Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

February 8, 2023 10 AM – 12:15 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Medell Briggs-Malonson	**UCLA Health**	**Co-Chair**
Aaron Miri	**Baptist Health**	**Co-Chair**
Shila Blend	North Dakota Health Information Network	Member
Hans Buitendijk	Oracle Health	Member
Sarah DeSilvey	Larner College of Medicine, University of Vermont	Member
Steven Eichner	Texas Department of State Health Services	Member
Cynthia A. Fisher	PatientRightsAdvocate.org	Member
Lisa Frey	St. Elizabeth Healthcare	Member
Hannah Galvin	Cambridge Health Alliance	Member
Rajesh Godavarthi	MCG Health	Member
Valerie Grey	State University of New York	Member
Steven Hester	Norton Healthcare	Member
Jim Jirjis	HCA Healthcare	Member
Bryant Thomas Karras	Washington State Department of Health	Member
Kensaku Kawamoto	University of Utah Health	Member
Steven Lane	Health Gorilla	Member
Hung S. Luu	Children's Health	Member
Arien Malec	Change Healthcare	Member
Anna McCollister	Individual	Member
Clem McDonald	National Library of Medicine	Member
Deven McGraw	Invitae Corporation	Member
Aaron Neinstein	UCSF Health	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Kikelomo Adedayo Oshunkentan	Pegasystems	Member
Naresh Sundar Rajan	CyncHealth	Member
Alexis Snyder	Individual	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
Thomas Cantilina	Department of Defense	Federal Representative

Name	Organization	Role
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
Ram Iyer	Food and Drug Administration	Federal Representative
Meg Marshall	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
Nara Um	Federal Electronic Health Record Modernization (FEHRM)	Federal Representative
Micky Tripathi	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Sweeney Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Seth Pazinski	Office of the National Coordinator for Health Information Technology	Director, Strategic Planning and Coordination Division
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Alexandra Mugge	Centers for Medicare and Medicaid Services	Presenter
Lorraine Doo	Centers for Medicare and Medicaid Services	Presenter
Alex Baker	Office of the National Coordinator for Health Information Technology	Presenter

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

Michael Berry
Good morning everyone, and welcome to the February 2023 HITAC Meeting. I am Mike Berry with ONC, and we are glad that you could join us today. This meeting is open to the public, and your feedback is welcomed, which can be typed in the Zoom chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled at about noon Eastern Time. Let's get started with our meeting. First, I would like to welcome ONC's executive leadership team to the meeting, and with us today are our National Coordinator Micky Tripathi, Steve Posnack, the Deputy National Coordinator, Elise Sweeney Anthony, Executive Director of the Office of Policy, and Avinash Shanbhag, the Executive Director of the Office of Technology. I will begin rollcall of our HITAC members, so when I call your name, please indicate that you are present, and I will start with our co-chairs. Aaron Miri?

Aaron Miri
Good morning.

Michael Berry
Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning.

Michael Berry
Shila Blend?

Shila Blend
Good morning.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Sarah DeSilvey?

Sarah DeSilvey
Good morning.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Cynthia Fisher? Lisa Frey?

Lisa Frey
Good morning.

Michael Berry
Hannah Galvin?

Hannah Galvin
Good morning.

Michael Berry
Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Michael Berry
Valerie Grey?

Valerie Grey
Good morning.

Michael Berry
Steven Hester? Jim Jirjis?

Steven Hester
Good morning. Sorry, these is Steve Hester.

Jim Jirjis
Jim Jirjis here. Can you hear me?

Michael Berry
I can, thank you, Jim. Bryant Thomas Karras?

Bryant Thomas Karras
Present.

Michael Berry
Ken Kawamoto?

Kensaku Kawamoto
Here, good morning.

Michael Berry
Thanks, Ken. Steven Lane?

Steven Lane
Good morning.

Michael Berry
Hung Luu? Arien Malec?

Arien Malec
Good morning.

Michael Berry
Anna McCollister? Clem McDonald? Deven McGraw?

Deven McGraw
Here.

Anna McCollister
Did you hear me? I was here, just on mute.

Michael Berry
Thank you. Aaron Neinstein?

Aaron Neinstein
Good morning.

Michael Berry
Eliel Oliveira?

Eliel Oliveira
Good morning.

Michael Berry
Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning. It rolls right off your tongue now.

Michael Berry
A lot of practice. Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Michael Berry
Alexis Snyder?

Alexis Snyder
Good morning.

Michael Berry
Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
Sheryl Turney?

Sheryl Turney
Good morning.

Michael Berry
Good morning, and now, our federal representatives of the HITAC. Thomas Cantilina? Adi Gundlapalli? Ram Iyer? Meg Marshall?

Meg Marshall
Hi, good morning.

Michael Berry
Alex Mugge?

Alexandra Mugge
Good morning.

Michael Berry
Ram Sriram?

Ram Sriram
Good morning.

Michael Berry
Nara Um? All right. Thank you so much, everyone, and now, please join me in welcoming Micky Tripathi for his opening remarks. Micky?

Welcome Remarks (00:03:51)

Micky Tripathi

Thank you, Mike. Good morning, everyone. Thank you so much for attending the HITAC meeting today. I will be relatively brief because I know we have a really jam-packed agenda, which I am looking forward to participating in as well. I want to first thank the members of the Interoperability Standards Workgroup for diving into draft USCDI Version 4. I am really looking forward to receiving your recommendations at the HITAC meeting on April 13th, which is coming very soon, as I think we know. Your feedback, as well as the public's feedback, will inform us in determining the final USCDI Version 4, which we expect to release in July 2023, as per the regular annual cadence that we have now set up on USCDI. The public are certainly encouraged to submit feedback via the USCDI website by April 17th, and you can search for USCDI on HealthIt.gov for more background information and for how to submit comments.

Also, in other ONC standards news, we recently released the latest Interoperability Standards Advisory Reference Edition. Just a reminder that the ISA is updated on an ongoing basis as well, so please submit your feedback on the ISA at any time. I am very much looking forward to today's discussion on the FY '22 HITAC annual report. I want to acknowledge and thank the members of the workgroups for their tireless efforts, and I know it is a ton of work. That includes Aaron and Medell, who serve as co-chairs of the workgroup, and workgroup members Steven Lane, Eliel Oliveira, Jim Jirjis, and a former HITAC member, Brett Oliver. Thank you to all the HITAC members who have contributed along the way to ensure that that annual report reflects the views of the HIAC.

There are three ONC events and one HHS event that I just wanted to highlight. The first is the Sync for Genes webinar where you can learn how HL7, FHIR, and other standards have been tested throughout the genomics pipeline. That event is scheduled for February 28th from 2:00 to 3:30. The next is the first joint CDC/ONC Industry Information and Collaboration Day. That should be a great day. The event is going to provide an overview of CDC's and ONC's plans for modernizing public health data and information systems.

As I think all of you know, I have been working very hard and very closely to support the CDC in all their efforts to execute the Moving Forward Initiative initiated by Dr. Walensky, as well as the Data Modernization Initiative and the North Star Architecture. That event is going to be held virtually and in person at the Department of Health and Human Services on February 27th and 28th.

The third event is the ONC Health IT Certification Program Developer Roundtable, where ONC discusses topics such as the certification of program updates, certification deadlines, and developer requirements. That event is scheduled for March 22nd from 12:00 to 1:30. You can find all these events and register by visiting the events page on HealthIT.gov. The last event I want to highlight is something I mentioned in the last HITAC meeting, but we are now very, very close. It is an HHS event. I look forward to seeing many of you HITAC members at the Monday meeting, the February 13th at the Department of Health and Human Services to recognize the first group of QHINS who have been approved to proceed to implementation of the TEFCA interoperability network. We are very excited about that.

As I think I described before, it is a big milestone in 21st Century CURES Act implementation, and we are going to have a really great program. It begins at 11:00 and goes through 12:30. It will be in the Great Hall of the Department of Health and Human Services. For general public awareness, though, it is in the Great Hall. We are capacity constrained, so it will also be livestreamed on HHS.gov/live, and you will be able to get the livestream event as well. That event will be kicked off by Deputy Secretary Andrea Palm, and then

feature Secretary Xavier Becerra, Dr. Rochelle Walensky, the CDC Director, CMS Deputy Administrator Jon Blum, and the Veterans Administration Undersecretary for Veterans Health Affairs Dr. Shereef Elnahal.

They will all be speaking at that event, so we very much look forward to being able to achieve and really recognize these organizations who have stepped forward to help us achieve this critical milestone, and as I think all of you know, we believe very strongly that TEFCA is really important to the next level of interoperability that all of us want to be able to get to be able to get patients better access to their own information as well as be able to provide the capabilities for providers and other stakeholders, such as public health agencies, payers, and other key stakeholders, to be able to exchange information to improve the quality, efficiency, safety, affordability, and equitability of healthcare.

We also think TEFCA is extremely important and, indeed, vital to scalability of the FHIR API ecosystem that we and CMS have been working very hard on pushing to get an ecosystem that supports FHIR APIs to improve the quality, efficiency, and ease of health exchange across the entire healthcare ecosystem. So, we are very excited about that, as I said, and hope to see HITAC members there, and for those who will be joining us via livestream, you are welcome to do that, and we really hope to see you there virtually as well. I think that is it. In closing, I would like to thank each of you again for joining us today. Let me turn it over to Aaron and Medell for their opening remarks.

Opening Remarks, Review of Agenda, and January 19, 2023, Meeting Notes – HITAC Vote (00:09:54)

Medell Briggs-Malonson
Thank you so much, Micky, for all those wonderful opening remarks, and we all look forward to the event on the 13th, so it is going to be a wonderful event, as you mentioned, and I also do hope all the HITAC members are able to attend in person, or at least virtually. Also, a wonderful good morning to the rest of the HITAC committee. We had a great meeting last month with lots of information and lots of wonderful participation, and our agenda today is going to be just as exciting. So, I will turn it on over to you, Aaron, in order for us to go through your welcoming remarks, as well as our agenda.

Aaron Miri
Yes, ma'am. Welcome, everybody, to the February edition of HITAC. It is super exciting. It was interesting, Medell and I were catching up yesterday, and I happened to catch up with some former HITAC members yesterday evening, just reminiscing about how much work this committee has done over the past several years, and it is astonishing. Here we are in 2023 to look backwards a little bit and pat yourselves are in the back. It is incredible. The amount of work you all have done is incredible. For all the new members that are really getting ramped up and part of our family, you are part of something that is amazing, so, if you take a minute, step back, and look at how much work has been done, that is just awesome. Next Monday, the RCE announcement event should be another culmination of those efforts, so, congratulations to all of you.

So, with that, let's go through today's agenda. After we vote on our previous minutes, we are going to talk about our favorite topic here, the Annual Report Workgroup, and hopefully call for a vote and your approval of those. We will go through the Interoperability Standards Workgroup. Next, we will go through the CMS advancing interoperability and improving prior authorization processes proposed rule. After that is the HHS alignment, the pharmacy standards in Part D NPRM. We will go to public comment around lunchtime, and

then we will adjourn about 12:15. So, a fun, action-packed agenda for today, exciting for February, and we look forward to today's discussion. Medell, over to you.

Medell Briggs-Malonson
Thank you so much, Aaron. Let's proceed to our first piece of business for today. I would like to call a motion in order to approve the January 2023 notes from our last meeting as written. Do I hear a motion?

Sarah DeSilvey
Sarah DeSilvey, motion.

Medell Briggs-Malonson
Thank you, Sarah. So, we have a motion on the floor from Sarah. Can I receive a second?

Hannah Galvin
Hannah Galvin, second.

Medell Briggs-Malonson
Excellent. So, the motion has been appropriately motioned and seconded by Hannah. And so, we will call for the vote. All in favor of the approval of the January 23 as written say aye.

Several Speakers
Aye.

Medell Briggs-Malonson
Opposed, say nay. Any abstentions? Excellent. The motion has been carried, and all of the January 23 meeting notes have been approved. Thank you so much to all the committee members. And so, what we will do now is proceed on over to talk about our next piece, which is one of the things that Aaron and I love so much, which is the annual report. Aaron, do you want to go ahead and kick us off?

Revised Draft HITAC Annual Report for FY22 – HITAC Vote (00:13:01)

Aaron Miri
Absolutely, I am happy to, Medell, and with pride. Let's go into it. So, obviously, we are talking a little bit about what we have been doing this far for the past year, and as a reminder, what we are going to do today is really just talk about any net changes or comments we got after last HITAC meeting. There was a member who provided excellent feedback. We really appreciate them walking through that so that everybody is eyes wide open and understanding exactly what is going on, and I hope you had a chance to read the annual report. We are not going to go through it at the voluminous length that it is, but we are going to talk about it and talk about the changes. So, obviously, our meeting schedule's next steps are discussion of the draft HITAC report for today. We will discuss the draft supplemental background research document, and of course, we will call for a vote. Next slide.

All right, here we are. We are at the February 8th meeting, a super exciting time. I do want to take a second, though, and thank the ONC team for the amount of work that has been done by them and the Accel team. Incredible, as always. Michelle, Elise, team: You all are just awesome, and this could not happen without

your work and your effort, so I really just want to say thank you for that. Here we are at the February 8th meeting to approve, and we will transmit thereafter to Dr. Tripathi. Next slide.

So, we are at this stage. We vote to approve the revised annual report and supplemental background research document. For you all that are new to the committee, as a reminder, this is required as per 21st Century CURES to be able to explain what we have been working on, what we are seeing in the landscape, and then, of course, ask for any other topics we wish to pursue, so it is a very important piece of document that lives on forever, as every document does in the federal government. So then, we will transmit the final report, and of course, then, the national coordinator can forward that annual report to the Secretary of Health and Human Services and to the Congress. Next slide.

So, the topics are grouped in several target areas as defined by 21st Century CURES. 1). I know Medell did a phenomenal job of explaining it last HITAC and one we really feel passionate about as a committee is the design and use of technologies that advance health equity. This is a new topic, but one that is critical. 2). Technologies to support public health, as we have seen with the several past years of the pandemic and beyond that, 3). Interoperability, 4). Privacy and security, another topic that is near and dear to my heart, and 5). Patient access to information. Next slide.

So, let's talk about the outline for a second. The outline of the draft report has a foreword and introduction, then goes into the IT infrastructure landscape, then talks about the infrastructure gaps, opportunities, and recommendations. We talk about the progress for FY '22 that HITAC has made, which is, as I was saying in my opening talk, just remarkable with the amount of work that we are doing, and on a volunteer basis at that, so, kudos. We will conclude, of course, with the appendix of the document. Next slide.

So, how this goes: The draft supplemental background research document is very similar. It has the overview, it has the IT infrastructure landscape analysis, then it goes to the infrastructure gaps, and concludes with the appendices. Next slide. We want to go through the changes, though, so I believe we need to pull up the document, please, Accel team, so we can talk through the nuanced changes of items that we talk through as a group.

Medell Briggs-Malonson
That would be great. While we are pulling up that document, as Aaron mentioned, we really do appreciate everyone's review of the annual report as well as the supplemental research document, and we did receive some wonderful recommendations, specifically from Deven, in two primary areas, which was actually in privacy and security as well as patient access to information. So, those are just the main areas we want to just review so that everyone can focus in on those revisions, and then we will go towards the vote.

Aaron Miri
Scroll down, please, to the few changes there. As Medell said, Deven, thank you. Your comments were phenomenal and caused great, great discussion, and that is exactly what we look for, so I appreciate you.

Deven McGraw
Oh, thank you.

Aaron Miri

All right, let's keep going. We have to go down to the red lines, I believe.

Medell Briggs-Malonson
Exactly, and I believe they are blue lines in this one.

Aaron Miri
Blue lines, thank you for the correction. Yes, they are, they are blue lines.

Medell Briggs-Malonson
Yes. Not that we are being political.

Aaron Miri
No, it is not that at all!

Medell Briggs-Malonson
I believe we can continue to move on. We will go directly to some of the recommendations, and we will go to those two primary areas. We can continue on down to privacy.

Aaron Miri
Yes, we need the red-line version, Accel team. Is this the red-line version or is this the final version? I just want to make sure. We may have the wrong document pulled up. That way, folks can just see it easily.

Medell Briggs-Malonson
Yes. Thank you so much, Accel team and Michelle. Once we do pull that out, we can just go directly to Page 10. Excellent. We see that revised, great.

Aaron Miri
There we go. Perfect.

Medell Briggs-Malonson
Wonderful. So, one of the recommendations was really to focus on being a bit more specific, especially when it came to some of our immediate opportunities with the appropriate exchange and use of data. So, after the wonderful comments that we received, the Annual Report Group actually did have a discussion and decided to accept those recommendations, making sure, when it comes to the opportunities, for No. 1, track work under way in TEFCA to adopt use cases that support the exchange of data for treatment, payment, and healthcare operations, so, really making sure that it was very, very clear that the whole point of that exchange is to impact all those various different domains. This was the same piece that was actually made throughout the rest of the recommendations. There was one other revision as well, I believe.

Aaron Miri
I think so.

Medell Briggs-Malonson
It was in the patient access to information. Accel team, maybe we can just scroll through. Got it. Well, I think what we may have done is that a lot of the various different comments were still encompassed within

our current recommendations, but making sure to just provide a little bit more feedback there, but it looks like we have taken a look at all of the true revisions to the annual report.

Aaron Miri
We are thinking of little edits in here, like "before" there and minor things like that, but from a content perspective, HITAC, what is important here is that the degree of what we had talked about over the past several months stayed intact: The focus on health equity, the focus on privacy and security, making sure that we consider all standards, looking at things that are coming down from public health, and making sure there is equitable access to information, all those items. Again, I do hope you all have had a chance to look at this in detail, even the new committee members.

Medell Briggs-Malonson
Great, wonderful. Well, Accel team, I think we are okay with the report, and we can…

Unknown Speaker
Speaking rapidly, with that being said, we are coming up on some big activities.

Medell Briggs-Malonson
Great, wonderful. Some of the same exact type of content changes were made in the supplemental research document that we also hope the HITAC members had a chance to take a look at, so we made sure that the themes that were modified also, of course, went through the supplemental background research document as well.

Deven McGraw
So, are the changes that were made from the previous version marked in a way that we can see them, other than those minor wordsmithing changes that we just showed? Because I am now confused. You were very kind about saying that you reflected on my comments, but now I cannot figure out where the changes were made, if they were made.

Medell Briggs-Malonson
Deven, they definitely were incorporated. All of the various different comments that were provided were discussed in detail, and then, the primary content change, which made sure there was a ribbon throughout both the annual report document and the supplemental background research document, was making sure that we added in that additional domain of treatment as well.

Deven McGraw
Okay.

Medell Briggs-Malonson
Great. In addition to that, I believe all of the red-line versions were directly sent to all of the HITAC members, so you can definitely see all of those different items, and it is the same thing that we are seeing right now on the screen, so thank you for that. Any other questions or comments about the annual report or about the supplemental background research document?

Anna McCollister

I guess my only question… I looked through these and read them, but did not do that with… I had provided feedback and comments because I was not involved in HITAC last year, since this is an annual report, so I just wanted to make sure that the assumption that I made, which is that this is a report about last year, was correct.

Aaron Miri
It is both. It is about the work that was done last year and items that are ongoing and need to be focused, along with our prioritization of things in the upcoming year, because everything is important, but you cannot boil the ocean, so what is that order of operations to knock it out? So, it is actually both.

Medell Briggs-Malonson
But always, your comments, review, and insight are so incredibly important, especially also for the new members, and so, to what Aaron mentioned, it is kind of a bridge because it is focusing on a lot of the different priorities or thoughts and perspectives from last year's committee, but also, it is going to set the foundation for this upcoming year as well. So, we do want to make sure that it does not seem like it is a separation between last year's work and this year's work because we absolutely need all of the HITAC members that are current right now, both new and veteran, to take a look at this and feel like this is appropriate for the annual report, and of course, if there are any questions, we are here to answer them because we do want to make sure it is approved and moves on for appropriate transmission.

Anna McCollister
So, have I missed my window for input, then?

Aaron Miri
There will be plenty more windows coming up.

Medell Briggs-Malonson
There are lots more opportunities for you to let us know, let the whole committee and everything else come into the workgroups as well as the annual report.

Aaron Miri
I look forward to your feedback, Anna.

Deven McGraw
I have to admit, I am not actually seeing the changes that I suggested, hence my confusion. I am looking through this red-line and I see the addition of the word "treatment," but not just to give people a sense of what I commented on, that the issue of data segmentation is more than about making sure that you adhere to minimum necessary, and in fact, it really plays a big role in making sure that we can better protect sensitive data, particularly in the wake of recent legal developments, and also noting that clarification of legal liability around data exchange with patients needs a higher priority than an outward three-to-five-year, and I guess I am just struggling to see where that got incorporated, even though I trust you guys when you tell me that they were, but I am looking for it, and I don't see it.

Aaron Miri

Michelle, maybe you could go right to it. I do not recall what page it is, I apologize. Could we go right to one of Deven's comments?

Medell Briggs-Malonson
While we are going to that, just for a bit more clarification, Deven, anybody's comments and recommendations come directly to the workgroup in order to be discussed, and so, when looking at the report in its totality, we also had discussions of based off all the work and content in the annual report and what our current priorities are, what do we think may be best to propose for this report and for the upcoming year? And "for the longer term" does not necessarily mean three to five years out, for instance.

And so, there was very robust discussion about every single comment and every single recommendation, and then, the workgroup did discuss what should be modified at that point in time, what should remain based off of just looking at the report in its totality and seeing how everything comes together, and then, that is how the various different decisions were made on if there was actual content change or if this seems to be still in the appropriate place in terms of an immediate opportunity versus a near-term or longer-term opportunity. So, I just want to make sure that there is clarification on that, that there was a discussion about every single comment, and some of them were directly incorporated into the content while with others, it was decided just to keep the report as is because there are other pieces of the report that do support some of those topics.

Deven McGraw
Okay. Well, that is important to know. So, it is a distinction between comments being taken under consideration and comments actually incorporated that resulted in changes, and the only change was essentially the addition of the word "treatment."

Medell Briggs-Malonson
Correct. We will just make sure, right here on Page 15, thank you so much. Here is some additional content change that was made in order for that additional clarification as well.

Aaron Miri
They are all there. And also, Deven, there is the crosswalk itself. When you look at the red-line versus the crosswalk, you can always send it back out to the committee so you can see those changes, because it is hard, because it is a big document, but in that crosswalk, it is actually pulled out.

Deven McGraw
Okay.

Medell Briggs-Malonson
This is also on Page 17, some of the additional pieces as well. So, what the workgroup tried to do was analyze every single thing that all of our HITAC committee members recommended, and then, along with the ONC team and the rest of our support team, make sure that it was concise, but also fully integrated into not only the report in the appropriate places, but definitely the supplemental research document, as you see here, because there are two totally different things, the annual report, which will be transmitted, of course, to Micky and then on to Congress, but also the supplemental research document, which provides all of the color and the background for those initial recommendations.

Aaron Miri
Hannah, I see your comments there. That is fantastic, as well as Deven's. It looks like the comment list was emailed out to all the HITAC members. It is on the calendar invite, and also posted to HealthIT.gov, so hopefully that helps pinpoint and precision where the updates were that you gave us, Deven.

Deven McGraw
Okay, thank you.

Medell Briggs-Malonson
Moving forward, Aaron and I will think about some ways, along with our colleagues, so that we can make sure that this is as clear as possible, just what this process is, and with the document, but we really want to reassure everyone that any comments you make and any other insights that you provide are thoroughly reviewed for incorporation into the report as well as into the overall supplemental document.

Deven McGraw
My apologies for not seeing what Hannah pointed out. I did not get a chance to read these documents in their entirety before this meeting, so admittedly, I was less prepared than I should have been, and I apologize for taking up the group's time on that, but thank you. I appreciate it.

Aaron Miri
I also see Hannah's comment, so, Hannah, I am going to call on you for a second here. Do you have any questions you want to ask directly, just so we avoid the typing and just talk through it?

Hannah Galvin
No, thank you. I think the piece that Deven got at… Any of the annual report really does touch on data segmentation, the gaps there, and the need, and I really appreciate that. I think that is an area that we really do need to work on as an industry, but I do think that the piece that Deven got to that I did not see was specifically the needs in light of the Dobbs ruling and some clinical safety issues, which, Deven, was what I took your comments to be saying, and that may have been a decision of the workgroup that was already addressed in the comments or adequately addressed elsewhere in the document, but that was the piece of Deven's comment that I did not see captured. Otherwise, I think there is a lot of meat around data segmentation.

Aaron Miri
So, I just want to make sure I understand correctly that you are at a good spot now. I just wanted to make sure we answer and address any questions there.

Hannah Galvin
Yeah, I am in a good spot, but I can also see where there is a meaty piece of Deven's comment where I also do not see that piece very specifically captured or addressed, but I think the committee's discussion may have addressed that and said, "It is addressed elsewhere in the document, so we are not going to take that word for word." I do not want to Monday-morning-quarterback the workgroup, but I also do not see the word-for-word capture or even the spirit capture of what Deven was saying in her comment directly in that

section on data segmentation. Also, I think that it is fine if the committee took a look at that and said, “Hey, we captured that elsewhere in the document.”

Medell Briggs-Malonson
Hannah, if I can actually respond to that, especially about the data segmentation, when it came to especially sensitive public health information, we actually did have a significant discussion about that during the annual workgroup, and there is a section specifically that does talk about sensitive patient health information already in the supplemental research document and in the annual report, so that is why, when we did have that discussion, we felt like it did capture, especially clinical decision-making, how to make sure patient safety is upheld, and, of course, how that data may actually be transmitted.

We felt like it was captured in some of these other areas, so you are absolutely right. It may not be word for word, but we were trying to be very thoughtful to say that with this large volume of information that we have and all the different areas of priorities, does this still flow appropriately and are we still getting the vast majority of the core of what all the comments were? So, if you do look in the area that is specifically for the sensitive patient health information, that is where we thought there was a nice overlap that way.

Hannah Galvin
That makes sense to me. I do not know if that makes sense to Deven.

Deven McGraw
It does. It really was about making sure that the issue of data segmentation was appropriately tied to the context of sensitive data, but absolutely, data segmentation is an important feature to be pursuing for a whole host of reasons, minimum necessary being one of them, but I would have put that way on the bottom of the list versus some of these other priorities, but it feels a little bit like we are… As long as data segmentation is noted as a priority, that is the most important aspect of this, even if it would have been framed slightly differently if we had written it, but it is there, and that is the important thing. I agree.

Aaron Miri
Good deal, all right. Good conversation, by the way. Any other questions or comments from committee members? Alexis, you had your hand raised. I just wanted to make sure if you had a question, we saw you.

Alexis Snyder
I think after all of the talk back and forth as my hand was up, I am good. I was just going to suggest that perhaps we hear directly from Deven what the actual comment was, and perhaps ONC could show us where you feel it was reflected directly in the report, but I do not want to continue to harp on the issue at this point.

Deven McGraw
I think it is wordsmithing, and it did not have to go in exactly as I wrote it. I think the spirit is captured, but thanks, Alexis.

Medell Briggs-Malonson
Thank you all. We really do appreciate them. We love this type of discussion. One of the things we would also say is that, again, for all the various different documents, all of our meetings are very transparent, and

also, there are recordings of the meetings where you can see all the various different discussions, and so, we do also encourage taking a look at the documents, and if there are questions, all of those different videos are available, or of course, you can just join in on all those various different hearings because we do want this to be very thoughtful and intentional and capture all the perspectives and insights of each of you because your expertise is just beyond words, and so, we do want to make sure we are doing what we need to do in order to make the appropriate recommendations in all of our reports, all of our documents, and all of our various different ways that we communicate back to ONC in other areas.

So, we really do appreciate it, and as I said, we will take a step back and see how we can make this even more streamlined so that it is very clear in terms of the materials that HITAC does receive and when we are requesting for the various different comments, and we will try to just button it up a little bit more. We will do that.

Aaron Miri
Hans, you are up.

Hans Buitendijk
Thank you, Aaron, and sorry about a moment ago. I had to reboot, so I missed a little bit of it, but there was one comment I wanted to make in context of this, not for the suggestion to change the document. I support what is there, and it has the elements in there that allow us to move forward, but in this particular context, I want to highlight that as we look at the short-term, immediate opportunities and long-term opportunities that data segmentation is mentioned under “immediate opportunities.” I wholeheartedly agree that that needs to be discussed and explored on what we can do, but the moment that that conversation starts, consent management and privacy policy management will immediately follow. So, with some of the elements that are listed in the long-term opportunities, we should not be surprised that they are going to come up as part of the discussion of the immediate elements because they are so tightly related. It does not need to change the documents in any way, I am not concerned about that, but just as a general comment as we start to plan implementing some of these topics in more detail.

Medell Briggs-Malonson
Absolutely, and Hans, we all agree with that, and that is part of the new structure that this annual report was presenting. I want to make sure that everybody is very clear. There are immediate opportunities, meaning these are things we are going to start now, but for the longer-term, we are not thinking we have to wait five or 10 years from now. We know that they are literally the roots for so many other conversations, so a lot of the intermediate opportunities with just saying we need to this now to either say we need to A). Gain more information, or B). To actually start to execute something, which will then directly feed into some of the “longer-term” opportunities, which means they are more contingencies, not that we are necessarily going to put that off to the side in terms of prioritization.

Everything in this report and everything that everybody said is top priority. We really want to get to it, but sometimes, Point A has to come before Point B, exactly as you mentioned, Hans, so we expect for all those things to occur. It was just trying to wrap our arms around, as a committee, what we are going to start with first in order to get to all the other items as well.

Aaron Miri

Okay. Other questions in the group? Anything else? Medell, I am not really seeing any other hands. What do you think?

Medell Briggs-Malonson
I think we will go ahead and start our vote for approval. So, may I receive a motion in order to approve the fiscal year 2022 annual report, as well as the supplemental research document?

Hans Buitendijk
So moved.

Medell Briggs-Malonson
Great, it has been moved. There is a motion. May I receive a second?

Steven Lane
Second, Steven Lane.

Medell Briggs-Malonson
Excellent, thank you so much, Steven. It has been appropriately moved and seconded, and we now we will call for a vote. All in favor of approval of the fiscal year 2022 annual report document as well as the supplemental research document, please say aye.

Several Speakers
Aye.

Medell Briggs-Malonson
All opposed, please say nay. Any abstentions? Excellent, the motion has successfully been carried, and therefore, we have an approved annual report. I want to celebrate for all of you all. I know that Aaron mentioned this before, but I also want to give some incredible special thanks to Michelle Murray, as well as the rest of the ONC team, for the massive amount of work that went into this. I also want to say I am incredibly thankful and feel so much gratitude for the annual report group because we have had some very robust conversations with a lot of great content going back and forth, so, thank you to my co-chair Aaron.

I also want to sincerely thank Steven Lane, Eliel Oliveira, Jim Jirjis, as well as Brett Oliver, whom I met for the very first time this past weekend, and I just want to thank all of you all for all of your participation on the Annual Report Workgroup. And then, of course, to the HITAC committee, this report came directly from you all, and so, I want to thank you all for all your hard work from all the various different workgroups and taskforces from which we pulled this information in, and then, of course, from all of your revisions and all of your comments throughout these many, many months. So, really sincere gratitude to all of you all, and we have a very robust report, and we look forward soon to actually starting on this year's report. Thank you again, Aaron.

Aaron Miri
I am super excited. Congratulations to all of you. So, let's go on with the agenda, I would say, right? Is it time for the next one? Next up is the Interoperability Standards Workgroup update.

Interoperability Standards Workgroup Update (00:42:54)

Sarah DeSilvey
Hello, everybody. This is Sarah DeSilvey, who is the co-chair. I apologize for not being on camera. I come to you from rural Vermont, and I am having some technical issues today, so I will be off camera. I believe I am here with my co-chair and colleague Naresh.

Naresh Sundar Rajan
Yes.

Sarah DeSilvey
And so, we are going to give a brief update on the work we have been doing weekly in our Interoperability Standards Workgroup. It is our honor to be here today to present to HITAC, and we really welcome all of the immense investment, akin to any report that has gone into the precedent, the previous year's work in the IS WG, and this year's effort. Next slide, please.

The agenda is to briefly review the Interoperability Standards Workgroup membership, and then to go and review the Interoperability Standards Workgroup charge, and then we will go into the work plan and timeline. Naresh, anything else to add at this time?

Naresh Sundar Rajan
We are good.

Sarah DeSilvey
Okay. Next slide, please. This is the Interoperability Standards Workgroup. As you can see, it has many members from this HITAC committee, and also critical experts and subject matter experts from the history of standards development and from the community. It does create a very lively and robust conversation with experts across the standards and IT ecosystems, so we are very grateful to everybody who participates in that work. The meetings happen weekly, again, and are really quite a wonderful direct application of some of the elements we are addressing here in HITAC, and we do encourage others to attend. Next slide, please.

I just want to remind and ground the whole HITAC and public regarding the charge of this year's Interoperability Standards Workgroup. We have two principal tasks. These tasks are in common from previous years' IS WGs. Our principal charge is aligned with public comment. It is to review and provide our expertise and recommendations on draft USCDI Version 4. Underneath that overarching charge, there are really two specific sub-charges that are directing our work. The first is to specifically lean into new data classes and elements from draft USCDI V.4, and for each of these analyses of new data classes, we pull in all the different expertise from the IS WG. Again, we have experts in standards, we have patient experts, we have clinical experts, we have terminologists and informaticists, and it is really our task to turn each of the data classes over to understand implications for implementation of these standards and whether or not we need to include other voices in that work. So, our first charge is to analyze any new data classes, and I will discuss briefly how we are diving into that work.

It is also our charge to look very critically at existing Level 2 data classes that were not included in draft USCDI V.4 to ensure that we are elevating things of critical interest aligned with the priorities of standard development. Again, we will review those priorities later on in the presentation, but insofar as the priorities of moving elements into USCDI, we also look deeply into Level 2 data classes to make sure that we are elevating things of interest. Some of that is also knitting things, so if there is something in Level 2 that relates to a new data class from USCDI V.4. We had a fair bit of conversation in our meeting yesterday regarding alignment of Level 2 and USCDI V.4 data classes that have a common aim. Next slide, please.

This is our rough order of reviewing those new data classes. This is the first sub-element of our overarching charge. The overarching charge is to review USCDI V.4. That first element is to review all of those new data classes. What we wanted to do in addition to the prioritization for approval is to have an order of addressing the elements. This is to first allow straightforward elements to be focused on early so that new members can become familiar with the process. We have a fair number of new members. Naresh and I are also new, so I do want to acknowledge that we wanted to make sure that people felt familiar with the asynchronous process and understood how to engage in the work because we really wanted to make sure that everyone could feel a part of the work we have ahead of us.

We also wanted to really lean into any elements that are of particular community concern or need, multistakeholder engagement in addition to the members of IS WG. The Interoperability Standards Workgroup has a precedent of bringing in subject matter experts on different elements of standards. We have already identified a need to pull in experts on physical activity from the physical activity IG work happening at HL7 right now.

We have already identified a need to pull in experts across the CMS and CDC public health ecosystem and the social care ecosystem when we identify and address facility information, and we know the elements related to advance directives and the goals elements, those treatment intervention preferences and care experience preferences, are also of very particular concern to the ecosystem and have related IGs and HL7 work as well, so, both of direct import to existing standards development and of direct import to the community, so those elements are identified for needing community perspectives and needing subject matter expert input, so we tried to build space for those.

We are probably going to be focusing on those elements, physical activity, facility information, and the intervention and care experience preferences, in the latter half of this month and the beginning of March, understanding that we need to complete our review of USCDI V.4 well in advance of the end of March in order to get a final recommendation back to this committee. So, yesterday, we had a robust conversation in which we started to deep dive into the first elements on this list. It was a wonderful collective conversation, and we look forward to going further. We are, again, very, very grateful for our community subject matter experts who come to bear in that task, and we are grateful for their participation. There is really wonderful public attendance in that meeting as well. We usually have a thorough conversation in the chat. Next slide, please.

We just wanted to remind the HITAC and the community and public in general that regarding the prioritization that is applied to new data class and identification, we utilize this prioritization in our own work, so when we are making recommendations on USCDI V.4, we do try to highlight where there are these aligned prioritization criteria. Our colleague Al Taylor from ONC presented them at the last HITAC, but I do

feel like it is important to pull these back in. There are many elements that align with the conversations you can see happening in the annual report. I just want to make sure that everyone sees the concepts of health equity in public health are throughout our mission within HITAC and IS WG.

They are in the annual report that we were just discussing, but they are also here in our prioritization. You can see it is critical that we focus on addressing behavioral health, mitigating health and healthcare inequities and disparities, addressing the needs of underserved communities, addressing public health interoperability, in addition to representing important additions, modest standards over implementation guide development, modest developmental burden, modest implementation burden, and result, modest aggregate lift. So, those first four bullets, again, are the prioritization criteria we use as we analyze every new data class, and you can see those principles throughout the annual report as well. Anna, it looks like you have a question. I wonder if I can answer it for you.

Anna McCollister
It is less of a question and more of an issue that I have raised on the workgroup that I wanted to raise before the full committee with all of the ONC staff on board. One of the concerns that I have with those criteria is one that is common amongst criteria with all of the federal agencies that I have interacted with, and it is that there is no consideration of reducing the burden and the workload on patients. For understandable reasons, and I am pretty sure this is mandated in the legislative language, there needs to be consideration for workload and burden on the hospital systems, healthcare providers, and the EHR companies. I get that, but allegedly, this is to benefit taxpayers, patients, and citizens, and nowhere reflected in this is the requirement that it decreases the burden on those of us about whom this data is supposed to reflect. So, I think that is a significant missing element, and I would love to find a way for it to be included in this criteria for prioritization.

Sarah DeSilvey
I want to echo that. When you did mention that in the IS WG, you were heard loud and clear, and if I am remembering correctly, Al Taylor, the representative from ONC, thought this would be a good conversation for this committee, for HITAC to address that missing prioritization criteria in our work this year to ensure its inclusion in the future. Again, thank you for voicing that critical need, both in IS WG and in HITAC today.

Anna McCollister
You are welcome.

Sarah DeSilvey
Hannah?

Aaron Miri
Hold on one second. From a prioritization perspective, we want to get to all questions at the end. Let's finish the presentation, then we will go in order of hands raised, if that is okay, HITAC, just to keep the cadence so we keep the time. Otherwise, we will never get through the presentation because questions will keep coming up every single slide.

Sarah DeSilvey
My apologies.

Aaron Miri
No problem, thank you.

Sarah DeSilvey
Next slide, please. So, this is our upcoming workgroup meeting timeline. You can see that we are aiming, again, to complete our final recommendations at the end of March so that we can complete our report back to HITAC in the middle of April. Next slide, please. All right, here we are with questions.

Aaron Miri
Thank you for all the patience there. First up is Ken.

Kensaku Kawamoto
Thank you. I agree with looking at all stakeholders, and patients in particular as well. I just have an overall comment. I think a number of us have always had this comment. Of course, we want to reduce implementation burden, etc., but the challenge that it has to already be implemented already by many folks and it has to be easy is that USCDI, for the most part, just becomes a rubber stamp of what is already happening in industry rather than saying what is really important, and it may not already be implemented by a variety of folks and whatnot, but we need to do it.

I will just bring up again that we certainly should consider things like if it is already implemented widely, if it would be very minimal for everyone involved, because yeah, that is low-hanging fruit, maybe even a fruit that has already dropped on the ground that we are picking up, but I do think it is important for the USCDI process to acknowledge the limitations of that and to really look at if there are things that are important that we need in society, etc. that do not meet some of those criteria, but really should be prioritized because otherwise, it essentially will be a rubber stamping mechanism. Thanks.

Aaron Miri
Good points, thank you for that. Hannah, you are next.

Hannah Galvin
Yes, thanks. So, I just wanted to comment as well on the overall USCDI process, and I know with USCDI V.3, we started to introduce SOGI data and social determinants data, and now, looking at screening tools for alcohol and substance abuse and behavioral health screening tools, more sensitive data that brings back our discussion on data segmentation, the public perception of USCDI and its implementation by vendors and organizations, understanding that USCDI is the means by which data should be shared if that data is available and if we are sharing the data, but without other legislation requiring that data to be shared, USCDI in and of itself is not requiring that data to be shared, and through other conversations throughout the industry, I have noticed that that is still a point of confusion.

If there is a data element in USCDI Version 2, or Version 3 now, even though there are some SVAP workgroups that are going on, looking at how some of that data can be shared, there are groups that are thinking, “Well, now we must share that data because it is part of these data sets” without necessarily all of the infrastructure in place to think about some of the sensitive data elements, and now we are introducing some more sensitive data elements. So, as we handle those data elements, we should think about

emphasizing the purpose of having these data sets, what is required versus suggested, and the fact that we may not be there yet to have a requirement of sharing all of these data elements.

Aaron Miri
It is a great point, Hannah, and I will tell you that in the industry right now, what is going on is a lot of confusion, depending on where they are reading. I point people back to the ONC blogs all the time like "Here is the source of truth, read it for yourself" because there have even been a lot of vendors that have tried to approach providers, systems like myself, saying, "Oh, you must do this because of information blocking." It is like, what are you talking about? There are a lot of misnomers out there, so, to your point, how do we streamline that and how do we get clarity out there to prioritize? Good points. Steven Lane?

Steven Lane
Thank you. I just want to echo some of the comments that have been shared, both by voice and in the chat, by Hans in particular. This has been an ongoing tension year after year as we have been advancing the USCDI, and it especially came up as the scope of the information-sharing requirements changed from USCDI Version 1 to all EHI, so I think it is true that there is persistent confusion in the industry about what the role of USCDI is, and the good news is that the ONC team has really stepped up year after year as we have gone through this process and tried to further clarify for the workgroup members what the role of USCDI is, and I just want to say that for my part, I really appreciate the fact that USCDI is a slow, deliberative process that slowly raises the floor of technical standards, of definitions, of the real specificity that is required to continue to close that gap between what is routinely exchanged in all EHI, which I think we are all still trying to wrap our hands around, but the truth is that as things advance, as versions are added to the SVAP, we do see vendors doing the development.

I was invited to a meeting this morning about a major EHR vendor who is working through the SVAP process and incorporating new things that were put into V.2, and as V.3 is SVAP, we will see further advancements. So, I think there is tension, there is confusion, but we are making progress, and I really want to thank the folks who stepped forward to co-chair this process this year. I think we are going to make further progress as we go along.

Aaron Miri
Great points. I totally echo that. Next up, Ken. You are back up.

Kensaku Kawamoto
Thanks. I think the tension is that we do not want to require something that may be premature versus… A lot of the comments I hear from colleagues are that this process is way too slow, and by the time we get what we need, it will be 20 years later. I think maybe a compromise is ONC having a process for identifying things that are priorities that we want to move forward and having things like projects, pilots, etc. to test it out, to develop standards, etc. Right now, I think there is just too much of a dichotomy between what is going to move forward because it is already moving forward, again, this rubber stamping mechanism, versus things we identify as important but which we do not have a good way of bringing forward. So, that may be something to consider. Nobody wants standards that are enforced on people that do not work and have not been vetted, but in my mind, the only current approach is Argonaut, and that is pretty limited and EHR vendor-gated. So, I think that is something to consider. I think it is worth the investment.

Aaron Miri
Good thoughts. So, just to summarize, what you are saying is that it is about accelerating time to value. How do we get that on a faster track so we are not, to your point, waiting around 20 years, although that is a misnomer, but waiting around for some time? Is that correct?

Kensaku Kawamoto
Yeah, and there are many things that I have worked on where we have waited decades. Clem introduced things 50 years ago that still are not in widespread use. So, I think this industry has a history of things not moving forward for a very, very long time that are needed.

Aaron Miri
Very good point. Anna, you are next.

Anna McCollister
I just wanted to raise again a couple points that I raised in the workgroup, but just to bring my perspective to the attention of a broader group and ONC staff, one thing about the data that is part of the current USCDI as well as the proposed revision that has really bothered me is how many years after we started with Meaningful Use and some of the other data standards or requirements we still have absolutely no data about vital signs collected or generated by patients outside of the clinic. Speaking from my own experience, I have Type 1 diabetes, I have a continuous glucose monitor that generates data every five minutes, and that is incredibly important for not just my endocrinologist, but all my other doctors to see. My endocrinologist cannot get it in the EHR. It is in a separate portal, and he has to access it, and I am pretty sure the company charges him for that access.

Secondly, I have kidney disease caused by my diabetes, and I check my blood pressure a couple times a day. That is incredibly important for all of the specialists that I see. None of that data is collected, and just those two discrete fields are well-known data points, validated tools in terms of the legitimacy of the data they are generating, the data is structured, they have accessible APIs, and none of this makes it into the electronic health record. So, for me to take this data, I have to manually print it out and take it to each of my physicians. It gets to the prior point that I made about the burden on patients, but secondly, an important part of this is that all of this data that we are identifying here plays a critical role in the generation, the collection, and, frankly, the creation of new quality measures. I have been on the NQF committees now for 11-12 years, and I am always frustrated, occasionally depressed, by the limited quality measures that we have, and the biggest limitation for coming up with more meaningful quality measures is the data and the data that is accessible.

So, if we cannot get continuous glucose monitoring data and outpatient blood pressure monitoring data into the EHR, none of that stuff is ever going to be incorporated into quality measures, and the idea that getting stat levels when you go to the doctor, whether it is blood levels or the blood pressure that you get, even if they do three measures and do the average, that is a joke if you are thinking about what is actually happening in a patient's life and how things work on the outside. So, I think it is really important to think through not just the immediate elements and if this stuff can get incorporated from an informatics perspective. A). We know that it can, it is just an issue of will, and B). What are the implications downstream of choosing not to make this a priority? And they are pretty significant when you look at the role that quality

measures play in access, incentivizing physicians, and, frankly, creating data repositories for research that will be far more meaningful than just collecting data in the clinical setting.

Aaron Miri
You are exactly right, Anna, and I would say that if we ever want to truly unlock virtual care in telemedicine and telehealth for quality measures, which particularly is one of the biggest gaps right now in the virtual environment, we have to be able to link the continuum of care. You are exactly right, to making sure those personally generated health data… And you will see that in prior annual reports. We have actually called that out, where PGHD and that need to collect is critical in those data elements as it ties back from a standards perspective, so, spot-on comments, thank you.

Anna McCollister
I led an effort about 10 years ago, when Farzad Mostashari was the head of ONC, and I got at least 50 patients and parents to write into ONC to say, "This is a thing that matters." Nothing ever happened. I do not know what the political or nonpolitical political issues were that kept it from happening. It was certainly far earlier in this process than we are now, but we have spent a lot of taxpayers dollars on this process, and I feel like we need to think more about what patients need and what is going to benefit patients than what the restraints are upon EHR vendors and hospital systems.

Aaron Miri
Got it, you are exactly right. Next up, Bryant, please, and let's try to keep the comments a little tighter, as we are close on time.

Bryant Thomas Karras
I will shorten mine up. You can probably guess that I am going to echo Ken's comment, but say from a public health perspective, we are seeing a similar hesitation. We have tried to leverage the existing Version 1 of USCDI and get nonreality barriers to leveraging those data elements. I think the HELIOS acceleration to try to accelerate the use of public health in FHIR is critically important, but we really need some more real-world vendor participation and customers of those real-world vendors to enable these mechanisms so that we can start to see the reality happening. In our public health implementation initiatives, we have had to turn to doing exchanges from public health agency to public health agency using FHIR because we have not found that reality of authorized use of the data elements that are supposed to be exposed and accessible for public health query. It has to happen soon, or we will have missed the boat.

Aaron Miri
It is a great point. I do apologize, we are running very tight on time and we have folks waiting to speak next, so, Hans, Ken, and Hung, I do not want to discount your comments, but if I could ask, maybe we could take those to the IS WG Workgroup itself, just like Medell had speculated there. Let's directly prompt those, and we can continue the discussion. I just do not want to get so off track that we shorten the other presentations, which also have meaty content, if that is okay. All right, let's move it over to the next group. Next up would be Alexandra Mugge.

CMS Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule (01:09:47)

Alexandra Mugge
Hey there, thank you. That was a tough act to follow, so, apologies for jumping into the conversation here, but thank you guys so much for having us today. We are looking forward to talking with you and seeing what questions you might have for us as well, so I will run through all this content, and we should have plenty of time left for discussion as well. Go to the next slide. Thank you.

So, my team at CMS is the Health Informatics and Interoperability Group. We are part of the larger Office of Burden Reduction and Health Informatics, and at CMS and within our teams, we talk about this journey to interoperability, which is a journey built on a foundation of privacy and security. There are a lot of steps in this path to interoperability, and what I want to talk to you about today is our proposed rule, which is certainly one of those steps, and it includes a large number of the programs that we oversee here at CMS, and it pulls all those teams together with a common goal of streamlining data exchange. We have often said that this path to interoperability is a journey and not an endpoint, and that is because we know that things will continue to evolve, and we have to continue to evolve with it. So, as technology evolves, we will continue to evaluate our policies and continue to evolve with it, as you have all likely seen with our proposed rulemaking.

So, because I want to cover a lot in this proposed rule, I do want to say up front that all of the policies we are going to talk about today link back to that concept of making sure that patients and their care teams have access to the right data at the right time to make the best decisions for their care. So, in everything that we do, that is our foundation of what we are trying to achieve here for patients. Go to the next slide, please.

I am sure you all are very familiar with two of our previous rules, but I am just going to talk about them quickly for some context up front. In fact, I am going to talk about all this as a trilogy of CMS interoperability rules. The CMS interoperability and patient access final rule was published in May 2020, and it was the first time that we engaged payers in the interoperability space. Today, even in this conversation so far, we have had multiple references to Meaningful Use, or what is now the Promoting Interoperability Program, and the requirements that that put on providers to engage in technology adoption, interoperability, and data sharing, but this final rule from May 2020 was really the first time that we engaged payers in this space, by putting interoperability requirements on the payers as well. I am going to refer to that rule as Rule 1.

And then, in December 2020, we published another proposed rule that was focused on interoperability and prior authorization. That rule was never finalized, but I do reference it throughout this presentation, and we will refer to it as Rule 2. The new proposed rule that I am going to talk about today, or Rule 3, actually replaces Rule 2 by withdrawing that rule from the federal register, so it would no longer be an active proposed rule, and it replaces those proposed policies, which are very similar, and in some cases, almost exactly the same, but these new policies in Rule 3 have been enhanced by the public comments that we received on Rule 2, and also based on other advances that have taken place over the last two years. So, a lot of this is going to look super similar to many of you, but know that this is the next step, phase, or iteration of the previous proposed rules.

If you could go to the next slide, we will start talking about what is actually in Rule 3 here. So, on December 6th, we released the proposed rule with the short title of "Advancing Interoperability and Improving Prior Authorization Processes." This rule has a comment period that is now open and will remain open until March 13th. I am sure we will hear from many of you, and we look forward to reading your comments. This rule, of course, continues to demonstrate our continued commitment to interoperability and reducing burden in healthcare. The rule has a focus on prior authorization, which has historically been a significant source of burden for the provider community, and I should say also for payers.

We know that there is a lot of work that goes into prior authorization by payers, so it is an extremely burden some process on the healthcare system as a whole, and with this proposed rule, CMS is attempting to streamline that historically burdensome process to save time for clinicians so they can put that time back into taking care of the patients. Just like I said up front, all of this really should come back to making sure that patients have the right data that they need and that they are getting the right healthcare services that are best suited for them.

So, on this slide, we have a list of provisions, and I am not going to go through those because I am going to talk about each of them in a little bit more detail in just a moment, but the rule does include requirements for both payers and providers. It brings together both large sides of the programs that CMS regulates. When we talk about impacted payers, which is going to be the bulk of the policies that I will talk about up front, that includes Medicare Advantage plans, the state Medicaid and CHIP fee-for-service agencies, Medicaid and CHIP managed care plans, and the qualified health plans on the federally facilitated exchanges, or the marketplace. So, that is almost every payer that CMS regulates, and it covers a significant population in healthcare.

When we talk about the impacted providers, that is going to include eligible clinicians, eligible hospitals, and critical access hospitals in the Promoting Interoperability Programs, or again, what was Meaningful Use, and I know that you are all very familiar with it. So, we will get to the specifics of those proposals in just a moment, but I wanted to clarify the full scope of who is impacted by this proposed rule.

There are also five RFIs in the rule, and each of those RFIs will cover a wide range of topics, but they are all related to the use of technology and standards to drive a better healthcare future state, so, seemingly unrelated topics, but really all rooted in that technology connection. And then, I am going to make just a couple of more general statements up front before we dive into the rest of the slides. The implementation date for each of the policies we are going to cover today is January 1st, 2026, so I will not repeat that on every slide, but that is consistently the implementation date for all of the proposed policies.

Now, what is interesting about that date is depending on who I am presenting to or talking to about this rule, they will either say, "Why did you give so much time? We need this sooner" or they will say, "That is too soon, we are not going to be ready." So, I look forward to seeing the comments that come through on that date in particular, and I just want to note that we probably could have proposed an earlier date because the standards and the technology are ready. It is not a question of that piece of it, but we wanted to make sure that these policies were done right and implemented in a way that they are going to be successful the first time.

Some of the policies that are in this rule require bidirectional data exchange, so, really, engagement on both the payer and provider side, and so, in order to do that, we have to make sure that the implementation is solid on both ends of the equation. It also means that, as the EHR developers in the room and on the phone will understand, we know that when it involves EHR development, that involves not just the development time, but the time it takes to roll that out to the providers and ensure that they have implemented the processes in their workflows as well. We understand all of that, and this date was chosen with all of that in mind. So, again, we look forward to your comments or any thoughts you have.

The next up-front statement I want to make is while we are talking about prior authorization in this proposed rule, that is for prior authorization of medical items and services only. These policies would not apply to drug prior authorizations. That is something that comes up a lot. I am sure we will hear about that, but drugs have their own standards, their own timelines, and are under their own regulations, so they are not included in the prior authorizations that I am going to talk about today. Again, it is just medical items and services.

And then, finally, just ending this slide on a good note, I want to say that while there are some up-front costs associated with this rule, we do estimate in our regulatory impact analysis as part of the rule that we would say this rule, if finalized as proposed, could save the healthcare industry over $15 billion over a 10-year period, and that is based on just the reduction of time spent on prior authorizations alone. That is how much burden and extra administrative time we are spending in the prior authorization process that we believe can be removed from the healthcare system just through adding some of the technologies and the proposals that we have here.

So, let's go to the next slide and talk about what those proposals actually are. The first API that we are proposing is actually an evolution from a previous rule. So, in the CMS interoperability and patient access final rule, what I referred to as Rule 1, which was finalized back in May of 2020, we finalized that impacted payers were required to build a patient access API to be able to view their data on an application of their choosing using Fire Healthcare Interoperability Resources, or FHIR, based API.

That policy is already in place and patients already have access to their data, but with this new proposed rule, we are proposing to build on that API so that patients would also have access to information about their prior authorizations, to be able to see the status of their prior authorizations, what is open, what is pending, what has been decided, so, taken together, the patient access API would now include claims and encounter data, including the cost data or the provider remittances in enrolling cost-sharing pieces, it would include all data classes and data elements in the USCDI, which ONC has previously adopted and I know you all have talked about quite a bit, and it would include data about priori authorizations, so it would really bring a fuller picture of the patient's healthcare status and the data that they have with their payer into that API.

So, that is great for patient transparency, and we are enthusiastic about this proposal. We are also proposing in this rule that the impacted payers would report metrics about the use of their patient access API to CMS on an annual basis. We know that there is work to be done in engaging patients in this space. Not all patients know that they have access to their data through an API right now. Not all patients have engaged in their data. Some of them do not want to, but those that do, we know that there is work to be done in engaging patients, and by collecting some of this data from the payers and looking at our own Blue Button data, which is our own patient access API at Medicare fee-for-serve, we can begin to assess how

to engage patients and what more needs to be done to ensure that they are making the best use of this data that is now available to them.

On the next slide, we are going to talk about the second API that we are proposing for impacted payers, which is the provider access API. So, we are proposing to require that payers would implement and maintain, again, a FHIR-based API to facilitate the exchange of patient data from the payer to the provider. So, this would include the same data that patients are looking at in the patient access API, with the exception that it would not include cost data or any cost-sharing data, but it would include otherwise the same data that the patients are seeing, thus facilitating a better communication between the patient and provider because they have access to the same information. So, again, that API would include all data classes and data elements included in the USCDI, claims and encounter data excluding that provider remittances and enrollee cost-sharing information, and it would also include that prior authorization data that I mentioned, again, mirroring the patient access piece.

On the next slide, we are going to talk about the payer-to-payer API. So, in Rule 1, we finalized a policy whereby we propose to require that impacted payers would be required to send data at the patient's request from one payer to another payer starting back on January 1st, 2022. After finalizing that rule, we heard from multiple impacted payers and from the community at large that that policy was extremely challenging to implement because we did not specify a mechanism for that data exchange. By not specifying an API or any mechanism for data exchange, we created a lot of challenges for the implementation, which could lead to differences in implementation across the industry, poor data quality, and operational challenges. So, this was a learning experience for us at CMS, and we chose not to implement that policy and announced that we would not enforce that policy at that time.

In this proposed rule, we are proposing to actually rescind that previous payer-to-payer data exchange policy and replace it with a policy that uses a FHIR-based API to exchange data from one payer to another when a patient changes health plan. This would be, again, the same data that we have talked about for patient access and provider access APIs. It would be all data classes and data elements in the USCDI, claims and encounter data excluding cost, and certain prior authorization data, and this data would flow with the patient when they move from one payer to another through that API, so therefore, a patient would not lose their data when they changed payers, they would be able to bring it with them, but it also introduces opportunities for payers. Then, payers can better serve their patients because they have a better view of that patient's current healthcare status.

So, imagine a patient coming into a payer that has diabetes. If the payer could see that up front, perhaps they could reach out early in the year, instead of having to learn this throughout the year, to say, "Hey, we see you have diabetes. We might have services that help you in particular in your situation. Here are the resources for you under our payer/patient relationship. Here is how we can help you maximize your healthcare benefits."

Another example of a way that payers could use this goes back to the prior authorization use case. If a patient has an active prior authorization under a previous payer, why should they have to apply for a whole new prior authorization, potentially giving up services at the time that they have with their new payer? Instead, that prior authorization could potentially be carried over with the patient and, at least for some period of time, honored under the new payer because they received that data from the previous payer. We

are not proposing to require that, but we do believe that that is an opportunity for payers to maximize the data that they have to improve the patient experience and ensure that they are getting care. I do see that there is a hand raised, but I think we are going to wait until the end for questions, but somebody can feel free to interrupt me if that is incorrect.

So, going on to the next slide, this is where we are actually going to get into the real meat of the prior authorization process. So, everything that I have talked about to this point has been about data sharing and one-way data exchange that helps bring some transparency to the prior authorization process, but did not really touch the prior authorization process itself until now. So, in this next API, we talk about the prior authorization process itself and the use of bidirectional data exchange to help facilitate that electronic prior authorization process, and this is where we start to reduce burden in healthcare by facilitating that process.

So, we are proposing to require that impacted payers would implement a prior authorization API that would allow clinicians, through their own EHRs or practice management systems, to query 1). Whether the prior authorization is even required, if it is required, then 2). Determine what data is needed and what documentation is needed to submit the prior authorization, and then 3). To actually facilitate the process to support an electronic prior authorization away. I say it that way, that it would facilitate the process. We are talking about a FHIR-based API. It would facilitate the process of the electronic prior authorization request, but I do want to note that this would also require the use of the X-12 278 standard in order to be HIPAA-compliant unless the payers and providers are part of an exception process that allows them to use a straight FHIR transaction. So, we can dig into that a little bit later. There is a diagram that actually shows this process, and I can talk about it a little bit more at that point.

So, we refer to this API as the prior authorization requirements documentation and decision API. I will just refer to it as the prior authorization API from here on forward, but again, this helps to streamline many of the challenges that we have heard about around the prior authorization process. It standardizes and automates certain parts of the process and aims to remove some of the historically time-consuming and burdensome effort on providers and their office staff. I want to be clear that it does not automate the decision process itself. Payers will still need time to make those decisions, but it does streamline the data flow and submission process, as well as the response process, to ensure that we are reducing some of the time that it takes to look up those requirements or gather all of the data. It can all be done on an EHR with the right technology in place.

Now, that said, we know that not all the prior authorization challenges that we have heard about are going to be fixed by simply adding this technology layer. This API is great, we clearly believe that it is valuable to implement, but it is not going to remove all of the challenges of prior authorization, and therefore, we are proposing several nontechnical policies to further streamline the prior authorization process. One is proposing to require that payers provide a reason for denial when they are denying a prior authorization request. This is regardless of whether the request comes through an API, fax, portal, what have you, any means. Whatever it is, if the payer is denying that prior authorization, they must include a reason for the denial, and this would thereby hopefully facilitate a more successful resubmission or would allow a provider to determine a different course of treatment for their patient, but without that reason, it is really unclear for providers and for patients how to move forward when a prior authorization is denied.

The second nontechnical proposal that we had here is standardizing the prior authorization decision timeframes. We are proposing that prior authorization decisions would need to be made within 72 hours for urgent or expedited requests and within seven days for nonurgent or standard requests. This is a significant reduction in the time that is currently required, and we believe that by making sure this data is available and available electronically, we believe that we can get down to those shortened decision timeframes. I should note we also seek comment on even shorter timeframes in the rule, but the proposal itself is that 72 hours and seven days.

And then, finally, to bring even more transparency to the prior authorization process, we are proposing to require that payers would support certain prior authorization metrics on their own websites. So, this data would not be reported to CMS, this would be reported on their own websites, but it would be metrics such as how many prior authorizations are approved, how many might be approved after they were previously denied, so, approved on appeal. That type of data would be reported by the payers on their websites. I think we have recently seen several articles talking about denials in prior authorizations. This would make that data directly available to patients and providers and anyone seeking that information, again, directly on the payer's website.

So, I am going to shift gears in this next slide and talk about the requirements on providers. So, in order to ensure the adoption and use of this critically important prior authorization API and to fully round out the electronic prior authorization requirement, we need to make sure that we are not just requiring payers to build the API, but also that we are ensuring that providers will actually use it. So, to do that, we are proposing a new measure that would be reported on under the Promoting Interoperability Programs by eligible clinicians, eligible hospitals, and critical access hospitals. It would report on the unique number of prior authorizations that are requested using the prior authorization API using data from their certified EHR technology.

So, using data from their cert, for every prior authorization that they request in an API, that would count towards their score in the Promoting Interoperability Program, directly adding some accountability for using that API by providers and ensuring, again, that we are rounding out this entire electronic prior authorization process and not putting the burden on one side or the other, but having everyone come to the table and work together to get to this electronic prior authorization process.

On the next slide is the image I promised to you, which is the diagram of how this data flow would work. So, on the left-hand side, we have the provider, and on the right-hand side, we have the payer. The data flow is, again, through a FHIR-based API, but you see sandwiched in the middle there, we still have the X-12 278, which is required, under HIPAA, to be the prior authorization standard, so, to be HIPAA-compliant, we would include that X-12 278 at some point during this prior authorization process unless you have an exception to use an all-FHIR-based approach, which I know that the Da Vinci team does have an approved exception, and there are several payers that are using an all-FHIR-based approach for prior authorization at this point in time, but again, only because they have that exception. So, hopefully the visual is helpful for folks and we can take additional questions on that if needed.

On the next slide, I also want to talk about some of the standards proposals that we included in the rule. So, we did propose specific technical standards for each API. There is a set of required standards, which are standards that have already been adopted by ONC for use, and I will review those in just a moment,

but we are also proposing or recommending a set of recommended implementation guides to support these standards and these APIs. We are also proposing to continue the standards advancement process, which we finalized in Rule 1, which is similar to ONC's SVAP process, which allows developers the flexibility to use updated versions of the standards that we are requiring. So therefore, it gives a little flexibility.

We know the regulatory process can be a little bit burdensome and constraining if we keep people locked into a specific set of standards. We want to avoid that by giving this flexibility and allowing developers to move up to a newer version of the standards as long as they maintain those connections and can still meet the requirements of the policies. So, it is actually a little easier to talk about this if we go to the next slide, with the chart included. This includes the required standards, so, like I said, we are proposing a few revisions to our standards requirements on existing APIs and revising the language to be a bit more clear on which standards are required for which API in these rules. These standards are all adopted by ONC for use, and we point to them in our rule, so we are very aligned with ONC in the use of the standards here, and again, there is an advancement process that allows developers that flexibility to use more updated versions of these standards, should they so choose, as long as they can maintain that connection and maintain the intent of the requirements in what would be then the final rule.

On the next slide, we have the list of recommended implementation guides. So, I am going to pause here and just really strongly encourage that folks would use these implementation guides when building the APIs. Again, we are not requiring them, but these IGs are what gets us to interoperability. It ensures consistent implementation. It is one thing to make a FHIR-based API; it is another thing to say, "Implement it in this way to ensure that consistency across the board in the implementation and to ensure that we get to interoperability." So, we are strongly recommending the use of these IGs. We may require them in future rulemaking, in fact, I think it is likely that this will come up again in future rulemaking, but we are not requiring them at this time. So, that is something to think about for those implementers and those who engage with implementers in this process going forward.

On the next slide, we are wrapping up here. I just quickly want to talk about some of the requests for information that we included in the proposed rule. Again, these are on a wide range of topics, but all tied to that use of technology and healthcare to advance a better healthcare future state. So, we included RFIs on accelerating the adoption of standards related to social risk factor data, electronic exchange of behavioral health information, and, on the next slide, RFIs on improving the electronic exchange of information and Medicare fee-for-service, advancing interoperability, and improving prior authorization processes for maternal health, and advancing the Trusted Exchange Framework and Common Agreement, or TEFCA, which I know there is a lot of exciting work going on in TEFCA right now, and there are going to be a lot of developments in the near future, so we are enthusiastic to see what comments we get on all of these RFIs, including the TEFCA one, to see how CMS and ONC can work together to continue advancing healthcare in that technology space.

The next slide is just helpful resources, which you all have access to in the copy of the deck that you have, and then, finally, how to comment on the proposed rule, just highlighting that the comment period does close on March 13th. I know that we will hear from a lot of you, we look forward to it, so please make sure that you submit your comments by then, and with that, I am going to wrap up and open it up for a Q&A, and I see we already have some hands raised.

Medell Briggs-Malonson
Alex, before we jump on into that, I just wanted to say first thank you for a wonderful presentation, really highlighting the proposed rules. As an emergency physician and a healthcare system administrator, trying to make sure that we have expedited access and more equitable access for our most vulnerable population is so important, and highlighting these metrics, especially for there to be data transparency and accountability, is so incredibly key. So, you are correct, we have a lot of people that have comments, and there have been a lot of great comments, and I am going to go based off of who raised their hand first. So, Jim, you are up first.

Jim Jirjis
Yes, thank you. I want to draft off a comment you just made about transparency. So, it seems like this is such a worthy thing. I am so glad we are focusing on this because so much cost in healthcare is people faxing back and forth and filling out forms. So, if there is anything that automation and such interoperability principles should help is reducing some of the burden on payers and providers, so, amen to that.

The transparency side, however… I just wanted to comment on the reason for denial, and my specific advice is to make sure that we are very granular on that because we get a reason for denial now. It is "did not meet benefits," right? And so, we want to avoid landing in a place where we are equally nontransparent about why something was denied. For example, in the front end of the process, when a service reaches out to the payer to say, "Does this need prior auth?", the answer is yes, and then "What data?", it should also indicate what rules are being used to determine granularly whether or not there is a denial or an approval. And then, the reason for denial should be granular enough to point to the specific thing that was not met. Otherwise, we could land in equally murky waters and really not get to true transparency.

The reason I say that is because the metric for this should be that denials go down because either the providers then learn, because they know what the rules are, and then may not actually submit things that they should not, or the payers then would be able to transparently indicate what specific rule. So, in summary, I just want to make sure that we are granular enough in our requirements for what the reason for denial is, linking back to the rules.

Alexandra Mugge
Good point, thank you.

Jim Jirjis
The second thing I put in the chat was that automation is going to help us, and we want patients to get their medical services and durable medical equipment soon. Why would we have seven days and 72 hours? Why wouldn't it be 72 hours for routine and then one day for expedited, given that automation is going to help us adjudicate things faster?

Alexandra Mugge
So, I do want to say a couple things on that point. You make all very excellent points, so, thank you for that. I do want to hone in on that timeframes question because we have heard a lot of different things, and I would be interested to hear folks' feedback, but prior authorization is still a **[audio cuts out] [01:39:50]** process that requires someone to review medical records. I am sure some things can be automated, maybe an instant turnaround timeline, on certain items and services, but there are a lot of things which require

payers to really review that information, and not that I should be speaking for payers, though I actually can, because we are a payer, but even at Medicare fee-for-service, I think we would say that sometimes we have to review the medical record, and that is not something that can happen necessarily overnight.

It does sometimes take a little bit of time for review, and at this point in the game, where we stand today, the prior authorization process is not all electronic, and this data is not flowing the way that we want to see it happening as of 2026 and going forward, so I do not think that right now, payers are in the mindset where they can be because they have not experienced this yet, but a few years from now, if these policies are implemented as proposed and everything goes smoothly with implementation, we could see a different mindset, a different future state for healthcare, where we could talk start talking about 24/48-hour turnaround or instant turnarounds for real-time decision-making for some prior authorization because we make all of this data so easily accessible and available and really actionable. I think a lot of folks would argue that we are just not quite there yet.

Jim Jirjis
And the granularity?

Alexandra Mugge
The granularity piece was an excellent point. I think you make a great point there. I think that is something that we look forward to reviewing in the comments.

Medell Briggs-Malonson
Great. All great comments, and absolutely, we hope to get to that optimal point of expedited prior authorization also including the medical review. Hans, you are up next.

Hans Buitendijk
Thank you, and thank you, Alex, for this update. It is really helpful. I wanted to highlight with two comments. One is the point that you made about the strong encouragement/recommendation to use the Da Vinci guides, and I think that is a very helpful approach that aligns very well with the HITAC recommendations and suggestions that were made earlier last year around the need to learn more, yet have some foundation to begin working on, which includes not only what happens between the provider and the payer back and forth on the edge, but their respective IT ecosystems that they have to ensure that they can figure out what best way to coordinate those different components that are part of it, by using and pointing to these guides as a point of reference, use that as much as possible. In some areas if you get further out by using it, but not exactly, it will be very helpful to help build that guidance and create the workflows that we need. So, that has been a very helpful aspect of the proposal that we have recognized.

This is not specifically a question for you in a way, although it ties into that, but at the same point in time, this rule addresses the payer side, but leave some aspects of the providers on MIPS and otherwise and having a provider access API and their role in ePA in general, but on the ONC side, there is a rule that everybody is anxiously awaiting the arrival of imminently, that it is time to increasingly get challenging that having read, having reviewed the rule and getting ready to provide comments, not having the other one makes it harder in some areas to understand the full picture. I understand that you cannot respond to that, but I just wanted to highlight that without that piece of the puzzle to understand how that works and how one complements the other, and we anticipate that it will complement very much, but there will surely be

some questions about that, that it makes it very hard to respond in a timely fashion, so I wanted to create awareness of that across a number of different perspectives. We are trying to figure out how to respond in a comprehensive way and that makes sense. So, just as a note.

Alexandra Mugge
I totally understand. Thank you for that.

Medell Briggs-Malonson
Thank you, Hans. Hung?

Hung S. Luu
Yes, thank you so much for that presentation. I just wanted to clarify something. At our institution, we have a process where we have customized a prior authorization queue where we try to collect as much documentation and information as possible in preparation for submitting a prior authorization. What really, really slows it down is the proliferation of these portals for practically every vendor that kind of slows us down because of the fact that once we log onto the portal, we oftentimes find out that there are additional documentation requirements, it needs to be a particular format, or what have you, and so, this would be honestly a godsend for our institution. But, I just wanted to confirm that this is meant to decrease the individual portals that we have seen for practically every payer that really consumes a lot of our time in terms of logging on, tracking those for every single one. Is this intended to be able to submit and also track the progress of the submission using the native EHR and not through any vendor portal, or is that not within the scope?

Alexandra Mugge
I should have mentioned this earlier. I do not think I introduced myself. Lorraine Doo from my team is also here as well, so we may both tag-team this question a little bit, but there is discussion included in the rule on other mechanisms of prior authorization that are available and whether those should remain in place or whether this API should replace them in all cases. We do understand that in some areas, this API may not be feasible for lack of broadband, etc., so there may be a need to maintain other types of prior authorization, which could include portals, fax, or other things.

There is discussion of that in the rule, and we do see comment on it there, so I will sort of leave that there for a moment, but I do think our goal is to get the industry to electronic prior authorization for the very reasons that you are saying, to streamline that process to make the requirements better known up front so that you are not logging into a portal and saying, “I have to go back and get 15 other documents.” We want that transparency in the requirements, and also that automation in the ability to submit directly through the EHR, to answer your question directly, so we do expect that that would be something that would be in place, but to the extent of those other technologies continuing to persist, I think that is something we need to seek comment on and have a better understanding from both the payer and the provider side of the equation. Lorraine, what else did I miss from that discussion? I am sure there are other things that were talked about that I am missing.

Lorraine Doo
I think you said it exactly right in that that is exactly the kind of information that we need to understand, is how it is implemented today and what those issues are. We are definitely aware that there are those portals,

and we have seen them, but to really understand how they are operationalized today and what the opportunity is with the API, that can help alleviate that, but that is the kind of input that we need, and as I put in the chat, there is less than one month to go for getting those comments.

Medell Briggs-Malonson
Wonderful. Well, thank you all. Everyone, we have less than five minutes, so I would love to get through the next three questions, and then we do have to move on to the next presentation, so, for the next three people, if you can keep your questions or statements as brief as possible so that we can allow time for everyone. Anna, you are next.

Anna McCollister
I will try to be brief. I will make sure I am brief. First of all, kudos for this. It is incredibly important. I take a variety of medications, I am living in prior authorization hell, and it happens now even for generic medications. It is absurd. Just since this call began, I have had six notifications from my pharmacy about stuff that I need to do for prior authorizations. So, with that said, one of the things that is frustrating for me, and I have a private insurer, but for my mother, who is on Medicare, is that there is no mechanism by which patients can actively engage in the prior authorization other than calling the insurance company line.

The only mechanism for appeal that is given to patients is to write a physical letter, put it in the mail, and send it to a P.O. box with some unnamed bureaucrat at the other end who may or may not get back to you within a month, and if you are doing this, I think the burden on patients to manage the process between the payer and the provider is incredibly significant, and if there are ways that we can use this technology that you are building, which is really good and very important, to also facilitate and at least acknowledge the role that patients have to play in facilitating this process, that would be incredibly helpful, and I just got another prior authorization notification just now. I can deal with this a lot better than the vast majority of people on Medicare, so, anything that CMS could do to acknowledge the reality that not all providers are super psyched about this process, and there are gatekeepers in the providers, and it takes an incredibly long time to get them to submit the stuff, and they have other things to do, and patients have to carry the burden.

Alexandra Mugge
I definitely hear that, thank you.

Medell Briggs-Malonson
Thank you, Anna, for sharing your own personal experiences and advocating for patients. Ken?

Kensaku Kawamoto
Really exciting work, thank you. Two quick questions. The first is whether the CMS rules will have any guidance or requirements on transaction charges that can be charged to do this, and the second related is I think you mentioned there would be copay estimates that would be provided, like “If this prior auth goes through, it should cost about this much.” I was just wondering whether manufacturer coupons would be accounted for because that is a big part of high-cost medications these days.

Alexandra Mugge

So, for the first part of the question, that is not addressed in this rule, the transaction charges. That is not addressed in this rule, but is covered in a range of other rules to get that guidance, and it is in place. The piece of the patient cost-sharing that is included in the patient access API only is for their claims and encounter data. It would not include estimates, so we are not looking at advanced EOB-type estimates, and therefore, it would not include any other coupons, discounts, or things of that nature. Again, it is only for past claims that the data would be included that would include the enrollee cost-sharing as it has been calculated, not forward-going estimates. So, I just want to make sure that that is really clear. Of course, out of the No Surprises Act, there are other efforts that are going on in relation to advanced EOB and creating those estimates, but that is not included at this time in the APIs that are proposed in this particular rule.

Kensaku Kawamoto
Thank you.

Medell Briggs-Malonson
Thank you. Last, but definitely not least is Raj.

Rajesh Godavarthi
Thank you, great work, looking at the proposal. So, there are two questions I have. One is when I read the rule that you plan to apply this decision-making process when there is a process on the payer side before rendering the summaries, and on the inpatient side, when they ask for extensions and things like that, they tend to review the process before they approve it. So, does this rule apply beyond the outpatient directives to inpatient as well, where it is applied?

Alexandra Mugge
I am not sure I completely followed that.

Rajesh Godavarthi
Does this rule apply for inpatient revisions and extensions that, typically, payers tend to see and approve?

Alexandra Mugge
So, in terms of the data that is made available, it would include all of the patient's claims, and that would be inpatient, outpatient, or anything that is processed through the insurance. In terms of prior authorizations, it would be any prior authorizations for medical items or services that are being processed by the payer. So yes, that would include, again, inpatient or outpatient. The deciding factor is what is being processed through the payer.

Rajesh Godavarthi
That makes sense. The second question is in the documentation section of the rule, you talked about codification or codifying the rules, and it seems a little vague in terms of what exactly you are looking for or, or what you interpret as the meaning of "codifying the rules."

Alexandra Mugge
Lorraine, do you know what this is in reference to?

Rajesh Godavarthi

It is okay, we can take it offline. Thanks.

Alexandra Mugge
If we are talking about codifying the requirements, and that is just in terms of codifying them in our Code of Federal Regulations and where they would be dated, but I am happy to address it if there is something more nuanced there that I am not catching.

Lorraine Doo
Yeah, I think so.

Rajesh Godavarthi
Thank you.

Medell Briggs-Malonson
Wonderful. So, thank you again, Alex and Lorraine, for this amazing presentation, and to the HITAC members, of course, there is that link for any additional comments or recommendations directly to this proposed rule. Again, I want to thank you all for coming to present this. We are going to proceed on forward, and I will turn it over directly to Alex Baker to give us a presentation on pharmacy standards and Part D of NPRM. Alex?

HHS Alignment – Pharmacy Standards in Part D NPRM (01:54:36)

Alex Baker
Hi, folks. Thanks for listening to this presentation today. We wanted to give you all an update about a new piece of ONC policy that has been proposed in a CMS rule and some of the thinking behind that. Go to the next slide. So, in mid-December, CMS released their contract year 2024 Policy of Technical Changes NPRM, which is their routine policymaking that focuses on, among other things, Medicare Advantage and Medicare Part D policy for… These usually come out in the previous fall and are finalized in the year prior to the applicable contract year.

In this rule, ONC has included what we informally call a rider, so this is an ONC rule in a small section of the Part C/D rule, but we have done this in order to propose to adopt two standards on behalf of HHS under ONC's authority to adopt standards in Section 3004 of the Public Health Service Act. So, this is short, maybe 20-30 pages, in a very large, thousand-page CMS rule, but that is where you can find this ONC section.

We have done this and worked with CMS on this proposal in order to advance what we are hoping is a new aligned approach to adopting certain standards that both ONC uses in its certification program, that CMS uses in its Part D program, and that other pieces of HHS that may touch the different stakeholders involved in these pharmacy transactions may use, and I will talk a little bit more about that on the next page, but we will just note that the comment period for the CMS rule closes on February 13th, so, just a little bit here, if anyone is interested in providing comments on this rule. Next slide.

So, a little bit more on the rationale for this. Historically, as folks know, both we at ONC and the Part D program have sought to align where we are adopting standards for electronic prescribing, medication history, electronic prior authorization over the years, really since the early days of the certification program,

and as long as Part D has been adopting standards for their program, we have collaborated on ensuring that we are moving forward together to adopt standards for different stakeholders in the industry, but have generally done this through our separate rulemaking vehicles. ONC is doing this under its authority to adopt standards, and CMS has done this under its authority to adopt standards under the original Medicare Modernization Act.

In discussions with CMS, we have recognized that there are opportunities through this approach for potential misalignment that can add additional regulatory burden and confusion for stakeholders in the transition to the current version of the NCPDP script standard for e-prescribing electronic prior authorization, which is Standard Version 2017-071. Because of when the Part D rule was happening and when ONC's previous rule was happening, we ended up with a period during which we needed to exercise enforcement discretion in the certification program to communicate to stakeholders that it is okay if they moved ahead, given that Part D had already finalized its policy.

This was about six months in the end before the ONC rule could be finalized in which we were making this update for the certification program. So, not a huge period that we needed to do this, but it definitely resulted in a lot of confusion for industry, a lot of work on four different components of HHS to make sure that we were communicating this appropriately, and that people in the industry understood how we were doing this alignment across programs given that stakeholders were subject to both of these.

So, what we are seeking to do through this rider on the CMS rule from December is a new approach to standards adoption in which, at least for the two standards that we propose to adopt here, ONC is proposing to adopt the standards under our authority, and then CMS will cross-reference those standards as well as the timing for those standards that ONC includes as part of that adoption proposal. Next slide.

Just a little more detail on the actual proposals in the ONC rider. So, we are proposing to adopt two standards in 45 CFR 170.205 under the authority delegated to ONC in the Public Health Service Act around standards adoption. The first is the NCPDP Script Standard Version 2022-011. This is a new version of the script standard that ONC uses in its electronic prescribing certification criterion, and Part D requires a Part D plan as part of their requirements. We are proposing to adopt this in their regulation and proposing as part of this that the current version would expire by January 1st, 2025.

So, given the nature of these two standards, there is backwards compatibility between them, so this is the case where both standards can be acceptable for a certain period before we require only use of one standard by different programs, and so, this is built into this proposal, where, once that is finalized, if finalized, then both of these would be available for use until that January 1st, 2025 date, after which only the 2022-011 version would be allowable for any program which references our adoption of that standard. There is also a request for comment in that rule about whether January 1st, 2025 is appropriate given the different uses of the standard or whether ONC should finalize a later date on which the current version would expire. The proposal also includes a proposal to adopt the NCPDP Real-Time Prescription Benefit Standard Version 12. This supports real-time benefit tool requirements in the Part D programs, as I will talk about a little bit on the next page.

It is important to note that these proposals in the CMS rule are only for adoption of these two standards in ONC's regulations. They do not include any proposals at this time for updates to the certification program,

but notes that ONC would seek to align with the standards we have adopted here in any future rulemaking we do as we consider future updates to the electronic prescribing criterion and, for the real-time benefits standard, note that in the Consolidated Appropriations Act of 2021, which folks may be familiar with, there is a provision around updating the qualified electronic health record definition to say that this needs to include or be capable of including a real-time benefit tool, so we believe that this is something that ONC will need to address through future rulemaking, given the ways that that statutory qualified electronic health record definition informs what is included in our certification program and that we would be looking to the standards proposed for adoption here as we consider future rulemaking. Next slide.

So, that is the ONC rider piece of it, and then, for the Part D program proposals, again, as I mentioned, as part of these proposals, instead of adopting these standards in their regulation, as they have done in the past, they are proposing program requirements and then cross-referencing ONC's standards adoption proposals and the timing for those proposals as part of their proposals for the Part D program. So, for their requirements for Part D programs around e-prescribing, they are proposing to align with our proposal for adoption of the updated script standard and the date for retirement of the current version of the script standard, which, again, allows for that transition period for Part D plans up until the date that may be finalized as part of the final rule.

And then, for the real-time prescription benefits standard, they are pointing to our proposed adoption of this standard as part of their requirements for prescriber real-time benefit tools implemented by Part D plan sponsors, so this is a policy which Part D already has actually finalized, back in May 2019, but as part of that Consolidated Appropriations Act of 2021, Congress stated that they needed to name a standard that was associated with those requirements, so, in this rule, they are moving ahead and seeking to do that by proposing to point to our proposed adoption of the real-time prescription benefit standard. So, I will stop there, and I am happy to answer any questions folks may have.

Aaron Miri
Wonderful. So, before we go to questions, just so we stay as close to time as possible, Medell, if you are in agreement, I would like us to move to public comment so we can go ahead and try to hit as close to the noon hour as possible. Mike, if you are in agreement? Accel team, could we please move to public comment?

Public Comment (02:06:28)

Michael Berry
We can do that. Let's go to the public comment slide and open up our meeting for public comments. If you are on Zoom and would like to make a comment, please use the hand raise function, located in the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your lines. So, let's pause for a moment to see if any members of the public raise their hand. While we are waiting, I just want to remind everyone that the next HITAC meeting is going to be held on March 9th at 10:00 a.m. Eastern Time, and if you are looking for presentation materials from today's meeting, they can always be found on HealthIT.gov. I am not seeing any hands raised at this time, so I will turn it back to Aaron. Thank you.

Aaron Miri

Wonderful, all right. So, let me take some questions with the remaining couple of minutes here. First up, I see Clem did have his hand raised. Clem?

Clem McDonald
I wonder if these standards that we are talking about are available for review. Are they publicly available so that people who want to comment on them could review them and make a comment? I think not, actually, and I think that is a problem.

Alex Baker
These are both standards created by the NCPDP, so those are not on their website for review, they are instructions about being able to review those standards in person in the rule, but those are NCPDP standards.

Clem McDonald
Are they available for the public to review, or do you have to buy them?

Alex Baker
I think in order to, you need to participate in NCPDP to gain full access to those standards.

Clem McDonald
I think that is a problem for something that becomes a federal requirement. I would just like to make a point of that so that we could fix it going forward.

Alex Baker
We will note that.

Aaron Miri
Good point. Other comments or questions from the HITAC members? All right, Alex, thank you for the presentation. Good job.

Alex Baker
Sure thing, thanks.

Aaron Miri
Wonderful. Medell, do you want to close it out?

Final Remarks and Adjourn (02:08:57)

Medell Briggs-Malonson
Sure, I am more than happy to. Once again, thank you, everyone, for another amazing HITAC meeting. We have so much great information from all the various different presentations. I want to explicitly thank all the presenters as well for bringing out that information, and, of course, back to the members for the robust comments, and so, we do always appreciate your engagement. Aaron, any additional last-minute items as well?

Aaron Miri

I echo exactly what you said. Great job, and have a happy Valentine's Day next week. Enjoy it, and it should be a wonderful day before on the 13th for that Monday for the exciting event, and a good Valentine's Day on the 14th. Enjoy.

Medell Briggs-Malonson
Have a great day, everyone.

Aaron Miri
Bye, everybody. Thank you.