data elements to be accessible through certified health IT modules, and with that, USCDI defines the floor for what is available to be shared through the certified EHRs, and that sort of goes back to the previous slide, where you can see that as the data moves through these different cogs, USCDI provides that standardization coming through EHRs, and so, the USCDI is currently incorporated into HL7's FHIR US CORE implementation guide as well as the C-CDA implementation guide, which allows for consistent transmission of these data elements, so that is sort of the USCDI component of it.

But, I think it is also really important to think about how USCDI has a predictable expansion on an annual basis so that over time, we can expand it, and rightfully so, I think we need to think about how to do that in a parsimonious way. We have to think about what is needed, and we cannot turn it to accommodate myriad use cases. So, in the case of thinking about how we could support CMS and quality domain, we really had to think about how USCDI could be expanded in ways that were really specific to quality domain, so that really triggered the launch of the USCDI Plus program, which is similar to USCDI, but an extended data set, and that allows us to look at numerous use cases, including the quality domain [inaudible] [01:04:56] for example, and allows for harmonization across all of that. So, over to you, Joel.

**Joel Andress**

Thanks, Kyle. So, in brief, as CMS has been working on its digital quality measure transition work, we have begun the process of mapping quality measure data requirements to the FHIR standard with the intent both to develop FHIR standard specifications for those measures as well as to identify the data elements that are going to be required for the system to support quality measurements as a use case, at least initially, so it provides us a starting point for that.

As part of that project, we have been collaborating with ONC and with other federal partners to evaluate what data requirements are existent in quality measurement in general as well as specific to our own program uses so that we can plan for future standardization of data that can be captured for the purpose of quality measurement, but also to ensure that those data, as we have stated, are useful for other use cases as well and are standardized across those other use cases, and so, we expect that that conversation will extend from quality measurement into other arenas as various stakeholders are ready to begin that conversation and transition into FHIR. Kyle?

**Kyle Cobb**

Yeah, next slide. I think this essentially just emphasizes what we just said in terms of standards. From the ONC perspective, they underpin our mission to promote health IT infrastructure and advance information exchange. Without them, it is not possible, and Joel, from a CMS perspective?

**Joel Andress**







I think from our perspective, data standardization is probably not a terribly hard sell to make, especially to people in the information technology space, but from the measurement perspective, we see this as allowing us to have broader access to data to provide for better validation of the data that are being collected, to be more effective at supporting our measured development with larger data sets with a broader array of types of data than we currently have access to because it breaks down a lot of these data system silos that currently exist, and allows us to both access a greater body of research data directly, but also to feed the results of our quality measurements into analytic and research efforts that support improvement in the quality of care and care delivery in the systems, so it really does hit a lot of targets that we have been wanting to aim for for a long time. It gives us a lot of opportunities within quality measurement. Kyle, back to you.

### **Kyle Cobb**

Sure, thanks. Next slide. So, we have talked about USCDI, and I mentioned previously that USCDI is implemented through a variety of HL7 standards, including FHIR and C-CDA. In this case, we are looking at FHIR, and I think specifically, before I hand it over to Joel, we are reminding people that there is a new API requirement for health IT modules, which is quickly approaching at the end of this year, but it is our population health services for individuals and groups for the G10 certification criteria that has incorporated the US CORE implementation guide. So, it is now going to be ubiquitous with EHRs, which will support CMS activities. Joel?

### **Joel Andress**

All right, thank you, Kyle. Next slide, please. So, CMS set out to build a roadmap, essentially, that lays out our future vision for what a quality measurement looks like. We can go to the next slide. I will start talking about what that involves. So, I am not going to belabor the point too much on the evolution of quality measures, but simply say we have been pushing to move towards greater exchangeability of data, breaking down some of the barriers and silos that have built up in data systems, and allowing for a freer flow of healthcare information to the various points in the healthcare system that require it. ECQM has gotten us some of the way, but it did not really get us as far as we had hoped, I think, and so, we view digital quality measures as helping push us further along the pathway to this ultimate goal of interoperability. Next slide, please.

And so, what we have begun to do is build off of a lot of the existing work that CMS has put into place in support of interoperability. We have identified, as I believe I said, FHIR as a standard that is probably here to stay for at least a good long while, and it has the flexibility to provide us the capacity for interoperability we need if we take advantage of the regulatory and policy levers that we have available to us to make it useful for our programs. Obviously, that is a pretty important caveat, and that is something we have been looking at. Next slide, please.

So, what are we talking about when we are referring to digital quality measures? It really boils down to two things, and it really lays out ECQMs as sort of a subset of digital quality measures, but not the entire universe of them. So, one thing to point out as well is that our initial work does focus on ECQMs. That is primarily because we want to use them as a model to build this out to incorporate other data sources. Basically, the two pieces of a digital quality measure as we have defined it are as follows. One, you have to be capturing structured data through a digital source, so, EHRs fall within that, but so do others, potentially, such as registries and Medicare claims, but they have to do so in a way that is standardized.





And then, secondly, they have to exist within an environment of interoperable systems that take advantage of those standards, and if you do not have both of those together, then you do not get the interoperability for digital quality measures that you need, and so, they are not really digital in the sense that we are thinking about, which is that they allow for ready exchange of data digitally across the healthcare space, and that is really what we are aiming for here.

I think we have some questions. I think we will address those as we get to the end, but in short, I think we are wanting to query the source data as much as possible so that we have insight into the work that is being done, and because we see the data elements as being critical pieces of the infrastructure for an interoperable system across many use cases. Next slide, please.

So, in building our roadmap, we identified four main areas of engagement. In terms of this presentation, we are focusing primarily on data standardization and a little bit on the advancing use of technology, such as FHIR APIs and adaptive tooling for use of both FHIR standard and API capabilities, but of course, we are also looking into how this then relates to issues around data aggregation across multiple systems and how programs can and should align the requirements in an environment where we are focusing on the capture of individual data elements more so than entire measure concepts as the basis for how the system operates. Next slide, please.

So, if we think about where we are in terms of data standardization, we know that there are some serious gaps in terms of how we want to approach this. There are significant limitations to the standards that currently exist, and adoption is not as fast as we would necessarily hope. There is not a consistent, universal approach to data mapping, and quality assurance of the required data tends to be fairly limited, in part because the data are so difficult to capture and then transmit across different spaces, and because those data system silos exist, it means that you have a limited capacity to look at data across those systems across the digital platforms and for a broad variety of uses. It also means that data are generally most useful for the people who are requiring a specific instance of data submission and less useful in being transmitted to other arenas, even if it can be done so interoperably.

And so, much of what we want to accomplish in a future state of data standardization is to provide for a common set of data format standards that allow us to have an agreed-upon capture of specific data elements that can be ported across many use cases. We want to establish bodies of these data standards, and we are looking at USCDI and initiatives like USCDI Plus as a way of defining commonly accepted standards for data capture that can be used in quality measurements, of course, but not just there, and Kyle will be talking more about that later, and also to be able to automate the process of data collection and mapping along with certain kinds of internal processes for quality measurements and other use cases like auditing and data validation.

We see the interoperability function as being critical to this because it allows us to exchange the data elements from point to point, and they do not only have validity or utility within the program or the immediate environment in which they are being captured, and that really is a key limitation currently that makes it difficult for us to perform all the functions on data, utilization as well as validation, as an example, or to be able to port it over into other use cases, like quality improvement, development of new clinical guidelines, or even delivery of care.







And so, we see standardization as the fundamental groundbreaking piece to all of this. Nothing else really happens effectively until we have been able to build a process for standardizing data and modeling out how those data are able to engage, and it is with that in mind that we have been interacting with ONC. Michelle, I think you asked to have an opportunity to give a comment at the end of this slide, so I will turn it over to you for a second, and then Kyle [inaudible] [01:18:18] will return to the presentation.

**Michelle Schreiber**

Thanks, Joel, and hi to the HITAC group. This is part of what I work on a lot at CMS, and there is a whole group behind this, so I thank Joel for this. The story of quality measures is not so much quality measures per se, it is the story of how we get interoperable data, and I think the challenges that we have had in getting that are exactly what has been outlined in some of the chat that is going on, that really, until we get to a point where we have very clear national strategies and approaches to patient identification, to data sets, to data types, to what our definitions actually are, how we are going to use this, in other words, the work of USCDI and many other committees or projects like Gravity Project and others, until we have that, it is very difficult to do.

But, quality measurement is something that is universally used in healthcare. Every facility, every provider has some mandate to report quality measures, and so, this becomes a very good use case in helping to drive standardization through these data elements and having a more national alignment around this, and that is why we are so deeply committed to the work that USCDI and others have been doing.

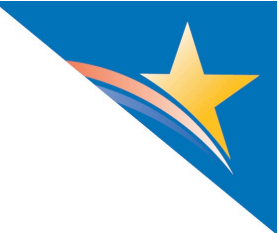
Just a couple of other questions is how does this live within the AUC? I think you will start seeing other recommendations on AUC, so it is a little early to comment on that, and in terms of the support in data element definitions, we actually baked those into the measure specifications around quality measures, and hope to achieve a point at which these will almost be modular plug and play within the measure specifications so that the data elements that are standard are actually going to be included.

We anticipate that at some point, and I cannot tell you that point, that we will only develop quality measures that include data that has been standardized through the USCDI or the new USCDI Plus process, and we also anticipate that at some point, we will not take quality measures actually that are not digital. Our goal at CMS is to transition, and we have been very public about this, to all digital quality measures, hopefully by the end of the decade, but it is onerous and tedious work mapping all of this, making sure the workflows align, but I think it is supporting the work of ONC and certainly the USCDI to do this. So, with that, thanks for letting me interrupt, Joel, and Kyle, let me turn this back to you.

**Kyle Cobb**

Thanks, Michelle. And, I think we can go forward a couple slides and onto USCDI, and we will break at the end for questions, which I am sure there will be many, around the process, but I just want to quickly set up why we are not using USCDI for this and just tell a short story. So, the USCDI core principles were really appealing to CMS and to us when we were thinking about how to transition to this new quality reporting model. The challenge, however, was that it is a smaller data set, and we were just not able to expand it to meet all of the quality reporting needs. So, with that, I think we will go to the next slide.





As we were having discussions with CMS last year about how USCDI could support this quality measurement domain, we were also having separate conversations with HRSA, FDA, and CDC, who had similar needs, to have these standardized data sets that would be harmonized across so that we would have that consistency, and finally, that there was a real commitment that these data sets be developed in a transparent way that included public submission and comment. So, let's go to the next slide.

So, enter USCDI Plus, and I think that this is really where we have landed in finding a place where we can develop these, as Michelle said, specific use cases that really dive deeper into standardization universes, whether it is public health or quality measurement, that are still harmonized across so that there is consistency across them all the way down to USCDI. And, I think that may be the last slide. We are starting USCDI Plus quality measurement with CMS, we have been working on a public health USCDI Plus data set with CDC, and there is also an initiative with HRSA going on as well. Next slide.

This is just a somewhat generic slide of how we see the process of developing the USCDI Plus data sets. They are driven through engagement of a wide variety of stakeholders, it is a public and transparent process, and as we can see, the benefits are strong and allow for interoperability. With that, I know there are lots of questions, and I am going to stop. I think we do have one last slide that Joel was going to summarize the key takeaways in how this supports CMS's initiative. Joel?

### **Joel Andress**

Sure. As Michelle pointed out, I think this needs to be understood. Quality measurement has a lot to offer in terms of modeling out the standardization and infrastructure that needs to be put in place for interoperability. Because we already have a process in place for defining quality measures and the evidence that data elements are there, it puts CMS in a position where it became evident in talking with a lot of our federal partners that we were in a position to be able to divine earlier than most what exactly we need to get the ball rolling for interoperability, and that means we get to be the guinea pig for this in a lot of ways.

But, as Michelle said, the issue is not fundamentally just one of quality measurements, although, of course, we have our program needs and we need to serve those, but it is about how we push forward on quality measurement in a way that is going to fit with all of the other interoperability initiatives that are in the healthcare universe and about modeling a path forward to bring all of those into the data standardization conversation, into the infrastructure alignment to establish best standards for defining data needs, for ensuring the standardization is maintained, for providing the critical infrastructure that allows us to build a learning health system, this is really a starting point.

I think someone in the chat made the point that more needs to be done in order to align this. I think that is absolutely correct. The work that we are doing specifically with ONC speaks to a particular use case, which is certification for health IT systems that supports our quality reporting programs, and of course, our initial requirements watch that pretty closely, but it is also a building block against which other needs for quality measurement can be built by other stakeholders, and as well, it is a building block against which other use cases can start building their set of data needs, and as those are being built around them, we then have a point of comparison.

If we need something like blood pressure within quality measurement, then we have a definition for how that is captured, a standard for capturing blood pressure that can be propagated out, potentially, to other





use cases, and we can ensure that there is standardization of that information. I do want to stress that the data standardization is the foundational piece for our roadmap to digital quality measurement and interoperability, frankly, but it is not the only one. It is not the only step in the path. There has to be the right tooling developed to take advantage of any data standards and of granular data elements. One of the things we ran into when we were talking to programs here at CMS is that frequently, the programs did not really understand what we meant when we were talking about the opportunities that the FHIR standard gives to us.

It gives us the ability to capture data in a way that it has not been captured before, with a reduction of burden across the entire system, and so, we have to really start thinking about the data we are capturing less as being quality measures that we are capturing and more about data elements that we are capturing that can be used for quality measurements, but that also can be used for many other things, and that has to be a shift in how we are thinking about data burden, administrative burden, utilization, the value of the data that we are capturing, and also the systems that we are building to capture and exchange those data, and I think this is going to require, in many ways, a fundamental reworking of how we build our reporting requirements in our programs, and how we are communicating those requirements to stakeholders, and how we are working to align them, and that is a big part of what we are working through with ONC, and I think we are both looking at this, if I am not speaking too boldly, Kyle, as an opportunity to model that out, learn from it, and then improve upon that process in future use cases.

**Kyle Cobb**

It could be.

**Joel Andress**

So, I think that covers most of what needs to be said here. There is still a lot to learn, and we will be wanting to share that with the broader community as we do.

**Aaron Miri**

Thank you guys. I appreciate it very, very much. Great updates. I will help facilitate the question-and-answer. I see we already have a few hands raised. I think before we get into Q&A, real quick, I would just say, using my prerogative here as cochair and with my CIO hat on, just to remind you that a lot of electronic health vendors in the IT sectors still have not adopted FHIR or have FHIR available for their customers, and so, especially your ambulatory, long-term care, and non-acute side are still living about 10 years ago with the standards and direct point-to-point interfaces, so I always encourage CMS just to remember that not everybody has a modernized electronic record, or they are still on paper because there was no funding available in the original acts to fund those types of facilities. Again, remember the long-term care and other types of facilities in this when looking at quality measures. All right. Now onto the hand-raising here. First up is Dr. Briggs-Malonson.

**Medell Briggs-Malonson**

Good morning and afternoon, everyone. Thank you so much for this wonderful presentation, and it is such a wonderful vision to really see the interoperability of trying to bring together so many of our different systems, but one thing that I mentioned in the chat that I just want to bring to the forefront is really considering the voice and the experiences of our quality patient safety as well as our health IT teams. What





occurs often is that we develop these plans at a very high level, but sometimes those plans are not directly interpreted down to the people that have to do this work in each one of our healthcare facilities.

And so, I love what you mentioned, Joel, and what you said exactly, that we are trying to move away from just the reporting structures that we have had before, but really looking at identifying the right data elements in order to be part of this more interoperable, more highly efficient system that we are all envisioning, but one thing that we do know, between our various different healthcare facilities, between our various different health records systems, there are significant variations even in the data element and how each one of these facilities understands some of those data elements, especially as it pertains to quality of care, patient safety indicators, and now, of course, as we are bringing in more of the health equity analytics, even more of our social structural drivers of health.

So, my main caution is as we are thinking about the technical aspects of this, simultaneously making sure that we are thinking about the people that are going to have to do this work in each one of our facilities to ensure that it is as successful as possible, and we experience this when we transition from our standard manual abstractions of quality measures into the ECQMs, and so, a lot of those different lessons learned, we should really consider them and make sure that we do not fall into the same pitfalls that we did before, and instead, we are more innovative and we are bringing the people that are doing the work along with us as we are implementing these larger changes.

**Aaron Miri**

Well said, Dr. Briggs, by one of the foremost minds of the country on this, and I will say not within just the four walls, but also, when you have more hospital at home and caregivers, it could be your spouse and others that have to collect these data measures, so, great points there. Next up, Dr. Steven Lane.

**Steven Lane**

That is a tough act to follow, Medell. Thank you for those comments. I have a whole list of questions, so I will maybe put a couple of them out, then let Aaron go and come back again. Obviously, I have been very involved in USCDI and its evolution over the last few years, and I think like a lot of people, and as we have seen in the chat, a little confused by the desirability of separating out this USCDI Plus. Why isn't this just seen as part of USCDI?

And, what I have come to understand is that USCDI is really meant to be a floor that applies across the industry for multiple stakeholders, multiple use cases, and that this effort is really meant to bring together specifically the federal agencies to identify their unique needs that may not apply in absolutely every situation. There may be systems, as mentioned in the chat, like long-term care, social services, etc. where these things just do not apply. I just want to check my thought here with your team. It seems to me that if you are a vendor of certified health IT, an EHR vendor, if you are a provider, then really, there is not going to be a meaningful line between USCDI and USCDI Plus. If you are one of the folks that needs to do this kind of reporting, you are going to need to build your system and build your processes so that you are collecting all the data in both USCDI and USCDI Plus in order to get your work done and meet your requirements. Do I have that right?

**Kyle Cobb**





USCDI Plus increments USCDI, and I think a nice way to think about this is currently, the FHIR US CORE implementation guide includes USCDI Version 1, and so, with the CMS reporting, we might see something like a specific implementation guide like QI Core, for example, that is an established FHIR implementation guide, that has US CORE as part of the base, it shares all of these profiles, but it expands. So, the implementation guide structure has not been determined yet, but really, the idea is that it increments on what is the base existing functionality required for certified health IT modules right now.

**Steven Lane**

That makes a lot of sense, and I do want to extend to your and your team a willingness and, in fact, enthusiasm on the part of our interoperability standards workgroup to collaborate in this effort. In our preceding task forces, we have really spent a lot of time working with the entire ONC team to evolve our understanding of USCDI and how to move it forward, and I think the more we can collaborate in this effort, the better. I am going to sneak in one more question before I come back the next time. I do not know if you were on when we were speaking about TEFCA, but I am curious if you see opportunities to leverage the evolving TEFCA as a tool in support of these digital quality measures and their reporting, and possibly see that as a way to support this exchange.

**Denise Webb**

I think that is a question for Joel or Michelle.

**Michelle Schreiber**

I was going to say, gee, Kyle, I thought you were going to answer that. This is Michelle. So, the answer is yes, Steven. I think it is actually extremely important because TEFCA speaks to getting the holistic picture of the data. We know that patients get care in multiple different places, and now it is going to be care at home, care at CVS, care wherever, and that is not all coordinated, and rarely in one system's or one hospital's electronic medical record, and so, we think the interoperability and the ability of them to gather that data from all points is extremely important, and so, the answer to your question is yes.

**Aaron Miri**

Well said, Michelle, and well said, Dr. Lane, and I would say as a helpful hint for everybody listening, no one health system or one exchange has all the data, and in fact, if they claim that, most of the time, their data elements are missing something, so it is very interesting, but I think it is a well-stated point, Michelle. Next up is my digital twin, Aaron Neinstein.

**Aaron Neinstein**

Hi. It is tough to follow Steven on this since he is chairing the workgroup, but I want to add onto his comments and share some concerns about moving towards a potentially duplicate or parallel process alongside USCDI and encourage us to think about using this as a use case and an opportunity to push the USCDI standards further and to add to them, and then, only if we learn that it really is a distinct use case and really requires a separate set of standards that we use that as a process of exclusion to get there rather than starting from that point because I could foresee a year from now, people who feel a need to add to the data standards, not knowing who to go to if we create a parallel structure or a parallel workgroup. Who do you go to? Do you go to USCDI or USCDI Plus?





Over time, there could become a real divergence and not only create duplication of effort and, potentially, confusion on the ground as to how we implement these standards as provider organizations, but also, frankly, risk watering down what we are trying to accomplish with national data standards by creating confusion, and so, I think this is a really wonderful use case to push data standards and would love to see us keep it holistic and consistent and use this to push USCDI further. Thank you.

**Aaron Miri**

Thank you, Aaron. I appreciate you, as always. Next up is Hans.

**Hans Buitendijk**

Thank you. I really want to just jump in and underscore and support Aaron's statements he just made. I think it is important that from a perspective of burden reduction, alignment of data, and consistent reuse of data that we have one consistent view of USCDI that ultimately, over time, is EHI that is the data that we are mostly targeting and that we use the data wherever we can, but it is for quality measures, for public health, for care, for payment, whatever. If it is the same data, it is the same data, and it will appear in multiple USCDI Plus sets because it is relevant in multiple, and how do we manage that? So, in the end, I completely agree with Aaron on his assessment of how we need to look at this. Thank you.

**Aaron Miri**

Good deal. Dr. Lane, I know you already went. I will let the people who have not asked questions yet go first and then come to you, if that is okay with you. So, Ryan, you are next.

**Ryan Argentieri**

Thank you so much. Just to maybe take a few steps back, and I am going to try to answer a few questions, for those of you who do not know me, I am the Deputy Director of the Office of Technology and have been charged, along with some of my colleagues at ONC, to help kick off the USCDI Plus work, so, just a few things to make sure that everyone is clear on. One, we wanted to bring this to you today as a beginning of the conversation, and so, this feedback is really helpful, and we appreciate it. We probably should have stopped to clarify a few things.

One, specific to equity and SDOH, we are seeing that as being a recurring theme across all of the domains that we have started this work on, not just quality, so we are working on the ONC side to try and figure out the best way to start collecting that information and feedback and to bring it to groups like you at the HITAC and to share some of those findings because of the previous hearings and just to echo all the sentiments that have been made here, so that is one point I wanted to make. The second is that we absolutely understand and we do not want to do anything that is redundant or duplicative in nature, but we have seen so far, especially on the public health side, that having conversations about everyone, including downstream users of the data, whether they are in the health record or not, having conversations just about what are the most important data elements and then how that information is currently being exchanged or interpreted has been beneficial on its own, just to also help refine all of the work that we are doing at ONC.

And then, the third one I will make, and then I think some others might potentially want to jump in, is to the point that Dr. Neinstein made. We are going to have plenty of opportunities, especially for the quality domain because we have not started those listening sessions yet for people like Abby at OCHIN and others who are involved and are subject matter experts in this space to provide us with feedback that will be







incorporated into what happens with the work. So, I will stop there, and maybe there are going to be more questions now that I open this up, but I will stop and see if anyone else wants to jump in after me, and we can keep the dialog going.

**Aaron Miri**

Thank you, Ryan. I appreciate that. Any other follow-ups to folks that have presented? All right.

**Kyle Cobb**

Sorry, I would just say, to underscore Ryan's point, I am seeing in the chat some confusion just in terms of this play between USCDI and USCDI Plus. I think they really will have the core USCDI base, and the governance for all of the USCDI Plus use cases and USCDI will be the same. I think we are perhaps saying the same things, but in different ways, but there is continuity, and I think to Dr. Lane's point, from somebody looking at a system, there will be no difference, and you will have a US CORE implementation guide and other implementation guides that are specific to quality or whatever type of use case that you are executing.

**Aaron Miri**

Got it. And, Michelle, did you want to jump in as well to comment to what Ryan and Kyle just said?

**Michelle Schreiber**

Aaron, I actually wanted a slightly different comment, and it was back to one of your original comments, Aaron or others, about recognizing that there are places that are not as developed in their EMR technology as others because they were perhaps left behind in the original meaningful use funding way back when, and I just wanted to make the point that we are very, very cognizant of that, and it will likely be an issue of timing as to how this happens, most likely seeing this first play out perhaps in the hospital space where they are a bit more used to their electronic medical records, but the directionality of this, Aaron, has to be the same no matter what, and I think that is something that we all have to keep in mind.

**Aaron Miri**

Absolutely, with equity at heart.

**Michelle Schreiber**

Yes. Equity has been a tremendous use case for this because it may have been you, but somebody pointed out that that has to be foundational, and the way that we are going to be able to look at the data and try really analyze and understand it from an equity lens is only going to be through doing this.

**Aaron Miri**

That is exactly right. I really applaud CMS for taking that approach. Okay, next up in the queue is Ike, and then Dr. Lane. Ike, go for it.

**Steven Eichner**

Thank you for that, and Ryan, thank you for all your work and your team's work on USCDI Plus. I do think that it is important that public health at the state and local level be engaged very early on in working on USCDI Plus because it is really those levels of public health entities that work very closely with healthcare providers on exchanging data, and to that same end, it is important that healthcare providers be included in conversations about USCDI Plus very early on so that there is a clear map or clear differentiation between





the two environments and we really develop a framework that works well for all parties, and state and local public health are really interested in participating early on, and there are lots of opportunities to collaborate, and we look forward to it, and certainly invite you to reach out or share with us the best ways public health can get engaged.

**Aaron Miri**

Awesome. The state of Texas is again leading the way there. That is fantastic. I love it. Sorry, Dr. Lane, I was wrong, I missed Clem, I apologize. So, Clem, then Dr. Lane. Clem, go for it.

**Clem McDonald**

So, I always worry about the separations. So, the big tension in standards is everyone wants to be free, but if you standardize, you have to do it the same, you are not free. So, I see all kinds of ways people escape from standards, different mechanisms, so I really would like to see some examples of things that would not be in USCDI Plus. Is this data that is already being collected, or is this added burden on the primary care physicians, who are disappearing as a kind of provider nowadays?

**Aaron Miri**

Dr. McDonald, what is one more click or one more thing to gather, right? No, you are right. I think clinician burden or physician burden, period, is important to keep in mind. Great points there. All right, Dr. Lane?

**Steven Lane**

Aaron, I never mind bringing up the rear. I typically do that on hikes with my family. So, one other question that comes to mind: Aaron, as you said, there is no one system that has all the data, and as an individual, I may be very interested in not only my health data, but the quality of the care that I am receiving, and I am curious how much consideration is being given at CMS to making some sort of quality report card or scores available to individuals so that they can see their own care gaps, not just from the perspective of their patient portal at a single or multiple health systems, but more of a holistic view. When they are involved in CMS payment programs and CMS is collecting this data, is the goal to make this data available, ideally using that same FHIR standard and leveraging the patient access opportunities, to individuals so that they can use it to act on and to inform their own care?

**Michelle Schreiber**

It is Michelle, and I will take that question. The answer is in general, yes, one of the clear goals of CMS has been to transparently provide information about quality to consumers so that they can make the best informed care choices. We do that right now through Care Compare, where we show, basically, for most facilities, quality data. We are very transparent around it, we have Stars ranking programs, but your point of individual reports back to patients, I think, is a bit of a bigger ask, but an interesting concept for the future. Once one has this data in a digital and ingestible form, there is no reason why that could not be done in the future, and there have been some initial steps that CMS has taken, such as My Healthy Data and Blue Button 2.0, for example. Those have been ways of giving to Medicare beneficiaries, at least, their data, and I think that it is a fundamental commitment of CMS to ensure that patients have data about their care and the quality of care.

**Aaron Miri**







Thank you, Michelle. Very well stated. And, I will say, from boots-on-the-ground experience, the Star program does make action happen, and I know many hospital CEOs that are like, "I did not know my hospital was one-star. We are going to become a two-star and a three-star immediately." They get on it from a quality perspective, so it works. All right, Mr. Posnack, you are up next.

**Steve Posnack**

I will be the same as Steven in taking up the rear. So, I really appreciate the dialog and the comments in the chat. I think they are reflective, and perhaps it fits together a few points and confirms, perhaps, folks' assumptions on things. For us, this is really a story about coordination and the practical aspects of making progress in a very heterogeneous, disparate ecosystem in which we work, the different programs and authorities that drive healthcare, and asking ourselves if there is a better way to coordinate and work together.

And so, I think we appreciate the dynamic of needing to engage in different fora in order to make progress, but let's recognize and say out loud that that is the current status quo. The USCDI Plus is not necessarily creating more new deviating paths. In fact, we look at it as a way to coordinate better and to start to help people converge and collaborate in new ways so that as data elements that are referenced across different programs and different components, we can use the USCDI Plus activity coordination to help resolve those differences and focus attention, and ultimately, as the chat was recognizing, flow things from these different activities or parallel processes into USCDI, which is the ultimate goal. It is to keep building and raising the floor for USCDI.

But, the other thing I would emphasize for everybody, because at times, we recognize the policy aspect, is that it takes real, pragmatic, everyday engagement to get the data elements submitted and to have those conversations, and so, instead of waiting for people to come to us, we are going to those communities and to those groups as the national coordinator to say we recognize that all this work is going on in the quality space, CMS is the big partner here for us, so let's work with them in that ecosystem to get everybody involved, and start thinking through, and look across as we start to see common data elements that really do not belong in this special use case, the belong in USCDI. Let's go ahead and do that.

And then, the same thing is happening with public health, as we noted. That is the first one out of the gate. And, that is beyond the CDC ecosystem. It goes to state, local, and territorial health authorities and healthcare providers, as is referenced. And so, looking at ways to create new coordination opportunities that we think will yield better results, but right now, we have all those parallel processes in place. That is currently the status quo, so we are looking at ways to make that better, more efficient, more organized, and to curate all this information over time. I think all of us here are reflecting on the 18 years that ONC has existed. Things move fast, things take time, things take numerous cycles, and this is part of a new process of finding ways to converge when those convergence opportunities happen, and Aaron, as you noted, the differentiation between the technical deployments and capacity and infrastructure that exist out there is also something I think we have a healthy recognition for as well.

So, again, great points from everyone, I really appreciate the engagement, and I just recognize that I think we all share the same convergence points, and if anyone else has other suggestions about how we can best get all these different communities that exist today to converge together, encourage them to submit their comments into what I call the USCDI prime process and get those data elements in, because that is





the straightaway way, but we also have to recognize that these other communities exist, and we need to engage them now in order to continue to make progress and align their data element needs. Thanks.

**Aaron Miri**

Thanks, Steve, I appreciate that, and you are not going to be bringing up the rear. Two more questions were raised right after that, so you spurred more knowledge. More questions have come up. Next up is Ike again.

**Steven Eichner**

Thank you, and thank you, Steve, for sharing that viewpoint. I think one of the real opportunities for an intersection or leveraging the concept of USCDI Plus and USCDI is to have the health elements at the person level included in the USCDI, and the USCDI Plus really looks at describing use cases for that data in terms of broad standards of describing what is the use case for that data. For example, public health reporting, [inaudible] [01:56:00] reporting, and then a companion implementation guide at the technical level that says how you might operationalize that, whether you are using FHIR or other messaging standards, but I am really concerned about potentially duplicating data elements in the USCDI and USCDI Plus, and if we can come up with a good way of distinguishing what belongs in one and what may not be a person-level data element, but is useful for these other transactions, I think that might be a happy medium. Thank you.

**Aaron Miri**

Thank you, Ike. I appreciate that very much. Next up is Joel. You may be on mute, Joel.

**Joel Andress**

Yeah, I am here. I am just talking to myself. Sorry about that. One of the things we encountered when we started engaging with the USCDI process about two years ago is that there is a difference in the scope that is currently planned out for USCDI and the scope of information that we already need, just within the context of CMS, and as we think about bringing other stakeholders into the conversation, that only expands. I know we have talked with CDC, who have a quite extensive set of data elements that they are interested in pursuing, and part of the reason that the idea of USCDI Plus came along was as a way to build out standards that were not necessarily limited by the scope that had been defined for USCDI.

If you want to get to a place where you have everything in USCDI, I do not fundamentally disagree with that, and that was initially our thinking, but in talking with ONC about how that would actually work and in going through the conversations that we have been a part of with the ISWG. I think the reality is that as things are currently constructed, USCDI does not take in that much information, and I think there are some fundamental issues to be discussed around the willingness to apply the statutory requirements associated with USCDI with the expansion of data elements at that speed. We see USCDI Plus as an avenue for us to begin pursuing that discussion of data standardization in a way that gives us a release valve from that internal tension.

I think the question that is going to ultimately be put in place is as we put requirements forward for USCDI, USDCI Plus, if we merge them into one thing or have them side by side, what we envision is that you are going to have one definition for one data element, and it may live within a specific body or space of it, but we are not intending to develop multiple definitions to fit within different places as they exist, and Kyle, I





think in talking with you and your team about that, that has been a pretty consistent message that we have been getting in terms of the approach, and in fact, when we were asked to start putting together what our data requirements would be for the initial certification modeling, as a concrete example of this, we actually divided out and classified data elements by data elements that existed within USCDI, US CORE, and QI Core to identify where these data elements currently lived in terms of standards and to divine what the scope of the work that needed to be done for standardization would be. So, I think that certainly has been a part of the discussion with ONC as well. I just want to make that point because there are some concerns around that, and that is something we discussed.

**Aaron Miri**

Yeah, those are great points. Kyle, I just want to say one point to emphasize what you just said, which is that as you look at dates for enforcement and for things that go into effect, I would encourage you to make sure it aligns between providers and developers. Take information blocking as an example. Dates are misaligned, and with a lot of what the providers are being held account to, the developers are like, "Well, we have until December to do this, so you are not going to get an answer until December." So, as you look at alignment of definition, I would encourage you to look at alignment of dates and look at alignment of a lot of things, because what is happening right now in the ecosystem is a lot of confusion, and when there is confusion, people just pause and throw their hands up like, "Eh, it is not my problem." So, just a nugget to add to that.

**Kyle Cobb**

I just want to thank all of the feedback on the difference between USCDI and USCDI Plus. The feedback today has been incredible. Just to continue a little bit onto what Joel said, I think one of the real challenges is trying to figure out how we keep this USCDI core that really supports [audio cuts out] [02:01:38] and facilitates patient access, and how we keep, that and then extend it to support these use cases like quality or public health, and I think that this feedback will be really helpful in terms of how we figure that out because we really do not want to burden providers with having to implement the full public health quality domain suites in addition to the USCDI core, and so, there is a real tension there, and a balance, and I think it will come down to governance and figuring out that balance over time, to Steve's point.

**Aaron Miri**

Wonderful. Well, I really appreciate all that. I do not see any other hands in the chat, but that was a very robust conversation. I will just make an impassioned plea from the provider community, sort of tongue in cheek, to please not resurrect the terminology "meaningful use." Let that stay in the past as we move forward and blaze new trails. That would be my only impassioned plea, but other than that, thank you so much for a fantastic dialogue and conversation. I applaud CMS. This is not easy stuff, but it is necessary for us to really embrace a new digital future and a new normal and ensure an equitable future for everybody, so, thank you for all of your work and for all the presenters today. That was great, great work. So, I am not seeing any other hands on this. Denise, I think we may be ready to go to public comment here.

**Denise Webb**

Yes, I think our transition is next to Mike.

**Aaron Miri**

Perfect.





## Public Comment (02:03:49)

### **Michael Berry**

All right, great, thank you, Aaron and Denise, and we are now going to open up our meeting for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press \*9 to raise your hand, then once called upon, press \*6 to mute or unmute your line, so let's pause to see if we have any public comments. And, I would like to remind everybody our next HITAC meeting will be held on June 16th, and all materials for today's meeting can be found on HealthIT.gov. Just search for the HITAC calendar. And, I am not seeing any public comments, so we can leave the slide up, and I will transition to Aaron and Denise.

### **Aaron Miri**

Good deal, all right. Denise, do you want to start with the closing comments, and I will close it up?

### **Denise Webb**

Sure, you bet. Well, it did not look like we were going to use our whole meeting time, but we sure filled it on that last presentation, which was a really important topic, and I think we will have further conversation on that topic when the workgroup brings back their recommendations at the next meeting, so I look forward to that. Excellent discussion today, and I appreciate everybody's active input, and I look forward to talking to you all next month.

### **Aaron Miri**

Yeah, I would absolutely agree. Thank you for everybody's participation and the comments. I think they were very robust. I love our focuses on an equitable, data-driven future that is measurable, that is meaningful, and that is fair and reasonable. I think that is an important aspect from this HITAC as resonating themes, and I appreciate CMS and the agencies wanting to hear it out, saying, "Hey, what is real, what is really going on, and where does the rubber meet the road?" I think all of us, especially those of us on the provider side, are willing to share real-world stories from our health systems. If you ever want to jump on a call and talk to the folks and the clinicians with boots on the ground, "Hey, what are your bugaboos?", I think all of us are willing to be an open door just so you learn so that future rulemaking incorporates the realities on the ground, so I really appreciate the open ears.

And, I would lastly like to close on by just saying I think all of you as a HITAC and your participation as the point of this group of a very elite group of minds around the table to spur ideas, and spur notions, and drive forward these common themes. I know Michelle knows this well, but I would point CMS back to our annual report that we produce every year as a HITAC as mandated by law back to Congress that thematically spells out various data items and mismatches and things that we have come across that we have needed help on. As we alluded to today, the patient-matching concern and those similar thematic things may also be good breadcrumbs for you to pull up what is really happening on the ground. So, with that, I thank all of you again. Have a wonderful, wonderful afternoon wherever you may be, or as it is still morning time on the West Coast, have a good rest of the morning, get a cup of coffee, and we will see you again soon. Be safe.

### **Michael Berry**

Thank you, everybody.





**Final Remarks and Adjourn (02:06:23)**

