Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

July 11, 2024, 10:00 AM – 12:40 PM ET

VIRTUAL

MEMBERS IN ATTENDANCE

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

FEDERAL REPRESENTATIVES

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

ONC STAFF

Micky Tripathi, National Coordinator for Health Information Technology
Elise Sweeney Anthony, Executive Director, Office of Policy
Avinash Shanbhag, Executive Director, Office of Technology
Seth Pazinski, Designated Federal Officer

PRESENTERS

Alex Baker, ONC
Elizabeth Holland, CMS
Aryanna Abouzari, CMS
Samantha Meklir, ONC *(Discussant)*

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

Seth Pazinski
Good morning, everyone. I am Seth Pazinski with ONC, and I will be serving as your Designated Federal Officer for today's HITAC meeting. As a reminder, the meeting is open to the public, and we welcome public feedback throughout the meeting. During the meeting, you can make comments in the Zoom chat feature, and we will also have the opportunity to give verbal public comments, which is scheduled towards the end of our agenda today, so we are going to go ahead and get started with our meeting. I am going to start by recognizing the ONC executive leadership that is on the call today. We have Micky Tripathi, our National Coordinator for Health IT, Elise Sweeney Anthony, the Executive Director of the Office of Policy, and we also have Avinash Shanbhag, who is the Executive Director of the Office of Technology. We welcome ONC leadership to the call. Now, I will do the rollcall for HITAC members, so when I call your name, please indicate that you are present. I will start with our co-chairs. Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning, everyone.

Seth Pazinski
Good morning. Sarah DeSilvey?

Sarah DeSilvey
Good morning.

Seth Pazinski
Good morning. Shila Blend?

Shila Blend
Good morning.

Seth Pazinski
Good morning. Hans Buitendijk? Michael Chiang?

Michael Chiang
Good morning.

Seth Pazinski
Good morning. Derek De Young? Steve Eichner?

Steven Eichner
Good morning.

Seth Pazinski
Good morning. Lee Fleisher? Hannah Galvin?

Hannah Galvin

Good morning.

Seth Pazinski
Good morning. Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Seth Pazinski
Good morning. Steven Hester?

Steven Hester
Good morning.

Seth Pazinski
Good morning. Bryant Thomas Karras?

Bryant Thomas Karras
Present.

Seth Pazinski
All right, good morning. Hung Luu?

Hung Luu
Good morning.

Seth Pazinski
Good morning. Trudi Matthews?

Trudi Matthews
Hi, everyone.

Seth Pazinski
Good morning. Anna McCollister?

Anna McCollister
Good morning.

Seth Pazinski
Good morning. Deven McGraw?

Deven McGraw
Good morning, everyone.

Seth Pazinski

Good morning. Katrina Miller Parrish?

Katrina Miller Parrish
Good morning.

Seth Pazinski
Good morning. Aaron Neinstein?

Aaron Neinstein
Good morning.

Seth Pazinski
Good morning. Eliel Oliveira?

Eliel Oliveira
Good morning, everyone.

Seth Pazinski
Good morning. Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning.

Seth Pazinski
Good morning. Randa Perkins?

Randa Perkins
Good morning.

Seth Pazinski
Good morning. Rochelle Prosser?

Rochelle Prosser
Good morning, everyone.

Seth Pazinski
Good morning. Dan Riskin?

Dan Riskin
Good morning.

Seth Pazinski
Good morning. Mark Sendak? Fil Southerland?

Fillipe Southerland

Good morning.

Seth Pazinski
Good morning. I see you are on, Derek De Young. Thank you. Zeynep Sumer-King?

Zeynep Sumer-King
Good morning.

Seth Pazinski
Good morning. Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Seth Pazinski
Good morning. And now, I will go to our federal representatives of the HITAC. Keith Campbell?

Keith Campbell
Good morning.

Seth Pazinski
Good morning. Jim Jirjis?

Jim Jirjis
Good morning.

Seth Pazinski
Good morning. Meg Marshall? Alex Mugge?

Alex Mugge
Good morning.

Seth Pazinski
Good morning. Sheryl Taylor, who will be filling in for Ram Sriram?

Sheryl Taylor
Yes, good morning.

Seth Pazinski
Good morning. I see also that Hans Buitendijk has joined. Thank you for letting us know. Is there anyone else I missed or who joined late? Okay. Now, if you will, please join me in welcoming Micky Tripathi and Elise Sweeney Anthony for their opening remarks.

Welcome Remarks (00:04:15)

Micky Tripathi

Great. Thanks so much, Seth, and good morning, everyone. Welcome to this HITAC meeting. ONC has been very busy, as many of you may know. We are usually pretty busy, but we have been extraordinarily busy in the last period of time. In my opening remarks, I want to talk about two rules. I know today, we are going to be talking about the appropriate disincentives rule, but yesterday, as I think all of you know, we released the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) rule, and this may be the first time in the history of ONC where the frequency of our rule releases is actually higher than the frequency of the HITAC meetings, so we are going to talk about the appropriate disincentives rule today, even though I know a number of you are reading through the HTI-2 rule, which came out yesterday. Obviously, we will have a lot more time and a specific workgroup task force looking at HTI-2, but I am happy to share my high-level thoughts on that as well so that all of you can get, at least, our perspective on the importance of HTI-2.

So, first, on appropriate disincentives, a few weeks ago, the United States Department of Health and Human Services (HHS) released a Final Rule that establishes the disincentives for healthcare providers that are found to have been committing information blocking. It is a really important piece of the 21st Century Cures Act provisions related to information blocking and really puts down the final cornerstone of the foundation for the information-blocking policies that were triggered by the 21st Century Cures Act statutory provisions related to information blocking. We have had the enforcement provisions that were put into place by the Office of Inspector General (OIG) related to health information networks and certified technology developers, but the last remaining piece of the puzzle was the appropriate disincentives that were called for in the 21st Century Cures Act, but were put in the lap of the secretary to determine within existing rulemaking and authorities and with notice-and-comment rulemaking. So, that has been a very complicated process, but we are really delighted to report that we are able to finally release that and put it into place.

As I said, that sort of completes the cornerstones of the information-blocking regulatory framework going forward. As the secretary said in the press release, the important part is that it establishes the framework for appropriate disincentives and anticipates that there will be additional appropriate disincentives in the future because the statute, as I think all of you know, applies to the broad definition of “providers,” and as we look across the Department of Health and Human Services and all the various authorities that are there, we have to be cognizant of establishing appropriate disincentives for all of the actors who would fall under the provider category. This first rule applies to a subset of all the providers who would be a part of the actors who are subject to the rule, but importantly, it does lay down the regulatory framework upon which we can build and the first set of disincentives, so we are really excited to now be able to put those in place and now to be able to move forward with those important provisions from the 21st Century Cures Act.

The second thing is that I wanted to briefly touch on HTI-2. As I said, we will obviously be having a more detailed discussion of that on July 17th at 2:00 p.m. We will be doing a public webinar where we will do a deep dive on the various provisions. It is a big rule, a thousand pages, but I would argue that it just scratches the surface of all of the things that we need to do as a country and as an industry. I think importantly, it does have a number of components, so when you look at it, you see a bunch of different components related to certification, information blocking, Trusted Exchange Framework and Common Agreement (TEFCA), information sharing, and a whole bunch of things, but I think there is an underlying theme that is really important for us to recognize, which that it is starting to bring together all of the various things that we think about as interoperability components and starts to bring some coherence to them in a way that all of us

have been working really hard to be able to do, to firmly establish the 21st century digital healthcare system that all of us want to be able to have and have been laying the foundation for a number of years.

Importantly, what does that mean, how do we think about that, and why do I say that? I will just point to three things that I think are really important, thematic things that may not jump out, but are really important in the way we have been thinking about the construction of the rule. One is expanding the horizon of interoperability so we start to think more and more of what interoperability really ought to be, which is one ecosystem that has various dimensions to it. In particular, there are provisions in there related to adoption of standards and certification criteria for public health IT systems, which are fully within the authority of health IT from an ONC certification perspective, but have not been things that we have explicitly considered, and working closely with the Centers for Disease Control and Prevention (CDC) and jurisdictions, we now want to be able to introduce the voluntary certification requirements related to public health IT systems.

I think that is a really important part of being able to move forward with the kind of interoperable public health architecture that is integrated as much as possible with the healthcare delivery system. For too long, they have been living separately, and as we know from the pandemic, we saw the cost that we pay in dire need from not having interoperability. For a long time, one of the things that we have heard over and over is the challenges that we are facing. Even though we had certified electronic health record systems to have standardized output and transmission of different types of public health data streams, we were still seeing too much variation on the receiving side. As people like to say, we had certified the pitchers, but not the catchers.

So, we now want to start the process of saying here is a foundation for being able to certify the catchers as well to allow greater interoperability across the ecosystem to make it easier for public health practitioners to be able to spend more of their time on public health activities directly serving the American public and not on wrangling data, trying to figure out disparate data, and trying to figure out data that is misaligned or not aligned with standards that are deployed in the healthcare delivery system on a day-to-day basis. So, we think it is a really important set of provisions, we are delighted to have worked very closely with the CDC on that, and we think it will be a great benefit to the public health ecosystem and to the jurisdictions who have to do a lot of custom work right now and work with custom technology platforms. This is a way of being able to elevate the market and get us all to a much more standardized approach, and also reduce the burden on providers for public health submissions, which, of course, is a barrier to our being able to have better public health interoperability. So, that is one important component about expanding the horizon of interoperability.

The second is a set of revisions related to certification of Application Programming Interface (API) requirements on payers that have been coming from Centers for Medicare & Medicaid Services (CMS). So, I have been working closely with CMS as well. As many of you may know, they had the interoperability and patient access rule, and in January, they released the interoperability and prior authorization rule, which has now put into regulation requirements on regulated payers for Fast Healthcare Interoperability Resources (FHIR)-based APIs to make available information to members, to make available information to providers with provider access API, to make available information from plan to plan, with patient permission, when a patient goes from one plan to another, which happens something like 30% of the time in the country today, and prior auth and specifications and requirements for prior auth capabilities, all of them based on core standards of FHIR APIs as well as United States Core Data for Interoperability (USCDI), Creating

Access to Real-time Information Now (CARIN) Blue Button, and all of those associated implementation guides.

So, what we are proposing in the rule is adoption of standards and certification requirements related to the certification of those systems, because just as we think it is very, very important to have conformance on electronic health record systems to improve interoperability. As we expand our idea of what interoperability ought to be, which is payer data as well, we ought to do everything we can to have more and more conformance of those systems as well. If you believe that certification and conformance is required for clinical interoperability, then surely we must believe that conformance is really, really important for public health and for payer data and payer interoperability as well. So, we are very excited about that set of provisions.

The second thing I will point to is expanding the capabilities of interoperability. We want to expand the horizon, but also the capabilities, advancing FHIR capabilities in areas such as Clinical Decision Support (CDS) hooks and subscriptions. Right now, everything I just described is about standard FHIR APIs making data available in a read pattern of exchange, but, as we know, APIs do a lot more than that. They do a lot more than just surfacing data so that someone else can look at it or download it. There is basic interactivity of systems that APIs enable that we want to start taking advantage of, and those more advanced FHIR features are really important to the industry as well. So, we are proposing to make a number of those things into regulatory requirements. There has already been a lot of work on those through efforts like the Argonaut Project and a number of the FHIR accelerators, so we are delighted to be able to pick up on all of that work and say, “Let’s now get those over the line and get those adopted into certified systems.”

The other thing I will point to with respect to capabilities of interoperability is leveraging approaches to scalability for FHIR APIs. I think one of the issues that we are having in the market with respect to adoption of FHIR APIs is that without scalability, it is still really hard to get more rapid diffusion of FHIR API-based interoperability. So, TEFCA is an important part of that. In the proposed rule, we have anchor points for the public-private governance in TEFCA that, as we have seen and are seeing, is so important for establishing trust for safe and secure nationwide interoperability.

We also have a proposal to require dynamic client registration, the so-called Unfair, Deceptive, or Abusive Acts or Practices (UDAAP) protocol, in certified electronic health record systems, but that actually does not work unless it is in a trust framework, so we think it is really important for scalability of FHIR APIs, but we think that the TEFCA is a great place to be able to fully instantiate what UDAAP will be able to provide to the market under a trust umbrella that would actually make that kind of approach to dynamic client registration actually work because you need both of those things. So, we are very excited about that. I think all these things help us to push the frontier of FHIR-based capabilities, both from a functional perspective as well as from a scalability perspective.

The last thing is that we have put in a number of things that are in different places, so I just want to string them together so that everyone understands. Being able to directly address patient points is an important part of interoperability, so I would point to a few things, some of which I have mentioned, just to put them under the umbrella of things that are really important from a patient perspective. It is critically important that we get prior authorization to be as automated, simple, and behind the scenes as possible with the kind of interactivity, tracking, and traceability that all of us expect every day from UberEats and Lyft, but that we

somehow do not have in the healthcare system. So, the pieces of that are the proposed certification requirements on the electronic health record (EHR) side.

For the other side of certification of prior auth, the CMS interoperability rule puts requirements into place for regulated payers to have prior auth capabilities on their side. Now, I want to make sure we have the other side on the provider side because obviously, it is not going to work if it is just on one side. We have talked to a lot of payers and gotten a lot of feedback from them of the importance of having that on the EHR side, which we agree with, and certainly, working with our CMS partners, we want to make sure we are able to fully support everything that CMS has put into that role to make sure it is actually real. Coupled with that are the proposed requirements for the certification of the payer side of that equation as well. Again, if we want to make sure it is conformant on the provider side, we want to make sure it is conformant on the payer side too. Again, otherwise, we will still have too much variation in the market to allow it to be scalable.

The second thing is the payer-to-payer API. It is very important for patients who are going from one plan to another to have the assurance that, with their permission, their information will actually flow so that when they get to that new payer, which was not a choice of theirs in many cases, because they changed jobs or something happened and they were forced to go to another payer, they want to make sure that payer is not looking at them as a green field or starting with a blank slate. We want to make sure that new payer has information that can help with the continuity of care. So, I think that is why that payer API certification requirement is so important, to make sure that that actually can happen.

With access to imaging, we have a proposal in there to help us move forward with interoperability for imaging. It is a proposal to surface links to allow more native internet capabilities to be able to use links to be able to directly get access to imaging information for patients or providers as well, but the idea is to allow us to move forward and hopefully get us away from handing a patient or a provider a CD-ROM and expecting that they are going to be able to do something with it. We want to make sure that we are moving forward on something that is a real pain point for everyone. I will flag two other things, and then I am going to turn it over to Elise.

With the real-time benefits check, it is a statutory requirement, but something that we believe is really important from a patient care perspective as a pain point for patients to be able to get information at the point of care from their provider about the coverage from their health insurance and whether it will cover a particular drug, if there are lower-cost alternatives that are available to them, what their copay is, and all of that. Too often, those choices are not presented to the patient, and/or the patient shows up at the pharmacy and finds out that their insurance does not cover it or the copay is way higher than they thought, and all of a sudden, we are now in this vicious loop where the patient is not actually able to get the medications they want and need. So, we are really excited about the real-time benefits check because it is a huge step forward for customer experience, and we are delighted to be able to make that a part of the proposal.

The last thing I will mention is the provisions for protecting care access, which is related to strengthening protection for access to lawful reproductive healthcare by creating an exception in the information-blocking set of regulations that would apply when an information-blocking actor chooses not to share certain information because that actor believes that sharing that information could risk exposing patients, providers, or those who help them to legal actions based on lawful reproductive healthcare in the circumstances that the patient is in. We have had a lot of discussions with providers across the country and have been very

concerned about this, both from their perspective as well as from the patient's perspective, so we are happy to be able to put this forward as well as part of the proposal.

We think that is an important part of the fundamental trust that patients need to be able to have in the healthcare delivery system and with their patients. They absolutely need to be able to have that trust, and they need to have trust with payers too, but they absolutely need to have trust with their providers, and we think this is an important step to assure that they continue to have that trust and continue to feel that that is not a barrier to their seeking of the care they choose and want. Hopefully, that gives you some perspective on the important policy underpinnings that we think are vital to the interpretation of HTI-2, and I know I have taken up a lot of time, but let me turn it over to my colleague, Elise Anthony.

Elise Sweeney Anthony
Thanks so much, Micky. As Micky said, we are super excited about HTI-2 being out. I do want to note a couple of things on that. It is available on our website. Once it is on public display in the *Federal Register*, we will also update that to reflect our website as well, so just keep in mind that the comment period has not started until you start to see it on public display in the *Federal Register*, and then it will be published in the *Federal Register*, and that will kick off the clock for public comment. We do look forward to all the comments that are going to come in. As folks know, we read every single comment. It really helps us to decide where we are in the policy and whether what we have is the right balance or whether there are some things we should consider adjusting. I know folks are busy and have a full workload besides reviewing our rules as well, and we really appreciate the time you take to make your comments, so whether it is a sentence, two sentences, 10 pages, or 100 pages, it does not matter. We read all the comments, and I encourage folks to take a look and tell us what you think.

So, with that, we have a number of other updates going on at ONC in the midst of all these other things, believe it or not. We are really excited about the work that is going on, and I want to make sure we give you a little bit of an update on some of those things. The first one is the USCDI Plus program. We recently completed one of the first real-world implementations using the Health Level Seven (HL7) FHIR bulk data access standard as part of a federal program. This is a joint effort between ONC and Health Resources and Services Administration (HRSA), and is a huge improvement over manual reporting. It helps to reduce the recording burden on the federally qualified health centers that HRSA serves. In April 2024, HRSA began accepting and receiving FHIR-based Uniform Data System (UDS) deidentified patient-level submissions via UDS Plus. So, to date, HRSA has received UDS Plus submissions from an initial cohort of HRSA-funded health centers representing 2.2 million patients from different parts of the country.

I also want to update you on another part of USCDI Plus, and that is USCDI Plus Cancer. So, ONC and the National Cancer Institute are hosting a USCDI Plus Cancer post-summit summary. This follow-up webinar to the recent cancer research data exchange summit is designed to provide updates on our use case development activities and share pivotal findings that emerge from the summit discussions, including the cancer registry data element list. You can register through HealthIT.gov if you are interested in attending.

Next up is Standards Version Advancement Process (SVAP). So, ONC published the Standards Version Advancement Process, or SVAP, approved standards for 2024. The 2024 SVAP includes the advancement of nine standards, including USCDI v.4 and HL7 standards related to FHIR, C-CDA, and public health. Starting on August 19, 2024, health IT developers participating in the ONC health IT certification program

can voluntarily incorporate a new version of standards into their certified health IT modules. I know I am going a little bit fast, but we are dropping some of the links in the chat. I want to make sure we get through all of these items for you.

The next one is Leading Edge Acceleration Projects (LEAP). The ONC Leading Edge Acceleration Project, or LEAP, health IT program is seeking applications to fund projects that will address one of two areas of emphasis. The first is developing ways to evaluate and improve the quality of Artificial Intelligence (AI) tools in healthcare, and the second is accelerating adoption of health IT in behavioral health settings. Applications will be accepted until 12:00 p.m. Eastern Time on July 12th, 2024. In addition, CMS recently released an information bulletin developed in collaboration with ONC that provides examples of state Medicaid information technology expenditures to improve access to and coordination of treatment support services from Medicaid beneficiaries with mental health conditions and/or substance use disorders that may qualify for enhanced federal matching rates, and we will drop the link in the chat for that as well.

Here are the feedback opportunities coming up. The public comment period for the new USCDI Plus Maternal Health draft data set is still open. ONC is asking for feedback on how the data classes and data elements support an understanding of how maternal health may impact outcomes in both mother and child. So, comments are due by July 31st, 2024 at 11:59 p.m. Eastern Time. Submit your comments through HealthIT.gov. Another item that is also out is the annual comment period for the Interoperability Standards Advisory, or ISA, and that is open until August 12th, 2024.

So, if all of this is not a reason for our listeners to sign up to stay aware of all the great activities that are under way, I do not know what is, so please do check out our website. You can also sign up for our listserv, where you see a lot of these updates as they are coming through. But the annual comment period for the ISA is open until August 12th, 2024, and as a reminder, the ISA is available on the newly designed Interoperability Standards platform, and that new platform is a one-stop shop that houses all of the ONC standards initiatives, so that includes the ISA, the USCDI, USCDI Plus, SVAP, and Project US@. So, check out HealthIT.gov, and to be more specific, HealthIT.gov/ISP, and you can comment there.

In closing, I just want to thank everyone for everything that they have done in terms of their contributions to our work at ONC. As you can see, there are so many initiatives that we have under way, and all of it really moves towards advancing the care continuum and think about how health IT can support that. So, from our rules, to our initiatives, to our standards work, you see that across our work, and we really appreciate all the time that you take to contribute to that effort. With that, I am going to turn it over to Medell and Sarah for their opening remarks.

Opening Remarks and Review of the Agenda (00:28:03)

Medell Briggs-Malonson
Thank you so much, Micky and Elise. We recognize the incredibly large volume of important impactful work that you as well as the rest of the ONC leadership and the staff are pushing through, and as HITAC, we are always eager to support and help in any way possible. So, good morning once again, everyone. I hope that everyone is staying cool and safe during this incredible climate change that we are having throughout our country as well as our globe, and we are excited today just to dive a little bit more into some of the ways that we can directly assist ONC with some of these very important initiatives. I will turn it on over to my amazing co-chair for her welcoming remarks as well.

Sarah DeSilvey
Thank you so much, Medell. I just want to echo appreciation for the leadership of ONC. What an amazing HITAC opening update, just an incredible amount of effort, and as one who works in a rural Federally Qualified Health Center (FQHC), I am really looking forward to the UDS applications and all of the new innovations coming across the ONC ecosystem. Again, welcome. I am coming to you from Vermont, which has suffered the sequelae of Beryl. I am happy to go through the agenda today, and thank you all for joining us in the summer. I know the summertime is tight, so we appreciate all of you taking time out from your workdays and your families to be with us today.

So, I am going to go through the agenda. We already did the call to order and rollcall. We are very, very grateful for the leadership, presence, and vision of ONC and the presentations of Micky and Elise. Thank you so much. We are going through opening remarks. As noted, there is a lot of new, breaking, hot-off-the-press stuff to review, but we are going to hold that because we are going to be going into our first item on the agenda, the HITAC task force charges, then we are going to be going into presentations from the Annual Report Workgroup, which is really a high-level discussion of potential topics led by the co-chairs, Medell and Eliel. Then, we are going to segue into the overview of HHS information-blocking disincentives Final Rule. As always, we will have public comment, and then we will go into our final remarks and adjourn at 12:40 or correlating time zones. Thank you so much for being here. We are very, very grateful to have all of you here today, and I am going to head back to Medell to introduce our next section.

Medell Briggs-Malonson
Thank you so much, Sarah. I would also like to introduce Seth who is actually going to take us over some of our HITAC task force charges. Seth, I will turn it on over to you.

HITAC Task Force Charges (00:30:39)

Seth Pazinski
Thank you, Medell. I am going to go over charges for two task forces that we will be launching, the HTI-2 Proposed Rule Task Force as well as the Health Equity by Design, or HEBD, Task Force. I am going to try to keep my comments fairly short. We did leave some time if folks have questions or want to share any initial thoughts as we move the HITAC into focusing on these two task forces. So, we plan to start the HTI-2 Proposed Rule Task Force immediately and aim to have our first meeting next week.

The HEBD Task Force will kick off upon the conclusion of the HTI-2 Proposed Rule Task Force. The reason for that is that the committee needs to complete their work on the HTI-2 Proposed Rule within the 60-day public comment period, so we are starting with that task force first, and then we recognize that members of the HITAC are likely to be interested in serving on both task forces, and we recognize that it is a time commitment for HITAC members to participate in a task force. So, we wanted to be able to stagger them so that folks would have the opportunity to participate in both if they are interested in doing so. So, once the HTI-2 Proposed Rule Task Force finishes up, we will kick off the HEBD Task Force, and I would anticipate that to be around mid-September. So, we can go to the next slide.

I am going to start with the HTI-2 Proposed Rule Task Force charge. The charge here is for HITAC to review and provide recommendations on the HTI-2 Proposed Rule , and we are taking a similar approach to what we took for the HTI-1 proposed rule, so we plan to have one task force, but have that split into three

subgroups focused on areas outlined in the specific charge, so we will have a group focused on the public health aspects of the rule, another group focused on the standards and certification provisions, and finally, a group focused on the information-blocking and TEFCA provisions. So, we will start the work. The initial meeting of the task force will be the full group, where ONC will provide an overview of the rule, and the following week, we will start our individual subgroup meetings. Towards the end, the task force will come fully back together and compile a single set of recommendations to present to HITAC.

If you are not planning to be on the HTI-2 Proposed Rule Task Force, I just want to state that you will still have the opportunity to inform the HITAC recommendations, so we are anticipating that the task force will provide an update and have a discussion of their initial conversations and draft recommendations at the August 15th HITAC meeting, and then, the task force would present their final recommendations to HITAC, and HITAC members would, again, have the opportunity to review and provide any edits before bringing it to a vote at the September HITAC meeting.

And then, as I mentioned earlier, the HITAC recommendations do need to be transmitted to the National Coordinator prior to the end of the 60-day public comment period so that we can consider them as public comments on the rule, and we will not know the exact date when the public comment period will end until the HTI-2 Proposed Rule is published in the *Federal Register*. However, we are expecting that the September 12th HITAC meeting will work as far as fitting within the 60-day public comment period and wrapping up the HITAC recommendations. Go to the next slide.

So, we had a wonderful response to our call for volunteers to serve on the HTI-2 Proposed Rule Task Force, so I wanted to just thank everyone for their interest and for volunteering to be a part of the task force. This is the current roster. If you did volunteer and you are not seeing your name here, please just email me, and you have my apologies. We will get you added right away. Also, we are in the process of firming up the task force co-chairs, so we anticipate we will have the co-chairs identified by the end of this week so we can get the group up and running next week. We can go to the next slide.

So, today is going to be our last call for any HITAC members that wish to be on the task force, so please email me today if you want to be added and are not currently on the roster. If your name is on the roster slide for today, then we have got you, no further action is needed at this point, and again, many thanks to everyone who volunteered. I look forward to working with you all on the HTI-2 Proposed Rule Task Force.

We are going to move now to the Health Equity by Design Task Force, and then we will pause for any questions or remarks that HITAC members have. We can go to the next slide. The overarching charge here is to focus on providing recommendations on industry resources that can help advance standards adoption, help organizations incorporate the equity data standards, as well as incorporate Health Equity by Design principles into their organizational practices. So, we have two specific charges. The first one is going to focus on reviewing a draft crosswalk, and ONC will provide the draft crosswalk to HITAC and to the task force to review. This is going to focus on a crosswalk between the HHS 2011 survey-based equity data standards with USCDI, and our aim is to have recommendations from HITAC by the February timeframe. We can go to the next slide.

And then, the second charge here targets recommendations on industry best practices, approaches, and resources that can support health IT users and their organizations in the incorporation of Health Equity by

Design principles into their health IT design development, deployment, analytics, and policies. We are really looking for recommendations that are concise, but detailed enough to help organizations get started and navigate how to start building Health Equity by Design into their implementation efforts. The aim here is to have recommendations from the HITAC in the March timeframe. We can go to the next slide.

So, while we are not anticipating this task force will start until the middle-of-September timeframe, we do want to get the roster and task force co-chairs in place, so please email me by July 16th if you would like to participate on the task force, and, if you are participating, if you would be interested in participating as a task force co-chair for this task force. Again, if you are not planning to participate in the Health Equity by Design Task Force, you will still have an opportunity to inform the HITAC recommendations in this space, so the task force would be bringing updates to the full HITAC committee while it is operating, and then you will ultimately have the opportunity to vote on the final recommendation. So, if you are not planning on participating, you will still have the opportunity to engage with and inform the HITAC recommendations.

And then, I think we can move to the next slide. In closing, we have a lot of work ahead with two task forces lined up back to back, and we are thrilled to have the HTI-2 Proposed Rule out and are looking forward to having your recommendations on that, and we are excited to build off of prior work with the HITAC, both through HITAC hearings and through the input we have received through the annual report on Health Equity by Design that have informed the creation of the Health Equity by Design Task Force, so we are excited to continue the work in that area. At this time, I am going to turn it back over to Medell to open it up for any questions or comments that HITAC members have.

Medell Briggs-Malonson
Thank you so much, Seth, for providing these overviews. These two task forces are going to be incredibly important for, of course, not only improving the efficiencies of our health IT systems, but also to promote greater high-quality equitable outcomes for all of our patients here within the country. So, we are going to go ahead and open it up for any questions that people have regarding either the HTI-2 Task Force or the Health Equity by Design Task Force. Any questions about the charges? Yes, I see Bryant's hand.

Bryant Thomas Karras
Hello, everyone. My video is not coming on. There we go. So, we are really excited and ready to get going on the task force, so we are looking forward to next week. I had one question. Can you talk a little bit more about how the three separate sections that you described in the HTI-2 Task Force will operate? Will there be a separate series of meetings that are assembled, and will there be the opportunity to invite additional representative members to flesh out the expertise that may be needed in each of the components?

Seth Pazinski
Yes, I can address those points. Typically, for the HITAC task forces that have addressed the ONC rules, we have not extended it beyond the HITAC members, but I certainly would welcome that feedback as we start the task forces if there is a feeling that additional expertise, as we have done on other task forces, would be good to bring in. We can certainly do that. Our policy there is just that the balance of the membership has to be a majority of HITAC members who would be serving on the task force, so I think we do have about 20 members at this point. We also just want to be aware of the overall size of the task force, but yes, that is an opportunity if the HITAC members feel that some additional outside expertise would be beneficial. We can work on inviting additional experts to join the task force.

For the subgroups, what we did last time worked well, although I want to also acknowledge the time commitment, so, definitely be aware of that as you are volunteering to be on the committees. Certainly, you can participate as much as possible, but when we are having the individual subgroup meetings, we would anticipate each of those meeting once per week for a total of three task force meetings because we are trying to be conscious of the time commitment. What typically works is that HITAC members will split into the areas they are most interested in, and again, you are certainly welcome to participate in multiple or all of the subgroups, but that just helps address the overall time commitment on behalf of the HITAC members. And so, we also have a program staff lead who will be working across all three subgroups and individual ONC staff leads that will be supporting individual groups. So, through the co-chairs and the program staff leads from ONC, we will be looking across the different workgroups to make sure that, if there seems to be some misalignment or questions from one group to the other, we can help make those connection points.

Bryant Thomas Karras
Thank you, Seth. For the public health section, obviously, I am thinking about the membership that we assembled for the prior two public health task forces. I am thinking that we could extend invitations to members of those prior commitments who could hit the ground running, understand how a task force operates, the rules of the road, and what would be involved in participation, but I also think that, since time is of the essence, we need to line up those invited speakers that would address details in each of the different F criteria that are laid out in the proposed rule, because I think that there is a lot to cover in a short period of time.

Medell Briggs-Malonson
Thank you so much, Bryant. Thank you, Seth. Michael?

Michael Chiang
Medell and Seth, thank you very much. I just have a comment that is pretty similar to Bryant's, but I hope it is not exactly the same. I obviously think Health Equity by Design is extremely important, and my comment is that, from a National Institutes of Health (NIH) perspective, we have a lot of activity going on to develop standard representations for how you report things like race, ethnicity, sex, and gender, and the concern sometimes comes up that we should really be doing it consistently across HHS, especially if data are collected in EHRs. And so, my comment is just that I think it would be amazing to coordinate that among agencies, and along those lines, would you consider having somebody who represents NIH, like somebody who is one of the people who does that, as a member of the task force?

Seth Pazinski
Yes. So, my colleague, Sam Meklir, is also on the line, who will be serving as one of the SMEs helping out with the Health Equity by Design Task Force, so, Sam, I will turn it on over to you to talk about some of the efforts to coordinate across HHS.

Samantha Meklir
Yeah, thank you so much for the comment. I appreciate that. As we look to staff the task force, we have reached out to colleagues in key opdevs, including our friends at CMS and The Assistant Secretary for Planning and Evaluation (ASPE), and we appreciate your input, as well as NIH's. We very much want to do this in a collaborative, coordinated fashion that leverages the expertise of our colleagues within the

department and really pushing out an approach that supports broader alignment policies and goals and is obviously coordinated and really timely for some of the changes that are also coming out of Office of Management and Budget (OMB) on race and ethnicity as well. So, we are very much planning a coordinated approach and have already invited colleagues to staff the task force as well.

Medell Briggs-Malonson
Thank you for that answer, Sam. Ike, I recognize your hand, but I also had a quick comment that is related to what was just mentioned. I am incredibly excited about the Health Equity by Design Task Force, of course, but one of my questions was the idea behind doing the crosswalk, which is part of Charge No. 1, towards HHS 2011 data elements versus all of the new data elements that the industry is currently already capturing, including, of course, in USCDI, both Tracks 4 and 5 as well as what the OMB is already proposing, so we are more aligned with it and being future-facing versus taking a look at older data elements which many of us that already do this work have actually far surpassed, and of course, we would want to bring any other organizations or agencies towards where we need to be in the future as well. I am just curious about defining Charge 1 to be a crosswalk toward the 2011 guidelines.

Samantha Meklir
Thank you so much for that question. We may need to think about how we communicate that because it is very much intended to achieve exactly what you outlined, and so, we very much want to delineate the relevance of USCDI and use what is up to date, but we are very cognizant that, as we look out across the broader landscape, often, there is great familiarity and reference to 2011, so the more we can make and delineate where that crosswalk exists and support reference to the USCDI, we think that that will be very helpful, and really, this crosswalk effort builds upon the types of documents. Our friends at CMS, for instance, put out a standards table that focuses on equity standards, and they indicate, where applicable and relevant, where they align with the USCDI. We want to get really granular and make that connection very clear, so it very much is intended and aimed at the intent of your question here. Does that address your…?

Medell Briggs-Malonson
It does. I agree, maybe some additional clarification or language is needed in that charge, because for me, when I read it, it seemed like we were trying to go backwards to a much older standard.

Samantha Meklir
Thank you. We are very much trying to pull people forward here. The focus in the crosswalk is stemmed from USCDI and making that delineation clear. So, where there are references to 2011, at present, across many programs, they now have a document that they can use that shows where it aligns with the USCDI, and then identify the tools, resources, and approaches that help support and inform implementation approaches as well.

Medell Briggs-Malonson
Thank you so much, Sam. I appreciate it. Ike, I see your hand.

Steven Eichner
I have observations and questions on both aspects. First, looking at HTI-2, one of the things we can leverage is not necessarily only extending participation in the task force to non-HITAC members, but looking

to non-HITAC members as subject matter experts to share their ideas and viewpoints as subject matter experts. We have done that very frequently for both committees and task forces to extend the input and extend the information available to HITAC as we have developed our material, so that is something we really should look at, not just from a public health perspective, but across the board with respect to HTI-2.

Looking at Health Equity by Design, as we were talking about in the Annual Report Workgroup the other day, I think it is really important that we ensure that Health Equity by Design includes across what domains we are considering equity so that it is not just race and ethnicity, but also including culture, disabilities, and a bunch of other components, and recognize that up front because we do not need to silo addressing those issues, forget about a community, come back later, and say, "Oh, this should have been included from an equity by design perspective." We are not doing ourselves justice if we are not including a wide set of issues as we are considering equity. I just want to make sure we get that captured and that we are being as inclusive as possible in our discussion.

Annual Report Workgroup – Discussion of Potential Topics (00:51:30)

Medell Briggs-Malonson
Thank you so much. I really do completely agree with everything that you said. As we all know, you cannot provide high-quality or high-value care if it is not equitable, so it is not its own separate domain, it is part of advancing health overall, so those are all incredibly important components that I am sure we are going to go deeper into during this task force as well, so, thank you for that. Any other questions or comments regarding our two exciting task forces that are coming upon us? Okay, not seeing any, Seth, thank you so much. I really do appreciate the introduction to these task forces.

Once again, if you are interested in participating on the HTI-2 Task Force, please let Seth know by today, and if you are interested in participating on the Health Equity by Design Task Force, please also let Seth know by the close of the business day on Tuesday, July 16th. I really do appreciate all of that. All right, well, we are going to go into the next section, which is also a section that is near and dear to my heart, especially with my additional phenomenal co-chair Eliel. And so, we would like to give a quick update on all of the amazing work that is occurring within the Annual Report Workgroup, and today in particular, we would like to present to the whole HITAC committee some of the various different potential topics that have been identified to be included in the annual report for fiscal year 2024. Next slide.

And so, just as a quick update, we are going to go over the workgroup membership as well as our meeting schedules and next steps, and then Eliel will lead the discussion of potential topics for the HITAC annual report for fiscal year 2024. Next slide. This is a list of all of our workgroup members. As you all know, we expanded the Annual Report Workgroup this year, which has been incredibly amazing because we have had even more additional perspectives, insights, and voices in order to help to guide what we are thinking about and placing within the Annual Report Workgroup in order to reflect all of the amazing work that HITAC has done throughout this year. Next slide.

Now, going over our meeting schedules in the next steps, we have completed three meetings to date, our last meeting on July 8th, in which we had developed the list of topics for the annual report, and what we have done so far is started to develop the crosswalk of topics for fiscal year 2024. One of the things that we will present during the next HITAC meeting is what that crosswalk looks like, and especially for our new members, it actually has various different aspects of that crosswalk, from the topic, to the gaps, to the

challenges, as well as proposed HITAC activities. And so, we will continue to work on the crosswalk for the next three additional meetings of the Annual Report Workgroup, and then, that crosswalk will also go and be developed into the draft annual report. We will bring that back directly to the full HITAC committee on October 2024 during our in-person meeting, and then, we will hopefully wrap it all up and tie up all the loose ends in order to prepare for it to be submitted directly to the National Coordinator for his review and approval, which will then be submitted directly to Congress. Next slide.

In terms of our meetings schedule for the full committee, once again, we are going to provide today just an update on the topic list, and next month, we will also provide an update on the crosswalk and really gather all of your additional thoughts and insights in order to be incorporated into the annual report. We will continue to bring it back in terms of the status of the report development, and on October 17th, as mentioned, we are going to go deeper into reviewing the draft of the full report, and then hopefully approve it by November 7th. Again, this is a much more condensed timeframe this year than what we have actually had in prior years, so we are trying to finalize the entire report before the end of the calendar year, so we are working really, really quickly and diligently in order to finish this report. Next slide.

In terms of our next steps, I mentioned most of this, but we are finalizing our crosswalk of topics on gaps, opportunities, and recommended activities across the five various different target areas over the summer, and then we will be back next month in order to present that crosswalk to the full committee. Next slide. So, I will turn it on over to Eliel for him to lead us through an overview of the potential topics that have been developed. Eliel?

Eliel Oliveira
Thanks, Medell. Like Medell mentioned, we are going to go over the topics today, and in the next HITAC meeting, we are going to go over the crosswalk itself with everyone and see more details at that point to reach our goal by November. Next slide, please. To start with, we want to pose some questions to you beforehand before we go over the topics so that you start thinking about these specific questions, as we covered in the topics today. Are there any questions or comments about the draft topic list that you are going to see here? What other topics should be added to the draft topic list, and should any topics be removed from the draft topics list? Again, to remind you, we are changing a little bit of the timeline of the report this year. If you have not been on the Annual Report Workgroup before, we would not necessarily follow the yearly schedule. The reports were usually going out in February, but now we are trying to basically bring it in to be transmitted to Congress by December. So, it is a bigger group and a shorter timeline, so this year is going to be a little different. Next year, we are going to be back on the 12-month schedule, but for now, we are following the yearly schedule. So, keep those questions in mind. Next slide, please.

Here are the topics that we have. We have covered the first two so far in our current workgroup meetings. Like Medell said, for the next three meetings, we are going to be detailing the next three topics. So, as you can see, there are going to be more details on the first two at this point as we evolve on the other three, but the first topic is related to health equity and the design and use of technologies that advance health equity, and we have talked quite a bit about the use of artificial intelligence in health and healthcare and how we are going to be implementing health equity by design, and I think we had a good discussion about that that we would implement in here. There is the fact that we have already defined health equity by design maybe a couple of years ago and have had great discussions, and of course, there is more to be done, but how do we put into action some of the things we have talked about in the past?

The second topic is the use of technologies that support public health. As you know, we had a public health task force last year, and there is much more here to do, and we discussed quite a bit about how we could be optimizing public health data exchange infrastructure. As you all know, we came out of a pandemic, we have made some tremendous advancements on how to exchange data for public health, but we believe that there are ways to further optimize that infrastructure.

The third topic is interoperability. It is one topic that is always part of the Annual Report Workgroup, and as we can see here, we have two areas that we are covering this time, supporting interoperability standards for laboratories and pharmacies, again, with eyes on public health, the pandemic, and all the support that we need on those two aspects, and then, improving long-term and post-acute care interoperability. As many of you may know, they use electronic systems as well, but they are not certified EHRs for the most part, and that creates some challenges, and we are going to be discussing how that can be advanced in the interoperability topic area.

The fourth one is privacy and security, again, another topic that is always part of the Annual Report Workgroup discussions. We are talking about a couple of different ones, the privacy and specificity of health and personal data, both in general, but also for consent, how we address those two specific aspects of the sensitivity of data, and the lack of disclosure accountability. I think we all used to say “account of disclosures,” but I think we thought that “disclosure accountability” is a better term to be used here. And then, there is the transparency in use of deidentified data. We see that these two specific subtopics are linked, and are also distinct alongside. So, we want to deep dive on that, and that discussion has not taken place yet, like I said, but we are looking to that point. Finally, there is patient access to information. We have talked quite a bit about PGD, or patient-generated health data, and we are going to be addressing a bit more on that front. Next slide, please.

So, some of the new topics for the HITAC members to comment on are listed here. We talked about interoperability a little bit with supporting imaging in HTI-2. Improving behavioral health interoperability, further improvements of data quality and sharing, supporting data standards for diverse abilities, and all that on interoperability are things to consider adding. Under patient access to information, how are we reducing patient burden? So, that is all that we are considering for this report round, and then, I will go to the next slide so you can see again the questions that we posed earlier. Are there any questions or comments that you would like to share with us, what are the topics to consider, and should any be removed? Thank you. Deven, I see your hand first.

Deven McGraw

Thank you very much. This is an incredible scope of work proposed here. It is hard to imagine that you would take any of them off, frankly, because they are all pretty important, and I was glad to see that, in the patient access category, it is not just about patient-generated data, although that topic keeps getting pushed to the side because we still have not, frankly, gotten access to the point where it is not too hard for patients to do, so I am glad that we are still taking that topic on and adding that. Some of these privacy and security topics, or, in fact, all of them, are very needy, and in prior versions of HITAC, there were entire committees who were dedicated to just those topics alone.

So, I almost feel like the list of topics on here is so broad that it is hard to know why all of us would not want to participate in this, because some of the neediest and most important topics are being considered by this workgroup alone. So, I guess my question is if it is too late to join, for one, because now I am seeing things on here on which I have a fair amount of experience that I hope I could contribute to that, and secondly, I guess I am sharing a bit of confusion, which I shared before when we talked about the annual report. What does this workgroup do? Because it seems to sort of take on, in some degree of depth, a lot of topics that arguably could use their own deep dives.

Eliel Oliveira
Thanks, Deven. I am going to tap into Seth here for a second to answer your first question.

Medell Briggs-Malonson
Yes, and then, Deven, I am happy to answer some of the other questions that you asked as well.

Deven McGraw
I realize I had many of them.

Medell Briggs-Malonson
Yes, so I am happy to do so.

Seth Pazinski
I will just highlight a couple of points in response, Deven. From an ONC perspective, one of the things that is incredibly valuable that comes from the Annual Report Workgroup is taking some of these broad topics here and starting to break them down into the various aspects, as you were pointing to, within that broad scope. That would fit into things that ONC, as well as HITAC, can influence or address within these broader topics. It is a good way to help feed future hearings or task forces of the HITAC, and that has happened in a number of cases. Public health is a good example where that was elevated as a priority, addressed in the Annual Report Workgroup, and then, subsequently, for the next two years, we had dedicated task forces developed that addressed public health data systems.

So, that is one of the things that is the primary thing we look at when we work on the workplan, so when we put forward a draft workplan at the end of each calendar year and then finalize that, we start by looking at the annual report and what is coming from there. And then, in addition, while all the recommendations from HITAC go to the National Coordinator for health IT, this report in particular, by statute, is delivered to the secretary of HHS, as well as Congress, so it is also an opportunity for HITAC to voice specific interests and recommendations to the secretary and to Congress.

Medell Briggs-Malonson
And then, to answer some of your other questions, Deven, in terms of how to provide feedback. First, this is why we bring these topics directly to the full committee of HITAC. A lot of these topics are actually extensions of last year's annual report, in which we could not go as deep into them. If you already have some insights or perspectives on some of these topics, we welcome them, which is why we are actually presenting them to HITAC right now, and then, next month, when we come with the crosswalk, you will see even more of the details of the gaps and challenges, and we absolutely want everyone's perspectives and feedback. This is not a workgroup that is in isolation.

What we are trying to explicitly do is bring the various different concerns, such as patient-generated health data, which you mentioned. Yes, HITAC continues to feel that this is a very important topic, and regardless of what else occurs outside HITAC, we have clearly stated that this is an area we want to explore and help to guide and make sure that it is as efficient as possible. And so, we are trying to represent the voice, the concerns, and the recommendations of HITAC in this report so that it can go to the various different entities, as Seth mentioned, in order to hopefully be implemented into more thorough action. And so, we definitely want your expertise. We know, for instance, you are an expert in privacy and security in so many different ways, so we want some of your thoughts, and if you are really interested, we can actually give you some of the areas that we are discussing right now so that we can get even more of your expertise at the table to be incorporated into it, but we want everyone to take a look at these topics and highlight them. Fil just put some specifics in there as well. We want to get your perspectives on these topics.

Are these the right topics? Are we missing any topics? As we go through the more thorough crosswalk, which has more details, we want you all to go through with a fine-toothed comb and say, "This is spot on, this is not correct, we need to think about this," because that is the whole point of the annual report, to represent who we are and what our concerns and recommendations are.

Deven McGraw
That is helpful. Thank you all.

Eliel Oliveira
Thanks, Deven. When you see the crosswalk, things like having the history and background that you have of what took place in the past, one of the sections of the crosswalk is recommendations going forward. Task Forces are some of the things that come out of that, and we might bring certain specialists to be able to solve a specific challenge, and that is in the area of privacy and security. So, your background in the past of what has happened or not happened would be greatly appreciated here.

Deven McGraw
Yes, though there is a lot of "not happened."

Eliel Oliveira
I hear you. Thank you for that.

Sarah DeSilvey
Just as a reference, we have a slide that expands on 2023 here, and then, the next slide is new topics, correct? That is just for everyone's understanding.

Eliel Oliveira
Yes, and we can go back and forth if folks need to. Just ask. I see Michael's hand up next.

Michael Chiang
Eliel and Medell. I really like this list, and I wanted to specifically comment on two of the items. One of them is interoperability. I just wanted to make a plug for this issue of supporting interoperability standards. I loved what Micky said in the beginning about access to imaging from patients. In my piece of the world, which is

ophthalmology, ophthalmologists are totally struggling with lack of adoption of basic standards like Digital Imaging and Communications in Medicine (DICOM), and it really continues to be a free-for-all. ONC has actually been a huge help in partnering with NIH and National Eye Institute (NEI) on this, and I just wanted to make the callout, that I think this term "vendor-neutral archive" is kind of a misnomer sometimes. There are some vendors that use vendor-neutral archives to be vendor-specific and promote their own products. After the last meeting, I talked to Rob Anthony about this, and I understand it is not completely straightforward for ONC to address all these issues, but I think they are extremely important, and whatever we can do with it in this annual report would be a big benefit.

My other comment is about AI. Ashley Beecy and Chris Longhurst gave presentations in one of the retreats before, and I have been thinking about that since then. I just think that this concept of local assessment of broad AI algorithms is extremely important, the general issue being some mechanism for consistently evaluating the performance of these systems based on real-world data, and I hope that is something that can make its way into this report. The last comment that I wanted to make along the lines of AI is that I think one of the challenges is, to say the obvious, how we get these systems integrated into EHRs, which involves all these questions about actual integration into workflow and how they get used for billing, and I just think that is one of the barriers. How do we integrate AI with real-world care? To the extent that that can make it in here, I think that would be awesome.

Medell Briggs-Malonson
Thank you so much for all of those comments, Michael. There have definitely been conversations similar to that within the Annual Report Workgroup, but you brought up so many other important pieces for us to capture, so, thank you for that.

Sarah DeSilvey
It looks like we have Mark Sendak next. Thank you, Mark.

Mark Sendak
Hello. So, building off of Michael's comment, obviously, I work a lot in AI, so when I see that it is under health equity, I understand the need to prioritize those concerns, but so much of what I see in the world is not people building and implementing AI to advance health equity, it is for all sorts of other things. So, I would just want to make sure that there are other concerns related to implementation and local governance, but also, I think one of the biggest gaps is patient access to information and disclosures. So, if I can be helpful, I am happy to be, but I definitely would want to try to weave in some of the AI concerns in other domains.

Medell Briggs-Malonson
Mark, thank you for that. I am happy to answer that, and I saw your question in the chat, but then I saw your hand, so I thought we would discuss it. Eliel and I can tell you that there was an extensive conversation about artificial intelligence and how it is not just in the target area of advancing health equity, just as what you mentioned, because AI is emerging as such a huge, important aspect of the future of the delivery of healthcare, as well as public health, as well as other forms of system efficiencies in so many different ways, even patient engagement, as you mentioned. And so, we were initially trying to focus this, and therefore, once you see the crosswalk, it is really specifically focused on accessibility and the decrease of bias in

some of our various different models and algorithms, but your point is very well taken, and this was something that we discussed in the workgroup.

What I would say is very similar to what was mentioned to Deven. We absolutely want thoughts from everybody on HITAC, and so, that is why we are presenting these topics, so if you think we are missing something already, we can already tell you the team is capturing everyone's comments and feedback that is being provided verbally. If there is anything else that you all feel should be included in the topics or expanded within these topics, please let us know because we are happy to include it, and we continue to work that into this report, because this is our report, not just the report from the Annual Report Workgroup.

Mark Sendak
Thank you.

Medell Briggs-Malonson
Thank you.

Sarah DeSilvey
Thank you so much. Any other comments from the co-chairs on Mark's comment? All right, then we are on to Lee. Thank you so much.

Lee Fleisher
Thank you. This is a phenomenal list, and I am thinking of my previous role as a regulator. I am thinking of a couple of the areas, and I am really curious how you are thinking and would love to get engaged because the long-term and post-acute care was what my role at CMS was, and I might just say that is a mess in the ability to track it from a public health perspective. We have had numerous conversations, and I think the ONC was even there at one, at Duke Margolis Institute about laboratories and how we collect the data from laboratories. As you are thinking about this and thinking about what the secretary can do, not just about regulations, but in advice to the White House and OMB of what statutory authority we need for this country to be able to collect, how does this report interface and how are you thinking about it? As the others have said, I would love to get engaged in that aspect.

Sarah DeSilvey
Any thoughts from the co-chairs on this one?

Medell Briggs-Malonson
Eliel and I were both looking at each other. Go ahead, Eliel.

Eliel Oliveira
Lee, those are great thoughts and comments. Going back to what Michael was saying about AI, we recognize the placement of AI in health equity. It is not even fair. It might have to be its own topic at some point, since there is so much there, but I think we have felt that there is a lot going on in AI, and it is moving so fast, but bias is something that was not very clear that folks were paying attention to. I think the same goes for Long-Term and Post-Acute Care (LTPAC), and I am trying to connect the dots here. We could say the same for mental and behavioral health. Because each one of those topics are so complex, it is coming out the way it is at this point, but yes, we firmly believe that the workgroup needs to figure out how to

strategize on how to make some impact on this front because both for behavioral health and LTPAC, we have seen, after or during the pandemic, how hard it was to understand what was going on there, and some of that was because of the lack of data.

So, I am connecting these two dots also with what ONC is funding through the LEAP project that we talked about earlier, which is AI data quality, which is quite important for everything that we do, and the second one was the lightweight integration of clinical data in behavioral and mental health settings, which I think would be leveraged as well by the LTPAC interoperability aspect. The thing that I highlighted that I think would be very important here is that these topics are so large, and LEAP is a great way to test things out, but I think the recommendation eventually would be for ONC, being the convener of other agencies, to look at these things from a much larger perspective because we are not going to be making an impact on AI, LTPAC, and mental health with very small steps going forward. There is so much here that needs to be done at a large scale.

Lee Fleisher
I appreciate that, and in laboratories, it is really how Clinical Laboratory Improvement Amendments (CLIA), that tri-agency, thinks about it to collect the data because I know CDC is very interested in that.

Medell Briggs-Malonson
Lee, again, because of your expertise and experience, we definitely welcome your thoughts and insights, and especially as you see the crosswalk with the gaps and the challenges to ensure that we are thinking about the challenges and representing the challenges in the most reflective and impactful way, and also the recommendations, to your point, so they can be hopefully as actionable as possible, so we welcome your insights and expertise on that.

Sarah DeSilvey
Thank you so much, Medell. One of the things that I heard Medell and Eliel say very early is that this is our report. This is a collective HITAC report, even if the work is driving the structure and charge, so we will all have opportunities to weigh in with our expertise, even if we are not able to make those workgroup meetings, and this is evidenced by the collective editing and refinement of the last report. The great thing about our two co-chairs is I know that they will ensure that all the expertise of our diverse group is represented in the report, and we are really thankful for this early vetting of even the topic areas. Anything else to say there, Medell or Seth?

Seth Pazinski
The other thing I will share as members think about their feedback is one of the ways, again, that we use the annual report is to inform what the workplan will be for the HITAC, so if you think about how the HITAC operates, whether a topic is ready for a deeper dive, like through a task force, or maybe a more exploratory conversation, like through a hearing, or just a presentation and discussion at the meetings, it is helpful to get that feedback as well and helps us understand how best to integrate that work and engage HITAC on it.

Sarah DeSilvey
We can see that in this year's workgroups. Look at the Health Equity by Design Workgroup. I think we can see the movement of ideas and topic areas in the workgroup making it into very specific areas of charge

for HITAC over an iterative process, so, thank you so much for weighing in on that and the importance of written statements. Moving on, we have about seven minutes left for this topic. Rochelle, do you have another question or comment?

Rochelle Prosser
Sorry, I am at the airport. Hi, guys. My question was for maternal health. Is that a separate task force looking at how we can look at AI and interoperability in that space? I am at the airport; I do apologize.

Medell Briggs-Malonson
Thank you for that question, Rochelle. Maternal health, as we know, is an incredibly important topic for us to dive into and really think about how we can have the appropriate standards, which is even directly with some of the work that ONC is also leading with USCDI Maternal. That is something for us to try to figure out where in the annual report to actually detail that and how we are thinking about that in terms of AI, so it may be reflective in terms of where it currently is underneath a first target area of making sure that we are using AI to promote greater health equity and justice in the most responsible and ethical way, including, for instance, in all of these different domains that we know we have had persistent inequities. Thank you for that comment, and that is definitely something that we can explore.

Eliel Oliveira
Yes, I appreciate that, Rochelle. My perspective, as you know, is that there is a very large federal focus on maternal health through several initiatives. I think I even saw another announcement yesterday by the White House and ONC on USCDI Plus for Maternal Health. So, that is not to say that it is not part of the report. It is a great point to ask how we weave that into the report, but at the same time, we recognize that the administration is very focused on maternal health already. I do not know specifically what other areas here we can address. As you mentioned, AI maternal health is one area of expansion and attention as well. Thank you for that comment. We will address it in the workgroup.

Sarah DeSilvey
Before we close, can we just land on the new topic slide? I just want to make sure everyone understands the new areas of work that the Annual Report Workgroup is recommending, and I want to open up opportunities for further questions and just note that, due to the diligence of care of our Annual Report Workgroup co-chairs, they will be back at the next meeting with further information on the expanded topic areas and will do a crosswalk. Any other questions from HITAC before we move to our next agenda item, or final comments from either of the co-chairs or ONC?

Medell Briggs-Malonson
No. I just want to say thank you all for all of the robust conversation already. We are very excited about this report and very excited about all of your perspectives that we can incorporate into the report, so please do not be shy. Do not hesitate to provide some of the different feedback that you think is necessary in order to make this report very robust, very comprehensive, and, most importantly, very impactful so that we can continue to help to provide recommendations, not only to ONC, but also to our secretary and Congress. We are very excited about how this report is already shaping up.

Eliel Oliveira

Yes, thank you, everyone. We are really hoping to hear as much as we can from all of you with your advice and guidance. At the same time, you understand how much there is out there for us to address, and it becomes a hard workgroup in some ways on how to distill exactly what goes in and what does not yet necessarily, so it is a tough process to build the final report because there are so many important topics. We would love to hear your feedback on that as well and what to prioritize, not that there are things that are not important, but again, there are so many. Thank you so much.

Sarah DeSilvey
Thank you both, and thank you to all of the workgroup members. It is just an amazing opportunity to communicate the perspective and expertise of HITAC to such critical areas. I am now going to segue into the next presentation. It is my honor to introduce Alex and Elizabeth Holland. They are going to present on the HHS information-blocking incentives Final Rule. Welcome, Alex Baker, Elizabeth Holland, and Aryanna Abouzari. Are you with us?

Overview of HHS Information Blocking Disincentives Final Rule (01:27:11)

Alex Baker
Yes. Can you hear me?

Sarah DeSilvey
Yes, welcome! Alex, are you leading first as a speaker?

Alex Baker
Yes.

Sarah DeSilvey
Thank you so much.

Alex Baker
Very good. Hello to everybody. We wanted to take some time to talk about the 21st Century Cures Act Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Final Rule, which was released and published in the *Federal Register* earlier this month. Let's go to the next slide. So, just as disclaimers, the materials here are based on the document published in the *Federal Register* on July 1st, 2024, but while these are an attempt to accurately summarize the rule, for the actual text, folks should go to the document. Next slide.

So, we presented on the proposed rule a while back, so folks may remember the broader context, but just to recap on the background here, as folks know, the 21st Century Cures Act added Section 3022 of the Public Health Service Act related to the information-blocking provision of the Cures Act. That section defines information blocking for several types of actor, including healthcare provider, and specifically to healthcare providers, information blocking is defined as when conducted by a healthcare provider, such provider knows that a practice is unreasonable and likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

As folks may also remember, the Cures Act outlined two different paths of enforcement for the information-blocking provisions it established, so, for health IT developers, health information networks, and health

information exchanges that OIG determines have committed information blocking, the Cures Act gave the secretary the authority to impose civil monetary penalties of up to $1 million per violation on those actors. However, for healthcare providers, the Cures Act said that if OIG determines a healthcare provider has committed information blocking, that healthcare provider shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable federal law as the secretary sets forth through notice and common rulemaking. And so, this Final Rule is addressing that provision of the Cures Act when healthcare providers commit information blocking as determined by OIG and must be referred to an appropriate agency to be subject to these appropriate disincentives. Next slide.

So, again, this Final Rule was published on July 1st, 2024, and the effective date is 30 days after that publication, which goes to July 31st, 2024. It is important to note that this rule builds on a variety of different regulations that have come before to implement these provisions of the Cures Act, the 21st Century Cures Act Final Rule, which outlined issues such as exceptions to information blocking and other issues around how information blocking is defined, as well as OIG's grants, contracts, and other agreements, fraud and abuse, information blocking, Office of the Inspector General civil money penalties rules, which was released last summer in 2023, and focused on the enforcement mechanisms against those other actors that are not healthcare providers that are subject to the information-blocking rules. Important antecedents of this now are focused on healthcare providers and enforcement of rules. Next slide.

So, I just want to remind folks who healthcare providers are under the information-blocking regulations. So, in the 21st Century Cures Act Final Rule, ONC finalized that healthcare providers would be defined according to the definition in Section 3000 of the Public Health Service Act, which has been codified in 45 Code of Federal Regulations (CFR) 171.102. As you can see, that healthcare provider definition is very broad and includes a wide variety of different healthcare provider types who are subject to the information-blocking regulations.

It is important to note for the purposes of this Final Rule, and we will return to this towards the end, that this Final Rule does not address information blocking by all of these healthcare provider types, so, because the Cures Act focuses on establishing these disincentives under applicable federal law, we have focused on programs for a subset of these providers in this initial rulemaking. However, as we discuss in the Final Rule, we believe that ultimately, appropriate disincentives should be established for all these different healthcare provider types that are subject to the regulations. Next slide.

So, digging a bit more into the content of the Final Rule, we start with a section which provides some definitions of terms in this section of the Cures Act, so we define "appropriate agency" to mean a government agency that has established disincentives for healthcare providers that OIG determines to have committed information locking, and we establish a definition for the term "disincentive" to mean a condition that is imposed by an appropriate agency on a healthcare provider that OIG determines has committed information blocking for the purposes of deterring information-blocking practices, and we note in the Final Rule, reiterating the proposed rule, that a disincentive could be any condition that, in our estimation, would deter information-blocking practices among healthcare providers that are subject to the regulations. Next slide.

This section also discusses other aspects of the Cures Act provision, so we go into some discussion about authorities under applicable federal law, and we note that in our view, this means that the appropriate

agency may only subject a healthcare provider to a disincentive established using authorities that could apply to information-blocking by a healthcare provider subject to the authority, such as healthcare providers participating in a program supported by the authority, and this is important to understand the whole structure of the Final Rule. Unlike with the other types of actors, where the Cures Act focused on civil monetary penalties for those actors, for healthcare providers, it focuses on the authorities under applicable federal law, and that means that we have looked for other existing programs and existing authorities under which we can establish these disincentives and, for this rule, have focused on several authorities that are administered by CMS in order to establish the initial set of disincentives.

We also note in this section that a healthcare provider may be subject to each appropriate disincentive that an agency has established through notice in common rulemaking and is applicable to the healthcare provider, so it is important to note that the statute refers to appropriate disincentives in the plural, and does not include any specifics around needing to limit the disincentives that a provider could potentially be subject to if they have committed information blocking and been referred to an appropriate agency that may have established multiple disincentives for information blocking. However, there is a modification in the Final Rule, which we discuss, to account for scenarios in which an appropriate agency could exercise discretion in a certain scenario to not impose one of the disincentives that it has established, and this reflects one of the final policies for one of the disincentives that we will talk about a little bit later. So, the takeaway here is that a healthcare provider could be subject to each of the disincentives that an appropriate agency has established, but there may be scenarios in which the agency would determine that they are not going to impose a certain disincentive. Next slide.

So, we next turn to a discussion of the OIG investigation and referral process. An important caveat to note here, repeated from the proposed rule, is that this section does not include any regulatory provisions related to OIG's process. This is discussion that we have worked with OIG to develop and that is provided for informational purposes only to help the public understand what OIG's process may entail as they go about investigation, and we would refer folks to that July 2023 OIG Final Rule, which included additional discussion of the investigation process.

An important clarification in this section of the Final Rule is that the Final Rule states that OIG will not begin investigating healthcare providers until after the effective date of the Final Rule, which is the end of July, and will exercise its enforcement discretion not to make any determinations regarding conduct occurring prior to the effective date of the rule for information-blocking disincentives. And so, essentially, it is important for healthcare providers to understand that none of the disincentives that have been finalized in this rule would be applied to conduct that occurred before the effective date of this Final Rule based on how OIG plans to proceed with investigations, and this is consistent with the clarification that OIG made in its Final Rule about how it would approach investigations of the other actors that are subject to the information-blocking regulations.

This section also reiterates some discussion in the proposed rule about the anticipated enforcement priorities that OIG expects to use, so, the rule discusses how OIG has a limited set of resources and will make decisions about when it pursues potential information blocking, and that it will focus on practices that resulted in, caused, or had the potential to cause patient harm, practices that significantly impacted a provider's ability to care for patients, practices that were of long duration, and practices that caused financial loss to federal healthcare programs or other government or private entities. Next slide.

This section also discusses the referral process that OIG would engage in when it refers a healthcare provider to an appropriate agency after it has made a determination that that healthcare provider committed information blocking and discusses how, once OIG concludes its investigation and is prepared to make a referral, it will send information to the appropriate agency indicating that the referral is made pursuant to the statutory requirement, and that this communication could include information such as the dates when OIG determined the information-blocking violation occurred, analysis to explain how the evidence demonstrates the healthcare provider committed information blocking, copies of that evidence, and any additional information that it provides based on its consultation with the appropriate to the agency to the extent permitted by applicable law. Next slide.

The Final Rule then discusses several provisions generally related to the application of disincentives, so, in a new section of the CFR, it lists the finalized disincentives that are being finalized in this rule. If a disincentive is finalized for information blocking, we would expect to include it in this section of ONC's regulations so that it is clear what the disincentives are for information blocking for healthcare providers. We also finalize provisions around common elements of a notice that would be sent to a healthcare provider by any appropriate agency that is subjecting that healthcare provider to a disincentive or disincentives and finalize that the notice will include a description of the practice or practices that formed the basis for the determination of information blocking referred by OIG, the basis for the application of the disincentive of disincentives being imposed, the effect of each disincentive, and any other information necessary for a healthcare provider to understand how each disincentive will be implemented.

Finally in this section, we reiterate some discussion from the proposed rule about the ability of healthcare providers to appeal a disincentive administratively. This is a discussion that we included in the proposed rule, in which we stated that a healthcare provider's ability to administratively appeal a disincentive would be based on the authority used to establish the disincentive and whether that authority provides for such an appeal. So, we certainly had a lot of interest from commenters on the proposed rule about whether we would establish a new independent appeal process for the disincentives, and we reiterate that we did not propose such a process, but instead, given that we need to establish each of these disincentives under applicable federal law, we are focusing on how any administrative appeal would be limited to what is available under those different authorities. Next slide.

The Final Rule also includes final policies around a transparency policy for information-blocking determinations, disincentives, and penalties. It is important to note that this final policy applies to all of the actors subject to the information-blocking regulations, which includes healthcare providers as well as health IT developers, health information exchanges, and health information networks. Specifically, we finalize that ONC will publicly post information about actors that have been determined by OIG to have committed information blocking on the ONC website, and this would include identifying the information-blocking practices, identifying the actual actors who committed information blocking, for healthcare providers, identifying the disincentive applied, and then, linking to any other information about the determination that may be available from a US government source, for instance, if OIG has enforced a civil monetary penalty against one of the actors to which that is applicable and includes information about that enforcement action.

We discuss in the Final Rule that we believe this public posting of information about actors is important to provide transparency and to how and where information blocking is occurring within and impacting the

broader nationwide health information technology infrastructure. We also note several more minor modifications to this policy, including clarifying that no posting would occur until after any available administrative appeals process has been completed. So, again, as noted on the previous slide, that is contingent upon such process being available under a given authority, but we note that this transparency element, in which ONC has posted information about those who have committed information blocking, would not occur until after such an appeals process was completed. So, that completes the main overarching process elements of the Final Rule, and I am going to now turn it over to several colleagues from CMS in order to talk about the actual disincentives that have been finalized under CMS programs. Elizabeth, are you on the line?

Elizabeth Holland
Yes, I am here.

Alex Baker
Can we go to the next slide?

Elizabeth Holland
Thank you, Alex. My name is Elizabeth Holland, and I work at CMS in the Center for Clinical Standards and Quality. I am going to talk first about the Medicare Promoting Interoperability program and the disincentives established for eligible hospitals and critical access hospitals, or CAHs. So, this Final Rule is limited to Medicare disincentives and just a few healthcare provider types. So, we have finalized our proposal that an eligible hospital or CAH that commits information blocking will not be considered a meaningful EHR user during the calendar year of the EHR reporting period in which OIG refers its determination to CMS.

The impact on an eligible hospital will be the loss of 75% of the annual market basket increase for all of their Medicare payments. A critical access hospital would have its payments reduced to 100% of the reasonable cost when they usually get 101% of the reasonable costs. So, if an eligible hospital or CAH is already not a meaningful user during the applicable EHR reporting period due to its performance in the Medicare Promoting Interoperability program, imposition of this disincentive will result in no additional financial impact to the hospital. Next slide, please.

Now we are going to talk about the Quality Payment program, and specifically the Promoting Interoperability performance category, of the merit-based incentive payment system, or MIPS, under the Quality Payment program. So, we have finalized our proposal that MIPS-eligible clinicians would not be considered a meaningful user if OIG refers a determination that the MIPS-eligible clinician had committed information blocking. As a result, if the MIPS-eligible clinician is required to report on the Promoting Interoperability performance category, they would not earn a score at all in the performance category, and generally, under MIPS, there are four performance categories, and the sum of the scores you receive in those performance categories totals 100.

So, right now, the Promoting Interoperability performance categories is worth 25% of their final score, and this year, the payment threshold for 2024 is 75 points, so that means if you are not a meaningful user, you would lose 25 points, and if you receive a perfect 75% score, you would earn a neutral update on all your Medicare Part B payments, so that can have a big impact, and only if you get perfects in cost, quality, and improvement activities would you earn that 75%, so this could have a big impact on clinicians. Again, it is

all the Medicare Part B payments. We did modify our policy for this disincentive to clarify that if MIPS-eligible clinicians are found to have committed information blocking and it is referred to CMS by OIG, the disincentive would only apply to the individual, even if they report as part of a group, so, if this occurs because of the way we are applying the disincentive, when it is reported to us, and let's say it is reported in 2024, the group would not be submitting data until 2025, so they would be able to pull the individual and have them submit separately, so the whole group is not impacted.

Before I turn it over to Aryanna, I am going to make a plug. Yesterday at 4:15 p.m., we released the CY 2025 physician fee schedule proposed rule. In that proposed rule, there is a request for information. It discusses CMS's work with CDC and ONC to explore the Promoting Interoperability performance category and how it could advance public health infrastructure through a more advanced use of health IT and data exchange standards. There are goals, we lay out a bunch of questions, and this Request for information (RFI) is similar to the one we had in the Inpatient Prospective Payment System (IPPS) proposed rule earlier this year. So now, I am turning it over to Aryanna. Next slide.

Aryanna Abouzari
Thank you, Elizabeth. As part of this Final Rule, the Shared Savings program finalized a proposal to establish a disincentive for healthcare providers, including Accountable Care Organizations (ACOs), ACO participants, and ACO providers and suppliers, that have engaged in information blocking as determined by OIG. On an annual basis, CMS will screen ACOs, ACO participants, and ACO provider/suppliers for an OIG determination of information blocking and then deny or review or remove those providers from a Shared Savings program for a period of at least one year. CMS has also finalized that, in the case of an ACO applicant that is a healthcare provider, CMS may deny the ACO's application to participate in a shared savings program for the upcoming performance year, and for ACOs that are already participating in the Shared Savings program, CMS may terminate the ACO's participation agreement.

In response to stakeholder feedback, CMS has also finalized the alternative policy that was discussed in the proposed rule to consider an OIG information-blocking determination in the light of the relevant facts and circumstances, such as the nature of the healthcare provider's information blocking, the healthcare provider's diligence in identifying and correcting the problem, the time since the information blocking occurred, and whether the provider was previously subject to disincentive in another program prior to applying a disincentive. The consequence of receiving a disincentive for the Shared Savings program is that the ability of healthcare providers to participate in the program for at least one year will be restricted from receiving revenue that they might otherwise have earned if they participated in the program. And then, as part of the Final Rule, CMS has clarified that we will determine whether it would be appropriate for the period to exceed one year if OIG has made any subsequent determinations of information blocking. That is all I have for the Shared Savings program. Alex, back to you.

Alex Baker
Great. Thank you so much, Elizabeth and Aryanna, for presenting on that and for all of the wonderful collaboration with CMS on this rulemaking. So, on the final slide here, I want to circle back to what I noted at the beginning to remind folks that the policies in this Final Rule only apply to a subset of the healthcare provider types that are subject to information-blocking regulations. We included a request for information in the proposed rule, asking the public about other healthcare provider types that we should prioritize that are part of the definition for establishment of additional disincentives and what those disincentives could be,

understanding the limitations in the law around needing to establish disincentives under applicable federal law.

We received a lot of very helpful feedback on this RFI that we will take into account. We want to note that we have not set any specific timeline for additional disincentives rulemaking in this Final Rule, but we will continue to review those comments and explore how we can establish additional disincentives that will ensure that any of the healthcare provider types that are subject to the regulations could potentially have a disincentive available if they are found to have committed information blocking. Next slide. There are resources about the Final Rule available on the ONC website, such as a couple of fact sheets that I encourage folks to look at. I would also encourage folks to look at the wide variety of other resources that are beyond the scope of this rule around issues such as the information-blocking exceptions, etc. Next slide. That is it for my slides. I am happy to take questions.

Medell Briggs-Malonson
Great. Thank you so much, Alex, Elizabeth, and Aryanna, for such a comprehensive presentation on the disincentive rule. This is very exciting. I think we have all been waiting for this, and it is really going to make sure that we are continuing forward the way that we should in so many different ways. And so, we are going to open it up to the HITAC committee to see if there are any questions for the three. Any questions at all? Yes, Rochelle, I see your hand.

Rochelle Prosser
Thank you for this very all-encompassing presentation. It was very interesting. The one thing that came to mind was the question of other areas. I had mentioned my question about pediatrics for the other section. I think it is applicable here. As we know, we are still on CD-ROMs for pediatrics, and most are in an ACO or an overarching group. Is there any ability to provide better outcomes and standards using this program going forward with image sharing in pediatrics? It is currently on a CD-ROM. If you lose the CD-ROM or forget it, you have to chase the ambulance down the highway, and when you get it to the facility, the software system that it is originally uploaded on is not within the receiving system, so it becomes a blocking and it becomes an outcome, especially in acute settings. Have we considered pediatrics? I know there are other programs in data sharing and image sharing, but there is no standardization, so how can we use this to promote healthier outcomes for the pediatric population?

Medell Briggs-Malonson
Thank you, Rochelle. Any thoughts or reflections on that from our presenters?

Alex Baker
Specifically related to establishing information-blocking disincentives, that would certainly be a healthcare provider population that is included in the definition, but I understand that it is certainly an area where folks may be less likely to be covered under the disincentives that we have finalized in the Final Rule discussed today, and so, I think that will certainly be an area for consideration in the future as we look at some of the other HHS policy levers and authorities that could more specifically apply to the pediatrician population, but unfortunately, I do not have too much more to add to that.

Medell Briggs-Malonson

Thank you, Alex. Enterprise Security Services (ESS) mentioned, especially, Rochelle, in terms of all of the interoperability between imaging, that is, of course, a priority for many of the different agencies, so I think that, over the next upcoming month or two, we are going to see a lot of different movement in that area, which will also include making sure that we are taking care of not only our pediatric population, but the adult populations and other, more marginalized populations, so it is an exciting time with a lot of work that is already in flight, and so, thank you so much for that question. Michael?

Michael Chiang
Thanks, Medell. Alex, I want to apologize in advance for asking somewhat of a half-baked question, but I feel like information blocking is a concept that reflects a spectrum of behaviors, from very minor to very blatant, and I am curious if your group has discussed whether there is any mechanism for creating almost the equivalent of a traffic ticket for minor infractions that are annoying to providers and patients, but really do not rise to the level of a severe thing that requires loss of MIPS privileges. I would just love your thoughts about that spectrum concept.

Alex Baker
I think that is a very important concept for the rule, and we have certainly gotten a lot of comments from the public about that. The process in the Cures Act that we are implementing through this Final Rule is dependent upon an OIG investigation and determination that a healthcare provider engaged in practices that can be determined to be information blocking that do not meet any of the exceptions, and that also, the healthcare provider knew that the practice was unreasonable, so I want to reiterate that difference in the standard in the definition of information blocking for healthcare providers as opposed to the other actors, where, for a practice to be information blocking, they would have known or should have known that the practice is information blocking, but for healthcare providers, OIG would need to determine that the healthcare provider actually knew that their practice was unreasonable and was interfering with the access, exchange, and use of electronic health information.

So, for the process being implemented here, it is a significant practice that the healthcare provider knows they have committed. Also, we noted that OIG has laid out some information about the types of considerations that they would make around when they would pursue an investigation, which is obviously a fairly resource-intensive process in that they would be looking at practices that do have significant patient harm effects, significant effects on federal healthcare programs, so again, this Final Rule is really focused on those more significant actions that are defined by the law, and so, we did not focus much on other types of actions that would be outside of that, where they may not constitute information blocking as defined by the law. So, it is probably out of scope for this rulemaking, but is certainly an area that may be worth discussing in other contexts.

Medell Briggs-Malonson
Thank you, Michael, and thank you, Alex, for that response. Any other thoughts or comments about the disincentive rule? This is your time. We have all the experts here. All right. Well, again, I want to sincerely thank Alex, Elizabeth, and Aryanna for all of their time putting together this presentation and providing an overview of the Final Rule. We know that this is so critical in order to ensure appropriate interoperability as well as the best care that we can for both our patients and our communities, so we do appreciate your time here, and all the information. Well, we have now concluded the vast majority of all of our presentations for today's HITAC meeting, so I will turn it on over to Seth now to lead us through public comment.

Public Comment (02:05:14)

Seth Pazinski
All right, thank you, Medell. We are going to open it up for public comment. If you are on Zoom and would like to make a comment, please use the raise hand function, which is located on the Zoom toolbar at the bottom of your screen. If you are participating by phone only today, you can press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. We will give folks 30 seconds or so to queue up, and while we are waiting for that, I just want to give a couple of reminders. One is to remind everyone that the next HITAC meeting is going to be held on August 15th, and also, I want to remind everyone that all HITAC materials are found on HealthIT.gov and available to the public. I am going to check in with Accel. Do we have any folks on the line?

Unknown Speaker
No public comments.

Medell Briggs-Malonson
Actually, Seth, I do see one hand. Sheryl Turney?

Seth Pazinski
Go ahead, Sheryl.

Sheryl Turney
Thank you very much. I do appreciate the topics that were brought forward today, and I think they are very timely. There were two things that I wanted to raise, one of which is that with a large majority of providers, certified health IT systems are “out-of-the-box” type of solutions, and for those solutions, it becomes difficult for providers who do not have IT resources to make available the connection to other providers, payers, etc. that are required because they do not have the people on staff.

One of the things we have been discussing and thinking about is floating the idea of encouraging some of these certified health IT vendors to offer their products with default networks, and there are some national networks already, such as eHealth Exchange, that has a proving ground that can be utilized by third parties without them actually having to sign up for services, but they will make available some sort of package for these smaller providers. I do not know if CareQuality has the same option, but I think it is something we should explore, and I do believe that would bring us a long way in terms of encouraging some of these smaller providers who are still important to our business, because it is the largest majority of providers, to be able to share data with other providers, as well as payers. That was the first topic.

The second one is in respect to the patient. I have brought this up before, but I do think it is important to note that one of the challenges patients have is they become very fond of their patient portals in some cases, and there is no real ability for them to electronically share data easily, without downloading it to a PDF and then sending it that way, to other health systems that they may be required to work with that do not have the exact same patient portal. So, for instance, I am going to pick on MyChart. If you have MyChart and someone else has AllScripts, the patient has to basically download the PDF in order to send that through their own email. It would be advantageous to the patient to have the ability to exchange that data

within their portal, and then be able to use the portal of their choice, rather than having to select another third party in order to do that, because that just adds more burden to a person that is already dealing with a chronic illness. So, those are the two points that I wanted to make.

Seth Pazinski
All right, thank you so much, Sheryl. As a reminder, we do include time for the public to make verbal comments towards the end of all of our HITAC meetings, as well as our subcommittee meetings through the task forces and workgroups of HITAC, so we are delighted to have some public participation today, and I encourage folks in the future to take advantage of that opportunity, as we are always interested in welcoming your feedback, and with that, I will turn it back to Medell and Sarah to close us out.

Final Remarks and Adjourn (02:09:47)

Medell Briggs-Malonson
Thank you, Seth, and yes, I would love to reiterate exactly what you mentioned. We love comments and recommendations directly from the public, and so, please, any time that you do have a thought or you want to make sure to include your voice in the conversation, we absolutely welcome that. Once again, thank you, everyone, for a wonderful HITAC meeting that has been full of robust conversation. I personally look forward to HTI-2 and really diving into that, as well as our two task forces that we are being charged with. So, I really look forward to us rolling up our sleeves and helping to assist ONC, as well as the rest of our governmental agencies, and, most importantly, focus on our patients in order to improve our health systems. Sarah, I will turn it on over to you.

Sarah DeSilvey
Thank you so much. As usual, Medell says it much better than I can, and we share philosophies, but thank you so much to all of our presenters today. The thing that I am left with is the immensity of the work and the critical importance of all of it. I am so grateful that all your expertise is laid to bear on all the topics at hand. Please do return your interest to Seth on involvement in the different workgroups, and I have my weekend homework, which is reading the HTI-2, because I was not able to read it prior to this meeting due to all the pressing things at hand, and we look forward to seeing you in a month, but please do get back to Seth regarding your interest in the different workgroups, and we look forward to your comments on everything. Again, presenters, thank you for keeping us up to date on what is going on and for ensuring that the expertise of HITAC is able to bear witness to the work. Have a lovely July, and we will see you soon.

Medell Briggs-Malonson
Bye, everyone.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Maggie Zeng: HHS Information Blocking Disincentives Final Rule

Maggie Zeng: https://www.healthit.gov/topic/information-blocking#Disincentives

Maggie Zeng: HTI-2 Proposed Rule

Maggie Zeng: https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-patient-engagement

Derek De Young: Is there a reason we limited the real time benefits check to just Pharmacy? (NCPDP)

Hannah K. Galvin: This information blocking exception is really needed! I would encourage ONC to consider more use cases than reproductive healthcare (e.g. gender affirming care, immigration status, etc.) as well. Thank you for including this.

Rochelle Prosser: +1 Hannah

Rochelle Prosser: Thank - you Micky!

Maggie Zeng: USCDI+ Program

Maggie Zeng: https://www.healthit.gov/topic/interoperability/uscdi-plus

Seth Pazinski: More info on UDS+ https://www.healthit.gov/buzz-blog/interoperability/uscdi-milestone-onc-and-hrsa-modernization-initiative-goes-live

Maggie Zeng: Standards Version Advancement Process (SVAP)

https://www.healthit.gov/topic/standards-version-advancement-process-svap

Maggie Zeng: Leading Edge Acceleration Projects (LEAP) in Health Information Technology (Health IT) Notice of Funding Opportunity (NOFO)

https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information

Susan Clark: Applause to the FHIR bulk data for UDS reporting for FQHCs. That should be a significant burden reduction for those critical providers.

Maggie Zeng: CMS- Informational Bulletin

https://www.medicaid.gov/federal-policy-guidance/downloads/cib06142024.pdf

Seth Pazinski: Register for USCDI+ Cancer Post-Summit Summary Update Webinar here...

Seth Pazinski: https://www.healthit.gov/newsroom/events

Maggie Zeng: USCDI+ Platform

https://uscdiplus.healthit.gov/uscdi

Mike Lipinski: ONC proposes to use the HIPAA definition for reproductive health care, which would defer to OCR's interpretation of such term. We'll go into detail more on this in the webinar(s). Reproductive health care means health care, as defined in this section, that affects the health of an

individual in all matters relating to the reproductive system and to its functions and processes. This definition shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care.

Maggie Zeng: Interoperability Standards Platform

https://www.healthit.gov/isp/

Anna McCollister: It's great to see the focus on solving so many of the "patient pain points" in the HTI-2 proposed rule!!

Jim Jirjis: i would like to join the HTI-2 task force

Rochelle Prosser: Congratulations Everyone!!!! Happy to serve.

Rochelle Prosser: I would like to serve on this Task force for the Health Equity Task force.

Keith E. Campbell: Per Michael's comment on standardizing how we represent health equity and social determinants of health… We need general capabilities to normalize data across all domains. It is part of attaining data safety and effectiveness.

Keith E. Campbell: We need to make sure we are not creating new data silos, and have a pathway for general data normalization within healthcare.

Rochelle Prosser: +1 Medellin

Rochelle Prosser: Medell

Sarah DeSilvey: Gravity can assist here as our lens for risk is expansive to include all social drivers that affect equitable outcomes.

Keith E. Campbell: Can interoperability include evaluating safety, quality, and efficacy of the exchanged data?

Keith E. Campbell: Or could data quality be its own topic?

Medell K. Briggs-Malonson: @Keith, data quality, safety, and relevance are incorporated into these topics of interoperability.

Fillipe Southerland: Thank you to the Annual Report Workgroup for the highlight of LTPAC interoperability. I'd like to encourage a task force around this topic and LTPAC certification as we've done for other specialty sectors. LTPAC greatly impacts healthcare spend and it is so important that we integrate this sector from a technology and policy standpoint. I'd further encourage increased reporting on interoperability and certification uptake in LTPAC and other specialty sectors.

Eliel Oliveira: +1 Fill

Katrina Miller Parrish: Terrific work Workgroup! Thanks!

Rochelle Prosser: This is amazing perspective and feedback

Rochelle Prosser: Question for last section on Annual Report:

Pediatric Dara and Image sharing in Acute care and Emergency services. There is a reliance on CD ROM wheee the reading software is not equal or capable of image retrieval this hinders survival and treatment outcomes. This is affected in multiple areas. Health Equity, AI, Interoperability, healthcare data blocking, etc

Rochelle Prosser: +1Adele

Derek De Young: As a patient with MyChart - Share Everywhere is available to everyone as well that can help patients share their clinical record with any provider that is on a non interoperable EHR: https://shareeverywhere.epic.com

Eliel Oliveira: 👏

Rochelle Prosser: Thank you Derek for this link

Sheryl TUrney: Derek thank you for the link

Katrina Miller Parrish: 👍👍

Adele Stewart: Thank you all for your work!

Bryant Thomas Karras: Thank you ALL

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

RESOURCES

HITAC Webpage
HITAC - July 11, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO on 8/20/2024.