Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

February 17, 2022, 10:00 a.m. – 12:30 p.m. ET

VIRTUAL

Speakers

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

Jonathan Nebeker	Department of Veterans Health Affairs	Federal Representative
Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Micky Tripathi	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Sweeney Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Tammy Banks	Individual	Presenter
Mike Lipinski	Office of the National Coordinator for Health Information Technology	Presenter

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

Mike Berry
And good morning, everyone. I am Mike Berry with ONC, and I would like to welcome and thank you for joining the February 2022 HITAC meeting. We are always very pleased that you are with us today. As a reminder, your feedback is welcomed, which can be typed in the chat feature throughout the meeting or could be made verbally during the public comment period that is scheduled at approximately 12:15 Eastern time this afternoon. So, let us get started with our meeting.

First, I would like to welcome ONC's executive leadership team to the meeting. And with us today is our National Coordinator, Micky Tripathi; Steve Posnack, 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 the HITAC members along with the federal agency representatives of the HITAC. So, when I call your name, please indicate if you are present. And I will start with our co-chairs. Aaron Miri.

Aaron Miri
Good morning.

Mike Berry
Denise Webb.

Denise Webb
Good morning.

Mike Berry
Medell Briggs-Malonson.

Medell Briggs-Malonson
Good morning.

Mike Berry
Hans Buitendijk.

Hans Buitendijk
Good morning.

Mike Berry
Thomas Cantilina. Steven (Ike) Eichner.

Steven (Ike) Eichner
Good morning. Present.

Mike Berry
Cynthia Fisher.

Cynthia Fisher
Good morning.

Mike Berry
Lisa Frey will not be able to join us today. Raj Godavarthi. Valerie Grey.

Valerie Grey
Good morning.

Mike Berry
Adi Gundlapalli.

Adi Gundlapalli
Good morning. This is Sanjeev Tandon for Adi from CDC.

Mike Berry
Okay. Thank you. Steven Hester. Ram Iyer. Jim Jirjis.

Jim Jirjis
Present.

Mike Berry
John Kansky.

John Kansky
Good morning. Mike, we cannot hear you.

Mike Berry
I am sorry. My computer switched to mute. I am back. So, where did I leave off? I think –

Aaron Miri
Mr. Kansky was your last one. Mr. Kansky was the last one.

Mike Berry
I am sorry?

Aaron Miri
Mr. Kansky was your last one.

Mike Berry
Okay. Thank you. Ken Kawamoto.

Ken Kawamoto
Good morning.

Mike Berry
Steven Lane.

Steven Lane
Good morning.

Mike Berry
Leslie Lenert.

Leslie Lenert
Good morning.

Mike Berry
Hung Luu.

Hung Luu
Morning.

Mike Berry
Arien Malec. Clem McDonald. Jonathan Nebeker. Aaron Neinstein.

Aaron Neinstein
Good morning.

Mike Berry
Eliel Oliveira.

Eliel Oliveria
Good morning.

Mike Berry
Brett Oliver.

Brett Oliver
Good morning.

Mike Berry
James Pantelas. Raj Ratwani.

Raj Ratwani
Good morning.

Mike Berry
Michelle Schreiber. Abby Sears.

Abby Sears
Good morning.

Mike Berry
Alexis Snyder.

Alexis Snyder
Good morning.

Mike Berry
Fil Southerland.

Fillipe Southerland
Good morning.

Mike Berry
Ram Sriram. And Sheryl Turney.

Sheryl Turney
Good morning.

Mike Berry
Good morning to you all and thank you. Now please join me in welcoming Micky Tripathi for his opening remarks. Micky?

Welcome Remarks (00:03:48)

Micky Tripathi
Great. Thank you. And thank you, everyone, for joining our February HITAC meeting. Today, in my opening remarks, I will try to be brief and we will just cover a few things that we have posted on healthIT.gov in the way of communication and information back out to the community and to the market and then turn it over to Aaron and Denise for the rest of the agenda.

Since the last meeting, we have made updates to healthIT.gov and got a bunch of blogs up there that I wanted to just point to, and also a couple of FAQs that we posted up there as well that I just wanted to call attention to.

So, first, we published the final report from our contractor, the Urban Institute, and their subcontractor, Health Tech Solutions, on a draft set of measures for developer reporting under the EHR reporting program. I wanted to thank the HITAC for their review and recommendations that informed the final report. And that report is now informing on **[inaudible] [00:04:45]** rule making that has been notified in the unified agenda to implement the HR reporting program, condition and maintenance and certification requirement under the Health IT Certification program. So, you can find that report on healthIT.gov.

Let me point now to a couple of blogs and FAQs, but I just wanted to first say we get a ton of feedback, which we really appreciate. We get phone calls, postcards, letters, emails, tweets, and they come to us directly, they come to the staff bubble, they come to me, they come to my boss, the secretary. Thank you very much. And sometimes they come to the White House through Congress. We appreciate any and all feedback and we make every effort to take all of that and try to help that inform us as to where there are areas that perhaps there is still sort of gaps in understanding or opportunities for us to do more outreach or

opportunities for us to do more education. And there is a wide variety of ways we can do that. We can do that via blogs, we can do that via fact sheets, we can do that via FAQs, and other kinds of things like webinars. All of those things that you see on our site. So, I just wanted to first say thank you to the entire community for your ongoing feedback and engagement and just let you know that we take all of those things into account as we think about how can we communicate back. And all of that feedback shapes both the form as well as the content of what we provide back because it helps inform us of what is really needed and where there might be gaps.

The other thing is we try to be as responsive and as timely as we can to that input. It is complicated on our side because it does require a bunch of coordination. For example, with FAQs, we coordinate with the Office of General Counsel, the Office of Inspector General, the Office of Civil Rights for things that directly overlap with HIPAA, and so that is an iterative process that has a lot of collaboration behind the scenes that may not be apparent when you just see an FAQ that has a four-line response. Trust me, there has been a lot of work going on behind the scenes to get us to those four lines.

So, anyway, I just wanted everyone to know that we appreciate your feedback. We work as hard as we can to be as responsive and timely as we can to that feedback. And now let me just point to a few of the things that we have posted on healthIT.gov.

Let me go through a couple of blog posts. The first blog post and accompanying fact sheet describes the conformance review process with respect to certification. The ONC Health IT Certification program compels participating developers to ensure that their certified health IT conforms to the full range of requirements during and after lab testing. When suspected issues arise with certified health IT, sometimes those are called nonconformities. The certification program's conformance review process helps provide a path to resolve them. So, we have a blog on that just to sort of point to there is a conformance review process here and here is how it works and pointing people to the parts of the CHIPL, the certified health IT product list, where you can go and you can see where are the nonconformities and what is the status of those.

Next blog describes our lantern tool that we built to monitor the nationwide implementation of FHIR APIs that enable patient access to their electronic health information using apps. And that tool tests endpoints published by the EHR developers to assess if apps can interact with the endpoints without special effort and reports the results through a public-facing dashboard. We have gotten tremendous feedback on that. I think it is a real testament to the OTECH team for building that and putting that into place with our partners, Miter, and we welcome you looking at that blog and any feedback or thoughts you have on where we should go with that and how we can further develop it and how we can make it more and more useful to the community. That would be very much welcome here.

The last blog I would point to is about our Inferno test tool. So, beginning next month, Inferno, which is our test tool for the standardized API for patient population services certification criteria, next month that is going to support beta testing for the HL7 FHIR U.S. Core Guide 4.0.0. And this new version is expected to include a bunch of enhancements from the previous version, which was 3.1.1, and we are looking forward to getting early feedback from health IT developers who are interested in using the new version in the future as part of Inferno testing. Inferno is going to be really important this year as we move into the full certification requirements on health IT developers for the FHIR 4.0, so we very much welcome your input and please start banging away on it and let us know what you think of it. That will be really important and really helpful to us and hopefully helpful to all of you.

Let me just point to a couple of FAQs that we posted over the last few days. There is one on harm and where considerations of harm come into play as it regards to denying a request for information, for example. We have gotten a lot of feedback and a lot of questions on that, so hopefully that FAQ will provide some guidance about how we think about that with respect to information blocking. And as you will see if you look at that, it follows directly the HIPAA constructs related to that. Because wherever we could, we tried to align with it to make those complementary regulatory frameworks to help the market.

Second is a blog related to notification to patients of newly available information and how is that treated with respect to information blocking. The third is how should patient requests to delay release of results be treated in the context of the information blocking rule. And then finally, how should one think about compliance with other laws or government programs for data sharing in the context of information, such as public health reporting or the ADT notifications that are required in the CMS interoperability rule. So, we have an FAQ that discusses that as well.

Hopefully, those are helpful. Again, as always, please provide us feedback if there are further questions you have on any of those. But as I said, we are trying to do everything we can to be responsive to the questions and the concerns that we are hearing and get as much clarification as we can out to the market as quickly as we can.

Let me now turn to just a final comment on our annual meeting. We have adjusted the annual meeting format to provide more opportunity for all of us to participate. Earlier this month, we held education sessions and office hours to discuss TEFCA, information sharing, and the USCDI, and I want to thank everyone who participated in those sessions. We had very high attendance and very high engagement in those sessions, so we really appreciate that.

The next dates to mark in your calendars are April 13th and 14th, and that is when we plan to host panel sessions, an exhibit hall, and networking to discuss health IT and health equity, public health, patient access and advocacy, and health information exchange. And that is kind of the more traditional annual meeting that people have been accustomed to. So, as I said, April 13th and 14th are the dates for those.

So, let me close now, again, by just expressing my thanks to all of you who are participating in a HITAC subcommittee and been working diligently to provide recommendations to the HITAC. I know we are going to hear a number of reports today. We really appreciate all of the effort. We absolutely know how much work that is, and we could not do this without you. So, thank you so much for all of your efforts.

Let me turn it now to Aaron and Denise for their opening remarks.

Opening Remarks, Review of Agenda and Approval of January 19, 2022 Meeting Minutes (00:12:32)

Aaron Miri
Thank you very much, Micky. Appreciate that update. And great work to the ONC staff. Those blogs have been very, very, very helpful. In fact, I was in a medical exec committee last night speaking with a member of our physician leaders and referenced those blogs for clarity's sake and others, so really appreciative and it is translating to boots on the ground. So, thank you for that.

So, welcome to all the HITAC members and welcome to all of you listening in today this morning. Denise, do you want to say any welcoming remarks?

Denise Webb
Good morning and welcome, everyone, and I echo your comments on the blogs. I know the FAQs have been really helpful to a number of healthcare organizations that I have been interacting with. So, thank you for that from ONC.

Aaron Miri
Wonderful, wonderful. All right. So, we are going to go through the agenda really quickly for today and then we will turn it over to Denise for the approval of the minutes from the last meeting you all should have gotten. So, for today, as you are seeing here, we are going to go right now to that. Then we are going to talk about one of my favorite topics, annual report work that has been done for the past year and hopefully we get a vote from the HITAC today on the finalizing of that so we can get to work on transmitting that and then get to start on this year's report.

Then we are going to hear from Mr. Steven Lane and Mr. Arien Malec on the Interoperability Standards workgroup. Some good work going on there. At 11:05 then, we are going to talk about e prior auth, one of our favorite topics that has come up many, many, many times over the years. We will have a short break, and then we will go to the information sharing and the ONC Cures Act final rule. We will hear from Elise and Mike kind of walking us through that and clarifying or answering any questions and kind of walking through some of those updates. We will go to public comment and then final remarks.

So, that is a busy, packed day, but it should be fun and it should be a good discussion as it always is. And I appreciate all of your feedback and comments and dialogue and commentary. It is so critical and often really translates in the subgroups as we are meeting and we reference those comments.

So, Denise, turn it to you.

Denise Webb
Great. So, before we begin with our presentations, we need to go ahead and approve our minutes from the January meeting. So, if I can have a motion to approve those minutes, please.

Aaron Miri
Motion.

Jim Jirjis
Second. Jim Jirjis.

Denise Webb
Thank you, Jim. And all those in favor, say aye.

[Multiple ayes.]

Denise Webb
Any nays? Any abstentions? Okay. That order of business is complete, and so now we can transition back to you, Aaron, to talk about the annual report and hopefully get a vote for that.

Revised Draft HITAC Annual Report for FY21: HITAC Discussion and Vote (00:15:41)

Aaron Miri
Yeah, absolutely. So, thank you again. I do want to, upfront, thank one of our members who did cycle off, Caroline Petersen. She co-chaired this with me for the majority of the year, so I am going to try my best to carry the lantern for both of us. And hopefully next year I will have a new co-chair for this report workgroup as we grow and expand. All of you, especially the newcomers, please volunteer, consider it. It is a fun group and it really speaks a testament to the work that has been done over the past year. It is amazing when you look back and think about all the things that we work through and work on and being able to report that back to Congress as per law is something interesting. So, next slide.

All right. So, really, we are going to quickly go into schedule and next steps. I think it is pretty apparent which meeting this is. And a discussion, of course, of the draft and looking for your certification, hopefully, and vote on it. Next.

So, we are here. We are at the approval stage. It is a very exciting time and, again, look forward to conversation. Next.

All right. So, where we are right now is it is at your point and your inbox and your opinions here matter. And to look at this report, especially for the new folks, you should have gotten all the materials probably last Friday. You have read through them. You have seen that even the feedback we got – which was fantastic, especially a number of new folks did comment in because they just joined the HITAC, and we really appreciate that feedback. So, we did incorporate what we could incorporate. Every single comment is listened to, catalogued, itemized. If it needs further explanation, we follow up, or it maybe incorporates as sort of a larger them. It is one of those things that I take a lot of pride in making sure that, as I have always said, every voice is heard, every comment is heard and considered around the HITAC, and that your opinion matters. So, I hope you saw that resonate through the work and you saw that resonate through the feedback and the comments.

I want to take a lot of credit and thank Michelle and the ONC team. They painstakingly go through this, I do not know, probably 10,000 times over the course of the year and catch every semicolon and comma and hyphen. Surely, nothing is perfect, but they do a really good job. All right. Next slide.

All right. So, let us pull up, I should go through, I guess we can go through any comments first that folks have. And I see Dr. Lane with his hand raise.

Steven Lane
Yeah. I just wanted to say, just to give a huge thanks to Aaron and the folks on this workgroup who have done this work and just to point out to the new members of the HITAC that this is incredibly important. It is a real opportunity that we have as a federal committee to provide directed input, and a lot of thought goes into this. This is really our chance to say this is where we think this ought to be going over time as opposed to simply responding to the charges and the tasks that we get from the ONC. So, I really want to encourage people to participate in this process, to step forward to co-chair this with Aaron or without him perhaps. Perhaps co-chairing the HITAC is enough and someone else could take this on next year. But I just wanted to highlight this is important work and thank you so much, Aaron, for all that you do.

Aaron Miri
Yeah, I appreciate that Dr. Lane. And I should have thanked Dr. Oliver, Dr. Lane, and Dr. Jirjis, three very skilled and gifted folks that we are so blessed to have on the committee. And so, join us. That is another plug for join us for next year. We are volunteers, so please jump in and give your feedback.

All right. Can we pull up the crosswalk really quick? Let us go ahead and do that. It is sort of an executive summary, top level, just to give folks a glance at how this…perfect. All right. Let us go down a little bit there. It is a very detailed and robust report, I will say.

And again, as part of the charge…again, this is an orientation. The way we do this, and we have learned since the HITAC was put together in the very beginning what the structure would look like, we try to make it as common sense as possible, including, especially for the new folks maybe reading this for the first time or read it for the first time just the other day, stories. After the executive summary, we actually put into plain English what this means. Right? If we were able to accomplish these things which we feel are important, what would care look like. What would it seem like from a patient experience, a provider experience, interoperability? How would cybersecurity and privacy be strengthened? These are hard issues, though, so make no mistake about it. But we do try to put it in a common language for folks just to understand how important this is and some of the common bugaboos that we all encounter even as we all become patients in our healthcare systems. What happens?

So, if you look at this one for an example with the public health data systems, and I am not going to go through every single item here. Hopefully, you have had a chance to read, so I am looking for your feedback. You will see that each of these sections was thoroughly vetted, thought out. Your feedback mattered. I want to call attention to folks like Hans and others who have provided phenomenal, phenomenal feedback. So, thank you for that. You just joined and already you jump in two feet in, so thank you for that, Hans. Folks like that that really provided feedback. This report is a culmination of your work and what we have been doing.

But even if you look at this first one with infrastructure, we are really talking about how are we sharing information across the way. What is incongruent now where there are issues? A lot of faxing that is going on, especially with tests and whatnot. How do we make sure that we are capturing the full panacea of what is really happening out there? And what I also appreciate about this HITAC is our approach to seek first to understand. We want to listen. We want to understand. So, even if you see in this recommended activities: listening, understanding better, really working together across lines to just hold hands and listen and embrace and say, okay, this is truly the problem statement we are trying to solve. Too much of health IT has been episodic in nature, and so how do we really make this a comprehensive manner.

So, if you keep scrolling, please, down the executive summary, that is how this should be read for you. It is one of those where it is togetherness, it is listening, it is fact based, and it is action oriented. Right? Where we have charge and where we have authority. And where we do not, where we can make recommendations to ONC to do so. Right? The HITAC also has those limitations as written into the law. So, what can and cannot we do? We go to that line and say listen more, talk to folks, encourage folks to convene more, those sorts of things. And then, of course, the state level. A lot of times we think so much of the federal level. How can we involve the state level and tribal and territorial areas outside of the 50 states that are still U.S. land?

How do we incorporate that? So, even if you look at health equity. That is one that I am very passionate about. And ensuring that and understanding where the collection of data is and is not, put that in form USCDI future standards. Right? Those kinds of things are our mechanisms.

So, anyway, long-winded orientation to this. But for you reading it, as you prepare to vote on it, I just wanted to make sure everybody was in the same mindset here about the approach, the governance, and obviously the output of what this is. And every year, we build up on the prior year's work and so it gets better year after year, or so I think so.

All right. Any comments or questions from the HITAC? Looking for any feedback. Please raise your hand. Looking for any hand raising here. All right, I see Sheryl Turney.

Sheryl Turney
So, I first of all want to congratulate you all for doing such a great job on this report. I know it is a phenomenal amount of work and it definitely shows. The one area where I would like to see us highlight an opportunity is in the area that talks about patient matching. I know I have probably brought this up in a variety of venues already, but one of the issues that both providers and others have shared is the fact that there is a lack of a digital standard for capturing information on ID cards which requires a lot of manual work. And every time there has to be manual intervention, you introduce the opportunity for error. So, I do think that highlighting the ability to have a standard for a digital ID card and that is part of the certification process will go a long way to improving the quality of the data at its capture point.

Aaron Miri
Great. Great point, Sheryl. And I totally echo that on the provider side. We are one of the largest health systems here in Florida and it is amazing what happens when you try to connect disparate data sets without that primary key. It is very difficult to key in on secondary factors to be 100 percent certain. So, great, great point. Mr. Eichner. Or Ike as he calls it.

Steven (Ike) Eichner
Thank you, sir. In looking at the use case that is described in the report about public health and technology fairly early on, I think we might want to substitute a different use case in because, as document, it conflagrates several different concepts all together about using an HIE or a resource for information is necessary for public health activity and who is defining what that data is. And under HIPAA, public health can define, ultimately, what data set is necessary for a particular task and protects providers who **[inaudible] [00:25:14]** align by that definition for HIPAA protection. The language that is described in the report really talks a little more broadly about disease surveillance and may actually not be accurate because if public health were looking at protecting visitors and tourists, I might be interested in getting both influence rates both in my local environment from my residents as well as potential visitors. And that is not really laid out in that story. So, we might want to –

Aaron Miri
So, just to orient folks again because it is a long report, you are speaking of the first use case story, the common language story of what we would hope to see with public health reporting. Is that what you are referring to? Or are you referring to the actual entry in the –

Steven (Ike) Eichner

Absolute.

Aaron Miri
Got it. Got it.

Steven (Ike) Eichner
You just want to flip out that story for something else that is a little clearer and more easily understood by everybody.

Aaron Miri
Got it. Got it. Okay. Yeah. So, in this case, we are trying to show what a panacea view of public health reporting could look like, what our discussion was, and I would invite Dr. Lane or Dr. Jirjis or others to also comment, or Dr. Oliver. As we worked through what could happen, the goal was to try to show an environment of seamless data access. As you know, Steven, in Texas, there has been a heavy reliance on fax machines across the noncentralized public health authorities across all of Texas. So, what could happen if we eliminated that? Or mitigated that tremendously, right? So –

Steven (Ike) Eichner
Oh, absolutely. I wholeheartedly appreciate the goal. I just think if we update the story a little bit, it might be clearer to describe those goals and stay focused on a few rather than going down some blind paths.

Aaron Miri
Got it. Got it. Okay. We could definitely – given that that is, I think, more aspirational than anything else, maybe there is a way to look at that or maybe even amend it for next year to be a little more specific. I can appreciate that.

Steven (Ike) Eichner
Yeah. And happy to – just feel free –

Aaron Miri
No, absolutely. Please join the committee and we are going to double click on that next year, for sure. I think we have learned a lot these past two years and highlighted a lot. So, thank you for that. Abby?

Abby Sears
Hi. Thank you. First of all, I think this is beautiful, and I love the way the illustrative stories at the top about the target areas is particularly easy to read and to understand what our priorities are. I am going to say some things, and I think it is probably… I am going to let you guys decide if it is too late to put them into this version or if we can take them as considerations and priorities for next version.

The first thing is the target area. I would love to see an area that looked at health equity and have its own separate subsection like you do for interoperability or for public health. I think that would be incredibly powerful and would set the stage for making sure we are thinking about that. And in that area, it would be about closing that digital divide. It would be related to making sure that we are creating and supporting and encouraging, and if I may be so bold, requiring more culturally competent technology to support the different patient demographics and different patient needs.

The second thing I would put in that would be making sure that our policies, that it is not just incremental change, which I absolutely love incremental change but that we put forward strategies that are included in the incremental change on how we are going to close the last mile. Because the last mile is where our patients with the biggest challenges are actually sitting. They are not sitting in the 80 percent. They are sitting in the last 20 percent. And from a policy standpoint, it is hard for me when I know that something that we are moving forward is the right thing to do and it is the right next step, but it is an insufficient next step. So, I am wondering if we could put something like that in that area as well.

And then just as you are doing the interoperability, consider the closed loop referral. One of the biggest challenges for our patient population is really access to referrals and getting that information back. And as we do value-based pay and we are moving to value-based pay, if that data is not coming back, part of the infrastructure in the system that serves some of the most fragile patients will continue to be at a disadvantage related to value-based pay because their information for their closed loop referral or for their referrals is not making it back except for on faxes. And I think small practices and the safety net are at a disadvantage. And again, from my standpoint, it is really how do we look at the whole and make sure that we are closing that divide.

So, I will just leave it there. I suspect my comments are too late to actually be included this year, but if they could be, it would be wonderful. Otherwise, I would really ask that we think of that as we put forward the format for the next version.

Aaron Miri
Yeah. I completely, wholeheartedly agree with you. I do know there is some rigor with the way HITAC was put together in 21st Century Cures in terms of our charges. Perhaps in each of those charges, there should be a callout specifically for health equity and healthcare equity and health data equity and really double click and highlight that. Asterisk, star, whatever we have got to do under each of those sections. We will definitely look at it. And I think you are right. I think next year, we really need to expand upon that and go into it. And I see it every single day in the course of care. It is critical important. So, thank you, Abby, I appreciate that.

Other… I was muted. Other feedback, other comments? Let us see. All right. Denise, sanity check me here, please, ma'am. Do you see any other hands raised? I do not, but there is a lot of folks.

Denise Webb
I am checking, and I do not see any others.

Aaron Miri
Yes, ma'am. I do not either. Well, if you do not mind helping me on this one, I think we are ready to call for a vote.

Denise Webb
All right. And so, just before we take the vote, I just want to clarify for everyone that we are voting on this revised draft. We are not entertaining any changes to this draft today, so you will be voting on the revised draft as is. And thank you for everybody's input which will tee up our conversation for the 2022 workgroup, annual report workgroup, and we can entertain changes or new formats in the new report.

So, with that, what I would like to do is entertain a motion for approval of the revised FY '21 Draft HITAC Annual Report for advancement to the National Coordinator. And if I could have a motion for that, please.

Aaron Miri
Motion.

Steven Lane
Second.

Unidentified Speaker
Second.

Denise Webb
All right. And all those in favor, please say aye.

[Multiple ayes.]

Denise Webb
Any nays? And any abstentions? All right. So, our revised draft is approved by our committee to move forward to the ONC. Thank you, everyone. It was a lot of hard work on behalf of the workgroup and all the support we got from Accel and ONC. Thank you.

All right. With that, I think we are ready to transition to our presentation on the Interoperability Standards workgroup and their update. And so, I think I am turning this over to Arien. Is that –

Steven Lane
Actually, no, we are going to tag team.

Denise Webb
You are going to tag team.

Steven Lane
We have both got our act together now.

Denise Webb
All right. Great, Dr. Lane. Okay. Well, I am turning it over to the two of you, and I will help moderate and facilitate any questions that come up.

Interoperability Standards Workgroup Update (00:34:22)

Steven Lane
Well, thanks so much, Denise. And thank you, everyone, for the chance to present on the work of our workgroup so far to date. Just a reminder that the interoperability standards workgroup is a new workgroup within ONC that was chartered to replace the work of the prior USCDI Task Force and the interoperability standards priorities Task Force that a number of the members of the current workgroup were also involved in. So, even though it is a new workgroup, we have a lot of continuity amongst the membership and the tasks before us. Let us go to the next slide.

So, we are going to go through the charges of the workgroup, some of the specific questions that we have been asked to address, membership, talk about the meetings we have had, the presentations we have had and are planning, and the timeline for our remaining work. So, let us just dive in.

So, the overarching charge for our workgroup this year was to review and provide recommendations on the draft USCDI Version 3, as well as other interoperability standards. So, as I said, in the past few years, we have had two workgroups running simultaneously or somewhat staggered in their work, and this time we decided to put it all together.

Our specific charges. The first one focuses on USCDI. You will all recall that the Draft Version 3 was recently published, and as part of the standard process for public review of the USCDI versions, there is a HITAC Task Force. We are looking specifically at the new data classes and elements that were proposed for inclusion in the Draft V3 and providing comments on those, as well as any other data classes and elements that were not included in the Draft V3 which have been leveled as Level 2. And just as a reminder, the ONC has developed and evolved a process for receiving and evaluating proposed data classes and elements that come in from the public and other agencies, evaluating which of those are sufficiently mature based on technical standards and applicable use in the community to be ready to be included in USCDI. Those that are of that maturity are labeled as Level 2, and it is from amongst the Level 2 elements that there is a selection for what will be included in the next version. So, that is what we are dealing with with our Charge 1.

And in Charge 2 – so, that Charge 1, we will be coming back to the HITAC in April with our recommendations specific to USCDI Version 3. And then, subsequently, we will be turning our attention to the interoperability standards of the advisory, or the ISA, where we will be collecting input for the applicable standards and data elements, vocabulary, etcetera, that should be used to support nationwide interoperability. So, that work will carry us through April and May, and we will be back in June to complete that. There may well be some other areas of interest that are raised by members in our workgroup. This has happened in years past where people are so enthusiastic about impacting the direction of nationwide interoperability that they want to provide additional input to the HITAC and to the ONC. So, we may be coming back and requesting the opportunity to have a few more meetings, perhaps in the late summer/early fall, but we will let you know how that goes. Next slide.

So, these were some specific questions that have been asked and which the workgroup is hoping to provide input on. Specifically, within the items that have been included as Draft V3, we are looking at the data class and element names and definitions that have been provided. We are looking at examples of value sets to better define the scope of those data elements. One second. And then will be going to look at other data elements. I am sorry, one second. Sorry, the squirrels are way more interesting than my presentation. So, we will then be looking at other data elements that the workgroup members feel should be added to the Draft V3, again from the Level 2.

We will also be looking at barriers to development and implementation or use of any of the data elements that might warrant them to not be included in V3. Perhaps things were proposed for Draft V3 where members of the workgroup feel that there are going to be some substantial challenges and that they should be held back. So, what should be added, what should be changed, what should be perhaps removed.

And then within the standards bulletin that was published simultaneously with the Draft V3, there were some very specific questions that the ONC asked for feedback regarding. One was regarding sex assigned at birth and gender identity, both data elements that have been included in USCDI but additional work has gone on within the community by the Gender Harmony Project to evolve the concepts behind those data elements. And so, we are going to provide input on whether those data elements should be updated to reflect the Gender Harmony Project's work. And then current and previous address. I think we have heard here at the HITAC about the ONC's Project USA and the new specifications that have been published for patient address and whether those should also be incorporated into the next version of USCDI. So, we are looking at those questions, in particular. Next slide.

So, these are the members of our workgroup, a really great group of folks with diverse background and tremendous enthusiasm and energy. Some folks are new to this effort and are really bringing a new perspective which has been very helpful as we are tackling these questions. And I just really want to thank everyone for their participation and engagement.

And then, Arien, I will pass it to you to talk about the rest of our work.

Arien Malec

All right. So, we have already gotten into the thick of things. As usual in these things, we have got a pretty aggressive roadmap in order to get to the presentation in April. So, if we go on to the next slide, we focused our initial meetings on addressing some of the requests that ONC had for us to look at Gender Harmony and Project USA. Both of those meetings were truly fantastic. I think if you have some spare time to listen to the testimony or go to the transcript, both the Gender Harmony readout and the Project USA readout were truly, truly amazing. In particular, I think we got really crisp content out of the Gender Harmony presentation that we got that will better inform recommendations for USCDI going forward. And then for Project USA, I think we have a path forward for the future for address normalization. And part of the task for the workgroup is going to be to look at the specific recommendations for USCDI V3 to make sure that the U.S. healthcare system is ready for a world where address information is better normalized according to some of the fantastic specification work that has been done in collaboration between Project USA and AHIMA.

And then we have an upcoming meeting for health status. We voluntarily took this one because the proposed additions to USCDI in terms of how they split across a variety of statuses, as well as how we accommodate accommodations and accommodation status into USCDI, I think are two pretty clear callouts that we need to get good testimony on to make sure that we are not just capturing observations about a patient but also capturing how to transform care and daily living to better support people whose needs warrant or need additional accommodations. So, I assume that that upcoming presentation is going to be as informative and illustrative and mind-opening as the previous two that we have had.

If we go on to the next slide. And then as Dr. Lane noted, we are also sort of parallel tasking that time with a review of our Charge 1A and then going forward with Charge 1B. So, we are hard at work, already cross mapping USCDI Proposed V3 or Draft V3 with a matrix to look at proposed additions leading up to, as I said, our April readout to the full Task Force.

So, I think – is there one more slide. That just gives you a roadmap for the heavy work that we have ahead of us getting towards our finalized recommendations. So, we are going to be hard at work capturing

feedback, memorializing that feedback into a recommendations letter, putting those recommendations together for consideration for this group. And be prepared for some deep thoughts coming your way for a vote on the April meeting.

I think with that we turn it over to Q&A.

Denise Webb
Great. Let us see if we have some questions. I do not see any hands up. I do not know if there are people that are just on the phone. It is not looking like there are any questions.

Steven Lane
I will just point out, Denise, that in our Task Force meetings last year, there was a lot of interest in the whole question of disability status. And so, we are going to try to bring forward a number of discussions, as we have said, at our March 1st meeting to try to tease that apart. I think it is important that we get that right or as right as it can be to help with terminology going forward.

Denise Webb
All right.

Ariel Malec
The presentation was so good, it did not require any questions.

Denise Webb
You guys nailed it. All right. Well, if there are not any questions, I guess we thank you both for presenting and for the work you are doing. And we will move to the next presentation on e prior authorizations RFI workgroup – or excuse me, Task Force. And that is Sheryl and Tammy, and Aaron will be moderating and facilitating questions.

e-Prior Authorization Request for Information Task Force Update (00:47:25)

Sheryl Turney
Fabulous. Hopefully, you can hear me. Thank you for the opportunity to come speak today. And I just want to start out by saying Tammy has been wonderful to work with. She is representing NCVHS in that role and has been a fabulous co-chair, so really appreciate the opportunity to work with her and also work on this Task Force. So, I am going to go over the first few slides and then turn it over to Tammy and she is going to review the last few slides. So, can we advance the deck, please? Wonderful.

I am going to first talk about… review the charge with everyone here as well as who we have on the Task Force. So, we can go to the next slide. Essentially, the charge that we received was – and I am pretty much going to be reading this. But essentially, it was ONC has issued a request for information and that was published in January and it seeks input from the public regarding support for electronic prior authorization processes. ONC is requesting comments on how the ONC health IT certification program could incorporate standards and certification criteria related to electronic prior authorizations. We were charged with providing input and recommendations in response to the RFI – hopefully, everyone on HITAC has had a chance to review it – for the electronic prior authorization to inform future rule making and other actions in this area. And then our recommendations are due by March 10, 2022.

So, as you can see, we have a very short period of time in order to do this work. I am going to talk a little bit, once I share with the subcommittee membership, on what our scope and approach is as well. We can go to the next slide.

So, we did have a few changes since the initial membership was shared with HITAC relative to our membership. Denise was unable to – it was not Denise. Sorry. One of our members was unable to attend so dropped out, and then we added a couple of members. Dave Degandi from Cambia and Patrick Murta from Humana. So, this is the current membership for the subcommittee. Any questions so far? All right. Go to the next slide.

And we are going to talk a little bit about our approach. We can advance. Okay. So, in essence, this is basically, and I am not going to read all this slide, but this is a little summary of the meetings that we have had so far and the approach that we took. We essentially took the RFI and broke it up into sections, and we focused initially on reviewing the capabilities that were presented as an example in the RFI to determine are these the types of capabilities that we were believing were going to be important for the support of electronic prior authorization or were there expansions that we needed in order to go beyond what was initially presented. And then we looked at some opportunities for overall principles and recommendations, admittedly, at an accelerated pace.

We also looked at do we need to have anyone come in to speak. And we did because not all of the members of the subcommittee were familiar with the implementation guide sort of referenced in the RFI, and there are three of them from DaVinci: the documentation templates and rules, the coverage requirements, as well as the prior authorization support. So, **[inaudible] [00:51:03]** came in and spoke about those things. Then we also had most recently John Kelly from Edifecs come in and talk about the attachment standards that have been discussed, as many of you know, for many years. Just to ensure that we are all in the same place related to being able to provide the appropriate input. And we do have plans for a very small presentation from CMS coming up in our next meeting and then also Hans was kind enough to agree to do a presentation regarding some of the discussion around bundles.

The topic of electronic prior authorization is complicated, as we all know. We have been discussing it for the last several years. And we had in-depth conversations with the intersection of clinical administrative data. The good news is the implementation guides have made a lot of progress since those original discussions have taken place. But there has been maybe not as much proof of concept or pilots going forward, and there may be some hindrances to those things that would allow the work in that area to mature. And part of it is the fact that it is so embedded in all the different systems that our providers and hospitals and other stakeholders that are involved in the electronic prior authorization process use, and they do not all have the same levels of specification, the same maturity, the same capability. So, we are trying to acknowledge that as we are moving through our process to review the recommendations.

To date, we have actually gone through, as I said, the capabilities, the Section 2, Section 3, and we still have on our plates to go through Sections 4 through 7, which is basically the information on patients, providers, payers, etcetera. So, we do still have a lot of work to do and we only have a few meetings left. To that end, we did decide to add an additional meeting on March 7th so we would have a better ability to present for this group. I do not believe they have actually added it yet to the timeline that you see showing now with the work plan, but we did just decide to add that additional meeting so we can be as prepared as possible for the submission of our recommendations and comments in the March 10th meeting to HITAC.

And so, for a deeper discussion relative to our meeting, I am going to turn it over to Tammy. But before I do, does anyone have any questions about our process? All right, we can go to the next slide, and then Tammy can take it from here. And hopefully, I know we are a little early, so hopefully she is on.

Tammy Banks
I am on, Sheryl, and thank you for your kind comments. If you want to move the slide forward a little bit more. This just goes to the guest speakers that Sheryl had discussed. And if you want to move one more slide forward, I am going to be giving a highlight of the summary of the topics and discussion that we have gone through. So, if you want to go to the next slide, let us just get right into the meat.

As Sheryl mentioned, we spent the initial meetings reviewing and compiling the key prerequisites and functional capabilities needed to successfully process and complete a prior auth. So, we did not just look at the minimum criteria. We took the full workflow perspective on what a successful, least burdensome process would be. And so, I am going to be sharing these highlights. And I also want to thank all the Task Force members. They were all highly engaged in this process, which has made this task definitely a pleasure.

Successful PA requires patient-specific responses. This includes a covered benefit and a provider who is in or out of the patient's provider network. Therefore, the prior authorization responses must be for a patient-specific coverage benefit based on their specific plan coverage. We also acknowledge the need for patient matching and patient electronic cost estimates to empower the patient in their healthcare choice. Payers are encouraged to be transparent with their guidelines and routinely evaluate prior authorization submissions and rules that are typically approved and consider implementing a trust and verified framework, more commonly known as "gold carding." This is to really minimize patient care delays and provider burdens. The payer functional capability should be sufficiently robust to convey comprehensive, actionable documentation requirements upfront. Subsequent requests for supplemental information should be the exception instead of the rule.

The PA process must be incorporated within the existing provider workflow and allow role-based delegation to the back office staff. Physicians or their designee will trigger a PA, but they will not typically process a complete PA. The completion of a PA typically occurs by their designated staff; therefore, it is crucial to ensure role-based delegation is included within the workflow to the back office staff to maintain a high level of productivity based on the practice's preferred workflow.

Patient involvement in all work and data flows when opt in. The Task Force was very vocal on this need for patient engagement which is currently a gap in the prior auth workflow. The patient should be able to know or engage in their PA when they request it and opt in, which would include accessing it from a portal or other digital tool of their choice. They should have the option to request a PA, check the status of their PA with detailed messaging in plain language, respond to supplemental information requests, know how much a service will cost if authorized or denied and the breakdown of their out-of-pocket costs, and what recourse they have if a request is denied, and automatic forwarded copies of all submissions and responses in plain language. Basically, be a part of their healthcare decisions.

We are taking into consideration that PA functional capabilities may occur in different systems. An RCM PMS vendor can send a PA request to a payer and request supporting documentation from an EHR, and the EHR may send requests for supporting documentation, and **[inaudible] [00:57:51]** work with a smart

app to complete a PA and send confirmation over to the RCM PMS vendor. Additionally, PA is not always an interaction between a payer and a provider. As we continue to flesh out minimum functional criteria, we realize health IT vendor certification encompasses all these vendors, so our criteria need to be vendor agnostic.

Health IT vendors must meet the HIPAA privacy and security requirements. Privacy and security of the data should be considered during and alongside of the EHR development, not after the fact. If you want to go to the next slide.

Standards. We concur that multiple standards can coexist and be used by stakeholders to meet specific business needs effectively and efficiently, preserving existing standards and infrastructure while moving toward an innovative process with new real-time information exchange within the clinical workflow. An example of this transitional approach is moving supplemental information exchange from the current document based to a database exchange. To encourage this innovation, the exception approval process for testing emerging standards needs to be amended to be less burdensome for beta testers and more proactively supportive of innovation.

We encourage standardization but also encourage innovation. We are examining providing baseline functional criteria for the certification to be adopted at scale with more innovative functional criteria provided in a transitional, iterative, phased-in approach. This will allow innovators to lead the way by continuing to advance functionality within the roadmaps ahead of the adoption curve. The goal is standards APIs that can be implemented by all certified EHR systems and other health IT vendors to supports interoperability. And again, laying the foundation for patient engagement was mentioned previously.

The Task Force encouraged continued testing in real settings to validate and improve the standards and the use of human-centered design to ensure patients will benefit from these advancements, putting a stake in the ground to lead all stakeholders…payer, provider, vendors…toward adoption at scale. You want to go to the next slide?

Baselined, phased-in certification criteria must be enabled by all healthcare stakeholders. Payers, vendors, and other healthcare stakeholders need to be able to send and receive the required information within the workflow to meet the business need. These stakeholders need the ability to come together and match to the same requirements and ensure API conformity. Proprietary capabilities and APIs increase the burden and should be avoided and discouraged.

We discussed an ONC proving ground focused on the development of the functional criteria for each of the phases for the innovation roadmap as we realized that success can only be realized if all stakeholders have the functional criteria to share accurate and compressive information required to complete a PA. If information is not accurate, complete, or sent for most of the patient mix or a patient setting, it results in a one-off workflow. Incentives for development and use of the technology to level out the playing field for the smaller stakeholder groups are needed, again, across the gamut of stakeholders – providers, payers, and other healthcare stakeholders – to increase integration and reach adoption at scale across these stakeholders.

Additionally, and a big point, any technology proposed for certification should be affordable and accessible to all healthcare stakeholders from all locales, settings, sizes, and resource levels. **[Inaudible] [01:01:30]**,

clearinghouses, and other technology enablers could be a roadmap to FHIR to support small payers and providers who could utilize the FHIR-based capabilities to support this direction and level the playing field. We could not leave patients in underserved communities behind in improving this process. It would exaggerate the healthcare disparities that already exist in our country.

We have a lot more work to do in a short period of time, but we really do look forward to providing you a report on this important topic shortly. And I just want to thank you all for the opportunity to co-chair this Task Force and appreciate working with you, Sheryl. So, with that, I think we open up to questions.

Sheryl Turney
I think we see one question from Cynthia.

Cynthia Fisher
Thank you, Sheryl and Tammy. And I would like to thank the Task Force. As you look at prior auth, and I am representing PatientRightsAdvocate.org, as we look at what the patients really seek, it is they want to have in their prior auth financial certainty. And ultimately, patients are looking for a binding and complete price upfront. Actual prices, not estimates that have no accountability. So, when you were looking at what really is needed in the healthcare system, it is like any other marketplace. It is that patients seek to have a binding complete price when they are getting planned services in a hospital as well as having complete bills that reflect that price.

So, I think what is really important is that hospitals that have contract physicians, such as anesthesiologists and radiologists or NICU folks that maybe contract, the prior auth includes all of the practitioners even if they are supposedly out of network or a private equity owned group, either by a hospital or an independent firm. But when we get this prior auth, what is the complete care for that colonoscopy in that prior auth? And to see the total actual price that the consumer is going to pay. Because based upon their plan, they will want to also be able to compare prices not only within that same hospital system as to their plan and other prices, but also a prior auth in another hospital system or at a standalone center, whether it be surgical or imaging.

So, as we look to building this platform or these standards or coming across systems, I think it is really important to look that we are moving to a world with these price transparency rules into a competitive environment where both hospitals and insurance companies and middle players are going to be needing to compete to disclose complete prices so that the consumers can choose. So, I just want to put that there, that it is not just the out-of-pocket costs that matter and it is not shielding them from actual prices. Wherever we can design systems that can move to a world that actually functions for choice, I think it is far better for us to move to that entity rather than backwards on what has been quite broken for decades.

Sheryl Turney
Tammy, let me take this one if you do not mind, and then if you can add. Because I actually brought this up, Cynthia, in the Task Force meeting. And we did discuss the fact that we need to have a connection and not look at this in a silo completely separate from price transparency. So, the RFI does ask for the patient input, and we will be at least requesting that this not be looked at in a silo and that prior authorization relationship to cost transparency be looked at more as an integrated solution as we move forward. Because right now, as you know, today, it is a very disparate process that has been put in place for cost transparency and it does not very easily tie to the workflow for what has been put in place for electronic prior auth. So, I

assure you that a conversation has taken place and will continue, and we do really appreciate that input. And Tammy, go ahead and pile on.

Tammy Banks
Yeah. I just wanted – the reason Sheryl and I were smiling is this has really been a key discussion point within the Task Force. But if I can even make it one step further that the group went, thinking about bundles. Right? Why not look at it from a treatment plan and not an isolated service procedure or a durable medical equipment? So, could prior authorizations be looked at across a complete plan when there are more services that are being performed is one of the directions and some of the language that we are fleshing out which would just take it one step further. Right?

Aaron Miri
Yeah. It would be amazing to bundle in a prior auth with advanced care planning or something.

Tammy Banks
Exactly. You go in for a patient episode and it is – anyway. It is something we are fleshing out.

Aaron Miri
That is fantastic. Arien Malec, I see your hand is raised, sir.

Arien Malec
Thank you. So, first of all, just thanks to Cynthia for really raising this issue persistently and consistently through the HITAC. It is a really needed area.

Maybe a couple of other things that the workgroup can consider or contemplate in this space. One is the forward looking to an advanced EOB ruling or readiness for advanced EOB. There is a pretty clear connection between the preservice work that we are doing and we are trying to facilitate here with EPA and getting to advanced EOB and having payers and providers who can meet the advanced EOB rule set. The second is to look at additional specification around eligibility information and connect between eligibility and EPA in ways that enable us to create a more holistic administrative process that better serves patients. And in particular, things like accumulator information, coverage specifiers, and other things that are sort of optionally in the eligibility transaction could be pulled out and serve as better triggers for EPA transactions.

The general gist is let us look at EPA as part of a move to put more of what we sometimes call the revenue cycle in the care delivery system setting…let us put more of that process in the hands of patients and preservice and make sure that anything else that is post-service is on an exception basis as opposed to sort of the mainline work is reconciling financial information post-service and surprising patients. So, as we think about this work, let us be thoughtful. And I see the Task Force chairs already doing this. Let us be thoughtful about the system that we are designing that optimizes the collection of as much of the administrative payment process of healthcare upfront, preservice, so that we do not surprise patients and we let patients and providers concentrate on care and not concentrate on billing. So, this work is vitally important and thanks for the Task Force members and the chairs.

Sheryl Turney
Cynthia?

Cynthia Fisher

Yes. Thank you very much, Aaron, for that. And I would just like to say that I think we need to think rather than also designing the systems for how the systems are multilayered now, is how do we simplify and streamline, to Aaron's point, that the patient is well-informed in advance of care. And I would like to give an example on even this advanced prior auth. We know the patient, young woman, who went into Mass General for a breast reduction. Now, that can be under plastic surgery, and at a cash price, it is $11,000. However, this was deemed as medical necessity and would be covered by her father's insurance plan. As it turned out, it could get evaluated as a prior auth but did not get that information in advance of care of what that overall price would be. And as a $7,500 deductible, you looked at $11,000, and finally, after many, many, many weeks and several months, actually, trying to understand what the insured rate would be, it was $58,000. Over $58,000 estimated. And it turns out that is where the bill ended up. They went through the insurance, still had a $7,5000 deductible.

So, when you look at these egregious levels of price differences for the same young woman by the same surgical team, she should have the option that her father's plan, in some way, could pay that cash price, that that hospital, Mass General, gets the cash upfront from his business at $11,000 versus paying over $65,000 for the same exact surgery, same surgical team, same – the same, all in.

So, these are the kind of problems consumers are facing because being a small business owner, having premiums go up at 18 percent on insured coverage, people are trying to figure out how they save all of their workers on these monies. And when the hospital gets that cash up front and will take a cash price at $11,000, we should not just think about blocking that information from the patient to see this type of choice. And contractually, I think when the hospitals and providers get paid right away in cash at this much lower rate, that anybody who has insurance should have the option to be able to pay that cash through their business covering rather than at a premium because that is a shopping price and the hospital does not have to spend all the money to collect it. But I think if we go into these systems as they are now, we are preventing people from saving, as that family could, north of $50,000 to that family's small business.

So, I just want to put that out there that this is real and there has got to be a much better way to let people see their options and have other ways to pay.

Aaron Miri
Got it. All right. Any other comments from HITAC? I do not see any. Any parting words, Sheryl or Tammy?

Sheryl Turney
Well, first of all, I want to thank HITAC for your input today because we are very much looking forward to bringing that back and building it into our recommendations and overall principles going forward. And as you know, this is really tough work and we are so appreciative of everyone who has volunteered their time to be on this subcommittee. I just really want to thank the support we are getting from Accel and ONC as well. Thank you. And I see Clem has raised his hand.

Clem McDonald
Excuse me. Cheer on these recommendations we heard about trying to get stuff simpler and faster and better. But I also heard a little bit of whisper. Is part of this group also doing attachments? Because that is sort of an ancient activity that I have been involved in. It has got to be 20 years, maybe more. And it would be great because this is a longer gestation than 10 elephants or 20. But the question is, is it really going to be born? Or is this part of a different discussion?

Sheryl Turney
Well, the RFI, Clem, asks specifically about certification process. And, of course, because so much of the work in electronic prior authorization would require some level of attachments or at least supplemental documentation, whether that comes structured or unstructured, etcetera. The goal we would all love to see is that the material comes in digitally and then eliminates the need for an attachment per se. But that goal is something that we are not going to be able to achieve in the next two to five years. We are still going to be working with systems that, unfortunately, are disparate and that are not all hooked to a hospital system, especially as you are working with value-based care arrangements. More and more, the providers of those services are not the providers that are necessarily connected to those mature EHR systems. So, it is a problem that we do need to address in our RFI. And Tammy, I know you have an opinion on this as well.

Clem McDonald
I was involved and most of the things that are wanted are documents. I mean, you want to see this report record, the **[inaudible] [01:16:21]** record, the chest x-ray. That is doable. I mean, it has been doable for a long time. So, I do not know what is the hang up?

Tammy Banks
Well, Clem, you will see our recommendation in regard to attachments one way or the other. And we are still discussing it, so we do not have a full, fleshed out recommendation. But PAs need supplemental information at times. It is the only way to handle all of the PAs. And you are right. Today we are document based. But as we look at these recommendations, we are trying not to just look at today. We are looking at the future. So, how do we get the documents digitized but then move to a more data driven exchange of information through APIs. So, yes, we have to get the document based and get them moved digital, so that is step one for phase one, potentially, and then move into a more innovative process which allows date to be more –

Clem McDonald
Well, do not let excellence be the enemy of sufficient because it is a struggle. I mean, people spend a lot of time on all this paper and it is fairly easy nowadays to ship a document around. I mean, they do it everywhere. I mean, you want to label it. That is part of the issue, but that was all worked out in many of the iterations of the attachments. How do you say what you want? And then you have just got to read it because that is what they need to do. That is at least step one.

Tammy Banks
Right. And ONC has done a fabulous job. I mean, the CCDA is required for the health IT vendors, and we have the two – so, we have a lot of the baseline functionality that we can work with. And so, Clem, your discussion is also front and center of our dialogue. So, we look forward to grappling with that and coming back with a recommendation in the report.

Aaron Miri
And that is a good plug also, Tammy, for the full definition of EHI coming live this October. Right? Just reminding everybody again.

Tammy Banks

Exactly.

Aaron Miri
October is every bit of information, so that will also shine a light on a lot of exactly what Clem is talking about and what you are talking about. So, all right. Good points, Clem, as always, sir. Other hand raised? We have got about three minutes left before the break. Okay. All right, Hung, go for it.

Hung Luu
So, I just want to add that I think we are doing a great job in terms of designing the architecture to make it easier in terms of what the ONC has purview over. However, a lot of the insurance companies have their own processes. They have set their own portals with their own information requirement. And so, while we can standardize and require data elements for the different EHR systems to be able to capture it and transmit it, the issue is that some part of it is going to still be manual. Right? I mean, this is to Sheryl's point. It is fragmented and not everybody has the same capabilities. I think until we can make the system more streamlined, it is going to place an undue burden on the clinical staff because they are going to get questions from their ancillary staff.

And so, I think that Cynthia's vision is definitely laudable, but until the process is streamlined and simple, it is going to be challenging for each hospital system that a patient approaches and wanting a prior authorization quote to provide that to the patient due to the fact that it is just so cumbersome. And so, I think that the issue is that we are going to be butting up against what the ONC has purview over and what it does not. I mean, I think the authority necessarily stops at what the EHR is capable of but does not finish off with that process of how do you standardize acceptance of the prior authorization by the different insurance companies so that we are not having to deal with ten different portals every time you want to submit something.

Aaron Miri
Yeah. And the good news, that coordinating function, I also like to remind folks that the ONC is a fantastic coordinator across functions. So, even if it is something that does not have direct purview over in some form or function, there are other ways to coordinate as entity. And I think they do a great job of bringing those folks to the table, as you see the federal representatives here from across various agencies. So, the good news is that the HITAC could recommend in partnership with others in collaboration efforts. So, that is the good news.

All right. Let us see. One minute, I think, so I think at this point we are going to say any further comments or questions, please direct them via email. Sheryl and Tammy, great job. you are still working on synthetization of those comments and the feedback. So, with that, Mike, if you are good with it and, Denise, if you are good with it, I say we go to break and keep the schedule and be back at 11:30 a.m. Eastern time. I would remind the committee that we are going to be pausing but still live, so you may want to mute your mics and others. Thank you.

Information Sharing under the ONC Cures Act Final Rule: Transition from USCDI to Full Scope of EHI Definition (01:21:40)

Mike Berry

And hello, everyone, and welcome back from the short break. We will now resume the February HITAC meeting and I would like to turn it over to Aaron to introduce our next speakers. Aaron?

Aaron Miri
Thank you very much, Mike. Welcome back, everybody. Hopefully, you got a quick break in there. All right. So, up next are two fantastic and just incredible speakers, and we always learn a wealth of new knowledge from them. So, introducing Elise Sweeney Anthony and Mike Lipinski from the ONC.

Elise Sweeney Anthony
That is quite the introduction, Aaron. I hope that we hold up to that. So, I am going to go ahead and start and then I am going to turn it over to Mike, and we will go through a number of aspects related to information blocking with a particular focus on the transition from USCDI to the full scope of EHI. And we thought this might be a good time to do this. We are always happy to come and share kind of what we have been working on or to provide an overview of a topic that some may be familiar with, others may be getting to know as well. So, information sharing is always something we are happy to talk about and that is what leads us to today.

So, to start out, a couple of disclaimers to share. One, the materials contained in this presentation are based on the provisions contained in the 21st Century Cures Act and 45. CFR Part 171. And while every effort has been made to ensure the accuracy of this restatement of those provisions, the presentation is not a legal document. The official program requirements are contained in the relevant laws and regulations and please note that there are other federal, state, and local laws that may also apply. And this communication is produced and disseminated at U.S. taxpayer expense.

All right. So, to go ahead and get started, we thought that we would start with kind of looking over at 21st Century Cures Act. And for many folks who were involved in the review of the Cures Act final rule a few years back, there are many presentations that we can give that are hours long on particular sections, from the exceptions to information blocking more generally to the overall provisions that exist in Title IV. But today, we are going to give a little bit of a snapshot discussion of some of the kind of fundamentals or the foundational components and then we will talk more about EHI.

So, to start out, the 21st Century Cures Act, in particular, Section 4004 which is in Title IV, focuses on information blocking. So, this particular Section 4004 discussion information sharing and what that should look like. The scope of the information being electronic health information, for example. And importantly, it also identifies that through rule making there should be certain reasonable and necessary activities that are not considered information blocking. We call those in our rule exceptions.

So, those exceptions lay out situations in which the information may not have moved. It was not shared, it was not accessed, exchanged, or used, but there is a reason why. And that reason, through the exceptions, would take you out of the information blocking landscape. And there is a number of different ones. There are some related to privacy. There is one related to security. There are some related to the operation of the technology. So, it could be that the technology was down at the particular time that the request for information came in and it was not sent. So, there are practice reasons and there is a very practical environment that we look at and we think about in relation to the exceptions themselves. And those were identified in the Cures Act final rule.

In addition, the Cures Act lays out that the Office of the Inspector General would investigate claims of information blocking and that there also was consideration that we work with others at HHS. For example, OCR, the Office of Civil Rights. And this is a great opportunity for me to mention that Kathryn Marchesini is on the line as well, and she is our chief privacy officer and she works very closely with OCR on a range of different issues, including as it relates to the development of this rule when we were in the development phases, but also on an ongoing basis on a number of different projects that we are engaged in. and we are very thankful to, one, have her here at ONC and all the insight that she brings, but also to also have her on the line.

So, in addition, it also talks about the penalties for information blocking, and those penalties depend upon the actor. So, if you are a developer of certified health IT, if you are a health information network or a health information exchange, as those terms are defined by the rule, then you fall under a category for penalties that would involve up to $1 million per violation penalties. And those would be civil monetary penalties. If you a healthcare provider, again as that is defined through the Cures Act final rule, then you would be subject to what is called appropriate disincentives. And on appropriate disincentives, HHS is considering what those should be, and when the time comes for that to move forward, then that would be through notice and comment rule making as well. In addition, the Office of the Inspector General is also working on a rule related to civil monetary penalties as it relates to the first three actors that I discussed.

The other thing that I wanted to note is one of the parts that 4004 lays out is in relation to the complaint process. And this is really important because this is how we find out that information blocking may have occurred. So, complaints that are coming in to ONC through this complaint process, we have a portal – a feedback portal and a particular information blocking section that highlights this, and we have the link further on in the slide deck. But it is super important because this is how we find out what is happening on the ground. This is how HHS is able to take in and see where an actor may be engaged in information blocking. And there is more information on our website about what that process looks like as well.

All right. So, when we talk about information sharing, and that is the way we like to think about the opportunities that are presented by Title IV, generally, but specifically 4004, and there is benefits to the patients as we know in terms of patient engagement. Patients really being part of their actual care continuum, having information that can help them understand the decisions that have to be made and participate in those decisions as well. Being an active part of their care continuum, that shared decision making.

In addition, easier access to your health innovation. We live in an electronic world, and many of the different areas that we operate in allow for that flexibility to access your information electronically. And as the healthcare landscape catches up and moves into that 21st century world, we have seen a lot of amazing innovation in terms of how different actors and just generally the healthcare landscape is supporting patient access. So, we are really encouraged by that and excited by that. We meet with a lot of different stakeholders and we really see that there is innovation happening, that actors are really trying to identify how can we best support patients. And that is something that we are looking forward to and it goes towards the innovation aspect of 4004 as well. How can we innovate into this 21st century world, this 21st Century Cures world, in which access is more readily available to patients?

And then clinicians as well. And clinicians, as well as developers, we hear a lot about the requirements that are placed on those two particular actors, which is true. The information blocking provisions apply to

healthcare providers, also applies to developers of certified health IT, along with HINs and HIEs. But all of those particular actors, they also receive a benefit through Section 4004 as well. There are many situations from when we first started to hear about information blocking around that 2015 time period when we released the information blocking report that was sent to Congress. And Congress really requested and wanted to hear more about how this is happening. Way back then, and still today, we hear about situations where those in the healthcare system, the landscape, whether it is providers or others – HINs, HIEs, developers – need to access information that they may not have within their system, within their landscape. And trying to access that information, sometimes they end up having impediments to that information flowing.

You can think of providers, for example. Right? So, a provider who is not affiliated with a particular hospital and they are in a rural care environment and they are seeking to provide care for their patient who has been seen by a specialist elsewhere. And when they try to get the information, because they are not affiliated with that particular hospital or that particular provider group, they have problems accessing the information in the same way that someone else may. The information sharing provisions in 4004, and what we have put into the regulatory framework to implement that through the Cures Act final rule, addresses that. It is not just about patients. And patients are, of course, critical to the landscape, but the opportunities to providers and others in the landscape who are supporting the care continuum, supporting what patients need, is also important. It is important that they have the information they need to support care.

We think about care innovation, care coordination, even the choice of software and how you choose to put your system into place to support the needs and the particular specialty that you might be involved in are critical. And same with developers as well. The innovation that we have been discussing and the provisions that are in place support the landscape for developers to really work with providers and ensure that they have what they need. And all of that is really part of how we think of information sharing and what 21st Century Cures Act is all about and particularly in Title IV.

So, as we have that kind of landscape, let us talk a little bit about where we are. So, in 2019, we released the proposed rule. In 2020, we published the final rule. We also released an interim final rule that adjusted some of the dates in consideration of the public health emergency of COVID-19. And here we are now with April 5, 2021. The applicability date has happened and we are almost at a year, believe it or not. We are almost at a year of this applicability date being live, as it were, where providers, health information networks, health information exchanges, and developers of certified health IT are held to the information blocking requirements.

And with that in mind, so now from April 5, 2021 through 10/5, so October 5th, through that date, is when the USCDI kind of linkage exists in terms of EHI, and we are going to talk about that a little bit. And then as Aaron was noting earlier, after 10/5, after October 5th – so, starting on October 6th – is when the broader scope of EHI comes into play.

So, let us talk about the definition of information blocking. So, 45 CFR 171.103 for those who are like me and live in regulation, here is what the provision looks like. And the information blocking is a practice, right? So, that is the first thing to think about. It is a practice that has occurred or is occurring. But information blocking does not exist if there is a law that says you should not share the information. So, that is the first thing to consider. There may be situations where there is a law that says do not share this information. If that is the case, then information blocking has not occurred because you are not sharing information that

you should have shared because the law requires that that information not move. In other situations, maybe there is not a law, but you have not shared the information, and as I said before, there is an exception that applies. Again, that kind of takes you out of the information blocking landscape.

The other important piece of the definition is "interfere with." Interference or interfere with, and that is really important because has there actually been an interference with the movement of electronic health information. And that is another part of the evaluation, of that kind of case-by-base analysis of the elements of information blocking.

And then the other piece that I wanted to highlight is the knowledge standard, and that is really important when you are thinking about the actors that are at play. So, if you are a developer of certified health IT, if you are a health information network or a health information exchange, then your knowledge standard is that you should have known. You should have known that the activity that you are engaged in was information blocking. And that is a different standard from healthcare providers. Healthcare providers have a standard of did they know. Did they know that what they were doing is information blocking? And that is what Congress has laid out in Section 4004.

The other piece that I just wanted to highlight and just make sure that folks are focused on is what you see at the bottom of the slide. So, that version, that USCDI version, is Version 1. And that is really important because as many folks know who follow ONC's activities, we actually just released Version 3 of the USCDI for comment, and that is out for comment now. So, we are always thinking about the next stage of how do we expand the core data for interoperability, and that is what it stands for, the United States Core Data for Interoperability. How do we expand that to really include more information? And some of that information that is in USCDI Version 1 is not – there has been updates from USCDI Version 1 to what we are now considering for Version 3. But the reference here is to Version 1, so that is currently what is in regulation at this time. So, I just wanted to highlight that as well.

A couple of other things to note on the next slide before I turn it over to Mike – there we go. So, a couple of things I wanted to highlight are around the synergies between HIPAA. And Mike will talk a little bit about this as he goes into the EHI in more specific areas. But HIPAA and the alignment to HIPAA is really important. And we heard a lot about this as we were developing the rule. In fact, when we were going through the process of reviewing the comments, there were a number of comments that called for even more alignment with HIPAA than what we had included in the proposal.

So, if we go to the next slide, there we go. Okay. In the next slide, this is the proposed EHI definition. So, this is what was in the notice of proposed rule making that we released, and you can see that there is alignment to HIPAA here, particularly the electronic protected health information. You can even see that there are references directly to HIPAA here. But what we heard through the comment process, including through the feedback that the HITAC provided, is that it is really, really important that we do as much alignment to HIPAA as possible. And that is where we landed with the final definition for EHI if we go to the next slide.

And here you can see in the definition, there are a couple of different pieces to note. One, not only is there alignment to the electronic protected health information definition, or EPHI, that exists under HIPAA, but there is also specific alignment to the designation record set. So, it is the EPHI that would be included in the designated record set and as those terms are defined by HIPAA. Now, this is a definitional construct, a

regulatory framework, that many stakeholders are familiar with. If you work or are involved in the covered entity landscape or the VA landscape, then designated record set is a regulatory framework that has existed for many, many years as part of HIPAA. So, we thought alignment to that made a lot of sense to make sure that as we are moving towards this landscape of electronic health information and supporting the needs of the landscape in terms of the movement of that information, that we are using a definitional construct that is already in place.

The alignment also includes thinking about psychotherapy notes. So, psychotherapy notes as well as certain information that is developed in anticipation of some type of proceeding or administrative action, whether civil, criminal, or administrative, that those are not included in the definition of EHI. The other thing to note is that the definition, even though it is aligned to HIPAA, it applies whether or not the entity is a HIPAA-covered entity. And that is really important to keep in mind.

The other thing that I would note is that the definition of EHI is not limited to information that is recorded or exchanged as per a specific interoperability standard. And we will talk a little bit about the USCDI, and here is an important part for me to just reference again. The reference to the USCDI is to the data elements represented in the USCDI, not to a particular standard by which that information has to move between April 5th and through October 5th. It is about the data that is represented in that USCDI.

So, if you look at this last bullet, why is this important? Because it is really important for us to go back and look at the 21st Century Cures Act. And in that Title IV, there is not a discussion of information only moving as it relates to a particular interoperability standard. It is really about the movement of information overall. What we included in terms of the USCDI reference that takes us through October 5th is really to support the transition to this broader scope of EHI that you see starting on October 6th. So, there is lots of information that is included in the data elements represented in USCDI, but after October 5th, that landscape, that body of information becomes even greater.

And that really supports the needs of the landscape. It supports the needs of patients. And limiting the information only to a standard we know is also not we have heard is critical. We have heard that it is critical for things like clinical notes to be able to move as well. I know we are all patients – and I always say this, right? We are all patients, and as patients, being able to review your clinical note if you choose to, to take a look at it, to talk to your doctor about it, to engage with your care team and use any of that information, including the clinical notes, as a means to do that is critical. So, I always think about that shared decision making in that landscape of the patient being a part of their care continuum.

So, next slide. So, now we are going to talk about some specifics related to the scope of EHI. And Mike, along with Kathryn, put together a wonderful blog post, and I suggest that everyone read it. Great title, "Say Hi to EHI." Great title that talks about EHI and how to really think about it in the landscape of information blocking. So, let me turn it over to Mike to kind of go through this great chart that helps you to visualize what I have been talking about so far.

Mike Lipinski
Thanks, Elise, and good morning, everyone. I see there is quite a live – I have had an opportunity while Elise was presenting to follow the chat. Quite a lively debate in the chat and comments and I think questions. Hopefully, we will be able to answer them today. I could probably have an answer for every one of them I

saw, but I do not know if we will get to them all. But I want to finish the presentation and give you some time to comment and ask questions about that.

So, what you see on your screen right now is obviously, as Elise referenced, the blog that we have written. I am not going to go through the whole blog, but it talks about the considerations you want to have in terms of what type of data is EHI. And I think the one thing to emphasize is – and then she showed on the screen what we proposed as the definition and where we ended up. And we ended up there using terms from the HIPAA rule that are widely understood by the healthcare industry and already is a set of EHI that is currently collected, maintained, and made available for access, exchange, and use.

And we put together also, because we saw some misconceptions when we were talking with folks, about the scope of various data. So, we are hoping that what you see on your screen here, this infographic, will help give you some scoping understanding of EHI and what the actual data we are talking about. Some of the questions we get when we talk about what is data with stakeholders that is EHI, it is not even EHI so you are not really going to get into a situation where you have to either move that data or respond to a request for that data under the information blocking regulations. You will, if it is a patient, have some responsibility, obviously, under the right of access of the HIPAA privacy rule.

Well, let us move over to the next slide. So, a couple of points that we wanted to highlight again are highlight our FAQs. We issued four yesterday, one last Friday on the harm exception hopefully providing some clarity, and we have issued about nine just on EHI. This one on your screen talks about what is EHI and when is it limited and it is really focused on what EHI you have. Another FAQ that is not in this slide presentation but worth mentioning is how do you go about fulfilling a request for access, exchange, and use. And generally, you want to fill it in the way it is requested and not to try to artificially restrict or otherwise influence the scope of the request. So, you want to keep that in mind as well.

Let us move to the next slide. I think we are going to transition here. Yeah. And so, in some of the comments that I was seeing in the chat and so forth, the one thing that Elise mentioned earlier, too, is Congress gave us the definition of information blocking, including those knowledge standards. ONC did not create those. And for providers, it is both unreasonable and they knew what they were doing was likely. And that is the thing. You have to remember that the interference standard is quite broad. It is likely to prevent, materially discourage, or inhibit access, exchange, or use. So, keep that in mind. And in terms of determining if somebody had the requisite knowledge standard, OIG has dealt with that, the Office of the Inspector General, in enforcing the anti-kickback statute. And so, they have ways of determining in particular circumstances whether or not somebody had the requisite – the actor had the requisite knowledge standard.

But again, what we were really asked to do was to identify reasonable and necessary activities that were not information blocking. And so, we bucketed those into three overall policy goals we were trying to achieve with them, and it really was looking at the landscape of information blocking and the health IT infrastructure as it was when we finalized this rule. So, that includes all the actors covered. So, not just actors that have certified health IT and are participating in promoting interoperability programs or other payment programs that require the use of certified health IT, but also pharmacies and labs and long-term post-acute care that are covered by the information blocking definition, both from a statutory perspective and from a regulatory perspective, to make sure that these exceptions were broad enough to assess each particular fact and circumstance.

So, it takes into account what did you have available, what were your resources, and we will talk about a couple of the key exceptions here. And like Elise said, we could talk for hours about this, and the privacy exception is one that I would also love to talk about and we have talked about in other presentations, so I will refer to those. We just did one recently for an upcoming conference. But just understanding was a precondition is versus what is required by law. I think we have seen, even by attorneys, a misunderstanding of what required by law is, and it is not necessarily a lot of the HIPAA regulations because those are permissive and they just say that certain conditions must be met before the information can be shared. And so, the privacy exception sets up that you need to have policies in place to meet those conditions and satisfy those conditions so that the information can be exchanged. So, whether it is consent and authorization or it is the minimum necessary standard that would apply in an operation setting or a payment setting. So, I just wanted to keep that in mind as well.

And let us move to talk really quickly about a couple of exceptions. So, we are going to talk about the infeasibility exception, the content and manner exception. Some of those reference the fees exception because the fee exception really comes from the perspective that any fee could be an interference. Right? And we have heard that so many times from stakeholders through the rule making and prior to the rule making and still to today depending on what that fee is and what it is for. Right? And so, we acknowledge that, but then we said some fees are reasonable, and therefore, there is an exception. And so, you need to be keeping that in mind as you are providing access. And depending on if it is manual effort, for example, when it is a patient requesting the information, that there is a fees exception that allows for certain charging in that case.

But let us jump to the next slide and talk a little bit first about content and manner exception. So, this is where ONC kind of put a bit of a stamp on the interoperability space. Because as Elise noted, Congress did not require any standardization of EHI, but obviously we are aware that some of those providers, and particularly business associates like the EHR developers, are participating in EHR – well, now they are promoting interoperability program. There are other ones that require the use of certified health IT. So, we wanted to leverage that and leverage interoperability. I mean, Congress put a definition in the Cures Act as to interoperability.

And so, this particular exception first allows the market to try to handle that request of EHI, but if there cannot be terms reached there, it goes through an alternative manner approach. And particularly, you are moving on when it is technically unable to do one of the other ones, one of these – and you see them on the screen, the different alternative manner. Ultimately, our goal is to get the EHI out and moved for access, exchange, and use. So, the last option is always alternative machine readable format. One obvious thing that I want to emphasize here is that it has to be agreed to by the requester. And it is still important to assess whether or not this exception could be applied to a particular circumstance because when we talk about the next exception, this is one of the factors. What happened here? Was it really the requester that said they did not want it in those particular formats or did you not even attempt to provide the EHI in one of these formats? So, that is a consideration when we are going to talk about the infeasibility exception shortly.

But obviously, we wanted, initially, just market terms to work, but if they did not in the format of the requester, this was an opportunity to focus on standardized approach for access to EHI, which we continue to support through certification program. As you are aware, the already continuing version of USCDI. So, we are doing what we can under the authorities we have to standardize EHI as much as possible. But again, info blocking

was much broader than the certification program in terms of the actors covered and the type of EHI we were talking about.

So, let us move to the next exception. So, the infeasibility exception. So, in the final rule, it broke down into three separate conditions. So, you had some, such as an uncontrollable event – and we have actually gotten questions about this one as well. Like, there is a public health emergency for the COVID-19 pandemic, does that just mean I have the infeasibility exception? And the answer to that just clearly is no because we say in the rule it has to be due to those events. So, you would have to draw a connection. In some cases, that may be true. Some hospital systems have been overwhelmed at times by the pandemic and maybe they do not have the resources. So, again, going back to that fact-specific circumstance, that part of the exception may apply to you under the circumstances. Others may not have – there may be no surge, may not be many cases in their area, so they cannot just assume there is a nationwide public health emergency, I can use that exception. So, I wanted to point that out.

Segmentation, obviously, is another one. And it cannot unambiguously segment certain data depending on your tech capabilities. You could have the ability to take that exception. And then obviously the big one is the factor test. So, is it infeasible under the circumstances? And this is such an important test from the broad perspective of information blocking because it looks at each circumstance – each actor's circumstance. So, it allows it to be applied to long-term post-acute care. It honestly allows it to be applied to a large healthcare system who for years we have heard allegations that they have not shared EHI with local competitors. And then it applies this test to that circumstance. And it is particularly looking at are they providing the same access to anyone else.

And how does that relate to the content and manner exception? It is a really good connection that you may not see on its surface. So, that first part of the content and manner is try to reach terms on whatever way the request is being made. It may be there could be pretext and they are like, "I am not providing it this way." And so, you go to the other three alternative manners and perhaps the requester says no, I do not want it in any of those ways, I want it in the way I requested and I know you can do it. So, then you come to the infeasibility if you could never reach agreement, and that is one of the factors. Are you providing that EHI in a way to someone else? Remember, you can charge fees for that access, including a profit, under the fees exception. So, when you look at the infeasibility exception, particularly this part, this condition, it is really going to look at the particular facts and circumstances as to whether or not all these factors taken together – do you meet the exception or not.

And I think I want to also emphasize here, even if you do not meet an exception, it does not mean you committed information blocking. Right? Again, the practice itself has to be information blocking. So, you have that. And then very importantly, it is an intent based statute and regulation, so it is really going to go to what was the actor's intent there. We are hoping to issue more FAQs about different things, like we have talked with stakeholders who are trying to comply, sometimes it takes time to figure out is this EHI, do I have this EHI, is it feasible for me to make this EHI available in the way it is requested. That may take time. And as we have talked about in other contexts and issued FAQs about, it is really – a delay, it has to be an unnecessary delay. Right? Or illegitimate delay. So, as we said in other contexts, there are reasons for legitimate delays, and so depending on the facts and circumstances, the delay may be legitimate there and you do not have an interference. This is just one example for you.

I am going to stop – well, actually, I think we can go to the next slide, but these are really just your resource slides. All of you guys, definitely Steven Lane, based on his post in the chat, know all about our resources and where to find them. But for those who do not, this slide should help you figure out where to go to find those resources.

Okay. I think we can go to the last slide which is just if you want to report information blocking, you can go specifically to that link and on our website through the portal. And then the last slide is just I think the closing slide. So, now I think we can open up for questions.

Elise Sweeney Anthony
All right. Sounds good. Aaron and Denise, we will leave it to you in terms of – I do not see any hands up yet, but I am sure folks have questions.

Denise Webb
Well, I have a question.

Elise Sweeney Anthony
Okay, Denise.

Denise Webb
I have been thinking about this a lot, and as we now have TEFCA published and the landscape for health information networks and EHI is evolving and changing, and eventually patients may want avail themselves of an HIE that provides individual access services and go to their provider and say I want my EHI sent to this HIE. Obviously, connecting to an HIE involves financial investment and those kinds of things. So, I imagine if it is a small clinic, they could consider looking at all those facts and circumstances around that request and possibly do the factor test with the infeasibility exception. Would that be correct to assume?

Mike Lipinski
I think they can – I will jump in first. I mean, I think they could definitely do that. The thing that we are unable to do is to give an advisory opinion, which would be to apply that exception to the facts and tell you based on all the facts you provided, yes or no, this exception would apply. And we just – at this point, we do our best to say here is what we can do, which is focus on the terms, explaining the terms in the definition, explaining what we think would or would not likely be interference. Obviously, you have to take into account the circumstances and the knowledge and the intent behind whatever particular action there was. I could sit here, and we debated. There are many times I can talk about where doing certain actions opposite of what we said in a particular FAQ could be interference.

I think the other piece is, I would just mention when it comes to HIEs, because it is actually Congress and the president who signed, that would be President Obama, signed the Cures Act. Right? Weighed in on HIEs and the value of HIEs, particularly to patient access, with Section 4006 of the Cures Act, so I think it is worth reading that where they wanted to see and they actually amended other parts, that business associates would also help to provide patient access where they can. So, those are just some other considerations that we even mentioned in the rule, trying through info blocking to also implement where we could 4006, whether it is through EHI export or other steps that we can take such as TEFCA.

Denise Webb

Well, I would just comment that I think that ONC FAQs are helpful, but what I'm hearing constantly from provider organizations is the best way to train their people is scenario-based training. And there are just no scenarios. There are no examples to say, well, here is an example. I mean an illustrative example. So, I think that continues to be a challenge for provider organizations. I am personally trying to help some clinics with educating them on these rules. And it always comes back to, well, can you provide some use cases, can you provide some scenarios. And I think that has been a constant ask of ONC. But I understand the balancing act you have when it comes to that from a regulatory standpoint.

Elise Sweeney Anthony
Yeah. And Denise, just to add to what Mike said, there are examples in the rule. There are also some examples in the FAQ in certain situations. Now, as Mike said, they are all fact specific. The scenarios, I should say, are fact specific. We try to give some general examples, but one differentiating fact could be a determination of whether information blocking occurred or did not occur. But I think taking a look at some of the examples in the rule and then in the FAQs might be helpful.

Mike Lipinski
Yeah. I mean, what we have been able to do in the rule, the proposed rule and the final rule, and we can always continue to do again, is to say what we think could or could not be interference. But when you talk about scenario based, I suspect you want to know whether or not an exception can apply and that is where we just go back to. Because ultimately, whatever ONC would issue there, it is really going to be OIG that comes in who does the investigation and makes a determination of whether or not you met that exception or not and whether it even applied in that circumstance. So, we could not really give a scenario where we said, under all this, this exception would apply because it could be inconsistent with what OIG would end up determining in the end. And that would be problematic for stakeholders and the department in terms of implementing this regulation.

Denise Webb
It looks like we have some hands up, so I should get off the floor here and let Dr. Lane go next.

Steven Lane
Yeah. I just wanted to ask about what you are calling the factor test. I did not know if that was a new term of art. I had never seen that before. A quick Google search just leads me to medical tests for rheumatoid factor and clotting factors. So, I think I understand in your slide what you are talking about, just the various factors that could constitute infeasibility under the circumstances, but can you just clarify your use of that term?

Mike Lipinski
Let me make sure. Am I off mute? Yeah, I am. So, that is directly from the reg text. It says these are the following factors that will be assessed to determine whether it was infeasibility under the circumstances. It also includes certain factors that are not to be assessed in that circumstance as well, which includes whether or not, I believe it is competition, it would lead to more competition. So, it is directly from the reg text. So, I just called it a factor test because it says the following factors will be assessed. Exactly. Thank you.

Denise Webb
Okay. Clem, you are up.

Clem McDonald
Well, there are two key issues or questions I have. One is if you anticipate that the care providers or the systems will not just deliver? I mean, that they will hold back and be kind of crummy about it? I guess in the past, there was some of that. Second thing is can we promote email? Tell everybody, if you say you can take it as email, they can send it to you. I mean, it is just the simplest thing, but we are terrified of the privacy in some institutions. And they know that it is legal to send email if the patient says send it as email. So, I think we should promote email. And, of course, there is some secure email, too, which is golden, but patients do not always have those setups. So, two questions. Do you think the organizations are going to use these tricks as tricks to avoid sending stuff? And the second thing is can we really shout about using email and encourage medical record systems to send email? Every other system does. I do not know if medical records systems do or not.

Mike Lipinski
Go ahead, Elise.

Elise Sweeney Anthony
To start off on the kind of provider question, we hope not. We hope that there is full support and implementation and really following what is laid out in the Cures Act final rule and that providers do kind of participate in this in support of their patients, in support of what is needed across the care continuum. So, that is not our… our hope is that that happens and we do not want to see scenarios where there are attempts to sidestep the provisions. Now, that said, if an entity does sidestep and a claim comes in, that is something that could be reviewing, right? It could be reviewed whether the facts and circumstances of what the provider has done is information blocking. And an evaluation of that would include looking at whether they knew what they were doing could be considered information blocking. That would be part of the analysis.

On the second question, remind me again, Clem, your second question.

Mike Lipinski
Email.

Elise Sweeney Anthony
Email. Right. So, email. And Kathryn Marchesini, our chief privacy officer, is on, so I want to give the floor to her as well. I will note that email is a way that information can move. And OCR talks a lot about this in reference to HIPAA. The other point that I would keep in mind is under the content and manner exception, there is a conversation between the requester…the patient, for example, and the provider or whoever they are requesting the information from regarding how they want to receive the information, going through that step that Mike had talked about. So, that could be a mechanism by which the patient says yes, I would like to receive the information that way.

And that just goes generally, before I turn to Kathryn, that goes generally to something you will see across the Cures Act final rule and everything that we do at ONC. When we are thinking about policy, when we are thinking about technology, we are really thinking about how do we support flexibility for things to happen effectively and the way the patient may want or the way the provider or others in the landscape may want things to happen to support what they need for care. So, you will see that in the content and manner exception is a perfect example. You also see that in things like the privacy exception that allows for the

consideration of a number of different things, including the patient's wants and desires. So, with that, let me just turn it to Kathryn and see if she wants to add anything as well.

Kathryn Marchesini
Sure, yeah. Thanks, Elise. Just a couple of things I would like to mention. The HIPAA privacy rule, there is actually guidance out there on patient right of access that specifically speaks to this and the concerns around liability that the company might have. Really, it is about if a patient does want to receive information by unencrypted email, or I would say some other unsecured manner, if the individual requests it that way, as long as the individual was warned or they actually accept that there are security risks associated with releasing that information via unsecured transmission, overall, you can see from the guidance that OCR has issued that the covered entity is not responsible if there is a breach or the liability about the disclosure once the actual transmission has occurred. So, I just wanted to share that. I think the only concern that I would bring if that is going to be encouraged as a way to share information, the conversation about what happens to that information once it is maintained and received by a third party that is not covered by HIPAA,I know there are some comments in the chat about non-HIPAA covered entities. So, I just wanted to bring that to the discussion if that is talked about. Back over to you, Elise.

Mike Lipinski
I just wanted to add a couple quick points. So, one is I literally, personally, meet at least once a week with a stakeholder group. Probably more than that. And then I would say ONC, if you added everybody up together including our national coordinator, Micky Tripathi, multiple times a week. And I will say everybody is trying to do the right thing. Every stakeholder that I have talked to, including providers, are really just trying to understand the rule and how it applies. I think ones where we have heard where they have done something that could or could not be info blocking, I will say it that way, it is still just a misunderstanding, like they do not understand what is required by the law compared to HIPAA and they are misapplying some of that. So, I do want to say that my engagements have been, whether it is with the large EHR developers, are all trying to do the right thing, I will say. I will say it that way.

And the other piece I just want to say is, because I saw a comment in the thing, like there are no disincentives, providers may or may not be doing the right thing. The one piece about that is the applicability date was April 5th. So, the department or OIG has not issued the rules yet and they have discretion there in terms of when they will exercise their enforcement which they noted in the proposed rule for focusing on HINs and HIEs and developers of certified health IT. But once these regulations are effective, theoretically, they can go back to April 5th to take enforcement action if they so chose if they propose it that way and finalize it that way. So, just keep that in mind, too. Not to say they are going to. I just want to say that it is quite clear the regulations are applicable to all actors as of April 5th.

Clem McDonald
So, that answers my first question. I would just like to do a little follow-up on the email –

Denise Webb
Clem, can we hold on your second part? I know everybody has a question, too, but to be respectful to our public, we do need to go to public comment. And then if we have some time, we can take the remaining couple of questions. All right, Mike. We are going to turn it over to you for public comment and then we will see if we have enough time.

Public Comment (02:08:32)

Mike Berry
All right. Thank you, Denise. Great. Thank you. So, as Denise noted, we are going to open up the meeting to the public for any comments. 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 star nine to raise your hand, and once called upon, press star six to mute or unmute your line. So, let us pause for a moment to see if we have any public comments. And I am not seeing any public comments at this time, so I will turn it back to Denise and Aaron.

Denise Webb
All right. So, Clem, if you could quickly ask your next question.

Clem McDonald
I think we should focus a little bit on email. I mean, security risk terrifies everybody. But realistically, if they are not putting their name and address in there, just an email, it is not a big deal. And in terms of the medical data, most people have normal results and a lot of the people are old. They are not at any risk. So, I think they scare people with that security thing and privacy thing, and I think we should probably suggest specific ways it should be sent to minimize bad problems and at least highlight that it is available.

Denise Webb
All right, Clem, I should mention I just finished reading the AMA playbook on patient records and electronic access. For all of you on the committee who come from a provider organization, if you have not seen that playbook, I highly recommend it, and it specifically speaks to the issue of using email. It is a great resource, and I recommend you all look at it.

Clem McDonald
Can you put it in the chat?

Denise Webb
Can I put it in the chat?

Clem McDonald
Yeah.

Denise Webb
Yeah, sure, if I can find it real quick.

Clem McDonald
Or a link.

Denise Webb
I can do that. Ike, I know you put your hand down. Did you still have a question before I go to Alexis?

Steven (Ike) Eichner
I will pass for right now. Thank you.

Denise Webb
Okay. Alexis, you have your hand up.

Alexis Snyder
Yes, I was going to say in regard to the whole email conversation, it is my understanding, and if someone from ONC or from privacy can correct it or not or confirm, that those health entities that have an electronic system, even if they do not have a portal, if they are keeping electronic health records, then if a patient requests the information to be sent to them electronically, even via email, then that needs to be followed through with. Otherwise, that would be blocking as well because they have electronic capabilities.

And the second comment to that I would state as well is that this really speaks largely to the need for a standard way of sharing electronically because there are health systems that send secure email. There are other health systems that will use a third-party verification system and you have to upload your ID and answer a bunch of questions before they can even send anything out whether the email is secure or not. So, I think that just speaks volumes to different health entities delivering the information to patients different ways and we really need standards for the electronic process.

Elise Sweeney Anthony
And I just wanted to highlight, I think we are very supportive, I am just using patients as the example here, but as we have noted before, the applicability under information blocking and the benefits of information blocking are not just to patients. Right? It is a really important point. I think provider to provider, provider to HIN or HIE, and provider to developer and that relationship as well.

But just to talk about the patient, for example, patients being able to access information in a way that works for them is extremely important, and that flexibility exists throughout what we do at ONC whether you are looking at content and manner exception on the information blocking side of our house, as it were, but also on the other side of the house in terms of the certification program where we talk a lot about supporting mechanisms like application programming interfaces. Because to Mike's point, in terms of us hearing from stakeholders, one of the environments in which some of these innovative technologies have been helpful, such as APIs, is for patients who may have a cancer diagnosis or have another diagnosis that involves a diverse care team that may be located in different systems across different platforms and across different networks. And having the ability for them to be able to pool their information or have someone on their behalf pool their information to help them with their care, whether it is care coordination or also having a second provider look at your case to help you determine your next steps. Right? So, a second opinion.

There are so many different scenarios in which having flexibility in the technology that is used to support patients is need. Email is one scenario where that could be helpful, but APIs are another example. And I am sure many folks on this call could highlight others as well.

Denise Webb
All right. Ike, you have your hand back up.

Steven (Ike) Eichner
Thank you. From a public health perspective, public health is engaged in a variety of aspects of healthcare and health surveillance. When public health is acting as a healthcare provider or providing services like immunization registries that are designed to share information across the healthcare continuum, that is one

set of scenarios. Another set of activities are disease surveillance activities where we are collecting data that really is not designed, our data collection efforts, to be used for coordinating healthcare. Additionally, many of those registries and systems are managed or controlled by state laws that have very specific requirements about with whom and in what circumstances data may be shared. So, how do we resolve those components?

Additionally, for some of our registries, like cancer registries or some of our reportable disease systems, we are very appreciative of the software provided by CDC, but the function of the software does not support querying of the data by providers or the underlying pool does not really have the ability to support that kind of query or support direct access by patients. So, that is an issue that we need some help and guidance and probably some collaboration to work through.

Elise Sweeney Anthony
I can start and I will see if Mike has some thoughts as well. So, I think there are a couple of components to that. the first is that when we are talking about information blocking and the information blocking regulations, we are not just talking about the data that is in an EHR, for example. And I kind of want to put quotes up on that. Right? Even in that context, it is not just data that is in an EHR. It could be data in other systems as well. And that is really not different from what exists currently under HIPAA in terms of the flow of information and supporting the flow of information and when you think about the designated record set. So, I just want to put that overlay on it.

The other piece is required by law, and there are also other areas in the exceptions that talk about if the law allows the information to move. Now, that required by law provision that I talked about earlier in terms of elements of information blocking, again, that is in reference to a situation where the law says you cannot share this information. So, you do not share the information. You not sharing the information does not mean that you are an information blocker in that context. Right? So, if a state law says or a federal law says or a local law says you cannot move this information, then that is something that is considered in the information blocking analysis.

So, let me stop there and I will see if Mike has any additional –

Mike Lipinski
Yes. I just wanted to weigh in on a couple of things there. One, obviously, I think you were getting at, Ike, that in certain instances you may meet the functional definition of HIN, as Elise talked about earlier, particularly maybe in that immunization registry situation. It goes to what you are controlling, too, and whether two or more parties are able to exchange across it or is it just more like a possible clearinghouse as a different example.

The one thing that Elise mentioned about required by law, the statute just said unless required by law. What we did and what the department did through the regulation was interpret that in a certain way to include, as Elise mentioned, not just federal laws but state laws, even certain court decisions, federal administrative body decisions as well. So, if your state, as Elise was saying, said that you cannot share what would be EHI with certain actors even, because I am well aware that that has occurred in certain states we have looked at, then as Elise said, you would not even need an exception or so forth.

But be careful with those. I just said I have seen some, and they are pretty clear about the way they operate, some operate differently. I have seen some California laws that say you need to do something before you share the EHI. So, there is still an expectation that you fulfill that precondition before sharing, so that does not just mean you do not share it at all. Right? It just gives you the ability, under info blocking, you have to go through the steps to fulfill those conditions before you share it.

Denise Webb
Well, it looks like we do not have any other questions. Thank you so much, Elise and Mike.

Elise Sweeney Anthony
It was our pleasure. We are always happy to come. Information sharing is our favorite topic.

Denise Webb
It is a hot topic. Everybody wants to talk about it. All right. So, I think that concludes our agenda today. And I am going to turn it over to Aaron for any concluding remarks he might have if he is there. He might have stepped away. Are you there, Aaron?

Aaron Miri
I am here, yes. I had technical difficulties. I was trying to unmute and undo my video there. Anyway, I am here. All right. So, we are finishing up. So, thank you very much. I appreciate that, Elise and Seth. Fantastic job, Mike. Thank you very much, everybody. Great meeting and see you next time.

Denise Webb
Yes. Thank you, everybody, and appreciate everybody's contributions and engagement. And have a good month until we see you in March.

Aaron Miri
That is right. Be safe.

Final Remarks and Adjourn (02:19:24)