Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

November 9, 2023 9:30 AM – 4:00 PM ET

VIRTUAL & IN-PERSON

Speakers

Name	Organization	Role
Medell Briggs-Malonson	**UCLA Health**	**Co-Chair**
Aaron Miri	**Baptist Health**	**Co-Chair**
Shila Blend	North Dakota Health Information Network	Member
Hans Buitendijk	Oracle Health	Member
Sarah DeSilvey	Gravity Project	Member
Steven Eichner	Texas Department of State Health Services	Member
Cynthia A. Fisher	Patient Rights Advocate	Member
Lisa Frey	St. Elizabeth Healthcare	Member
Hannah Galvin	Cambridge Health Alliance	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Valerie Grey	State University of New York	Member
Steven Hester	Norton Healthcare	Member
Bryant Thomas Karras	Washington State Department of Health	Member
Kensaku Kawamoto	University of Utah Health	Member
Steven Lane	Health Gorilla	Member
Hung S. Luu	Children's Health	Member
Arien Malec	Individual	Member
Anna McCollister	Individual	Member
Clem McDonald	National Library of Medicine	Member
Deven McGraw	Invitae Corporation	Member
Aaron Neinstein	Notable	Member
Eliel Oliveira	Harvard Medical School & Harvard Pilgrim Health Care Institute	Member
Kikelomo Oshunkentan	Pegasystems	Member
Naresh Sundar Rajan	CyncHealth	Member
Alexis Snyder	Individual	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
Jim Jirjis	Centers for Disease Control and Prevention	Federal Representative
Meg Marshall	Department of Veterans Health Affairs	Federal Representative

Name	Organization	Role
Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Micky Tripathi	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Sweeney Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Seth Pazinski	Office of the National Coordinator for Health Information Technology	Director, Strategic Planning and Coordination Division
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Shelly Spiro	Pharmacy Health Information Technology Collaborative	Presenter
Wesley Barker	Office of the National Coordinator for Health Information Technology	Presenter
Chelsea Richwine	Office of the National Coordinator for Health Information Technology	Presenter
JaWanna Henry	Office of the National Coordinator for Health Information Technology	Presenter
Mike Lipinski	Office of the National Coordinator for Health Information Technology	Presenter
Jim Hansen	HHS Office of Inspector General	Presenter
Alex Baker	Office of the National Coordinator for Health Information Technology	Presenter
Tim Jackson	Centers for Medicare and Medicaid Services	Presenter
Aryanna Abouzari	Centers for Medicare and Medicaid Services	Presenter
Elizabeth Holland	Centers for Medicare and Medicaid Services	Presenter
Jessica Warren	Centers for Medicare and Medicaid Services	Presenter

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

Michael Berry
Good morning, everyone, and welcome to the November 2023 HITAC meeting. I am Mike Berry with ONC, and as you can see, we are in person at HHS headquarters in Washington, DC, and I would like to thank everybody in the room and virtually for joining us today. This meeting is open to the public, and your feedback is welcome, which can be typed in the Zoom chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled at 3:50 Eastern Time. I would like to get started with our meeting and welcome ONC's executive leadership team to the meeting. Here with us today is our National Coordinator Micky Tripathi, Steve Posnack, our Deputy National Coordinator, Elise Sweeney Anthony, the Executive Director of the Office of Policy, and Avinash Shanbhag, the Executive Director of the Office of Technology. I would like to begin rollcall **[inaudible] [00:00:51]** so when I call your name, please indicate that you are here. I will start with our co-chairs. Aaron Miri?

Aaron Miri
Good morning.

Michael Berry
Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning.

Michael Berry
Shila Blend?

Shila Blend
Good morning.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Sarah DeSilvey? Steve Eichner? Cynthia Fisher? Lisa Frey?

Steven Eichner
Mike, this is Steve Eichner. Sorry, I did not hear my name. I am present.

Michael Berry
Some people are virtual, so we might not hear them. Hannah Galvin?

Hannah Galvin

Good morning.

Michael Berry
Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Michael Berry
Valerie Grey? Steve Hester?

Steven Hester
Good morning.

Michael Berry
Bryant Thomas Karras?

Bryant Thomas Karras
Present.

Michael Berry
Ken Kawamoto?

Kensaku Kawamoto
Good morning.

Michael Berry
Steven Lane?

Steven Lane
Good morning.

Michael Berry
Hung Luu? Anna McCollister?

Anna McCollister
Good morning.

Michael Berry
Clem McDonald?

Clem McDonald
Good morning.

Michael Berry

Deven McGraw?

Deven McGraw
Good morning.

Michael Berry
Aaron Neinstein? Eliel Oliveira?

Eliel Oliveira
Good morning.

Michael Berry
Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning.

Michael Berry
Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Michael Berry
Alexis Snyder? Fil Southerland?

Fillipe Southerland
Hi.

Michael Berry
Sheryl Turney? And now, the Federal Representatives of the HITAC. Jim Jirjis?

Jim Jirjis
Present.

Michael Berry
Meg Marshall?

Meg Marshall
Good morning.

Michael Berry
Michelle Schreiber? John Garguilo? All right, and as I said, many of these people are virtual, so we will probably see them in the Zoom chat. Thank you, everyone, and now, please join me in welcoming Micky Tripathi for his opening remarks.

Welcome Remarks (00:02:45)

Micky Tripathi
Good morning. It's good to see everyone in person **[inaudible]**. So, usually, I say I will be brief, but the team gave me seven pages **[inaudible]** memorized something inside **[inaudible]** got a lot of stuff waiting and some important turning points and transitions for the HITAC, and I look forward to the meeting. Lastly, I want to go through a few of the things that have been going on. I will talk about the **[inaudible]** transitions **[inaudible]**. So, last week, we embraced a new proposed rule to establish disincentives for healthcare providers that have committed information blocking. As we know, that has been a long time coming.

CMS has been very hard work over the last couple years **[inaudible]** seen strong support in **[inaudible]** to get that out, so we are really happy **[inaudible]** to get that out. The 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking. That is a department rule, and the rest of the schedule **[inaudible]** believe, but as you see, if you go through it, it has multiple agencies involved because of this need to **[inaudible]** to contribute in the future to appropriate disincentives. On November 15th, ONC and CMS will host an information session on the proposed rule that you can check on the Information Blocking website, where you can access fact sheets and information about the proposed rule, and sign up for the information session.

Steve Posnack
There is an audio issue.

Wendy Noboa
Could you not use the microphone and project loudly? For some reason, it is not picking up the microphone. **[Inaudible – crosstalk] [00:05:00]**

Micky Tripathi
Can you hear us? Can you hear me?

Unknown Speaker
That is not better.

Micky Tripathi
Not better?

Unknown Speaker
Maybe stand right underneath the mic.

Micky Tripathi
What if I stand out here? **[Inaudible – crosstalk]**

Unknown Speaker
There is a mic right there.

Micky Tripathi

All right, how is this? **[Inaudible – crosstalk]** Do I need to make eye contact with all of you? Is that good?

Unknown Speaker
We are double-checking right now. Okay, it is better.

Micky Tripathi
All right, good. **[Inaudible – crosstalk]**

Micky Tripathi
With respect to the disincentive rules, I think as you may have heard from the secretary, part of it is that it establishes a framework. It gets us **[inaudible] [00:06:00]** information the regulatory framework for us to approach this idea **[inaudible]** 21st Century Cures Act and identifies an initial set of disincentives and, as the secretary says, sets us up for the potential for future disincentives as well as we start going through the maturation of Information Blocking.

Medell Briggs-Malonson
Sorry to interrupt. It seems like this location is going to be better. We want to capture all of your words.

Micky Tripathi
Okay, how is this?

Aaron Miri
Great.

Medell Briggs-Malonson
Everyone says it is great.

Micky Tripathi
Okay. Also, today, we are very much looking forward to receiving the recommendations from the Pharmacy Interoperability and Emerging Therapeutics Task Force. They have done a tremendous amount of work, and there is a lot of excitement around that, as we have seen over the last couple of sessions when we have talked about that. So, I want to thank Hans and Shelly, along with the Task Force members, for your commitment over the past four-plus months to develop recommendations, so we really appreciate your contributions to that. It is certainly going to inform us how we should approach pharmacy interoperability, because it is an important part of the ecosystem, and we are really excited to **[inaudible] [00:07:29]**.

Page 2. Before I give updates from ONC, I want to take a moment to reflect on the amazing work that all of you have done throughout 2023, and actually, I have to look at the bullet points because you have done so many. This is our last HITAC meeting for this calendar year, and I want to thank all of you and all the presenters for the tremendous amount of time and energy. We could not do what we do without that. We have had nine full committee meetings, which included our first in-person meeting since 2020, and now, I guess this is the second one since then. We launched four subcommittees: The HITAC Annual Report Workgroup, the Interoperability Standards Workgroup, which informed USCDI Version 4, which is really important to all of this work, as you know, the Health Data Technology and Interoperability Certification Program Updates, Algorithmic Transparency, and Information Sharing Proposed Rule Task Force, or the

HTI-1 Task Force, as you can see we like to call it, and finally, the Pharmacy Interoperability and Emerging Therapeutics Task Force. I want to thank all of you again and all the subject matter experts.

The HITAC submitted 102 recommendations so far to ONC this year. Thank you very much. We look through all of them **[inaudible] [00:08:48]** good example, as all of you know. The HITAC Annual Report to Congress was also completed, and work certainly continues toward completing the FY23 report by early January. That is also a significant amount of work, and it is just a really great document of all the hard work you all have been doing. So, thank you again for a really successful and productive year.

So, here are some updates: A reminder to register, please, for the ONC annual meeting on December 14th and 15th. We posted a list of sessions and descriptions of everything being planned for this year's annual meeting. You are going to hear about all the key issues that you are used to hearing at our annual meetings, such as the intersection of healthcare and public health and policymaking, and if you go to the events page on HealthIT.gov, you will see how to register. We are really excited to be able to feature at that meeting, the first day, we will be recognizing the first set of QHINs that we designated as going live. They are achieving the destination status and will have signed the Common Agreement, and they will have the infrastructure in place to actually be live. So, for all intents and purposes, they will be live, so we are really excited about that.

As you recall, in February, we had an event where we recognized six at first, and later seven, QHINs who had been approved to move to implementation, and now we have a substantial number who are actually ready to move to implementation, so we are really very, very excited about that. There will be signed Common Agreement Version 1.1, which starts us on the path with IHE-based exchange, and then, we are working hard on Common Agreement Version 2, with the anticipation that they will adopt that before the end of the first quarter of 2024, which enables FHIR-based exchange, with the expectation that FHIR-based exchange will take place in 2024. So, there is a lot of stuff to do between now and then, but we are really excited about that progress, and we really want to thank the entire community and the QHINs for all the tremendous hard work and commitment.

As I slipped in there, we did Common Agreement Version 1.1. That was an update from Version 1.0, which was the original one that was out there that the candidate QHINs had originally looked at. It is available on our website. We published a blog with mostly some technical details from an administrative perspective, and as I said, that is the one with technical and clarifying changes fully placed FHIR-based exchanges. So, on the first day of the annual meeting, as I said, we are planning an agenda to be able to celebrate that moment and mark the milestone, and you will be seeing more details about that.

[Inaudible] [00:11:50] I want to bring your attention that this week, someone published USCDI Version 4 October 2023 Errata. This errata updates three laboratory data class data elements with changes to the applicable vocabulary standards for specimen condition and acceptability of results interpretation and scope clarification for a Result Unit of Measure. We also addressed concerns about misalignment within USCDI Version 4 applicable vocabulary standards and requirements in C-CDA and FHIR implementation guides, and you can read that on HealthIT.gov. It is USCDI Version 4 Errata.

Finally, I want to thank those of you who were able to participate in the joint event we had with CMS, which was a really great event, on the Enabling Patient Access to Health Data for Actionable Results. I know a

number of you participated directly, and hopefully we can be there to see it. We did have patients, providers, health IT developers, and payers discussing how HHS policies can really impact in practice and how to maximize the impact of these policies. We highlighted a number of educational tools and resources, so we are really excited about that. The event video is live on the website, so please view the event's video recording on HealthIT.gov.

So, this is the part where we move to transitions in our family here. It is a really important milestone for those who are going to be rolling off and for those who have terms expiring at the end of the year, so I want to be able to talk about that and recognize that this is the last committee meeting for 11 HITAC members whose terms expire at the end of this year, and I want to take this opportunity to express my and our appreciation to each of you for all the hard work you have done and for your outstanding contributions, and we recognize that it is not a trivial task to decide to join HITAC, so we very much appreciate it. I do have some Certificates of Appreciation for those here in person. I think Cynthia actually is not here. Let me just go through because I want to make sure we individually recognize each of our members.

The first person I want to thank is Cynthia Fisher. I do not know if she is on Zoom, but Cynthia has served as a HITAC member since January 2018. She was a member of the Trusted Exchange Framework and Common Agreement Task Forces, the Interoperability Standards Priorities Task Forces, and the Information Blocking Task Force. Cynthia, here is your certificate. Next, I want to thank Lisa Frey, who I think is on Zoom. For the past three years, Lisa has served as a committee member and provided her perspectives as a health IT expert, and that is your certificate there, in the ether. Thank you so much, Lisa. I also want to thank Valerie Grey, who I think is on the Zoom as well. In addition to serving as a committee member for the past six years, Valerie was a member of the USCDI Task Forces and Interoperability Standards Priorities Task Forces for a number of years, as well as the Information Blocking Task Force. So, thank you, Valerie, and your certificate is there as well.

Next is Ken Kawamoto, who is here. For the past six years, Ken has served as a committee member and was a member of many subcommittees, including the USCDI Task Forces, the Interoperability Standards Priorities Task Forces, the Conditions and Maintenance of Certification Requirements Task Force, and the Interoperability Standards Workgroup. I have no idea what Ken is going to do with all his free time. Thank you so much. **[Inaudible – crosstalk] [00:15:36]**. Oh, did I miss? Okay, thank you. Next, I want to thank Steven Hester, who is also here. There he is. For the past three years, Steven has served as a committee member and has provided very valuable expertise in health IT. We are going to miss you.

Next is Steven Lane. It is hard to imagine the HITAC without Steven Lane. Steven has served as a HITAC member for the past six years, and has had multiple roles, and always volunteers for almost everything, including being co-chair of the Interoperability Standards Priorities Task Force, the USCDI Task Force, the HTI-1 Proposed Rule Task Force, and the Interoperability Standards Workgroup, along with being a member of the Information Blocking Task Force, the Public Health Data Systems Task Forces, the EHI Reporting Program Task Force, and the Pharmacy Interoperability and Emerging Therapeutics Task Force, as well as peppering all of us with emails, comments, and thoughts along the way, which we always appreciate. So, thank you very much, Steven, for all of your contributions. Next, I want to thank Arien Malec. Is Arien on the Zoom?

Aaron Miri

I do not see him.

Micky Tripathi
Arien is a stalwart member of his community, as you know, and certainly of the HITAC. He has been serving as a HITAC member for the past six years as well. He served as a co-chair for the Trusted Exchange Framework and Common Agreement Task Forces, the Interoperability Standards Priorities Task Force, the Public Health Data Systems Task Force, and the Interoperability Standards Workgroup. There is a lot of overlap with Steven Lane. In addition, he participated as a member of multiple Task Forces, including the Information Blocking Task Force and the Intersection of Clinical and Administrative Data Task Force, so, thank you so much, Arien, wherever you are. We very much appreciate all of your contributions.

Next, I would like to thank Clem McDonald. Clem has served as a HITAC member since January 2018. I have known Clem since 2001 during my time in Indianapolis, and Clem was the one who got me interested in and excited about health IT, for better or worse. He has been a member of the USCDI Task Force, the Interoperability Standards Priorities Task Forces, the Public Health Data Systems Task Force, the Adopted Standards Task Force, the HTI-1 Proposed Rule Task Force, and the Interoperability Standards Workgroup. Thank you, Clem, for all of your help.

Next is Aaron Miri, who I think is here. Aaron has been an instrumental member of the HITAC, having contributed six years of service, with the past three as co-chair of the HITAC. In addition, he served as co-chair of the Annual Report Workgroup and of several subcommittees, including the Trusted Exchange Framework and Common Agreement Task Forces, the Health IT Care Continuum Task Force, the Information Blocking Task Force, the Intersection of Clinical and Administrative Data Task Force, the USCDI Task Force, the Public Health Data Systems Task Force, the HTI-1 Proposed Rule Task Force, and the Interoperability Standards Workgroup. His leadership has been evident to all of us. He has been highly valued by all of us here throughout his tenure, and especially while serving as chair. Aaron, thank you.

Next, I want to thank Alexis Snyder. For the past five years, Alexis has served as a committee member and a member of the ICAD Task Force, the Adopted Standards Task Force, and the Pharmacy Interoperability and Emerging Therapeutics Task Force. Here is the certificate for Alexis. Finally, I understand Sheryl Turney is not going to be able to join us, but I want to thank her as well for her service as a HITAC member for the past six years. In addition to being a committee member, she served as co-chair of the ICAD and the E-Prior Auth Request for Information Task Force. She was also a member of multiple subcommittees, including the TEFCA Task Forces, the Interoperability Standards Priorities Task Force, USCDI Task Forces, the Information Blocking Task Force, Public Health Data Systems Task Force, the EHR Reporting Program Task Force, HTI-1 Proposed Rule Task Force, and the Pharmacy Interoperability Task Force. So, please join me in thanking each of these HITAC members for their very significant contributions.

We are looking forward to expecting the Comptroller General, who heads the GAO, to announce at least two new HITAC appointments by the end of this year. Secretary Becerra will also be appointing a new member very soon, and we expect a handful of congressional appointments as well. These new members are anticipated to start their three-year term on the HITAC in January, so we look forward to them joining us. Regarding the upcoming co-chair vacancy, I am really excited to announce that Sarah DeSilvey will be the next HITAC co-chair as of January 1st, 2024. We are really looking forward to Sarah's leadership and addition to the HITAC, and I want to extend my congratulations to her. Thank you.

Lastly, as this is our last full committee meeting before the new year, I want to thank everyone. It is my wishes and our wishes for a happy holiday season. Thank you again for everything you have done and for everything you do together, and now I will turn it over to Aaron and Medell. Let me apologize in advance, too. I am going to have to leave right after lunch break to get on a flight, but I very much appreciate you. Thank you.

Opening Remarks, Review of the Agenda and October 19, 2023, Meeting Notes – HITAC Vote (00:21:43)

Aaron Miri
Thank you, Micky. We appreciate that. Thank you, Elise, and thank you, team. Good morning, HITAC, and good morning to all of you in virtual-land too. Good morning. Happy November. Obviously, there are a whole host of emotions for me personally. We will get to that much later on in the show, but we have a packed agenda today, Medell, and it is a very exciting agenda. It is great to see you all in person again, just like it was in June. It feels like we have turned the page and put the past behind us in terms of being virtual-only as a HITAC. It is wonderful to see you all and to see the work you have done, as Micky alluded to, and I just want to thank you, Micky, on behalf of the entire community. You and your team have done an exceptional amount of work, and it is truly appreciated by the provider community and the entire healthcare ecosystem writ large what you guys are doing to move the needle on Information Blocking and all the other components of the 21st Century CURES Act. Great job to you. With that, Medell, over to you.

Medell Briggs-Malonson
Yes. Thank you and good morning, and I echo everything that my co-chair said. This is a very important meeting for all of us, not only because it is the very end of a highly productive year and also a year in which all of our voices were truly provided directly to ONC and to so many other agencies, but again, as Aaron mentioned, ONC has done some phenomenal work this year, and we want to thank you for allowing us to be part of it. As we proceed on to this meeting, especially with 11 of our HITAC members actually transitioning, this is also a time for us to celebrate them today and really say thank you for all their amazing contributions throughout these years. I will not speak too much because it is a little bit of an emotional day, but we have a wonderful agenda ahead of us with some amazing information. Without delaying any further, we are going to jump right on into the agenda, as we will institute a formal meeting.

Aaron Miri
All right, let's get started, then. I have just called to order with the opening remarks. First up is the Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 recommendations. It is a really good expansion of the discussion we had last HITAC, and we will go into recommendations there. We will break around 11:10. At 11:20, we will do the ONC Office of Technology update, with Avinash giving us the update there. At 11:50, we will talk about the HITAC 2024 work plan, which will be a great discussion. We will break for lunch around 12:15 and reconvene around 1:15 p.m., going into the ONC objectives, benchmarks, and data update. Seth, Wesley, Chelsea and JaWanna will walk us through that. We will break at 2:10. Next slide, please.

At 2:20 is a great update on the HHS Information Blocking overview of the regulations. Elise and Mike will walk us through that. We will have many guests joining us from OIG and CMS. And then, public comment

will be at 3:50, and we will adjourn right about 4:00 p.m., so it is a packed agenda, Medell, but it should be an exciting day, and we look forward to the updates.

Medell Briggs-Malonson
Yes. So, we are going to go over a few housekeeping items as well before we go directly into approving the minutes. Once again, for all the in-person attendees here, all the microphones are right here at the very top, so please speak very clearly towards those different microphones. In addition, would you please make sure that all your computers are muted if you are currently on the Zoom, and we will be able to receive all the comments there. If you do want to speak, just as we did in our last in-person meeting, you are going to flip your name card this way. That way, Aaron and I do know that you have a comment at that point in time.

And of course, as we all know, we are in a federal government building, so if you need to go anywhere, we have to have an escort. I would like to call it just our personal concierge service. So, please remember that you cannot go anywhere outside this room without an escort. Once again, for all of our virtual HITAC members, if you do want to make a comment, just go ahead and raise your emoji hand, and we will be able to see you too. Aaron and I are both tracking, as is our amazing Accel team. Last but not least, of course, all the wifi is on this sheet. Okay, I went through a few housekeeping items.

Steve Posnack
One thing for everybody to know is that your power strips may not be on by default, so if it looks like you are on battery, you may just have to flip the switch on the strip.

Kensaku Kawamoto
So, literally, if we need to use the restroom, we need an escort?

Medell Briggs-Malonson
Yes. **[Inaudible – crosstalk] [00:26:07]** All right, why don't we go directly on into the minutes? First, I would like to make sure we review the various different minutes from October 19th. Do I have a motion to approve the October 19 minutes as written?

Sarah DeSilvey
I so motion.

Medell Briggs-Malonson
All right, I hear from Sarah DeSilvey, who provided the initial motion. Is there a second?

Aaron Miri
Second.

Medell Briggs-Malonson
Aaron Miri has provided a second, so the motion has been appropriately proposed and seconded. Is there any discussion? Not seeing or hearing, I will call for the vote. All in favor of the approval of the October meeting minutes, please say aye.

Several Speakers

Aye.

Medell Briggs-Malonson
Any opposed? Any abstentions?

Bryant Thomas Karras
Abstain.

Medell Briggs-Malonson
Great. I see one abstention, so therefore, the motion carries, and the October 19 minutes are approved. Excellent. So, we are going to go directly on into the first part of our meeting. I would like to introduce Shelly Spiro and Hans Buitendijk, who are going to go over our Pharmacy Interoperability and Emergency Therapeutics Task Force 2023 recommendations. Shelly and Hans?

Shelly Spiro
Thank you very much. I am Shelly Spiro.

Hans Buitendijk
Shelly is on mute. We cannot hear you yet.

Shelly Spiro
I am not on mute, I am speaking. Can you hear me? **[Inaudible – crosstalk] [00:27:42]** Okay. I am Shelly Spiro…

Aaron Miri
There you go.

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Recommendations – HITAC Vote (00:28:10)

Shelly Spiro
Sorry, the audio is bad. I will try it again. This is Shelly Spiro, Executive Director of the Pharmacy HIT Collaborative. I just want to thank everyone, and I realize that for four months, for 17 days out of those four months, more than 25 hours of calls, and even more with the work we have done on the spreadsheets and recommendations, we came up with 34 recommendations, which is huge, probably one third of the recommendations that have gone out to HITAC. I would like to thank Hans, my co-chair, the HITAC members who participated in the Task Force, and the subject matter experts that were appointed. We had approximately 15 members publicly attending all of the meetings. I personally want to thank Tricia Lee Rolle from ONC, who helped to bring pharmacies' issues forward. She is a pharmacist, and is very much thanked by the pharmacy profession. I would also like to thank Mike Berry, Maggie, the Accel team, and all of those who supported the work of this Task Force. Go to the next slide.

So, this is our agenda. I am not going to read through it. You will be going through it, but we have a robust agenda for you, and as I said before, we have 34 recommendations to get through today. Go to the next slide. These are the charges that were given to us by ONC: Identifying recommendations to support

interoperability between pharmacy constituents and exchange information necessary for medication management, patient safety, and consumer engagement. We met our due date of today, and were able to get all of our documents in for the HITAC members to review. Our first charge was public health emergency use authorization and prescribing. We had some short-term and long-term goals, and most of our efforts in our first few calls really showed that there was a real need in the public health arena. Go to the next slide.

Our second charge was to identify opportunities and recommendations to improve interoperability between pharmacy constituents. This is mainly for pharmacy-based clinical services and care coordination. Our third charge was to identify standards needs to support prescribing and management of emerging therapies, including, but not limited to, specialty medications, digital therapeutics and gene therapy, among others that came out during our discussions. Our last charge was to identify policies and technology needs and considerations for what we call virtual telehealth types of services, where medications are being prescribed online, and that group also needs to be integrated into an interoperable solution. Go to the next slide. I am going to turn it over to Hans for his portion.

Hans Buitendijk
Shelly already hit on how we had quite a bit of participation, and I am really appreciative and thankful to everybody who was able to join the Task Force and provide input. As you go through the list, you will see quite a range of experience and perspectives that we had. We had patient and caregiver perspectives, we had large pharmacy chain and community pharmacy perspective, we had IT developers, we had public health, we had pharmacists, and we had other providers as well. So, there was quite a range and a lot of different agencies and various representatives as well.

As you go through the list of recommendations you can see that there has been a lot of thought put into this to get it together, and we have been trying to combine that into the 34 recommendations that we have, but that was not the only group we were able to put that into.

Unknown Speaker
Can you speak louder?

Hans Buitendijk
Speak louder? Okay, I will try to do better. I will actually **[inaudible] [00:32:33]**. In addition to the Task Force, we also had a number of presenters. If you go to the next slide, there will be three slides' worth of presenters based on the topics that we have. Again, you start to see a wide variety of perspectives that are in there. I want to thank everybody that was able to present. Can you go to the next slide as well? I appreciate all of the input, thought, and consideration that went into this. If you go forward one more slide, you will see as well that all the topics that we had others present on provided a backdrop. Plus that, we had a number of members of the public that provided feedback during the official public comment period at the end, and the chat was very active. Those thoughts that jog your memory or ideas, recommendations, and considerations as well. In the end, it was the Task Force that pulled it all together to get the recommendations that we have. So, Shelly is going to go through a little bit of insight on the use cases and topics that actually started emerge from all those conversations.

Shelly Spiro

Thank you, Hans. Hans will go into how we actually broke out the recommendations, but because a lot of our discussions overlapped many of the charges, we came up with a way to discuss use cases and the themes in different topics. So, our use cases are bidirectional access to individual patients' data supporting testing through a treatment process, focused on the administrative data between pharmacists and other healthcare providers, to incorporate pharmacists into the care team, which is a focus on care coordination across the care team members, also consumer engagement, focusing on pharmacist interaction, daily sharing, also data-driven, medication-related, population-level interventions related to population, who qualifies for our need for interventions, pharmacy quality measures and clinical services that focus on capturing data, reporting that data in the measures, and this is important since pharmacists are not recognized as providers in the Social Security Act. Go to the next slide, please.

Also, there are value-based quality measures across the care team that focus on these measures for team coordination of the care team, especially for value-based payment models that pharmacists have been working with payers on, public health focusing on interactions between pharmacists and public health agencies, and patient safety focusing on capabilities and advancing patient safety, which are all very important issues for the pharmacy profession. Go to the next slide.

So, we also came up with some themes and topics that were related back to the 34 recommendations that we put forward. We have standards in data exchange, pharmacists as another provider collaboration and data-sharing needs, pharmacist-public health collaboration and data-sharing need, pharmacist-specific setting populations, especially for long-term, post-acute care, and other practice settings that entail the use of EHR systems exchanging with pharmacies and prescribers, and pharmacist data capture, our opportunities to advance data capture by the pharmacists and the care team members, especially including public health agencies. Go to the next slide.

Also, there is information sharing and blocking. Because of some contractual practices where pharmacists are not recognized in the Social Security Act as providers, that has caused some issues, and we need more awareness and education around that topic. Jurisdiction variations of standards and rules: Again, this is where we come into the problem, as pharmacists are not recognized in the Social Security Act, and have caused a lot of issues in relationship to interoperability. Resources and funding, some challenges and needs, and also, privacy and consent came about, which we know is an overarching issue that ONC is dealing with. Go to the next slide. I am going to turn it over to Hans. Thank you.

Hans Buitendijk

So, I think we are going to start with recommendations, but before we jump in, I wanted to go to the next slide to orient everybody on how this document is organized. One of the things we ran into when we started the conversation with the Task Force is that on the question of the first topic, we just wanted to get through quite a range of topics, quite a range of topics otherwise, and they started to come back and become return topics that were applicable to other questions as well. What we ended up doing is that the recommendations are not aligned in these documents with the questions, but they are aligned by like recommendations.

So, we have a number of general recommendations on very specific IT capabilities that we looked at, there are some very specific topics around patient matching and emerging therapies, but also on the certification and funding thoughts, network participation, and then there were some parking lot topics. So, rather than trying to address that by question, you will see the structure that there is a recommendation, there is a

rationale, and then we have a reference for each one of those to indicate which of the questions we wanted to address and which of the use cases are relevant that this would apply to, and which of the themes and topics would apply to. That is how you can keep things together, but you have the opportunity to go back to the questions, and when you go to the end, the appendix, if you go to the next slide, that is not only where you will find the roster and the abbreviations. We have quite a few abbreviations, which everybody likes in healthcare. The more abbreviations, the better.

At the end you'll be able to flip around. You can see that if you have to go by the questions now that we have asked that, you can start to look right inside and identify which recommendations actually address that particular question as well. So, that is just from a navigation perspective to see how it is all tied together, and with that, we will jump into general recommendations, and Shelly is going to kick us off.

Shelly Spiro

Thank you so much, Hans. I apologize for not being able to be there in person. I have had some health issues, but it looks like you are a great group, and I am sorry I am missing all the fun. Go to the next slide, please. We have several general comments, and this is the first recommendation: "Recommend ONC initiate collaborative initiatives with patients and caregivers, including the CDC and other public health organizations, bidirectional sharing and/or exchange, access to public health, and identifying the appropriate relevant data sets that are needed on capturing this data." Go to the next slide. Just as a reminder, each of the recommendations has a rationale with it. They were just very long, and we had a very, very active discussion, and Hans has done a great job of actually putting the information into a way that is usable for ONC to react to these recommendations.

So, the second recommendation is to engage NCPDP and HL7 standards development communities, including the pharmacists, other providers, public health, and such, recommending that "ONC, in collaboration with CMS and other agencies as appropriate, consider enhanced funding to accelerate the progress, availability, and use of both emergency user interventions and normal operations." Go to the next slide, please. So, our third recommendation is to recommend that "ONC work with these agencies and other authorities to clarify the role associated in health IT capabilities." These are critical standards to support the pharmacy and pharmacists in their role and resulting obligations to public health. Pharmacists play a very important role. We are the No. 1 immunizers in the United States, and there is a lot of public health data that pharmacists are capturing, not only just in immunization being given, but also clinical services. Go to the next slide, please.

The fourth recommendation is that "ONC identifies the needs and capabilities relevant to pharmacy versus pharmacists and identifying opportunities for advancing interoperability." Go to the next slide, please. Recommendation 5 is "to identify and address obstacles," of which we have a huge amount, "those beyond technology standards to share in between pharmacists and other providers and patient and caregivers. ONC should consider how they can use the regulatory authority and issues and guidance to eliminate some of these obstacles among various pharmacy settings. ONC should provide additional guidance and identify approaches, including considering a focused modular certification program for pharmacy management systems." These can be further described in the feedback on HTI. Go to the next slide, please.

So, the sixth recommendation is to recommend that "ONC with federal policymakers to address gaps where pharmacy benefit managers and payers are not considered covered actors in the 21st Century CURES

Act." This is really important because pharmacists work closely with the payer community, especially as we move to value-based payment models, and we will be sharing clinical information and are sharing clinical information with those payers today. Go to the next slide, please.

Recommendation 7 is to recommend "ONC convene stakeholders, including pharmacists, other providers, caregivers, online, National Association of Boards of Pharmacy to handle this virtual telehealth where a prescription is being prescribed online." We need to make sure that those providers are moved into sharing information interoperably, not only amongst pharmacies, but with others in the care team. Go to the next slide, please.

Recommendation 8 is to recommend that "ONC work with the pharmacists and pharmacy public health and such on reporting syndromic surveillance reporting and other data collected, such as electronic clinical quality measures, for public health. This should include addressing and supporting standards available to report this information and reporting requirements and capabilities." We just want to make sure that pharmacists are included, the same as any other provider, in sharing this information and access to public health information. Go to the next slide, please. I think we are going to turn this over to Hans.

Hans Buitendijk

So, the next set is a set of recommendations that are focused on some particular capabilities that would be helpful to advance in some fashion. The first one, Recommendation No. 9, recognizing that this is very much a collaboration to expand some of these topics, is for "ONC to collaborate with CMS, payers, healthcare providers, including, but not limited to, pharmacists, standards development organizations, health IT vendors, and other relevant stakeholders to adopt standards for and a Condition of Participation requiring the electronic exchange of data elements necessary for identifying what medications in a formulary require pre-authorization and security, and any required pre-authorization and securing to provide any informational component that is involved in determining which drugs get covered with and without prior authorization and what costs captured and accessible do pharmacies, pharmacists, other providers, and patients."

That is quite a mouthful and quite a range, but it identifies that in the space of prior auth, in the space of having insight into that understanding of what is available, it is important that the information necessary can be exchanged in the pharmacy/pharmacist context as well. So, that is the first one, but a very big one, that we talk quite a bit about.

The next recommendation, No. 10, is going to advance further some thoughts that Shelly already identified. "ONC should work with other relevant agencies and industry to advance full interoperability between EHRs and PBMs, and other teammates about drug providers, etc., that it is in the chain to the drug that is available in coverage terms." So, for these ones, 9 and 10 and look at some of the use cases. There is a fair amount of spread across the variety of data being used **[inaudible] [00:46:56]** financial coverage and otherwise, and we suggest what work needs to be done to help advance that. That is what 10 is about, to further flesh that out.

In terms of 11, that is where we focus on working with other policymakers and the pharmacy community to advance the ability for patient-facing pharmacy apps and portals to facilitate two-way communication between pharmacies/pharmacists and the patient or caregiver in order to improve patient care through

greatest pharmacist-patient/caregiver interaction for such things as sharing fill status, with reason/issues, and interactive messaging. As we have seen in other areas, including the pharmacy/pharmacist space as well, interaction between not only pharmacists, but also others in the pharmacy, and the patient, or caregiver, or both is extremely important to make advancements.

Let's go through Recommendation 12, "further collaboration with FDA, CDC, STLTs to have a look at the FDA's Sentinel surveillance program and how pharmacy data sharing would be important for the surveillance as part of a unity." It takes a little bit further what can be used and can be plugged in further. And then, we jump to the next one, "continued collaboration with the FDA, providing guidance to further advance transparency as part of the proposed decision support intervention certification criteria in HTI-1 that are needed to ensure greater clarity of authority, delegation of authority, responsibility to reviewing the proceedings regarding future machine learning, software/hardware data set combinations that achieve artificial intelligence levels, capable of self-initiative, self-management, and self-control within the practice setting, overseen by local and state regulatory authorities."

So, it addresses further the system perspective that comes across is to extend many of the flaws and capabilities that are addressed for the provider community, hospitals, various settings, etc., but that the pharmacy needs to be integrated with them so it can take advantage of the same capabilities, and it needs to address the same challenges that are there.

That brings us to 14, "ONC should collaborate with pharmacies and other provider communities, including health IT vendors, to establish appropriate reporting mechanisms directly from pharmacy to care team members, and vice versa." A little bit of that was touched on in earlier recommendations, particularly some of the first, about the integration of the pharmacy and the pharmacists in particular with the rest of the care team, sharing data, being able to get the relevant clinical data to the pharmacists as they provide their services, and also recognizing that pharmacists are increasingly providing services that go beyond the filling of a prescription, and that data is being exchanged in both directions.

That brings us to 15, which is where we are focusing on collaborating again with pharmacy communities, patients, and caregivers to develop guidance and perspective for data capture from patients by pharmacists and pharmacies, focusing on how, as we integrate more, there is educational data that is going to be, could be, or is best captured in the pharmacy/pharmacist setting and how we can better advance it. What are some guidelines to improve on that ability and the associated quality and otherwise, given the role that everybody plays there? Go to the next slide.

We are then going to potential for interoperability privacy policy and consent infrastructure around topics that, as we integrate more and better, we recognize that pharmacies and pharmacists are included in there, and that if there are any considerations around privacy policy and consent **[inaudible] [00:51:32]** the pharmacy setting as well. So, "to ensure appropriate sharing of health information, including but not limited to clinical data and medication fill administration, consistent with applicable law and patient preferences," and exploring that there are a number of different considerations of other organizations that are active in trying to advance there, and the intent here is to ensure that pharmacies/pharmacists are very much a part of that conversation and discussion in that advancement area. I believe I am getting close to the last one. Oh, I still have a few more to go.

Recommendation 17 has lots of capabilities that we described, inclusion of specific prescription status change interactions. There are a few already in place, such as exchange/cancel/prescription fill. They should be included as required interactions for both prescribers and the pharmacy in the United States Core Data for Interoperability and ONC certification program. "Consideration should be given to improvement/inclusion of patient and caregiver for relevant notification and awareness."

That brings us to 18. "Recommend that ONC explore the need and readiness for standards-based secure instant messaging capabilities in addition to current management capabilities that use direct messaging in a variety of messaging paradigms." That identifies that there are different means and ways to interact further, particularly with patients and caregivers, but also other care team members, and there are some mechanisms available, but the instant messaging capability is of substantial interest as well. Next slide, please.

"Recommend that ONC includes event notification capacities for pharmacies and pharmacists as part of a focused modular certification approach." Again, it goes back to the care team integration. As we include pharmacies and pharmacists, we want to address the need for consistent ability to give event notifications to all those that need that, which includes pharmacists and pharmacies, and to do so consistently. On to 20, meaning we will go to the next topic, for which I will hand it back to Shelly.

Shelly Spiro

Thank you for tag-teaming this, Hans. There are a lot of recommendations to get through. Go to the next slide, please. Under patient matching, we have "recommend that ONC include pharmacy community in the advancement of patient matching." This should be no different than we are doing with any other provider within the Trusted Exchange Framework, advancing pharmacies' ability to link patients with the right record. It is really important that pharmacists be included in this information and ensuring that the pharmacy community is following the same as any other providers when it comes to patient matching. Go to the next slide, please.

Next is Recommendation 21, "recommend that ONC establish learning collaboratives across pharmacies/pharmacists and other provider-patient jurisdictions and government agencies to explore more methods, such as tokenization and privacy-protecting record linkage, in combination with relevant standards, in order to fully and accurately incorporate pharmacies and pharmacy source data and how it can be implemented and leveraged across surveillance, research, and other national HIT priorities." Go to the next slide, please.

Recommendation 22 will start with emerging therapies. Go to the next slide. "Recommend that ONC work with labs, device manufacturers, National Library of Medicine, LOINC, SNOMED, and industry organizations to address mapping of pharmacogenomic information." We use pharmacogenomic information for predicting potential adverse drug reactions and in oncology. As more biologics are used within our healthcare system, this becomes really important because pharmacogenomics can be evaluated by pharmacists to see that appropriate medications are being prescribed to those patients and optimizing their therapies. Go to the next slide, please.

Next, we go to specialized focus certification and funding. Go to the next slide, please. Recommendation 23 is "to pursue a set of standards in technology and framework to advance interoperability among

pharmacies and pharmacists that are common with the provider community, deployed through a potential certification program, and also described in HITAC's feedback that was done with the HTI-1 Proposed Rule." Go to the next slide, please. I just want to remind everyone that there is a large amount of rationale that is in the actual report document that goes further into identifying obstacles and other barriers and areas, so I definitely refer you to the report.

Recommendation 24 is to recommend that "ONC initiatives and develops a certification approach in collaboration with critical industry organizations, such as NCPDP, HL7, and others, especially to look at the different types of settings that pharmacies deal with, the community, clinics, specialty pharmacies, and especially the long-term post-acute care arena, where multiple medications are being prescribed, and needs to be shared, especially during transitions of care." I just want to thank Anna and Alexis for bringing their work and the consumer's perspective to our recommendations. It was very much needed. Bidirectional access to individual patients' data supporting testing and treatment, incorporate pharmacists into the care team, consumer engagement, and data-driven, medication-related population-level, interventions are all areas. Pharmacists played a very important role in the COVID-19 pandemic and in ensuring that test-to-treat programs in other areas are covered. Go to the next slide, please.

Recommendation 24, "these should utilize the standards that are used by the ONC current certification process, such as the HL7 C-CDA FHIR-based implementation guide, SMART, NCPDP Script, direct messaging, and other IHE document exchange." Consideration should be given specific certification and consider bidirectional certification of e-prescribing transactions and standards that Hans spoke about earlier, including the clinical exchange of clinical FHIR resources, such as the Pharmacist Electronic Care Plan, which is highly adopted in the independent community setting, and we are also working on a new FHIR resource, called the Standardized Medication Profile, that will be used for transitions of care and to incorporate different types of medication lists available, and those are things we are working on now, and we hope ONC will help us in that continual effort as we begin to move this, especially in projects like the PACIO Project at HL7, which stands for "Post-Acute Care Interoperability," which is overseen by CMS and Meyer. Go to the next slide, please.

Recommendation 25 was to "recommend that ONC collaborates with pharmacists and providers, especially with IIS, which is the forum that is used for recommendations to the different public health organizations, including other relevant clinical data that would lead to electronic clinical quality measures, working with CDC and STLTs, and making sure that we identify the minimum data set within USCDI standards for pharmacists to exchange relevant clinical data registries, EHRs, and possibly other pharmacy information systems."

The scope should consider not only prescription-related data, but also non-prescription-related data, such as over-the-counter supplements and homeopathic medications, where the pharmacist provides test-to-treat services like we have seen with Paxlovid, and really testing patients for COVID, and more are growing in these test-to-treat programs within the pharmacy community for strep and for other types of issues that are being brought to the pharmacist. The pharmacist is seeing the patient much more than any other provider because of the refill capabilities that at least every 30 days, and sometimes every 90 days, that the patients are receiving their medication, they should be interacting with the pharmacist. Next slide, please.

Recommendation 26 is to "recommend and consider including an ability to capture and exchange race and ethnicity." We would like to see this more in the e-prescribing functions, especially through the certification program, and as a point to follow, USCDI Version 4, and reference the CDC race and ethnicity code set. These are really important, and if we can get that exchange with the pharmacist, we can help share that information with public health and other areas. Go to the next slide, please.

Recommendation 27 is to "recommend that ONC works with HHS, enabling the receipt of incentives to develop and adopt a certified health IT under ONC's HIT certification program through full recognition of pharmacists as providers, since we have an issue that pharmacists are not recognized in the Social Security Act as providers." Go to the next slide.

Recommendation 28 is to "recommend that ONC include different pharmacy settings, such as specialty pharmacies, pharmacy management system vendors and requirements, long-term post-acute care, community pharmacies, clinics, and hospitals." Pharmacists are in all those areas. Go to the next slide, please. I think I am turning it over to Hans.

Hans Buitendijk
Yes, and that brings us to the last set of recommendations, so we have a few more to go. The first couple are about network participation. As we are progressing each, if you go to the next slide, there is a very specific focus on a recommendation that "ONC recognize interactions between pharmacists and other providers as a critical component of the Trusted Exchange Framework treatment exchange purpose, and address the barriers and encourage education for pharmacies and pharmacists to join Trusted Exchange Framework as it is operationalized. This should address both the ability for pharmacists to query other providers as well as other providers to query pharmacists for patient data."

So, further expanding that, with the tools around Trusted Exchange Framework, pharmacies and pharmacists should be part of that and help advance that as well. Go to the next one, 30. It is along the same lines, but now focuses on public health. "ONC recognizes the pharmacist with public health interaction and reporting is a critical component of public health exchange purposes and address the barriers to consistent standardized data elements and formats across the public health community, including CDC and STLTs, considering regarding frameworks to address APHLs based on reporting approach. This applies to pharmacy interoperability and reporting to public health by all providers."

Then, if we go to the next one, quality measures, we had a healthy discussion in certain places and particular questions as well, but use cases touched upon the need for quality measures and to help or to take advantage of the opportunity and ability for quality measures to set the direction and help drive things forward. Next slide. The first one, Recommendation 31, is "recommend that ONC work with CMS, STLTs, and other relevant agencies to develop value-based incentive structure using quality measures so that prescribing providers, patients, and caregivers can be timely and accurately informed at the point of e-prescribing regarding where they can fill all prescriptions, routine or urgent, in a manner that optimizes patient care and needs.

Such incentive structure should address availability of information, whether the prescribed recommended medication or intervention is available or may be in a defined timeframe at the pharmacy." So, if a patient prescribed medication or service has been or is to be considered **[inaudible] [01:05:14]**. So, by introducing

some measures around the ease **[inaudible]** of other examples where that would be helpful to help move progress forward in that space.

Continuing with 31, which was long, "Data should include the status of drug supplies, expected time for medication availability, detailed tracking, etc." So, there is quite a bit of data, and the suggestion is for a cross-sectional workshop focused on the patient and caregivers before the providers, pharmacies, and pharmacists that goes through the use case model to further inform existing standards, what is needed, what existing gaps are, and it includes those identified in the HITAC Intersection of Clinical and Administrative Data Task Force report. There was a very specific set of recommendations there that we did not feel we needed to repeat, but we wanted to pull into it because they are very helpful in better understanding the space. I think we are safe now to go to 32.

The next one, 32, is "recommend that ONC work with CDC as per STLTs in particular to identify a shared superset of key operational metrics critical to situation regulation during declared emergencies across different data sources, such as hospitals, clinics, pharmacies, etc., and include support for that set, which covers pharmacies as data sources as well into the HELIOS Aggregate Data initiative to ensure patient guidance covers these measures." So, not only on the intermediate care integration with the care team, the patient, caregivers, and otherwise, but also in the reporting like this, for emergencies.

Recommendation 33 is about "ONC working with public health organizations, including CDC and STLTs, to create a set of metrics, clinical systems, and outcome measures specifically addressing identification of gaps in advance of exchange of critical data between pharmacists capturing clinical data related to immunizations, medications, and treatments prescribed, dispensed, and administered and case reporting identified during the pharmacist encounter. Measurements should align with principles of measurement science, specifically around feasibility and the ability to readily capture data appropriate to the level of analysis. Additionally, measures should be proved to the quintuple aim of safety, outcomes, cost, health, equity, and burnout, and with a focus on the measured entity, the pharmacy, health plan, hospital, etc., to have the ability to improve the measure."

That brings us to the last recommendation, 34. "Recommend that ONC work with CMS to establish quality measures as part of a performance program aligned with an ONC-defined certification approach focusing on measures that advance the adoption of interoperability." And then, there is a series of examples there around time the patient needed to call the pharmacy, how much time the patient needed to spend communicating with the pharmacy, payer, or provider, how many bidirectional interactions were involved, how much time it task for a variety of prescriptions to be filled, and other best outcome-focused measures, such as medication adherence rate, pharmacist detection and prevention of potential adverse drug events, patient counseling time, activities and outcomes, physician consulting time in activities and outcomes, and disease management in practice.

So, with that, I am going to take just a quick breath because we have gotten to the parking lot. There is a wide range of recommendations that address the four key topics that were raised by ONC. There was quite a bit that we did not talk through. Interestingly, a lot of it started to come up in the first discussions across the spectrum of what you have heard in the team today, so it was a very productive set of discussions, but we still had something left for the parking lot. Shelly will get us through that, and after that will come the next steps.

Shelly Spiro

Thank you very much, Hans. I appreciate it. Go to the next slide, please. These are the areas that we felt were out of the scope of the charges but were related to what we hope would be future work. There is the interaction with and usability of technologies by users yielding concerns regarding more that can be or should be done to support the consistent use of interactions of such technologies. Some variations can lead to user errors and, in turn, impact patient safety, while others lead to inconsistent data across providers that challenge analytics. The ONC certification program includes criteria on the use of appropriate design guidelines and development. These are some of the certification criteria, and it is important that pharmacists be part of this, even if it is through voluntary certification, but we have to give them a way to identify which of the certification criteria apply to pharmacists and pharmacies.

The Task Force suggests that ONC and HITAC should further explore opportunities to align health IT in terms of common terminology, surveys, questions, and assessments that can further advance consistency in data quality, particularly between pharmacists and other providers, while retaining flexibility to advance new and alternative approaches. Pharmacists have a lot of good technology available, and if we are not able to share it, that is a real loss for our patients, so we want to be part of this process and work with our system vendors to actually go through some certification to help with interoperable exchange, especially as TEFCA comes into play soon.

With that, I think we are at our last slide, with which we are hoping to open up discussion, and hopefully we get a positive HITAC vote on all of the hard work that not only ONC has done. I also want to thank Micky Tripathi, Steve Posnack, Tricia Lee, Mike, and the others at ONC who really brought this issue forward. For the last 13 years, we have been trying to engage ONC to do more with pharmacy outside of e-prescribing because pharmacists do play a pertinent role in clinical services and providing clinical services, especially with the high amount of access that pharmacists have in working with our patients, so we believe that leveraging technology will be better for all providers and the care team, and most importantly to the patients that we are taking care of. With that, I will turn it back over to the chairs to lead the discussion.

Aaron Miri

Fantastic, thank you. Great job, Shelly and Hans. Great job with this entire Task Force. This is a tremendous amount of work, and it is really educational. There are a number of items here going deep into it, and that has truly brought issues to light that need to be addressed and resolved, so thank you for your leadership here in getting us to this point. As was stated earlier, we will be taking a vote on this at the very end of this discussion, and in proceeding with the vote, we will go to break. So, with that, we have a little bit of time for questions and comments, both from those online as well as those in the room. As Medell said earlier, if you have a question, please turn your placard on its side so we can see you, and we will do our best to go in order of those who put their placards up. First up, Medell, you are recognized.

Medell Briggs-Malonson

I really do not have any questions, but I want to commend Hans, Shelly, and the rest of the committee on this amazing body of work. I took several notes over here, and one, I want to commend the entire committee on really centering patients and caregivers in all these different recommendations. I must say that my favorite recommendations are No. 14 and all of the quality and accountability metrics. The reason why 14 is so critical is because I think this recommendation can really advance our transitions of care as patients

do end up leaving our healthcare facilities and go back to the community, and this is also critical for reducing readmissions as well. And then, of course, accountability is key. I just want to say congrats on this wonderful body of work. It is amazing, and thank you for all of the work that you put into this.

Aaron Miri
Hear, hear. Great comments, Medell. Thank you. Next up is Ken.

Kensaku Kawamoto
Thank you. You have done some really great work. There are so many recommendations that I think prioritization is critical. I think you recommended that one of the prioritizations be sending the dispense info around. I think that is great. There are some commercial solutions and technologies we can use with PBMs and whatnot where we can tell how often people have been filling, etc., but when we have investigated it, those are hard to get outside of those approaches, for example, to service a FHIR interface.

Another topic of real importance is we know patients oftentimes do not take their meds as prescribed, and having that information easily available and not just through specific technology that EHR vendors have decided to make available to us would be really important, so I think that is a great way to prioritize the recommendations. I really like the idea of basically having the retail pharmacists act like clinical pharmacists who are embedded within the clinics and are on teams that really work through these issues with patients. It all makes sense to me, if it can be done. For example, how wonderful would it be if a medication recommendation could be done at the retail pharmacy instead of being like, "I don't know, there are all these medications," and avoiding duplicates. "Do they really need to have these two medications?" If they can act in that role, wouldn't it make all sorts of sense from a patient perspective for the data to be shared?

I guess my main question is if the incentive structure there, and I think I saw a recommendation for ONC to work with CMS and other entities to figure that out, but I am just thinking of every time I go to a CVS or Walgreens and there is a line of seven people. Maybe it is just the time that I go, but they are waiting 20 minutes just to get the meds. Imagine if you added all these other things, and now people are waiting 40 minutes. I am sure there is going to be a lot of pressure to get this done, so that might mean increasing staffing. Could you comment on if the incentive structure exists, and if not, could you give some thoughts on how to actually incentivize the retail pharmacists to do what we would expect clinical pharmacists to do when they are in a healthcare system setting?

Hans Buitendijk
Shelly, **[inaudible] [01:16:39]** around that?

Shelly Spiro
Yes, this is Shelly. Thank you for that question. Pharmacists are highly trained and receive a Doctor of Pharmacy degree from our colleges of pharmacy, are stuck in a dispensing mode because of our payment models. The pharmacy profession is working very hard to change those models. Under their practice act at the different state levels, pharmacists should be providing services, but with the shortages that are occurring and the time that it takes to receive a medication and talk to the pharmacist, there is a lot that has to be done. I can assure you that this is a high priority for the pharmacy profession, and we are hoping to leverage technology to improve those types of services that we can provide, not just dispensing functions and picking up a prescription, but really engaging with our patients for their needs.

There is a lot that pharmacists have to offer for preventative care, and we do have many of those models, and through the Pharmacy HIT Collaborative and on behalf of the Joint Commission of Pharmacy Practitioners, we have spent a lot of time assuring that clinical services can be captured and documented within the pharmacy management systems, and we are preparing to work with ONC, and the standards development organizations NCPDP and HL7 are doing fabulous work in ensuring that we are able to capture that information in an interoperable way following what ONC is trying to do with advancing interoperability. Pharmacists have a lot of training to assess a patient, to optimize their medications, and to ensure that there is a historical way to capture discontinued medications and adverse drug reactions.

There is so much we are doing in pharmacy, and the only way we can improve this is by leveraging the technology moving forward. Many times, when I go to the doctor's office, I have to wait 40 minutes to an hour to see my provider in person. Telehealth has really improved that. We are hoping that, in the future, as we fix the issues and the barriers that we are seeing on interoperable exchange, that will improve, to answer your question, and I hope I have answered your question.

Aaron Miri
Go ahead, Hans.

Hans Buitendijk
I would like to add to Shelly's comments and a question on the first and second parts about the collaboration and governance. There was a fair amount of discussion about prioritization. You see numerous use cases in these topics. I have a feeling that we can get to a specific prioritization out of these ones, these are the two to go after, but more of a recommendation that this is the breadth and depth of what needs to be addressed. Sprinkled throughout many recommendations, you see "ONC work with," "collaborate with," or "find an environment like Trusted Exchange Framework," or "set up a workshop."

There really needs to be that community that pharmacists and pharmacies are part of or that have very specific focus areas to work through that. There is so much to be done that it is hard to put a priority at this point in time on which one is the most important, but if we have a collective way to work through identifying what is first, second, and third and then work from there, it would be helpful to then to make progress. That is why you see many recommendations having "work with" or specific contexts like TEFCA, workshop, or other methods to do that.

Aaron Miri
Great points, Hans and Shelly. Thank you, and thank you, Ken, for that question. I also echo your sentiments on technology helping to reduce the burden, dealing with duplicate sigs and other issues that are common between transitions of care like that. Great points. Anna, you are next.

Anna McCollister
I was a member of this workgroup, and kudos to Shelly and Hans for all the work they did, and to all the other members as well, because there were certainly a lot of them, so, thank you for that. Let me suggest to staff as you consider implementation of these guidelines that perhaps you go back and look at the use cases that were developed to fully center these recommendations because that will give context to why this support is needed. In a lot of the conversations that I have made, again, wearing the hat of the very complex

patient, as I currently take 19 different medications and use five different devices, three of which stay attached to my body 24/7, one of the sources of burnout and frustration is interactions with pharmacies.

One of the things that truly frustrates me is that, there are a lot of the data, one medication I need is only existing in one form or another within structured data fields that somebody has somewhere, whether it is distribution or supply chains. When I go to the pharmacist, they have information in a structured format that they will show me that I am not able to see through my app, and just having information that is already there, already in a structured format, and already being shared within the pharmacy system would be immensely helpful in preventing the amount of time I have spent going into a pharmacy and not being able to get medication and the literal hours upon hours that I have spent on hold with Walgreens and other pharmacies trying to find out the status of medication, etc.

Some of this data is not "health" data, it is about distribution, access, and availability. It is already structured and already being exchanged, so I would like to encourage ONC to think this through expansively about all the things that are preventing patients from actually being adherent and getting the medications and how we can think expansively about the structured data that exists that can be included in this process.

Aaron Miri
Great point, Anna, and I can tell you, from the provider community side, one of the things **[inaudible] [01:22:59]** managed dialysis center, for those patients that are on tremendous amounts of meds that are going through chronic kidney disease and other ailments, the number of medications they are on, which you alluded to, is tremendous, and oftentimes, we hear their frustration on becoming a human med reconciliation process. They have to be able to do that. It is incredibly frustrating, and they often suffer from that because medication adherence and persistence, as we know, is tied directly to education, what you are doing, and why you should be doing it.

Anna McCollister
Well, it is education, but I am plenty educated. It is really about access, being able to access and understand where the supply is, where you are going to get it, and what you need to do to make sure that you get it. That is the biggest time suck for me when it comes to healthcare.

Aaron Miri
Great points. Thank you for bringing that up. Hannah? Sorry, was somebody in line? Fil is next, thank you. Fil, then Hannah.

Fillipe Southerland
Thank you. I just wanted to take a minute to say thank you, Hans and Shelly, for the great discussion. There was such a diversity of discussion on this Task Force and you did a great job **[inaudible] [01:24:03]**. I wanted to also thank ONC for the opportunity to talk about pharmacy as a specialty HIT sector. I think coming from the Long-Term and Post-Acute Care space, I think these conversations and the ability to drive into these specialty sectors is so very important as we start to look at the shift to value-based care models. A great portion of our Medicare spend is on **[inaudible]** perspectives play such a key part in **[inaudible]**.

Aaron Miri
Hannah?

Hannah Galvin
Thanks. I also want to thank the group for this incredible work. I have a couple of things to bring up and echo some of Anna's points. Understanding which pharmacies have the supply and which pharmacies can divide their services, especially in this highly distributed environment, where some pharmacies provide different services and where, now, the vendor space is growing and there are third parties that now do home delivery and blister packaging of meds, can provide this wider array, but there are also patient safety issues, and if we do not have standards around whether a medication is the type for blister packaging versus a single supply medication, in our clinical experience, that has provided medication and patient safety issues as well. So, we encourage including that in standards development, but I think it is really important that as the vendor space becomes more and more distributed and varied in its offerings, we consider all those different offerings in looking at this space and what is offered at the consumer level as well as what we are used to.

Aaron Miri
Great points. Thank you, Hannah. All right, online, I see that Clem McDonald has a question. Clem?

Clem McDonald
I do not have a question. I am just complaining about the sound. The audio is bad over Zoom.

Elise Sweeney Anthony
We will definitely be working on it during the break. The team has been working mightily on the side to increase it. In the meantime, could everyone speak up a little bit and help us out as we try to work through this?

Aaron Miri
Yes, thank you, Elise. We appreciate that. Thank you for your patience online. We know it is difficult. All right, Steven?

Steven Hester
Thanks. Thanks again for the work. There are a lot of great recommendations there. I was actually just going to reiterate what Hannah was speaking about. More and more, it is not just the large retail pharmacy where you find the patients coming in. A lot of times, you can ask where they are getting the meds, and it used to be from one place, but it has now become so many different places. I think the definition clearly covers that, but I would just ask that we make sure that we are pushing for that information across the board. There are so many areas where patients are getting medications today that were more streamlined 10 years ago, and certainly, oftentimes, when patients come in and ask where they got the medication, they have no idea where it has come from, so I think some simplification of that is really important.

Aaron Miri
Good point, Steven. Bryant?

Bryant Thomas Karras
Thank you to the Task Force. Those are amazing recommendations. I was not able to participate directly, but I clearly see the voice of public health showing through in so many of the recommendations. Thank you

for that. I applaud that many of those recommendations involving public health reference working with ASPR, CDC, and STLTs, state, territorial, tribal, and local health departments. That is always a huge challenge. That is such a diverse group to try to bring to the table to make sure the implementations of those recommendations come through in a way that helps and not hurts public health infrastructure. I think there is a lot packed into those recommendations that I hope CDC recognizes needs investment and readiness from the public health partners. As many people have said, there is an opportunity for pharmacies to be that engagement space. As we saw clearly with vaccine distribution in the US, they are the front door of public health in so many ways, so I think we really need to step up and engage with that **[inaudible] [01:29:23]**. Thank you.

Aaron Miri
Great points. It is time to activate pharmacies to be on **[inaudible] [01:29:30]**. Fantastic point. Shila?

Shila Blend
Thank you. I was part of this group. There was a lot of great discussion, and I echo Bryant's comments on public health because I have been part of projects where they use pharmacies for blood pressure and some of that front door access as well for vaccines, but the comment I wanted to make kind of comes off of Steven's. I come from North Dakota, and the hard part with our laws is that the pharmacy needs to be pharmacist-only, so that has impacted quarantine/CDC. Keep in mind as you are working with these recommendations and things that not every pharmacy is a Walgreens or CVS. There are a lot of smaller pharmacies. Some are connected to hospitals, and some are just your hometown mom-and-pop shops. So, as we are making requirements for pharmacy in different aspects, just keep that in mind.

Aaron Miri
That is a great point, and something we also learned from the pandemic, as those pharmacies were engaged and activated in vaccine distribution, so that is a great point. Ken, you have another question.

Kensaku Kawamoto
I just have another comment around the whole value **[inaudible] [01:30:41]**. It seems like a really big win area. A lot of these issues are probably covered in the CMS-covered age range or coverage area with poly-pharmacy, complex patients and that kind of issue as well. It just seems like such a **[inaudible]**. Medication issues are such a big part of clinical safety and whatnot. If this technology could also have the incentives align, it could be really transformational. It seems really hard because it is not just about the technology. You have to change how people are financed and how things are staffed, but I think there is such tremendous potential in this area, and it would be really great to see.

Aaron Miri
And advancing things like pharmacogenomics and other advancements. Great points, Ken. Any other questions from those online or in the room? Okay. Everybody is wowed. We very much appreciate the work there that you guys did, and that leadership there. Great comments by everybody in the room. We will now move to a vote to advance these recommendations to the national coordinator. Do I have a motion to vote?

Steven Lane
I will happily move that we approve these recommendations, with great thanks to the co-chairs and the entire Task Force.

Aaron Miri
Absolutely, thank you, Steven. That is our first. May I have a second?

Medell Briggs-Malonson
This is Medell Briggs. I second that motion.

Aaron Miri
Wonderful. Thank you very much, Medell. All those in favor, please signify by saying aye.

Several Speakers
Aye.

Aaron Miri
Any opposed? Any abstentions? Congratulations, co-chairs. Recommendations are approved. Well done.

Shelly Spiro
Thank you very much.

Aaron Miri
So, with that, I believe we will take a break. We will reconvene at 11:20.

Medell Briggs-Malonson
I think we have some housekeeping.

Aaron Miri
Oh yes, some housekeeping.

Medell Briggs-Malonson
I will always wear my housekeeping hat.

Aaron Miri
I love it!

Medell Briggs-Malonson
So, once again, if any of us who are non-HHS employees leave this room, we have to have a chaperone, or a concierge-liaison. We are going to linking **[inaudible] [01:33:16]**. So, at 11:15, please be back in the room, ready to start.

Aaron Miri
Yes, 11:15. Thank you.

Michael Berry
Welcome back from our short break. **[Inaudible] [01:33:32]**

Medell Briggs-Malonson
Thank you so much, Mike. Once again, just because we know that there have been some audio issues in the Zoom world, when all of us do speak in the room, please try to make sure to keep your voice elevated. Also, watch the cadence of how you are speaking as well. So, while some of us are faster talkers than others, be as slow and as clean as possible so that everyone can hear. If Aaron and I get notification that somebody may not be able to hear you, we will just give you two thumbs up, which means that yes, you are doing awesome with your presentation, but also, just increase your volume a little bit as well. Thank you, everyone, for coming back from our break, and we are going to jump right on in for the Office of Technology update with Avinash Shanbhag, so we will turn it over to you, Avinash.

ONC Office of Technology Update (01:34:26)

Avinash Shanbhag
Thank you very much. I will just mention that I will speak slowly, but my accent might not be captured by folks on Zoom, so if you do have difficulty getting my accent, give me a thumbs up or something. First of all, I appreciate and thank everybody in HITAC for inviting me to give you a quick rundown of the work that we do in the Office of Technology, which is within ONC, and I would say we are a part of the policy **[inaudible] [01:34:57]**. Before I begin, I would just thank the previous group, led by Hans and Shelly, for their awesome presentation. As you guys were giving us the recommendations, I was writing down all the various activities that would work that will now come back to the Office of Technology, but without **[inaudible]** that work, and certainly **[inaudible]** around standards, automation, and **[inaudible]** certainly make us **[inaudible]** things like this.

What I wanted to do was give you all a quick introduction to the organization structure of the Office of Technology so that you know the people that are behind some of the work that your Task Forces have been supported by so you will have an understanding of various activities that the Office of Technology does, and then I will focus in on the work that we do selection programs that we are mounting from the previous discussion, some of the work that we do with standards, and also automation. Next slide, please.

So, basically, the Office of Technology has four divisions that we have established to focus on specific areas of health IT and regulation. The first division, the Technical Strategy and Analysis Division, is really a combination of both understanding where the bleeding-edge technology lies, some of the work around AI **[inaudible] [01:36:38]** question support technology are being led by the Strategic Initiatives branch, and some of the work that really is on the back end of understanding how the data works, and you will hear about it in the afternoon Data Analysis branch that fit in with the Strategy and Analysis Division that is led by Mera Choi.

Then, we have the Standards Division, which really interfaces with all the standards bodies, including HL7, NCPDP, IHE, and others, to make sure that the health IT standards that are put in place are really established through joint community engagement of **[inaudible] [01:37:15]**, and again, ONC **[inaudible]** coordinators with other federal agencies to make sure that when we come with a voice, it is a voice of **[inaudible]**. That is led by the Standards Division. The Certification & Testing Division, led by Rob Anthony, really is the group that keeps the trains moving in the certification program. I heard a little bit about you all wanting more certification, which is **[inaudible]** to that group's skills, I am assuming, but again, that group really makes sure of compliance, of course, and really, the things that are necessary to make sure that we

have confidence that certified health IT that is used by providers **[inaudible]** opportunity to make recommendations.

Finally, this past summer, we established a new division, the Network and Skill Ready Division, and this was to take into account the importance of not just standards, but how they would interplay with infrastructure and networks that are out there, and some of the comments I heard in the morning are reflecting that this is standards and practice. Also, again, having a sharp focus on health IT standards alignment across Health and Human Services that has been established, again, as you heard from the national coordinator about ensuring that HHS also uses the standards that are established by the agency, we have actually established an alignment branch that is focused on working with all the various agencies to ensure that standards that have been established in HHS through our regulations are now used by other agencies for other activities. Next slide, please.

So, again, I wanted to run through some of the various activities that the team has done. It is not a large team, we have a very small office, but the work has really been involved. Within the selection program, some of these vendors are available to all of you. We have over 900 active certified EHR products, and 97% of hospitals and 90% of **[inaudible] [01:39:33]** providers are using certified EHR technology, and over 97% of hospital patients have electronic access to their medical records. Really, the digitization of health records has been established, certified EHR technology is well established, so really, the next challenge we are facing right now is to ensure that digital EHR themes can be leveraged to actually improve the health and healthcare of patients. Next slide.

Again, there are various activities that the certification program does conduct, so I wanted to mention them briefly. As you all know, at the end of 2022, we had the epoch of our CURES rule finally coming online with certification required of all the technical requirements established in the CURES rule, and again, as you see here, over 98% of all the EHR products really are certified to the CURES requirement, and this is both a testimony to not only the hard work of the team, but I also wanted to thank the industry, because again, without industry participation working with us, this would not have worked, and understanding and interest in certifying their products, which, again, is a voluntary program, is really useful.

We also had put some **[inaudible] [01:40:55]** through ongoing requirements to ensure that certified health IT is still able to achieve the requirements for support through technical certification programs, and those were through the real-world testing and attestation requirements. Again, in the first round that occurred this year, we got 100% compliance, which is really awesome. That never happens. We are very excited about that. Finally, I think the HITAC team has heard about the Standards Version Advancement Program, which is really a way for us to make sure that industry can move forward and advance standards and not just wait on certification and regulation to catch up. We had over 45 developers take advantage of it. We could obviously improve on it, but it feels like we are on the right path of encouraging industry to advance to the new standards. Next slide, please.

Briefly, I wanted to mention what the certification program also does. It ensures that the technologies that are building to the standards are held to those standards by having a robust testing program, and I wanted to briefly mention that the test tools that are managed by the team are really a plethora of both those that are funded and developed by ONC because we saw a lack of market participation, and Inferno is an example where ONC actively supports and develops it, but we also work with various agencies, including

NIST, which has been a really great partner with us in building the best tools to support many of the requirements that are put **[inaudible] [01:42:40]** programs, so I want to acknowledge the work that NIST does. Also, we have been working with other associations, such as HIMSS, who are essentially industry partners who have worked with us to build industry input into the groups. Again, ONC's role is to make sure that testing capabilities to various activities are there so that when health IT is building standards, they are robustly tested, so that is some of the work that the team does. Next slide, please.

That was on the solution program. I will not belabor the work that the Standards Division has done on making health data standards become more robust. I think the HITAC team has been very deeply involved with the work on the United States Core Data for Interoperability, so all I will mention here is that we have had four versions of USCDI thanks to the input from HITAC. We do not accept all your input because, again, the balance that ONC does is to make sure that there is both an ability for us to capture the important elements and priorities, but also make sure that they are implementable and usable by the industry.

So, in some cases, we have not accepted all the recommendations, but trust that those recommendations are still there with us, and we are actively thinking of ways in which we can progressively use those recommendations and **[inaudible] [01:44:08]**. But again, I wanted to thank HITAC for the work that you all have done and the input that has really helped us make sure that these standards are in place and have grown sufficiently from Version 1 to Version 4, and as we speak, we are already in the activities towards building Version 5. Thank you again to HITAC for all your input in the work that we do with USCDI particularly. Next slide, please.

Not to be outdone, we also have a streaming service, USCDI+. Sorry, that is a little joke. We have an extension to USCDI, the USCDI+ program, that launched last year with really strong support and really under Dr. Tripathi's interest in making sure that the work that we do in standardizing data really expands to also include all the various programs and leads that may be required for specialty **[inaudible] [01:45:14]** status or other program leads that the government funds. I am happy to mention that the USCDI+ program, which started last year with quality measures, has expanded to several petals in this flower. The picture has become a flower. I never thought of this as a flower, but we are actively working with various agencies to expand the USCDI+ program, starting from quality measurement to include public health.

Also, you heard last month, I believe, from Kyle on cancer, so we will be working closely with research. We are also expanding our base to work with CMS on other activities, and also working with SAMHSA on behavioral health needs. So, we are expanding this program and we are encouraging and working with federal agencies to make sure that those activities get repeated, and if they work based off USCDI, those data elements can kind of be coordinated so that it is not piecework activities from different agencies. So, we are very excited about USCDI+. Next slide, please.

One of the areas within the USCDI+ program that I wanted to highlight, because it has not really made the news, is the work that ONC has been engaging with HRSA, the Health Resource and Service Administration, who are essentially supporting the use of health IT in areas that are underserved. The work that ONC has been engaged with over the last several years has been to build out the health IT platform that is used by the primary care providers to report back to HRSA on various quality measures. This is of importance to us because this is where standards come into reality, and really, the value and engagement of all the work we do with standards is to make sure at the end that we reduce burden, improve healthcare

quality, and ensure that providers at the end are able to spend more time with the patients rather than working on health IT.

This has been very exciting because the work that has gone through UDS, and just to address Clem's question, I will just get into it. UDS stands for Uniform Data Systems, and this is a program where all the grantees from HRSA report back to the HRSA agency on the latest quality metrics. The work that has happened is to help take those technologies using the latest FHIR-based standards about API standards that HITAC has worked on and helped recommend to make sure that those reports can be much more streamlined and easier for both the pitchers and the catchers, for the primary care physicians and providers that report it and for HRSA to process it. Again, in our nomenclature, we are calling this program the Uniform Data System LASS program, just to go with the feeling, but again, this is something we really hope will be a beacon to figuring out what else needs to be happening so that the value of health IT can really impact the provider and the patients in a better position. Next slide, please.

Up until now, I have spoken a lot about data standards, which are really important, because one of ONC's missions is better health enabled by data, but data standards also need to be aligned with some of the network standards. As you all know, we have different networks, and if they need to talk to each other, we have to establish a standard way by which networks can communicate. The Trusted Exchange Framework and Common Agreement has been, again, I won't belabor on the work that has happened, but we are excited to do that, and as everybody mentioned, this upcoming year, we will be releasing Version 2.0 of the Common Agreement.

Along with that will come the QHIN technical framework, which is the technical standards that underpin the TEFCA network. We will publish Version 2.0 of that framework, and it will include some of the requirements around using facilitated FHIR implementation guides, and again, this is all based on the work that happened this year in terms of building the standards, working very closely with our mass coordinating entity, but also testing those standards with many of the health standards organizations, such as HL7. The exciting thing here is that the team is also making sure that the base network standards for interoperability, on which TEFCA work will also be ready and be available for industry to put **[inaudible] [01:50:43]**. That is something we will be working on, and we certainly want to expand some of the participants to include other groups on top of providers in the future. Next slide, please.

Until now, I talked about the work that the Office of Technology does in data standards and networks. We talked about certification. But again, the common theme in all the work that we do is coordination and collaboration, both internally and externally. I will just say that all the work that I have mentioned here is a joint activity between the Office of Technology and Office of Policy. Every activity here, like USCDI, is basically a technical policy document that has both standards and a policy requirement.

So, on that note, a lot of what our office does is coordination, both internally and externally. I mentioned this very briefly in the beginning, but I wanted to emphasize that aligning health IT standards with various agencies is one of the highest priorities for us, and again, we have a whole group that is dedicated to supporting it, and we work a lot with various agencies to provide technical assistance to make sure that these existing standards that are adopted by the industry are known to them so they can leverage it as opposed to building or writing new ones. That is an area of coordination primarily with federal agencies and whoever their designees or grantees are.

I will not talk a whole lot about the cancer moonshot because we recently heard from my colleague Al and Stephen Konya from ONC on the work we do, but again, that is an area where a lot of ONC work is to make sure that we coordinate amongst the federal agencies because lots of federal agencies, including NCI, the National Cancer Institute, CMS, and CDC all have stakes in that activity in making sure that work gets reflected and coordinated across the industry and the health IT standards organizations, such as HL7 and other organizations that are building standards to it.

So, a lot of that work that the team does is to make sure that they are all aligned and are able to move in the right direction. We are also engaged with our Assistant Secretary for Planning and Evaluations team here at HHS on the Patient-Centered Outcome Research Trust Fund. That is a program that was established several years ago, and really, the main theme of it was to build data capacity and infrastructure, and some of the work that ONC does in working with our internal HHS agency team at ASPE is to make sure that they are able to reflect to them the needs that are coming through based on our experience with the certification and the **[inaudible] [01:54:07]**, so that is an area, again, where some of the coordination that happens is within the agency level, but really reflects a lot on the work that is happening **[inaudible]**.

Finally, a new activity that we have not yet published but is still in the works is this work that we call, which is to align all the federal FHIR investments that are happening across the federal agencies and industry, mainly the federal agencies, and this is a reflection that we had in the last year that several agencies are all interested in moving forward on FHIR standards, and the reflection was that it would be worthwhile for agencies to know what other agencies are working on which use cases and/or activities.

You could have CDC, CMS, and even ONC and the VA all interested in working and building off FHIR, and there was a reflection that it would be worthwhile for us to coordinate and make sure that if the use cases are at least aligned, we could all focus our investments in a concerted manner. This work has internally begun. We plan to publish something early next year for both public input and federal agency input, but it is something I am very excited about. This is something we heard from our HL7 colleagues who also work on the FHIR standards. They wish that there was one voice coming from federal agencies, and we hope that this document and the work that we do provides that activity. Next slide, please.

I have a few final things and then only a couple more slides. Firstly, the Leading Edge Acceleration Project is a program that we described previously to HITAC. This is where we are looking at some of the advancements in health IT to understand where the industry is moving. In the past, we have funded work on early incarnations of bulk FHIR, we looked at areas around semantic web, and there have been some interesting activities put in place. We have two areas of interest. In 2023, we have established two areas. This is an open-ended question to the responders to advance FHIR capabilities. We made a fairly high-level description of what advanced FHIR meant.

I am happy to note that we did actually award that LEAP grant. It is a cooperative agreement with Health-e-Link, which is going to leverage advanced FHIR capabilities to actually do advance care planning. Again, those programs are fairly high-level. We are not very tactical here or being very specific about the way in which they were **[inaudible] [01:57:16]**, and the idea of the activities is that they let us understand what is happening and what the challenges are in improving it, and are really the only kind of experiments for us to know where the standards lead to. So, we are excited about the work that is happening on exploring the

use of advanced FHIR, and also, we have begun focusing on data quality. I think you heard about it a lot. We actually recently had a virtual tech forum on data quality.

One of the areas that we have funded, which was awarded to Boston Children's Hospital, is to focus on data quality, and they are going to look at the USCDI data as an example of identifying the challenges and how to work on them. We are very excited about it. These are two-year programs, so we will learn the results in two years, but hopefully, we can get more information in the next year. Next slide, please.

So, wrapping up what Office of Technology does, I would put it into three buckets. One is the certification program. That is really the train that needs to keep running, so that is an area where we definitely keep our focus, and we will continue to do that as regulations come in and implementation happens next year. On the standards side, which is where HITAC also provides a lot of input and our teams work with the various acts process, we are definitely focused on data standards through all the various programs like USCDI and the USCDI+ program, but also working on network standards, including ensuring that the technical standards for TEFCA Version 2 and Version 1.1 all get formally established and introduced.

Finally, the biggest part of our work, which is really the most important, is the coordination within the agencies, across the agencies, and also with industry. Again, we feel we have a unique mandate, which is not just to focus internally on the agencies. Our mandate is to make sure that there is nationwide interoperability, which definitely cannot happen without industry participation. So, hopefully, this gives you a fairly high-level overview of the work that the team does, and I am happy to answer any questions you have.

Aaron Miri
Thank you, Avinash. Wow, that is an exhaustive list. Excellent job. It is very impressive, and we appreciate it. We only have time for two minutes' worth of questions, so let's be brief, as a lot of folks have questions. Ken?

Kensaku Kawamoto
Thank you. I will try to be brief. Excellent work. My main question was around the compliance certification. So, first, in our real-world use of some of these FHIR interfaces, one thing we have noticed is there are certainly things in USCDI that say, "You shall, if it is available, use the standard code set," and it is not. Encounter types are all local-institution-specific. I do not necessarily want it to get that deep because it will probably come down to health system levels to do that mapping, but looking at the real world, not just **[inaudible] [02:00:32]** etc., if the standard says, "You shall use it if available," which we find with labs and all that kind of stuff, I think that would be great to look at because in real-world use, for this kind of data, we often say that even though the standard in USCDI says it shall be standard, we are going to have to use institution-specific mapping. I think that would be useful.

As another part, I do not know if this is a compliance requirement, but I think speed is really important. There are so many of these interfaces that are so slow that could take a minute to pull past medications for a typical geriatric patient, and obviously, you cannot use it. So, I think information to provide or public reporting on it for real, typical patients would be useful, and there are similar kinds of things for bulk FHIR. A lot of vendors use the approach of using individual, patient-level queries that will take two minutes per

patient, and obviously, that does not scale. Even if you technically need requirements so you could theoretically pull 10,000 patients, it would take you a day.

Avinash Shanbhag
Thank you. Those are great points. I will just pick on speed because it has been the most recent discussion we have had. We are looking at various options, including, perhaps, having a workshop to understand where the challenges are, so we are actively working on that with industry vendors and also some in the standards community. Sometimes, standards are great, like FHIR, where the initial, first version of the standard was great and you could get all the data every time, and then, immediately, people realized that getting all the data all the time is pretty slow. So, again, I completely acknowledge that. Real-world testing is an area which we want to learn.

As I mentioned, this is the first open self-test we have given to the industry, so we have just gotten our first version of data from the industry on how well they think they did, so I will look into that data to see if we can tweak it in the future to be much more sensitive and be able to be transparent on some of the mappings that we know exist. You mentioned labs, which are a great example. We recently established exchange with LOINC, but we also know that many labs do exchange in local codes, and again, it depends on the scope of an institution. That is a place we want to look.

Aaron Miri
Thank you, Avinash. I appreciate it. Again, I am so sorry, Anna and Bryant. We are out of time for this section. Avinash, I am certain your information is available. We can reach out with further questions. Please engage then or during the lunch break so we can have this dialogue and feed this information back. We have to stay to time. So, with that, I want to transition to Mike Berry for the next section, which is the HITAC 2024 work plan. Mike?

HITAC 2024 Work Plan (02:03:47)

Michael Berry
All right. So, we are going to dive right in. I just want to give everyone an overview of how we developed the work plan for HITAC for next year. First, we take a look at all the meeting notes and transcripts from all of our HITAC discussions, we look at the recommendations that you have sent to us, and also the recommended activities from the HITAC Annual Report Workgroup. We consider the ONC's legislative requirements, our existing work plan, and even emerging issues when we are thinking through this. We did meet with the HITAC co-chairs to view the work plan and got their input as well. So, today, the goal is to just review these topics and the timing that we are going to meet with the HITAC on these topics and look for other opportunities for work for next year, and then we will have anywhere from 11 to 13 new HITAC members next year, so they will have a lot of interest in contributing to the work plan as well, but the plan is to review it once again at the January 2024 HITAC meeting and see if there are any updates. Next slide.

These are the target areas from the CURES Act that I am sure people are familiar with. The HITAC is helping us advance these priority areas on interoperability, privacy and security, use of technologies that support public health, patient access to information, and design and use of technologies that advance health equity. So, all their work has to fall into one of these buckets in order to stay in scope. Next slide.

I want to give a brief overview of the activities the HITAC has completed this year. The annual report for FY '22 was approved earlier this year. In February, the HTI-1 Proposed Rule Task Force submitted all their recommendations earlier this year, and of course, the Interoperability Standards Workgroup meets every year. This year, they met to talk about USCDI Version 4. So, later on today, I can move up the Pharmacy Task Force recommendation to the "completed category," so we are happy about that. And then, the HITAC Annual Report Workgroup, which Aaron and Medell co-chair, is finishing up their meeting report with all the members' input. They will be presenting the annual report at the January HITAC meeting, so that is in progress and expected to be completed later this year.

Here is a sketch of the work plan so far. As you can see, there are meetings planned for 11 months out of the year, so I have plugged in the date so that you have a reference. All the HITAC members should have all these calendar invites and holds. There is an opportunity to have a break somewhere, like in the summer. We have done that in the past. The HITAC Annual Report Workgroup will finish up in February with a vote on the FY23 report, and then they will pick up again in the May timeframe to start on the FY '24 report.

The Interoperability Standards Workgroup will meet when the USCDI draft Version 5 comes out for public feedback. That has typically been in January, so when that draft Version 5 gets released, we will convene the IS Workgroup to gather your recommendations on Version 5. We have USCDI+ on here, which Avinash recommended that he already talked about in his slides. One of the things we really would like the HITAC to dive into is the USCDI+ cancer domain. This is pretty time-sensitive for ONC and USCDI+'s team, so we are looking at opportunities to bring the HITAC into the fold. That is either going to be a separate Task Force or perhaps an additional charge for the IS Workgroup, so just look forward to that.

In addition, the HTI-2 will be released. The proposed rule is expected to be released sometime soon. We will see what the timing is on that, but we will reconvene the Task Force for HITAC members and federal representatives on the HITAC to take a look at that proposed rule and provide your recommendations. As for some other topics we are considering, once the HTI-1 rule is finalized, that will provide an overview to the HITAC on what is in that rule, and of course, we are going to look for opportunities to provide the HITAC for opportunities on TEFCA as well. Next slide.

So, here is the charge for the HTI-2 Proposed Rule Task Force. This is just the information that is currently in the unified agenda. The specific charge will be added to it once this rule is released. The recommendation will be due within the public comment period once that is announced. So, any HITAC member or federal representative of the HITAC that is interested in participating in this Task Force should send their name to me and Wendy on my team, and we will add your name to the roster. Next slide.

This slide is really a compilation of topics from the HITAC annual reports. As you can see, there are quite a few, and I do not think the HITAC or ONC is going to be able to get to all of these, but they are all important. We met with the co-chairs to talk through these to kind of structure the topics to indicate where HITAC could make the most immediate impact by providing their insight, expertise, and recommendations, so the ones in the top bucket there, the health equity data, the LTPAC one, consent management, sensitive data, and lab and pharmacy data, are the ones that are really top of mind for ONC, and that is what we would like the HITAC to dive into.

For example, on the second bullet of LTPAC community-based and social determinants of health data exchange and health and human service interoperability, we will be hearing a data update this afternoon as part of the ONC policy objectives, benchmarks, and data update presentation. So, that ties to that work. And then, for the fourth bullet, the lab and pharmacy standards, of course, the Pharmacy Task Force recommendations we have heard today will help inform potential future work for both labs and pharmacy standards, so we look forward to having HITAC's input in those areas. Those are the ones that, as I said, are of greatest need.

With the other one that is listed there, the HITAC co-chairs identified the second block in particular, and we will look for opportunities in that area as well, and the other ones listed below are further down. We wanted to document all of the topics that the HITAC has brought to their annual report process, and they are on this side. Next slide. I think that is it. That is a snapshot of what the work plan looks like. As I said, we will get your feedback today and then meet again in January to give you the final work plan. So, with that, I will turn it over to Medell to get the conversation started.

Medell Briggs-Malonson
Thank you so much, Mike. Thank you for providing an overview of all the exciting work that we as HITAC will be taking part in this year. So, we will open it up for discussion. Once again, if you have any thoughts or recommendations on this report, please put your names upright, or of course, if you are on Zoom, please raise your emoji hand. Any thoughts or additions to Mike's report? Jim?

Jim Jirjis
I just have a quick question on the USCDI anticipated Task Force. Did you say that would be focused specifically on cancer or the cancer domain to start with? Because they are working on that domain currently, and on others, but that is the one that we understand they are going to get the HITAC's input on.

Medell Briggs-Malonson
Any additional questions? Ken?

Kensaku Kawamoto
I think it was done with algorithm bias and transparency, but I think it would be great to have some deliberations on large language models. It seems there are some aspects of it that are not going, perhaps, as fast as they should, but maybe too fast. There are aspects of it that seem like they have not been encountered before, like the fact that even the model developers do not actually know why it is doing what it is doing, and the fact that it is nondeterministic, where you can have the exact same inputs and you have no idea where… You use the model a week from now, and it gives you completely different results from what it does today. So, industry is going to move forward. I think some industries might say things like, "Oh, these regulations do not apply because…" and just claim that regulations should not apply. We do not want to overregulate this and kill innovation, but I think it is worth thinking about, and it would be great for HITAC to look at that next year.

Medell Briggs-Malonson
Thank you, Ken, for that recommendation. We know there are multiple different levels of artificial intelligence, and it is moving very quickly through our industry. How do we make sure that it is used so that it is as safe, equitable, and fair as possible? Thank you for bringing up large language models.

Aaron Miri
And secure.

Medell Briggs-Malonson
And secure, absolutely, in every single way. We are learning so much more about how they are functioning in healthcare, so thank you so much. Anna, I believe you are next.

Anna McCollister
I think there were others before me, but I will go ahead and go.

Female Speaker
You go.

Anna McCollister
I just wanted to weigh in here and others that we addressed the large language models and some of that stuff when the recommendations were made for HTI-1, and if I remember, one of the things I was pushing for was making sure that stuff does not get entered into the clinical setting by certified health IT until the developers can actually explain the source of their information and the logic behind it. AI is critical. It is going to provide incredible benefits and innovations within health and technology, but before it actually gets inserted or uses data from clinical records, we need to really understand how that works because a lot of the uses of clinical data with AI have not really turned out all that great. But, we did put in our recommendation for HTI-1 that given the opticality of the subject, it needs to be addressed again in HTI-2.

Medell Briggs-Malonson
Thank you so much for that recommendation. Aaron is going to help.

Aaron Miri
Deven is.

Medell Briggs-Malonson
Okay. **[Inaudible – crosstalk] [02:14:35]**

Deven McGraw
Right on the left side, which is totally fine…not politically. So, the new topics are exciting, as are the continued ones that we have responsibility for. Is there an expectation that there will be additional workgroups created to handle some of these, and what is the general process for that?

Michael Berry
Yes, that is totally possible. We have not gotten that far yet. The topics, especially in the top block, are very timely, as you can see, so, whether it is a Task Force, or something incorporated into an existing workgroup like the IS workgroup, or a presentation to the HITAC, we are looking into what format we can bring these topics to.

Medell Briggs-Malonson

Thank you for that recommendation.

Deven McGraw
My only thought is that for some of them, there will be some necessary subject matter expertise, even among committee members and the public, that might not fit an existing group. Thank you.

Medell Briggs-Malonson
I fully agree with you, Deven. In fact, that was going to be my comment at the end because even, for instance, with the talk of health equity data, several of us straddle both worlds of health equity and data, but we are probably going to need to bring in additional experts that are purely health equity as well as purely, for instance, in the health IT world in order to be able to provide the most robust recommendations. Steven?

Steven Lane
I just wanted to highlight the comments about LLM. As noted, we did talk about that in our comments around HTI-1, and now we are going to see the final HTI-1 coming out, so I think there is a great opportunity, perhaps, to look at how that ended up in the final HTI-1, think about what the next iteration would be, planning ahead for HTI-3, for example. I think the idea of discussing that in a workgroup or Task Force and figuring out where we are now, where we are going, and what that next step would look like would make sense.

Medell Briggs-Malonson
Thank you for that as well, Steven. Eliel?

Eliel Oliveira
Thank you. I guess I wanted to highlight some of the things that we talked about in Avinash's report on the grade certification level that we have achieved so far, and thinking about the ONC and the fact that are all saying how the **[inaudible] [02:17:15]** should not be able to access that information, so the need that was some additional data access. I guess I have a combination of a question and a **[inaudible].** That is it is probably an opportunity now to have an additional certification tier for the systems and EHRs, and I know how hard that is, but at the same time, as you all know, folks are not necessarily going to do things without enforcement, and we know that. On the Information Blocking example, we have been trying that for so long.

But I wanted to use my Sentinel hat right now to highlight the fact that we have no sense of over-the-counter medications that are used or labs that are being done at home now, and that becomes very challenging. Please have inventory access to conversation with labs. It could allow us to get to that hole in the data that we are currently seeing. I guess the idea is a recommendation on expanding the certification criteria. I think we have it here in LTPAC, pharmacy labs, and probably **[inaudible] [01:18:25]**

Medell Briggs-Malonson
Yes, in terms of making sure that they are as strong as possible with the interoperability. Great points about all the other new integrated models that are out there that we are not capturing, which is just as critical to have in order to provide quality care. Wonderful. Aaron, I see your hand up front.

Aaron Miri

All right! So, I applaud the work plan. Excellent, ambitious strategy, and excellent work by the ONC to keep pushing forward. I would encourage the HITAC to continue to lean in on bringing the additional federal agencies in. like OCR, FTC, all the other ones who are also working on AI affects, hallucinations, and all the other items. I will put my privacy and security hat on. The waters are very muddy, and it is not clear where the ball stops, and as a covered entity and a provider health system, we often are approached with, "Oh, this the unicorn's tears. This will solve all the problems," an AI algorithm with no rhyme or reason, no reason to understand and believe the outputs, also no way to look behind the cloak to see how that algorithm derived an answer that could or could not be clinically viable for our providers, so the ONC's work here is critical as a convening entity to bring people to the table, to have those discussions, and to figure out where policy should live, who has jurisdiction, and how to drive that outcome.

Then, furthermore, as we look into the research area, as many of you also intersect with that, how do we do responsible and ethical research with data that is not biased? That is a critical area. I saw it on the workplan. I am very pleased to see that. The HITAC has a great opportunity to continue to drive that conversation forward. Remember what the charges of the HITAC are on privacy, security, interoperability, etc. Keeping that in clear line of sight, but having these crucial conversations and discussions, raises the issue to the top so that people can work on it. So, I applaud the work plan. I think it is very ambitious. It is excellent for this committee to be part of that, but also to drive the conversation forward. Thanks.

Medell Briggs-Malonson
Thank you, Aaron, and this is why we will miss you, but those are all great points. Ken?

Kensaku Kawamoto
I do think this is really moving fast. Lots of health systems are already moving forward with these in production. This stuff is going by now with a lot of health systems, responding to patients with auto-generated messages, things like that, summarizing patient charts using these large language models, etc., so I think it is going to be moving really fast. I think it has to stand up. I am not sure it should wait for 12-month cycles of review. It probably needs to move faster than that. One anecdote: I was talking to an employee who was building these GPT-based models, etc., and was talking about pretending to be patient talking about suicide, and it says, "Tell me more. How would you do it?" And then, the final answer was "That would be one way to do it." So, people can already get it now. You do not have to go to a health system to interact with these kinds of systems, but there is real potential for danger, though lots of potential for benefit, but the bottom line is this is already starting to get deployed in production and clinical settings now. I am sure of this, so stay on top of it.

Medell Briggs-Malonson
Ken, thank you for that variety of precautions like privacy and security, because we all know how gray an area it is. As I mentioned, the industry is moving very quickly, and that is the whole idea and purpose of HITAC in addition to supporting ONC with any additional recommendations, to really try to highlight when there are some areas we need to be very laser focused on, so thank you for that. Anna?

Anna McCollister
I have two quick points. Part of the reason that I got into health quota stuff to start with was frustration with quality measures and outcomes measures. There was an effort when Farzad Mostashari was head of ONC to get diabetes patients to talk about the importance of including patient-generated health data in electronic

health records systems such as blood glucose data, CBM data, and blood pressure data. All of the data that is collected and generated by patients in the home setting is not incorporated into the EHR. We know that is complicated, and it is a lot of data, and it is messy for a whole bunch of reasons, but if we are looking at really using these data sources for quality measure development, that kind of stuff has to start being included. I do not know what the technical process is for doing that. I certainly should not be the one designing it, but I would like to see, whether through this committee, ONC, or somebody at the state, a presentation focused on technology specifically. That has to be part of it if we are going to use this data for quality measures.

Secondly, at one point, maybe at my first HITAC meeting, though I do not remember which one, we started with the charges, and amongst the charges was diversity, equity, and inclusion, which is totally important. I cannot remember what the other ones were, but one of them was reducing industry burden, which was important, and I raised the point that it struck me that there was no focus and no part of the charge that looked at reducing the burden on patients, and I would like to revoice that.

I do not know if this is the proper forum for that, but theoretically, that is what this is all about, and my example with using the structured data around access and where things are in terms of inventory and that kind of thing is not typically within the health domain, but it is the kind of thing that ONC could bring in or suggest that we capture, as it is already being captured, to reduce the burden on patients because so with much of this stuff, the burden rolls downhill, and the cumulative burden of all of it is truly substantial. Sure, you get into the portal, but then you have to reset your password, and one little thing turns into two to three hours very easily because you have to interact with so many different things. So, I would like to raise that again and ask if we can add that to the charge because theoretically, this is all about patients, patient information, and data as a mechanism for promoting and preserving the health of patients, and creating tools that are overly burdensome and cumbersome on patients as well **[inaudible] [02:25:20]**.

Medell Briggs-Malonson
Anna, excellent comments, and I know if Aaron Neinstein was able to join the meeting today, he would absolutely second your comments about patient-generated health data. That is the reason why we added some of those aspects into the Annual Report Group, and if this is not the forum to center the voice of patients, I do not know what forum is, and so, thank you for that as well, because we do know that there is a large amount of burden that is placed on patients, let alone if there is any level of health data or health technology literacy challenge as well, and that actually adds onto it also, so thank you for that. As we proceed on for next year, we will definitely continue to center that, and I hope all of us continue to center the patient in all of our recommendations coming out of all of our various different workgroups. Dayo, you had a question.

Kikelomo Oshunkentan
It was kind of a comment. To echo what Anna said about capturing patients' health information in terms of glucose monitoring, blood pressure, and so forth, at one point, CMS was looking into PHR, personal health records, and attaching that to the patient portal for some EHRs. I hope that maybe we can revisit that because sometimes the data, the settings, and the glucometers are off, so to incorporate it directly into the clinical data gives me great pause. I think that would be one avenue to pursue in terms of making our data points richer so we can really take good care of our patients to see that holistic view of them outside of **[inaudible] [02:27:16]**. Thank you.

Medell Briggs-Malonson
Thank you for putting your placard up to give that. Thank you so much for that. I think we are just about at time. Mike, once again, and to the rest of the ONC team, thank you so much. We are so excited about next year. Did I miss Jim? See, I have blind spots, sorry. Please, Jim. Real short, as we are going into lunch.

Jim Jirjis
Since we keep bringing up where the patient is, maybe one way to do it… And I know you are not suggesting we should have the patient **[inaudible] [02:27:53]** but within each of **[inaudible]** part of the output could be a clear communication of how efforts in, for example, the pharmacy group if there was a section that, instead of it being tempered throughout, a section on each Task Force that actually deliberately reduces having directly **[inaudible]** patient uptake to improve a patient's… Maybe if we have a little bit of formality within each of them, it could help emphasize that.

Medell Briggs-Malonson
Jim, thank you for that.

Jim Jirjis
[Inaudible – crosstalk] [02:28:24] because in the Annual Report, etc., there could be a section telling how all these activities add up to **[inaudible]**.

Medell Briggs-Malonson
I think it is an excellent thought, and I think it is very important for us to be intentional when we are actually providing our recommendations, and I think it would be good to a section in all of our workgroups and our work moving forward and to hardwire intentional effort to specifically talk about our patients, the impact on our patients, and centering the voice of the patients and their caregivers. I am happy that my blind spot was revealed **[inaudible] [02:29:02]** provide that, and I am looking around one more time, and I am looking on Zoom. I do not see any more comments, so again, Mike and ONC team, thank you.

We are proceeding into lunch at this time, so, again, since I am the one ending up with all the housekeeping, here are the rules. Let me make sure I have all of them. Again, if you are going upstairs, we still have to be escorted. The cafeteria is upstairs on the eighth floor, which is the same as the penthouse. If you are going outside, you can actually leave the facility. Again, you have to be escorted outside, but when you come back in, you have to check back in with security, wait in the lobby, and then be escorted back up, so there are a couple more steps if you decide to go outside for lunch. Our next session is going to start promptly at 1:15, so if everyone can be back in the room in their seats around 1:10, we can start the second half of our amazing day.

Jim Jirjis
Leaving and entering the building **[inaudible] [02:30:00]**.

Medell Briggs-Malonson
Well, that is your job, to help them make it a little bit more efficient, right? Thank you, everyone, and we will see you back at 1:15.

ONC Objectives, Benchmarks, and Data Update (02:30:54)

Michael Berry
Hello, everybody. I hope you enjoyed your lunch break. We are going to get started with our afternoon session, and I will hand it over to our co-chairs to kick us off.

Aaron Miri
Wonderful. Welcome back, everybody. Hopefully you had an exciting lunch. We have a very packed agenda, so we are going to get right into it. Let's launch into it. Next up is the ONC objectives, benchmarks, and data update with Seth, Wesley, Chelsea, and JaWanna. Welcome.

Seth Pazinski
Thank you, Aaron. We were all doing our vocal exercises before this, so hopefully we are speaking loud enough for all to hear. I am Seth Pazinski, Director of Strategic Planning Coordination at ONC. I am going to go over ONC's objectives and benchmarks. This is a CURES Act requirement. Really, the intent behind this is to inform you all of what is happening at ONC and what the plans are for the coming year, and to give insider information into the HITAC's work, particularly the HITAC Annual Report. This presentation gets incorporated into that document.

You have heard a lot already today between Micky, Avinash, and Mike talking about plans coming up for things in the works, so I will try to be efficient in going through that and then hand it off to my colleagues Wesley, Chelsea, and JaWanna. They are going to take a deeper dive into some of the findings and work that ONC has been doing in the social drivers of health space. You saw that best when Mike presented earlier about one of the topics that was in the priority list for HITAC in the coming year, and this is in that area, so we thought it would be good to do a bit of a deep dive and share what these plans are to impact work in that topic in the future. Go to the next slide.

As I mentioned, this is a CURES Act requirement. For our objectives, we build off the 2020-2025 Federal Health IT Strategic Plan. That plan is another statutory requirement from ONC, and that helps define the direction overall for the federal government with regard to health information technology development. We can go to the next slide. So, ONC has two objectives. Again, these are built into our federal health IT strategy to advance and develop the use of health IT capabilities on the tech advancement side, and there is the second objective around establishing an expectation for data sharing. This is where TEFCA or Information Blocking policies come into play. Go to the next slide.

So, we group our work broadly within these four buckets: Standards, certification, which you heard a lot from Avinash earlier about our activities in those areas, exchange, which brings in some of the policy components and expectations for data sharing, and then coordination, which really cuts across all that we do. Go to the next slide.

One of the areas I also want to focus on in this presentation is trying to connect the work of ONC to the priority target areas from HITAC, of which there are five, and those are communicated through the HITAC Annual Report. One area that was recently added was around health equity, so, in that space, I am just highlighting some of the work that you all are familiar with through USCDI and some of our other standards activities, as well as a program that ONC implements that is focused on public health informatics workforce

in a program that we trained over 1,300 students as of October of this year. That is continuing on over the next few years. We can go to the next slide.

So, we will not spend much time on USCDI, as you guys are all very familiar, but we will go into the next slide, which is USCDI+. The main thing I will highlight here, as Mike Berry mentioned, is the USCDI+ cancer space, which you all heard about recently. That is an area where we are anticipating some work for the HITAC coming up next year. We are working on finalizing when and how to approach that, along with the USCDI Version 5 draft that the HITAC will be working on as well. Next slide.

So, there is also a lot happening in the standards space that we have done, such as our big old turn of the crank with the SVAP standards, and I wanted to highlight some areas. Avinash talked a lot about FHIR in his presentation, so we will be highlighting a few things happening in that space, but we also want to highlight public health, which is another HITAC priority area as well as a HITAC Task Force to provide some recommendations. For our public health activities, this gives you an update on some of the standards related to public health. We can go to the next slide.

Also, Avinash talked about this. This is our policy of how we are leveraging both from a regulatory standpoint and an investment standpoint across the department. We are looking to leverage the government, particularly HHS, and its investment efforts into health IT to make sure we are using that to help adoption of HHS-adopted standards, so that work is under way, and we will start to work with our partners, both through providing technical assistance to our partner agencies within HHS as well as just to identify the scope of Health IT investments from HHS agencies. We can go to the next slide.

Here we have certification. One of the things that is interesting here that we talk about sometimes at ONC is the long tail from when a policy is put into place to when you see that impact on the ground. One thing I will highlight here is the work that the committee did back in 2019 with regards to the ONC CURES Act final rule. We are really starting to see some final aspects of that work coming to compliance. So, the big theme in space that we saw was the first round of results for real-world testing, and we also saw certified API technology and the certification **[inaudible] [02:37:35]** available over the past year. So, it can be a long window at times to see those results on the ground, but they do come to fruition. Next slide.

We have heard a lot about TEFCA, and there are certainly some communications from ONC in this space and exciting events to come that Micky talked about at the ONC annual meeting. We are looking to celebrate TEFCA going live and the first set of QHINs going live, and a lot of work has been put into putting that infrastructure in place and getting ready for data to start moving through the QHINs. Go to the next slide.

So, I will talk a little bit about information blocking. You are going to get an overview of the rules, so I will not spend too much time on this slide. You will get more details on that in the upcoming presentation. I am going to jump to the next slide. We are now in our third fiscal year since Information Blocking complaints became available, and so, as you can see, it is trending up as far as the number of complaints we have been getting through the ONC complaint process. That is for the first three years. The trend has continued as far as the majority of those complaints coming from patients through their third-party support, and the majority of the alleged information blockers are identified as healthcare providers, so that has been consistent with what we saw last year. Go to the next slide.

Jim Jirjis
Could I ask a question?

Seth Pazinski
Sure.

Jim Jirjis
Go back a few slides. On the 30% of complaints that come from patients or a representative **[inaudible] [02:39:25]** for most of those **[inaudible]**.

Seth Pazinski
That is a good question. I can pull it up and find out. **[Inaudible – crosstalk]**

Jim Jirjis
So, 30% of the complaints were from patients or a representative of the patient. I was just asking if the majority of those came from organizations on behalf of patients filing complaints or if the majority are actual individual patient complaints. **[Inaudible] [02:39:53]**

Seth Pazinski
Feel free to jump in. **[Inaudible – crosstalk]** Stick to the plan, all right. Speaking of plans, we have the FY '24 plan. Go to the next slide. So, just looking ahead of this a little bit, as you all know, the HTI-1 final rule is on our unified agenda to come out, as well as HTI-2, so those are the two significant rules, along with the provider disincentives rule-related Information Blocking that you will hear about later. Go to the next slide.

So, on continued work on health equity, as I mentioned, we have what we call the FIT program, which is related to the public health informatics workforce. That continues, so we are looking to increase the number of individuals who are trained for that program. Go on to the next slide. You heard about USCDI Version 5, which will come out next year, and that will be a focus for the committee, and then, again, the USCDI+ cancer initiative is another area we will be looking for HITAC feedback on next year. Go to the next slide.

So, ONC continues to be busy on a variety of efforts around maturing and increasing the adoption of FHIR standards, including several IGs related to FHIR, including the bulk data IG. Go to the next slide. The thing I want to highlight here is not an ONC rule, but an HHS rule, and the agenda for this is in the secondary financial resources. This is around standards for health information technology, and this is, again, a step in leveraging the department's investments and driving HHS-adopted standards for its investments, so that is something that is on the agenda to note as a proposed rule. We can go to the next slide.

So, highlighting a couple areas in the public health standards space, one of the things to highlight there is looking for ways to incorporate the USCDI+ work into standards development organizations as well as the FHIR **[inaudible] [02:42:27]** development. Go to the next slide. So, looking ahead, again, tying back to several years ago and the committee's work on the ONC CURES Act proposed rule **[inaudible]** going to be finalized. The next significant regulatory models in there will be related to functionality for EHI export criteria, which requires that functionality to be available to users by the end of this calendar year. Go to the next slide.

So, for TEFCA, you have heard mention of the go-live that is anticipated next month, in December, but also the release of the next version of the common agreement, which will incorporate a pathway for FHIR standards. Next slide. I will not go into this, as you will hear more about it in the next presentation, related to both the OIG final rule and the HHS rule disincentives for healthcare providers that have committed information blocking. On the last slide for me before I turn it over to my colleagues here, these are just the five areas that come from the HITAC Annual Report, starting with the three priority areas that are defined in CURES, which are interoperability, patient access to information, and privacy and security, and the two that have been added by the committee over the past years refer to health equity and public health. With that, I am going to turn it over to Wes Barker from ONC, who is going to start into that deeper dive on social needs.

Wesley Barker

Great. Thanks, Seth. I am Wes Barker, the Branch Chief for Data Analysis at ONC. I will try to kick things off by doing an overall data update on the work that our team has accomplished in the past year, then I will turn it over to Chelsea Richwine and JaWanna Henry to do some more comprehensive reporting on analysis and research done on social needs data collections. Next slide. So, as I said, I will give an overall data update really quickly, then turn it over to Chelsea, who will take a look at some of the analysis and research we have accomplished in the past year through different inflection surveys, specifically on social needs data collection and use, which includes perspectives from both patients and providers, and then, Chelsea will turn it over to JaWanna Henry, who will report on outcomes of a recent project, a collaboration with the Open Note Project, patient and clinician perspectives in the collection, usage, and sharing of SDOH data, providing some more granular understanding of how individual patients and clinicians feel about SDOH collections this year. Next slide.

So, taking a look back over the past fiscal year, which ended September 30th, the data analysis team accomplished a lot, and you can see the topic areas that we did formal publications on. You can see we published a data brief, we had seven academic papers published, we published 16 ONC Buzz Blogs, which is a lot, one of three blogs that were published all of last year, so we were very busy putting out results from our analysis work and all the research we have done over the last few years with a lot of these topics, so if you have not checked them out, please do. Go to HealthIT.gov/data to find all our data briefs, quick stats and analysis work, and obviously, go to the Buzz Blog to find our Buzz Blogs. Next slide.

So, we are in the midst of FY ’24, and we are already hard at work at putting our work out. Chelsea and our colleague Katherine have already put out completed analysis work on HINTS, which is the newest survey from NCI that reports out individual Americans usage of health information and access to health information. So, we released a data brief just a few weeks ago that reported on that latest data, and we are hard at work continuing to report out on the latest data from HINTS.

Stay tuned in the next week as two papers are published on that data. **[Inaudible] [02:46:51]** we are also going to be taking a look at some new topics and recurring topics from the data collection from **[inaudible]** to the American Hospital Association survey, a recent survey of health information exchange organizations, as well as a new data collection block agreement with the American Board of Family Medicine. And so, you can see the topics there. They cover the gamut of the topics that Seth had talked about in terms of the agenda objectives and benchmarks that ONC is planning for in the next year, so we look forward to reporting

out on all these topics in the coming year and coming back next year to provide another data update to see how far we have gone. I will now turn it over to Chelsea for her presentation.

Chelsea Richwine

Thank you, Wes. As Wes mentioned, ONC has access to a number of data sources on social needs data collection and use, and today, I want to highlight findings from three different national surveys that provide perspectives from both patients and providers. Next slide. So, the first is a survey of hospitals that comes from the 2022 American Hospital Association IT supplement to their annual survey, and it asks about hospitals' collection, receipt, and use of data on patients' health-related social needs. The second is a physician survey that comes from the 2022 National Physician Health IT Survey, and this one asks about office-based physicians' method of documenting social needs training in their EHRs, as well as their perceived importance of having access to this information electronically. The final survey is a patient survey, which is really a 2022 Health Information National Trends survey, a survey of individuals, actually, and it asks about comfort with providers sharing information about the social needs collected through screening and patients' comfort with sharing with other providers for their treatment purposes. Next slide.

So, I will dive right into the hospital results. These are from the American Hospital Organization IT supplement. This figure is showing hospital collection and receipt of social needs data from outside sources in 2022. So, in the first column, we see that in 2022, most hospitals, about 83%, reported collecting social needs data internally, and just over half, about 54%, reported collecting this information directly. In the second column, we see that a majority of hospitals, 60%, also receive social needs data from outside of their hospitals and patients. Next slide.

This figure is showing the different methods and tools used for social needs screening among hospitals that reported collecting data internally. So, overall, we see inside of the figure that a majority of hospitals, 74%, reported using a structured electronic screening tool for the social needs data collection, and among those doing so, they are using either a customized or homegrown tool, an externally established tool, or a combination of the two, so, a modification of this tool. Going back to the left-hand side, in addition to a structured electronic screening tool, 29% also used diagnoses codes, and both of these methods are those that would likely result in structured data that would then be able to be exchanged and used. Beyond this, 36% used a free-text note, an unstructured note, for collecting social needs data, and 20% were using non-electronic methods. Next slide.

So, as I mentioned in my first slide, a majority of hospitals, 60%, reported receiving social needs data from outside sources. Forty-six percent reported receiving this information from health information exchanges, so that was the most common cited method of receiving information from outside sources, but hospitals also received data from other healthcare organizations as well as community and social service organizations. Next slide.

So, finally, this last slide highlights the different uses of social needs data collected internally or received from outside sources. While the rates differ, the most common uses were common across the two, and the most common uses were for uses such as informing discharge planning, informing clinical decision making, and making referrals to social service organizations, so, really to the benefit of the patient, but there were also uses reported, such as informing community needs, assessments, or other equity initiatives, as well as for conducting population health analytics. Next slide.

I will transition now into the physician survey results. Next slide. Similar to the hospital survey, there is a question asked in this survey about physicians' collection of social needs data, but this is specifically methods of collecting data in the EHR. Overall, in 2022, 63% of physicians indicated they use at least one of three methods to document screening in their EHR, and the most common was using clinical notes or free-text notes. So, 89% of those documenting in the EHR were using free-text notes to collect social needs data. A little over half, 54%, were using methods that result in structured data, such as check-box, button, or diagnosis code, 30% and 41%, respectively. Next slide.

The next question related to social needs data collection and use in the physician survey was asking physicians about their rated importance of accessing or having access to social determinants of health or social needs information electronically in their EHR or in electronic **[inaudible] [02:52:46]**. Overall, most physicians reported that it was very or somewhat important. However, it is worth noting that this varied by specialty. Primary care physicians had the highest rating of importance of accessing social-determinants-of-health information compared to medical or surgical specialists. It is also worth noting that only about a third indicated it was very important, and about 50%, half across the board, indicated it was somewhat important. This question really sheds light on whether physician perceive it is important and kind of sheds light on whether they are using this information in their normal practice to do things like important clinical decision-making or to refer patients. Next slide, please.

Finally, we will get into the patient results. So, the last two sets of slides are really getting at providers' and hospitals' collection and use of these data, whereas the HIMSS data set speaks to the patient side of their comfort with this information actually being collected and shared for their treatment purposes. And so, this figure here is showing individuals' comfort with their providers sharing information with each other for their treatment purposes related to three specific social needs. This is for food insecurity, transportation issues, or housing instability. Across the board, we saw about 6 in 10 individuals nationwide reporting they would be comfortable with this social needs information sharing, so while this is a technical majority, there are still roughly 40% that express some level of discomfort with this information sharing. Next slide.

We also see that comfort with information sharing varied by whether individuals actually had a recent experience with that social need, so the way the question was phrased in the first slide was "If you were experiencing this issue, would you be comfortable with it?" This analysis is showing that if you said that you experienced that social need in the last 12 months, are you comfortable with your information being shared, and we saw across the three different social needs that rates of comfort were actually lower among those who experienced the social need. Next slide.

We also saw that comfort with social needs information sharing was lower among individuals who had negative experiences in the healthcare system. So, individuals who reported experiencing discrimination in care, reported little or no trust in the healthcare system, or felt that they received an average or poor quality of care all reported lower rates of comfort with their information being shared compared to those who had more positive experiences in the healthcare system. Next slide.

I will try to wrap it up by pulling all of this together. Together, these three data sources provide three very different, unique perspectives on the collection and use of social needs data in both inpatient and outpatient settings. First, we see findings from the hospital survey that show that hospitals frequently screen for need

and are using the data to inform clinical decision making and connecting patients to resources, but also to conduct population health analytics and inform community needs assessments. Finding from the hospital and physician surveys also indicate that structured data collection, which can help facilitate the exchange and use of these data, is more prevalent in hospital settings. We saw higher usage of structured data collection techniques in the hospital settings, whereas free-text note data collection was more common among physicians.

Finally, findings from the patient survey suggest that while a majority of patients are comfortable with social needs information sharing, there is quite a bit of variation here. Comfort varies based on personal experiences, so there is certainly a lot of room to grow here. Ongoing measurement will be important for tracking progress in social needs screening and documentation, particularly using methods that would support the exchange and use of data and informing efforts to increase patient comfort with social needs information sharing, particularly in confidence that data collected are being used to help them get resources they need. I will pass it on to JaWanna to talk about this a little bit more.

JaWanna Henry
Great. Thank you so much, Chelsea. Could we go to the next slide? So, Chelsea shared some of the survey or quantitative data on the hospital selection, exchange, and use of SDOH data, methods physicians are using to collect SDOH data, and their perspectives on the importance of collecting that data. Additionally, she shared the survey results related to the patient's comfort in sharing SDOH-related data. I will now share some of the qualitative data on patient and clinical perspectives related to collecting, using, and sharing SDOH information. I will share perspectives from individual participants across various demographic groups. These perspectives are not meant to represent perspectives of that entire group or be considered generalizable. However, it is information that I will share today to give you insight into the quantitative data that was previously shared. Next slide, please.

Before I get started going into some of the details of the project, I do want to say thank you to the entire project team, our folks from ONC, as well as Open Notes, who are working tirelessly on this project to make this work happen and to be able to have these results to present to you today. Next slide.

So, the purpose of this project was to understand how SDOH can be more effectively captured and utilized to improve care. So, you will see the three goals that we have here. Understand that the project team started out by doing an environmental scan, so they did a scan of the literature for current documentation practice of SDOH, and they also looked at patient and provider perspectives of SDOH's role in EHR. Some of the things that we considered in how to structure this product and some of the questions is understanding that SDOH can be captured or not captured in an EHR at all and is not in a standard and useful way. Also, how they are captured in an EHR can better enable their use for improving care, and lastly, we try to understand the hopes and concerns of both patients and providers in collecting and sharing this information. Go to the next slide.

I will really focus on our focus groups that we did for this project, and so, we had our patient groups as well as our provider groups, so you can see here that we had 10 live patient groups that were conducted virtually, and you can see some of these patient groups that were used to collect this data participate in those focus groups. And then, for our providers, we had 10 asynchronous healthcare professional groups that were conducted virtually, so you can see those different provider groups listed there. For our providers and for

our patients, we had at least 100 participants, so overall, we had about 200 participants for our focus groups across this project, and this is just a reminder that as I start getting into some of these perspectives, these are individual participants, and this information should not be used to generalize the results to the population. Next slide.

So, in these focus groups, when they started talking with the patients, patients were asked about their experiences with being asked about SDOH. In addition to food, transportation, and housing, if you go to the next slide, many of those focus group participants were okay with being asked about transportation problems and safety, but you will see here that there was some disagreement with whether they were okay with sexual orientation, and what they definitely did not want to be asked about was their income. Go to the next slide.

You may ask yourself why, so this is where we get into some of the perspectives that were shared. So, looking at some parents and guardians, there was a theme around fear and trust. A participant from the Black patient group indicated that as they may be sharing this information about their income or provided financial information, it may come across as her not be able to financially provide for her kids, so there is this fear or concern that someone would contact Child Protective Services and have them show up at her door. A participant from the care partners for children's group said something a little different, saying that having that data collected made him happy, but there was still concern among folks that training was provided to those people who were collecting that data so that there was not bias based on those in payments about the patient, and noting that that can change from provider to provider as that information is shared. So, again, they were generally okay with it being shared, but they were also wondering who would receive it as well. Go to the next slide.

Just continuing on, talking about that fear and trust related to ambivalence about sharing that information, we also heard from another participant from the Black patient group indicating that when they go into their doctor, when they think about their relationship with their provider, they do put their trust in that provider, but there still was some concern in sharing that information because you do not know who knows who and where they are getting their information, so there was some concern. Another participant from the rule group indicated that if it is not relevant to the care needed, they did not think it should be shared. Lastly, just for this slide, we had a response translated into English from a participant from our Spanish-speaking patient group that everyone should decide what information to share or not, and they also included that whoever is asking for that information should explain what and why that information is being collected. Go to the next slide.

Continuing on with some additional points about sharing that information, again, going back to fear and trust in sharing that information, this person, another participant from our Black/African-American patient group, said it is always up to the person if they share that information or not, and for them, it was about having more options rather than none **[inaudible] [03:02:54]**, indicating that they may be going through something and not realizing that some of that information that is being collected actually impacts their health. So, for them being asked the question or having it within their chart, their response was "Wow, maybe this is something that is affecting."

And then, there was a response from a participant from our patients with disability group. One of the things you saw in an earlier slide was that disagreement about sexual orientation and gender identity. This

participant indicated, “Obviously, not having to reintroduce my gender identity and sexual identity to every doctor that needs to know, it would be nice. Not having to come back out every couple months would be great.” So, that gets to having to constantly answer the same question as a patient. Go to the next slide.

In general, I have given you some perspectives on fear and trust and the ambivalence that these patients have about sharing their information, so this is kind of a recap of the themes we have heard from some of the patient groups. At the end of the day, they want control of what is shared with others. For them, yes, they get the paper, and they are asked to sign it, but there is still some misunderstanding in that information that is shared. They would like to designate who they can share the information with and who can share it, so there is just this tag from specific to individual data element. They also only want the information that is relevant to be shared, and again, that is with permission. They do not want information shared with clinicians who rarely see them.

Lastly, there is still that concern about bias. You heard all of these things and some of these perspectives that I have shared from the patients, and just for the patient section, if I am accurate with my slides, I just want to close with this quote. “I think that I would like to know if this information is being shared, and to whom. There ought to be a hide button with each social determinant answer to keep some answers confidential to other providers.” That was someone from our inpatient group. Oh, I do have one more slide. Next slide.

One of the things we also wanted to capture was looking at some of those barriers for providing and sharing SDOH information. So, when you look at this table, you will see a column for providing and a column for sharing. As you go through the different roles, you will see again that these are some of the perspectives that I shared. The thing I want to highlight from this slide that was not in some of the slides that I showed previously is that one of those barriers is digital literacy or that digital divide, and in addition to that digital literacy or digital divide, just noting that this is related to electronic data collection through a portal or an app. There is also the issue of that primary language being something other than English. That is a barrier to providing information from our patients. Go to the next slide.

So now, as I did not want to leave you with just talking about our patients. I wanted to provide some perspectives from our healthcare professionals as well. Generally, they agree it is important to ask about SDOH, but one of the things that also came up is that most of them, at least of the ones that we heard from, do not explain to the patients why they are asking for or documenting that information. Next slide.

For our healthcare professionals, I just have two slides with tables, again, focusing on those barriers that are related to EHRs. So, here, I will not go through each item one by one, but you can see these differences in those barriers when it comes to collecting and documenting, and then there is that barrier where we are talking about utilizing. The one thing to highlight here, which is obvious, is this one around utilization. It is hard to use the data if you cannot find it, so that is one of the key things that we found from that provider group. Go to the next slide.

I will not go through each one of these roles because you all can read it. It is very clear, again, that some of these barriers are not related to EHRs, so you can see the ones for collecting and documenting, and then you can see the ones for utilizing, and I did want to share some background on a couple of the ones that are listed here. From a time perspective, this mainly focused on mentioning time for clinicians and staff

to actually collect, review, assess, and figure out what to do with the information. You may say that that sounds familiar, but in addition to that, there was also this idea of being able to have time for professionals to actually develop relationships with their patients. Of course, when you look at EMRs, there is this lack of a standard process in the EHR, not just a standard, for collecting that information when we are thinking of those processes in the clinic for using the information. The last thing I want to touch on on this slide is the lack of awareness. This lack of awareness is more about understanding or being aware of the value of SDOH and what we actually can do with the information. That is what we heard. Next slide.

So, here, I just wanted to provide a recap of what I have shared from our patient and provider perspectives from these focus groups. Going through the list, patients consider certain types of SDOH as sensitive, so they express concern about how this data could be misused or used. Again, this is highlighting that digital divide and those language barriers, and this goes along with other factors for patients who are able to provide that SDOH information. From our providers, this looks at that limited time as well as staffing, again, that lack of awareness, and additional resources were barriers for providers in collecting and using SDOH data. That was not related to EHRs.

When it comes to the EHRs, some of the barriers to collection and use were the standardization of workflow and the digital literacy from our providers. They experienced these barriers in collecting SDOH information and using the EHR. This slide is really just this 10-minute presentation to highlight how providers and patients agree on the need to share data between each other, and there are concerns and challenges that may inhibit that sharing. So, what I have shown is that there are opportunities to improve the development and workflow, as well as education for our patients and our providers. Again, this was a short presentation, but there will be more information and a deeper dive into one of our sections at the annual meeting.

Medell Briggs-Malonson
Excellent. Thank you so much, Seth, Wesley, Chelsea, and JaWanna for this wonderful presentation. We will now open it up for discussion. Please let us know… On this side **[inaudible – crosstalk] [03:10:07]**. Okay, it was Hannah, then Bryant? Oh, it was Bryant, Hannah, Shila, Sarah, and Steven.

Aaron Miri
We got it.

Medell Briggs-Malonson
Okay, thank you. Bryant?

Bryant Thomas Karras
Thank you for saving all the questions until the end. Now I have to remember what I was going to ask. I think this question goes first to you, Seth, but it was brought up by several of the team members as a thread, both in the plan you listed and the Public Health Informatics Treating Program, the PHIFP grant. Is there any evaluation going on? You mentioned the success of many graduates that have already come out of that, and it is continuing. Is there any evaluation of how those graduates are successfully finding positions in public health agencies and meeting the need of the known gap? And then, we still have more gap. Are there thoughts about continuing or expanding the number of institutions that are offering those trainings and going beyond the initial four or five years that were planned?

Seth Pazinski
Maybe Elise wants to step down.

Elise Sweeney Anthony
I am happy to take it. So, we are really excited about the PHIFP program and the progress it is making. It is in the **[inaudible – crosstalk] [03:11:42]** program.

Bryant Thomas Karras
The first graduates?

Elise Sweeney Anthony
Yes, so we are continuing forward with that. Each of the consortia there **[inaudible] [03:11:50]** not part of the program are analyzing and keeping data on how the program is progressing. In terms of whether to further expand the program, at this point, I do not think they are expecting that further funding would be available to support the continuance of the program past the time that is allocated. We are looking at different ways… As part of the funding opportunity that was placed, there is a component related to sustainability, and our hope is that the funding that we have provided through this program can lead to a sustainable program over time, but there would not be additional funding at this point to expand the program as far as we are aware. The sustainability part of it is something we are going to have to **[inaudible] [03:12:36]**.

Bryant Thomas Karras
I have a quick follow-up. It reminds me of the anthrax attacks back in the 2000s. There was an investment that the National Library of Medicine made in public health informatics training, and it lasted for four short years and then disappeared, so we had a four-year surge in graduates that did that, and then they disappeared. There was a sustainability requirement for that too, but it just never happened.

Elise Sweeney Anthony
Yes, the sustainability part is something we thought about even in the development of the funding opportunity, which then obviously **[inaudible] [03:13:19]** as well, so we are hoping that that continues. The way the program is set up is there are different types of educational opportunities that are placed through this depending on what each grantee said they wanted to do with the resources, but there is a curriculum that attaches to that, so our hope is that there is continued excitement for participating in the curriculum and taking these courses beyond the time period of the program, but sustainability is something we also **[inaudible] [03:13:49]** as well. It is an important area for health informatics, and as Seth mentioned, there has been tremendous progress already.

Medell Briggs-Malonson
Thank you so much, Bryant and Elise, for that. Hannah, you are up next.

Hannah Galvin
Thanks. I just have a brief comment for JaWanna and the team. Thank you for providing this very important and helpful data. There are a number of resources not used, which is this most recent data. This really drives home some of the issues that we have been challenged with and are tackling around giving patients control and allowing patients to drive their own data sharing and control over who has access and privacy

preferences. You may be aware, as I believe it was mentioned in the ONC blog, that Pew Charitable Trust also did a similar series of patient-focused groups that came up with similar conclusions around social drivers data, that patients do want to share data, but have a lot of concerns about how that data, specifically this type of social drivers data, could be used and **[inaudible] [03:14:59]** around who it is shared with. I think it is really important to have **[inaudible]** in the patients, and so, I applaud you on that really important work that your team has done with Open Notes, so thank you for sharing that.

Medell Briggs-Malonson
Thank you. **[Inaudible] [03:15:16]** Shila?

Shila Blend
Thank you, team. This has been great. Nice presentation, with a lot of data. My thoughts again, with the privacy **[inaudible] [03:15:28]** because as social drivers of health have been **[inaudible]**, we have heard "This is great. We are going to be able to help the patient more knowing this data." But privacy is an important aspect. A lot of it really needs some of the discussions had around the 42 CFR Part 2 data, where you would think in our profession that this is to help the patients. We are beyond that, but in many settings, there is a real concern sharing that. I come from a rural state, and there are a lot of hospitals around me where, when you walk into a hospital, the person knows you, or even if that is available, they can look it up and say, "Well, I am having trouble affording food." That can make it difficult for a patient to want to share information or their mental health aspects, as well as, as you talked about, the bias. So, I think it is something that we really need to take into consideration as we move forward with social drivers of health really push for. Thank you for that.

Medell Briggs-Malonson
Thanks, Shila. **[Inaudible]** aspects of it as well. All right, Sarah is next.

Sarah DeSilvey
Thank you so much, ONC friends, for **[inaudible] [03:16:46]**. It is very, very near and dear to my heart as the Gravity Project technology director. I have a methods question on the physician survey. I am specifically just noting that in some instances, the physician survey **[inaudible]** by the provider types, and thinking about the fact that, in many settings, it is the clinical social works, nurses, nurse practitioners, or **[inaudible]** providers who are doing direct care regarding SDOH and social needs, so I am specifically wondering about the methods of the included providers in the physician survey, especially within the context of the vast role in the complex care team of nurses, NPs, and social workers, who do a lot of direct care regarding social determinants of health.

Chelsea Richwine
We actually were just having a discussion about this right beforehand. It is an inherent limitation because it is a survey solely of the physicians themselves, and so, some of the questions, particularly in other parts of the survey, where we are asking about use of health IT, there are a lot of "don't know" responses. So, it is an inherent limitation, and we were just talking about whether we can expand it a little bit or even ask a question in these physician surveys like "Who at your practice is responsible for collecting this information?" That would give a little bit of level setting or context for these responses. We do see "don't knows," and even a yes or a no gives a little bit more context, but those are really important things.

Medell Briggs-Malonson
Thank you for that question, Sarah.

Steven Hester
[Inaudible] [03:18:15] we think about the SDOH interactions in healthcare, I think a significant potential to really make a shift in what we do in terms of how we treat patients. This is a real opportunity in terms of looking at change and addressing some hard topics. One of the things that we **[inaudible]** CMS questions to learn a bit about that in our health system, and one of the big pieces on that that comes across is that, though it is not easy anyway, the data is the easiest part in the sense that getting the question asked and asked appropriately with the emotional intelligence that has to come with that is a big deal, and it is really hard to even take all of us in this room and say we are going to standardize that and do the same thing because that emotional response becomes so different with patient interactions.

So, whatever we do, moving forward, we need to keep that in mind because lots of times, those commissions want to ask those questions, but on the back side of it, if you do not have a plan for getting the answer that was unexpected, not just one, but if you go through a list of questions, you may get 10 out of 10 with some answers you did not expect. Not knowing how to handle that can be a real barrier for patients from a trust relationship standpoint and sharing that information with anyone else going forward, and so, this is just a **[inaudible] [03:19:44]** of this, but I think it is a really delicate topic. How we take this on and just implementing rules before we figure out how to do some education around that and support what it looks like on the back end to take care of patients.

Medell Briggs-Malonson
[Inaudible] [03:20:02]

Chelsea Richwine
I will just add briefly to that. I will say that one thing that we are looking at is we have a paper in the works right now looking at whether screening rates and uses of data are higher at hospitals that have programs or strategies in place to actually address the social need. **[Inaudible] [03:20:20]** which is really promising. Hopefully, that paper will be out sometime, but it is something we were looking at, at least to the extent that we can.

Steven Hester
Yes, because there are secondary products on markets that help make those connections, and some of those have been really beneficial. It is just still a challenge on the back end. There are not necessarily enough not-for-profit resources or entities out there who can meet the needs, and a lot of these become really complex problems, but that is really important.

Medell Briggs-Malonson
Steven, thank you so much for that, because we do know, not only from this study, but many other studies, that a lot of our healthcare facilities do shy away from actually addressing social drivers of health, merely due to the fact that they do not have the support or they do not feel that they have the expertise in their personnel to address these social needs. So, I also wanted to say thank you for this amazing presentation. You all know this is an area very near and dear to my heart in every single way. There are two aspects, though, that I want to make sure we are bringing to the table. This data has to be owned by the patient and

by the community. What I mean by that is that it has to be very much locked down and secure, but at some point, we need to shift away from having our physicians, nurses, or even social workers trying to grab that data, and we have a way that this data can be collected in a very secure way.

The reason why these are social drivers versus determinants is because they change, maybe from day to day, month to month, or year to year, so this is also going to be very different data collect than even other demographic information. Most of our demographic data does not change day to day or month to month. Social driver data does, so as we are building these systems, we also have to think about how we can allow our patients to provide that information in a manner that lacks resistance, and also, they have to know that we are keeping their data secure and private, and they have to know what we are utilizing it for.

The second thing I want to add into there goes back to how this data is different. Most of our structured fields are almost binary, yes or no. Social driver data is not. It is very hard to collect this type of data in a very simply structured field because even if we say, "Are you experiencing housing insecurity?", if somebody marks up yes, what does that even mean? Housing insecurity, even homelessness, spans a wide variety of definitions and timeframes, and so, those are the things we have to think about, and we really want to make sure we are moving towards the interoperability of this, but also making sure it is actionable in a relevant way, and this almost goes back to Kim talking about natural language models. This is an area where we need to think about natural language models, but then test them so we can have more information, but it is still categorized somehow in a structured manner. Again, wonderful presentation. Thank you all for always centering this. We still have some more work to do, as **[inaudible] [03:23:30]**. All right, I saw Deven next, and we are almost out of time.

Deven McGraw
This is very quick. I actually just put a comment in the comments. It was interesting to me that income data was among the most sensitive categories. This is not data that has to be collected from the patient through an interview. If the patients are sensitive about income data and not just when they are asked about income data, income data is readily available from data brokers, and it is highly predictive about different health status things. It is used in predictive algorithms all the time, and patients usually have no idea that this data is already flowing into healthcare systems, so I think we have to be mindful that it is not just through interviews that this data is going to come in the door.

Medell Briggs-Malonson
Thank you so much, Deven. Steven, and then Eliel, I think. Am I correct on my timing?

Steven Lane
No worries. I will go briefly. I really appreciated your comment about how this changes. I think of SDOH data like vital signs. Every time you measure it, it is going to be different. Steven, I really appreciated your comments. They were very spot on. The emotional weight of a lot of these questions speaks to how hard it is to get the right answer. Sarah, I am just thinking about the work that Gravity is doing. It would be nice to have a matrix or prioritization to **[inaudible] [03:24:56]** easier things to collect in SDOH.

These are the things that we should be asking for first to start to build trust instead of going through the really meaty stuff that we know makes people uncomfortable because this is a journey. We have been collecting blood pressures for 100 years, but we have not been asking these questions, and most places

are still not. We are still at the very beginning of a journey, and I think we need to be very sensitive to that experience in building that trust for providers, patients, and other caregivers, and we need to know that we are not going to be able to run. We are going to have to crawl first.

Medell Briggs-Malonson
Thank you, Steven. I know we are at time, but we are just going to break really quickly, so, Eliel, maybe you can close us out.

Eliel Oliveira
Sure. I think many of you know as well how much work we do in this area and how much we care about it, so I am very appreciative of the report. I am going to take that PowerPoint and share it with many colleagues that need to hear some of this, but some of the things I am hearing also could be taken to the next level in ways to add some of the ground experience we are seeing and questions that we want the answers to. There are quite a few in my mind, and I will give you some examples. There is a lot of needs assessment collection that is beyond the walls of healthcare providers. There is duplicated work out there in the communities. We have so many types of community health workers in Austin trying to do the same thing, and many of them are not inside of the healthcare provider setting, but it is taking place and is very important.

And then, there is the fact that we are collecting quite a bit, but not necessarily using it. I have seen examples of providers who we know are collecting EHRs and standard templates and are preparing others. When you ask them what they are doing with it, they say, “We just collect it because CMS is reimbursing for that and we are doing what the EHRs require, but we really do not do anything.” And then, there are the ones that try to, the ones who face challenges with financial services, but do not really get to the end of anything, and you all know that very well, so I think that is another area to understand because **[inaudible] [03:27:12]** 40-70% of the services that are referred do not get to the end. There is a lot of busy work that does not get results.

The final one is the fact that the collection of these needs happens in specific settings at a specific time. It is very different than the reality of when individuals face challenges. I may lose my job today, and suddenly, a spate of challenges appears, and I am going to see a doctor six months from now, but that is too late to address changes that are happening today. What I am trying to instigate here is that these are just mine, and I am sure there will be others. There is probably a need to bring groups together to figure out what questions to ask next for surveys and studies like we have done, which are tremendous, but there is quite a bit of wasted opportunity out there.

Medell Briggs-Malonson
Eliel, that is a wonderful way to end the session. Once again, thank you all for the amazing presentations. We really appreciate it. We are going to go to break now for five minutes. We are going to start exactly at 2:20 with no delay, and again, if you step out of the door, you need an escort.

HHS Information Blocking Update (03:28:32)

Michael Berry
Welcome back **[inaudible] [03:28:35]** overview.

Aaron Miri
All right let's get right into a very fun topic that I know is at the top of everybody's mind here. It is the overview of Information Blocking regulations. Elise? Do you want to take a sip of water? **[Inaudible – crosstalk]**

Elise Sweeney Anthony
I am Elise Sweeney Anthony, the Executive Director of Policy at ONC, and information blocking is among all the wonderful things I get to work on. The reason it is wonderful is that the engagement of information blocking **[inaudible] [03:29:07]** sharing **[inaudible]** our national coordinator talks about. So, today, we are going to have a number of our colleagues share a little bit about their piece of the Information Blocking framework, but I thought it might be good to give some reminders in terms of how the Information Blocking framework works. ONC has done its part of the puzzle, as it were, and that the first piece from the 21st Century CURES Act, which calls for information blocking to be addressed. There are two components to that. One is setting out the definitional structure: What are the definitions that are going to support this framework?

So, in the CURES Act final rule, which has unbelievably been out for some time now, we talk about and put into place as ONC what that definition **[inaudible] [03:29:54]** looks like, and that includes things like definitions for what that body of information is that should move **[inaudible]** electronic health information. It also includes definitions for how to think about each of the actors. What the CURES Act calls for is that certain actors should not be Information Blocking. If they are Information Blocking, then they are subject to civil monetary penalties or appropriate disincentives. In a little bit, our friends at OIG will talk about the civil monetary penalties, and those relate to health information networks or exchanges, as well as developers of certified health IT that are subject to those $1-million-per-violation fines, which my OIG colleagues will talk about in a second.

Healthcare providers are subject to what is known as appropriate disincentives, and in its rule that was recently released, HHS sets out what those appropriate disincentives are. Now, as you will see in the rule, they are focused on CMS, but we talk about how these are what we are looking at right now, but we do have a request for information, including a request for comment, in the rule that asks if there are other disincentives that should also be considered by HHS. Moving back a little bit to the CURES Act final rule that **[inaudible] [03:31:12]**, not only did we lay out the definitional structure, EHI, definitions for each of the different types of actors, which, for the purposes of healthcare providers, we used definitions from the Public Health Service Act. We also laid out what we call reasonable and necessary activities that do not constitute information blocking. That is the phrase that is used by the 21st Century CURES Act. For purposes of the rule, we refer to those as exceptions.

So, those are pretty much situations where information should move, but there is a reason why it did not move, and there are eight of those exceptions. Some fall into a category of information not moving at all, and others fall into a category of information that is moving, but how does that information **[inaudible] [03:31:54]**? So, some of you might recall **[inaudible]** manner in terms of how that information moves. On the other side of it, you might not be moving the information because of privacy or security, a type of situation where you are protecting from harm.

So, as we think about information blocking, how the framework works is important because we have that one piece of the puzzle, which is the CURES Act final rule, which lays out that framework. As many of you

have seen, particularly those of you who worked on the HTI-1 Proposed Rule, there are certain aspects we would update over time in terms of that framework in how we think about the exceptions based upon what we are seeing and what seems necessary, but the framework is laid out there. And then, with the OIG rule, which came out earlier this fall, that lays out what the CMP structure looks like and what OIG's goal is as part of that framework, so that is the second piece of that puzzle.

The third piece of the puzzle is what our CMS colleagues are applying for, and they will be talking about what that means in terms of the disincentive being applied to a healthcare provider who is found to have been information blocking. So, collectively, these three pieces of the puzzle put together what information blocking looks like from the definitional side in terms of what the expectations are, all the way over to which penalty or disincentive structure applies if you do not do what is supposed to be done.

So, we thought it would be helpful for us to bring all of those pieces to the table, and my piece is indeed the shortest because we want to leave most of the conversation and most of the presentation for our OIG colleagues and the CMS colleagues in relation to those two recently released rules. I should note that the OIG rule is a final rule, and the appropriate disincentives rule is a notice of proposed rulemaking, so we are looking forward to receiving public comment on. That is an HHS rule that includes CMS policy, so that is not a rule that we are bringing to the HITAC for review, but if HITAC members have comments, we do encourage them to submit them individually. With that, let me go ahead and turn it over to our OIG colleagues. I think the goal is for us to go through the entire presentation and then ask questions.

Aaron Miri
Right. We will ask questions at the end.

Elise Sweeney Anthony
So, with that, let me turn it over to my OIG colleagues.

Aaron Miri
Jim, are you on the phone?

Jim Hansen
Yes. Can you hear me okay?

Aaron Miri
Yes, sir.

Jim Hansen
Great. Well, good afternoon, everybody. My name is Jim Hansen, and I am a senior counsel with HHS OIG. I am with the Affirmative Litigation Branch. First off, I want to apologize. I fully intended to be there in person today, but I was feeling a little under the weather, so, with the flu season and all, I thought I should play it safe. With that said, I am here to talk about information blocking and specifically OIG's CMP final rule. Next slide, please.

So, on the slide, this is sort of the background for Information Blocking enforcement. This is the provisions of the 21st Century CURES Act, which is the enabling statute that gives OIG its authorities in information

blocking. Specifically, this is looking at Section 3022(b), which describes OIG authorities, which includes the authority to investigate claims of information blocking. And then, if you look at 2(a), which is the bolded language there, this is the part of the 21st Century CURES Act that basically describes what OIG's final rule is because the CURES Act bifurcates the penalties for Information Blocking conduct dependent on the identity of the actor.

So, in OIG's final rule, the actors that are subject to a civil monetary penalty are developers, networks, and exchanges. If you look at 2(b), that discusses our providers. Although OIG will be investigating information blocking by all types of actors, OIG only has the authority to impose a CMP against health IT developers, offerors of certified health IT, and health information networks and exchanges. I noted on the slide here that there is the proposed rule that just got published recently for disincentives, and I will leave it to CMS and my ONC colleagues to discuss that. Next slide.

So, this slide describes the lifecycle of an OIG administrative enforcement case. These cases typically begin one of two ways, which is we either receive a complaint, such as receiving a complaint from the public from our OIG hotline, or we get a referral, such as from another federal or state agency partner. So, we will get the complaint, we will get the referral, and then we will decide if we want to investigate or not based on the allegations. If the answer is yes, then we will begin our investigation and conduct that, and I will get into detail about investigations on a later slide. We will go out there, we will gather information and evidence, and after that, if we believe that the evidence shows that Information Blocking conduct did occur, then we will approach the target here.

Through a process we call informal notice, we will approach the target, contact them, let them know our understanding of the facts, the conduct, and the law, and give that entity or person an opportunity to engage with us and tell us anything that they would like to regarding our beliefs of the case. At that point, if possible, one way to end the liability is that we can enter into a settlement where we would settle our CMP authority on the facts of the case for some amount of money. If we cannot agree to a settlement, then the next stage would be that OIG would formally impose a penalty, and if you look there, it is 42 CFR 1003-1500. Those are the OIG regulations that discuss our formal imposition of penalties and what that looks like. Finally, if the target chooses to not pay the penalty and seeks to appeal, then the target would get an ability to appeal the case in front of the HHS Departmental Appeals Board, which is a bank of HHS administrative law judges, and I will discuss that a little bit more later on, too. Next slide, please.

So, as I just mentioned, all of OIG's investigations typically start with either a referral or a complaint. So, for information blocking, OIG is going to be receiving complaints from two different sources. One of those is the ONC reporting information blocking portal online, and another source is the OIG healthcare fraud hotline. We have said to the public that basically, there is no wrong way to submit a complaint, and that we will be looking at both sources of complaints to review information blocking.

So, in addition to receiving complaints, once OIG gets a complaint, if we decide that this conduct can be more appropriately resolved by a different agency, we can refer the conduct out to a different agency. For example, the 21st Century CURES Act explicitly states referrals to the Office for Civil Rights if we believe this conduct would be more appropriately resolved under the HIPAA enforcement authorities. It also mentions referrals to the Federal Trade Commission if we believe that the conduct is really anticompetitive in nature. That would be more appropriately handled by that agency. So, it is important to remember that

OIG will not always be the final stop on an Information Blocking complaint, depending on the facts and circumstances. Next slide.

So, in our final rule, we set out some anticipated enforcement priorities, and we set these out so that the public can understand what we think is important in allegations and to help them understand how we would likely allocate resources and what conduct we would prioritize investigating. As you can see on the screen here, the enforcement priorities we set out were conduct that resulted in, is causing, or had the potential to cause patient harm, conduct that significantly impacted a provider's ability to care for patients, conduct that was of a long duration, conduct that caused financial loss to federal healthcare programs or other government or private entities, and then conduct that was performed with actual knowledge. So, while these are guide sticks for us that we will use when evaluating complaints and conduct, it is important to know that these are not dispositive, and we are going to review every allegation on its specific facts and circumstances. Just because, for example, maybe conduct does not hit one or more of these stated priorities, that does not mean we would not investigate that conduct. Next slide, please.

So, OIG's final rule was published on July 3rd of this year with the effective date for enforcement of CMPs to begin 60 days later, so we are now living in a world of CMP enforcement that began on September 1st of this year, so enforcement is live. We did state in the final rule that we will not be imposing CMPs for Information Blocking conduct that occurred before September 1st, so that is sort of a safe zone. However, we did say that even though we will not be imposing CMPs for any conduct that occurred before the effective date, we still have the ability to look at allegations of conduct in actors that occurred before that effective date to just see if that conduct is still occurring. We basically said that if we receive many claims relating to the same kind of conduct by the same actor, some of those claims occurred before the effective, and some of those occurred after, we do not have to close our eyes to the allegations that occurred before. We can examine that just to understand which kind of conduct and which actors we should be prioritizing our investigation against.

So, on the scope of the OIG rule, as I think Elise might have mentioned already, the CMP is limited to certain types of actors. Not every type of actor can get an Information Blocking CMP. The scope is limited to health IT developers of certified health IT and those that are offering certified health IT, and then, health information exchanges or networks. We said in our final rule that our office is relying upon ONC for definitions of many things, including the definitions of actors, so it is important to understand their definitions in order to understand the nature and scope of OIG's investigations. Next slide.

So, let's get back to investigations. OIG has been conducting CMP investigations and enforcement for several decades now, and our office does have a lot of experience that comes from that. For example, one thing we commonly use is our documentary subpoenas and testimonial subpoenas. There is an amendment to the Public Health Safety Act that ensured that OIG would have the ability to issue document subpoenas and testimonial subpoenas in Information Blocking CMP investigations. So, for those who do not know, with an OIG document subpoena, we can subpoena a person or entity and seek documents relevant to investigations. In this case, it would be documents related to Information Blocking conduct, and those can look at things like internal documents, emails, communications, and things like that. Testimonial subpoenas operate similarly to how depositions in civil cases operate, so it is sworn testimony where, basically, we compel testimony from someone, where we sit you down, you swear to tell the truth, and then we get to ask questions.

So, those are two tools that OIG uses frequently in investigations, but it is important to remember that there is no formula to OIG investigations, and it really depends on the facts and circumstances of the individual investigation, and it never follows a pattern. For example, we may issue a documentary subpoena. We may just call up a target and see if they would be willing to discuss the facts of the case with us. It just really depends on what is needed for the particular situation. Next slide.

So, in our final rule, we have put into regulation the basis for our civil monetary penalty, and also the amount of the penalty. So, OIG can impose a civil monetary penalty against any individual or entity that is described in 45 CFR 171.103(b) that commits information blocking as defined in 45 CFR Part 171. So, like I said earlier, OIG is relying on those ONC definitions for a lot of the relevant and important definitions here. The individuals and entity types in 45 CFR 171.103(b), again, are the health IT developers of certified health IT, the offerors of certified health IT, and the health information exchanges and networks.

So then, what is Information Blocking conduct? That is also defined by ONC, and that is defined as conduct that, except as otherwise required by law or meets an exception, is likely to interfere with the access, exchange, or use of EHI. So, remember, the definition "likely to interfere" is very broad. There does not have to be an actual interference with access, exchange, or use of EHI in order to violate the Information Blocking statute and regulations. It is just likely to. One example that we discussed in the OIG final rule was a contract clause, maybe an EHR contract that had an unconscionable clause, that even if it was never actually exercised by any of the parties, just having the clause in the contract may be likely to interfere with the access, exchange, or use of EHI. So, just remember that the definition is broad.

Finally, the CMP does have an intent requirement, and for these actors described above, it is "knows or should know." So, these actors can either have actual knowledge of their conduct that is interfering with EHI, or they should know, so it is sort of like a negligence standard. They could have found out about their conduct, but they chose not to. So, getting down to the amount here, OIG may impose a penalty of not more than $1 million per violation. In our final rule, we said a violation means an ONC-defined practice to mean an act or omission by an actor. Rewinding that back a bit, OIG can impose a penalty of up to $1 million per act or omission by one of these actors described above. Next slide, please.

In our final rule, just to help the public understand our view on violations and the number of violations, we provided several examples of hypothetical scenarios that we are going to walk through, just to help people understand when it would be one violation versus two or three. So, in these hypothetical scenarios, we said to assume all the elements of information blocking are met, including the intent standard. So, let's walk through this first one.

In this case, a health IT developer, D1, connects to an API that has been supplied by a health IT developer of certified health IT, D2, and D2's API has been certified in ONC's certification program and is also subject to the ONC condition of certification requirements. So, here, a healthcare provider using D1's health IT makes a single request to receive EHI for a single patient via D2's certified API technology, and then, D2 denies this request. So, in this example, OIG said we would consider this to be a single violation, one CMP, that affects a single patient, and the violation is that D2 denied the healthcare provider's request to exchange EHI through D2's certified API. Next slide.

In our final rule, we provided another example, and here is one that has multiple requests, but still only one Information Blocking practice. So, here, a healthcare provider, using technology from a health IT developer, D1, makes a single request to receive EHI for 10 patients through the certified API technology of a health IT developer of health IT, D2. So, here, D2 is taking a single action to prevent the provider from receiving any patient's information via the API. OIG would consider this as a single violation affecting multiple patients. Why is this a single violation? This is a single violation because, again, like in the first instance, D2 only took a single action, which is a single act or omission, to deny all requests from the provider. Now, as far as the number of patients goes, that is something that OIG would consider when determining the final amount of the CMP, but again, here, it would only be one CMP for this scenario, one violation. Next slide, please.

So, in determining the CMP amount, remember, the statute authorizes a CMP of up to $1 million per penalty, so how would we determine that penalty? So, OIG has regulatory factors that it considers when determining the amount of a CMP. The first couple of bullets are factors that have been included in OIG's regulations 42 CFR 1003.140, and these factors include the nature and circumstances of the violation and the degree of culpability of a person against whom a civil monetary is proposed. Keep in mind that for information blocking, it is "knows or should have known," and OIG considers actual knowledge of the action to be a degree of higher culpability of that person than simply "should have known."

And then, there is history of prior offenses, if this person has committed information blocking in the past, or other wrongful conduct or such other matters as justice may require. So, these final two bullet points are factors that the 21st Century CURES Act specifically gave to OIG to consider when determining the amount of the Information Blocking CMP. So, that first one there is the nature and circumstances of the information blocking, including the number of patients affected, the number of providers affected, and the number of days the information blocking persisted. That second one is the harm that resulted from the information blocking, including the number of patients affected, the number of providers affected, and the number of days information blocking persisted.

So, we said this in our final rule, and I will say it here. Factors are not double counted. OIG takes a holistic view of the facts and circumstances, and also of these factors. These last two from the 21st Century CURES Act are somewhat similar to the factors that have already existed in our regulations before then. We are not going to double count them, so we will just make sure that the penalty amount is appropriate, and we would not be stacking factors to get a larger CMP amount. Next slide, please.

Here is another example that we included for violations in our final rule, and this one involves multiple violations, so let's walk through it. A healthcare provider using health IT supplied by a health IT developer, D1, makes multiple separate requests to receive EHI for several patients via certified API technologies supplied by a health IT developer of certified health IT, D2. Each of these requests for EHI is for one or more patients. Here, D2 denies each individual request, but does not set up its system to deny all of the requests made by the healthcare provider through D2's certified API technology.

So, here, D2 is taking separate, distinct actions to block each one of these individual requests. We said that each one of these denials would be considered a separate violation, so separate violations would mean separate individual CMPs. And then, the number of patients affected by each denial is something we could consider when determining the amount of the CMP levied per violation. Again, just like in all the other

examples here, the really determinative factor in deciding how many violations have occurred is the actions of D2. D2 is taking three different actions here to deny three different requests for EHI. Next slide, please.

So, just to expand upon that last slide here, the healthcare provider using D1's health IT made one request for one patient's EHI, and then a second request for three patients' EHI, and then a final request for five patients' EHI, and in the hypothetical, D2 is denying each one of these requests sequentially as they come in. These would be three separate violations, and OIG would be using the number of patients affected as one of the factors it considers when determining the amount of the CMP. Next slide, please.

So, as I mentioned earlier, how do these cases resolve? After OIG has conducted an investigation, during which maybe we have issued a document subpoena, taken some testimony, or conducted other investigatory steps, now we get to what we call informal notice. What this means is we approach the target and talk to them about our understanding of the facts and circumstances of the case and explain to them what we believe their liability is. And then, again, this is the time in the lifecycle of the case where the target definitely has an opportunity to talk to us and present us with any information it wants to. We provide that opportunity to targets, and we encourage it to make sure that we have all the information right, or if there is something that we should consider and have not, this is their time to talk to us about it.

At that stage, if both sides can come to an agreement, we may be able to resolve the target's CMP liability through settlement, and that would mean we could agree to resolve with some amount of money paid and adjust the CMP to some amount where we can both agree to resolve the liability. And then, as I mentioned earlier, if we cannot agree to some kind of resolution, then we would get to a formal demand letter. This is the formal imposition of the CMP, and this is a letter issued to the target that explains the facts and the legal basis for the imposition of a CMP.

Basically, there are two options at this point. The first option is that the target can agree to pay the CMP amount, and then it is over, or the target can appeal the imposition of the CMP. So, it is important to note with the demand letter that logistically, how this works is once we issue it to you, you have 60 days to either pay the CMP or appeal. After those 60 days elapse, then the imposition of the CMP becomes final. As a practice tip, you have either 60 days to pay or appeal. As I mentioned earlier, there is an appeals process here, and the 21st Century CURES Act said that the appeals process would be the same appeals process that OIG has been using for its other types of CMPs, and those regulations are all in 42 CFR 1005, and just as an overview, again, the appellant gets to appeal their case in front of an HHS administrative law judge, and at that time, they get to present any kind of arguments of fact or law that they would like to regarding the imposition of the Information Blocking CMP. Next slide.

Just to wrap up from the OIG end here, in our final rule, we mentioned that we would be establishing an Information Blocking-specific self-disclosure protocol. For those of you who may not know, OIG has a self-disclosure protocol for healthcare fraud matters right now that entities can use to voluntarily disclose conduct for a reduced-penalty payment. I do not have any updates on that, but it is just something that is out there. Finally, in our final rule, we were asked about whether OIG would be issuing advisory opinions, and we said no, but we would like to say that our colleagues at ONC have requested the ability and the money to issue advisory opinions in their latest budget request. So, that is it for me, and that is it for the OIG presentation.

Elise Sweeney Anthony
Thank you so much, Jim. Before I turn it over to Alex and the CMS team, we just dropped a couple links in the chat. I always like to make sure folks know where to find things, so we did put the links in the chat. If you are not following the chat, then here are a couple ways you can find the OIG rule. If you just go to FederalRegister.gov and type in 88 FR 42820 into the search bar, it will come up. That rule was published on July 3rd, 2023, and Jim talked about the relevant effective day of September 1st, 2023. For the disincentives for healthcare providers rule, go to the same website, FederalRegister.gov, search for 88 FR 74947, and you can find the rule there, because everyone loves reading rules, right?

Aaron Miri
Of course!

Elise Sweeney Anthony
So, you can find the information there. We will probably reiterate this a couple of times, but I do want to note that for those who are going to be commenting on their own, comments close on January 2nd, 2024, and the *Federal Register* website says that to be assured consideration, comments should be put in by no later than 5:00 p.m. that day, so I just want to note that. We will mention it several more times in the presentation, and we did drop them in the chat. So, without further ado, I do want to also note Mike Lipinski, who is on the line, leads our regulatory portfolio, and one of the key players in that portfolio has been Alex Baker, who has been absolutely instrumental in putting together and supporting HHS's work around the appropriate disincentives rule, along with others like Beth Meyers, my deputy, and Elisa as well, who have done a lot of work to help us bring this to where it is today. So, Alex Baker, I am going to kick it over to you, and in addition, Tim Jackson, Aryanna Abouzari, Elizabeth Holland, and Jessica Warren from CMS will **[04:06:08]**. Alex?

Alex Baker
Great. Thank you so much, Elise. My name is Alex Baker. I am the branch chief in the ONC Regulatory and Policy Affairs Division in the Office of Policy, and I am joined by a number of CMS colleagues, including Elizabeth Holland in the Center for Clinical Standards Quality and Tim Jackson in the Center for Medicare and Medicaid, who will cover their pieces of theirs in just a moment. Next slide.

Here are a couple of the usual disclaimers. The materials in this presentation are based on the NPRM that has just been released. Every effort has been made to ensure the accuracy of those materials, but this presentation is not a legal document, and the official proposals are in the rule. ONC can present information that is in the proposed rule as it is contained in the published rule. It cannot interpret that information, clarify, or provide further guidance, and HHS cannot address comments made by anyone during the presentation or consider such comments in the rulemaking process unless they are submitted through the formal comment process. Next slide.

So, as Elise just mentioned, the proposed rule was published on November 1st, and that is when the public comment clock started for 60 days, which means that comments, again, are due on January 2nd, and there is a link to Regulations.gov, where comments can be submitted. Next slide. Now, as Elise has also mentioned, these are some of the key headlines here around why we published this proposed rule. This implements the secretary's authority contained in Section 4004 of the 21st Century CURES Act around establishing appropriate disincentives for healthcare providers that commit information blocking as

determined by OIG, and it complements the OIG rule that you just heard about by establishing those disincentives for the healthcare providers that are not covered under OIG's authority to implement civil monetary penalties. Next slide.

Again, as I think we previously covered, there were a number of actors identified in the information blocking definition in Section 4004 of the CURES Act, including health information technology developers, exchangers, or networks, and healthcare providers. It is important to note again, here, that if information blocking is conducted by a healthcare provider and such provider knows that a practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information, that is different from the specific definition for the other actors, which states that they know or should know that a practice is information blocking. As Jim also noted, the CURES Act creates two different paths to enforcement for different kinds of actors, the CMPs that he described and the appropriate disincentives for healthcare providers, specifically that OIG must refer healthcare providers who have committed information blocking to the appropriate agency to be subject to appropriate disincentives using authorities under applicable federal law as a secretary since the authority. Next slide.

So, just to remind folks of healthcare providers that are subject the Information Blocking regulations in the ONC CURES Act final rule, ONC adopted the definition of "healthcare provider" in the Public Health Service Act in 45 CFR 171.102, and this is a list of the different healthcare provider types that are identified in the Public Health Service Act definition, so there are a wide set of different healthcare provider types that are identified here. Next slide.

So, what does the proposed rule do? We start with discussion of that specific provision of the CURES Act that relates to enforcement for healthcare providers, which we call the disincentives provision in the rule. So, we have defined certain terms in that provision for the purposes of the rule. We propose to define "appropriate agency" to be a government agency that has established disincentives for healthcare providers that ONC determines have committed information blocking, we proposed to define the term "disincentive" to mean a condition that may be imposed by an appropriate agency on a healthcare provider that OIG determines has committed information blocking, and that is specifically identified in a **[inaudible] [04:11:46]** CFR section that we are proposing this rule which would list the disincentives that have been finalized for healthcare providers.

It also notes that the CURES Act does not provide any further guidance about what appropriate disincentives would be or any illustration to that effect, so, under this proposal, a disincentive would be any condition, again, established in common rulemaking that would deter Information Blocking practices among healthcare providers that are subject to Information Blocking regulations. Next slide.

Another important piece of this provision is the phrase "authorities under applicable federal law," which we propose to interpret to mean that an appropriate agency may only subject a healthcare provider to a disincentive established using authorities that could apply to information blocking by healthcare providers subject to the authority, such as healthcare providers participating in a program supported by that authority, and that is the reason why we have worked with CMS to use certain authorities under applicable federal law to establish these disincentives through existing programs. It finally notes that the CURES Act does not limit the disincentives that would be imposed on a healthcare provider, and so, if a healthcare provider is referred by OIG to an appropriate agency, that healthcare provider will be subject to each of the appropriate

disincentives that the agency has established, and that referred to the bulletin for **[inaudible] [04:13:42]**. Next slide.

So then, we get into a little bit more of the process that would take place to go from an OIG investigation to the imposition of that disincentive. There is a section that is largely based on the OIG rule that you just heard described. It is important to note that the information in this NPRM is not a regulatory proposal from OIG, and is just providing information based on the rule that they have finalized for a couple of the specific places where their discussion in this rule speaks to healthcare providers, so I will just focus on those, as we have already heard about the specifics of their investigation process.

So, one of those pieces that is specific to healthcare providers is to note the anticipated priorities the OIG would have for healthcare providers. These are largely the same as for the other actors, but because the standard for information blocking by a healthcare provider already includes actual knowledge that the practice meant information blocking, that was not included **[inaudible] [04:15:01]**, so this is just to specify these are practices that resulted in, are causing, or have the potential to cause patient harm, significantly impacted a provider's ability to care for patients, were of long duration, and caused financial loss to key federal healthcare programs or other government and private entities, and there is a request for comment if the public wants to suggest other priorities specific to healthcare providers. **[Inaudible] [04:15:31]** a lot of the material that we heard around OIG's coordination with other agencies as part of its investigation and referral process. Next slide.

And then, the rule specifically talks about the referral process that OIG would pursue for healthcare provider that has committed information blocking that they are seeking to refer to the appropriate agency. So, during the investigation of information blocking by a healthcare provider, prior to making a referral, OIG plans to coordinate with the appropriate agency to which it would refer its determination of information blocking. Once OIG has concluded its investigation and is prepared to make a referral, it would send information to that appropriate agency indicating that that referral was made pursuant to the statutory requirement and discusses some of the information that OIG would provide to the appropriate agency to explain its determination, which would include the dates, when OIG determined the Information Blocking violations occurred, analysis to explain how the evidence demonstrates that the healthcare provider committed information blocking, copies of evidence collected during the investigation, and additional information that it may want to share with the **[inaudible] [04:17:01]**. Next slide.

So, the rule then discusses a couple of specific conditions around the application of disincentives. As I noted, the rule proposes to list various disincentives that are finalized in this new rule CFR subpart to be clear what the disincentives for healthcare providers are. It also proposes several elements of the notice that a healthcare provider would receive from any appropriate agency that has subjected that healthcare provider to a disincentive or disincentives so that there is a commonality in the elements of that notice across agencies, so that would include a description of the practice or practices that form the basis for the determination of information blocking, the basis for the application of the disincentive or disincentives, the effect of each disincentive, and any other information necessary for the healthcare provider to understand how each disincentive would be **[inaudible] [04:18:06]**.

Finally, this section notes that while the CURES Act, as folks just heard, identified that the appeals for actors that are subject to CMPs would be done under existing authority that OIG has, or other CMPs that it

proposes that the CURES Act does not give any instructions around how appeals work for healthcare providers, appeals by healthcare providers of a disincentive would be limited to any appeal rights that are available under each of the disincentives. Next slide.

And then, finally, we propose several transparency provisions for information blocking. These proposals are not just for healthcare providers, but are for all actors subject to the Information Blocking regulations, and this builds on a lot of the information that ONC is already putting forward about information blocking to help the public understand. So, we propose to include on ONC's website information about the determinations by OIG, including identifying the Information Blocking practices, the actors who committed information blocking, and any settlements of liability at the civil monetary penalties level and disincentives administered. I believe that publicly listing information about those actors that have been determined by OIG to have committed information blocking will be important to provide transparency into how information blocking is occurring and impacting the nationwide health information technology infrastructure. Next slide.

With that, I am going to **[inaudible] [04:20:05]** into the actual proposals to establish these disincentives, so I am going to just turn it over to my colleagues from CMS to discuss these specific proposals by different CMS programs. Elizabeth, are you online?

Elizabeth Holland
Yes, I am on the line. Hello, everybody. I am Elizabeth Holland, and I work in the Centers for Clinical Standards and Quality in the Quality Measure and Value-Based Incentives Group. So, you may recall that we have this little thing called the DHR Incentive Program. Now, those programs are no longer paying incentives, but we still have the penalties in place, so we decided for information blocking that we would propose that an eligible hospital or critical access hospital would not be a meaningful user in any calendar year if OIG determined that they had blocked information.

What that really means is that if we get an OIG referral to CMS, say, in 2025, we would determine that that eligible hospital, for example, was not a meaningful user in 2025, and thus, they would be subject to the payment adjustment in 2027 because that is how our existing regulations work, and we are going to adopt that also for information blocking. For critical access hospitals, it is a little different. If they were found to be blocking information in 2025, they would also get the payment adjustment in 2025, the same year. What we are saying is if a hospital did not participate at all in the program and they are already subject to a payment adjustment, they would not get an additional payment adjustment.

The other thing to understand, too, is that for hospitals, they are still governed by the HITECH Act, so they are limited to five hardship exceptions, so that means if they cannot demonstrate meaningful use in a particular year, they have five chances to claim a hardship exception, and as you recall, we started paying money years ago, and then the disincentives started kicking in, so many, many hospitals are hitting that five-year ceiling every year now, so they no longer have an easy way out to claim a hardship, and so, this could potentially result in hospitals losing a lot of money because for eligible hospitals, it would be a loss of 75% of the annual market that has to get updated for cause, and instead of 101% of reasonable costs, they would only get 100%. Next slide, please.

With our sister program, we talk about clinicians. So, under the Quality Payment Program, we have MIPS-eligible clinicians. You may know that we have four different performance categories, and one of them is

the Promoting Interoperability performance category, and that is what eligible clinicians do to demonstrate meaningful use. So, we are proposing the same sort of penalties under MIPS, which is the Merit-Based Incentive Payment System, which is one of the tracks of the Quality Payment Program.

We are proposing that if OIG finds that they were info-blocking, we would determine that the date we get the referral is the date we would say they are not a meaningful user, and again, they would potentially be subject in two years to a payment adjustment. MIPS is a little different because, as I explained, there are four performance categories. So, the problem for clinicians is that Promoting Interoperability is 25% of their total score. You may have read the little rule we released on November 1st, the physician fee schedule final rule, and in that, we proposed a performance threshold in 2024 of 75.01%. That means that even if you get the 25% for information blocking, you are minus 25%. It will be very hard for you, and you have to be perfect at everything else to get to that 75.01%. If you do not get there and you have 75%, you get a neutral adjustment, and if you are under that, you are getting a negative payment adjustment, and that could be nine percent. So, this also has the ability to be very painful to clinicians. On the next slide, I think I am turning it over to Jim.

Tim Jackson
Thanks, Elizabeth, and good afternoon, everyone. Jim Jackson here to cover the shared savings program. Our disincentives do follow a little bit within what Elizabeth had just described, but we have some important distinctions I will walk through very briefly. So, first and foremost, we are proposing to revise our Shared Savings Program regulations to establish the disincentives for providers, including ACOs, ACO participants, and ACO provider suppliers that engage in information blocking. We are going to screen the ACOs, participants, and provider suppliers for an OIG determination and deny the addition of a healthcare provider as an SSP participant for the period of at least one year. In the case of an ACO participant that is a healthcare provider, we propose to deny the ACO's application to participate in the Shared Savings Program for the upcoming performance year. For ACOs that are already participating in the program, CMS may terminate the ACO's participation agreement for the upcoming performance year. That lays out the overall approach for the disincentives, and now we will talk briefly about the results or impacts.

So, the results are not receiving the revenue they might have otherwise earned if they had participated in the Shared Savings Program, so that covers the ACO participants, the provider suppliers, and the ACO itself, as I just walked through. CMS would be determining if the appropriateness of the period could exceed one year if OIG has made any subsequent determinations that you may have heard from OIG previously and that Alex had provided at the beginning of this part of the briefing deck. That concludes our Shared Savings Program proposals. I believe I am turning it back over to Alex now. Next slide, please.

Alex Baker
Thank you, Elizabeth and Tim. Now, the important thing that we discussed and the overall important thing to understand about these proposals is that unlike the CMPs that can be imposed upon other actors, the actual monetary impact for these proposals will vary based on the individual care provider receiving the disincentive, as these disincentives are fully established under those other authorities and are partially determined by other factors, such as for hospitals, 75% of your market basket increase is contingent upon the total volume of IPPS payments that you received from CMS for any eligible commission. There are many factors each year that go into the score for the Promoting Interoperability Program. There is your

performance in other categories that affect your total score, so it is important to note that there are different factors that will impact the ultimate value of one of these disincentives for healthcare providers.

Despite those caveats, we did seek to provide some estimates to illustrate the potential impact that could be associated with two of the disincentives we proposed. We looked at eligible hospitals and how much the value of losing that market basket increase that a hospital might realize their burden could potentially equate to, so, for the estimates we did, the median disincentive amount based on the full range of hospitals that are part of the IPPS system was about $400,000.00, ranging from $30,000.00 on the low end up to $2.5 million on the high end.

We also looked at potential impact on hospital admissions. This is based on 2021 results, so, as Elizabeth noted, I know there are changes that happen in the program each year that affect this, but nonetheless, to show what this could have been in 2021, we estimated that losing that quarter of the MIPS for **[inaudible] [04:29:41]** individual disincentive **[inaudible]** $686.00 for an eligible clinician, which could range from nearly zero to about $7,000.00, plus commissions. We also looked at the potential size of the impact for groups that could be impacted by this proposed disincentive **[inaudible] [04:30:13]** MIPS. And so, we emphasized six eligible clinicians in 2021 that equated to a disincentive of about $4,000.00 for a range of different group sizes from two **[inaudible]** forming that equated to about $1,000.00 to $150 million. Next slide.

So, finally, as we noted, these performance disincentives were **[inaudible] [04:30:55]** different providers, eligible hospitals, critical access hospitals, all of the MIPS providers that are eligible clinicians in MIPS, all of the providers that can potentially participate and do participate in the Medicare shared savings program, but that does not cover all the different healthcare provider types that were represented in that big list of the definition in 45 CFR 173 **[inaudible] [04:31:25]**. And so, potential **[inaudible]** the request for information about other disincentives that HHS should consider establishing in the future and asked the public to identify those specific healthcare providers and potential disincentives to the established, as well as requested information about the healthcare providers that HHS should prioritize in future rulemaking for disincentives. Next slide.

Again, comments are due by January 2nd, and more information can be found on the ONC website, some additional fact sheets, as well as the actual text of the proposed rule in the *Federal Register*. Next slide. And that is it. We will take questions to the degree we can speak to them.

Medell Briggs-Malonson
Mike reminded me to mention that if you are submitting comments to Regulation.gov to do by 11:59 pm Eastern Time. That is the part that was emphasized. Thank you, Mike. Thank you from those of us on the West Coast. All right, so, thank you to all of our presenters for this incredibly important information. I anticipate a very robust discussion. So far, I have Steven, Jim, Bryant, Aaron, and Eliel. That is the order that we are going to go in. Try to keep your comments concise so we can try to get around to everyone as well. Steven?

Steven Lane
Thank you very much. I really appreciate this presentation. All of the discussants really provided a lot of great information. I want to point out that there are only a couple of us in the room who are actually practicing

healthcare providers to whom these rules would apply, so I think we might have a particularly cogent perspective on this. This is, again, a very thoughtful proposal, and I really appreciate the fact that this is a draft rule that is meant to apply an initial framework that can be built on over time, so I do not think we expect this to do everything, but I do have a few very specific observations.

One is a little concern that the disincentives that are being proposed are insufficient to dissuade impacted providers from engaging in information blocking. We have potential multimillion-dollar CMPs for the other two actor types, and we have predicted impacts of $300.00 for providers. It is just not comparable. Having said that, I am sure that my colleagues in organized medicine and healthcare generally are going to be up in arms about the horrible burdens this is going to provide to them, and they will fight tooth and nail to keep this from going forward, so rather than focusing on how to actually make this stronger for the providers who are already impacted, I suggest that this is great, let's take what we have here, and we should focus on other opportunities in this cycle that we can have to expand the scope of the rule and come back to the impacted providers in a year or two and see what progress can be made. When we do that, I would suggest specifically disallowing a claim of the hardship exception as a vehicle to avoid the impact of the disincentives related to Promoting Interoperability. It should not be a hardship that causes me to block information.

In part of the request for information, it is clear that there are a lot of providers who are not covered by these suggestions, and I think we do have an opportunity, and I will put this in as a formal response to the RFI, but there are clearly additional provider types from the applicable healthcare provider definition that should be impacted, and I would suggest the following prioritization. I think laboratories should be at the top of the list. Laboratories do not share information. It is impossible for me to query Quest and get all the historical data from a patient, even though I should be able to, so I would really hope that in the second cycle, since it is too late for the first cycle because it is not in the NPRM, we would use CLIA licensure as an opportunity to force laboratories.

We talked about pharmacies and pharmacists at length earlier today. They want to be providers, they want to be seen as providers, they should be treated as providers, and we probably have an opportunity to use FDA licensure as a way to incentivize data sharing by pharmacies and pharmacists. My understanding is that CMS licenses post-acute and long-term care facilities, so we have an opportunity there to use another available lever to work on them.

With the others, I do not know what levers you are going to use, but clearly, behavioral health providers should not be exempted from this rule. With the way it is structured today, many of them would be, so we should figure out how to get the social workers, psychologists, MFTs, etc. under the umbrella. With non-physician providers such as PAs, nurse practitioners, and all of that group, similarly, there is no reason to leave them out of the sway of this, and the same for physical and occupational therapists, as well as registered dietitians and nutrition professionals. I think all those folks should be included. Again, you missed them in the NPRMs, so we cannot do it in this cycle, but certainly, we should do that for Cycle 2.

Lastly, with the notion for repeat offenders, I am very concerned that there are a lot of providers who are going to say, "Oh, $300.00 or $1,000.00 for a hospital? Who cares? I will just pay the fee and go on blocking because it is in my financial interests to do that." So, we really need to make sure that those providers who repeatedly and knowingly engage in it… They can claim, "Oh, I just did not know" the first time, but you should be coming back next year and saying, "Are you still doing what you did last time, where you said

you did not know?" If you repeatedly and knowingly engage in information blocking, especially when they are not directly impacted or meaningfully impacted by these disincentives, I think we need to look at other ways to get at those beyond that history of prior offenses, which is taken into account for the other actor types.

As I said, we need a process to go back in subsequent years, double-check, and make sure that people have changed their behavior. I think there should be multipliers applied for repeat offenders. If you go back and find that they are doing that, there should be a way to notch that up. Another idea is that that offenders would be required to bear some of the costs of the OIG investigation, and my understanding from legal friends of mine is that you can do that, even though the CURES Act does not permit specific civil monetary penalties.

Medell Briggs-Malonson
[Inaudible] [04:38:41] Steven, thank you for those incredibly thoughtful comments. This is another reason why you have been such a staple on the HITAC, so, thank you so much. Jim, you are next.

Jim Jirjis
I just had a question. Did I hear you right that providers were chosen not to **[inaudible] [04:39:07]**, or is there? Did I miss it?

Alex Baker
Elizabeth, do you want to respond to that?

Elizabeth Holland
Sorry, I am having trouble hearing the question.

Alex Baker
Just reconfirming that if a provider already failed Meaningful Use for another reason, this proposal would not propose an additional penalty.

Jim Jirjis
If someone decides year after year not to participate and just take the hit, they will suffer no additional penalties if they block information. Is that correct?

Elizabeth Holland
That is correct. That is our proposal. If I can speak to one of the other points, the non-physicians that the other gentleman mentioned are actually all MIPS-eligible clinicians, so they would be subject to this. Dietitians, nurse practitioners, and PAs… All of them are MIPS-eligible.

Steven Lane
So, the MIPS piece?

Elizabeth Holland
Yes.

Jim Jirjis
Unintended consequences, perhaps, for the OIG to **[inaudible] [04:40:21]** other providers for the rest of them. Let me use an example. The concern is unintended consequences in a large health system where people are **[inaudible]** versus a small. Let's say there is a hospital company **[inaudible]** was chosen to **[inaudible]**. The consequence of information blocking occurring could be multiple different penalties, versus that company deciding to, instead, have each hospital. There may be unintended consequences if some people change their otherwise efficient propose to an less efficient, burdensome approach that contain potential penalties that otherwise were information blocking **[inaudible]**.

Elizabeth Holland
So if you spread the blocking around, you might be able to avoid an enterprise fine?

Jim Jirjis
No, what I mean is if there is an enterprise approach and **[inaudible] [04:41:26]** examples of something occurred versus you have 190 hospitals and it happens in two of them, there is a continued risk. It is not like you are trying to **[inaudible]**. I am not sure what the solution to it is, I am just trying to **[inaudible]**.

Medell Briggs-Malonson
Great questions and comments, Jim. I appreciate that. Bryant, you had your placard up, but you have taken it down.

Bryant Thomas Karras
Steve said it way better than I could.

Medell Briggs-Malonson
Well, thank you. I still wanted to acknowledge you for that.

Bryant Thomas Karras
I second the comment about the $300.00. Alex, it does not seem like that is going to change hearts and minds, so I am curious to see if those projections bear true. I look forward to hearing what happens when we hear back from you.

Alex Baker
I will remind folks that that is sort of taking every rudimentary calculation, taking every MIPS-eligible clinician, all the different earnings that they have, and taking a median for it. OIG will still have discretion to decide who they are going to investigate and **[inaudible] [04:42:50]** specific number other than **[inaudible]**.

Bryant Thomas Karras
Right. I can see large practices looking at that number, even the higher-end number, and saying, "Eh, we are just going to pay the penalty. It is easier."

Medell Briggs-Malonson
Thank you, Bryant. I think several of us feel that way, that this is so incredibly important to patient care, so without having some true teeth in the game, people will accept the small penalty of the disincentive versus

complying with what we are all trying to aim for. That is the thought about that the smaller penalty for, I would say, individual physicians as well as larger systems. Aaron?

Aaron Miri
I first want to compliment and say thank you. I appreciate the agencies working together to get us this far. I want to echo what Dr. Lane said in that we need to start now and go forward. I am sure we will ramp it up over time. This is as good as it can be right now, but we can get better in the future as it takes hold, so again, I want to say thank you for that. I also want to echo the real-world examples where, even today, there is information blocking from large physician groups, usually under private equity, that have other motives for that data behind the scenes and refuse to share back, so this should help begin to alleviate that bottleneck and give some teeth to it, although again, we have highlighted that there is room to grow, but this is a start. It begins to make the point that you cannot withhold data, period.

I am not sure if my question goes to OIG or CMS, so forgive me on this. I did not hear what happens if an individual patient brings forward an Information Blocking request and if the OCR would be involved at that point for other purposes, being that you could, at some point, be impermissible under HIPAA if you are not giving the patient their information directly. Is there an intersection point here with OCR, and how does it come into play with these various activities?

Alex Baker
Jim, do you want to speak to OIG's coordination with OCR?

Jim Hansen
I think that was addressed to me as the OIG guy. Thanks, I was having a little trouble hearing. I would answer the question by saying to keep in mind there is a provision within the CURES Act about duplicate penalties, so we have to be understanding about that, but I will say this. There will be coordination between the agencies, and one of the tasks will be deciding whether this is better handled by information blocking and the Information Blocking CMP or whether this is more of an OCR task.

Mike Lipinski
This is Mike. I will just jump in there to illuminate the fact that the factual situation can be a lot different between information blocking and a HIPAA right-of-access allegation or complaint. For example, you have different timing. While, under HIPAA, it is generally 30 days, there is a proposal out there, and as we all know, that comment period closed, to make it a lesser period of time, down to 15. The Information Blocking rule does not set a specific timeframe in terms of response, so it is based more on whether it was unreasonable, the technical capabilities, and so forth, so it looks at the facts and circumstances.

Another thing is there is some differentiation, and again, our colleagues at OCR have a rulemaking out there that they have not finalized yet, as to third-party-access. There are differences between the Information Blocking regulation and the current state for HIPAA right of access in terms of both who can have access and for what reasons and fees as well. I just want to lay that out there because I think that is going to have a huge impact in some of the decision making by our colleagues at OIG in terms of what cases they take and do not take and whether they use discretion to refer to OCR and so forth.

Aaron Miri

Got it. Thank you very much. I am hearing that the legal answer is “it depends.” Thank you.

Medell Briggs-Malonson
Thank you for that question, Aaron, and thank you so much, Alex and Mike, for answering. Next is Eliel, and we do have about 10 minutes before we go to public comment, so everyone will try to keep it concise.

Eliel Oliveira
Yes, and I think this might be for Jim as well on the CMP. I think the **[inaudible] [04:47:51]** with the health information exchange on that work, and several examples on the penalties related to certified systems and users of certified systems, and oftentimes, the networks do not necessarily have certified systems, and **[inaudible]** are required to. Some of the examples were **[inaudible]** how we can picture the enforcement activities that are taking place for health information exchange, and then, OIG is **[inaudible]** like we say in the industry, if you have seen one health information exchange, you have seen one health information exchange.

There are health information exchanges that cover multiple states, and others that are very focused on small communities. The big ones probably do not **[inaudible] [04:48:42]** the penalties, and the little ones will shut down and affect communities that are trying to collaborate with SDOH. I am still **[inaudible]**. That is my key point, and I am trying to see if Jim can give us some idea of examples on health information exchange and the fact that you are not necessarily using certified EHR, but certified health IT, and prepare for **[inaudible]**.

Medell Briggs-Malonson
Thank you, Eliel. Jim, do you have a response to that?

Jim Hansen
Yes, and I apologize, Eliel, I did not hear everything you said, but I think I heard most of it. I think I have two responses. The first one is that OIG cannot comment on specific factual scenarios, facts, and circumstances. It is all going to come down to case-specific things, so I do not think I can give you a specific answer to that scenario that you are describing. The only other thing I will say, too, is that it really depends on the definitions, and I know you were talking about HIE definitions and scenarios involving HIEs. I guess I will just say to fully understand the ONC HIE/HIN definitions that are relevant to information blocking.

Medell Briggs-Malonson
Thank you so much for that. We have Deven, followed by Shila.

Deven McGraw
Thank you. This question is for Jim and reflects the fact that I have not had a chance to read through the entirety of the most recent rule, but I certainly did read the OIG final rule, and I am very interested to get a sense of what constitutes knowledge of a violation, that you are Information Blocking, in the case of a provider if the standard is expected to be prior. For example, when we work to get copies of medical records for patients using a citizen platform, getting their information on their behalf, we still often face a lot of friction from providers in getting this information, and I usually write emails to many entities and to compliance officials in these entities saying, “Look, here are the consequences of what you are doing. Here is why we think you are risking an Information Blocking violation.” It is not my determination. Is that sufficient? Do they

have to know they are violating or not, or do they have to be aware of the conduct that might be causing an obstacle?

Medell Briggs-Malonson
Jim Hansen, I believe that question was directed to you.

Jim Hansen
Yes, and I heard it. Hi, Deven. I am going to have to go back to my response from last time, which is that I cannot comment on a specific fact scenario like that as far as the intent standard goes in your specific question.

Medell Briggs-Malonson
We appreciate that.

Jim Hansen
I just do not think I can answer that right now. Sorry to leave you hanging.

Medell Briggs-Malonson
No problem. Thank you for that question, Deven. Shila?

Shila Blend
I do not think you can answer this one either, but I want to stay on top of **[inaudible] [04:52:22]** because it is great seeing the disincentive for the providers, but one thing since information blocking has come out that has circled in my mind, especially coming from the HIE space, is where you have providers willing to share information and connect, but it is not necessarily the provider, but the vendor. There is not a full definition of what excessive fees are, so you have a vendor that you can connect to, but who is asking for quite a large fee to make those connections and do different things. In the future, I think more guidance around what exactly constitutes that.

Steve Posnack
Submitting those would be a good start.

Medell Briggs-Malonson
Shila, thank you. Jim, was there any other comment on that?

Jim Hansen
No. I am going to have to go back to my stock answer here. I cannot comment on specifics like that, but it sounds like a good idea to submit a comment to ONC regarding definitions for “excessive fees.”

Mike Lipinski
I was just going to jump in and say that is probably more in our court in terms of interpretation of the… The baseline is that a fee can be an interference, and then we establish an exception for reasonable fees, so I appreciate that we are getting… And we establish the criteria of what you can use to determine reasonableness fees, and also specified certain fees that could not be charged, including patient access, which was one of the ones referring to the HIPAA privacy rule in that example. So, I am happy to entertain

questions on that. Generally, you are going to be talking about for us to consider any type of guidance, the facts and circumstances are going to matter, as I think you have heard a lot of times already today, either from Jim, or us, or in the past, to be able to give any type of guidance as to reasonable or excessive fees.

Steve Posnack
This is Steve. Just to make one additional plug on this, this is specifically a reason why we have asked for advisory convening authority, because as Mike was noting and Jim noted, it really comes down to digging into the facts surrounding the interaction and being able to unpack those and provide a reasoned analysis across the rules of how we would interpret it, and then, as we have indicated in the budget paragraph, that would be binding from an enforcement perspective, so that would be respective folks staying within that advisory opinion. So, it is an evolving landscape. It is a new law and a new set of rules, and I think that is something for everybody to keep in mind. I know it may feel like a while since the disincentives rollout, and certainly, the CURES rule is three years old. Notwithstanding our experiences with HIPAA, at this stage now, 20 years later, it is still a new legal landscape.

Medell Briggs-Malonson
Yes. Well, thank you, Steve, for that. Also, thank you, Mike, and a special thank you also to Jim Hansen from OIG for being so gracious with answering our questions as well. I do just want to reiterate for all of the HITAC members that if you do have additional opinions on this, please make sure all of your comments are in play. And so, we are just at public comment time, so I will turn it over to you, Mike.

Public Comment (04:56:20)

Michael Berry
All right. We are going to open up our meeting for public comment. If anyone from the public would like to make a comment, please raise your hand. Otherwise, if you are attending virtually, please use the raise hand function located on the Zoom toolbar at the bottom of your screen, and if you are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. Let's pause for a moment to see if any members of the public raise their hand. In the meantime, I just want to remind everybody that the next HITAC meeting is scheduled for January 15th, 2024. I hope you all can make it. Also, all of today's presentations are always kept on the HITAC page on HealthIT.gov, so you are welcome to look there. I am not seeing any hands raised, so I will turn it over to Aaron and Medell to close us out.

Final Remarks and Adjourn (04:57:09)

Medell Briggs-Malonson
I am not going to take too much time, but I just want to say thank you to the HITAC for all your participation, and especially also to the ONC leadership, as well as to the staff **[inaudible] [04:57:19]** fantastic year, and I look forward to all of the returning HITAC members in January. We will see you in December.

Aaron Miri
Absolutely, thank you, and thank you all, HITAC. First of all, I want to say thank you to the ONC staff, Elise, Steve, Avinash, Mike, and, of course, Micky, for always being here with us. I cannot say enough words. It has been six years for me on the HITAC, and two years prior to that on the policy committee. I just want to ground us in why we do everything we do. In 2012, my oldest daughter, Madeline, was born. My wife had preeclampsia and hypertension, and it was a troubled pregnancy and birth, but they were both healthy. In

2015, my second daughter was born. It was a Saturday. I was at a hospital about 40 miles north of Dallas, Texas, and 40 miles north of Dallas is still in Dallas, but net net, the two hospital systems did not transmit data, but the physician needed to see the records from Madeline's birth, and could not get them. I got in my car, drove over there, physically got the records, drove back, and I was so frustrated.

I said, "You know what? I have to change this." That is why I joined the policy committee at the time, and I have been so passionate about information availability, not information blocking, and what we are doing there, so I want to applaud you. This helps the Madeline and Morgans of the world. This helps everybody as we move forward into new phases. I encourage the HITAC to be bold and to continue to push forward. Make sure we are being fair and equitable in all that we do, and remember that you are serving on this committee because you are an expert in your domain. You were selected specifically for that domain expertise, and you provide that back. It is the collective sum of those opinions in a very fair and respectful manner in which we are able to derive feedback and give advice and counsel to the ONC and to the agencies that we are honored and blessed to serve with.

So, with that, I conclude my service on HITAC. I appreciate all of you very much for the years of support. I will say that this is not goodbye, but I will see you later, and I am always around. Thank you again, and have a safe travel home. For those of you on the phone, thank you very much.

Medell Briggs-Malonson
[Inaudible] [04:59:20] all of you at ONC and here on HITAC. This committee would not be what it is without your presence and contributions, and we **[inaudible]**. On behalf of HITAC, on behalf of ONC, we thank you.

Aaron Miri
Thank you.

Michael Berry
Thank you.

Medell Briggs-Malonson
Safe travels home, everyone.

Aaron Miri
We are adjourned. Thank you.