Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

January 18, 2024, 11:00 AM – 2:15 PM ET

VIRTUAL

MEMBERS IN ATTENDANCE

Medell Briggs-Malonson, UCLA Health, Co-Chair
Sarah DeSilvey, Gravity Project, Co-Chair
Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Michael F. Chiang, National Institutes of Health
Derek De Young, Epic
Steven (Ike) Eichner, Texas Department of State Health Services
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Hannah Galvin, Cambridge Health Alliance
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Bryant Thomas Karras, Washington State Department of Health
Hung S. Luu, Children's Health
Anna McCollister, Individual
Deven McGraw, Ciitizen
Katrina Miller Parrish, Humana Health Insurance
Aaron Neinstein, Notable
Eliel Oliveira, Harvard Medical School & Harvard Pilgrim Health Care Institute
Kikelomo Oshunkentan, Pegasystems
Randa Perkins, H. Lee Moffitt Cancer Center & Research Institute
Rochelle Prosser, Orchid Healthcare Solutions
Dan Riskin, Verantos
Mark Sendak, Duke Institute for Health Innovation
Fillipe Southerland, Yardi Systems, Inc.
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, CyncHealth

FEDERAL REPRESENTATIVES

Keith E. Campbell, Food and Drug Administration
Jim Jirjis, Centers for Disease Control and Prevention
Meg Marshall, Department of Veterans Affairs
Alex Mugge, Centers for Medicare and Medicaid Services (attending on behalf of Michelle Schreiber)
Ram Sriram, National Institute of Standards and Technology

ONC STAFF

Micky Tripathi, National Coordinator for Health Information Technology
Steve Posnack, Deputy National Coordinator for Health Information Technology
Elise Sweeney Anthony, Executive Director, Office of Policy
Avinash Shanbhag, Executive Director, Office of Technology
Seth Pazinski, Director, Strategic Planning and Coordination Division
Wendy Noboa, Designated Federal Officer
Mike Lipinski, Director, Regulatory and Policy Affairs Division
Jeffery Smith, Deputy Director, Certification and Testing Division

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

Wendy Noboa
Good morning, everyone and welcome to the January 2024 HITAC Meeting, and a new year with HITAC. We are so glad you can join us today. I am Wendy Noboa from ONC, the Designated Federal Officer for HITAC. Reminder that this meeting is open to the public and your feedback is welcome. Comments can be made via the Zoom chat throughout the meeting or can be made verbally during the public comment period at 2:00 p.m. this afternoon. Let us get started with our meeting. First, I would like to welcome ONC's executive leadership team. Our National Coordinator, Micky Tripathi, Steve Posnack Deputy National Coordinator, Elise Sweeney Anthony, Executive Director of the Office of Policy, and Avinash Shanbhag, Executive Director of the Office of Technology. And now, I would like to begin with roll call of our HITAC members. Just a reminder, this is just roll. Let us start with our co-chairs. Medell Briggs-Malonson.

Medell Briggs-Malonson
Good morning.

Wendy Noboa
Sarah DeSilvey.

Sarah DeSilvey
Good morning, all.

Wendy Noboa
Shila Blend. Hans Buitendijk.

Hans Buitendijk
Good morning.

Wendy Noboa
Michael Chiang.

Michael Chiang
Good morning.

Wendy Noboa
Derek De Young.

Derek De Young
Good morning.

Wendy Noboa
Steve Eichner.

Steve Eichner
Good morning.

Wendy Noboa
Lee Fleisher.

Lee Fleisher
Good morning.

Wendy Noboa
Hannah Galvin.

Hannah Galvin
Good morning.

Wendy Noboa
Raj Godavarthi.

Rajesh Godavarthi
Good morning.

Wendy Noboa
Bryant Thomas Karras.

Bryant Thomas Karras
Present.

Wendy Noboa
Hung Luu.

Hung Luu
Good morning.

Wendy Noboa
Anna McCollister.

Anna McCollister
Good morning.

Wendy Noboa
Deven McGraw.

Deven McGraw
Good morning, everyone.

Wendy Noboa
Katrina Miller Parrish.

Katrina Miller Parrish
Good morning.

Wendy Noboa
Aaron Neinstein.

Aaron Neinstein
Good morning.

Wendy Noboa
Eliel Oliveira.

Eliel Oliveira
Good morning.

Wendy Noboa
Kikelomo Oshunkentan

Kikelomo Oshunkentan
Good morning.

Wendy Noboa
Randa Perkins.

Randa Perkins
Good morning.

Wendy Noboa
Rochelle Prosser.

Rochelle Prosser
Good morning.

Wendy Noboa
Naresh Sundar Rajan.

Naresh Sundar Rajan
Good morning.

Wendy Noboa
Dan Riskin.

Dan Riskin
Good morning.

Wendy Noboa
Mark Sendak.

Mark Sendak
Good morning.

Wendy Noboa
Fil Southerland.

Fillipe Southerland
Good morning.

Wendy Noboa
And Zeynep Sumer-King.

Zeynep Sumer-King
Good morning.

Wendy Noboa
And now for our federal representatives of the HITAC. Keith Campbell.

Keith Campbell
Good morning.

Wendy Noboa
Jim Jirjis.

Jim Jirjis
Present.

Wendy Noboa
Meg Marshall.

Meg Marshall
Good morning.

Wendy Noboa
Alex Mugge for Michelle Schreiber. Ram Sriram.

Ram Sriram
Present.

Wendy Noboa
Thank you. And now, please join me in welcoming Micky Tripathi and Elise Sweeney Anthony for their opening remarks.

Welcome Remarks (00:03:13)

Micky Tripathi

Good morning. Thanks so much, Wendy, and good morning, everyone. Thank you for joining the first meeting of 2024. I want to welcome first our co-chairs, one of them our new co-chairs, Sarah and Medell. Thank you in advance for everything you are going to do in leading us over this coming year. Also, I want to welcome all of the new members, all the current members, and the new members in particular. We are very excited to have you join us and that includes both the members as well as the federal participants. We have a very exciting year ahead, building on a very exciting 2023 set of accomplishments by this committee as well as the Health IT industry at large. I will be relatively brief. But this is the first time that we have met since we had a couple very big events at the end of last year in December. One was the go live of TEFCA, which are extremely excited about. Five qualified health information networks are now live actively transacting.

The other two that were approved for moving forward with implementation we anticipate in the first quarter will also be going live. They are hard at work getting over the finish line with respect to going live as well. That is a huge accomplishment. Thank you to HITAC for all of the support and advice you have given us along the way. Certainly, thank you to the QHINs for committing themselves to getting this done in 2023 and getting us to the next chapter in network interoperability. The other thing that was notable in December among a number of notable things was the release of HTI-1. That was the Final Rule that has a number of very important policy elements in it related to information blocking, certification of health IT systems, and public health and then finally, a set of relations related to AI in electronic health records and establishing a framework for transparency of the use of AI enabled tools in electronic health records.

Again, I want to thank the HITAC for all of your advice along the way as we worked on the NPRM, the comments from that. And then, we were able to get that Final Rule over the finish line, which we are very excited about the AI component in particular. It is a very important piece of regulation, I think, as it is really the first set of regulations coming out of the Biden Administration focused on AI and healthcare. The first new set of regulations since the executive order. We are excited about that and happy that we are able to work with the community, be responsive to the very good comments that we got along the way, and to now put that in place. In 2024, we have a number of exciting things underway that we can look forward to engaging with you on with your collaboration and advice. We are working very hard on TEFCA to get the common agreement Version 2, which instantiates FHIR-based exchange in place. We are working on getting that done in the first quarter of 2024.

We will be releasing the draft components of that for feedback this week, I think, it might even be tomorrow to be able to start getting feedback on the next version of the common agreement, which importantly opens up framework for FHIR-based exchange, and in particular what we call facilitated FHIR. So, the ability for those with FHIR APIs to be able to scale those APIs using the network infrastructure of TEFCA, but to be willing to do that with each other and to have a FHIR-based exchange participant under the TEFCA trust service umbrella, which we think is a critical component of scalability and FHIR APIs. The other thing I should mention, which is not an ONC rule but is very important, I know Alex is on, I think, and we have been working very closely with CMS. And we are really excited that CMS released the CMS interoperability rule yesterday, the interoperability and prior auth rule. It has a number of components to it that we have worked very hard together on with CMS.

We, in particular, are very excited about the opportunity to use TEFCA to help to scale those APIs to be able to allow both payers and providers to use the scalability framework and trust services of TEFCA to be able to get the kind of interoperability for their stakeholders and importantly, with each other for payers and providers to be able to use FHIR-based exchange, to be able to do the types of information exchange that will help benefit the whole administrative side of healthcare delivery system, which is badly in need of more modern types of interoperability. We are very excited about that and very excited to support CMS and the great work they are doing with that. The other thing I would note in that, which is a really important part of the way we think about standards and our strategy for standards going forward is something you may not have noticed in the interoperability rule but I think is really important is the provisions related to enforcement discretion on X12 and the use of the HIPAA standards, which fully allows the ability to use FHIR-based exchange for prior auth, for example, and for the other exchanges in there.

I would definitely encourage you to take a look at that section because I think it is a very important policy that is a part of the interoperability rule and, again, I think is a testament to the hard work that Alex and the CMS team have done to help us all move forward in interoperability. And let us see, I think that is it. I look forward to today's meeting. I know there is a presentation from the team on HTI-1. I very much look forward to that discussion and to the conversation. Let me now turn it over to Elise.

Elise Sweeney Anthony

Yes. That is right. Thanks, Micky. Hi, everyone. Welcome to 2024. I am still saying happy New Year so happy New Year, everyone. I wanted to give a couple specific updates and make folks aware of a few resources we have as well. But first, of course, welcome to our newest HITAC members and welcome back to all of our other HITAC Members as well. We are very excited for 2024. I cannot wait for you all to get a look at the work plan, which we will be presenting later on and looking forward to all the contributions that HITAC will provide in terms of recommendations along the way. Micky mentioned HTI-1. I wanted to give a couple of updates on where you can find resources on that rule. The Final Rule is published and you can find it on our website, in particular, but you can also find in the Federal Register as well. There are fact sheets on our website, healthIT.gov on particular areas. If you are interested in a particular area, please check out those fact sheets. They are a great, quick resource and can point you in the direction of the areas in the rule that might be helpful for you to take a look at.

We have started to have our information sessions. And there are several coming up. The next one will be on January 25. And that will be on HTI-1 overall. We will also have one on February 1. And that is a question and answer information session. Pretty much what we do is that my team is wonderful and we open the line and folks can ask questions and we answer as many of the questions as we can during those sessions. That is a great opportunity if you have questions for us to join that session. On February 8, we will have a presentation on the insights condition, which is one of the areas covered by HTI-1. I do want to note that we have the sessions recorded online. You can find the information sessions and these will be recorded and they will be online. You can also find the presentations that we use for those. The other thing I wanted to mention is, in addition to HTI-1 Final Rule being released and being out there, we are also working on HTI-2 Proposed Rule, which many folks are aware of.

I also wanted to thank the public, everyone who is listening in, for their contributions and their comments that they submitted on the provider disincentives rule that HHS released and the NPRM and the comments we received. Thank you so much for that. We are also working as HHS on the development of the Final Rule there as well. The other thing I wanted to mention was a huge thing for the annual meeting. Amazingly,

I cannot believe we are in January already, but in December, we had a wonderful annual meeting. Truly it was unprecedented demand for attendance, and we reached full capacity. There were amazing breakout sessions, amazing plenary sessions. The plenary sessions are actually available online, so we do encourage folks to check those out if you did not have a chance to catch it in person. There are great sessions on AI where we talk about AI in the healthcare landscape. We talk about also the HTI-1 Final Rule and provisions we have on algorithm transparency amongst many other things that were discussed as well.

I just wanted to let folks know that that information is available online. And, again, just a huge thank you for all of the work that HITAC did in 2023 and all of the work to come in 2024. We really appreciate all the time that you spend. As I often say, we know this is not your day job. All of the time you spend to really contribute to the recommendations and provide recommendations to ONC is truly appreciated. On behalf of myself and my team, I just want to say thank you. And we are looking forward to the new year. With that, I will turn it over to our chairs.

Opening Remarks and Review of the Agenda (00:14:02)

Medell Briggs-Malonson
Thank you so much, Micky and Elise, for all of those amazing comments and especially for giving us a preview of the upcoming year. I must say also the annual meeting was incredibly fantastic. It was great to be and share a space to talk about all of the different accomplishments of ONC and then, also to see all the HITAC has contributed to as well. This year is going to be destined to be an exciting year for so many different reasons. 1.) We are going to go even deeper into health equity by design and really streamline that focus continuing to be able to focus on USCDI as well as all of the various different HTI rules and also, watching the continuous growth of TEFCA and the QHINs in action. This year in particular, we are going to be able to see all the important seeds that ONC has planted and that HITAC has helped to nurture really blossom before our eyes. It will definitely be a year of growth and transformation.

I want to also say happy New Year. It is great to be back here with HITAC. It is wonderful to be in the company of all of these seasoned HITAC members and to extend a warm welcome to the many new members of HITAC. We are absolutely honored to have you on this committee. And we look forward to working with each and every one of you as we set new goals and accomplish our goals in this upcoming year of 2024. Now, I will turn it over to Sarah to give her opening remarks as well.

Sarah DeSilvey
Good morning, everybody. I want to echo what Dr. Briggs-Malonson mentioned, the warm welcome from our ONC colleagues and reiterate how powerful and engaging the ONC annual meeting was. I also want to make sure that we are grounding in our purpose here. Although the work of the committee is obscure to many, at base the work that we will do over the course of 2024 is about developing the capacity of our nation to craft, share, understand, and safeguard critical stories with the goal of health and health equity. This is a polestar for Dr. Briggs-Malonson and myself. And you will see these themes throughout our work in 2024. All of you are here because of your critical expertise to apply to the global charge. And we are very much looking forward to working with you over 2024. I am going to pass the microphone back to Dr. Briggs-Malonson to lead us through the agenda for the course of our next hours.

Medell Briggs-Malonson

Thank you so much, Sarah. We are going to go to our first official business and that is going over our agenda. We have already gone over the call to order and roll call as well as the welcome remarks. Then, what we are going to do is we are going to move into the introduction of our HITAC members and federal representatives. Then, we will discuss something that is near and dear to my heart, which is the annual report and provide a brief overview of the draft in order to receive your comments. Following that time, we will go directly into the HITAC 2024 work plan presented by Wendy. And then, we will take a quick break for 10 minutes before we come back to the exciting HTI-1 Final Rule overview. We will end our day by going into public comment followed by the final remarks. That is the brief overview of today. Let us move into the next piece. Sarah, should we move on to the introduction of our HITAC members and federal representatives?

Introduction of HITAC Members and Federal Representatives (00:17:33)

Sarah DeSilvey
Yes, we should. It is my honor to do formal introductions for all of the HITAC members to the work of 2024. Just a reminder, this is an opportunity to state your name, affiliation, and organization and any conflicts of interest. I will start with myself. My name is Sarah DeSilvey. I have a few roles. Rural Primary Care in Vermont and I also am Director of Terminology for the Gravity Project. My conflict of interests in contracts or work that I do with the Yale Corps working with CMS on quality measure development and consulting. In addition to that, that is my list of things. I am now passing it off to Dr. Briggs-Malonson to do introduction and COI.

Medell Briggs-Malonson
Thank you so much, Sarah. Again, my name is Medell Briggs-Malonson. I am an emergency physician and health equity practitioner. I am also the founder and CEO of Contour Health Solutions which, is a national advisory firm that provides clinical matter expertise to help technology companies, healthcare organizations as well as investors on how to develop and implement inclusive technologies that serve diverse populations. During my day job, I am the Chief of Health Equity, Diversity, and Inclusion at UCLA Health. And I currently serve on the Clinical Advisory Board for Health Gorilla. Sarah, back to you.

Sarah DeSilvey
I am now going to go through in alphabetical order. Shila Blend.

Shila Blend
Good morning, everyone. My name is Shila Blend. I am the Health Information Technology Director for North Dakota Health Information Network, which is a statewide HIE. I also do some work with our state EMS Association as a subject matter expert. And to disclose, I am also part of Yale Corps Group that has been working on a measure related to interoperability for CMS. Thank you.

Sarah DeSilvey
Hans Buitendijk.

Hans Buitendijk
Good morning. My name is Hans Buitendijk. I am the Senior Director of Interoperability Strategy with Oracle Health. I am active in a number of areas that in part could be considered a conflict of interest perhaps. I just joined as a stakeholder member the Cumulous Q Project that is an elite program project that was awarded

this year. I am active in HL7 as a work group co-chair in a couple of the different accelerators, Da Vinci, Argonaut, and the Executive Committee, Operating Committee, and the Helios Public Health focused group as a co-chair. I am actively participating with Commonwealth Health Alliance, particularly focusing on TEFCA and what is needed there and interacting with the TEFCA community there. I am a board member on the Care Quality and Steering Committee member. I am a representative in various areas for EHRA. That is a vendor community of EHR vendors on their Executive Committee as an ex officio chair and public health chair.

Lastly, Sequoia project active in interoperability matters, topics like public health, privacy, consent, and data usability all focusing on advancing interoperability in one way or another.

Sarah DeSilvey
Thank you, Hans. As a reminder, if you can, try to keep to the 20 seconds, even though it is hard when someone is doing as much as we all are doing with all of our many hats and leadership. Michael Chiang.

Michael Chiang
Hi, everyone. Michael Chiang. I am a new member here. My academic background is in ophthalmology and biomedical informatics. I worked in academia for 19 years and then, I moved to NIH 3 years ago as the Director of the National Eye Institute. I am involved in a number of data science initiatives at NIH and really excited to be here. No conflicts of interest. Thanks.

Sarah DeSilvey
Thank you so much. Derek De Young.

Derek De Young
Good morning, everyone. My name is Derek De Young. I work in research and development in the interoperability space at Epic out here in Verona, Wisconsin. I focus primarily in payer and provider interoperability with the goal of producing administrative burden, improving clinical care and then, of course, the patient and member experience through better access to data. There are a couple of other things. I am involved in the TEFCA work groups for payment and operations as well as HL7 Da Vinci projects as well.

Sarah DeSilvey
Thank you so much, Derek. Steve Eichner.

Steve Eichner
Good morning. My name is Steve Eichner. I am the Health IT Lead for the Texas Department of State Health Services. I am also actively involved in a variety of HL7 work groups and work extensively with the rare disease community, particularly the International Fibrodysplasia Ossificans Progressiva Association. I am also involved in a variety of Sequoia related work groups and have been involved in TEFCA work groups for the last 10 years or so. It is always a pleasure to work with HITAC and look forward to a productive year. Thank you.

Sarah DeSilvey
Thank you so much. We have another one of our new members, Lee Fleisher.

Lee Fleisher

Thank you so much. It is a pleasure to join you. I am an Anesthesiologist Professor Emeritus at Penn and former chair. I am a health services researcher and former Chief Medical Officer and Director of the Center for Clinical Standards at CMS and look forward to working with my federal colleagues again. I work with the Bipartisan Policy Center, Milken, Duke Margolis, and the NAM. My only potential conflict of interest is I direct a small advising firm, Rubrum Advising, which focuses on access to medical technology. Thank you.

Sarah DeSilvey
Thank you so much. Hannah Galvin.

Hannah Galvin
Good morning. My name is Hannah Galvin. I am a practicing pediatrician and the Chief Medical Information Officer for Cambridge Health Alliance, a public academic health system serving the Boston, Metro North area. I am also the volunteer cofounder and board chair of Shift, the independent healthcare task force for equitable interoperability, which is working to advance standards, development, and implementation guidance around granular data segmentation and patient driven consent. ONC sits on Shift's board in an ex officio capacity. I also sit on Sequoia's Privacy and Consent Work Group. And I am looking forward to our work on the HITAC this year. Thank you.

Sarah DeSilvey
Thank you so much. Rajesh Godavarthi.

Rajesh Godavarthi
Good morning and good afternoon. I am from MCG Health network, part of the clinical evidence-based technology. We provide for the clinical decision support. I am very excited to be part of this group. I represent HL7, Da Vinci committees as it is related to prior auth work. I am also a board member on WEDI and have been working extensively with HITAC for the last couple of years. Thank you.

Sarah DeSilvey
Bryant Thomas Karras.

Bryant Thomas Karras
Hello. I am Dr. Bryant Thomas Karras. I am an Internist, Biomedical Engineer, Senior Medical Epidemiologist, and an Informatician serving as the Chief Medical Informatics Officer for Washington State Department of Health. I will disclose it is not a conflict of interest, but for awareness that 46% of our budget for the Department of Health comes from federal sources. That does not dissuade me from having a voice that independently advises ONC. I also operate a small consulting group, Northwest Informatics, that has a contract with the Public Health Foundation. It has been reviewed by our ethics committee and has no conflict.

Sarah DeSilvey
Thank you so much. Hung Luu.

Hung Luu
Good morning. I am Associate Professor of Pathology at UT Southwestern Medical Center. And I also serve as a Director of Clinical Pathology and Children's Health, a pediatric healthcare system in North Texas. I

am a member of the Clinical Advisory Council for Health Gorilla. And I also receive salary support through the FDA broad agency announcements to work on a variety of projects supporting laboratory interoperability. Thank you.

Sarah DeSilvey
Thank you so much. Anna McCollister. Anna, we cannot hear you.

Anna McCollister
Hi. Can you hear me? My video is blocked so my apologies for that. I am Anna McCollister. I have done a variety of different things over the years. I am an independent consultant focused mostly on engaging patients and data use, access, policy, and governance working with private companies as well as nonprofit groups. In addition to HITAC, I have served on a number of FDA advisory committees both in drugs and devices. I helped to start a patient hacker movement in the Type 1 diabetes space and led efforts to get FDA to make medical device data accessible through accessible APIs. I have done a variety of other things over the years, mostly related to engagement of patients and patient communities with data and data policy.

Sarah DeSilvey
Thank you so much. Deven McGraw.

Deven McGraw
Hi. My affiliation has changed. I am now the Chief Regulatory and Privacy Officer for Ciitizen, which is a platform that helps patients gather all their health information so they are then empowered to use it and share it as they see fit. We particularly serve populations with rare disease and including rare cancers. I will put the other things in the chat to save time. I am looking forward to the year. Thank you.

Sarah DeSilvey
Thank you so much. We welcome another new member, Katrina Miller Parrish.

Katrina Miller Parrish
Good morning, everyone. I am a board certified family physician and Clinical Informaticist. I have worked in private and academic practice. Currently, I am the Director for Clinical Informatics at Humana, which insures Medicare, Medicaid, military, and government patients. I also served as the co-chair for data and research for the Institute for Medicaid Innovation.

Sarah DeSilvey
Thank you so much. Aaron Neinstein.

Aaron Neinstein
Good morning, everyone. I am Chief Medical Officer at Notable, which is an AI platform for healthcare operations. I have been a practicing Endocrinologist and on faculty at UCSF for many years. I spent over a decade in informatics at UCSF working on our Epic implementation. Most recently, I was Vice President of Digital Health. Also in the past, I was on the founding team of Tidepool, which is a not-for-profit that develops software for people with diabetes. And I am really passionate over my career on advancing patient experience, access to care, and patient access to data. Thank you so much.

Sarah DeSilvey

Thank you. Eliel Oliveira.

Eliel Oliveira
Hi. My name is Eliel Oliveira. I am a Sr. Director of Informatics at the Harvard Medical School, Department of Published Medicine and also at the Harvard Pilgrim Health Care Institute. And I am also the CEO of Connexus, which is an HIE based in Austin, Texas serving Central Texas. I am also one of the founders of Pulsar Health, which is an HIT startup that seeks to support solutions for SDOH coordination. And I serve as co-chair to the data research work group at **[inaudible] [00:29:09]**, which is the association of HIEs nationally. And I am also the principal investigator in one of the current ONC LEAP awards that's funding closed-loop referral systems design and development. Thank you.

Sarah DeSilvey
Thank you. Kikelomo Oshunkentan. We cannot hear if you are trying to speak.

Kikelomo Oshunkentan
I am so sorry. I was trying to unmute and start the video. Good afternoon or good morning all of you. My name is Dr. Kikelomo Oshunkentan. Most recently in my recent role, I served as Chief Medical Officer of Pegasystems which is a technology company. I am also an Independent Practicing Hospitalist. I sit on the HIMSS committee as Physician Executive as well as the North Carolina chapter of HIMSS serving in the DEI work group. It is wonderful to meet you all and I look forward to working with you.

Sarah DeSilvey
Thank you. Another new member, Randa Perkins.

Randa Perkins
Good morning, I am Randa Perkins. I am the Chief Medical Information Officer at H. Lee Moffitt Cancer Center and Research Institute. I am board certified in family medicine and clinical informatics. And I lead our clinical informatics team here at Moffitt. I also serve on faculty here at Moffitt as well as the University of South Florida. Thank you.

Sarah DeSilvey
Thank you so much. Rochelle Prosser.

Rochelle Prosser
Yes. I am a Registered Nurse and Certified Legal Nurse Consultant and Data Analyst. I am the owner and founder of Orchid Healthcare Solutions that created a platform for oncology to consolidate all therapeutics and oncology in one place. To disclose, I am part of the CancerX Accelerator and **[inaudible] [00:31:00]** Accelerator. Thank you.

Sarah DeSilvey
Thank you so much. Naresh Sundar Rajan.

Naresh Sundar Rajan
Good morning, everyone. This is Naresh. I am currently serving as chief data officer at CyncHealth, which is a statewide health information exchange for the state of Nebraska and the state of Iowa. I am an Informaticist by training with **[inaudible] [00:31:21]** of expertise in health data modernization,

interoperability, and standards across healthcare systems. I dedicated my career towards advancing public health and health information exchanges and other interoperability matters. Thank you.

Sarah DeSilvey
Thank you. Dan Riskin.

Dan Riskin
I am the CEO of Verantos, a high validity, real world evidence firm and clinical professor of surgery at Stanford. My clinical expertise is surgery and critical care. I worked for almost two decades in healthcare artificial intelligence. By way of disclosure, I am an executive and stockholder in Verantos. And it is a pleasure to be on the committee. Thank you.

Sarah DeSilvey
Thank you so much. Mark Sendak.

Mark Sendak
Hi, everybody. My name is Mark. And I am the population health and data science lead at the Duke Institute for Health Innovation. I am also co-lead and a leadership council member Health AI Partnership. ONC is a federal observer. No funding from them of Health AI Partnership. And other conflicts include licenses from Duke to several external startups including KelaHealth, Clinetic, Cohere Med, and Fullsteam Health. Thank you.

Sarah DeSilvey
Thank you so much. Fillipe Southerland.

Fillipe Southerland
Good morning, everyone. Fil Southerland, Director of Health with Yardi Systems. We are an electronic health record that services the long-term post-acute care space. Previously, I founded one of the first technology, health to technology startups in the long-term post-acute care space. And no conflicts of interest.

Sarah DeSilvey
Thank you so much. Zeynep Sumer-King.

Zeynep Sumer-King
Good morning. It is an honor to serve with so many accomplished colleagues. I am the Vice President for Regulatory Affairs and Global Services at NewYork Presbyterian Health System. We are a New York City-based health system with 10 hospitals and a number of different ambulatory care campuses. Prior to that, I was at the Greater New York Hospital Association, just a year ago and there represented about 200 hospitals, particularly focusing on health policy as it relates to health information technology and interoperability. I have worked with New York's HIE also to advance adoption and their policy strategy. Thank you. No conflicts.

Sarah DeSilvey
And now to turn to our federal representatives. Keith Campbell.

Keith Campbell
Yes. Good morning. I lead the SHIELD Program at the Food and Drug Administration. Prior to joining the Food and Drug Administration, I worked for the Department of Veterans Affairs as Director of Informatics Architecture for over a decade. Before that, I worked for Kaiser Permanente. My background is internal medicine, informatics, and computer science. Thank you.

Sarah DeSilvey
Thank you so much. Jim Jirjis.

Jim Jirjis
I am Jim Jirjis, also internist. I am the Division Director for Data Policy and Standards for the Centers for Disease Control and Prevention. In addition, once a HITAC member, a voting member for a few years. Before that, I was with HCA Healthcare as their Chief Health Information officer for 10 years. And prior to that, CMI and head of internal medicine at Vanderbilt Medical Center. I am glad to be here.

Sarah DeSilvey
Thank you so much. Meg Marshall.

Meg Marshall
Good morning. Meg Marshall with the Department of Veterans Affairs. I am with the Office of Health Information as director of regulatory affairs. I have been in this role for a little over a year. Prior to that, I have over 25 years' experience in the health IT industry focusing on policy.

Sarah DeSilvey
Thank you so much. Michelle Schreiber is not here today. Alex Mugge is here. Alex Mugge.

Alex Mugge
I am Alex Mugge. I am the Chief Health Informatics Officer for CMS and the Director of the Health Informatics and Interoperability Group. Michelle Schreiber is the official HITAC rep for CMS. And she is the Director of Equality, Measurement, and Value-Based Incentive Group or **[inaudible] [00:35:41]**. She and I coordinate on who is able to attend, but I am happy to be here today. Thank you.

Sarah DeSilvey
Thank you so much. Ram Sriram.

Ram Sriram
Yes. I am Ram Sriram. I am the Chief, Software & Systems Division at NIST, and also the Program Manager for the health IT program. We really focus on standards, testing, and measurements for enabling interoperability. Thank you.

Sarah DeSilvey
Thank you so much. I believe that is the list of our HITAC members both the federal and non-federal reps. I just want to reiterate that after listening to all of your introductions, it is an honor to work with you all. And I look forward to working with you over the course of 2024. I know my colleague, Medell, does as well. I am now passing it back to Medell to give the Annual Report Workgroup Update.

HITAC Annual Report Workgroup Update (00:36:35)

Medell Briggs-Malonson
Thank you, Sarah. And I definitely echo those sentiments. What an impressive group that we have. HITAC is always amazing. But I am incredibly excited about all of our new members and all the work that we are going to do together. Now, we are going to transition into the annual report. The annual report is something we actually conduct every single year. And we are going to go through the charge of the Annual Report Workgroup and what some of those different objectives are. But especially for the new members, while you may not have been involved with some of these different activities that HITAC is highlighting in this annual report, we still definitely want your input and your insight in order to A). really make sure we have outlined everything as clearly as possible. But then, also if there are new topics for this year that you want to make sure we think of and incorporate into fiscal year 2024 annual report, we want to capture that.

And I am going to take you through the entire process of the annual report. And this will likely be the very first HITAC voting item as of next month. Therefore, I want you to engage and lean into this. And we want to hear your feedback. Here is the overall update. First, we are going to talk about scope and the membership, review the meeting schedule and next steps for the Annual Report Workgroup. We are going to then dive into the discussion of the draft HITAC Annual Report for fiscal year 2023, as well as a more condensed discussion of the draft supplemental background research document. And I will provide more feedback on that as well. The overall charge of the Annual Report Workgroup is that the workgroup will inform, contribute to, and review draft and final versions of the HITAC Annual Report to be submitted to the Secretary of Health and Human Services and to Congress each fiscal year.

As part of that report, the workgroup will help track ongoing HITAC progress. In general, this is a very important workgroup as well as report, because this is highlighting all of the great accomplishments and the progress directly from HITAC. And the specific charge that we are supposed to do each year as per the 21st Century Cures Act is analyze HITAC's progress in those different target areas that we have already reviewed and will review again, assess the health IT infrastructure and advancements in each one of the target areas, analyze any existing gaps that exist and then, we as HITAC propose activities to address those identified gaps. This is an overview of all of the amazing members of the Annual Report Workgroup. And I as the co-chair, and Aaron Miri was also my co-chair during the annual report, and, of course, he rolled off as co-chair of HITAC and co-chair of the Annual Report Workgroup.

But I do want to continue to give a significant amount of gratitude to Hans, Hannah, Jim, Anna, and Eliel for all of their commitment to this annual report. It is a large amount of work, but they have always shown up and performed an exceptional job. And, of course, a sincere thank you to all of the ONC Staff that are truly the power behind this Annual Report Workgroup. Once again, thank you to everyone who is on this workgroup and we will be looking forward to the next year's Annual Report Workgroup as well. Here is the meeting schedule for the Annual Report Workgroup. All of the different meetings in gray have already been completed. Our next meeting will take place on January 31 to update the draft with all of the feedback that we received from the HITAC members. And then in February/March, we will do one additional meeting in order to ensure the report is completely finalized before it is transmitted to Micky for his review and approval and on to the secretary and Congress.

This is also a meeting schedule for the full committee, the full committee as an HITAC. Today, January 18, we are going to review the draft fiscal year 2023 annual report. And then, next month on February 8, we will call for a vote to approve the final version of this annual report. What are the next steps for the development of this report? Again, today we are going to review the draft report and the supplemental background. And please provide all of your different comments. As I mentioned, on February 8, we will have an official vote to approve the revised annual report. Then, we as HITAC will transmit the final annual report and supplemental background directly to Micky Tripathi, our National Coordinator for Health IT. And then, from there if Micky approves this annual report, we will then forward the final annual report and background directly to the Secretary of HHS and to Congress.

Once again, that shows the impact of HITAC in general and the work that we do. It does not just stay in this committee. It truly does continue on to impact many policies and programs throughout our country. Let us dive right on into the draft HITAC Annual Report. And all of you all received this report in advance and, hopefully, have reviewed it and thought about some of your different insights and comments. The topics are grouped in this report into all of our target areas that are defined by the 21st Century Cures Act. And the five primary target areas that we as HITAC are charged with is design and use of technologies that advance health equity, use of technologies that support public health, interoperability, privacy and security, and patient access to information. You will see that the report is truly delineated into these five different target areas.

The outline of the draft report is as seen. And it goes directly from the forward and the introduction all the way to the appendix. And, of course, this also summarizes all of the HITAC activities that have been in progress since fiscal year ‘23. I am very proud of all of the work that we did in 2023, including the fact we had nine HITAC meetings, two of them in person. We had 61 meetings of 5 HITAC subcommittees. We provided 155 recommendations to the national coordinator for health IT. And then, all of our various different subcommittee activities focus on our annual report, the HTI-1 Proposed Rule, which is now the Final Rule with many of our recommendations, interoperability standards. Pharmacy Interoperability and Emerging Therapeutics was incredibly exciting. And also, of course, our public health data systems. In the report, you will see an overview of the health IT infrastructure landscape analysis. These are our recommendations, our insights of what is going on in the space in our country right now.

Where are the areas that we see strengths and also some of the areas that we see needs for improvement? What it shows in the landscape analysis is that the 21st Century Cures Act requires an annual assessment of the health information technology infrastructure, both nationally and locally, that allows for the electronic access, exchange, and use of health information. In this analysis as mentioned, we cover all of those key topics in our five primary target areas, as well as the federal activities across these target areas. While there is the HITAC activity, there is also the ONC activities as well. In addition to that, the reason why we are convened as a HITAC is also to provide our additional subject matter expertise. There are some additional topics that we as HITAC have actually included into this annual report as forward thinking of saying, "This is what is going on right now.”

But we also need to pay attention to some of these additional items that are coming down as well and making sure that we are prepared for it and that as these new technologies or standards of programs emerge that we are setting up the best structures possible to address them. The landscape analysis is summarized in the annual report and goes much deeper into this context in the supplemental background research document. In addition to that, we are charged with doing gap analysis as what I mentioned. This

is identifying any existing gaps in the policies and resources. Which then, we offer various different recommendations on how to understand these gaps more as well as how to address them. These gaps are also summarized in the annual report. The recommendations for addressing these gaps, as mentioned, is that we have not actually separated into a tiered approach based off of the various different gaps that are identified.

The tiered approach to key opportunities as categorized underneath immediate opportunity, which means it correlates to the planned topics for HITAC consideration within the next one to two years, meaning this calendar year 2024, as well as extending into next calendar year 2025. When we as the Annual Report Workgroup were sending, we are like, "This is a great topic. This is a great gap that we need to fill." But we may need more time to actually address this gap. Therefore, there are now the longer-term opportunities, which means that these are potential HITAC considerations to begin in the next three or more years. Meaning, we have to have a couple of things in place first or we have to see how this rule plays out in order to then more inform what this opportunity can look like and what we can advise as HITAC. You will see in the annual report, there is immediate opportunities, which are things that we need to do now, and longer-term opportunities, which are those items we plan to begin in the next three or more years.

All of these recommendations are clearly outlined in the annual report only, not in the supplemental report. What do we need from the full HITAC committee? We have three questions for you and we will have a question and answer section after I briefly go over the structure and content of the annual report. The first question is do you have any questions or comments about the draft report. The second question we have for you is do you have any suggested revisions to the draft report. We are always open to feedback and revisions. We cannot change all of the material content within the report because this has actually occurred over months and months of time. And we are on a deadline to get this finalized and submitted to our National Coordinator. However, we still want to hear some of your thoughts. The third question is do you have any ideas for the parking lot list for future report. This tends to be the time of year that we all start thinking about what should go into the next annual report for fiscal year 2024.

We want to make sure the full HITAC, including our newest members start thinking about what we need to highlight in this upcoming fiscal year's annual report. Before we go into the discussion of a draft supplemental background, I am going to ask our Accel team to pull up the draft annual report for us to go through that. Thank you so much. Let us keep on scrolling through. Once again, all of you have received this. This is the table of contents, which we have discussed. This was a forward that was drafted by our ONC team in collaboration with Aaron and myself as the co-chairs for the fiscal year 2023 annual report. This is the very first page of the annual report. And one thing that we started last year, which we feel has been very impactful, especially for our congressional members and those within HHS who are reading this report, is that we are all thinking about the future of health IT in this country. We can see it and taste it and feel it in so many different ways. Sometimes, others may not be able to see the vision we are painting with some of our different recommendations.

What we now do in the annual report is that we start off the annual report with illustrative stories in each one of the different target areas to describe the scenarios or future of health IT as we see it and why we are making the recommendations we have. As we scroll down, for instance, when it comes to health IT infrastructure, you will see all of these illustrative stories about advancing health equity, the use of technologies that support public health, interoperability. These are stories that will walk the reader through why this area is so important and why we need to create this future of health IT to achieve what we are

describing in these stories. As we continue to scroll down, and patient access to information being the last one. Then what we do, we are also highlighting, as mentioned, the federal activities across the target areas. You can see a lot of what has been accomplished and was already highlighted by Micky and Elise here in this section.

In addition to that, this is where the true meat comes in in terms of our annual report. Once again, you have this, so you can zoom in if you have old eyes like me. I am leaning into the screen. I want to show you the structure of this just to make sure that everyone does understand this piece. This is the table that we have in each one of the various targets areas. It is divided into four primary columns. The topic at hand, the keycaps that have been identified, the key opportunities that have also been identified whether immediate or longer-term and then. going into the recommended HITAC activities. Underneath the target area of design and use of technologies that advance health equity, I will not go into all the detail because we do not have time, but we first start off with artificial intelligence with specifically looking at algorithmic bias and transparency really identifying some of the gaps that we have seen has HITAC and stating what we are recommending in order to address those key opportunities right now in the future.

This section is about adding additional transparency, making sure everyone understands what FAVES mean and how we implement FAVES as one of the key criteria for influencing algorithmic bias and transparency in all of our health technologies. The next sections are focused on reducing the digital divide. And we separated this into two different areas due to the conversation and Annual Report Workgroup. There is the general digital divide where we think about various different forms of access to different types of internet whether it is broadband or Wi-Fi, but there is also digital literacy and so many other aspects that contribute to the digital divide. We also wanted to focus on increasing access to and accessibility of telehealth services. Meaning, yes, making sure people have access and understand how to use the technology, but are we being inclusive in design so that people who may speak non-English languages have full access to telehealth. People that are living with cognitive or physical diverse abilities that they can also appropriately access the telehealth.

Then, we go into missing health IT infrastructure for health equity and social drivers of health data and really identifying some of the gaps and opportunities in this section, which are a little bit of longer-term opportunities solely due to the fact that there is still some infrastructure and initial steps that have to be put in place. Then, we transitioned into the use of technologies that support public health with the primary topics being gaps in infrastructure and standards to support data sharing for public health purposes with some of those key opportunities of how we leverage the existing infrastructure to simplify some of that bidirectional sharing and interoperability. You see the HITAC activities listed here.

Then, we move on to interoperability, which has many different highlights, especially from a lot of the work we have done this past year really leaning into laboratories and pharmacies in terms of interoperability and some of the various gaps that have been identified, even through some of our workgroups from this past fiscal year 2023 and some of the steps that we need to explore and especially in partnership with CMS, as well as some of the other federal agencies. One of the things I want to bring your attention to is that given the fact that we as HITAC have so many subcommittees, instead of repeating all of the different content that our amazing subgroups have developed and those recommendations, we have actually provided hyperlinks. We are saying ditto to what our subgroup already said. This is the perfect example here where we say, “Please refer to HITAC’s report to the national coordinator on Pharmacy Interoperability and Emerging Therapeutics because we are endorsing what our HITAC subcommittee has already put forth.”

Information blocking is also divided into two primary sections, in feasibility exception as well as registries. This is something that is very important, not only to ONC but also to HITAC. That is something we wanted to lean into for immediate opportunities that we can conduct within the next one to two years, which you can see there. We will keep going down the pages. And also, standards to support data linking and patient matching. This is an area and there is an asterisk. I want you all to pay attention to when you see the topic with the asterisks. The asterisks actually show that this is a continuous theme. There are certain themes in the Annual Report Workgroups that we see year after year. The reason why we wanted to highlight these is that shows there is still work to do and this is not something we can address in one year and goes away. It is something that is part of the continuous thread within the work that we do in health IT in this country and also as HITAC.

This is a perfect example for the need to continue to think about standards to support appropriate data linking and patient matching while also thinking about those unique needs of vulnerable populations. We see the recommended HITAC activities there. The longer-term opportunities within this section of interoperability, which is something that, again, we as the Annual Report Workgroup said, "We probably need a little bit more time for us to put certain pieces in place before we can jump into it this year." One of the perfect examples of that is supporting interoperability standards for long-term or post-acute care providers. Making sure that we are having that strong, bidirectional infrastructure in order to exchange clinical data information and other data between acute care facilities, public health facilities with our LT packs. It is incredibly important but because we need to do this in a stepwise manner, this is one of the reasons why it is underneath longer-term activities.

Once again, the next topic of streamlining health information exchange with an asterisk because we continue to see this as a theme within many of our annual reports, which is still showing the importance of developing and implementing guidance that enables increased consistency of all the various different data that is exchanged. Our next target area is privacy and security. This is an area that we all anticipate and know we are going to have a very strong focus on this upcoming year in HITAC as well. The very first topic of privacy of sensitive health data and, specifically, as it relates to gender and reproductive health. We know that there has been a lot of changes within our country, a lot of new policies.

And we as HITAC, as well as within the Annual Report Workgroup, wanted to make sure that this was definitely amplified as a very important topic along with ONC and many of our federal agencies and for we as HITAC to really help provide recommendations on how to build these systems appropriately in order to improve the technical and operational approaches of protecting sensitive health data, specifically, as a focus to gender and reproductive health. That was part of our immediate opportunities. As we continue on, we also see the privacy of sensitive health data and data consent, which goes directly into the consent of that transmission of that data as well. Also, the next sections under this category, lack of accounting of disclosures. This is something that has been discussed several times within HITAC as well. This is an area that we have put directly underneath immediate opportunities given the way that our health IT industry is changing so much.

The last topic in this section is cybersecurity events across the healthcare infrastructure. We know that there is a lot of entities that are always working on cybersecurity events. But it is still always one of those topics that HITAC is concerned about because we tend to be in the organizations that are directly impacted and we know the impact it can have directly on our patients, as well as our workforce and, of course, across the entire health delivery service. This is one of the reasons why this is still in here as a recurring topic as

well. The next target areas patient access to information. And the very first topic was limited guidance for safety and security of mobile apps. Again, there is an asterisk because it is a recurring theme. We also know this is a topic that, interestingly enough, it peripherally is related to ONC, but we know that this is very much related to the FDA and FTC and some of the other agencies.

We as HITAC, as well as the Annual Report Workgroup, felt this was a very important topic just to consider and explore what we can actually do in terms of guidance available and certification criteria, especially for those apps that are being promoted towards patient to ensure those apps are rooted in clinical excellence and integrity, and that they always do what they need to do, especially when it comes to the interoperability with other certified health IT modules. Patient generated health data was also something that was very strongly recommended to be put into our Annual Report Workgroup by our HITAC members, especially because we have so many different new systems of actually patient generated health data. What do we do about that in terms of currently we are lacking the standards of interoperability among various different platforms to bring in that patient generated health data in an appropriate way and really make sure it is relevant and that it actually assists in providing high value care to all of our patients.

Some of this different areas we are looking at is improving the standards and metadata to support the incorporation of that data into our health apps, wearable devices and other sources. And how do we actually utilize all of that? Longer-term opportunities, still in terms of patient reporting electronic health record update processes, this was also a topic that has been trending over multiple reports, including the next topic we will talk about in terms of what are some of the various best practices to improve those existing processes to review and respond to those requested changes. And once again, user friendly price of cost of data transparency. We know that there has been a huge push of greater transparency of the price and cost of the services that patients are actually receiving. What is the role as well in terms of what we can do from the health IT standpoint? It is a really inviting CMS provided update to the HITAC on its healthcare provider and health plan price transparency initiatives.

These are both longer-term activities. But this actually gives you a very brief yet comprehensive overview of the topics, the key gaps, key opportunities, and recommended HITAC activities in each of our five target areas. I will take a quick breath there, too. A lot of information so I will let that soak in. As we continue going down, I will not go as much into all of the different areas. But as Accel goes and scrolls through this, we, again, have a lot of additional context information about the accomplishments that we as overall HITAC have achieved, as well as the amazing work that ONC has continued to do as well. We truly highlight each one of our subcommittees and the incredible work that each one of our subcommittees and members have put in. And we, of course, end in conclusion of the overall success of the HITAC. Thank you, Accel, for scrolling through.

Thank you, Accel. We can go back to the standard slide sets and will quickly go through the supplemental document but not as in-depth as we did the annual report. What I just presented to you, you can see it is a significant body of work, was the annual report. What we also have is a supplemental background research document. What we have been trying to explore, this is still a work in progress and we will continue to iterate it this upcoming fiscal year, we wanted to have a report that anyone could pick up, read, and understand what HITAC has done. What are the priorities for HITAC, as well as what are the true recommendations from the HITAC? Something short, simple, very easy to understand. We also recognize some readers may need to have a more in-depth understanding of why the HITAC has provided certain recommendations as well.

If we proceed to the next slide, this is an overview of the draft supplemental background research document that provides much deeper analysis and in-depth information if anyone does want more context of why we made the decisions or certain pieces were in the annual report. This is truly optional, completely supplemental, but we wanted it there in case others wanted to take additional action on some of the recommendations. Here is the outline of the supplemental background research document. And as we look through this, and we are not going to go through it in very in-depth detail because it is a pretty significant document, but as you review the supplemental background research document, we do have the same three questions for you. 1.) Do you have questions or comments about the draft document? 2.) Do you have suggested revisions to the draft document?

Once again, we cannot change the vast majority of what is in that document. But if there are small revisions you are like, "Clarify this area," we do welcome that. 3.) Do you have and ideas for the parking lot list for future supplemental background research document? Once again, that is what is there for you in terms of taking a look at the supplemental document. And that was all emailed to the full HITAC Committee. And we appreciate your input and insights on that as well. Well, thank you for your patience as we went through this entire body of work. Again, I just want to thank our Annual Report Workgroup members for all of your expertise and all of your time. We are almost over the finish line. We will probably have to touch base one more time. But this is something that is very important and really highlights all the fantastic work that we as the HITAC do each year. At this moment, I will open it up for questions. And I see already we have several hands that are raised. Hung, it looks like you are first.

Hung Luu
First of all, thank you, Medell, to you and to the entire workgroup for producing this phenomenal document. I think it reflects a lot of hard work. My comment is that the interoperability section still reads as if our consensus is that if we could only improve connectivity, if everyone would just follow the existing standards, that is somehow going to produce the outcomes we want to achieve. My concern is some of the nuance that have been reflected in our discussion throughout the year has been lost in terms of their needs to be a look at are the data elements that we currently transmit adequate to meet the goals we want to achieve. What I mean, obviously, I am in laboratory interoperability, so I will use that as a jumping board. We know that results produced off of different IVD manufacturer platforms produce variable results, especially in critical tests such as troponin and some coagulation testing. Currently our data model does not include any information on the methodology.

When that information is transmitted between institutions, the receiving institution has no way of determining whether or not the results they are receiving are comparable with what they performed in house. They are left with the choice of how do they integrate that piece of information with what they produce in house in order to determine best course of care going forward. Also, the report touches on artificial intelligence. That has to be trained somehow. What is going to be used are the currently available data sets, which includes no information on methodology. We are in effect going to be producing a bias in artificial intelligence and machine learning models because there is no information there to teach these networks that there is a difference between laboratory results based on methodology.

And so, if we could insert a statement maybe that there needs to be an evaluation of whether current data elements are sufficient to support our anticipated hope for outcomes or whether we need to re-evaluate and come up with additional data elements to ensure quality data.

Medell Briggs-Malonson
Hung, thank you for all of those insightful comments and completely hear every single thing that you are saying. The ONC team is actually capturing all of these elements. But the fact of what you are saying is making sure that we do have that standardization and those almost reference ranges and methodologies for when we are transmitting some of this data that is incredibly important. I also fully understand and support what you are saying in terms of making sure as we are training our new AI data models, are they actually receiving the right data in order for us to be as effective and as impactful as what we need to be. Thank you for that. We are capturing it. We can take a look at the report right now. But we can also think about adding some of these items into our parking lot for this upcoming fiscal year 2024 as well. I appreciate those comments. Katrina.

Katrina Miller Parrish
Thank you. First of all, again, complements to everyone who had anything to do with this report. It is wonderfully phrased and very understandable. I very much appreciate that. This is a great segue into the advancing health equity artificial intelligence bias and transparency section. There may have been a conscious reason why this section is very focused on implementation and not monitoring as an algorithm is used over time. And I understand that and I have not read the supplement to see if that is further described. But I am a little concerned that it is only focused on implementation. And as we know and discussed in the annual ONC meeting, you really need to monitor that over time in various ways. That means especially with human subject matter expertise oversight. I am not sure if that should go in as an edit on this document.

I would love for that to at least be a parking lot item to be discussed. I am sure it is but happy to discuss more how that would be best put into future documentation.

Medell Briggs-Malonson
Wonderful. Thank you, Katrina, for that comment. We have discussed that at length. That is something that is very important to me because of my intersectionality between health equity and justice as well as health IT and thinking about artificial intelligence. We have definitely discussed, not only the design and implementation but as you said, how critical it is to effectively monitor for the outcomes and how it impacts very diverse populations. When I say diverse, in terms of everything and demographics. We have discussed those that have rare conditions as well. That is something we discussed at HITAC and on the Annual Report Workgroup. Let us take a look back. I am trying to recall if it is for sure outlined in the supplemental documents. But the fact that you saw that, let us take a look at that as well. That is 100% part of what our recommendations have been. That was something for not only HTI-1 but definitely as we are proceeding with looking at algorithmic bias and how to mitigate such. Thank you for that. Michael.

Michael Chiang
Medell, thank you for the presentation. I loved the draft of the report. I had a few questions and comments. One of them is that I definitely love the illustrative stories. My sense was that some of those examples seem feasible to do in 2024. Whereas others of them seemed a little aspirational to me. I just think it may be worth clarifying the intent of those. My second comment is that I think it was really important that the report discuss privacy and security. I think one of the challenges is that what I see is there is a lot of enormous variability in practice about how patient data are being used, what data gets shared, whether informed consent is obtained before doing that. I think all those practices by my sense are completely legal. But I just

wonder if there might be some acknowledgment that we would benefit from looking more closely about how we should be practicing in the future with regard to data sharing.

My last comment is that I loved the references and recommendations about listening sessions, things like the social drivers of health and standards. Just one thing that I think it would be awesome to consider doing that with other parts of HHS because that was called out in some areas but not in others. I am sure there would be a lot of interest in that.

Medell Briggs-Malonson
Thank you for all of those great questions, Michael. I am going to try to answer very briefly. I am getting a ping that we have four minutes left. 1.) We tried to make those illustrative stories to be exactly that, whatever the vision is. Whether we can accomplish that in a year or maybe it is five years but just stating why we are making some of those different recommendations. They were not necessarily like let us show where we need to be in a year or so. The other thing about some of the various different topics as well as about privacy, those are all fantastic comments. Let us see what we can do and we will work with the ONC staff to see if this is something we can make more clear in this report or if we need to put it in the parking lot. We will definitely address that in the upcoming year because that is a huge area of focus for us as well for this upcoming fiscal year. Listening sessions are great and we are looking for to all of that this year as well. Thank you, Michael, for those comments. Steven, we are going to go to you.

Steve Eichner
Thank you. Great job as usual. I have a couple of quick observations. 1.) Looking at patient privacy and patient involvement in control of their data, it seems to be something that was missing in recommendations or parking lot. And I know it is something we talked about quite a bit in several different threads. I think that still remains an important concept. Secondly, as we are looking at patient data linking, I think public health is an important contributor in that space and it needs to be part of that active discussion. We are heavily engaged and have long been engaged in matching data across our different data sets and do have expertise in that and certainly could benefit from improvements. Again, I think it is important that public health be part of that discussion at the state, territorial, local, and tribal environments, not just the CDC level.

In the same vein, looking at discussion about what public health technology needs are, I noticed there was a short-term case about having the RCE potentially present on what public health technology needs are. I strongly suggest you invite the public health community to present what their needs are as the ones who are really consuming it and are probably in the best place to be able to discuss what our needs and challenges are in that space. And in the same vein, looking back to the illustrative story, the talks about the use of TEFCA for syndromic surveillance reporting, we were actually engaged for the first half of that already and already have been for a number of years. The timeliness depends on what the interface that the hospital has in terms of whether they are reporting data on per patient data or whether they are reporting it on a daily basis. That is something that maybe we can provide additional clarity on what might be different or more useful illustrative story. Thank you.

Medell Briggs-Malonson
Thank you as always with all of your insightful comments. We have all of those captured. And we will definitely cross reference that with the report as well. Thank you. Rochelle.

Rochelle Prosser
Thank you. I really enjoyed the topic discussed about inclusion of those that have cognitive challenges in the use of AI in technology. In that space, it can be very optimistic in terms of knowledge and access. And that becomes an entire barrier regardless of your race and ethnicity. I really like the fact that you included that. The ask was is this something that is going to be long-term on your discussion? Or is this something that you looked at and will close for 2023?

Medell Briggs-Malonson
Great question. This is all long-term. These are all the things we are still working on for next year and advancing health equity and justice in all of our standards and policies and programs is a key priority for ONC and our administration. This is all long term, not one and done. I know we are at time. And, Aaron, I did not know if you have something very brief you want to add.

Aaron Neinstein
It will be super quick. Thanks, Medell. I want to commend the group for including patient generated health data in the report this year. It is great to see a focus on EHR integration of those data such as from continuous glucose monitors. I would love to see us go further. I do not think the report as stated goes far enough. I think we need to comment on the need for open and standards-based access to data from these medical devices. While they may not be technically considered actors who could be information blocking, we should set the expectation that the makers of these medical devices do allow open API-based access to data for patients and providers. These data are really critical for modern healthcare provision. And it continues to be too hard for patients across the country and for practicing physicians to access these patient generated health data from medical devices for their care needs. Thank you.

Medell Briggs-Malonson
Thank you, Aaron. Thank you for being such a huge advocate for all of our patient generated health data. And we appreciate that and your comments. Thank you, everyone, for all of your thoughts. Please continue to submit your ideas, recommendations directly to the Accel team. The Accel at ONC team will send homework reminders. We want to hear your voice. And we will be back next month with the final version of the annual report. Thank you all. Sarah, I will now take a break from speaking and turn it on over to you.

Sarah DeSilvey
Excellent. Amazing work by the Annual Report Workgroup. I think it was mentioned that there will be an opportunity to submit comments by January 26 by email coming from Accel. I am also honored to introduce Wendy Noboa, our amazing DFO, to review the HITAC 2024 work plan before we take a short break in about 15 minutes. Wendy, welcome and we look forward to hearing about the charge.

HITAC 2024 Work Plan (01:22:00)

Wendy Noboa
Thank you, Sarah. I will try to be brief since I am between you and your lunch right now. I want to take this opportunity to review the HITAC final work plan outlining our 2024 activities. We began drafting this work plan in the fall of 2023. And we brought that to the HITAC for discussion on the November 9 HITAC meeting. Since then, we have had a chance to incorporate your impact and look at changes that we can make based on your feedback. The process is to review the meeting transcripts and the discussions from last November

and review recommendations and activities outlined in HITAC annual reports. We also considered our legislative requirements and emerging issues. This presentation will look familiar to those of you who were with us in November. But as you saw this morning, we have quite a few new faces on the committee. I will read some of the main points and share with you what we have incorporated and changed since our last committee meeting.

You have seen this slide and heard this in multiple different ways. Most recently, Medell brought this up. These are the five target areas for the HITAC as outlined in the Cures Act. Interoperability, Patient Access to Information, Design and Use of Technologies that Advance Health Equity, Privacy and Security, and the Use of Technologies to Support Public Health. These are what all recommendations should advance. These five areas are where ONC can use our authority to impact these items and through standards, certification, exchange, and coordination. Those are the main ways that we take your recommendations and implement them in the real world. HITAC activities in 2023, just to give you an update, we have moved to the Pharmacy Interoperability and Emerging Therapeutics Task Force into the completed section. We have wrapped up many of our activities from 2023. The only item left in progress, of course, is the HITAC annual report for fiscal year 2023, which you just saw is in great condition. We hope to see that next month.

This is our HITAC 2024 work plan. Across the top here are our HITAC committee meetings. Each of these dates represents the meeting date that is planned. We have 11 meetings planned for 2024. We may get a small hiatus in the summer. We like to give you at least one month off. But these are full committee meeting dates as for now of 2024. When it comes to the HITAC Annual Report Workgroup, fiscal year 2023 report should wrap up next month. And they get a very small break before they launch into the fiscal year '24 report. That will carry them into 2025. For the Interoperability Standards Workgroup, you may or may not have been hitting refresh over and over again. But if you have not been hitting refresh, that is what we are here for. Draft USCDI Version 5 is now live. Hurry on down to check that out. That means the Interoperability Standards Workgroup will be addressing that from January until April. Recommendations will be due April 11.

We want to call at a special presentation happening on April 11. We will have a presentation on the Federal Health IT Strategic Plan. Not a task force or subcommittee but a special presentation to mark your calendar for. The last two topics are TBD in terms of timing. One, of course, is HTI-2 Proposed Rule. I am sure you are all waiting for that. As we know, that should be released sometime in 2024. Once the public comment period opens for that, we will allow the committee to commence. And then, we will probably run a pretty robust committee meeting one to three times per week throughout the public comment period. The last item here is USCDI+, again, timing TBD. This may become a secondary charge to the IS workgroup later in the year.

It may be its own subcommittee or it may be the topic of the hearing. We broke this up because USCDI+ is different than USCDI. USCDI+ is a service to federal partners to advance interoperable data effects that extend beyond USCDI for specific program requirements. This is beyond the core USCDI data set. And, therefore, it is not the same as the work that is going to commence from January to April by the IS workgroup. What a surprise. The IS workgroup 2024 charge. Today, we would like to charge the HITAC with commencing the IS workgroup for 2024. The overarching charge will be to review and provide recommendations on draft USCDI Version 5. And the specific charges are to evaluate draft USCDI Version 5 and provide ONC with recommendations for A). new data classes and elements from draft USCDI Version 5, which we considered for the final USCDI Version 5 release.

And B). Level 2 data classes and elements not in draft USCDI Version 5 that should be considered for the final USCDI Version 5 release. Those recommendations are due April 11. I think someone dropped a link in the chat to the brand new USCDI Version 5 draft. And also, you can check out the standards bulletin for more information. Here is a look at our Interoperability Standards Workgroup roster so far. A lot of interest. You will see we have a mixture here of HITAC members, federal representatives, and public SMEs. There is still time to join the IS workgroup. If this has gotten you interested, please send an email to me asking to join the Interoperability Standards Workgroup. As a reminder, if you are interested in participating in the HTI-2 Proposed Rule task force, you can also send me an email. The time for that is really going to be pending the Proposed Rule publication and the public comment period associated with that.

Finally, a look, again, at this topic slide. You will remember this from last time, but we have made some updates here. Things in bold are new and things with an asterisk are related to discussions we had back in November. We have gone ahead and further qualified laboratory and pharmacy standards to include inventory access based on your feedback. We have also pulled out reducing patient carbon and put that in the top bucket here. Finally, the human services interoperability, we have pulled this out to be its own bullet. This did not come from our discussions in November. But we anticipate this being a topic that is top of mind for ONC because HHS's data strategy from 2023 to 2028 has formally designated that ONC has the responsibility for leading the development and harmonization of interoperability standards between health and human services. We do anticipate this will be a topic that the HITAC can hopefully engage in.

Our second bucket here, these are topics that were flagged by our HITAC co-chairs. We further defined algorithm bias and transparency to include large language models. Our final bucket here, these are also topics of great interest. If there is an opportunity, we will definitely use that to engage the HITAC. But we have further qualified patient generated health data to include quality measures. With that, I would like to turn it to Sarah DeSilvey.

Sarah DeSilvey
Hello, everybody. Thank you so much for a review of the 2024 work plan. Again, it is my honor to the IS WG again with my co-chair, Steve. We welcome all that work. First, we are going to accept a series of before we transition to break. We have about four minutes. Bryant.

Bryant Thomas Karras
Thanks so much. And, again, an honor to serve. Wendy, in the last slide, you mentioned the charge of HHS interoperability. And a clarification. I know there is authority and scope for ONC. But is there a stretch goal or ability for topics around DoD and VA interoperability to be included in the goals or the outcome descriptions of that report, even though they are not HHS proper?

Wendy Noboa
That is a good question. I think this would pertain predominantly to HHS. Of course, anything human services related does have a place to extend beyond HHS and into other federal spaces. But for now, this is the direction from HHS. It will likely be precluded to that.

Seth Pazinski
This is Seth Pazinski, and just echoing that the HHS plan data strategy would pertain just to HHS.

Sarah DeSilvey

Thank you, Wendy and Seth. We have a couple more minutes, so Michael.

Michael Chiang
Sarah, Wendy, thank you. Reducing patient burden I think is really important as one of the priorities. I just asked one of the new people an ignorant question. I hear a lot about provider burden of EHRs. Things like they are usable but when people do workarounds, copy pasting text or using templated text. Is that something this group has considered or would consider in the future addressing, provider burden of EHR?

Wendy Noboa
If that is something of interest to HITAC and HITAC members, a great place to raise that is regarding the Annual Report Workgroup. They track the topics that are of high interest to HITAC and look for ways to operationalize that. That is a suggestion that you can always put forward to our Annual Report Workgroup colleagues.

Seth Pazinski
This is Seth Pazinski again. That has come up in past work that the committee said that. For example, the ICAD Task Force that looked at clinical administrative burden with a particular emphasis on prior authorization focused a lot on that provider burden aspect of things. I would definitely encourage you to engage through the Annual Report Workgroup process to flush out the topic in more detail.

Sarah DeSilvey
Just a note, we do have conversations regarding provider burden often within IS WG when considering adding other standards as well. It is one of the topics and themes that we consider as we consider adding new standards. We only have a couple more minutes. Mark.

Mark Sendak
This may build off Michael's question. Also as a new member, I am trying to understand the process of putting forth new priorities. I did see in the annual report draft, there were several mentions of the digital divide. There is a lot of work happening around the algorithmic transparency and ensuring equitable use of digital health tools. I am curious, at least in the work I do, I see a lot of the digital divide being exacerbated by AI and many settings not having expertise or capabilities internally. I am curious. What would be the path to try to think through and do some work around digital divide explicitly in the space of AI capabilities?

Wendy Noboa
Yes. That, again, is probably something we would have to raise with the co-chairs and the Annual Report Workgroup in terms of how to operationalize that. Certainly, as you saw in the topics, that algorithm bias and AI in general is a huge topic nationally at the moment but also something of high interest to ONC and the HITAC. Again, everything that HITAC does has to relate back to ONC authorities and what we can really act on. In some ways, there is some limitation to how we address that. But certainly does not preclude your point that it is very important to address AI and how that is going to play out in health IT.

Sarah DeSilvey
Thank you, Wendy. We are at time. It is difficult to get to the final questions. If you are able to put your comment or question in the chat so it can be logged, please do. It seems we are okay then. Thank you so much for transitioning to the chat. It is my honor now to head us into break. We are going to be having a 15

minute break and then, reconvening at 12:45 or quarter to the hour if you are in a different time zone. Thank you so much for the morning session, and we look forward to seeing you shortly.

HTI-1 Final Rule Overview (01:36:17)

Wendy Noboa
Hi, everyone. Welcome back. We hope you enjoyed that very short break. I would like to turn it over to Medell now to introduce our next presenters.

Medell Briggs-Malonson
Thank you, Wendy. And I hope everyone did enjoy that very short break. But now, we get to transition into an exciting presentation on HTI-1, the Final Rule overview. I would like to present Michael Lipinski, our Director of Regulatory and Policy Affairs Division from ONC, and Jeffery Smith, Deputy Director of Certification and Testing Division of ONC. Michael and Jeffery?

Michael Lipinski
Thank you, Medell. And I will do my best to make it super exciting and interesting today. And if I do not then, it is all on Jeff. Jeff has to do that part. Thank you all for being members of the HITAC and joining us today for this call. Good morning to those on the west coast and good afternoon for those in the Eastern Time Zone. I know there are a lot of new members, first meeting. We do not have a enough time to do a whole one on one on regulations and so forth. But I want to level set for you all if you are not familiar with everything that ONC has going for a regulatory perspective. Today, we are going to talk about what we are calling the HTI-1 Final Rule. The full name is on your screen. And it is an approach we are taking now. This is the first rule we are doing that where we are going to number the rules for shorthand reference to the rules. We have done a lot of rules prior to this. I have lost track of the exact number of regulatory actions we have taken. It may be up in the 20s.

From a transparency perspective, you can go to our website and we have all the rules in order, time, and a little description of them. You can click on them and go to those rules. We are trying to do for shorthand, easy way for people to reference. As you can seem they have long names based on the topics. And we are covering a lot more topics in our regulations because we have the new authority under the Cures Act for information blocking. No longer is it standard certification criteria and how it works within the certification program with other updates. It has that on the screen and we call it information sharing. If you are not blocking, you are sharing, right? That is just a little primer on why you see the HTI-1 moniker now or shorthand for our rule and we will be using that going forward. We are not renaming prior rules. This is No. 1 and the next one is No. 2.

On that point, I want to mention all the regulatory activity going on just in the past year and through this year with ONC. It has been about two years ago, we did what is called a request for information. It is an RFI on electronic prior authorization. I am certain many of the members have interest in that area. We just talked about it from a burden reduction perspective and CMS is doing work in that area. We coordinate with them. We do requests for information. What we got from that, the comments that we got back, are going to be part of our HTI-2 rule. If you had comment on that and are wondering where those comments are going, they are going to impact the letter HTI-2 rule. We have a provider disincentive rule. You had an RFI. This Final Rule went from proposed to final. We have been HTI-2 rulemaking, and we have another rulemaking

specific to information blocking implementing a statutory authority and instruction related to establishing disincentives for providers.

That comment period just closed on the second of this month. Where can you find out more about this? I want to give you that before we move on and just talk about this rule. Twice a year, the whole federal government submits to what is called a unified agenda and regulatory plan. That lists all the agencies planned regulatory activities for the next 12 months. That is done in the spring and the fall. Last one that went out is the fall of 2023. And it lists those three rules that I mentioned. You can find those @reginfo.gov. Why am I mentioning that just for that? It is also a really good place to go to understand where the rule is at currently because there are stages of rule. Sometimes there is a bit of a black hole. It is still with the department because we have a plan we are going to get out. Normally, almost all rules and provider disincentive was a unique one in that it did not go to OMB.

But most rules go to the Office of Management and Budget for review across the federal government, particularly if there is an interest in the action that is occurring in that rule. I can see that was added to the chat. You can see there on reginfo.gov if the rule has gone to OMB, Office of Information and Regulatory Affairs, for that review. Keep an eye on that for when it comes to HTI-2 to see if that rule has moved over to a more full federal government review. That is the last stage before, generally, it gets published for comment. Then, you have a comment period in which you all get to provide us input on the proposals and we take that into consideration and to issue a Final Rule. One last thing on the HTI-2 rule, we targeted on that fall agenda to publish in November of last year.

Obviously, we did not do that. We focused on the HTI-1 rule. But I mention that just in terms of the other piece of information I gave to you about always getting a check on reginfo.gov if you are wondering when it is coming because you will not really get a public notice of that until we do the spring agenda of what our new target date is. That usually comes in late spring, so there is a law between public notification on that. We are working hard and diligently on that one and keep an eye on reginfo.gov if you want to see when that rule makes its way over to OMB for review. Let us talk about the rule we finalized. We are actually coming up on an effective date on that rule. This is a bit of a disclaimer. It is just telling you we are going to do our best effort today to recite as accurately as possible the regulatory requirements in this rule. But if we do not get it quite right, just know that the official regulations are in the CFR, Code of Federal Regulations, as cited here in the rule itself. The rule will become effective, it is officially published, and will become effective I believe it is February 8.

That will be important when we talk about information sharing and some of the other provisions. My colleague, Jeff, will talk about compliance dates when it comes under the certification program. But the effective date does have substantive importance, particularly when it comes to information blocking as those exceptions. New exceptions will be available to actors covered under information blocking as of that date. This is an overview to understand why we are doing what we do. It is almost all the time, I would say, we start with what has Congress asked us to do via statute. On the left of your screen, we are implementing certain provisions still from the Cures Act, including the HR reporting program. We call it the insights condition now because it is part of the certification program. Continuing to make more data available. The API condition we find in the Cures Act, the ultimate goal, at least as Congress saw it, was to make all EHI available without special effort.

We are in the process. The USCDI tries to support that effort, also our efforts regarding USCDI+. And reasonable and necessary activities that do not constitute information blocking. The statute specified the secretary was to identify those and go through notice and comment and rulemaking. That is something we are always looking at in terms as summarized in the HTI-2 rule. We expect to be potentially looking at that again in terms of proposing new reasonable and necessary activities that do not constitute information blocking. Then, there is administration priorities. So, that is listed here. There are some other executive orders as well that have impacted our work on HTI-1. But these are top of mind and a focus for these. So, you, obviously, have the data driven response, which interoperability supports. My colleague, Jeff, will talk about USCDI Version 3, which we think will help address racial inequities and other inequities that occur in healthcare.

And DSI including its predictive decision support interventions. We use the term artificial intelligence as we do throughout as well in terms of what the criteria and what we are hoping it will achieve. Lastly, I am referencing the statutory authorities that we had under HITAC, which were very general in terms of establishing a certification program. Advancing interoperability Congress. And our agency is super focused on interoperability. If you look at the legislative actions that have occurred since 2009, including giving us the definition of interoperability when it comes to health IT in the Cures Act, you can see evidence of that. Interest in advancing interoperability. And we try to do that both through the certification program and as well through some of the exceptions that exist under information sharing or information blocking. This is how the rule breaks down. Essentially, we are going to talk about this today.

The first four topics you see here fall under the certification program. That affects any entity that brings forth a product that gets certified with the program. It does it in different ways depending on what criteria they get certified to. Obviously, anyone who is adopting these certified products and using these products, there will be an impact there as well. Information blocking is more of an umbrella. It is going to affect developers of certified health IT and generally most users of certified health IT because it covers the definition of healthcare provider that is very broad bringing in labs, pharmacy, long-term and post-acute care, even those that do not use certified health IT as well as health information networks and exchanges. I will talk about that one in particular. I will talk about No. 1 and then my colleague, Jeff, will talk about the other three. The new addition list approach. We can jump to the next slide. While I talk about it, let folks look at what we see as the benefits for this.

We proposed and finalized this approach. It will be called the ONC certification criteria for health IT. There are a lot of reasons we discussed in the rule. Many of them focus on perception and misunderstanding. If you have the 2015 edition, people are under the impression how old is that edition? That is nine years ago, right? What are the standards and functionality in that edition? In the Cures Act in 2020, we updated the edition with new functionality. It gave the wrong impression as to the recency of standards that are being used and functionality that is being used. It also created issues from an administrative perspective. As you all know, the HR incentive program, not the promoting interop program, cites to the use of certified health IT. They were always having to change it to the new edition that we would come up with. This way, we are going to avoid that type of problem.

What we are going to do is via our certified health IT products list, you will know whether you have a certified product because during certain transition timeframes, which we are about to enter, they can be certified to either the new standards we adopted or continuing to use the standard that was previously adopted. Eventually, and I will talk about this on the next slide, they are going to move to the more recent standard

that is better supporting interoperability. Overall, I think we got a lot of good feedback on this in terms of supporting it and we moved to this approach. As I mentioned, the way we are going to approach this is we are setting what we call expiration dates for criteria and standards. Generally, standards. When we are changing the functionality, we may add functionality to a criteria of which a product gets certified would have to meet. Sometimes we change it to a different criteria all together, which my colleague, Jeff, will talk about with the DSI criteria going from the CDS criterion.

And then, with the timeframes, like I said, we will know via the chat but what your product has been certified to if you are a user of health IT. I am going to move to the next slide to talk about compliance. And I am going to turn it over to Jeff. There are two forms of compliance now that we have in the certification program, the criteria themselves, which I mentioned in terms of standard that the product has to be certified to. And the assurance provision, which also applies to the developer. They are kind of a belt and suspenders approach to certification developer. And it really is geared towards helping the provider to be honest, the user of health IT because it is making sure developers are getting their products updated so you have the most recent functionality within a reasonable period of time and providing that to you in a set period.

The one thing that we had in the rule that did change from the Proposed Rule is we had this dependency in terms of when they would have to update the product and how it could vary depending on which functionality it was or standard it was. We got a lot of feedback that was creating complexity and confusion. And we listened to that. And in the Final Rule, everything is set with specific dates in terms of when a product needs to be updated to a new standard or criteria. There is no dependencies. It is specified now. Like I said, we think this will help providers most in terms of making sure you are getting the updated product in a timely manner. I will move to the next slide where I believe I am going to turn over to Jeff and he will talk about the programs. Jeff?

Jeffery Smith

Thanks, Mike. You clued into something I heard at the top of today's meeting. And that is confirming we are talking to the right groups of people by describing HTI-1 as exciting because it is exciting. I am going to go through some of the certification standards and functionality updates through our certification criteria. I will touch on many but not all. There is a lot in HTI-1. First, I want to try to set the table. I think most of you are aware but it bears some repeating. The certification criteria, the functionality, and standards that we have in the program seek to achieve simultaneous goals. Of course, we try to move the industry towards more functionality and more capability, as well as move the industry towards the use of better standards. And we try to do that in a way that accommodates development timelines because it is important that systems use the same standards and use implementation guides that are the same because it will fundamentally improve interoperability.

Beyond those two things though, we also try to achieve specific policy outcomes and policy goals. And, again, I think the group probably sees it, but it is worth underscoring that we do not have certification criteria for transitions of care just because we think that is a fun thing to do. We think that is a fundamental thing and it will fundamentally improve interoperability, the same with the public health reporting criteria. We have those to achieve a very important and fundamental goal and that is to improve the ability for public health officials to understand where in time and space diseases are occurring. And then, we will talk a little bit later about the DSI criterion. And the really important policy objective we are seeking there is multifactor but we are looking to interject transparency because we think that transparency in how predictive decision

support software was designed, developed, tested, and implemented will have an important cascading effect into addressing issues related to bias and discrimination.

It is important to think about these certification criteria in and of themselves as things that certified health IT developers need to conform to but also know there is a lot of work that goes into thinking about the bigger picture and how do we establish these criteria and how do we set these standards in a way that achieves second and third order effects. Here is a smattering of the standards. I will call them the marquis standards and certification criteria. We will spend a little bit of time on some of these moving forward. Of course, USCDI V3 is going to be the new baseline. And that is going to be supported by a new version of the CCDI Companion Guide and a new version of the US Core Implementation Guide. We also finalized a raising of the bar, raising of the floor really for minimum standard code sets. These are terminology standards, many of which are probably updated on a monthly basis or something less frequently than on a rule by rule basis. But we did move that floor up to be more current.

And then, on the certification criteria side, what you see here is a list of revised standards. Many of these revisions are very important and we will go through some of those. Hopefully, most of you are familiar with the USCDI. But if you are not, this is the national data set that every EHR is expected to be able to consistently and accurately generate data for as well as exchange and use data. This has its origins going back to the common clinical data set. And as a function of the ONC Cures Act Final Rule, we established the US Core Data for Interoperability. As this slide indicates, it is the minimum data set required for interoperability. We initiated an annual cycle going back the last several years to update from Version 1 to Version 3. And we have made available Version 2 and Version 3 through what is known as the standards version advancement process. I will not go into that. But, essentially, what that does is it allows developers to certify to newer versions of adopted standards and get credit for that via certification.

It was an important mechanism that we used to address the longstanding criticism of the program, which was that our standards requirements were getting in the way of innovation and getting in the way of developers moving to newer standards. We actually allow developers to certify their standardized API or their module certified to the transitions of care criterion to use newer versions of adopted standards. You can see this is Version 3. You can see that there are demarcations related to new areas from Version 1 and Version 2. These are policy decisions inasmuch they are technical decisions. The determination to include health insurance data is, obviously, an important policy decision. The same is true for social determinants of health data and health status assessment data as well as many others. This is the full set of USCDI V3 data elements. You can see we will have requirements within the program that ensures all modules that are certified to criteria that reference the USCDI will need to be updated by January 1, 2026.

As you can tell, we did expand, obviously, from Version 1 to Version 3. And there, you can see the certification criteria that do reference the USCDI. And I would highlight the view down, the transmit, as well as the standardized API for patient and population level services and then, again our transition of care criterion. With the implementation and with compliance with this, you will generally see a growing number of data elements and, hopefully, a growing standardization of those data elements and availability for various use cases. Quickly, the minimum standards code sets, as I mentioned, these are vocabulary and terminology standards that are required across to program. As you are likely familiar things like SNOMED and LOINC publish fairly regularly. And generally speaking, developers update their technology and adopt these new minimum standard code sets as they come out.

But certain criteria do actually require these. And we have a date. Generally speaking, we would expect developers to be on newer versions than the March 2022 version of SNOMED, for example, today. But we set the new baseline just to ensure it is the case. On the standardized API, this is one of the more robust and interesting and, I think, very important certification criteria within the program, not that we have favorites. First among equals is the standardized API. And we made several updates to this criteria. Obviously, moving the baseline support of USCDI V3 via the US Core Implementation Guide was moving that up. But we also adopted the Smart App Launch Implementation Guide Version 2. And Smart App Launch is an implementation guide that really helps facilitate the interactions between a certified health IT module server and a client. This will help with interactions and help facilitate the growth of an API based ecosystem around health data accessing clinical data and EHI through standards-based APIs.

We also made some clarifications and really kind of made permanent some clarifications, made legal some clarifications that we have had in the program for a while. As a function of the Cures Act, we had requirements that when a patient wanted to revoke access, that access needed to be revoked. Say they downloaded an app, they connected it to their patient portal using the Smart App Launch framework behind the scenes and then, they decided they did not want the app to have access to their information. That was a requirement in Cures Act Final Rule. And in this rule, we made certain by putting a time requirement that when a request to revoke access to health information was made by a patient that revocation needs to happen within an hour. Then, we also revised and standardized the service-based URL publication requirement. Essentially, the requirement we established in the Cures Act Final Rule, basically, said that for all health IT developers that have modules certified to this standardized API, they need to make available these endpoints.

Think of them as hyperlinks that would enable a patient to access their information that their providers, maybe at their specialist or primary care physician or a hospital. The requirement was a developer who had a deployed API technology would have to make available these endpoints for all of their customers and that would facilitate patients accessing their information. What we found was developers made these endpoints accessible in a myriad of ways. Some of them standardized using FHIR, some of them not standardized, some of them in spreadsheets, some of them in PDFs. I am sure there are some in Sanskrit somewhere as well. We finalized requirements at developers would have to use a standardized format. Again, I think in service of promoting an API based ecosystem, having more standardized means to connect patients' apps of their choice to certified technology is going to be helpful. Electronic case reporting. This has been in the program for several years now. But it has been in the program as a functional certification criteria.

That means there was no underlying standard that we pointed to as part of the certification program. And I think this is an important case study in how a lot of ONC certification criteria do evolve. Generally speaking, the same is true of the standardized API. It did not always used to be standardized. It used to be a functional API. For the longest time, case reporting was functional. We described it in the regulation text at 170.315(f)(5), we described how the technology ought to work using words. Over the last couple of years, there have been developments in the HL7/CDA context as well as the HL7/FHIR context to develop implementation guides and standards for case reporting. Now, case reporting is not a simple transaction. There are a few different moving pieces. But through our experience with COVID, there were some innovations that were developed. We finalized that health IT module must adopt at least one of the CDA or FHIR implementation guides to be certified under the program.

And really, we did this in recognition and based on comments from the idea that various public health agencies are in different places. Some of them may be better equipped to handle CDA over FHIR or vice versa. But the way that we establish this is for the first time, case reporting needs to be according to specific standards. And health IT modules have until January 1, 2026, to update their modules and provide this update technology to their customers. I will say here, and this is generally true of our other criteria and standards, nothing prevents a developer from waiting that long. In fact, a developer could tomorrow look at their implementation and say, "We have been using the CDA Implementation Guide for the last two years now," or, "We are actually looking to pilot and use the FHIR Implementation Guide." They could get certified to either one of those as of the effective date. Not that it has been our experience, but that is a possibility for the program.

For the users of EHRs and users of health IT, it is always worth asking the question of your developer, "When you plan to get certified to these new functionalities and these new standards?" The patient requested restrictions criterion, this was something that we offered actually several different alternative proposals for. The big idea here is that we are again, towards the eye of trying to achieve a policy objective. We received a lot of interest over the last several months leading up to the HTI-1 Proposed Rule. And subsequently, we received a lot of interest as well in trying to help think about how do we use certified health IT to help segment sensitive data. Of course, those of you who have been involved with the data segmentation through the privacy work for the last several years know this is not a new question. And in fact, the certification program today includes two criteria that would segment data at the data level almost using CDA based standards.

There are not currently any programmatic requirements to do that. But we do have series. I think at last check, we have about 80 different products that are certified to be able to segment data using the CDA standard at a fairly granular level. We put out a proposal with several alternatives, some with standards and some without standards, some with a full suite of standards, some with a kind of standard light approach. We got a lot of mixed reactions in terms of how do we leverage certified health IT to help patients request that their health information be restricted for use or disclosure. Where we landed was in requiring modifications or revisions to our view, download, and transmit certification criteria. And that is the E1 criterion as we refer to. And what we finalized with that health IT module that is being certified to E1 must support an internet-based method for patients to request a restriction on the use or disclosure of their data.

Now, we left a pretty high level. This gives developers flexibility to implement this functionality in a way that is kind of consistent with how they might implement other kind of patient portal or view, download, transmit functionalities. But we think that this is an important first step towards having a more robust conversation around the need to position patients to acts as stewards of their own data and to help them make determinations for their own selves what is and is not sensitive. Again, fairly high-level requirements here. And we will continue to monitor this space. This was one of the criteria that could have easily been considered a revision to our clinical decision support criterion and left at that. But due to the growing interest in AI and ML, we took a much closer look at a criterion that is currently at 170.315(a)(9). That is the clinical decision support criterion. And we made some proposed and finalized some changes to revise that into the decision support intervention criterion.

I have got a couple of slides here that we can spend on this. And then yesterday, we did do a deep dive on this. And I do believe I saw an email come through about the availability of that presentation. Rather than spending four slides like we do here, I think there are sixty or some odd slides in that presentation. But,

obviously, this is going to be a topic of conversation for some weeks and months to come. First and foremost, I think it is important to note that the use of AI and ML has been growing quite rapidly in deployed settings. And it has been used for both clinical and administrative applications. And I think there has been a tremendous amount of good and a tremendous amount of benefit has resulted from these deployments. But we also know that there are a number of challenges. And these are not isolated or bespoke, inadvertent errors that caused one or two patients to have problems.

These are systemic. These challenges have impacted hundreds of millions of patients. And we think in large part that some of these challenges could have been addressed if our requirements were in place a few years ago. Of course, we did not know what we did not know. And so, a lot of what we have learned over the last several years has really been a result of very intensive and rigorous peer reviewed literature. And so, it was with this kind of context in mind that we tried to think about what could ONC do through its certification to try and address some of these challenges. Here is about 15 or 20 slides packed into 1. But this is our answer to the question what can ONC do to address some of the challenges that we saw. We have an existing certification criterion for CDS. CDS was, actually part of the four elements that Congress used to define a qualified health records, qualified EHR.

It has been a longstanding function and the program we have had, I think, recognizable requirements going back to at least 2012 in terms of how a certified EHR or health IT should support CDS. But because the electronic health record is so central to the development of AI and ML driven decision support, both as a source for data and as a delivery mechanism for predictive outputs, we saw a genuine opportunity to make a fairly important impact here. And so, the question was how did we want to go about making that impact. What we did is we finalized the definition for predictive decision-support intervention. That is broad and inclusive. It is agnostic to use case and it does not consider the level of risk. We got a lot of feedback in the comment period around how we needed to do those things. And, generally, people had a lot of ideas about how do we constrain this definition to be more focused on the thing that matters. Well, I think it probably comes as no surprise to this group that when you ask somebody what is the thing that matters, there is a bunch of different answers to that question.

And so, we decided to keep the definition broad and inclusive. Then, it came down to a question about how do we apply that definition. And it is really in the application of the definition that you saw some constraining from what we proposed to what we finalized. And what we finalized was a set of requirements for health IT developers that supply a predictive DSI as part of their module. I think that was the big shift from the proposed to the final. And we can talk a little bit more about that. I think the other important thing is we actually made more uniform between what we proposed and what we finalized a set of requirements for health IT modules that I think we will have a much better and consistent user experience for health IT users over time. Some of those uniform requirements is that health IT modules must enable users to provide electronic data. Users need to be able to say if the intervention worked or if it did not. We did constrain that to evidence-based DSIs based on a lot of feedback and a lot of concern that our proposals were unworkable.

And we took some steps to clarify that for evidence-based DSI, users need to be able to say whether or not it needs to be able to provide feedback. We also made uniform the idea that any module certified to B11 needs to enable users to select either evidence-based predictive DSI or evidence-based DSIs and predictive DSIs. This is fairly consistent with the requirements of the A9 CDS criterion today. We do not say what kinds of evidence-based DSIs users need to be able to collect. We just need that they need to be able

to select the evidence-based DSIs. And the same will be true for predictive DSIs and B11. We are also requiring that health IT modules enable access to complete up-to-date source attribute information. This is the transparency information I mentioned for both evidence-based and predictive DSIs, as well as enable users to record change and access these source attributes. This is an important future proofing functionality. We know that a lot of the source attributes that we require are really meant to support deployed models.

And, obviously, developers who supply predictive DSI as part of their product will not have information on how that model is performing once it is deployed. At least now, the users will have the ability to modify the source that attributes and make updates to those source attributes out of the box. We also have requirements for risk management practices that need to be applied to predictive DSIs that are supplied as part of the health IT product. And then, to the boat and suspenders phrase that Mike used, we have new assurances maintenance certification requirements that essentially requires that on an ongoing basis, the information that is provided, the transparency information is kept up to date and remains complete and that this happens on an ongoing basis. Beyond the technical functional requirements of the health IT modules, these are the big picture policies that we think we can make a dent in.

And I really do think that as a focus area for ONC and as ONC is part of a larger group of federal civil servants really taking on the idea of how do we improve and optimize AI for the benefit for all Americans, these are some really big picture policies that we are looking to impact. Obviously, we talk about improving transparency but that transparency is really a prerequisite for trust. We know there is a lack of trust. And we are trying to get at, practically speaking, how do we get to trust? We do think that our requirements will help us get there. We talk about this information ecosystem. We will not spend time today on all of the source attributes and the particulars around those. But really, the idea here is that we are creating an information ecosystem that does not exist today. We are essentially setting requirements that the ingredients necessary for a nutrition label are available. We are not being prescriptive on how this nutrition label is presented or what is in it.

But we are saying there are 31 data points and descriptions that need to be available and need to come along with predictive models. And those data points can really be used to get to the question of is the predictive model being fair, is it appropriate, is it valid is it effective, and is it safe. Last but not least, we have some requirements around being able to tell when an evidence-based DSI or predictive DSI uses data that is salient to health equity. And this includes race, ethnicity, language, sexual orientation, gender identity because we think the knowledge of these use of these data will go a long way towards helping people understand whether the predictive DSI is appropriate for their patient. There are a lot of big things we are trying to achieve here. We could go on and on, but I will just say there is a lot of coordination going on behind the scenes if you do spend some time with the Final Rule.

We opine for probably a 1,000 or maybe 1,500 words around the ways in which FDA and ONC are coordinating. We are, obviously, coordinating with our friends at OCR who have an NPRM on the street looking for feedback. I think the comment period is closed. But they proposed to modify some of their regulations to make it illegal for users to use algorithms in a way that discriminates. What I would say there is a lot of coordination going on. There is also an executive order that was put out in late October. This would really force coordination. What we have been doing with the FDA has been just common sense. But nobody at the White House told us to do this. Nobody at OMB told us to do this. We thought it was a good way for FDA and ONC to collaborate on a lot of work that is of joint interest in the AI/ML space. And so, we

did it. And because of the executive order, there will be requirements around coordination. I think this is all heading in a good direction.

Moving on to the insights condition and maintenance of certification requirements, otherwise known as the EHR Reporting Program in the Cures Act Final Rule. We have got a couple of slides here and then, I will kick it back over to Mike to do some information blocking. I want to be cognizant of time here, so I will try to pace myself appropriately. As a function of the Cures Act of 2016, Congress did require an EHR reporting program through the process of looking at legislation and trying to translate that into something that is workable within the paradigm of the ONC certification program. We turned it into a condition of maintenance and certification requirements and called it the insights condition. This is meant to provide information on gaps that we do not have insights to in the marketplace. That is specifically around interoperability. How are our certified products operating the marketplace, and can we develop measures that help us get to answer questions around frequency of immunization reporting or type of patient access?

I think there is a lot over the course of the next few years of information that we are going to get that can really help us as policymakers and as interested parties understand the ways in which certified health IT are being used and ways in which it is not being used. We are hopeful that these measures will also provide information about consumer experience, as well as paint a broader picture around interoperability. There was a very long process. Many of you on the HITAC were involved in the task force that developed a process to develop these measures. Many months have been spent developing the measures that we will go through. And I will not belabor that much more than what is on the slide. But we have been through several rounds of public comment just leading up to the Proposed Rule. These are the measures that we finalized.

We did take a slightly more constrained number of measures than what we proposed. I think that was appropriate. Again, you will see here on the left the area that we are covering is interoperability. And inside of that area, we have distinct buckets that we are looking at in terms of individual access to electronic health information, care information exchange, public health information exchange and then, standards adoption and conformance. It is worth noting at this point that the Cures Act of 2016, actually, outlined other areas. We are more or less in Area 1 focusing on interoperability. There were several other areas that were included as part of the Cures Act, including usability and user centered design and security. And I think conformance to certification was another one. And there may have been one more. We decided to take a stepwise approach into implementing this program. And as you will see in terms of implementation timeline, we are also taking a stepwise approach to implementation.

You can see here some of the measures in the middle that are trying to get at providing insights. And I think that is really the main theme here is how do we understand what is going on. Many of these measures will not only give us insights on the things we are looking for, but more than likely give us a lot of insights on the things we did not know we were looking for. Over time, I think this is going to really paint a picture of interoperability that we have not been able to cobble together before and will, hopefully, help us make decisions moving forward in various ways. We did make some determinations and finalize some policies around which developers will have to report what. Part of the statute required that we develop measures that do not undo burden, small and startup developers. And the way we looked to implement that portion of the provision to develop a threshold approach to ensure that developers that have fewer than 50 hospitals or fewer than 500 clinicians do not have to report measures in the program.

Obviously, developers that do not have modules that are certified to the criteria that were in the right-hand column of the previous slide, they do not have to report measures. If you are a developer and you have over 500 clients, you are certified to a specific criterion, but nobody is actually using that thing then, you do not need to work on that measure. We did take some steps to try to ease reporting burden both in the development of the measures themselves, but also in how we are implementing the program and requiring developers to participate in the program. The measures will be reported in aggregate at the product level. This is something we hope to reduce reporting burden. We know that several developers out there have numerous products certified to the same thing or have different versions of products. We tried to take steps to reduce the burden of having to report what would be very similar numbers across different things.

There is a lot of devil in these details. And there is going to be a deep dive on the insights condition in a future webinar. I think we will have the date towards the end of this presentation. But it will be at that place we can get into some of the nitty gritty details here. In recognition of time, I will skip to the next slide. Again, in trying to figure out how to make the reporting of these data both relevant as well as to lessen reporting burden, we developed a cadence of reporting that would have developers collect data for a year, have six months to assemble data and then, they would report data. You can see here a mockup of Year 1 and Year 2 how we would expect this to transpire. Here, you have a breakdown of the measures by year. And, again, I am actually going to go to the next slide if I could. This gives you a better sense of the measures. And, again, there will be a deeper dive on all of this.

But just to give you a sense of how we are looking to implement this provision, we are not going to have all of the measures be reported Year 1. We will have a small subset reported in Year 1. And then, in Year 2, there is going to be that same subset plus a couple more. In Year 3, there is going to be the same set for 2026 and 2027 and then, a few more in 2028. Over time, we will get to all of the reported measures. But we will start with the measures that we think are most easily reportable and give us insights on some of the things that we think are most valuable, which is, again, not to pick favorites. But this is a way that we hope to ease implementation burdens alongside everything else. Mike, you have the stage again.

Michael Lipinski

Thank you, Jeff. I was looking at the clock, too, and I would like to say I really appreciate your patience. I am sure there are a lot of questions building. And to increase the level of excitement, as Medell said, is to get to that part. I will try to go through this quickly and give us somewhere between 10 and 15 minutes for questions. Information blocking. We did a rule, Cures Act. Hopefully, you are all familiar with that one. It was in 2020. And then, the big piece I want to mention is the concept of advisory opinions. It allows the agency to issue if you gave us a set of facts and circumstances, we can apply it to the law, the information blocking definition, the exceptions as well, and give a binding determination of whether or not we see that as information blocking, us, the department, OIG, our general counsel and so forth. We put forward a request for that authority. It was not in the Cures Act. We have asked for it in our budget request. Every agency does a budget request. It was in the first one and it is in the second one.

To get to the budget request really means the entire apparatus of the department, the federal government, and the Office of the President. It supports that authority. I have also seen comments on the disincentives, at least the America College of Surgeons is supportive of it, too. And I hope you are as well. I will explain a little why when we talk about the exceptions because, as I said, we can give more targeted guidance and opinions as to whether or not what you are doing or what you plan to do is or is not information blocking because, at this point, we give FAQs that tell you it would likely be or would likely not be an interference.

But that is only one element of information blocking. You have to take into account knowledge, exceptions, and apply it all to the facts. Another option for us is to update the regulations as best we can. They will still be somewhat generalized, but we can try to target a question or concern we get from stakeholders about how do you interpret this, where do these actions fall.

We have done that in this rulemaking, particularly with the health IT developer certified health IT definition, which includes the piece of offerings. We define offer of health IT. Proposed a final. We just tweaked it for clarity mostly. I will talk a bit about that. Here it is. We give a definition. This, again, goes to the advised opinions. We have identified activities that we do not think meet the definition of an offer and, therefore, you do not meet the definition of a developer of certified health IT. I can go on and on about donations. Donations of interoperable health IT, which includes health IT is really important. There is a safe harbor under the anti-kickback statute. We have worked with OIG and CMS over the years about that. There is a requirement for entities to meet that safe harbor to contribute 15% of the initial cost to it. But, generally, the point being is we want to see donations of health IT, particularly to entities that do not have the ability to support purchasing them themselves.

And we have concerns about if I donate it, am I now a developer, lower standard of knowledge. And now, I am subject to information blocking. That can apply to an actor that is not even a healthcare provider. It can apply to, for example, a payor who wanted to donate it. We want to support that. The only caveat to that is you cannot restrict its use. As long as you are not limiting interoperability of its use that donation is going to be acceptable under these regulations. And you would not be considered making an offer. The other ones we looked at were implementation and use activities. We got a lot questions about if I do this, if I do that, does that make me an offer? Offering a patient portal, offering an API, giving login credentials to other providers that may not be necessarily a part of the healthcare system, we try to adjust all of those, the same with consulting and legal services. I wanted to mention that.

The only tweak to the health IT developer definition beyond defining what an offer is, we made it clear about self-developers. As long as you are a healthcare provider that self develops their own but is not offering it then, you are not going to be considered a developer of certified health IT, too. On the information blocking one, which also affected the manner exception, is we removed the piece where, as you see here, we limited it to the USCDI because that time period had passed. That was a revision to that definition. Let us talk about exceptions. While not on any of the slides, I want to mention this concept, for lack of a better term, but we use in the rule preamble, stacking. That is really how do you use exceptions together. Maybe you use one exception like the privacy exception to restrict certain EHI, for example, reproductive health or Part 2 EHI. How do you use that in conjunction with maybe potentially the infeasibility exception, including segmentation?

We had a robust discussion about that. In the rule, I think it is 89FR are around 1350 up through 1354,1355, or 1356. I encourage you to look at that. We are not going to be talking about that today, but, hopefully, you find it helpful. Exceptions revision. Again, as I mentioned with the advisory opinions, we are, essentially, addressing issues for the most part outside of the new TEFCA exception where people are concerned about if I do this activity, what does this mean? Do I have to do all of this documentation that it meets the infeasibility under the circumstances? I do not even know if I meet it because I will not know until it comes in because it is a six-factor test of did I actually meet the exception. We are trying to provide a little bit more

certainty. But as I mentioned to you earlier, to provide full certainty for anybody, it would be best to have that advisory opinion of authority.

In control of events, just a simple change here to make it clear that it is not just if the actual public health emergency came up for us for the pandemic. If something happens by itself, it does not get you the benefit of the exception. You have to show that it negatively affects your ability to respond to requests for access exchange or use. Third party seeking modification use. Again, we got a lot of questions about if I have to let everybody write because write is in the definition of use. And in this case, modification use where we are talking about adding, deleting, or changing the record. Do I have to prove it is in feasibility? Do I have to prove that it meets the security exception? What we have done here is trying to say if certain entities are asking for this, which is not the healthcare provider asking their business associate to do it then, you can get the benefit of this more narrowly focused and scoped condition under the infeasibility exception. This is the one I said, since we scoped out the no longer applicable limitation for USCDI V1, that is the only change we made here.

We changed the name of it, so we can move on to the next slide. We do not need to talk about that. We will talk about the TEFCA. Actually, go back, I think I missed one. One more back. I do need to talk about this one quickly. This is the new one. The only thing we did comparative to the Proposed Rule is we defined what similarly situated was, essentially, by what it is not so what you could not use as a factor to determine if somebody is similarly situated. Large care versus small provider, patient versus a provider, those are not bases for saying that they are not similarly situated if you are providing this access, also if it is because it is a competitor. A lot of the things you saw previously that we had in the infeasibility exception for infeasibility under circumstances, we have applied it to defining what was similarly situated. But otherwise, it is still that same test that we proposed. You are not providing it currently, which means it does not matter if you provided it in the past, if it is not something you do now then, it does not meet this test.

And also, it has to be substantial number. We did not set a number. We think as we proposed, we finalized it and it will vary depending on the situation. We can move now all the way through this one. That is the one that I told you that we just changed the name. The new one, TEFCA manner exception. We decided it deserved not only its own exception now, we are at nine exceptions, but it also has its own subpart. If we are going to do any more related to TEFCA, it will fall under Subpart D if you are into that like knowing the specific subpart of the Code of Federal Regulations. That is where this one is going to fall now. We did not establish definitions of all the relevant terms in TEFCA. I think it is something we may look at as we forecast in the preamble of the Final Rule. It is something we might look at the HTI-2 rule as the common agreement is going through different versions. As you know, recently, a newer version came out.

What is different from the proposed in the final? The two big differences are based on comments we received. We applied back in the fees and licensing exception. And that was not only based on comments, but I think somewhat of a misunderstanding of how the agreement would work between certain parties and framework agreements would work between certain parties who participate in TEFCA. The other key one is the third bullet here, which is if there is a request via FHIR, API standards so, essentially, FHIR API, it would take you out of this exception. You would not be able to use this new exception in that case if that is how the request comes in. Would it make a difference if both parties were in TEFCA? You would not be able to use this as your basis for not saying, “No. I am only going to provide it to you via TEFCA.” Key

dates, move that over. This is really about the program and it is about compliance dates. We did not call it compliance dates. We will not get into why. But that is generally what it is.

It is when developers in the program have to meet certain dates and report certain information on the insights. We talked about the insight condition. But as I mentioned to you earlier, when it comes to the information blocking, as soon as this rule becomes effective, which is February 8, those exceptions become available and new conditions to any act are covered under the information blocking regulations. Other things that will have to happen from key dates is when products can start getting certified to the new functionalities and standards that are available under the program due to this new rule. Jeff mentioned some of this and we try to mention it all of the time. We have a lot of fact sheets available on the measure specs. I think there are six fact sheets, including the key dates one. We are always open to making more available educational sources. Feel free to tell us what you think we might need or would be helpful.

I saw somebody said that one of the slides that Jeff had was a great slide in terms of being helpful. We are always open to trying to develop those to help the regulated community and the public understand our regulations. We have some more webinars ahead. We have one just on information blocking coming up next week. We will have an open Q&A on the rule in February and then, one on insights, as Jeff noted. To you, Medell.

Medell Briggs-Malonson
Thank you so much, Mike and Jeff, for this incredibly informative discussion and overview of HTI-1. Again, it was very exciting. We have very limited time to address some questions. So, I am going to ask all the HITAC members if you have a question or comment, please also put it in the chat to everyone so we can capture your thoughts and your visions. However, I will open it up right now for any questions. If anyone has questions for Mike or Jeff, please raise your emoji hand. No questions. It was very thorough.

Michael Lipinski
There we go. If you do not have any today, you can reach out to either of us. My email address is just Michael.Lipinski@hhs.gov or through Wendy.

Medell Briggs-Malonson
Thank you for that, Mike. Mike, we see your hand up.

Michael Chiang
Jeff and Mike, thank you for the talk. I had a question about EHR data for AI algorithms. I know you talked a bit about that towards the beginning. This goes back to something discussed before the break, the role of ONC in trying to increase data quality in the EHR. I just feel like, ultimately, that is one of the potential challenges in developing good AI algorithms, so called "garbage in, garbage out." And that relates to usability and provider burden. My question is have you considered if it is feasible to create incentives for providers or certification criteria for EHRs for providing quality data? I realize that may require some research to define what high-quality data is. I would love your thoughts about that.

Jeffery Smith
I will start with the certification side of things and then, Mike, if you have some ideas on that. There are really two different ways that, at least in the three years that I have been at ONC and the several years following ONC prior to that, I can kind of discuss data quality. One of them is the notion that we can improve

data quality by improving adherence to standards. That means adherence to content standards like CDA and FHIR as well as vocabulary standards like SNOMED, LOINC, and RXNorm. I do think that is probably the primary mechanism, at least for the certification program that we can think about data quality because as you know, data can become not quality in various ways, numerous ways, too many ways. And it could touch everybody from data entry to processing. And so, there is a lot there. I do think though that one of the ways that we think about how to improve data quality is how to improve adherence to technical standards. So, that is one thing.

The other thing is I think variously, we have tried to encourage the industry to some success to use validators. We have got a CCDI scorecard. We stood that up number of years ago. And I do not know what the recent metrics are but they have never really been that high. But it actually allows clinicians to send a live CCD to our system and then, receive a grade on that system. We do know that several developers actually use the CCDI scorecard for their own internal calibrations and deployments. We are thinking about something similar on the FHIR side. That is the two ways that we think about it but, obviously, open to other ideas because data quality as a general issue is important and top priority in terms of how do we move forward to get computers to talk to one another, as well as how do we derive value out of the data gets collected.

Medell Briggs-Malonson
Thank you so much, Mike and Jeff. Mark?

Mark Sendak
Building off of Jeff's response, I would completely agree that a lot of the data quality is the vocabulary standards. Something I was excited to see in the preparatory material for today was some action to enhance adoption of RXNorm by pharmacies reporting data. I was going to ask is there similar action happening with laboratories to push towards uniform adoption of LOINC in the reporting of live results.

Jeffery Smith
Again, I will offer a piece of an answer and maybe Mike has some additional thoughts there. I will say publicly, there was a policy adopted by the Secretary I think last summer. And this was a directive from the Secretary to all of HHS to seek alignment on health IT and to seek alignment on, not just on purchases but also grantmaking and also other policy mechanisms that could encourage adoption. And one of the big takeaways from that policy will be that various other pieces of HHS have already started to and will continue to kind of work with ONC on their data issues and on their interoperability issues. From the program's point of view, I will not speak to anything specific to labs. But certainly, we are starting to lay the HHS policy groundwork to ensure that when labs or other kind of data systems under the HHS purview are being deployed or when money is going out of the door to deploy those systems that ONC is involved, that our standards are referenced, and that our certification criteria when appropriate can provide important guidance.

Michael Lipinski
I will add onto that. I would say labs and lab interoperability is a top priority in terms of the interest from Congress, for example. I will probably get the wrong fiscal year because this is all blending together right now, but we owe a laboratory interoperability report to them. We are working on that. We have always had an interest in lab interoperability. We had it as part of what was the EHR Incentives Program. The American Clinical Laboratory Association, I think, has a strong interest, too, in using standardized approaches to lab

interoperability, including LOINC. I will just say from that perspective, it is top of mind, at least when it comes to lab interoperability for us.

Medell Briggs-Malonson
Excellent. Thank you for that discussion. Jim?

Jim Jirjis
Yes. Can I comment on that now that I am with CDC? Just to bolster what was just said, I think I am actually on one of these committees. There are cross agency groups looking at this and a variety of things in lab. One of those is the very question you have around what levers are there that could reasonably be used like CMS is a nice lever for ONC certification? What might exist there to help compel labs to produce interoperable lab data according to LOINC standards? There is a lot of steam and energy going on there. It is not really clear that there is clear levers. But there is no shortage of calories being expended to try to determine what levers could exist.

Medell Briggs-Malonson
Thank you for that insight, Jim. Hung, I see your hand is up.

Hung Luu
I want to reiterate that we need to move past the point of view that if everybody would use LOINC that all of the issues with interoperability would be solved. LOINC definitely plays an essential, key role. But the granularity of information it conveys is not sufficient to support interoperability in future uses. It is one piece of the puzzle, but I really am concerned when we start talking about the fact that if everyone would just use LOINC, everything would be solved. It is not. We need to develop a data model that supports interoperability, which LOINC clearly has a place at. But it alone will not solve all of our issues.

Medell Briggs-Malonson
Thank you, Hung. And I think everyone that is in the chat agrees that this is just one component of what we really need to achieve optimal interoperability as we are all trying to achieve that. This was an amazing discussion. Again, thank you so much to Mike and Jeff for providing us with the HTI-1 overview. And this is all of the various different information here, also to provide any different feedback, especially for the public. I will turn it over to Sarah in order to transition us to the next portion of the meeting.

Sarah DeSilvey
Thank you so much. What an amazing presentation. A wealth of information from our ONC friends. It is my honor to bring Wendy back to the forward to help us walk through our public comment as we enter through our period of public comment. Wendy?

Public Comment (02:51:37)

Wendy Noboa
Thank you, Sarah. We would like to open the meeting for public comment. If you are on Zoom and would like to make a comment, please use the hand race function which is at the bottom of the Zoom toolbar. And if you are on a phone, please press star nine to raise your hand. Once called upon, press star six to mute or unmute your line. Let us pause to see if any members of the public raise their hands. Just a reminder,

the next HITAC meeting will be February 8 so fast approaching. Any HITAC materials can be found on HealthIT.gov. It seems there are no public comments.

Medell Briggs-Malonson
Yes, Wendy. I think there is a public comment, Adele Stewart.

Adele Stewart
Yes. Thank you so much. And I am so sorry. I joined late. But I was interested in one of the comments that I saw about human services data on the HITAC work plan and wanted to ask if it was possible to have a dialogue in accordance with the HHS 2023 to 2028 data strategy if HITAC had thought about how the inclusion of human services data in the data strategy might impact HITAC membership in the future and also, if the group had thoughts or was beginning to create a work plan to address whether that human services data would intersect with data standards like USCDI or USCDI+ and the development of those standards. Thank you all so much for your work.

Wendy Noboa
Thank you, Adele. And there are no additional public comments. I will yield the time back to committee. Medell and Sarah, go ahead.

Final Remarks and Adjourn (02:53:38)

Medell Briggs-Malonson
Thank you so much, Wendy. And thank you, again, everyone for allowing us to have an amazing first HITAC meeting of the year. It is very clear and evident that this is going to be a very energized and very insightful year for us ahead and also to make great contributions to the work that ONC is doing, as well as to the rest of the country. Sarah, any last closing words?

Sarah DeSilvey
No. Very briefly just echoing everything you mentioned. Thank you all for your attendance. We really look forward to your wisdom and insight over the course of the 2024 work year. I will see some of you on Tuesday as we kick off IS WG. And we look forward to seeing you on February 8.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Hans Buitendijk: double muted, but I'm on.

Steven Lane: There was little mention of TEFCA in the CMS rule release communications yesterday. It is good to hear that the plan within HHS is to encourage TEFCA engagement as part of CMS's progress.

Amanda Woodhead: Registration for the upcoming educational series on the HTI-1 Final Rule can be found here: https://www.healthit.gov/newsroom/events.

Deven McGraw: Other activities of note: Co-chairing the Sequoia Project's workgroup on consent (with Steven Lane); serve on the Trust Framework and Policy Committees of the CARIN Alliance (which promotes patient access to data); am on the Board of Manifest Medex (HIE in California); Also advisory Board for MedAllies, a QHIN; And on the Data Sharing Workgroup to an advisory committee for the CDC Director; also working on a NAM Steering Committee harmonizing a code of conduct for AI in health care.

Steven Lane: Tremendous collection of expertise and perspectives serving this year on HITAC.

Anna McCollister: I don't remember if I mentioned, but I am now a member of the board of directors for the Sequoia Project. In addition I am leading the formation of and co-chairing a new Sequoia Project workgroup that will develop strategies for engaging with consumers and patients on issues related to health data access, use and data standards.

Rochelle Prosser: WIsh to also disclose I am a Co Chair for the Commission for Nursing Reimbursement and the SCHEQ Board Member for 2024 to serve for three years in an advisory role. I focus on Oncology and pediatric Data sharing and digital health access to improve overall survivorship and Cancer in treatment outcomes.

Bryant Thomas Karras: forgot to mention that in addition to Serving on the HITAC FACA, I also advise CDC Advisory Committee to the Director (ACD) Data & Surveillance Work Group

Aaron Neinstein: Absolutely love the addition of these "illustrative stories" to ensure people are aligned on and understand the future state. Very important and useful addition to our Reports. Would love to see us continue this.

Kikelomo Oshunkentan: + 1 Aaron

Pooja Babbrah: Great to see a focus on price transparency

Anna McCollister: THANK YOU Medell for a great walk through!!

Susan Clark: I appreciated the emphasis on security for health apps.

Sarah DeSilvey: Amazing work, Annual Report WG

Pooja Babbrah: +1 Susan

Kikelomo Oshunkentan: Extremely thorough. Great job to the Annual Report WG!

Sarah DeSilvey: Regarding the AR topic of digital divide and standard data elements, gravity project has now addressed each of the domains in the recommended standards- health literacy, digital literacy, and digital access. Aligned value sets for each can be found within VSAC, with Gravity as steward, and on the accelerator confluence https://confluence.hl7.org/display/GRAV/Social+Risk+Terminology+Value+Sets to assist with that HITAC activity. Further terminology to support the documentation of digital access and literacy is in current build with SDOs and will be available in the value sets over the course of our 2024 update cycles.

Bryant Thomas Karras: Agree with Steve ! PH needs State Local Tribal and Territorial voice not just CDC. thank you

Seth Pazinski: Draft USCDI v5 link:

Seth Pazinski: https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi

Sarah DeSilvey: Steve and I welcome all HITAC members to the significant, very pragmatic and fun! work of ISWG.

Rita Torkzadeh: Woohoo for Author being in USCDI v5's Provenance Data Class!

Deven McGraw: I recall that ONC has done some work on the issue of provider burden - anything we would do should build on that.

Medell K. Briggs-Malonson: ONC has done a fair amount regarding provider burden. We welcome all ideas from HITAC members.

Donna Doneski: ONC should tag-team with CMS' OBRHI to address provider burden.

Rochelle Prosser: Can we add a focus from a Nursing perspective and burden in interoperability as well?

Rochelle Prosser: Most often Nursing faces the brunt of coalescing all technology proposed in all spaces of Health information and care.

Medell K. Briggs-Malonson: @Mark, this is a very important topic and focus for HITAC and ONC. We will speak more about the next steps for expanding on this topic.

Mark Sendak: Wonderful, I would be happy to help think through next steps

Medell K. Briggs-Malonson: @Rochelle, very important point!

Sarah DeSilvey: we will reconvene in ~ 7min.

Fil Southerland: Curious how the priorities identified in the previous slide make it into the broader HITAC discussion. For example, Human Services. Is this topic under consideration for inclusion in a future task force, a planned inclusion for a future HITAC monthly discussion, or is the priorities slide simply indicating internal ONC discussion that may or may not come to broader HITAC?

Carmela Couderc: https://www.reginfo.gov/public/

Fil Southerland: Seth - this is helpful. Thank you!

Steven Eichner: Where will what federal standards currently apply be clearly communicated, in simple terms (and accounting for SVAP)? This information should also include expiry/replacement schedules.

Rochelle Prosser: Nursing as end users and creators also have an input as Clinical Informaticist, data analysts, and Electronic documentation creators and content contributors and have direct line to patient interoperability can we add this focus to the future work or supplemental interoperability as the adopted HTI 1 anand others move forward?

Sarah DeSilvey: Rochelle, I want to thank you for directly speaking to the nurse voice. I am a nurse myself, as are many of the other HITAC members we welcome your highlighting of our unique perspective!

Mark Sendak: This is the amazing slide I am excited to use!

Medell K. Briggs-Malonson: This is a fantastic comparison slide of the HHS authorities over this area!

Mark Sendak: Yes, exactly @Medell

Rochelle Prosser: Absolutely agree

Sarah DeSilvey: Thank you, Mike and Jeff!

Steven Lane: Great presentation Mike!

Steven Lane: The Sequoia Project is advancing testing tools to be able to evaluate FHIR payloads for data quality and adherence to technical standards.

Keith E. Campbell: The quality of content needs to go beyond a transport standard like FHIR or an encoding standard like SNOMED, LOINC, RxNorm…

Eliel Oliveira: Great question on incentives. We see that anything that is related to payment is entered in EHRs using standards (procedures, diagnosis, encounters - ICD, CPT, etc.)

Keith E. Campbell: https://pubmed.ncbi.nlm.nih.gov/35015861/

Keith E. Campbell: Just using LOINC is not sufficient for quality data:

Keith E. Campbell: https://pubmed.ncbi.nlm.nih.gov/35639494/

Mark Sendak: Necessary but not sufficient. It's part of the problem

Mark Sendak: https://proceedings.mlr.press/v182/sendak22a.html

Jim Jirjis: There are cross agency groups looking at the Lab Loinc item to determine what levers there are to motivate this

Jim Jirjis: FDA SHIELD for example

Eliel Oliveira: My experience is that generally lab companies use LOINC, hospitals and in their internal labs do not.

Jim Jirjis: I agree . I don't think anyone is saying that loinc is the end all

Mark Sendak: agree

Mark Sendak: Just one piece

Sarah DeSilvey: My constant sleeping companion.

Adele Stewart: I can imagine, Sarah!

Mark Sendak: Thank you

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

RESOURCES

HITAC Webpage
HITAC - January 18, 2024, Meeting Webpage

Transcript approved by Medell Briggs-Malonson and Sarah DeSilvey, HITAC Co-Chairs, and Wendy Noboa, HITAC DFO, on 2/7/2024.