Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

May 17, 2023 10 – 11:30 AM ET

VIRTUAL

Speakers

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

Name	Organization	Role
Thomas Cantilina	Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
Ram Iyer	Food and Drug Administration	Federal Representative
Meg Marshall	Department of Veterans Health Affairs	Federal Representative
Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Micky Tripathi	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Sweeney Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Seth Pazinski	Office of the National Coordinator for Health Information Technology	Director, Strategic Planning and Coordination Division
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Lisa P. Goldstein	HHS Office for Civil Rights	Presenter

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

Michael Berry
Good morning, everyone, and welcome to the May 2023 HITAC meeting. I am Mike Berry with ONC, and we are glad that you could join us today. This meeting and all of our meetings are open to the public, and your feedback is welcomed, which can be typed in the Zoom chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled later this morning around 11:20 Eastern Time. Before we get started with our meeting, I would like to welcome ONC's executive leadership team. With us today is our National Coordinator, Micky Tripathi, Steve Posnack, the Deputy National Coordinator, Elise Sweeney Anthony, the Executive Director of the Office of Policy, and Avinash Shanbhag, the Executive Director of the Office of Technology. I would like to begin rollcall of our HITAC members, so when I call your name, please indicate that you are here, and I will start with our cochairs. Aaron Miri?

Aaron Miri
Good morning.

Michael Berry
Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning.

Michael Berry
Shila Blend?

Shila Bend
Good morning.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Sarah DeSilvey? Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Cynthia Fisher?

Cynthia A. Fisher
Good morning.

Michael Berry
Lisa Frey?

Lisa Frey
Good morning.

Michael Berry
Hannah Galvin?

Hannah Galvin
Good morning.

Michael Berry
Raj Godavarthi? Valerie Grey?

Valerie Grey
Good morning.

Michael Berry
Steven Hester? Jim Jirjis?

Jim Jirjis
Good morning.

Michael Berry
Bryant Thomas Karras? Ken Kawamoto? Steven Lane?

Steven Lane
Good morning.

Michael Berry
Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
Arien Malec?

Arien Malec
Good morning.

Michael Berry
Anna McCollister? Clem McDonald? Deven McGraw?

Deven McGraw
Hello, everyone.

Michael Berry
Aaron Neinstein?

Aaron Neinstein
Hi, good morning.

Michael Berry
Eliel Oliveira?

Eliel Oliveira
Good morning.

Michael Berry
Kikelomo Oshunkentan? Naresh Sundar Rajan? Alexis Snyder?

Alexis Snyder
Good morning.

Michael Berry
Fil Southerland? Sheryl Turney? And now, our federal reps of the HITAC. Thomas Cantilina? Adi Gundlapalli?

Adi V. Gundlapalli
Good morning.

Michael Berry
Ram Iyer? Meg Marshall? Michelle Schreiber?

Michelle Schreiber
Good morning.

Michael Berry
Ram Sriram?

Ram Sriram
Good morning.

Michael Berry
All right, thank you so much, everyone. Before we begin open remarks, I would like to introduce Shila Blend so that she can announce a new role. Shila?

Steven Hester
Hi, this is Steven Hester. I joined and just did not get through the list. I apologize.

Michael Berry
Great. Thanks, Steve. Go ahead, Shila.

Shila Blend
This is Shila Blend, and I just wanted to make a disclosure that I have been asked and accepted to work with CMS and Yale for their Centers Outcome Research and Evaluation on some of their interoperability work as part of a volunteer workgroup, so that disclosure is made to HITAC.

Michael Berry
Great. Thank you so much, Shila. Thank you so much, everyone, and please join me in welcoming Micky Tripathi for his opening remarks. Micky?

Welcome Remarks (00:03:48)

Micky Tripathi
Good morning. Thanks, Mike. Good morning, everyone, and thank you so much for joining today. It has been about a month, a month that has felt like 10 years, since we released our proposed rule on health data and interoperability, known as HTI-1, and that includes proposals related to certification program updates, algorithm transparency, and information sharing, so it covers a broad range of things. HTI-1 is a key component of the progress that we want to make in support of a care continuum and proposes ways to help accomplish the priorities that I see for ONC in the coming years. Just to refresh everyone's memory on those priorities, there are four: Continuing to build the digital foundation, making interoperability easier, promoting information sharing, and ensuring appropriate and proper use of digital information and tools. The rules cover many things in each of those categories, and we are really excited about being able to move forward with those. It would also implement certain provisions of the CURES Act and make several enhancements to the certification program, as I said.

Since the rule was published, we have been really busy doing education and outreach about the rule, encouraging public comment, and, of course, supporting the HITAC in your review, which we very much appreciate and look forward to hearing some of the first reports out from that today. We are really excited to continue hosting a series of information sessions to explain the rule, and the next session is going to be focused on information blocking or the information-blocking components of the rule, and is scheduled for May 18th at 1:00 p.m. Eastern Time, so that is just tomorrow. On June 4th, we are going to hold a patient-centric session on HTI-1, and you can register for these events and listen to the recordings of previous webinars by visiting the HTI-1 page on HealthIT.gov.

Finally, we have posted a Word version of the proposed rule and public comment template on our website to help make making comments easier. I want to thank the cochairs of the HTI-1 Task Force, who we are going to hear from today, Steven Lane and Steve Eichner, and all the HITAC members for their work to provide recommendations to ONC related to HTI-1. I know you are dedicating a ton of time and energy, and I greatly appreciate your efforts. We also look forward to the comments we are going to receive from the health IT community at large, and that will help us as we develop a final rule.

The public comment period is open until June 20th, 2023, and I just want to remind everyone that while we greatly appreciate any and all effort that people make into making comments on the rule, we accept any comments. We accept the 10- to 15- to 20-page magnum opus that covers every part of the rule; we also very much appreciate very short focused comments that might be just focused on particular areas that are of particular concern of yours or of particular interest, and all of those are things are things that we consider, so I just want to make sure that people realize and do not set themselves up for thinking that unless they can provide the 20-page magnum opus, it is not going to be helpful. Anything is helpful, and we appreciate that for the vast majority of people, this is not a part of your day job, this is something that you are doing in your extra time, as it were, and therefore, we want to make it as easy as possible and encourage everyone to give whatever comments you have because each and every comment is valuable.

Next, I want to flag for your awareness a healthcare blog series about predictive models, artificial intelligence, and machine learning in health. We have had a series of blog posts on this on the Health IT Buzz website, and the blog connects the dots between ONC's understanding of AI and the machine learning landscape and our HTI-1 proposed rule, so I strongly encourage you to read that blog series. I think it is really an excellent series from our Chief Privacy Officer Kathryn Marchesini, as well as Jeff Smith and Jordan Everson from our team, who have done a ton of great work in the area of AI and what you see there in HTI-1.

I also want to announce that the Leading Edge Acceleration Projects, the LEAP Projects, and Health IT Program issued a new special emphasis notice for 2023 LEAP and Health IT projects. We are very focused on having those be strategic in the sense that they advance particular kinds of capabilities or particular areas that are important to the four goals that I outlined before. So, the special emphasis notice for this round supports projects in two main areas. One is exploring the use of advanced FHIR capabilities. One of the things that you will see in HTI-1 is that we ask a series of questions about the next level of FHIR capabilities, things like subscriptions, for example, or CDS HOOKS, or FHIR links and other such capabilities with an eye toward getting industry feedback on how we move beyond the basic foundation that we set today.

What we set today is just about the requirement for a read-only FHIR capability supporting the USCDI that was required in the CURES Act rule, but that was really just to help the industry establish that basic FHIR foundation and basic FHIR capability, but it is really about the foundation being the opportunity for us to leap forward into the higher-level FHIR capabilities that all of us want and that are really where the magic of FHIR and wrestle APIs in general, and more modern internet exchange capabilities in general, will provide the kinds of value that we really want. So, that is what that first area is for. It is very much aligned with HTI-1, where we ask the industry for input on that. We also very much want to be able to support some projects that help us to push the ball forward and help us further develop and further mature those kinds of capabilities.

The second area is on identifying data quality improvements for USCDI data elements. One of the things that is a next-level problem for all of us is that we are exchanging more information, which is fantastic, and that shines a light on the fact that we have data quality issues in the exchange of information, even in the areas where it is standardized, like USCDI data elements, so this project is focused on how we think about what is the nature of those data quality issues and how we think about data quality improvements or potential for data quality improvements, and everything about just being able to have higher-quality data to

support the kinds of existing capabilities that we have today, but as you think about the future and think about AI and algorithms, the quality of data is fundamental to the quality of the algorithms, and if you have bad data, you are going to have algorithms that are not necessarily going to do the things that you want them to be able to do or think they are doing, or they are limited in certain ways because they are not able to take advantage of the broadest type of information that we think could be available to make for better algorithms, or less constrained algorithms, anyway.

So, that is really important in a wide variety of contexts, not just the basic interoperability features that we have been thinking about, but the more advanced kinds of uses that are now here upon us and real opportunities for us. So, you can view the special emphasis notice on the new Funding Announcements page on HealthIT.gov. Applications will be accepted until 12:00 noon Eastern Time on June 12th, so we are very much looking forward to seeing those proposals.

The last thing before I get off is that the June 15th HITAC meeting is going to be in person in Washington D.C. We are really excited about that and really look forward to seeing all of you there in person. Due to space constraints, members of the public who are interested in attending are strongly encouraged to register early. Registration for in-person meeting attendance will close on June 11th, so if you are interested in that and you are a member of the public, please get onto our website and register early. A virtual option will, of course, be available for those who cannot attend in person, and please visit the HITAC meeting calendar on HealthIT.gov to register. That wraps it up for me. Again, I would like to thank each and every one of you for joining us today and to the HITAC members for your ongoing support of everything we are doing. Now, let me turn it over to Aaron and Medell for their opening remarks.

Opening Remarks, Review of the Agenda and April 12, 2023, Meeting Notes – HITAC Vote (00:12:19)

Aaron Miri
Thank you very much, Micky. We appreciate that, and we welcome everybody to the May HITAC. As Micky alluded to, we have an exciting in-person meeting next month, but let's not jump too far ahead of ourselves. We have a great agenda for today. We welcome your feedback and input as always, and as we drive forward a new agenda in this year, it is exciting to have all of us roundtable, and again, to see each other next month will be even better, so we look forward to that. I also wanted to say a preemptive thank you to all the HTI teams. Phenomenal work, and a credit to the ONC team. I was telling Dr. Tripathi before we started just how much we appreciate the ONC team helping us to organize and herd the cats, per se, so we can really get down to business. Great job, everybody. Medell, I will turn it over to you.

Medell Briggs-Malonson
Thank you so much, Aaron. I also want to say good morning, everyone. It is always such a pleasure to convene with all of you, and I also want to go ahead and amplify what Micky said, as well as Aaron. There has been so much activity, not only by our HITAC members, but also from our ONC colleagues, especially surrounding the HTI-1 proposed rule, so I also want to express my sincere gratitude and thank you and look forward to all of the updates from our cochairs later on today. And so, we are going to have another wonderful meeting today, and we welcome all the comments and we welcome all the robust conversation on all of the agenda items. Speaking of agenda items, Aaron, I will turn it back on over to you to go through our official agenda for today.

Aaron Miri
Sounds good, Medell. All right, so, as I said, we have a great agenda for today. It is quick, but very pointed and very salient. So, right now, obviously, coming up at 10:20 here, we have the Health Data Technology and Interoperability Workgroup to talk about certification program updates, led by Steven Eichner and Steven Lane. Then, at 10:50, one topic that is near and dear to my heart that I always enjoy hearing updates on, from the OCR, the proposed rule on HIPAA privacy rule to support reproductive health care privacy. That should be a great discussion. Then we go to public comment about 11:20 and then adjourn right about 11:30 Eastern Standard Time. Medell, I will turn it back over to you.

Medell Briggs-Malonson
Great. Well, let's jump right on in to our first order of business, which is the approval of the notes from our last minute. So, I would like to call for a motion to approve the April 12th meeting minutes. Do I have a motion?

Aaron Miri
I will motion.

Medell Briggs-Malonson
Thank you so much, Aaron. Do I hear a second?

Jim Jirjis
Jim Jirjis, I will second.

Medell Briggs-Malonson
Thank you so much, Jim. So, the motion has been appropriately seconded. I would like to call for the vote. All in favor of the meeting notes as written, please say aye.

Several Speakers
Aye.

Medell Briggs-Malonson
All opposed, say nay. Any abstentions? The motion has been carried, and the April notes are approved as written. Thank you so much. So, let's jump right on into our first set of presentations. Again, as we have mentioned, there has been so much activity directly around all of our HTI-1 proposed rule, and the Task Force and the various different subgroups within that Task Force, so I would like to turn this right on over to Steve and Ike in order to lead us through some of our updates.

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule Task Force Update (00:15:32)

Steven Lane
Thank you so much, Medell, and we are very excited to be here to discuss and present a bit about the work that has been done by the HTI-1 Proposed Rule Task Force over these past few weeks. This has been a great effort with tremendous support by the ONC team in particular. I think this is my sixth year on HITAC.

I have had the opportunity to serve on and lead a number of Task Forces, and I must say the team just keeps getting better and better. They introduced a number of changes to our methodology this time around, so for those of you who are thinking of getting involved in Task Forces in the future, I want you to know that the process has really been refined tremendously. There are too many people involved in supporting this Task Force to call them out by name, but it has been quite a process getting this forward.

So, let's go ahead here to the next slide. This is what we are going to go through today. We are going to review our membership, the Task Force charges, the three working groups that have been meeting every week, working through the different components of the rule, and then talk a little bit about our path forward that will lead us to our presentation back here at the in-person HITAC meeting next month, where we will present our recommendations. Next slide.

So, this is the membership of the folks who have been meeting. Again, we have three different workgroups that have been meeting Tuesday, Wednesday, and Thursday, and sometimes Friday, so people have broken themselves up based on their interest. Some people are attending more than one meeting, and I will call out Hans Buitendijk in particular, who has been attending every single meeting, so there has really been a lot of input as we have gone through these items. Next slide.

Before I jump into the charge, I do want to acknowledge again the great and innovative work that has been done by the ONC team. Some of the things they introduced, which Micky mentioned earlier, such as putting up a Word version of the proposed rule, were very helpful. We all know that reading the PDF or the three-column view from the *Federal Register* can be challenging when you are trying to manipulate, organize, search, highlight, etc., so, having the Word version is very important. The comment template also has been greatly appreciated by members of the public and folks who are planning to comment. Other things that you may not be aware of are that the team has agreed to pull out the relevant text from the different portions of the proposed rule that go with each of the items that are being reviewed. So, you get the text from the preamble, the reg text, etc. all together in one place, and that has been tremendously valuable.

Also, as we will discuss more toward the end, there has really been an acknowledgement of the need to get input on these items from members of the public who really are representing the patient and caregiver perspective, and, as Micky mentioned, the decision was made to focus the June 4th public session on the caregiver and patient perspective so that we are assured, or at least have a better chance, of getting meaningful input from that incredibly important group of stakeholders. So, I just really wanted to acknowledge all of that important work on the part of ONC.

So, this was the charge that the Task Force was given, primarily to evaluate and provide recommendations back to HITAC on this new proposed rule. The charge was broken down into a number of areas that we will go through and talk about in detail. Specifically, the rule proposes to rename all the certification criteria within the health IT certification program as ONC certification criteria for health IT. It is pretty intuitive, but it is a change, and they are discontinuing the idea of having year-themed editions. Many of us have commented in the past that it has been a long time since 2015. Why are we still dealing with the 2015 edition? It tends to give the wrong impression of the speed of change in health IT, so I think this is part of the proposed rule.

The proposed rule intends to elevate USCDI Version 3 as the new baseline for core data interoperability across the country. Many of us have been involved in the advancement of USCDI over the years, and this obviously will help to move us forward. There has been a lot of discussion about implementing a new EHR reporting program, which is called the Insights condition and maintenance of certification and how that is going to improve the transparency of functionality from EHRs based on real-world results. And then, there are a number of proposals in the NPRM regarding information sharing and the prevention of information blocking. Next slide.

So, going on, this is actually the last slide for the charges. There is a long list of new and revised standards and certification criteria here. I am not going to read through them one by one, but I will highlight electronic case reporting, where we have had presentations here at HITAC in the past regarding the availability of specific technical standards and the fact that those had not previously been named in rulemaking, so this adds that in there, a number of advances to the various technical standards that we use for transmitting information, a big change in the area of clinical decision support, a renaming of that to DSI, decision support interventions, but also a lot of detail around transparency for those interventions, especially those that utilize AI and ML, and then, some areas that we have not yet tackled, such as new patient-requested restrictions, certification criteria, and a lot around how health IT developers are updating their certified health IT.

So, there is a lot of richness, as Micky and others have stated, and a lot to go through: The assurances, condition and maintenance of certification requirements, and then, a number of RFIs that are included in the proposed rule that our workgroup is also going through and trying to provide meaningful input. So, as you all heard, the public comment is open until June 20th. Our workgroups need to tie up their work and bring back recommendations to you by June 15. Next slide.

All right. So, I have had the pleasure of leading our Group 1, Steve Eichner has been leading Group 2, and Hung Luu, our fellow HITAC colleague, did step forward and has been leading Group 3, so you will be hearing from each of us in turn. Next slide. So, these were the Group 1 topics. I just went through all of them in a bit of detail, but this lists them out. So far as you can see, we have made it through most of them, but have a couple left to cover. Next slide. Group 1 has met a number of times. This is how we worked through it in terms of the topics of interest. Next slide. And then, we have a couple more meetings coming up, at least one of which will be informed by external subject matter experts.

So, for those of you who have been involved in Task Force work, you know that oftentimes, we will invite external subject matter experts to participate directly in the discussion. This is in addition to the amazing expertise that we get from the ONC staff, and, of course, the fact that all members of the public are always invited to participate in these calls. Oftentimes, the chat, which is also open to the public, is very active, as it is here today, and we get a lot of input and allow ourselves to discuss that sometimes, as well as the public comment period at the end of the sessions. I will also note that another change that the ONC implemented was that we moved up the public comment period so that we have more time to entertain public comments at the end, when those are brought forward. Next slide. So, that was it for Group 1. I will now pass it off to Ike, who has his hand up, who is going to talk us through the work of Group 2.

Steven Eichner
Thank you, Steven, and I would like to echo Steven's appreciation for the ONC staff and the support team for the Task Force. They have done an absolutely incredible job making it very easy for Steven and I and

the Task Force members to develop some really good recommendations, and we are looking forward to presenting them to the HITAC next month, but before we get there, here is a quick update of where we are. Next slide, please.

Like Group 1, Group 2 has also made a lot of progress going through the areas that it has been responsible for and preparing comments. One of the larger areas we focused on is decision support interventions, DSI, and that is really looking at the ability to connect decision support technology to EHRs and looking at the transparency of information sharing between decision support tools and EHRs with a lot of interest on patients and how not only providers have access to information about DSI tools, but patients as well, so I think we are going to have some really good and interesting recommendations in that space.

The workgroup has also been looking at the changing in the naming convention, looking at the assurance conditions and maintenance for certification requirements, and requirements for health IT developers to update their previously certified health IT. The workgroup, or the Task Force, is also looking at electronic case reporting, and that is scheduled to take place on Friday. We have a Task Force meeting with some external experts coming to speak with us about that, and then, we will close out our presentation material with patient-requested restriction certification criteria. Then, we will shift into developing and finalizing some recommendations and pass them to HITAC. Next slide, please.

This is kind of laying out our schedule for the next few weeks, or, sorry, looking at the past schedule. We did have some excellent presentations from external folks, as well as fantastic presentations from the ONC staff. Next slide, please. This lays out our schedule for the next few weeks. Again, the public and other HITAC members are welcome and encouraged to attend. The information for attending is readily available on the HITAC webpage. There will also be a presentation on the 24th on HTI for public health, so that may go into some of the electronic case reporting and lab reporting elements. Next slide, please. Now, I am going to turn the floor to Hung Luu to talk about Group 3.

Hung S. Luu
Thank you, Ike and Steven. I have had the honor of leading Group 3 through our review of the charge. Next slide. So, these are the topics that have been covered in our discussion so far, and in particular, in the discussion about the implementation of USCDI Version 3 as the current version, we have had robust discussion around perhaps making recommendations for flexibility in the implementation of future USCDI versions to encourage wider participation in the certification process by specialty EHRs and HIT vendors. Some of these vendors engage in particular products that have a very specific patient population, and may not have a need to collect and manage all USCDI data elements, and so, the current approach of requiring all the data elements poses a barrier to participation. Next slide, please.

This is our schedule so far. Just as with the other groups, we have had phenomenal presentations from ONC subject matter experts that have informed our discussion, and we have also had the opportunity to hear from external speakers, such as Sasha TerMaat from Epic, who have really provided important information to help the group carry out their charge. Next slide, please. This is our upcoming schedule, in which we will hear from a panel of external speakers to help generate ideas for the requests for information to the ONC on laboratory data interoperability. Next slide.

On May 25th, we will also continue our discussion on requests for information, this time on pharmacy, the FHIR subscription request for information, clinical decision support HOOKS request, the FHIR standard for scheduling request, and also the SMART Health links request, and we will also have a panel of speakers to help us generate ideas from that. Next slide, please. And so, this will be a final sprint to the end, in which we will be updating and finalizing recommendations and making our final recommendations to the HITAC committee for their vote on June 15th. That is all I have, and I will turn it back to Mike Berry.

Steven Lane
Actually, I think Ike is going to help to lead us through the discussion here.

Hung S. Luu
Oh, sorry.

Steven Eichner
Thank you, no worries. Hung and Steven did a great job of providing summaries for Group 1 and Group 3 activities. One of the other things that came up during past course discussions was really looking at how to better engage members of the public and patients in reviewing or participating in rulemaking and review activities. We reached out to ONC, and had some discussions, and learned quite a bit about some of the very interesting and useful things that ONC is doing to reach out to patients in particular, including an upcoming webinar on the HTI-1 rule, but also looking at potentially figuring out some additional ways of engaging the public through perhaps rare disease organizations and other components, really trying to help the public and patients understand how the contents of the rule apply to them, and creating mouthfuls of information that really enable greater understanding, kind of reflecting what Micky said earlier, about how to digest the vast and detailed information across the rules and make it ingestible and useful for patients to provide meaningful feedback to help further improve the rules.

I think that is something to explore a little bit more in the future. The Task Force overall is looking forward to having meetings over the next several weeks. We will then begin developing our report and presenting it to the full HITAC when we meet on the 15th. Steven, do you have anything to add?

Steven Lane
Yes. I just wanted to specifically call out Anna, who I see has also raised her hand, who stepped forward in her role as a patient advocate. She was joining the Task Force specifically with that perspective in mind. As we have all discussed, unless you are really actively serving as a patient advocate, it can be hard to balance that with our other areas of expertise, and I think Anna really made the point that this is a big rule, lots of information, some of which could really benefit from patient input. So, credit also goes to the ONC team that heard that and stepped forward. We had an offline meeting with leadership from ONC, and as you have heard, there was a decision made to focus the next public session on highlighting opportunities for patient and caregiver input. So, Anna, I would love for you to speak to that, if you like.

Anna McCollister
Thanks, Steven. I just wanted to basically confess that I helped raise some of the issues and take the blame for it to some extent. My biggest concern is that there are 60 days to get your head around it. Again, speaking from the perspective of a patient advocate, I know a lot of people who would care about these issues if they knew that it was happening and they understood the complexity and had the time to dig into

the rule. The vast majority of folks that I have spoken to who fit that description have no idea that this is happening and do not really understand or are not familiar with the process of providing input, so that was my biggest concern. This is an incredibly important and really big rule that is chock full of really important things that matter deeply to a broad group of patients, and I do not mean this in a pejorative way, but I am not even talking about patients who are relatively naïve to many of these issues, who are either earlier in their life of chronic disease or rare disease or who have just chosen not to get that involved in policy because they have other things to do, like maintain their health and work.

So, I am talking about people who are very much data advocates who are really interested in this kind of stuff and still have no idea that this is happening, and I am concerned that we are halfway through the comment period, and I am just wondering how realistic it is for us to assume that we are actually going to get input from the patient community, and ONC was awesome, they responded to my discussions and the points that I raised during the workgroup, and we had an informal separate call with a couple other non-HITAC-member patient advocates, and it was helpful, and now they are very open to hearing their feedback, but it is a concern of mine, and I do not know if there is a way that we can extend the comment period beyond 60 days. I know the government does that from time to time. I will defer to ONC on that. I am sure there are a variety of other concerns related to that kind of an extension that I am not aware of, but this is just a lot, and I want to make sure that we are benefiting from a lot of different perspectives, not just those perspectives of people like me and others who are professionals who work in this area.

Steven Lane
Thank you so much, Anna. I also want to acknowledge the fact that we invited another patient advocate specifically to come speak with us on May 3rd when we were addressing the decision support interventions and predictive models. So, many of you know Grace Cordovano. I think she has participated in HITAC meetings in the past, and she has had a longstanding focus on the need for greater transparency when decision support is utilized and helping individuals to understand the role that that plays in their care, so having that perspective as part of that discussion was also very helpful. Any other questions from the HITAC members, or anyone from ONC, Micky, anybody? If not, that is our report. We will be back next month with specific recommendations. Ike or Hung, were you going to discuss any of the other deeper dives that we have taken specifically around USCDI advancement?

Steven Eichner
If you would like to, that would be great. I touched on the DSI of it.

Steven Lane
That is fine. Another area of lively discussion has been about what is the impact of the advancement of USCDI on the whole health IT certification program and, as we raise the bar with new versions of USCDI, that it can make it more difficult on specialty EHRs to meet all of the criteria, so there has been some creative problem solving, thinking about ways that the ONC might consider managing USCDI going forward, whether it is all required to be managed in the same way by all systems, or whether some systems might be able to have sort of a lighter lift to managing some of the new data elements. We will try to put together some specific recommendations around that, with the idea of really trying to do all that we can to encourage participation in the health IT certification program and not to have certain health IT vendors unable to stay involved as we raise the standards across the board. Fil, thank you for raising your hand because I know you were very involved in that discussion.

Fillipe Southerland
Yes. Steven, thank you for opening up that discussion. Just to add some detail around the subject on USCDI, I think the group is generally supportive of the move from V.1 to V.3, but I think the concern here is that we do not want this to become an unintended barrier to entry for specialty EHRs, and specialty EHRs being… I come from the long-term post-acute care sector, but there are a number of other specialty use cases out there such as labs, pharmacy, HCBS services, and behavioral, so, looking at these services where, right now, we have an all-in approach for USCDI, where each of these EHRs must provide all data points, and just having gone through this process in long-term and senior care, we ran into an issue where we had certain pediatric measurements that were required, and that became a barrier to entry for our organization in that we were not tracking those metrics.

So, I think the committee had some thoughts around how we might address that for USCDI, where maybe we look at more of a parsed approach to consumption of USCDI versus the data sourcing, and also just looking at Section 4001 of the CURES Act, where it appears ONC does have the authority to look at medical specialties and sites of service, and we have seen examples of this through some of the pediatric-focused material, but I think there is really an opportunity here to look at different areas of the care sector into some of these specialty areas and to look to promote those, so I wanted to just put that out there as a key discussion point, and, as you said, Steven, I think we have a few recommendations that we will be proposing around that.

Steven Lane
Thank you, Fil. Ike, do you have a question?

Steven Eichner
Just one piece of clarification. It is not just looking at new USCDI elements, it would be looking at any USCDI element because some of the things that have been previously adopted might also fit into that category. It is also important to ensure that wherever we go with the USCDI or USCDI Plus framework combined, we do keep our eye also on the ball of public health issues and public components where we may need some flexibility so that we can address emerging health issues and disaster response as well, so we want to make sure that wherever we go, we have flexibility to address some diverse needs.

Aaron Miri
Yes, and Ike, I will remind the committee, for those of us who were here at the time, and Steven Lane remembers this, when the USCDI framework was put together, we actually came up and thought through a fast pass for an element or something related to, because we were in the middle of the COVID emergency at that point, so, to your point, how do we incorporate an emerging issue and address standards needs for updating quickly and rapidly versus waiting for some future version while, meanwhile, we are suffering with a pandemic? So, good point, Ike. Great point. Any other comments?

Steven Lane
Just one other comment that I think we all remember that this is HTI-1 that we are doing here in this first part of the year. Later this year, we are going to get to do HTI-2, so, one of the things that really comes up here is the specific path of rulemaking, where things have to be proposed and then commented on and finalized, so our workgroups and Task Force have been coming up with some ideas that are a little bit

coloring outside the lines, which is a term you have heard me use before, but the good news is we have another rulemaking cycle coming up, I understand they are already working on HTI-2, and we may see some of these new items come back at us later this year.

Aaron Miri
Great clarification, Steven. Thank you. To your point, we do not want to lollygag, so I like it. That is good. Anna, you have your hand raised.

Anna McCollister
I was just hoping to get a little bit more context on what Steven just mentioned in terms of what that means. So, is this the first round of feedback on the elements of HTI-1? Is HTI-2 going to be a refinement of these elements, or are there going to be additional elements? If there is a broader context that could be provided, please point me to it. My apologies that it seems to be missing from my brain at the moment, but it would be very helpful to have broader context about these proposed rules being rolled out if anyone could provide that.

Aaron Miri
Steven, do you want to give a 30-second overview?

Steven Lane
I really think that is a question for ONC.

Aaron Miri
Mike, maybe we could take this to someone offline? I know there is a whole writeup on it.

Elise Sweeney Anthony
This is Elise. Yes, there are writeups on the rules that we currently have listed as the ones we are moving forward. We can send that around to the HITAC. The summaries that are included are publicly available, they are part of the unified agenda, and we can send those back around to folks. I think there are also a couple slides that we presented on this a little bit ago as well, so we can pull those up and send them to the HITAC.

Aaron Miri
Perfect. Thank you, Elise. All right, I think we are at time for this topic. Great job, Steven and Ike. I appreciate you both, and your leadership there, and the entire Task Force. There is lots of work going on there. Okay, we are at the next section here, which is the Office of Civil Rights proposed rule. This is the HIPAA privacy rule to support reproductive healthcare privacy with Lisa and team, so, Lisa, I will turn it over to you.

Office for Civil Rights Proposed Rule – HIPAA Privacy Rule to Support Reproductive Health Care Privacy (00:47:20)

Lisa P. Goldstein
Thanks, Aaron, and good morning to everyone. Thank you for having me here. As mentioned, I work for the Office of Civil Rights, and for those of you who are not familiar with our office, among the things that we do is to administer and enforce what we refer to as the HIPAA rules, so those are the privacy, security, and

breach notification rules that are promulgated under the Health Insurance Portability and Accountability Act, and today, I am here to talk to you about the rulemaking that we released last month. Specifically, it is the notice of proposed rulemaking on the HIPAA privacy rule to support reproductive healthcare privacy. Next slide, please.

So, first I am going to talk a little bit about the current privacy rule. I think it is important to make sure we are all on the same page. There is always a lot of confusion about what HIPAA says and does not say, so we are going to start there, then we will talk about why we think there is a need for this rulemaking, why it is necessary, then I will go through some of the highlights of the proposed rule, as well as some of the resources for those who are interested in further understanding this topic as well and submitting comments on this. Next slide.

So, as I mentioned, I am going to start out by talking about what the scope of the privacy rule is. There is a lot of confusion all the time. We get a lot of questions about this, so I want to make sure we all understand that by law under the Health Insurance Portability and Accountability Act, HIPAA, and the HITECH Act, the scope of the HIPAA rules, including the privacy rule, is limited to covered entities and their business associates. So, what is a covered entity? It is a health plan, it is a healthcare clearinghouse, or it is a healthcare provider who transmits health information electronically in connection with a transaction for which there is a HIPAA standard.

Generally, it is a good rule of thumb that if a healthcare provider is billing insurance, they are generally going to be a covered entity. As I mentioned, it also applies to their business associates, and a business associate is a person which may include an entity that works for or on behalf of a covered entity. They generally have access to protected health information or performing a covered function. One of the things that is important to note as we continue throughout this presentation's discussion is that the privacy rule applies in some cases directly to business associates, for instance, the restrictions on uses and disclosures, and in other cases, it applies to business associates through their business associate agreement with the covered entity. Next slide.

The other thing to keep in mind when we are talking about scope is the type of information that is covered. We refer to that as protected health information, or PHI, and that is individually identifiable health information, or IHI, when it is transmitted or maintained in any form or medium, so that may be paper, electronic, what have you. There are certain types of information that are specifically carved out of PHI, and that is information that has been deidentified, health information that is in employment records, as well as health information that is contained within what we call FERPA information records, or Family Educational Rights and Privacy Act records. Next slide.

It is also important to keep in mind that, in general, when you look at the privacy rule as a whole, it prohibits the use or disclosure of PHI unless it is explicitly permitted or required by the privacy rule, and that is really important to keep in mind throughout this discussion. There are only two cases under which HIPAA requires disclosures, and that is to the individual who is the subject of the PHI, so that is through the right of access, or to the Secretary of HHS to determine compliance with the HIPAA rules. We cannot determine if you are complying with the rules unless we have access to that PHI, in many cases. All other uses and disclosures that the privacy rule allows are permitted. They are not required by HIPAA. There may be other laws that indicate that those disclosures might be required, but the privacy rule itself does not require those

disclosures. Covered entities are permitted to provide greater protections than are required by the privacy rule, and there are state laws that may also provide greater protections than are required by the privacy rule. Next slide.

So, why are we talking about this today? Well, we have heard a lot of concerns, particularly over the last year and a half, about the ability of law enforcement and others to access PHI. There are a lot of concerns and confusion through the media, members of the public, providers, and individuals across the board on what this means, particularly in the context of *Dobbs* and the related changes in state law with respect to reproductive healthcare. HHS is very concerned about the effect of the concerns and confusion that we are hearing, the changes in state law, and the effect that they are going to have on the individuals' trust in their healthcare providers and other covered entities. This trust really forms the foundation of our healthcare system. Without that trust, the quality of care that individuals receive will suffer, the care that providers can provide suffers, because individuals may not disclose all the necessary information to their providers to be able to provide individuals with the necessary advice and counsel on whatever their healthcare matter is.

There is also a concern that this will affect the willingness of individuals to use their health insurance to obtain care because they may not trust that the health plan will keep that information private and secure. And so, for all of these reasons, we believe that a federal solution is required. Go back to the purpose of HIPAA, as well as HITECH. It was to encourage electronic exchange of PHI. We have made a lot of progress in that area, but it does increase certain risks to the privacy of an individual's PHI. For example, an individual's PHI may be transmitted or maintained by regulated entities across state lines regardless of where the healthcare is provided, and so, this has generated a lot of concerns. Next slide, please.

So, we have heard these concerns and this confusion. The question is is there more education to do, or do we need to make changes to the rules? We took a look at the rules and identified some key purposes for which the privacy rule currently permits regulated entities to use or disclose PHI without an individual's authorization, and some of those include where it is required by law, for instance, where state law requires disclosing PHI to a public health authority for an overdose detection mapping program. For public health purposes, we obviously want to encourage public health disclosures for public health activities, for instance, on deaths attributed to COVID-19. It was really critical over the last couple of years that we had that information.

It is also allowed for health oversight activities, disclosing PHI to state Medicaid fraud control units for judicial and administrative proceedings, like disclosing PHI in a custody hearing pursuant to a court order, or disclosing PHI to law enforcement, for example, pursuant to a search warrant in a criminal investigation into Medicaid fraud or unlicensed healthcare. These are things the privacy rule currently permits, and as you can tell, there are some clear reasons why we would want to allow those, but there are also some concerns that we had. Next slide.

And so, to address those concerns, we issued a proposed rulemaking on April 12th that was published in the *Federal Register* on April 17th, just about a month ago, and the most significant proposal in there was that we proposed to prohibit regulated entities from using or disclosing PHI **[inaudible] [00:56:17]** dense purpose, that is, for a civil, criminal, or administrative investigation into or proceeding against any person, which is something I will come back to in a minute, in connection with seeking, obtaining, providing, or facilitating reproductive healthcare in certain circumstances. The second purpose for which we have

prohibited uses or disclosures is for PHI to identify any person to initiate such an investigation or proceeding in those same circumstances.

Now, as I mentioned, I am going to back to "any person." We want to keep note of the fact that this prohibition does not just apply where the user/discloser is for an investigation or proceeding against the individual, it is also for use against anyone else, so, a provider, any other covered entity, a business associate, friend, family member, or other who may assist an individual in obtaining reproductive healthcare. I want to note that also as part of the proposal, we have included a proposed definition of "reproductive healthcare." It is based on the existing definition of "healthcare," which was defined intentionally broadly in 2000, and we have similarly kept that definition for reproductive healthcare intentionally broad, and we propose to define it as care, services, or supplies related to the reproductive health of the individual. Next slide, please.

As I mentioned, we have proposed to apply that prohibition in certain circumstances, and there are three circumstances: Where the reproductive healthcare is provided outside of the state where the investigation or proceeding is authorized and where such healthcare is lawful in the state in which it is provided, the reproductive healthcare is protected, required, or authorized by federal law regardless of the state in which such care is provided, so, for instance, under EMTALA, and the third circumstance is where the reproductive healthcare is provided in the state where the investigation or proceeding is authorized and where the healthcare is permitted in the law of the state in which that healthcare is provided.

One thing I want to highlight here is that the prohibition on the user disclosure of PHI is based on whether the healthcare was lawful under the circumstances in which it is provided. It is not based on where the information resides, as long as it is within a regulated entity, so, a covered entity or business associate. It really is about where the healthcare was lawful when it was provided. So, for instance, if an individual who resides in a state where there are restrictions on reproductive healthcare, that individual travels to another state where there are fewer restrictions, obtains healthcare that is lawful where it is provided, and then travels back to their home state, if that information is then disclosed to a covered entity in their home state, whether by the individual or the performing provider, the prohibition still applies. I think that is something important to keep in mind. Next slide.

If you look at that proposed purpose we discussed, it is pretty broad, and the concern was that it would really encompass some beneficial uses. So, one of the things we have also done is to propose a rule of construction that would make sure we are not prohibiting the use or disclosure of PHI that is otherwise permitted by the privacy rule unless that user disclosure is primarily for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive healthcare.

So, for example, under the proposal, when read with the rule of construction, a regulated entity would be permitted to make a user disclosure of PHI to defend a person, including a regulated entity, against a lawsuit for providing lawful reproductive healthcare. For due process purposes, it is really important that we allow that. It would also permit the use or disclosure of PHI where it is sought to investigate or pursue proceedings against an individual for knowingly submitting a claim for reproductive healthcare to the government where the reproductive healthcare is not provided or is improperly billed, so it is something that might be considered a false claim, might fall under the False Claims Act or some other fraud and abuse statute.

These are all things we would not want to prevent from happening, so this rule construction continues to allow that. Next slide, please.

In order to effectuate the proposals pertaining to that prohibition, we have proposed that a regulated entity, before making that use or disclosure, obtain a signed attestation in certain circumstances, and this attestation provision is modeled under the existing authorization requirement. The attestation would be required where both of these conditions are met: Where the request is for PHI that is potentially related to reproductive healthcare, and I want to note that is where the PHI is potentially related to reproductive healthcare, not where the request is potentially related to reproductive healthcare.

The other condition is where the request is for one of the following purposes, and there are four purposes that we have identified as a permitted purpose, but we think could potentially be used to circumvent the proposed prohibition, and that is for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and to coroners and medical examiners. Because we are in a much more electronic environment today, we want to note that we have proposed to make sure that the attestation may be provided electronically, but it may not be combined with any other document. Next slide.

Also, as part of the NPRM, we have some proposals around the contents of that proposed attestation. So, for instance, we propose that the name of the individual whose PHI is sought, if practicable, will be included, as well as a statement that the use or disclosure is not for a purpose prohibited under the proposed rule, the requester's signature, date, and some other requirements as well. We also have asked for comments and specifically solicited comments on whether it would be helpful for us to share a model attestation, so we are looking forward to comments on all those things, but including that. In addition to those proposals we have related specifically to the prohibition, we have some others to clarify some existing provisions.

The first I am going to talk about is around personal representatives. The privacy rule today, in some cases, essentially treats a person other than the individual as the individual where the law says that the individual cannot legally make their own healthcare decisions or not have access to their information, and that is minors and others where this usually applies, and the privacy rule today generally defers to state law to determine who is a personal representative. There is a provision in the privacy rule that allows a regulated entity to make the determination that it would not be appropriate to treat that person as the individual's personal representative in certain circumstances.

Under the proposed rule, we would clarify that this provision does not apply, so that the regulated entity could not elect to not treat the person as a personal representative, where the reason for their determination to do so is primarily because that person is facilitating or has facilitated or is providing or has provided reproductive healthcare to that individual. So, the proposal still recognizes the interests of others and is narrowly tailored to not interfere with the ability of states to define the nature of the relationship between the individual and another person, such as a parent and a minor, but we do want to make sure that regulated entities do not take it upon themselves to make a determination where the individual is receiving reproductive healthcare because of facilitation by the individual who is the personal representative. Next slide.

Similarly, the privacy rule permits a regulated entity to use or disclose PHI where the PHI is about an individual where the regulated entity reasonably believes that that individual is a victim of abuse, neglect,

or domestic violence in certain circumstances. We have two proposals here. One is merely a technical correction to add a comma. For lawyers, for grammatists, we have made sure we want to add that. And then, we have also proposed to clarify that the permission does not apply where the report is based primarily on the provision of reproductive healthcare, where the report is based primarily on the individual being provided with reproductive healthcare, and it would apply where the report is about a concern of abuse, neglect, or domestic violence by the provider or by the facilitator of this reproductive healthcare. Next slide.

We also have in the privacy rule today a permission to disclose to law enforcement in certain cases. That is pursuant to process and is otherwise required by law, in compliance with, and is limited by the relevant requirements of an administrative request subject to certain conditions, and one of those provisions specifically addresses administrative requests, and what we are proposing to do here is merely to clarify our existing interpretation that the administrative request described within this permission is one for which a response is required by law. Next slide.

The last proposal I am going to talk about today pertains to the notice of privacy practices, or NPP. Again, under the privacy rule today, covered entities are required to provide individuals with an NPP for a variety of reasons, but so they understand what those privacy practices of the covered entity are, as well as their rights and the covered entity's responsibilities with regard to that PHI. Under the proposal, we would require covered entities to describe each type of use or disclosure that we are proposing to prohibit in sufficient detail such that an individual would be able to understand the prohibition and the proposed attestation, and there are two reasons for this.

The first is to ensure the individual has the information they need to make decisions about their healthcare and how the covered entity will treat the PHI the individual chooses to disclose, how to exercise their rights, and how to request restrictions. The second is to enable a covered entity to provide the individual with reassurance about their privacy rights and their ability to discuss their reproductive healthcare and any related care with the provider without fear of harm because it would inform an individual that their PHI may not be used or disclosed for the purposes the department is proposing to prohibit, so, again, going back to a rationale for the proposal. Next slide.

The last thing I want to leave you with before we turn to questions and discussion is a couple of resources. The first is to make sure that everybody is aware that actually, last June, we issued two guidance documents. The first is on the privacy rule and disclosures of information relating to reproductive healthcare, and the second is on protecting the privacy and security of an individual's health information when using their personal cellphone or tablet, and that is specifically actually aimed at individuals. Lastly, as I mentioned, the NPRM was published in the *Federal Register* on April 17th, so I provided you with the link, as well as the link to the fact sheet and other materials on it, and I do want to note that we are in public comment period right now, so comments are due on June 16th at 11:59 p.m., and we encourage everyone to submit comments, and we look forward to reading them. With that, like I said, I look forward to the discussion and any questions.

Medell Briggs-Malonson
Lisa, thank you so much for this amazing overview of this proposed rule. As a physician executive who supports and oversees many of our reproductive healthcare as well as gender health programs, this proposed rule has significant implications, and especially in a state that does have less restrictive laws, we

ourselves, both our providers as well as patients and even payers, have been in very thorough discussions about how to protect patients' privacy and how we can continue to ensure high-quality, equitable care, especially in the area of reproductive health and gender health, so, thank you for this overview. I highly recommend all HITAC, as well as the public, take a close look at this proposed rule and provide comments by the deadline in June. So, I see a couple of hands already, so I first want to acknowledge Alexis.

Alexis Snyder
Hi. Thank you, Lisa, so much for all of the really well thought out and provided information, which is so important for all of us. I have a couple of questions. My first is around how the privacy would enforce and, more so, ensure that patients are actually receiving that privacy information in lay terms that they can understand, and more so ensuring how they can access that, because most of the time, when a patient or a family walks into an appointment, they are just receiving an electronic pad to sign and say, "Oh, here is a pamphlet, or you can go online, or you can look at this about your privacy rights, and here, sign off on this," and patients or families very quickly just sign off to move forward with their appointment.

I think, even more so given that point, with this new information that is going to be so important when the rule actually does come out, I think that patients and families are very quick to realize when checking in at an appointment, "Oh, this is the privacy information I always receive, yes, I know I have it," and do not ask for a copy of it or do not look into it more and, again, just sign off. So, my concerns are, again, enforcing that lay language and making sure that it is being provided at the time of check-in at an appointment, and then, more so, again, making sure that patients are actually aware that this is an important thing that they should have access to and should look at before signing off on that.

Lisa P. Goldstein
So, I will say we are actually not making any proposals to change the requirements for making that notice available today. The privacy rule does have requirements pertaining to that today. If, as an individual, your healthcare provider is not providing that to you, OCR engages in or initiates enforcement in a couple of different ways. One is when we receive media reports, etc., we can initiate them on our own, but also, we have a whole process for obtaining complaints, so individuals can submit and file complaints with OCR, and we will investigate those complaints and engage in the necessary enforcement, so, whether it is providing technical assistance to the covered entity or the business associate or engaging in an enforcement action, but that information should be available. If not, again, I encourage our complaint process. Our complaint form is available electronically on our website, and I encourage you to do that.

Alexis Snyder
Just quickly in response, I think when someone does not know that the information in that privacy information is changed, so when this rule goes into effect and things get updated, patients are not going to submit a claim to your office that they did not receive it if they do not know that it is something different and that it is something that they may have signed off in the past, but now this is different.

Lisa P. Goldstein
Thank you. I will note that actually, when covered entities do update their notice, they are also required to notify individual patients.

Alexis Snyder

Okay. For whatever it is worth, I think that somewhere, there needs to be oversight in the future on how we ensure that people are actually having access to this, because if you do not know that you need to have access to it, you are not going to complain that you did not receive it, or that you did not receive it in language you can understand, lay terms.

Medell Briggs-Malonson
Thank you so much, Alexis, for that, and also, there are some comments about even patient education and patient-facing materials, and really where that scope may be, so thank you so much, Alexis, for that important question. Ike, you are up next.

Steven Eichner
Thank you so much. Thank you, Lisa, for your wonderful presentation. From a public health perspective, can you talk a little bit to how the proposed rule impacts reporting of things like pregnancy status to support disease investigation and those types of activities with specific attention to the inclusion of pregnancy and related information that is often passed from a healthcare provider through laboratory service to public health, recognizing that those three entities may potentially be in two or more different states?

Lisa P. Goldstein
So, I will start out with this. By law, under Section 1178B of HIPAA, for anyone who wants to go take a look at the specific language, the privacy rule cannot preempt state laws pertaining to reporting of disease or injury, birth, death…and I apologize, I am operating from memory…child abuse, public health surveillance, intervention, or investigation. That is the first thing I want to mention. As part of the proposal, we have proposed to clarify what the definition of "public health" is in the context of surveillance, investigation, or intervention.

It is important to keep in mind that even though the attestation that we are requiring is required for certain purposes, such as health oversight purposes and other such things, essentially, it still allows for the use or disclosure where it is not for a prohibited purpose. So, it all depends on the purpose of those. If it is for a civil, criminal, or administrative investigation, we talk about what we think about as a public health surveillance investigation or intervention versus a general criminal, civil, or administrative investigation as part of the proposal. I think it really depends on what the purpose is of the collection of that information. The reason the disclosure is being requested is what we need to look back at.

Medell Briggs-Malonson
Thank you, Lisa, and thank you again, Ike, for that comment. Eliel, we see your hand. We are going to take your last question and have Lisa answer it, and then we are going to move to public comment, and hopefully we will have more time for a bit of discussion before the meeting ends. So, Eliel, your question?

Eliel Oliveira
Thanks, Medell, and thanks, Lisa. This was such a great presentation. I appreciate all that. I think my question may not necessarily lead to a direct answer, but it still is extremely important to raise it. Given the climate that we live in today, this is such an important topic to be addressed, and I can see where this rulemaking will make a difference. Having acted as a privacy and compliance officer for other organizations in the past, I know how many years it took me to get an understanding of the HIPAA regulations to be able to manage well, and it seems to me that although this is very important for us to ensure some rules to

protect the rights of individuals, it seems to be very focused on reproductive health, and in some cases, like the use cases you described of different states and how different states are going to treat the law and the rights of individuals, it seems to me that it would still become very hard for individuals, and even organizations, to understand and be able to apply what we intended to do here.

The Fifth Amendment of the Constitution provides the right against self-incrimination. It is already the universal law of the land. This protection should be broader as opposed to being as specific as we are trying to make it here for a specific group of reproductive health and trying to understand the states' rights or desires as well to do what they need to do, but the Constitution is already protecting us. There are so many repercussions of the individuals incriminating themselves just by trying to seek care, and I am wondering if there is a pathway to actually seek a much broader rulemaking based on the Constitution as opposed to being so narrow at this point, and I know how hard it is for you to answer this question, but I wanted to throw that out there anyways because I am seeing how this may not serve us all. I am concerned now, but this is a specific problem if I should be saying to my providers, "No, I do not want you to share my data with anybody," and there are repercussions of that to my own wellbeing and other things that will escalate from that. Thank you so much again.

Lisa P. Goldstein
Thank you. I do want to note the privacy rule does permit an individual to request restrictions and request that a covered entity not disclose their information to others. A covered entity does have the ability to determine whether or not to accept that request, but that right to request restrictions does exist, No. 1. No. 2, it sounds like some of what you are looking for are protections similar to what is provided to Part 2 information, which is that that Part 2 information cannot be disclosed for use against the individual in an investigation or proceeding, and actually, if you take a look at the rule and the regulatory alternatives considered, we do talk about that. We did consider that as an option, and do talk about why we did not take that approach, but I would encourage you to take a look at that and see what you think and to submit comments on those proposals. We really do take them seriously, and look forward to reading them and seeing what people have to say.

Medell Briggs-Malonson
Eliel, that is such an insightful comment. I am really happy that we were able to end on it, and Lisa, we want to say thank you so much for coming, as well as to all of your colleagues, for putting together this review for HITAC, so thank you again. We are going to transition to public comment a few minutes late, but nonetheless, we are definitely going to address it, so I am going to transition over to Mike to lead us through public comment.

Public Comment (01:22:29)

Michael Berry
All right. Thank you so much, Medell, and as Medell mentioned, we are going to open up our meeting for verbal public comment. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. So, let's pause for a moment to see if any members of the public raise their hands, and while we are waiting, I will just remind everyone, as Micky mentioned at the beginning of our meeting, that the next HITAC meeting is on June 15th and will be held in person in Washington, D.C. We will also have a virtual option for those who cannot

join us in person. Also, all of the materials from today's meeting can be found on HealthIT.gov, and before I transition back to Medell and Aaron, I would like to transition to Seth Pazinski, the Director of Strategic Planning and Coordination here at ONC, for some important updates. Seth?

Seth Pazinski
Thanks, Mike. While we are waiting to see if any public comments queue up, I want to take the opportunity to quickly mention some upcoming ONC events that we want HITAC members and the public to be aware of. First, there are two upcoming ONC tech forum sessions. The first is Sink Your Teeth into Sync for Genes on May 25th, and then, the next will be the first in a series related to clinical decision support sessions, and that happens on June 7th. Then, as Micky mentioned and as was also mentioned by the HITAC HTI-1 Task Force cochairs, we are having information sessions on the ONC proposed rule, and we made a change to the topic for our information session on June 1st at 1:00 p.m. That is now going to be focused on impacts for patients and caregivers, so this will be in place of our originally planned session there, which was going to be a repeat of the general overview session on the proposed rule. So, at that, we are going to discuss some of the provisions of the rule, as well as focus on how the provisions advance the patient experience, and then we will also go over the comment process and ways to comment on the HTI-1 proposed rule.

You can register for these events or listen to recordings of previous information sessions by visiting the HTI-1 page on HealthIT.gov. Also, there is going to be a session on policy and practice supporting patient-ready access to test results. That event is going to be on June 5th, and it is going to be a virtual session to go over the immediate access to test results and how that is impacting the care paradigm for patients. And then, last but not least, I just wanted to give folks a heads up to save the date for the ONC annual meeting. That is going to be in Washington, D.C. in person on December 14th and 15th of this year, and this will be our first in-person annual meeting since 2020, so we are definitely excited at the opportunity to get folks together for that. So, all this information is on HealthIT.gov/events, so please check that out and register for any that you are interested in. Again, thanks for the opportunity to give those updates, and I will turn it back to Mike for public comment.

Michael Berry
Great, thank you so much, Seth. I am not seeing any hands raised, so I will turn it back to Aaron and Medell to close us out today. Thank you.

Medell Briggs-Malonson
Great. Thank you so much, Mike, and wow, Seth. There are so many amazing events that are coming up, so I really look forward to participating in those events. I absolutely look forward to seeing all of HITAC next month in Washington, D.C., as well as all of our amazing ONC colleagues, so, really great meeting, thank you all for the really excellent presentations and the engagement, and Aaron, I will leave it up to you to close us officially out.

Final Remarks and Adjourn (01:26:11)

Aaron Miri
Absolutely. I just want to echo what Medell said. Thank you all for a great discussion today, very robust topics, and it is really a great setup for next month in person, so please register, get there early, be ready to engage, and it will be a lot of fun. The in-person HITACs are very special and we get great dialogue

around the table, so I look forward to that. Be safe, enjoy your month of May, and we will see you next month in D.C. Thank you all.

Medell Briggs-Malonson
Take care, everyone.

Steven Lane
Thank you.