The Office of the National Coordinator for Health Information Technology

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

January 13, 2021, 10:45 a.m. – 2:15 p.m. ET

VIRTUAL

Speakers

Name	Organization	Role
Aaron Miri	**The University of Texas at Austin, Dell Medical School and UT Health Austin**	**Co-Chair**
Denise Webb	**Indiana Hemophilia and Thrombosis Center**	**Co-Chair**
Michael Adcock	Magnolia Health	Member
Cynthia Fisher	PatientRightsAdvocate.org	Member
Lisa Frey	St. Elizabeth Healthcare	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
Arien Malec	Change Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Individual	Member
James Pantelas	Individual	Member
Carolyn Petersen	Individual	Member
Raj Ratwani	MedStar Health	Member
Abby Sears	OCHIN	Member
Alexis Snyder	Individual	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem, Inc.	Member
Robert Wah	Individual	Member
Amy Abernethy	Food and Drug Administration	Federal Representative
James Ellzy	Defense Health Agency, Department of Defense	Federal Representative

Adi V. Gundlapalli	Centers for Disease Control and Prevention	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
Donald Rucker	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
Beth Myers	Office of the National Coordinator for Health Information Technology	Deputy Director, Office of Policy
Andrew Gettinger	Office of the National Coordinator for Health Information Technology	Chief Clinical Officer
Thomas Mason	Office of the National Coordinator for Health Information Technology	Chief Medical Officer
Lauren Richie	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Michelle Murray	Office of the National Coordinator for Health Information Technology	Staff Lead
Al Taylor	Office of the National Coordinator for Health Information Technology	Presenter
Alex Mugge	Centers for Medicare & Medicaid Services	Presenter
Bakul Patel	Food and Drug Administration	Presenter

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

Operator
All lines are now bridged.

Lauren Richie
Good morning, everyone. Good morning again to our HITAC members, and Happy New Year to you all. Thank you to the members of the public for joining our first meeting of the year here. It's great to see members in person after quite some time of just being virtual only. We have a full agenda to kick off our year today. I realize that the meeting is a bit longer than our past virtual meetings, so we do have a formal brief break right around 12:30 or so. We have some new faces and names in the committee. We welcome Dr. Steven Hester and Lisa Frey to the HITAC. Also, as a reminder, especially for our new members, please use the "raise hand" function in Adobe if you'd like to make a question or a comment.

We had an administrative meeting just before this, so I'm going to document the roll call from earlier. We have Aaron Miri, Denise Webb, Michael Adcock, Lisa Frey, Valerie Grey, Jim Jirjis, Cynthia Fisher, John Kansky, Ken Kawamoto, Steven Lane, Les Lenert, Arien Malec, Clem McDonald, Brett Oliver, Terry O'Malley, James Pantelas, Carolyn Petersen, Raj Ratwani, Alexis Snyder, Sasha TerMaat, Andy Truscott, Sheryl Turney, Robert Wah, Michelle Schreiber, James Ellzy, Ram Sriram, Adi Gundlapalli, and Jonathan Nebeker. Are there any other members that I have not announced or were not present on the earlier administrative call?

Denise Webb
Did you call Abby Sears?

Lauren Richie
Abby, are you on the line? I didn't catch her earlier. Do we have Abby?

Denise Webb
I see her in the participant list. Maybe she's not on the audio yet.

Lauren Richie
Okay, we will –

Denise Webb
She's saying she's here in the chat box.

Lauren Richie
Got it. Thank you, Abby. Also, from our ONC leadership, we have Dr. Don Rucker, Steve Posnack, Beth Myers, Seth Pazinski, Dr. Andy Gettinger, and Dr. Tom Mason. Before we turn it over to Dr. Rucker for opening remarks, again, I just wanted to take this time to offer any committee members the opportunity to disclose any outside activity with ONC. We'll just ask you to get into the queue by raising your hand, and then we'll jump right into the agenda. We'll start with John Kansky.

John Kansky

Thanks. I'm John Kansky. Just for transparency's sake, I'm acknowledging that I serve on the board of the Sequoia Project, which is the RCE, and perhaps not surprisingly, my organization occasionally participates in small contracts with the ONC. Right now, we're specifically supporting the national COVID response. Thanks.

Lauren Richie
Thank you. Raj?

Raj Ratwani
Good morning. This is Raj Ratwani with MedStar Health. The MedStar Health Research Institute has a contract with the Office of the National Coordinator.

Lauren Richie
Thank you. Ken?

Ken Kawamoto
Good morning. Just in general, I have honoraria consulting sponsored research licensing for code development with McKesson, Hitachi, Pfizer, Premier, Eclasis, RTI, Mayo, University of Washington, UC San Francisco, MD Aware, and ONC via **[inaudible] [00:04:07]** and Security Risk Solutions in the last three years, and was also an unpaid board member of HL7, and I've helped develop a number of tools which we might commercialize.

Lauren Richie
Thank you, Ken. Andy Truscott?

Andrew Truscott
Hi, I'm Andy Truscott. I'm the chair elect of HL7.

Lauren Richie
And, Steven Lane.

Steven Lane
I mentioned it in the earlier meeting, but I'll repeat here for the record that I served as the chair of the board of the Sequoia Project and the chair of the Steering Committee for Carequality, both of which are involved in the ONC's TEFCA RCE work.

Lauren Richie
Thank you. Carolyn?

Carolyn Petersen
Yes, I am an unpaid board member of HL7.

Lauren Richie
Thank you. Aaron, is that your hand in the queue?

Aaron Miri
Yes. I'm Aaron Miri. I am an unpaid board member of the Sequoia Project.

Lauren Richie
Great. Any others? With that, I will turn it over to Dr. Rucker for a few remarks.

Welcome Remarks (00:05:14)

Donald Rucker
All right, thank you, Lauren. First of all, we'll welcome everybody to the new year. I would like to thank Carolyn and Robert for their leadership and their chair service, and I'd also like to thank some of the folks who have served in the past on HITAC – Christina Caraballo, Anil Jain, Steve Ready, and Tina Esposito. I welcome Steven Hester and Lisa Frey, and finally, I would definitely like to welcome Denise and Aaron to their new roles as chairs. I've had the chance to have some personal discussions with both of them over the years in various things, and they are both very astute in understanding the complex landscape and, frankly, leading organizations through that landscape and understanding the challenges and opportunities, so I think it's a really great pair of folks as chairs, so I just want that to be known.

As folks know, this is my last time doing whatever I do on HITAC – I guess, leading ONC – with a change in administration. It's been an extraordinary privilege for me and a pleasure to work with the ONC team and to work with you. I think the ongoing work that you guys have done – we're even going to talk about some of it today, and fruition – obviously, everybody knows the Rule. I hope it will go down as one of the pivotal events in getting the American public back into knowledge about and control of their healthcare in a way that is truly empowering, truly modern, and in sync with the rest of our digital lives, so I want to thank folks for the work there.

Obviously, while there are a lot of legal considerations in making that possible, the underpinning is all standards, and you guys have done great work on the various standards suggestions and the reports – they're dry reading at times, but fascinating. I believe I've read all of them, so I guess there will be somebody else reading them from now on, but I actually hope to read a lot of it as well as time goes on. You're going to see the U.S. Core Data for Interoperability, which we've just released based in part on your suggestions. I do want to note that the shopping list of the suggestions for the USCDI was very, very long, both from folks in the HITAC community and the public at large.

We've really had to put in some powerful selection pressures because this is the data that we are asking essentially every EMR to steward and collect, and so, as things evolve, HITAC will no doubt be there for next steps, but it is heavily bounded by what we want to ask of every single participant in the EHR ecosystem, increasingly globally with our GDHP work on the International Patient Summary, which is the international version of the USCDI. So, for folks who didn't get their data field in, just blame it on me, but that's the explanation on that. So, it's out there, and obviously, further consensus.

I think as I leave and reflect on things, we have some extraordinary opportunities in front of HITAC. We see there is further evolution of standards. I think great work has been done on integrating clinical and administrative data. I think as we look at things like patient matching and identification, I would encourage folks to think very richly about patient matching as more than just a number, but really the entire package

of authenticating patients, the authorizations of what data patients are eligible to see – theirs and family members' – and then the consent process. It really needs to be an integrated whole.

I'll just close by saying that obviously, we've had an extraordinary public health emergency. I think it has shown and gotten me focused a lot on how we do health information exchange. It's something that has been very aspirational in the ONC work, literally since David Brailer and Secretary Leavitt started this back in the day. I think today, as we look around, with health information exchanges, especially the state and the local ones that are essentially the last mile, we have some extraordinary opportunities to really expand that in a very pro-competitive way so that all players in healthcare can compete in offering services to patients and that we can get in the folks like group homes, shelters, jails, schools – that whole milieu that is part of care – and do that in a robust, privacy-protecting way. Hopefully, we'll do it efficiently.

We should look at the public health emergency – the exigencies of COVID have required a vast burden of out-of-process reporting – spreadsheets and flat files flying around everywhere. There's a disconnect there when we've all invested in EMRs, and through our collective work, we all pretty much have EMRs. So, I think we really need to work with the HIEs to get that information to our public health authorities, to CMS, to FDA, to all of the public agencies that need data so that we're not doing this in a duplicative kind of way. There's an extraordinary opportunity here. It is well within the charge of HITAC to rethink the entire nature of reporting of health to government, and again, it's one of many, many opportunities, so I wish all of you well and look forward to your continued great work. So, with that, let me turn it over to Denise and Aaron to get things going. Thank you.

Remarks, Review of Agenda and Approval of November 10, 2020 Meeting Minutes (00:12:49)

Aaron Miri
Dr. Rucker, thank you so much for your leadership. Well, welcome, HITAC. Welcome to a brand-new year. It is 2021. Let us hope that 2020 is in the rearview mirror and we're moving forward. I am honored to be one of your co-chairs going forward with my partner Denise Webb. First, I did want to quickly offer thanks to Carolyn Petersen and Robert Wah for their phenomenal leadership over the prior couple of years. With HITAC being brand new and instituted under 21st Century CURES, we had to figure out the road, and they were phenomenal leaders in helping us in our committee, and so, I am honored to help take up the baton moving forward.

Secondly, I wanted to thank Dr. Rucker, the entire administration, all of HHS, and the secretary. You are correct in that COVID was an eye-opening event for a number of things, but your leadership was instrumental, particularly with the HITAC and the ONC, but across all of HHS, so I'll speak with my provider hat on now: The things and the opportunities that you and HHS helped alleviate, with barriers to overcome and hurdles to hop over that we didn't even know were hurdles until they hit us in the face, were instrumental, and I thank you on behalf of the entire provider community. There's a saying here in Texas, "Find grace in chaos." You helped us find that grace, and I want to thank you for that, so thank you for your leadership. Denise?

Denise Webb

All right. I certainly echo those comments. I really appreciate your comments, Dr. Rucker, and I want to extend my personal thanks to you, Carolyn, and Robert for your leadership, passion, and contribution to our collective work. The amount of work that we've gotten done in the last few years has been just awesome, and your leadership has definitely been instrumental in that, and I hope that you will stay involved in possibly different ways as you leave your position, and we are certainly going to miss you.

We have a busy agenda today. I need to quickly go over that with you. We're going to start our day with approval of the minutes, and then, Carolyn Petersen and Aaron Miri are going to give an update on the HITAC Annual Report workgroup, and hopefully, many of you got to look at the draft. It looks superb. There was a lot of good work. We will also get a presentation from Al Taylor in the Office of Technology at ONC, and he's going to tell us about that draft that just came out for the U.S. Core Data for Interoperability Version 2.

We're going to take a short break, and then we'll come back, and Alex Mugge from CMS and Steven Posnack from ONC will talk to us about the CMS interoperability and prior authorization proposed rule. Following that, Bakul Patel from the FDA is going to tell us about the FDA's digital health center, and then, finally, Lauren Richie will go over the HITAC 2021 final work plan. And, of course, we will have public comments after that, which are very important.

Aaron Miri
All right. So, let's get into it, then. Next on the agenda here is the approval of the prior minutes. Hopefully, you received that in your inbox, and I want to take a second to pop that up, and I will look for a motion for approval, please.

Sheryl Turney
This is Sheryl. So moved.

Aaron Miri
May I have a second, please?

Steven Lane
This is Steven. I'll second.

Aaron Miri
All right. All those in favor, say aye.

Several Speakers
Aye.

Aaron Miri
All those opposed, say nay. All right, the meeting agenda is approved and the prior minutes are approved. Denise?

Denise Webb

All right. So, we are going to start off with the update on our HITAC Annual Report Workgroup, and I'm going to turn it over to Carolyn Petersen and Aaron Miri, and if anyone on the committee has questions, please raise your hand and we'll be watching for those questions.

HITAC Annual Report Workgroup Update (00:17:42)

Carolyn Petersen
Thanks, Denise. Could we have the next slide, please? I think what you'll see today in our set of slides is somewhat similar to what you have seen in the past. There is a discussion of how we've proceeded as a workgroup, and we will then get to the discussion about the draft that you were sent. So, I will move quickly through the slides so we can get to the discussion.

What we have here is our scope. As you all know, we did quite a bit of work this year with regard to considerations around public health and COVID, and the scope of the workgroup's charge was expanded to include the target area of public health as well as our three priority target areas laid out in the 21st Century CURES Act. The overarching charge is to inform, contribute to, and review draft and final versions of the HITAC Annual Report, which will go to HHS and Congress. This report is intended to track our progress as well as to provide recommendations for ONC and the broader community. And, looking at what we have in our document this year, we have analysis of HITAC progress related to the target areas as well as assessment of health IT infrastructure and advancement, analysis of existing gaps in policies and resources, and ideas for potential HITAC activities to address those gaps. Next slide, please.

This is our membership – again, myself, Aaron Miri, and Brett Oliver were on the workgroup this year. Christina Caraballo was also involved through December. She is listed as a former member. And, we have our ONC staff, led by Michelle Murray and her team, helping us with the drafting of this document. Next slide, please. Next slide. Our meeting schedule – as you know, we've pretty much run through the bulk of our work. Today, we present the review draft for you. We hope to get your feedback and to present to you next month a final draft that can be approved and sent forward to the National Coordinator and to Congress. Next slide, please.

So, today, we'll be reviewing this report and suggesting edits. Next month, we hope you'll be able to approve a revised draft, and then the HITAC will transmit that final report to the National Coordinator. From there, it will go to the HHS and Congress. Next slide, please. So, now, we'll get into the discussion part of this work. Next slide, please. Our target areas: Interoperability, privacy and security, and patient access to information, as stipulated by the 21st Century CURES Act, and we have expanded that to include the use of technologies that support public health. Next slide, please.

The outline of our Annual Report remains the same, as it was in previous years. We start with the executive summary, foreword, and overview. We review HITAC progress in fiscal year 2020. We have a landscape analysis, a gap analysis, and we provide some recommendations for addressing infrastructure gaps in health IT. We provide suggestions for additional HITAC initiatives, and then there is a conclusion and some appendices of related information that would be helpful as you read the draft, and also, all the references that are noted. Next slide, please.

So, our progress in fiscal year 2020: We had eight meetings of the full HITAC and one hearing. We had 45 meetings of three HITAC subcommittees. We presented 52 recommendations to the National Coordinator,

and these activities focused on priority uses of health IT, the intersection of clinical and administrative data, and the U.S. Core Data for Interoperability, which we'll hear more about today. Next slide, please. With regard to the landscape analysis, we have an annual assessment of the health IT infrastructure, both at the national and local levels, allowing for electronic access exchanging use of health information. The intention is to cover key topics in each of the four target areas as well as federal activities across those areas. And, we note some additional topics in the landscape analysis for awareness. Next slide, please.

On to the gap analysis. This is, again, a requirement under the 21st Century CURES Act. We're looking for gaps in policies and resources for achieving the ONC fiscal year '19-20 objectives and benchmarks and furthering interoperability throughout the health IT infrastructure. Next slide, please. We have recommendations as well. These are arranged in a tiered approach, some being immediate opportunities that we anticipate could be or should be tackled in the next one to two years – that would be 2021-22 – and the longer-term opportunities which are things we could look at, but probably are something that may occur three or more years out. Next slide, please.

So, now we're coming to the discussion. We really want to focus on three particular questions for the group today: First, if you have any questions or comments that we need to answer to help you better understand the draft report, second, any suggested revisions that you have to the draft, and finally, any ideas you have for the parking lot list for a future Annual Report. In some years, we have had ideas for discussion points that came up that are not things we anticipated we'd be ready to tackle immediately, but that we don't want to lose sight of, and so, we put those in a list that we can consult in future years as we put the report together to see if we are ready or in need of going forward with those. With that, Aaron and I are ready for discussion.

Denise Webb
All right, thank you, Carolyn. We do have a question from Sheryl Turney. Go ahead, Sheryl.

Sheryl Turney
Thank you, Denise. Under "immediate opportunities," one of the things that I was looking at regarding both public health reporting and vaccine tracking is today, the immunity registries are not really set up for data consumption. They're set up for reporting to some federal group regarding the vaccine use, and as payers have been looking to provide vaccine monitoring for return to work and other types of activities, one of the things that we've identified is that there needs to be some sort of support to allow the consumption of data, and I know some of them are implementing Snowflake, but I do think we need to have some greater recommendation or more robust recommendations regarding data consumption and interoperability for that data, especially as we're currently trying to figure out how to reopen everything with the pandemic.

Aaron Miri
That's a really good point. Maybe we can also open up – if you don't mind, Accel team – the actual document itself and just go to the executive summary chart. That may be helpful so we can actually pull up that area and point to it as folks talk about it. There we go. Perfect.

Sheryl Turney
The one I had was on Page 5.

Aaron Miri

Thank you. That last one, "vaccine tracking" – there we go. Is that the one you're referring to?

Sheryl Turney
Yes, thank you.

Aaron Miri
All right, perfect. So, something robust about ingestion of the data, essentially, and normalization and standardization. Is that where you're going with this?

Sheryl Turney
Yes, exactly, and there are apps trying to work on this right now, and the big issue is how you streamline the interoperability. Really, the easiest way to get the data would be to get it directly from the provider, of course, but we don't have that full structure set up, so the next best approach is to use some sort of consumption of the data that's currently reported to the registries, which also are not consistent across the country, as we've already discovered. But, none of them are set up for any type of consumption activity.

Some of them have rudimentary data exchanges for HEDIS and Stars reporting, but typically, only on an annual basis, so A). They don't have the staff, and B). They don't have the technical setup. But, in the discovery that we've been working on, there are definitely some that are working on Snowflake. I don't know if it's for us to discover, but there is some activity going on that way. But, whatever recommendations we can put in to help beef up that data exchange are going to be really important coming out of this pandemic, as is having that data available to us and the third-party apps who need it for returning to work and returning to life.

Aaron Miri
Great points, okay. We can definitely take that.

Denise Webb
Thank you, Sheryl. Arien Malec is next in the queue.

Arien Malec
Thank you. Just on that point, one of the things that I have been noting in recent comments in this area is the need to have an incentive structure and funding structure that aligns incentives. One of the systematic issues that we're in right now is a result of an EHR incentive program without a corresponding public health incentive program and public health funding models, so I would recommend that the report – particularly since it's a report back to Congress – focus on the funding mechanisms and the associated interoperability requirements attached to those funding mechanisms that help us create an ecosystem-based approach rather than a forced-mandate-based approach.

As an example, we had an EHR incentive program that included bidirectional immunization registry components, but we didn't have a corresponding funding model for public health immunization information systems or a set of certification requirements for those systems that were matched to the level of funding, so as we go forward, if we want something to happen as an ecosystem and a nation, I think it's really important that we have a focus set of incentive-associated funding that is then matched with certification requirements, certification programs, and testing programs that make sure that we have a full end-to-end

system. As many people have noted, when we deployed immunization registry or deployed reportable labs on the ground, many people discovered that the EHR output didn't match the public health input, and a more careful approach to incentives and incentive matching would help us address those situations. Thank you.

Carolyn Petersen
Thanks, Arien.

Denise Webb
All right. Les Lenert?

Clem McDonald
I've got a couple comments. The idea of the data not being accessible at all is overstated. The CDC has two sets –

Leslie Lenert
I yield my time to the gentleman from Indiana.

Denise Webb
Yeah, I was just going to say – that doesn't sound like Les.

Clem McDonald
I thought you said Clem. Never mind, sorry.

Denise Webb
Les, go ahead, and then we'll get to you, Clem.

Clem McDonald
Okay, thank you.

Leslie Lenert
All right. I think for us not to call for a national patient identifier or a systematic schema for national identification based on state or regional identifiers is more consistent with the law, but whatever it is, we need to definitively identify patients to track vaccines, and without that, we're wasting our time. Secondly –

Aaron Miri
Hold on. Can you scroll down one item, Accel? That's literally the next bullet on here. It's exactly for that. We can specifically call out vaccination if you like, but we did talk about patient matching and public identification.

Leslie Lenert
Yeah, but how can we track who has been vaccinated in a diffuse ecosystem wherever people are going to go – stadiums or wherever – to get vaccinated and conduct population health programs to target the most vulnerable without an identifier and intel systems? We're just not going to be able to do it.

Aaron Miri
Agreed.

Leslie Lenert
So, our urgent point right now – we need to develop an emergent reaction to this. Enough time has passed, and if there is a use case for a national identifier, there could not possibly be a stronger one than trying to vaccinate the nation, especially with a vaccine that requires two doses delivered three weeks apart. In a nation with a fractured health system and with people who are underserved and at higher risk because of their lack of resources, we could not have a stronger call for a national – if you cannot come up with a single number, let's come up with a strategy to use state identifiers or some other approach.

Secondly, this call for public health to be part of an ecosystem that Aaron just said is the most important thing. Public health has been designed as part of – their data systems have been part of what's been called an information supply chain. They have focused on that for – generations of public health providers have been trained in this theory that all data flows upward for policy decision-making for public health, and now we are in a situation where public health does have some of the data flowing upward through vaccine information systems through IIS, which are among the best standardized public health systems and well supported by meaningful use to deliver HL7 D2X messages at a state level and pass those on to CDC, but public health – those registries often have capabilities for individual-level reporting on vaccines – without an identifier, but you can know that three Mrs. Smiths all born on this date have received their vaccine.

The problem is there is no infrastructure for public health for population reporting – that is to say, the flat FHIR type of infrastructure we were going to talk about with CMS later in the morning – there is no way for public health registries to respond to a list of patients from a population health provider to be able to deliver their vaccine stats. That is a significant lapse in our infrastructure that has to be urgently addressed right now so that the people who are trying to target the most vulnerable can regularly get an update from the only – these hierarchical public health systems that we have to do their work because this won't be done by public health. This has to be done by the providers of population healthcare, which are payers and the healthcare delivery systems that are taking care of people. So, two-way interoperability – it is possible with our technologies now to do this, but we have to get off our bums and get on with the work with this, and we are in an urgent situation and we need to create the capability to respond at a population level.

Aaron Miri
You're spot on, and I appreciate your comment that we have to get off our bums. I completely agree with all that, particularly given you have states like California now empowering dentist offices and others to now be able to vaccinate that typically do not have an EHR that conforms easily with state reporting mandates and whatnot, so to do the degree of it, you're exactly right. Let's see how we can articulate that and stress the urgency to get off our bums throughout the report, so that comment is well taken.

Denise Webb
All right. Clem McDonald, you're up now.

Clem McDonald
Okay. I'd first like to support everything that Les said, but I'd also like to say the interaction between public health and clinical data has problems on both sides. Public health has historically been divided by disease

or by infection. The unity could be better, and they sometimes dumb down things in the reporting requirement. Why can't they just aggregate it up rather than dumbing it down or asking the sender to dumb it down. Both sides need to do better, I think, but there are a couple little dumb things.

So, we have been getting data from CDC for a project we're working on in terms of the most – who should get vaccinated next, and it's the old guys – it's the old black guys, actually – but it turns out that 45% of the CDC surveillance sites don't have race codes, and that's a combination of cultural things where people don't want to ask because they think it's racist – it's just a complicated beast. The other thing that may complicate things is the scorched-earth privacy strategy which makes it really hard to know who the person is and connect them up, and I don't know how we're going to grapple with that, but somewhere along the line, central areas need to know the individuals for certain of these purposes, and it's not always allowed. Those are my comments.

Carolyn Petersen
Thanks, Clem.

Denise Webb
All right, it looks like the last person with their hand up is John Kansky at this moment.

John Kansky
Thanks, Denise. So, the report looks comprehensive and wonderful as usual. I want to acknowledge that. With regard to the section on uses of technologies that support public health, I appreciate the acknowledgement that I think echoed some of Dr. Rucker's comments at the beginning of the potential role for health information exchange that has been demonstrated through the pandemic response. I'm going to suggest that I can save a few words by, at the end of my comment, promising to send to the Annual Report team a short whitepaper that I coauthored with David Horrocks from CRISP. My comment is that there's an emerging model of health information exchange that is suggested that implies – I don't know if it's so much a policy gap as a policy opportunity because certainly, policy could be used to accelerate the nation toward this model, but it basically gives health information exchanges a more official designation at the state level and a responsibility for supporting public health while still entertaining free-market competition. So, for what it's worth, I'll share that short whitepaper in the hopes that it might be helpful.

Carolyn Petersen
Thanks, we'll look for that.

Denise Webb
All right. Is there anyone that's just on the phone and not able to raise their hand that has a question? No? Steven Lane has popped up with a question. Go ahead, Steven.

Steven Lane
Thanks, Denise. I simply wanted to say that I see that we have documentation of the increased health equity across populations as a longer-term opportunity, and I think that within our industry, this has really bubbled up as a high priority, especially in the context of the pandemic, and I suspect it's also going to be a high priority for the new administration. They've assigned some specific resources to focus on this, so I think we may want to consider moving this up in the priority list as we go through the year.

Aaron Miri
Okay, noted. We'll definitely look at that. One thing I do want to call attention to for the HITAC is something that we did add net new for this year. We did try to synthesize each targe area into a real-life scenario or story, so even if you look at Page 55 – if you don't mind, Accel team – just to show them an example of one, it tries to illustrate in simple English and stories – go to the bottom of the page, please – an illustrative story. So, each of the sections have an illustrative story to talk through that.

I do want to ask HITAC to take a look at these. Each area has something like this. We try to pull experiences, comments from the HITAC, last year's report, and feedback we've gotten from the community and the public to generate these, and each of them has something as to what this could mean if we were able to solve these challenges because it is getting complicated to explain. It is getting complicated. There are so many moving parts – particularly given the pandemic – that have been uncovered that must be addressed, like unique patient identifier and others, so I would ask HITAC to please take a magnifying glass to the report. Please let us know your comments and feedback and if these things resonate. We're trying to make this in a way that's digestible and meaningful to the community. Carolyn, is there anything you want to add to that?

Carolyn Petersen
No, I just want to reiterate my support for your comment, Aaron, about members of the HITAC sending us your feedback. We do see it as a group product, although a few of us work on it most intensively, and we are interested in being sure that it represents the thinking of the full HITAC.

Denise Webb
Aaron and Carolyn, do you have a specific date by which you would like everyone to finish their review and get comments to you?

Carolyn Petersen
There was a date in one of the emails that was sent out with the documents. I am looking for it right now.

Denise Webb
Okay. Just as a reminder for everybody – I recalled seeing it, but I didn't remember what it was.

Aaron Miri
Michelle Murray, do you know off the top of your head?

Michelle Murray
I believe it was Friday the 22nd.

Aaron Miri
That sounds right.

Carolyn Petersen
That would give people a bit more than a week, which would be reasonable.

Denise Webb

Okay. Everybody needs to mark their calendars and get their input in if they haven't had an opportunity yet. All right. Well, it looks like that concludes any questions we have, and thank you very much, Aaron and Carolyn. You guys have done a tremendous amount of work, and we really appreciate it.

Aaron Miri
Thank you to the ONC team, the Accel team, to Michelle and Elyse, and to everybody that is helping translate our long-winded monologues and soliloquies into actionable and readable words, so we can't do this without them. Thank you.

Carolyn Petersen
Yes.

Denise Webb
That holds true for all of our subcommittees and all of our work. We cannot do it without ONC and our Accel team. Thank you. Okay, with that, I think we're ready to move to the next presentation, from Al Taylor, on the draft of Version 2 of the USCDI.

Draft U.S. Core Data for Interoperability Version 2 (00:44:39)

Al Taylor
Hi, good morning. I think I got everything working. Thank you very much for the opportunity to present on the draft USCDI Version 2. Next slide, please. So, here's where we're at in the process. This is a familiar timeline to everybody, and we are right at the juncture of the new year. We have completed our prep and publication of the draft USCDI Version 2, and we have now published it for open comment, public comment, and HITAC comment as well, and we were fortunate enough to be able to get this published for the HITAC to begin consideration. Next slide, please.

I think Dr. Rucker mentioned earlier that the list of data elements submissions through the ONDEC system was really overwhelming, though not entirely unpredictable, but we did get a significant – we were really overwhelmed with over 600 submissions that were put in through the system. More than 60 separate, unique submitters from about the same number of organizations submitted data elements for our consideration. Using the rubric and scoring and evaluation process that we have publicized, we determined that over 100 of these data elements were considered to be Level 2, which means most mature – either most ready or actually most in use – and affected a broader group of stakeholders in health IT and healthcare.

There was a similar number of Level 1s and comment-levels, which means less mature or less broadly applicable, and I think it's interesting to note that almost half the data elements were duplicate submissions, which either means that they were identical submissions submitted by multiple submitters or there were submissions that really constituted a subset of other submissions or other existing data elements. So, it's just a tribute to how intense the involvement was across the whole breadth of the stakeholder community. Next slide, please.

As we published yesterday, this is an overall view of the draft USCDI Version 2 that we put out for public comment. It's a fairly modest change. It's not a big, dramatic change, and also, as Dr. Rucker pointed out, this was intentional because people are busy doing a lot of stuff, including responding to the pandemic, so

what we have here is nine new data elements, and we actually reorganized several existing data elements into other data classes, and I'll talk about that in a second. We also have two new data classes, diagnostic imaging and encounter information. These are the new data elements that we have added to the draft V2, and we are looking forward to hearing probably vigorously back from the public on these decisions – the decisions we made and the decisions we didn't make – and we're looking forward to working toward a final version later this year. Next slide.

Just to drill down into the new data elements and the new data classes, we added two provider details or provider data elements out of seven different provider data elements, these being what we consider to be a minimum set to identify a provider involved with care. Diagnostic imaging is obviously a new data class. It represents one of the bigger gaps in concepts of USCDI Version 1, and we added the new imaging order or the test requested and the imaging report, which could be in a structured or unstructured combination. "Encounter information" is also a new data class where several, but not all, of the new data elements were added to V2, with encounter type, diagnosis, and time or timing. The problem data class – we added two data elements that defined the timing related to problem concepts, including data diagnosis and resolution. Next slide.

One of the key areas of feedback we got when we were deliberating the actually excellent feedback on USCDI Version 1 was the issues around clinical notes and how the data elements within clinical notes – the note types – pose a little bit of a problem, and the diagnostic imaging, lab report, and path report narratives were really components of the larger, more complete reports for imaging, lab, and path, and as a result of that feedback, in order to maintain the context of the content of these narratives – these narrative segments – we reorganized them or reclassified them into their respective data classes, so diagnostic imaging now has narrative component as a big, separate data element, and lab and path root narratives are the narrative aspects of the lab reports. Next slide.

In addition to the new data classes and new data elements – and reorganized data elements – we have proceeded to update the existing versions of the terminology code sets that comprised the applicable standards within USCDI Version 1. We've updated them for the most current version, and it will be our intent, pending feedback from the public and the HITAC, that the versions should be updated as of the most current at the time, so it would be our intent – as long as that seems acceptable – to have the most recent versions as of when we publish the final USCDI Version 2 in July, but these are the most current versions as of today – well, yesterday. Next slide, please.

I meant to have this after the list of numbers of submissions. As the USCDI Task Force in 2019 predicted, we got way more data elements submitted – and actually, way more data elements that ended up as Level 2 – than we could even conceivably imagine to add to USCDI Version 2, and so, we had to implement a prioritization system in order to select the Level 2 data elements that did make it into the USCDI Version 2. One of the – not the first, but one of the elements of that prioritization, including what I think of as major concept gaps in USCDI Version 1 – as a clinician, I felt like the diagnostic imaging was one of the biggest gaps looking at the USCDI Version 1 from a high level, and diagnostic imaging was one of the classes that we added. Provider and encounter information also were major gaps, in my opinion, and so, they ended up – but, that doesn't mean that those are the only significant gaps. There are other gaps that did not make it, and we had to be very selective for a couple different reasons, including the burden of updating and implementing these changes as a result of the pandemic and other issues that are going on.

Part of our prioritization was to represent a modest technical standards development list, such as updating the U.S. Core IGs or the CCDA IGs. Those technical standards – we heard back from them after we published Version 1, that they actually struggled for some time. A lot of work went into accommodating the data elements that we added in Version 1, and it took them over a year and a half to adequately address those new data elements sufficiently for USCDI Version 1. And so, we deliberately looked for data elements that had already had substantial technical development in the standards, which are necessary to actually implement them. The FHIR and the CCDA implementations of USCDI are those implementation guides.

And again, as Dr. Rucker mentioned, we intended to have the vendor development community as well as implementation in the provider community to have not that much additional effort to implement them, and the reason was twofold. One is that they're overwhelmed with the work that they're already doing, but also, because we're going to be publishing versions approximately every year, we wanted to encourage incremental updates as opposed to waiting until the next proposed rule where, instead of 10 new data elements, a vendor or implementer had to adopt maybe 40, 50, 100, or something like that, so we were mindful of that, so we offered this as a small step toward improving interoperability in health data exchange. Next slide, please.

So, now what? We've got it published for public comment, and over the next several months, up until April 15th, we expect to get some fairly robust public feedback, as well as input from the HITAC. Once the public comment is complete, we'll process that like we did after all of the submissions ran in October of last year. We'll prepare the final version of USCDI Version 2 on or about the 1st of July of this year. Once it becomes a new standard – a standard version – it will be considered for the standards version advancement process that we outlined last year, and we also published the first version – the approved updated standards – for 2020, which was published this week.

And then, one of the strong recommendations from HITAC and the USCDI Task Force when they completed their recommendations was the HITAC wanted to have a say – and, we encouraged that – into how we improve the process – not only how we improve the USCDI itself, but how we improve the process, the submission system, the evaluation system, the decision-making prioritization around selecting data elements for the next version, and those are the things that we intend to undertake this year, and also in future years. Next slide, please.

So, we have the charge for the USCDI Task Force and the HITAC as a whole. Overall, these are similar to the charges we had for the Task Force in the past in 2019, but overall, we want revie and feedback on the entire process, the entire content of draft USCDI Version 2 development. The three specific charges are to evaluate what we put out as draft V2, and the appropriateness of it, and any changes the HITAC believes ought to be made. Additions, subtractions, and changes are all on the table, and that specifically includes the USCDI Version 1 data elements – so, all of the data elements in USCDI got added to the draft USCDI Version 2, and we added a small number of data classes and elements for Version 2 based on the Level 2 data elements that were submitted, so it's that combination of things.

So, we're specifically looking for input on the Version 1 data elements that were brought forward, as well as the new data elements that were added. We also are looking for feedback on the Level 2 data elements that we considered, part of the list of 109 data classes and data elements that were added, and whether or

not there's a belief that we should have added some of those Level 2 data elements into the draft Version 2.

And then, we look at the process evaluation – so, the overall USCDI process, how we put together the submission system, how the submission system works, and information provided to submitters to put in these submissions. We published some evaluation criteria ahead of time to give submitters more information about how to create a better submission, one that's more of a significant consideration, and we look forward to feedback on that. We also discussed the prioritization process for recommendation from the HITAC, and one that we carried out in order to winnow down the field of Level 2 data elements for addition. So, the prioritization process with these specific criteria that I outlined it for is one of the things that we're looking for, and in recognizing that the priorities that we set for that process to be selected on Level 2 data elements for addition, those prioritizations might change from year to year depending on overall environment in which we're doing the update for Version 3, and so, recommendations on those specific priority criteria for the USCDI Version 3 submission plan.

This is not intended specifically to force submitters into what their submitting, so they're not – the intent is not to have them not submit certain things that are outside of these priority areas, but it's particularly important for ONC to see those priority areas and to help shape our decisions about which of those new data elements are submitted for Version 3 and Level 2 data elements for Version 2 to possibly also be reconsidered for addition to the next version. Next slide.

And, that's – please back up one slide. So, the timelines – these are notional. The first one is less notional, and it's more of a critical timeline. April 15th is the cutoff for public comment, and we felt like it would be appropriate to have the HITAC also meet that deadline in order to give ONC ample opportunity to process all of the recommendations – not just from the HITAC, but from the public – and to have all those recommendations inform our decisions about what we put out in our final USCDI Version 2.

And, the other two are toward the end of the year, toward the end of the Version 3 submission process so that we can make sure we have it refined so that in the high season of submissions, which will be August, September, and possibly early October, when most of the submissions come in anyhow, to have that expansion process, the submission system tuned up, and the evaluation criteria put out to the public so they know what they're getting into when they make a submission. And, we are asking for those tasks to be completed by the end of that Version 3 submission process in September. And, that's all I have, but I'll open it up for questions.

Aaron Miri
Perfect. Dr. Taylor, thank you very much for that presentation, and I do want to open it up to the floor for folks to ask questions. I would say that also, for folks on the phone, if you're not dialed in to be able to raise your hand, please state your name, but we're going to go with folks raising their hands first. Let's see here. I am now scrolling down to see. Let's start at the very top here. Ken Kawamoto, please.

Ken Kawamoto
Great. Thank you very much. My question is it certainly does seem like there are a lot of Level 2 items that have been submitted, and there's a whole bunch in terms of already well-established data elements to consider including in the USCDI. Can you comment a little bit on the bandwidth available or resourcing not

just to identify things, but to grade and put on final touches, if you will, before getting it into USCDI versus things that are really important, but might not already be well exchanged? You might think of areas that are particularly important related to COVID, let's say, or related to social determinants of health. Maybe they're related to workflows needed for prior authorization. Can you comment a little bit on the – it seems like the default approach is if it's almost ready, we're going to take the easiest to push off the end and get it into USCDI, which seems completely appropriate in the COVID era, but what about things that require more than a little bit of a nudge? How do we go there? Thank you.

Al Taylor
Ken, are you referring to bandwidth on ONC's part or bandwidth on the community's part?

Ken Kawamoto
I'm thinking ONC, whether it's on moving it through the process or supporting it through pilot projects, et cetera, because from the beginning in the USCDI, the Task Force had identified – it's a kind of chicken-and-egg issue where the things that are most likely to make it are things that the industry is already doing and implementing widely and sharing widely, at which point it's just like rubber-stamping what's already happening, and there is an important role for that, but in the Task Force, we thought that there was also an important role of the things that are important and not being done that need investment, resources, and coordination, and how do we move those forward?

Al Taylor
For the most part, Ken, ONC is turning toward the community to provide the drive and the work that needs to be done in order to mature the standards, including not just the terminology standards, but also getting those standards – those concepts – into the exchange standards, like U.S. Core or CCDA, and one of the things that ONC is committed to is making sure it's very clear about where some of these submissions that might not have made it into USCDI – the draft of the next version – make it clear to everybody and provide a place to go to organize around some of these data elements that need additional work. There are some possible circumstances in which ONC will respond to development of it, whether it's through support of the HL7 cooperative agreement, where we do work on development, some sort of development of the U.S. Core IG, as well as other implementation guides as well. And so, I would say that there are those possibilities, but for the most part, ONC is turning toward a community to drive the maturity.

Ken Kawamoto
Okay, thanks. I think this will probably be an ongoing topic of discussion of the USCDI Task Force because again, it is a chicken-and-egg kind of thing. I think I've said enough about it, but it's been a recurring thing. Thanks.

Al Taylor
Perfect.

Aaron Miri
Thank you. Next we have Michelle Schreiber.

Michelle Schreiber

Thank you. This is Michelle Schreiber. I'm from CMS, and in a way, I'm echoing what Ken said, but with a little bit of a twist. So, CMS had also submitted some data elements to USCDI that are used in our quality measures, and as CMS is trying to move toward all-digital measures, having these standardized elements is really very important, so the lessons from quality measures in the country over the last decade or so are such that when we don't have agreed-upon standards, we get a bunch of one-offs, we get a bunch of proprietary measures that people have to pay for, and I'm concerned that we're starting to see that in data elements now, so we've been approached about, for example, clinical oncology elements that we know that there's a group working on, and we approached another group to ask if we could standardize around this, and they were like, "No, we're working on something entirely different, and our vendor has something else, and we have to pay for it," and I'm talking about big organizations here.

And, I'm very concerned that if there's not a capacity to expand USCDI relatively easily that we're going to fall into what happened with quality measures – a bunch of one-offs, **[inaudible] [01:08:36]**, proprietary elements that people are going to have to pay for that will create more one-offs, and it will be really very problematic. So, I guess my underlying question is what's the rate-limiting step of how we can get more standardization and more elements into the USCDI? What will it take so that we can avoid that sort of problem?

Al Taylor
Thanks, Michelle. I agree that the issue is that consensus standardization of the elements, and two areas where I have recognized that being an issue are in research, which has a lot of different ways of representing data, all of which is important for research or for that particular research effort, and in cancer as well because there are a lot of different data elements, data systems, and standards around how to represent cancer data. Those two jump out at me as I look at that, having worked in those two areas over the years.

ONC is not going to assess the – is not going to be the entity that tells the world that you guys all need to agree on one particular system, either the one that we pick or the one that we pick. It's going to be up to the community to recognize that there's a limitation in the ability to use those standards in EHRs specifically because of those difficulties in developing consensus standards, so if the – recognizing that because research has four, six, or eight different data sets or data standards, it's going to be difficult to get those into the standard system, which is – being part of USCDI means that all EHRs who update to the new version of the standards have to be able to have the capability of capturing this, which means it should serve a broader stakeholder community, not just the communities that specifically want these new data elements to be added to USCDI. So, it's that issue about whoever is using that data has to agree that there's one way of representing the data, and that one way can at least be proposed to be added to USCDI.

Aaron Miri
Dr. Taylor, thank you for that. So, next on the list, we've got Clem.

Clem McDonald
Thank you. So, I liked all those comments, especially the one from Michelle, and I'd just like to – the federal government pays for some of these things that then get turned around into something that people have to pay for. It's tricky because some of these things need support, but I think we should just say no to federally mandated coding systems that you have to pay for. It's just a burden. Just the management of this is a

burden. And, the CMS has done a little bit of that with ICB, so I hope they can get brave and push a little bit harder, but I understand it's tough.

But, I want to first, again, praise Don Rucker because in my 40-45 years of working in standards, he's been the grease on the standards development process like I've never seen before, and it's just happening now – alleluia, alleluia – where we just trudged along going an inch forward and a half-inch back until that. So, that said, getting back to the USCDI, I couldn't figure out for sure what it was saying, so I looked at the draft thing, and some of it is statements, some of it is comments to ISA, so it would be nice – and, I just saw how you get to that better tab and I might be able to get a better handle on it. Some of the earlier ones just say you do this and do this, and it's not quite as clear. I don't know – are units required at all? It's not clear. They should be if you're going to compute on them, but anyway, those are asides. I'm sure it will all come out, so I won't worry too much about that. So, thank you.

Al Taylor
Thanks, Clem.

Aaron Miri
All right. Let's go on next, then, to Arien.

Arien Malec
All right, thank you. So, first of all, I think Clem means CPT rather than ICB. ICB is the WHO standard and CPT is a proprietary standard that requires additional purchase. I want to double down on Michelle's comments on aligning USCDI to the uses for which interoperable data is required, and if we can't pull data out of EHR systems and automatically adjudicate clinical quality measures, or if we can't pull data out of EHRs and automatically adjudicate, for example, this ability determination with SSA, then I think we really need to question the role of USCDI, and to some extent, that cuts both ways.

If SSA is looking for areas for disability determination that are not routinely collected in EHRs or if clinical quality measures are looking for information that aren't routinely collected in EHRs, we've got an ecosystem problem, and I'll just be a pain and keep pointing out this ecosystem that if we don't think about suppliers and consumers and make sure that we have the interoperability requirements and the data collection requirements matched up against the uses like clinical quality measures, or immunization information registries, or SSA disability determination, or natural history, real-world evidence trials like recovery, then we're really doing ourselves a disservice as a nation, so I just really appreciate the alignment that's required between USCDI and the uses to which interoperable data are put.

Aaron Miri
Thank you, Arien. Next on the list is Mr. Steve Posnack.

Steve Posnack
Hey, thank you very much.

Al Taylor
Go easy on me, Steve.

Steve Posnack

For some reason, I can't get a video, otherwise I'd do that, but perhaps at the break, I'll get my Adobe Connect back online. So, I just wanted to pick up on Ken's and Michelle's points, as well as some of the items in the chat. So, for everyone's benefit, the other day, we released three different documents. One was the draft USCDI Version 2. That includes everything that Al just covered and what can be made available for everyone to comment on, both the public as well as the HITAC process. We also included the standards version advancement process decisions for 2020. That's an end-of-calendar-year type of thing, so those are final.

And then, to give you all credit and to show you that we do listen and implement your recommendations, there's something called the standards bulletin that we also published, which is going to be periodically published during the years going forward to help cumulatively bind together a number of different ONC standards initiatives to give people that context and information, so when it comes to the additional details, some of which Al covered in his slides today, that's now included in the standards bulletin with helpful links and other directions for people to go in.

But, the point that Ken, Michelle, and others have started to poke at a bit is I think – and, it was recognized by the earlier USCDI task for – there's going to be a tension and a balance that we're going to face perpetually, and that is why we tried to lay out that there are other opportunities for groups to continue to work together in a community-based way, but also recognition that at some point, policy prioritization will need to be put in place, and if there is a need to promote and get industry response associated with supporting certain data elements, then we may need to use the USCDI process to do that as well, so my answer is that it's going to be at both ends.

A good example of that is you need device identifiers for implantable devices. In 2015, we included that as part of the Common Clinical Data Set, the precursor to USCDI. There was unclear adoption in the industry, but we knew from the perspectives of policy and data element support that we wanted all EHR technology to support the data elements, and that would be a good example where we put forward a prospective requirement that the industry needed to catch up to. And so, there's always going to be this balance where we could adopt any data element that we want and include it in the USCDI, but there may not necessarily be the technical specifications fully specced out, fully tested in the industry, and that will have to catch up in cycles after the policy decision is made.

So, I think we're going to wrestle with this decision every year, and it's going to be a balance, and that's why we've tried to implement a predictable timeline for everybody to now when their participation is going to be most valuable, be as transparent as possible about all the data elements that are accessible via the ONDEC system, and that will be a continued dialogue that we will enjoy having with everybody because I think these are the types of conversations that we really want to have now when we look at what data elements we want to be broadly accessible, both for document exchange as well as for API-based exchange.

As you all well know from our regulatory briefings, the USCDI comes to life through the certification criteria that we have, both for CCDA document exchange as well as the secure standards-based API for FHIR that we've adopted as well. So, those are the two places where the impact happens, and again, we recognize that there will be times from a policy prioritization perspective that we'll have to be forward-leaning with

certain selections for the USCDI, and that'll change from year to year based on what's available and where we need to go.

Aaron Miri
Perfect, Steve. Thank you very, very much. So, I know that Jonathan Nebeker is trying to ask a question, but I believe he's having audio problems, so Ken, I think you're subbing in – tag-teaming in, WWE-style – to help Jonathan out and ask the question.

Ken Kawamoto
Sure. He just typed in an updated question, and he says, "I don't see any rationale in the doc on the ONC site. I modify my question. How and when can we have access to the rationale for decision-making?"

Steve Posnack
This is Steve again to answer that. I was just about to type in the chat. Jonathan, we provided the priorities that we used as our principles for selecting the data elements. There's a slide back that I think Al used to describe that. That is a rationale. We are not able to provide a data-element-by-data-element rationale. We looked at the holes; we looked at areas where there are significant gap impacts from our perspective that would enrich the USCDI going forward, and as Al mentioned, the various context dimensions that we had to keep in mind this year given its inaugural cycle – that is the dynamic of our rationale.

Aaron Miri
There's a thanks from Jonathan. "Perfect, that answered my question." Thank you, Steve, for doing that. Next on the list here is Mr. Les Lenert.

Leslie Lenert
It took me a second to come off mute. Thank you. I think this is a very opportune time, and I know the USCDI is a big ship that is difficult to turn, but the question that has to be put forward and that has already been raised by Ken and others is whether USCDI is 1). Adequate for our job fighting this pandemic in terms of understanding what vaccines have been administered, the first dose versus the second, and the different lots and the safety issues that might come up with that.

So, to make sure that the present USCDI is there for the data that are available – and, is it adequate for assessing the quality of vaccination delivery services? Can we develop metrics based on the USCDI – again, leveraging off some of the other remarks that Aaron or others have made about computable quality measures – does the USCDI support computable quality measures on the efficiency of vaccine administration in a world where there are changing denominators and a need to target resources to the most at-risk and to be able to judge the efficiency of providers, not just in passing out vaccines to healthy people, but to actually target those who are in greatest need for vaccination?

Al Taylor
Thanks, Les. The short answer is USCDI is not adequate for the amount of information that could be captured in exchange with just USCDI is not accurate. It's not adequate to capture all data elements for any – either in generic clinical quality measurement or any other program measurement – but it's not intended to be. It's not intended to solve every problem, but in general, it's a core device – that's why it's

called “core.” It’s not everything, just like the exchange standards are more of an 80% solution rather than a 100% solution.

Because of the amount of time it takes to develop the USCDI, update it, and then implement it, whether it’s voluntary implementation or required implementation, the big ship analogy is a great one. It’s probably not going to be able to be responsive to things like pandemics, which, God willing, will be completely over by the time we implement Version 2. There are other mechanisms, both within and without ONC, that can better address those. The Interoperability Standards Advisory is a very flexible, potentially very fast-moving resource as a guide compendium for standards and processes that can be used to respond to any number of different contingencies, including the pandemic response. There are also other program requirements that can be implemented more quickly through the CDC, FDA, or CMS that can better define what those requirements are for health IT and allow for adoption or adaptation by other mechanisms besides USCDI. So, I agree with you that in and of itself, it’s not adequate to respond to things like this pandemic.

Leslie Lenert
V2 should move a step closer to that. Otherwise, we risk irrelevance. Second, people have been seeing this pandemic coming for 25 years. The idea that we would have a respiratory pandemic of a highly infectious disease is not a novel idea that we just discovered in 2020. We’re going to have this going forward, so I think that the important thing is to learn the lessons, and I think the greatest challenge is that we consider work on standards that would be viewed as irrelevant in the present crisis.

Aaron Miri
Sounds good. All right. Next on the list, we have Jim Jirjis.

Jim Jirjis
Hey there. Quick question: I notice with the proposed HIPAA rules that there’s sort of a relaxation of this minimal necessary issue – for privacy reasons, only sharing the minimum necessary for the ask is often important in protecting patients’ privacy, security, et cetera. As we expand the USCDI, more and more risk of unnecessary noise at the very best or unnecessary sharing could arise. Do we believe that by virtue that it’s a restful API with USCDI 4 that the market will simply begin restricting the ask to some subcomponents of the full USCDI that then is under information-blocking protection, or do we believe that we should address the issue of oversharing, particularly as we add data elements over time?

Al Taylor
So, not being a lawyer or a renowned expert on HIPAA, I think USCDI defines what the capabilities of collection and exchange are, not the actual payload for a particular use for a particular exchange, and the content of a particular exchange is going to fall into that minimum necessary, so if the minimum necessary is my entire record, then that’s the minimum necessary. If I ask for my entire Blue Button download and the Blue Button download is entirely comprised of USCDI data elements, then that’s the minimum necessary. But, if the minimum necessary is my last lab report, then that would be it, even though that’s a component of my USCDI.

Jim Jirjis
Yeah, I view it less as an issue of patients asking. A payer, for example, might ask for information to justify an encounter, and there’s a finite set of data elements – see our prior auth piece. If, within the USCDI, that

becomes "Hey, I had a head cold, but please share the entire USCDI with us," that seems to be incongruent with what we're trying to do with minimally necessary, or in a particular – the urologic vasectomy data, or… I'm just curious if it's best for the patient than with other workflows.

Al Taylor
Yeah, it's not – so, the USCDI doesn't define what has to be in the response, it defines what could be in the response, and the request would have to be an appropriate minimum necessary request, and then the response would have to be a minimum necessary response.

Jim Jirjis
Thank you.

Aaron Miri
All right. Next on the list here, we have Mr. Ken.

Ken Kawamoto
Great, thanks. I really like Les's point and the commentary going on about how USCDI might not be the exact right approach, but we do need to figure out an approach to deal with something like a pandemic. We have to at least think of the approach in how things like this could work. One thing that I think is very interesting with something like COVID, too, is a lot of the base resources and infrastructure for sharing those exist, like sharing labs, sharing observations, et cetera. It really comes down to things like if the labs are boing LOINC-encoded, and if they're not, if they're being mapped at the source. I do think there's a – not to say that USCDI has to be the force that helps address this, but it would really be a shame if there wasn't at least one thread in this Task Force and in the HITAC to look at what HITAC can do to help address this instead of basically talking about the fact that we need to address it each time we meet.

Aaron Miri
That's actually a fair point, and I think that actually goes to another question that's been floating around here, which is what are the next steps for the USCDI Task Force, Ken? This may actually help speak to that, right? So, what is that? What does that look like? Those will be the action items that the HITAC takes, correct?

Ken Kawamoto
Yeah, it's things like can we be sure that if we use the immunization resource and share immunization data, the information that's needed for vaccine passports or knowing whether people are sufficiently protected when they need to come back for a revaccination – are there symptoms that are highly suggestive that we might want to encode? We have to keep in mind things like what Clem always brings up – we don't now want clinicians to have to check a checkbox saying the patient has lost sense of smell in a new checkbox because that would be kind of crazy. It might be important, but it would add so much additional burden.

But, I think it is something to think about, and there is probably low-hanging fruit in the area, but I think the USCDI process in general has not really addressed the notion of when we really need these value sets to be properly mapped to and coded, how do we make that happen? I think that's a completely – it's hard to really address when you're boiling the ocean, but if it's in terms of how we make sure that the value sets are properly used for these for vaccines, that becomes very doable. So, it could also address this issue of

how we look within a data element to make sure that the bindings of terminologies for things we really care about are really universally being done.

Aaron Miri
That makes sense. So, let me ask this general question: What are the next steps here? Let's clarify that. How do we get the USCDI Task Force back together and get it going so we can answer some of these questions and look through the details of this? What does that look like? Maybe I'll turn that over to ONC. Maybe you guys can clarify for us.

Lauren Richie
Sure, I'm happy to jump in here, Aaron. So, in terms of next steps for the Task Force, we are assuming that if you are on the prior Task Force, you are still interested. As just a quick review of the member list of those that are still on the committee, they are Terry O'Malley, who served as one of the co-chairs, Valerie Grey, Ken Kawamoto, Steven Lane, Les Lenert, Clem, Donald, Brett Oliver, Sasha TerMaat, and Sheryl Turney. So, if you are no longer available, just shoot me a note and let me know. I've heard from a couple of members who are interested in serving as co-chair alongside Terry, but I will confirm that offline, and then, we are looking to start the Task Force in the next couple weeks or so once we get schedules and everything lined up. And then, as Al mentioned, we'll try to wrap up in time for the April due date in terms of final recommendations.

Aaron Miri
That's great, Lauren. Is it possible for folks to take – I think this is a great presentation – maybe get some thoughts on paper or email and send it over to Al or ONC to collect those thoughts ahead of time in advance of the Task Force being spun back up?

Lauren Richie
Sure, that'd be great.

Aaron Miri
That might be a way for folks to collect their thoughts. I didn't want to miss this – Clem, you have your hand raised. Do you have another comment to make?

Clem McDonald
Yes, I do. There are two parts to this. We won't know what's needed more for some things until the USCDI comes into force, which is still 18 months away or something like that, but I think when you launch something, the next step is to figure out how it's doing, and I don't know that the Task Force can actually do that, but we could encourage the development of watching processes. So, how well is stuff being coded, to Ken's question? What really is happening? There are some aspirational things that we could do a lot more with if we had more code, but is that true? And, to the point about if we're sending too much stuff out, can we tell, can we look, or is anybody complaining, or can we look at it and figure out what's going on so that we can do this? Instead of guessing into the future, we can understand where there are problems and where things are succeeding or not.

Aaron Miri

That's a great comment, Clem, and as I often do for the HITAC, I will offer some real-world stories, just adding the vaccines. Even before they were finally approved in the FDA and CDC processes, just getting the SNOMED codes lined up and entered into the various EMRs that we all use took some hoops and hurdles because that was a challenge, they were not final codes, they were not finally approved, and it took some arm-twisting just so we could begin planning processes for boots on the ground, so the more we can have clarity on standards, and where that data goes, and the privacy of it, it will be easier to add something as simple as a vaccine, even in almost-approved status, into the EMRs and other systems as appropriate, which will help everything across the board, so I can appreciate those comments.

Clem McDonald
Well, that raises another issue because I understood that there was another set of codes for vaccines from CDC, so are we having dueling code systems for vaccines?

Aaron Miri
Right. No, you're exactly right. There's a whole lot of that that has to be worked through. I think that echoes everything we're trying to say here, which is that the landscape is still coming together, but I also do want to highlight the phenomenal work that even Version 1 was. You have to start somewhere, so to what Steve Posnack and others said, it was a bowling ball, it went down and didn't hit every pin, but it hit a lot of them, and now we get to roll again and just keep going until we get this right.

Clem McDonald
I agree. Hear, hear.

Aaron Miri
All right. So, I want to ask one more time if there are any other questions. We have about three minutes left before the break. If there is anybody on the phone who would like to speak up and ask a question, please do. Okay. So, with that, Denise, I don't see anybody else in the chat unless I'm missing something here on my computer.

Denise Webb
No, we're good. We're caught up with questions.

Aaron Miri
We are caught up with questions? All right, so we have about two minutes left. We can give folks that time back to grab an extra sandwich or whatever along with the break. Lauren, do you think that will work?

Lauren Richie
That sounds great.

Aaron Miri
All right, folks. Let's get to that. Oh, I'm sorry, I saw Jim Jirjis raise his hand. Jim?

Jim Jirjis
Yeah, one brief comment that I think is resonating with people in the chat that I just wanted to voice in case people can't read the chat is this notion that all our interoperability goals are contingent upon the public

trusting the system, and this notion of oversharing and going down minimal necessary will be important to address so that we don't cross what we're calling the creepiness factor where suddenly, we start getting the public awakened to the idea that their information, including HIV results and other things, is being overshared, setting back the goals of interoperability, and that seems to be something the Task Force ought to think about as USCDI starts –

Aaron Miri
Great point.

Denise Webb
Yeah, that's an excellent point.

Aaron Miri
"Don't be creepy with your technology." I like that. Okay, on that comment, we are going to take a break, then, and we will be back in 15 minutes. Thank you.

Break (01:38:44)

Operator
All lines are now bridged.

CMS Interoperability and Prior Authorization Proposed Rule (01:56:28)

Lauren Richie
Great. Welcome back, everyone. At this point, we would like to turn it over to Alex Mugge, Director and Deputy Chief Health Informatics officer at CMS, followed by additional remarks from Steve Posnack, our deputy National Coordinator. Alex?

Alex Mugge
All right, thank you. Thanks, everyone, for having us here today. I'm going to briefly go through our proposed rule for the CMS interoperability and prior authorization. The comment period for this proposed rule actually closed on January 4th, so the comment period is closed, but I'd just like to walk you through the policies and share what we are looking at. So, could we go to the next slide? One more. Jumping in with the patient access APIs – so, this is actually a policy that we had finalized in the first interoperability rule – or, the interoperability and patient access final rule. We finalized – this is a policy that payers implement a FHIR-based patient access API, and in this rule, we're building on and expanding that API policy by requiring payers to include information about patients' pending access prior authorization decision. So, in the first rule, we had required claims and encounter and some clinical information be shared. We're now including prior authorization. I just want to make sure – can everybody hear me? It sounded like someone was trying to interrupt.

Aaron Miri
Yes, we can.

Alex Mugge

Okay, I just wanted to make sure. So, as I said, we're adding some additional information to the API by requiring prior authorization information be included. We are also proposing to require several IGs that would support the patient access API. We had previously encouraged the use of these IGs and are now proposing to require them to help support and streamline this API build, so that includes the following: For claims and encounter information, we had proposed those be CARIN or Blue Button IGs, and for the USCDI and clinical information, we had proposed the Da Vinci payer data exchange, or PDex, ID. For formulary, we had proposed the payer data exchange, or PDex, drug formulary IG. These IGs would be supportive of the patient access builds, and you will hear these IGs repeated throughout this presentation because we had proposed them for each of what I will call our access APIs.

In addition to some of the technical build of the API, we had also proposed that impacted payers would be required to establish an attestation process whereby payers could request or require third-party application developers to attest to certain privacy policy provision prior to connecting to the payer's API to retrieve patient data. So, this privacy policy attestation is a significant new addition to the patient access API, and would just allow more transparency for patients into what is required in a third-party application privacy attestation – or, privacy policies – and would get the payers a little bit more involved in working with the patient on the privacy policies of these third-party applications.

Finally for this section, we had also proposed for payers to report certain metrics on a quarterly basis about the adoption of the patient access API and how many patients they have using this API to access their information. Each of these policies was proposed to become effective on January 1, 2023. I don't have a slide for it, but also included in this section in the proposed rules, we had proposed also that payers use the Da Vinci payer data exchange, or PDex, to plan that implementation guide to support the provider directory API that we had finalized in the first interoperability rule as well, so I just wanted to highlight that it's another IG we would be proposing to require for the provider directory API. Could we go to the next slide? I don't think we had it on there – no, but I just wanted to highlight again that that was another piece of the puzzle that was included in the proposed rule.

But, on this slide, I'm going into the next API that we have proposed. We proposed to require that impacted payers would build a provider access API that would provide payer-to-provider data-sharing of – again, it's similar to the patient access API, so it includes claims and encounter data. This would not include cost, so unlike the patients having access to cost data through the API, providers would not have that cost data included. We also proposed the API would include clinical data as defined in the USCDI Version 1 and also include pending active prior authorization decisions.

So, in many ways, this is very similar to the patient access API. We also propose to use the same implementation guides to support this API. In addition to the individual API for this purpose, as we'll call it, we also proposed the use of the HL7 FHIR bulk data access specification to facilitate data-sharing for more than one patient at a time. Each of these pieces of the API puzzle would be finalized or implemented on January 1, 2023. That is what we have proposed for all of those pieces of the provider access APIs.

Could we go to the next slide? The next slide covers our payer-to-payer policy. So, we also propose what I'm still calling our trio of access APIs. We have patient access, provider access, and then we have payer-to-payer API. In the first interoperability rule, we finalized a requirement whereby payers would exchange

certain patient data when a patient changes health plans, and that at a patient's request, a patient could ask for their data to move from their old payer to their new payer.

We encouraged the use of an API for this purpose, but we did not require it in the first interoperability rule, and in this interoperability and prior authorization rule, we are now proposing to require that this exchange be done via a FHIR-based API, and I'm going to sound like I'm on repeat here, but as part of the payer-to-payer API, we also included claims and encounter data, a certain subset of the clinical data as defined by the USCDI Version 1, as well as pending and active prior authorization decisions, so all of the same data that patients and providers would have access to would also go from payer to payer. One difference here in terms of the implementation for this API is that we did propose the use of the PCDE IG for the prior authorization data exchange.

We also proposed that payers would exchange those data not just at a patient's request, but also at a time of enrollment. If the payer has an enrollment period, they would send or make available the data via API for those patients that are changing payers at the time of enrollment. We also proposed for this API the HL7 bulk specification – again, for exchanges of large amounts of patient data, as we understand that this could be useful during enrollment when exchanging data on multiple patients, and again, we proposed that this API would be implemented by January 1, 2023. So, all three of those access APIs work together to make sure that patients, providers, and payers all have the information they need at the time that they need it and just better support transparency for the patients and help them to achieve better care and better care outcomes. Can we go to the next slide?

As part of the payer-to-payer API, we had sought comment on whether the new payers should consider information from old payers regarding prior authorization. So, breaking that down a little bit, we encourage payers to look at the data that they're receiving from a previous payer to help them assess a patient's needs and health data, and we sought comment on whether payers should be limited from requiring repeat tests and evaluations when it comes to prior authorization. So, if you have a patient who has a prior authorization under one payer and has an ongoing prior authorization, when they move to the new payer, we were asking to what extent that patient should have to redo some of the tests and procedures to prove that they still need that prior authorization or to what extent that should be considered already done from the data received from the previous payer. So, we did seek comments on that, and we received comments on that, and we did not make any proposals, but I just wanted to highlight that that is something we were seeking comment on and appreciate all the comments or feedback. We can go to the next slide.

I'm actually not going to cover this slide. I believe Steve is going to cover this in a couple minutes, but just because I keep referencing all these IGs, I just want to give a shout-out to ONC and thank them for joining us in this process as they are proposing to adopt all these standards in their regulation text, and Steve will talk about that in just a moment. So, a shout-out to ONC – hey, thank you! Go on to the next slide. So, in addition to what I've been calling the access APIs, we've also proposed two prior authorization APIs to help streamline the prior authorization process and really reduce some of the burden that we've been carrying from payers and providers and patients alike around this process.

So, the first API we proposed was the documentation requirement lookup service, or DRLS, API. We have heard quite extensively from providers that finding documentation requirements and requirements for prior authorization can be quite onerous, that payers store these requirements in various places on their website,

and that they can be very hard to find, so we propose that payers would build the DRLS API, which would allow providers to look up those requirements using – or, if their EHR is connected to the API, it would allow them to locate those requirements directly in their EHR. So, this API would use the CRD and DPR IGs under the Da Vinci Project, and again, if a provider has this built out in their EHR, they can connect to the API, and instead of having to search for the payer's requirements, they'd be able to pull those back directly, thereby streamlining some of the process and cutting back on some of the time that providers use trying to locate these requirements.

And then, the second API that we've proposed for prior authorization is the prior authorization support, or PAS, API, which would leverage the PAS IG if implemented. So, we are proposing to require payers would build this FHIR-enabled electronic prior authorization support API that would have the ability to send and receive prior authorization requests and respond electronically directly within a provider's workflow, so again, this would require that providers have this built out in their EHRs, but once available, that EHR would be able to connect directly to the payer to exchange prior authorization requests and responses, significantly cutting out some of the additional paperwork required there for prior authorization. Can we go to the next slide? I think we have a visual on the next slide that represents this a little bit better.

So, some of you may be asking yourselves, "What about HIPAA?" HIPAA defines the X12 278 standard for prior authorization. Prior authorization is a HIPAA transaction, and we have already defined that the X12 278 is the standard for that transaction, so this slide demonstrates how we are maintaining the integrity of those HIPAA standards, and as you can see here, the PAS IG sort of sandwiches the X12 278 between the FHIR-enabled PAS IG on the payer and provider side of the transaction, so this is just a visual to help you see how the 278 is still very much involved in this process and how we are maintaining the integrity of the HIPAA transaction standard in this proposed API. Can we go to the next slide? I am trying to power through this because I know Steve has a few slides as well, and we wanted to use some time for questions, but certainly, we're happy to follow up with anyone if we don't have time to get to questions here today.

So, in addition to all of these APIs that I have been talking about, we also propose several guard rails around the prior authorization process to help support the process and help streamline it and reduce some of the burden, and also improve transparency around prior authorization. So, here on this slide are a couple of the things that we had proposed. One is the denial reason. We are proposing to require that payers include a denial reason for a prior authorization request, and I want to highlight that this is regardless of the method that a provider uses to submit the request.

So, we know that there are existing mechanisms out there for submitting prior authorization aside from the APIs that we would hope to be in place on January 1, 2023. We understand that payers also do prior authorization through fax, portals, and phone. There are lots of different ways to do it, but regardless of that method, we would be proposing to require that this denial reason be submitted if a request is denied, and the purpose there is really to ensure that providers have the information they need to either submit an appeal, or resubmit their request, or work with their patients to explain why the request has been denied and find alternate courses of treatment, but they really need that information in order to be able to do that.

We also proposed a shorter authorization timeframe. So, we had proposed that impacted payers would have up to 72 hours for urgent requests and seven calendar days for standard prior authorization requests. This is a significant reduction from what we understand to be in practice today. Specifically, we understand

that in many places, for Medicaid, it's a 14-day turnaround, so we would be cutting that in half, and this is to ensure that patients are getting timely care and that providers are saving time by not having to continually follow up on their requests, but they're getting their turnaround on their requests in a timelier way.

We also proposed that payers would publicly report certain metrics about prior authorization – for example, the percentage of prior authorization requests that are approved and denied. So, I think there were about seven metrics that we had proposed, and this is to provide more transparency into the prior authorization process for each of the payers, and that will help patients to understand what their payers' prior authorization processes look like. It will also help providers to understand if they're contracting with a provider, not necessarily what to expect, but just to get some context on what the overall prior authorization landscape looks like with these payers. So, those are just a couple of guard rails in place and some transparency here to open up some of the process a bit more. Can we go to the next slide?

We also included several RFIs. I don't need to talk through each one of these on the slide, but I do want to highlight the third bullet down, the reducing burden and improving electronic information exchange of documentation of prior authorization. So, we did seek comment on ways to encourage or require providers to use the prior authorization APIs that are proposed in this rule. So, it's one thing to require the payers to build these APIs, but we also want to ensure that those APIs are being used and integrated with EHRs and can be used by providers, so we did seek comment on that, and we did receive some excellent feedback from the public, so we look forward to some more on that front, but just wanted to make sure I highlighted that before wrapping up.

So, the comment period for this rule is closed. We have received lots of comments and have already read through them and gotten some excellent feedback from stakeholders, and we are very grateful for that, but if anyone has any questions or feedback, I'm happy to take those after Steve presents his slides or follow up at a later time. Thank you very much, and over to you, Steve.

Steve Posnack
All right, thanks, Alex. I have my camera on. I appreciate going after the break. It gave me a chance to get some touch-ups with hair and makeup, so, thanks, everybody, and kudos to Lauren Richie for the timing. So, I'm going to stay on this slide for one second and use the mic to congratulate and thank Dr. Rucker for his time with us and his service to the country. A couple factoids: He happens to be the longest-serving National Coordinator we've ever had. He also happens to be the only National Coordinator that you all have had at HITAC, and that is just remarkable in terms of his commitment to our mission and his dedication to the work that we have. There are many other things that we could pile on to compliment Don, but I just wanted to thank him personally. I have obviously served in different roles during my time at ONC with him, and I just very much appreciate his leadership and all the things we've been able to accomplish these past four years.

So, as Alex touched on, one of the things that we have done is continue to strengthen our relationship with CMS, and this collaborative effort through the recently proposed rulemaking reflects that, so it's a coordination opportunity for us with our colleagues at CMS. Where is that intersection between those clinical and administrative areas? The ICAD Task Force, since we like to speak in acronyms – many of the things that you recommended are embodied and referenced as part of this proposed rulemaking, and those are things we took into account as well. So, we can flip over to the next slide, please. This is starting to steal

my thunder. As part of CMS's rule, we also accompanied – and, we used our general authority on behalf of the secretary to adopt standards and implementation specifications. We referenced all those implementation guides that Alex mentioned, and so, we've included them as part of the new section for standards and implementation specifications that we referenced for application programming interfaces.

We created kind of a new subparagraph for that, and importantly, this is something that's existed in the HITAC that we have not necessarily had the opportunity to do in a cross-department way as much as we would have liked, but this was a perfect opportunity for us to work together with CMS in that convergence of the two worlds, and I wanted to emphasize that we can independently adopt standards and implementation specifications, which we've done to a small degree in the past, but an important point is that there are no new associated or revised certification criteria that go along with these proposals. And so, at this stage, they are purely standards that are being adopted as part of our code of federal regulation text in service to the department's policy needs that CMS has established for their rulemaking as part of the proposal.

Alex already covered in great detail – as she always does when we both have to power through presentations – the implementation guides that were included in the proposed rule. As I mentioned again, I want to thank all the work that the ICAD Task Force did and the HITAC overall for its deliberations associated with a lot of the materials that covered the rules and the proposals. The next slide that I have, which you don't need to go to, is just a listing of the implementation guides, but that's available for everybody's reference, and we'll try to save a few minutes for dialogue.

Denise Webb
Thank you, Alex and Steve. I know we have a few people with their hands up for questions, and I put my hand up first, so I'm going to take the liberty of making the first comment, and I also want to say I do recognize that this rule is not final and that you might not necessarily be able to comment or answer all of those questions, but at least be able to get input from us. So, while this rule has some really great features, I think one of the things that is problematic – in the ideal, we would want this to apply to all payers across all benefit plans, and as I understand it, it doesn't apply to Medicare Advantage, that it is just CMS-regulated payers, which is what you have authority over.

One concern for us in the provider community and for patients as well is because it doesn't apply to the commercial side of the business for payers, you would think that if they're going to implement these things and do the work that they would use it across their different benefit plans to ease the burden on the provider organization so that they don't have to have multiple workflows to support because while a lot of these features will be really nice for the provider side of the house, until there's uniformity where all the payers have to do this, it certainly is not going to be a huge benefit to the provider side of the equation or necessarily to the patients in terms of them – for instance, if a patient is in Medicaid, and then they get a job, and then they're able to get commercial coverage, while there's a requirement for the Medicaid payer to send the information to the other payer, if that person falls back in Medicaid, there's no requirement for that other payer to send them information as I understand it. So, that's just my overhead comment. I'm sure I'm not the only one that has this sentiment, given the makeup of our committee.

Alex Mugge

So, if it's all right, I would like to go ahead and respond to that pretty much using words from the proposed rule, which is just kind of reiterating, but we do understand the desire for this to apply uniformly across payers. We can only control those payers that are within our scope, which would include Medicare Advantage – this rule did not include Medicare Advantage, and I probably should have been clearer about that up front in the first slides as well – so, this does only apply to Medicaid and CHIP fee-for-service and managed care, as well as the QHPs.

We did include some discussions in the proposed rule regarding Medicare Advantage and the potential for looking at this for future rulemaking, but as we also discussed, we believe that if payers are going to implement these policies that they have an interest in applying them across their other lines of business, and nothing about our proposed rule would discourage payers from doing that, so we highly encourage that if they have multiple lines of business, they roll this out so that they can get to that uniformity, and because we believe this will reduce burden on both sides of the equation. It will certainly make it easier for providers if they can do all of this from their EHR, but even on the payer side as well, just getting all of the information in that format in a FHIR-based API will make things better for them as well, which will help them get to those reduced timeframes for turnaround. So, I think all of this does work together and we understand the concerns, but I thank you for raising them and giving me the opportunity to clarify where our thoughts are and where we're going to go with that.

Denise Webb
Well, thank you, Alex, and I know Aaron also raised his hand, but I'm going to let Jim go next, and then you, Aaron.

Aaron Miri
All right, I suppose Jim can go first. Go ahead.

Jim Jirjis
I feel an obligation to defer to the co-chair.

Aaron Miri
No, sir. Please, go ahead.

Jim Jirjis
This is wonderful stuff, and I share your sentiment that Don Rucker's influence has been a tectonic plate shift, and I have much gratitude and appreciation. I love what I'm seeing in this. One question I had is around the notion of within the workflow, the providers having an opportunity to have access to what the rules are for a particular request, and then, on the flip side, there being a specific reason for denial. Is there any thought on how to define that so it doesn't end up meeting the rule, but still not being specific enough to allow providers to understand how to change what they're doing to either reduce denials or reduce requests? So, it's both of them, but how do we go far enough with specificity that we don't end up right where we were, but just with different synonyms that mean nothing?

Alex Mugge

That's a great question, and I think there's some work to be done there, and we've tossed around a few ideas on particularly those denial reasons, but I think that's a great discussion to be had, and thanks for raising it.

Denise Webb
So, we have Aaron and Arien. Aaron, go ahead, and then Arien, and then I think we need to move to our next presenter.

Aaron Miri
I'll be quick. Two quick questions: First, I just want to confirm that the intent is that either on the provider or payer side, there's not some exorbitant fee to use this interface, that this is part and parcel of transactional costs, not something that the provider system suddenly has to pay some special fee for or, if I'm leveraging my EMR vendor, a new transactional cost, which a lot of vendors do as an offering. There's not some special modifier that goes on top of this where I'm suddenly paying more money to use this interface. Is that correct? Is the intent that this is just some normal, standard business?

Alex Mugge
Well, that would be what we would be looking for. Steve, I don't know if you have any additional feedback on particular fees. That would be our intent, that this is a cost of doing business, but there shouldn't be a fee for using the API over fax or some other means.

Aaron Miri
Sure, I understand intent versus what happens in the real world, so I appreciate that and I applaud going this way. So, another quick question – I'm going to give a real-world scenario for you. Right now, we're trying to vaccinate thousands of people a day. We're shooting for an audacious goal of 100,000 people vaccinated at UT Austin in the Austin Metroplex in the next 30 days or so if possible. One of the issues we've run into is reimbursement and need for auth for certain types of plans for people who are coming in – just for the labor cost, we're not charging for vaccines. But, each of them basically tells us, "Oh, you've got a unique circumstance depending on your insurance company." Would this mean that for this subset of payers, they would all have to align their prior auth processes so that it all looks and feels the same so that I can begin to get more throughput on a faster method?

Alex Mugge
I can't speak to the particulars of your vaccination effort, the things that are happening there, and how that may vary, but just in terms of prior authorization policies across the board, we did not propose and would not be requiring payers to standardize their prior authorization policies or procedures. However, I would think that some of that standardization would happen naturally through the fact that this would be going through an EHR and through an API, so once this is in the FHIR format using the IGs, some of that standardization will happen naturally. That doesn't change that one payer may request 100 data elements to do a prior authorization and another one may only request 10, and those 10 may be different. We didn't go there, and I know there will be continued discussion in that area.

Aaron Miri
Got it. Thank you very much for the clarification.

Denise Webb
Arien, if you have a quick question, otherwise I would kindly ask those who are still in the queue with their hands up if we could defer your questions until after we finish going over the work plan if we have time, just to be respectful to Bakul, who's here to start his presentation.

Arien Malec
Sure. First of all, I just really appreciate the work. As Steve noted, it really does follow the ICAD Task Force. I have a couple of concerns on process, making sure that we've got enough time for comment, making sure that we've got the ability to scour the rule and go through it and provide appropriate comment. I think the comment period and the timeline has been a little accelerated, potentially by the impending administration transition, and I don't think that's helpful for what's going to end up being a long-running set of policy requirements. The second comment is that the one piece in the ICAD Task Force that appears to be missing is the naming of an attachment standard, and I think that if you look at what's required to do ePA, we're going to need to make sure that we have a standard for attachments to get the clinical documentation over as well as the ePA guidance. And then, I think the last comment is relevant for fees. As a clearinghouse, I think we would note that there are going to be some transactional fees associated with getting a 278 from a provider to a payer, so I just want to recognize that there is additional work required to make all these transactions happen. Thank you.

Alex Mugge
Thank you.

FDA Digital Health Center Presentation (02:28:57)

Denise Webb
Okay, with that, we are going to transition to the presentation on the FDA's Digital Health Center, and we welcome Bakul Patel to give that presentation.

Bakul Patel
Thank you so much, Denise. Can you guys hear me clearly?

Denise Webb
Yes.

Bakul Patel
Great. I am not sure what the protocol is. If you want me to turn on my video, I am happy to do so. Let me just try that.

Aaron Miri
Video is new for all of us, so there you go. You can help us figure it out.

Bakul Patel
Thanks. First of all, thank you so much for having me present and share an overview of the Center of Excellence we just launched on September 22nd, but I do want to echo Steve's comment from earlier about Don's leadership with ONC, and I really appreciate the great partnership that FDA has had, especially that

the Device Center has had with Steve and everybody at ONC, so, thank you so much for that. You'll be missed, Don, for sure, along with all the thought leadership that you have provided.

Having said that, let me just walk through a little bit of the overview and the intentions around this and how it all started. Hopefully, that provides enough context for us for a robust conversation after I walk us through the slides. So, the Digital Health Center of Excellence has been a journey – and I would call it personal – starting with our very first guidance document on mobile medical apps that eventually evolved into multiple policies that gave to the rise of this group that installed the Center for Devices at FDA, and it became apparent to us that this is something we need to take further, so let me just share that with you.

But, as you can imagine, the scope and the words of digital health seem pretty broad, so I hope I can provide you a little bit of context of the focus areas of what FDA is thinking about. So, on the next slide, I will just walk through some of the topics that I want to cover. I want to share what we are thinking and some of the scope of the spectrum that we see as digital health. I think it fits squarely in conjunction with health information technology, but it's just one piece of the puzzle as we start moving toward digital care, as people call it these days. And then, what we are thinking about – what do we want to achieve by having this Center of Excellence stand up, where are we starting out, and what are we going to do further?

On the next slide, you will start seeing a depiction of how I have been thinking about it and what we have been thinking about at FDA. It's really a continuum, and as the convergence of connectivity, data, and competing powers coming together either in the form of an EHR, clinical decision support, or some other software that's tracking and tracing COVID tests, vaccinations, or any other thing, it's really becoming a continuum where we are going to build this platform of care on top of this digital economy and the connections that exist.

Now, from a very pure, FDA-centric view, from a product perspective and from where the care is heading, we are seeing this movement from the clinic itself to the patient, becoming more patient-centered, and very much from a diagnostic and medical product perspective, you are seeing that the understanding of the physiology of patients in the wild is becoming much more relevant, not just during care, but also during clinical trials and other aspects. And then, the hope is with these powerful technologies – these predictions – we can start focusing on prevention earlier and earlier with smaller and smaller interventions.

So, that's the scope of what we've been thinking about, so if you go to the next slide, you can start seeing how we are focusing on things. When it becomes a medical product, even though the spectrum is from healthy living to management of care after it happens, we can see that a technology can become a medical product, it can be a device, it can be a combination of a drug or a device, it can be incorporated into that, so you're seeing chip-in-pill technology happening as we speak, and in the process of making those medical products – so, the manufacturing systems of drugs and devices – they're starting to use emerging technologies that will start predicting failures and other aspects that are going to be important for the safety and effectiveness of the product that we regulate. That's something we're focusing on.

And then, I want to highlight a couple things that are emerging, especially in the pandemic. There was a big demand for doing clinical trials remotely, and in studying medical products remotely, whether they're drugs or devices, with these technologies that are going to give you different insights, that's something that we are focusing on as well. Last but not least is the emergence of digital therapeutics, either their

combination with a drug, a device, or other aspects that may be actions that just provide a different therapy. That's something that's emerging, and as we are thinking about this, we are looking into the future and how best to start thinking about that, what are the best mechanisms to look for evidence, and so on and so forth.

On the next slide, you can start seeing that as we have been thinking through this, this has been part of our planned evolution for digital health. In 2017, when we had our budget appropriations, we were asked by Congress to stand this up. It took us a little bit, and then the pandemic happened, so things slowed down, as you can imagine, but really, the intent is to drive synergy and have one conversation or at least replace our conversation on digital health at FDA, at least when it relates to medical products. We want to make sure that our strategies, both within FDA and with the research community and other communities, are aligned in where we can take these technologies for the future, and selfishly speaking, how do we get FDA prepared for this digital health future? That's really how we started off the conversation.

On the next slide, you will see – and, I'll run through this as quickly as possible – where we ended. This is our goal. We want to empower all stakeholders to advance healthcare when they start using digital health as one of the things that they want to incorporate into their care. How are we going to do that? From our very small perspective, we want to connect and build partnerships like we are talking about today. We want to share knowledge, which means being bidirectional, both for FDA as well as FDA sharing what expectations are and what we are seeing. Connecting patients, providers, and researchers together is something that we want to do, and internally, we want to start innovating our regulatory approaches. And, as we start seeing some of this effort going forward, we believe those three big, ambitious goals will drive the empowerment of all stakeholders, and I think it's important for FDA to start leaning forward to start making those available and making known what is in the best interests of public health.

On the next slide are some of the outcomes we are hoping for, and this is just a handful I've picked to share where our thinking is. We want to get access to expertise because we know no one agency or no one entity can hold all the expertise, and we want to connect that. We also want to make sure that we are increasing awareness and understanding of where evidence matters, where evidence is important, and what evidence is important, and start thinking about what are the hurdles and opportunities that we can remove, and then, consistent application of our paradigms – our regulatory approaches – within our agency as well. So, these are a few outcomes we are hoping to get. It's going to be a journey for us for sure. This is a starting point in the next chapter of how FDA is looking at emerging technology.

On the next slide – so, people ask if it's all going to be in the group that I'm leading, and the answer is no. The whole concept of the Center of Excellence is really taking a very broad view, but also building a virtual infrastructure. The blue boxes here are showing what my group does on a day-to-day basis, but there are many other things that are happening outside of my group – for example, in digital pathology, virtual reality, and augmented reality, *in silico* modeling of clinical trials that can help advance clinical trials in a better way – and then, I just talked about advanced manufacturing. There is cybersecurity, which goes hand in hand with our interoperability initiative. So, it's bringing it all together, making this one place to start thinking about how we connect.

So, I'm going to share with you a little bit about how we are thinking of coordinating internally and making plans for coordination externally as well, working with the Office of the National Coordinator and other entities who have been very interested in advancing the scale. On the next slide, here's a visual view of

how we are thinking of coordination. Of course, the bottom box is talking about creating this virtual organization, but then, internally within the Device Center, there are so many things happening that digital health is touching every product area, from ophthalmology to prosthetics to cardiology and so on, and we want to make sure that we are consistent in the application of those policy areas, science, and so on and so forth.

FDA-wide, we also want to look not just from drugs, devices, and biologics, but also how we can help veterinary medicine, for example, or food supplies that may actually be helpful from a digital health perspective because it all comes down to my initial – when I mentioned the spectrum from healthy living to managing patients, and we may have some loose and distant connections, but at least we want to make sure we are staying connected in some areas versus others.

On the next slide, I wanted to go through some of the specific services that the Center of Excellence is trying to stand up. From a device perspective, since most of this work has been starting in and emerging from the medical device world, where software is a medical device and software can be inside a medical device, we've been working toward setting the right specific direction for digital health, making sure we are coordinating our regulatory science and research priorities, making sure we are creating shared resources so when a reviewer in Division A looking at orthopedics, for example, has an AI question, they can pull on the service to get understanding and resources from another area that has been experiencing the same thing, so making that connection point is the intent.

On the next slide, you'll start seeing how this can also help other parts of the agency. From an FDA-wide perspective, we also want to support the drug submission because the drug regulations are different than the device regulations, but we want to support their advancement as well. We want to make sure we're aligned in terms of spending our resources on the research areas we need to work on. For example, wearables have been a really hot topic for use in clinical trials all along, but the biggest question we get asked is what is the validity of those, and how much can you rely on those endpoints? So, those thorny questions have not gone away, and we are looking to find ways to synergize on that, also making sure that we don't end up creating – not just we, but other communities – end up validating it over and over again. When you're thinking about a product with another product, how do you make sure that the research community can align on those?

And then, external to FDA, we want to make sure we are partnering, coordinating, and hearing and learning from each other, not just the federal entities, but also outside of the federal entities, including industry, healthcare provider organizations, and researchers, for that matter. On the next slide – I just have a couple other slides – so, just to give you what I just talked about – I probably stole my own thunder here – providing clarity on regulations is going to be really important for all stakeholders outside of FDA. Just understanding how we are approaching digital health seems foreign to a lot of people. When it comes down to software as a medical device or which catheter you're going to use, it becomes really important for us to be that common place for people to come and understand what we are intending and so on. I don't see the Center of Excellence doing reviews. We are not set up to do that. The reviews and the product approvals and authorizations will happen as they happen today, but we are going to become a service to help and support those different offices to read the authorizations.

I do want to touch upon international harmonization. One of the unique aspects of digital health and software is that it does not know boundaries. It doesn't really matter where you download products from, but it does matter where they are used, so when it comes to the U.S. and it comes down to the regulations, the questions we are having from an FDA perspective for these technologies are the same questions other regulators are having as well, and they also struggle – but in a slightly different way – on privacy and security aspects of it, and certainly, in some aspects, they have an advantage because some countries have single-payer systems and we don't. We have a different mechanism here, but harmonizing internationally, making sure that our approaches are aligned, and, in some aspects, leading some of those activities is going to be some of the effort that we'll be working on.

On the next slide, just to give you a road map, in the fall of 2020, we launched – we are starting to operationalize this infrastructure in place, and we are literally starting small. We are starting internally to CDRH with devices, we're starting to coordinate this virtualness, and we're starting to build the same infrastructure FDA-wide. We already have some connections with which we collaborate on an ongoing basis with ONC, FCC, FTC, and OCR, and we'll continue to do that, but at this point, we are looking at what other opportunities are out there that can help us all get aligned in the space and at least be informed of where FDA can be, and that's really the goal, and I'm hoping that when it comes to digital health and FDA regulations of digital health, the Center of Excellence becomes the one-stop shop for any of those activities for any stakeholders at any point in time. That's the hope, and we want to create that knowledge infrastructure and then the actual infrastructure for FDA for that. If I'm not mistaken, I think that was my last slide, so I hope we have some time left for Q&A. I'd be happy to take some questions.

Aaron Miri
Thank you so much. We appreciate that very much. I know we're getting very, very close to time, so maybe we can take two questions max, but I'm sure folks can follow up with you here. Clem, I see you have your hand raised. Do you want to ask a quick question? And then, Carolyn Petersen after that. Clem?

Clem McDonald
Just a minute, I'm having trouble. I'll do it in the chat.

Aaron Miri
Okay. Carolyn, your turn.

Carolyn Petersen
Thanks, Bakul, for a really interesting and informative presentation. I am interested in learning more about how you plan to include patient and consumer representatives in your initiatives and how you will be using their feedback going forward on a regular basis.

Bakul Patel
Great question, and my apologies for not mentioning it. In fact, we have a Patient Engagement Advisory Committee that we have stood up. It's very young, and that's exactly where we want to get patients and individuals to opine on our approaches and policies. So, if you haven't missed it, a couple months ago, we actually held an advisory committee meeting on AI/ML and what it means for machine learning software to patients when they're seeing it or when their clinicians are using it, so we had a robust discussion on what it means to be transparent to the end user. How is the machine learning software telling, how does the user

know they're getting what they're getting, and how should they be incorporating it? So, absolutely, Carolyn, you're spot on, and my apologies for not mentioning it.

Carolyn Petersen
And, if I could ask a follow-on question, what are your plans for engaging with the HITAC and leveraging the resources and expertise we bring to further that patient and consumer engagement and perspective in the process?

Bakul Patel
Since this is so nascent and new off the ground, I definitely am very keen on figuring out how we can create this channel of engagement with HITAC, and it's going to be extremely helpful as we move forward. In fact, I recognize Jim, who was talking earlier – Jim and I had many conversations, Don and I had many conversations, and I want to continue this. I think the richness of this committee will probably be very helpful for us to not only inform, but also learn from you guys what are the needs and demands and how we think we should be on our mission of promoting and protecting public health. So, absolutely, Carolyn, and ideas on how we should do this on a regular basis would be very much welcome for us to consider, as we are still building it.

Aaron Miri
Bakul, thank you very much. It's been a great, great presentation. I have a question. In my capacity at the University of Texas at Austin as CIO, we have a number of research projects – as well as clinical operations, as you can imagine – that leverage consumer devices and whatnot in the field, and oftentimes, especially on the research side, we're working with a PI who's trying to work through what the right device is, what gives them the best fidelity, and what the right applicability is because the market is so broad, and it's a wonderful thing.

Would this group for FDA also be a sounding board for – in our case, we're trying to do a study looking at child psychology, and we're using consumer devices in the field to try and monitor sleep time and those sorts of things and how that affects things from a clinical perspective in the long term, and these kids present with other conditions down the road, such as depression, because they're not getting good sleep. Right now, we're working through that issue and figuring out what the right device is for our study. Would this be a clearinghouse for that, or is this meant to be "Hey, you have X device or X vendor to bring to us to help work through the processes"?

Bakul Patel
So, maybe not exactly like you're talking about because it's a scaling issue. We probably won't be able to service everybody to set up that infrastructure. One of the things that we are immediately starting off with is to publish the priorities in this space and the things that we've seen that people are already struggling with or people are already discouraged on, so I think we are looking for a way to communicate that, and perhaps this is where we want to set up a public/private way that we can work with folks like you to start understanding what those issues are and where we can provide pre-emptive guidance rather than trying to handle it on a one-on-one basis.

So, it's probably not scalable for this number of people, so we'd love to hear these thoughts so we can actually set up a mechanism – I don't want to say "self-serve," but almost pre-emptively, people can go look

up what resources are out there and work from there, and of course, after that, if you still have issues that you need to work on – this is a scientific need. If people are duplicating the same efforts, then we want to make sure that's minimized.

Aaron Miri
Got it. I'm going to follow up with another question. This is on behalf of Clem McDonald, who wanted to know how engaged this group was with FHIR. I think what he's referring to there is to what degree that is being based and considered working through and those types of standards and others.

Bakul Patel
FHIR is something of great interest to me, and in fact, Steve and I worked on interoperability issues for a very long time and are going to continue to do that. Specifically, FHIR itself is not something FDA focuses on. We focus on standards, we recognize those standards, and we ask manufactures of these technologies to implement those standards, and when they implement it, we – one caveat is we would ask fewer questions is because we know it's a standardized way of doing whatever they're doing. And, that's how I see it as we start moving forward, and we have recognized plenty of interoperability standards, and in the next round, we will probably start to think about what it would really mean if FDA recognized FHIR. Would it get implemented into lab services, in vitro diagnostic devices, or even other devices that we regulate and ask people to incorporate?

Aaron Miri
Got it. All right, we have about one minute left. Les Lenert, do you want to ask your question?

Leslie Lenert
Thanks. What are your plans for developing evaluation paradigms or strategies for e-health? It's such a different field, plagued by many of the problems with telehealth, which has been extremely hard to evaluate the impact of, and the FDA has to be the leading source of these models and paradigms for how to prove that both the data are what people think it is and are getting transmitted to the right place, but more importantly, that this is actually making a difference in people's lives.

Bakul Patel
So, interestingly enough, there are some things that we don't regulate and there are things that we regulate. For example, we don't regulate telemedicine, so to speak, where televisits are not regulated by FDA because it's really a communications platform. But, on the other hand, we do regulate lab devices that are communicating with other hospital infrastructures as well, and there are some standards that we recognize for that. So, there is definitely this jurisdiction boundary that we are bound with that we can't impose. What we can do instead of imposing is to recognize standards that may actually be helpful and give that signal that this is the way to do things in the right way.

Aaron Miri
Excellent. Cool, thank you very much. Excellent presentation. We have your email here, and I'm going to follow up with you personally, and I'm sure many people will. We're a resource for you, so thank you for that. All right, keeping to time, we are to Ms. Lauren Richie with the HITAC 2021 final work plan.

HITAC 2021 Final Work Plan (02:54:56)

Lauren Richie
Great. Thank you, Aaron. I'll put on my camera there. But, I just wanted to circle back on the committee's work plan for the year, especially for the public and those following along at home. We presented the draft work plan in November. We've since made a few tweaks, so I just wanted to confirm that with you. Could we go to the next slide? So, you all are familiar with the committee's priority target areas named in the CURES Act. In 2020, obviously, we added use of technologies that support public health in response to COVID-related activities then and moving forward. Next slide.

So, today, we'll just review the list of topics that are both confirmed and tentative for next year. We'll review what we've accomplished already, and then we'll talk about some additional opportunities for the committee beyond what's confirmed in the work plan. Next slide. Just so you know, a lot of thought went into this work plan. We reviewed all of the transcripts and the meeting summaries, looking at recommendations not just from fiscal year '19, but actually prior to that, all of our other legislative requirement, and of course, conferring with co-chairs. Next slide.

So, again, just to recap briefly, it's hard to believe all that we've accomplished in the last calendar year given the additional challenges – the COVID-19 hearing, completing the fiscal year '19 Annual Report, completing the ICAD final report – so, quite a bit was accomplished last year. We've got our fiscal year '20 report in progress, and of course, we'll be kicking off USCDI and any other COVID-related activities. And then, on the next slide, we'll get into our planned activities for the year.

So, again, we made just a few tweaks to this overall work plan. Notably, we shifted the EHR reporting program Task Force to begin in March, and they will convene between March and April, hopefully wrapping up in April and no later than May. The USCDI Task Force will begin here relatively shortly. The other adjustment that we made was moving the public health and HIE hearing to earlier in the year, so we'll be circling back, and perhaps even reaching out to a couple of HITAC members to help inform the agenda for that hearing. A few items are still on the TBD list. We've got TEFCA that we know is coming down the pike. The ISP Task Force – I think we wanted to see how things shake out a little bit with the USCDI and other standards-related activity, and then, we have our EHR contract guide that we anticipate coming next year as well for the committee's review. Next slide.

And then, this captures other ideas that have bubbled up to the surface in terms of HITAC suggestions as well as industry priorities. Where time and opportunity present themselves, we will try to address these, and they'll feed into the work plan at some point – at the very least, just to have an initial full-committee discussion to figure out next steps as they relate to some of the activities listed here. I know the committee had seen this particular work plan in our prior administrative call, but I wanted to open it up to see if there are any additional thoughts or questions or if there's anything we should include in this list here for consideration in 2021 aside from what's confirmed in the work plan. Next slide. I think that's it. So, if you want to go back to the next slide, any thoughts, questions, or reactions? Of course, some things may shift a bit, but for the most part, I think we've got our marching orders.

Aaron Miri

I think this is a great presentation, and hats off again to the ONC, and phenomenal listening and leadership, as I think we've been echoing the entire meeting, so this is just a representation of that. I know I'm personally looking forward to the privacy and security items, but that's just me because I'm a geek like that, but I think these are all great topics, and I look forward to it. If there is anybody with any questions, please raise your hand or speak up. Well then, Denise, anything before we move on to the next item? You might be on mute.

Denise Webb
That's our last presentation before public comment, I believe. We did have some people who didn't get to ask their questions. Let's see – public comment is at 2:00 p.m., so we have about eight minutes. Is Alex still on? Is she still available? If she is and if Steve is still on, then we still have questions from Les and Sheryl on the CMS presentation.

Lauren Richie
Denise, I'm just confirming that Steve Posnack did have to drop closer to 2:00, so he may not be on.

Denise Webb
Oh, and I guess Alex dropped as well. Well, I would ask Les and Sheryl – if you're able to type in and submit your questions for Alex or Steve, that would be great.

Aaron Miri
Okay. Do we want to open it up to any of the presentations and any questions folks may have had across the board about FDA or any of them?

Denise Webb
It looks like Les has his hand up.

Leslie Lenert
Hi, yes. Thank you. I just had a question for CMS as to what they were doing to test the standards that they're proposing in real-world environments, particularly at scale, to make sure they really have the impact on healthcare that they intend. I applaud everything that is in their proposals, but it seems to me that these standards are literally potentially revolutionary for healthcare and deserve the same sort of attention by the Innovation Center at CMS that some of its more modest proposals in payment have received, where there might be funding and a thorough evaluation of the impact on healthcare business processes and ultimately on the efficiency of healthcare. So, what I'd like to hear is what the plans are, if any, for those types of large-scale pilots and whether they think the Innovation Center might be a good sponsor for those types of pilots.

Aaron Miri
Great questions. I also wonder that, to be honest with you. Clem, it looks like you have a question.

Clem McDonald
Yeah, I figured out how to get back on. And, it's really up to the FDA, and maybe more generally to the Innovation Center, but with the reality of today's world with FHIR, where you've got the big IT companies jumping on board, Medicare jumping on board, along with the insurance companies and healthcare industry, but the FDA is not, that almost seems like a disconnect because the FDA gets data, gets patients from the healthcare system, and has to do post-release follow-up on the healthcare system, so there just

seems to be a mental block there, and if we could encourage them to reduce that block and incorporate and ingest – sort of what like Les just said – the standards that are being adopted across the board in healthcare…

Aaron Miri
Sure, I think that's a good point, and my hope also is that with this Innovation Center, we will reduce the number of vendors who claim FDA certification without adopting modern standards on the provider side, so I hear that. Other comments or questions? It looks like Steve is still on. Do we want to go back to that question we had earlier, Denise?

Denise Webb
You mean Steve Posnack? I think they indicated he had to drop off.

Aaron Miri
All right, he is off. Sorry about that. Any other comments or questions? We have about four minutes before public comment.

Denise Webb
Is Dr. Rucker still on?

Lauren Richie
He may not be. We have an all-ONC meeting starting at 2:00, so that's why folks have started to drop.

Denise Webb
Oh, okay. We wanted to open it up to the floor if anybody else had any accolades or farewells to say. I apologize that we didn't do that at the beginning of the meeting. We got going on our agenda pretty quickly there.

Aaron Miri
Okay. So, Denise, do you think we should go to public comment?

Denise Webb
Yup. I think that would be good.

Aaron Miri
Let's do it. Lauren?

Public Comment (03:06:03)

Lauren Richie
Great. I would ask the operator to open the public line, please.

Operator
Thank you. If you would like to make a comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press *2 if you would like to remove your line from the

queue, and for participants using speaker equipment, it may be necessary to pick up your handset before pressing *. We will pause for a brief moment to poll for comments. There are no comments at this time.

Aaron Miri
Wow. Okay.

Lauren Richie
They're shy. It's the first meeting of the year.

Denise Webb
Well, I guess we could yield time back to everybody for their day.

Final Remarks and Adjourn (03:07:01)

Aaron Miri
I do think that's a good idea. I do want to say thank you to everybody for listening and for attending. I see we have over 100 attendees. And, to the HITAC, great job as always for the new attendees. Hopefully, this wasn't too much like being thrown into the deep end of the pool, but you all did great, so, welcome. We look forward to an upcoming fun year, and as always, hats off to ONC. I will close by saying thanks again to everybody – to the entire team – and to Dr. Rucker and the entire administration for their efforts. Denise?

Denise Webb
I echo that, and I want to thank everybody. I thought we had some really great dialogue and input today, as we always do. This is a great group, and thank you to everyone for your participation, and thank you for all the support, ONC and Accel, and I look forward to talking with all of you next month, if not sooner.

Aaron Miri
That's right. Have a great one.

Lauren Richie
Just as a reminder, if you haven't already sent me a note to let me know of your interest in remaining or being added to the USCDI Task Force, just please let me know. Otherwise, we'll see you all again on February 10th.

Aaron Miri
Sounds good. Have a good one. Be safe.

Lauren Richie
Thank you, everyone.

Denise Webb
Thank you.