



# Transcript

## HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

April 15, 2021, 10:30 a.m. – 2:30 p.m. ET

VIRTUAL



# Speakers

Name	Organization	Role
<b>Aaron Miri</b>	<b>The University of Texas at Austin, Dell Medical School and UT Health Austin</b>	<b>Co-Chair</b>
<b>Denise Webb</b>	<b>Indiana Hemophilia and Thrombosis Center</b>	<b>Co-Chair</b>
Michael Adcock	Magnolia Health	Member
Cynthia Fisher	PatientRightsAdvocate.org	Member
Lisa Frey	St. Elizabeth Healthcare	Member
Valerie Grey	New York eHealth Collaborative	Member
Steven Hester	Norton Healthcare	Member
Jim Jirjis	HCA Healthcare	Member
John Kansky	Indiana Health Information Exchange	Member
Kensaku Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Arien Malec	Change Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Individual	Member
James Pantelas	Individual	Member
Carolyn Petersen	Individual	Member
Raj Ratwani	MedStar Health	Member
Abby Sears	OCHIN	Member
Alexis Snyder	Individual	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem, Inc.	Member
Robert Wah	Individual	Member
Amy Abernethy	Food and Drug Administration	Federal Representative
James Ellzy	Defense Health Agency, Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative





Jonathan Nebeker	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	Acting Executive Director, Office of Technology
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Leslie Kelly Hall	Engaging Patient Strategy	Presenter
Timothy Noonan	Office for Civil Rights	Presenter
David McCallie	Individual	Presenter





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

### **Operator**

All lines are now bridged.

### **Mike Berry**

Great. Thank you very much and good morning, everybody. And thank you for joining the April 2021 HITAC meeting. I'm Mike Berry. I'm with ONC. And I'm excited to kick off our meeting today. First, I'd like to welcome ONC's executive leadership team to the meeting. And with us today is our National Coordinator, Micky Tripathi, Steve Posnack, our Deputy National Coordinator, Elise Sweeney Anthony, the Executive Director of the Office of Policy, and Avinash Shanbhag, the Acting Executive Director of the Office of Technology. I will now call the meeting to order and begin with roll call. And let's start with our co-chairs. Aaron Miri.

### **Aaron Miri**

Good morning.

### **Mike Berry**

Denise Webb.

### **Denise Webb**

Good morning.

### **Mike Berry**

Amy Abernethy. Michael Adcock.

### **Michael Adcock**

Good morning.

### **Mike Berry**

James Ellzy. Cynthia Fisher.

### **Cynthia Fisher**

Good morning.

### **Mike Berry**

Lisa Frey.

### **Lisa Frey**

Good morning.

### **Mike Berry**

Valerie Grey. Adi Gundlapalli.

### **Adi Gundlapalli**

Yes, here. Thank you.





**Mike Berry**

Steven Hester.

**Steven Hester**

Good morning.

**Mike Berry**

Jim Jirjis.

**Jim Jirjis**

Present.

**Mike Berry**

John Kansky.

**John Kansky**

Good morning.

**Mike Berry**

Ken Kawamoto.

**Ken Kawamoto**

Good morning.

**Mike Berry**

Steven Lane.

**Steven Lane**

Good morning.

**Mike Berry**

Leslie Lenert.

**Les Lenert**

Good morning.

**Mike Berry**

Arien Malec. Clem McDonald.

**Clem McDonald**

Good morning. Present.

**Mike Berry**

Jonathan Nebeker.





**Jonathan Nebeker**

Hello.

**Mike Berry**

Brett Oliver. James Pantelas. I think James has a conflict today and won't be with us. But he will be joining us next time. Carolyn Petersen.

**Carolyn Petersen**

Good morning.

**Mike Berry**

Raj Ratwani. Michelle Schreiber.

**Michelle Schreiber**

Good morning.

**Mike Berry**

Abby Sears.

**Abby Sears**

Good morning.

**Mike Berry**

Alexis Snyder.

**Alexis Snyder**

Good morning.

**Mike Berry**

Ram Sriram.

**Ram Sriram**

Good morning.

**Mike Berry**

Sasha TerMaat.

**Sasha TerMaat**

Good morning.

**Mike Berry**

Andy Truscott.

**Andy Truscott**

Good morning.





**Mike Berry**

Sheryl Turney.

**Sheryl Turney**

Good morning.

**Mike Berry**

And Robert Wah.

**Robert Wah**

Present. Good morning.

**Mike Berry**

Good morning, everybody. And thank you once again. And before we proceed with our agenda, I understand that Jim Jirjis would like a moment to indicate a potential conflict of interest. Jim, please go ahead.

**Jim Jirjis**

Oh, yeah, Mike. Thanks. I think you had prompted me to this. With all of the work going on with HIE and the safer, SANER, we were approached as HCA to consider participating in a pilot program with HASA there in Texas. And you had advised that I might want to disclose that so I am. I think one of our CMIO's that is down in that market happens to be on the board for HASA. So, that's just a disclosure, I guess. There is no signed relationship. We're just considering it.

**Mike Berry**

Great. Thank you, Jim. I appreciate that. And are there any HITAC members who would like to report a potential conflict of interest that hasn't already been done so previously during our January 2021 HITAC meeting? If not, we can proceed. Thank you, everyone. And now, please join me in welcoming Micky Tripathi for his opening remarks. Micky.

**Micky Tripathi**

Great. Hi. Can you hear me?

**Mike Berry**

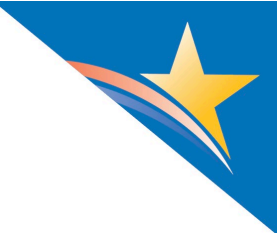
Yes, sir.

**Welcome Remarks (00:03:55)**

**Micky Tripathi**

I've got to check. All right. Great. Thanks, Mike. And welcome, everyone. Welcome and thank you for joining today's meeting. I'll just give a few introductory remarks and then, turn it over to the co-chairs. So, we've been really busy since the last time we met. I wonder if any head of ONC has ever said that we haven't been busy since the last time we met. But we've been really busy, even in this tenure. So, we've been doing a lot in COVID response activities. Work continues on working with industry to see if there is something that we can do to help with servicing appointment availability for vaccinations. And there is a little bit of evangelizing we've been trying to help with trying to get pharmacy organizations, EHR vendors, states to





try to align around a FHIR based approach to the extent possible to help to make incremental improvements to the vaccination scheduling experience that's available on different platforms.

Later this month, ONC is going to be hosting a little bit of a testing kind of arrangement to see if those who are willing to go forward with implementing the specification want to be able to test against reference of limitation against each other to help forward the industry in that against something related to a regulation or a mandate. But it's really just trying to get a coalition of the willing to move forward in the standards based way rather than in custom ways. The other thing that we're doing a lot of work on is with public health and public health infrastructure. So, we are co-leading with the CDC some work related to an executive order related to public health data systems. And top public health data systems can aid in public health emergencies. The HITAC is going to be really important to this effort. I think, as we mentioned in the January HITAC meeting, we're planning a public health hearing with the HITAC that will be held on May 13. And we'll expand the agenda of that day so it will be a full day of presentations.

But that will be an important input into that process. And I'm also excited to announce that we're going to plan a public health data systems task force with the HITAC as well to kick off in the next few weeks. We think it's really important for us to get the insight of HITAC members to inform our efforts on this work on public health data systems. And I'll come back a little bit later in the agenda to talk a little bit more about the charge and the details of that work. I'm looking forward to today to give the USCDI task force's final recommendations to the HITAC on Version 2 of the USCDI both with the data elements and classes. I know that that's been a lot of hard work. So, I commend Steven and Leslie for their shepherding of that and all of the members of the task force for that. I know that was no doubt very spirited discussions. And I'm looking forward to a spirited discussion today as well as we review those findings. We'll have other presentations today that Aaron and Denise will cover in a second, including a presentation by our OCR colleagues.

Tim Noonan has been generous enough to join us today and present on the HIPAA proposed rule. And I've been here a short time but have had the privilege of working with OCR and Tim, in particular, on a variety of things. And it's just been a great experience. And I'll thank Tim in advance for joining us today and also presenting today. So, just so you're aware, before I turn it over to Aaron and Denise, we had our annual meeting, I think, as you know, a couple of weeks ago. I want to thank everyone for their participation, for their comments on my casual dress. I did put on a regular shirt for today's meeting. But we had more than 3,000 people participate and got really great feedback. We welcome any feedback that all of you have on ways that we can improve it going forward. But I just want to thank everyone, again, for your engagement and your participation on that. I think, as you know, the information blocking rule went into effect 10 days ago on April 5. Steve Posnack and I co-authored a blog on the implementation data rule. It, certainly, encouraged people to go to that for more information.

Our team is very engaged in education and outreach with the industry. Elise Anthony and the policy team as well as Dr. Gettinger and Dr. Mason from our clinical team are doing a lot of virtual road shows week on week to help to answer questions, to help to engage the industry and various stakeholders, and welcome any input you have and thoughts on how we can improve our outreach and education of the industry. I also want to point out that we recently released an update to the certified health IT section of ONC's Health IT Playbook, which I think, as many of you may know, is really a great resource. And this is to reflect the requirements outlined in the Cures Act that impact the certification rule. So, you can find that on our website and we just want people to be aware of that as well. And then, finally, I wanted to just say how pleased we







all are at ONC that the HITAC annual report for fiscal year '20 has been sent to the Secretary of Health and Human Services and to congress.

I know there was great appreciation in the secretary's office for the report and just wanted to thank the annual report work group team for that and all of the HITAC members for a great report and for all of the work there. On the membership update, I just wanted to thank Dr. Amy Abernethy from the FDA who, I think, many of you may have seen in the media. But she is going to be leaving the FDA soon. I think next week is her last week. Amy is the principle deputy of the Commissioner of the FDA and the CIO of FDA as well. And she's been on the HITAC since February 2020. We've been privileged to have Amy's wisdom and guidance on the HITAC. And I, personally, just can't believe that she's leaving just as we're getting started here. We've already had the opportunity to brainstorm and do a lot together. And we have a couple of things that we're together later today as well as next week. And I know we're all going to miss Amy. And, hopefully, she won't go far.

So, I just want to, again, thank each of you for serving as a member of the HITAC. As always, I know it's a big commitment that we really, really benefit from all of your contributions and participation. So, I'm looking forward to the discussion today. And let me turn it over now to Aaron and Denise for their opening remarks.

### **Remarks, Review of Agenda and Approval of March 10, 2021 Meeting Minutes (00:10:38)**

#### **Aaron Miri**

Yeah. Thank you, Micky. And good morning, everybody. Happy April. It has been a very eventful April, especially on the provider's side of things as we've enacted the information blocking rules and all of the processes and whatnot. And so, I want to welcome you all. I think today's discussion around the HITAC will be excellent. And we're going to get into some meat of some really important topics and items as we get the ball rolling, as Micky was saying. I do want to share with you two quick stories though, I think, that sort of illustrate from the frontlines exactly what Micky was talking about. The first one, actually, happened yesterday where we had a patient that pulled aside one of our women's health surgeons and asked for their complete medical record. It startled the surgeon but, obviously, they knew the processes of what to do. But it is true. The public absolutely is aware that they can ask for their full and complete record and they expect it immediately.

So, that's just some context for you. And the second one, as we just crossed our 100,000 patient that we have vaccinated for COVID-19, and it is clear that people absolutely want their records. They want copies of their shot records. They want copies of things. And so, once again, information blocking and all of the work that these committees and folks are doing, the folks that Micky referenced, the work that all of you all are doing are paying tremendous dividends. And let that also be an eye opening comment towards any certified health IT vendor who still hasn't quite gotten the clue that records need to be shared. So, hopefully, as we move forward to a new dawn and a new era, we can get beyond that. But regardless, welcome, everybody, to April's HITAC. And I turn it over to my co-chair, Denise. Denise, you may be on mute.

#### **Denise Webb**

Yes, I was. Sorry about that. Good morning, everyone and welcome to our April meeting. I am also very excited and enthusiastic about our topics today. Both Aaron and I participated in the USCDI task force. And I'm looking forward to our co-chairs presenting today. And I know we'll have some lively discussions. But, hopefully, we'll have wide endorsement and approval by our blogger committee. So, yes, we've had a lot





going on the last month. I would have to say that all stakeholder groups across the healthcare industry have been greatly engaged in health IT activities and especially and including the patients we're serving. And so, we're doing really important work. I look forward to what we can accomplish today and learn. And before I have Aaron go over the agenda, I would like to welcome Steven Hester from Norton Healthcare in Kentucky. He is a new member of our committee. And Steven, if you want to unmute yourself and make a few comments.

**Steven Hester**

Sure. Thanks so much for the opportunity to be here and really just excited to be part of the group and just continue to help advance this work. And my hopes would be, from the provider side, to provide a viewpoint and just contribute in a number of ways. So, I really appreciate the welcoming comments and I'm excited to be here.

**Denise Webb**

Great. Well, I think you'll enjoy being a part of this very awesome group that we have. I will turn it over to you, Aaron, to go over the agenda for the day. And then, I'll handle the approval of the minutes.

**Aaron Miri**

Yeah. For sure. I will echo that also. Welcome, Dr. Hester. I'm glad to have you as part of the group. And thank you for all you're doing on the COVID-19 frontlines. I know you've been very busy there in Kentucky. So, thank you for that work. So, for the agenda for today, obviously, right now, we're going through our remarks. Our first up group will be the USCDI, United States Core Data for Interoperability, task force recommendations. That's a HITAC vote for us to up or down those recommendations. Next will be the proposed modifications of the HIPAA Privacy Rule, which I am looking forward to, to support and remove barriers to core data care and individual engagement. We'll have a quick break. And then, we'll go through the ISP, the Interoperability Standards Priorities task force update. And then, we'll have a good discussion about public health data systems as Micky was alluding to. We'll go to public comments and then, any final remarks and adjourn for the day.

So, it should be a pretty packed agenda, Denise, if we want to go and approve minutes from the previous meeting.

**Denise Webb**

All right. So, we need to approve our minutes from March 10. And if I could have a motion for approval.

**Steven Lane**

Steven Lane, so moved.

**Denise Webb**

Thank you, Steven.

**Andy Truscott**

Andy Truscott, second.

**Denise Webb**





Thank you, Andy. All those in favor, say aye.

**Group**

Aye.

**Denise Webb**

Any noes? Any abstentions? All right. It looks like our minutes are approved.

**Aaron Miri**

All right. So, then I think next up would be Steven and Leslie.

**United States Core Data for Interoperability (USCDI) v2 Task Force Recommendations –  
HITAC Vote (00:15:51)**

**Leslie Kelly Hall**

Good morning. I hope everyone is doing well. So, Steven and I are going to play tag team today on our slides and go through our recommendations. It's great to see all of you again and familiar faces and amazing work that everyone has been doing in this time of stress and now time of hope with the vaccine and the information blocking rule and many things coming ahead to us. So, thank you very much. So, let's go to the next slide. Today, we're going to go through our charges, our membership, do a little background. And then, Steven will take on the recommendations that we're making specifically. And we'll talk a little bit about the work plan next and also seek your guidance, which we always hope to have and act on. So, next slide, please. So, our charge today is to present to you the evaluation that we've done in the V2. And we've done it on our tasks and some CD's referred to throughout the report and all the presentation of 1A, 1B, and 1C.

So, we're looking at data classes and elements including applicable standards, new data classes and elements from draft V2 that include applicable standard, and then, the Level 2 data classes and elements that were not included. Now, I'd like to also point out that we had lively discussions way beyond this task. But we constrained our comments to these tasks, specifically, for the day. So, do not think that this is a glass half full. We will be filling this up as we go forward. Our next area and our next charge this September is to continue our evaluation. We'll look at the actual submission system and improvements, understanding a little bit more about the criteria and process use to evaluate and assign levels. We're also going to prioritize process. We're already looking at that process today and seeing how we can better improve that going forward. And then, we will be recommending our priorities for USCDI Version 3 submission cycle in September. So, a lot of work ahead.

There is no summer in ONC. Next slide, please. So, you'll see from the group of people on our committee, we have a great representation from HITAC. We also have wonderful representation from payers, providers, patient advocates, EMR vendors. So, it's a really great group of well rounded, well influenced people participating in this effort. Next slide, please. So, this is to refresh you of what the current draft of the USCDI is in V2. You can see that it is constrained. ONC did a great job of looking at what could be added, what had material gains, which was more, I'd say, easier to implement. And we took all of these requests, gave them considerable due diligence and then, added our comments as reflected in our first task. So, with that, Steven, I'll send it over to you.





**Steven Lane**

Thank you so much, Leslie. And let me really thank Leslie for stepping up into the co-chair position for this task force. I think most of you recall that we kicked this task force off with Terry O'Malley as the co-chair. Terry went through some changes in his demands and decided to step down from that role and Leslie very kindly stepped forward really bringing the patient perspective to the foreground in terms of the task force. We also had some other membership changes, some people who didn't have time to continue to participate. We were able to invite some members after we kicked off though these are people who were participating from the very beginning as part of the public participation. So, it's really been a very engaged group. We've been meeting weekly since the beginning of February. So, the work, as Aaron suggested, has been rich. The conversation has been, I think, quite thorough. And we bring you recommendations today really based on a deep discussion.

You'll note we spared you lengthy documentation. The report itself, I think, is only about 15 or so pages. The justifications were kept brief. But we are happy to dive in as deeply as anyone would like today. I think Leslie made a really good point about the charges that our group has. As with any task force, we're charged by HITAC and ONC to do specific work and analysis. And while the discussion clearly ranged beyond the scope that we were offered, our recommendations are restricted by that scope. So, we may well have some discussion after we present the recommendations. It goes a bit beyond the scope with which we were tasked. And I think that's the HITAC's prerogative. Looking here at the Draft V2, again, I want to highlight what Leslie said that the changes, which are represented by the stars here, are pretty modest. There were two new data classes that were introduced for diagnostic imaging and encounter information and a handful of new data elements.

But really, it was a modest advancement, I think, based on the challenges in the context of the pandemic. And that was what was proposed. A lot of public comment has come back that perhaps this was right on and that they hit it right on the mark. And then, there was other public comment that suggested that maybe this was too conservative in terms of the demands and the needs of the industry to advance the USCDI. And we had a lot of that conversation at the task force as well. Onto the next slide. This is just a reminder of the life cycle of USCDI that this is the first annual review cycle. But the intention is that USCDI will have the opportunity to advance every year based on both public input and submissions of suggested data classes and elements. The ONC's review of those submissions leveling them based on their readiness for inclusion in USCDI. Selecting a subset for inclusion in the next version. Publishing that and allowing for public comment and the HITAC task force review of that.

Then, ONC goes into a cycle of reviewing all of the input. And then, finally, publishing the next iteration of the USCDI. So, we are at the beginning of a process, which we, at HITAC, helped define. We've had two prior USCDI task forces that I've had the honor of participating in under the leadership of Terry O'Malley and Christina Caraballo. And now, we are continuing this process with the anticipation that it will march ever forward as we continue to expand USCDI to support the industry. We did have a rich discussion about what does it mean for something to be included in USCDI. What does it mean for data to be core? And we're going to come back to those issues. And as Leslie mentioned, in the second phase of our work, which we just began earlier this week, we're looking at providing input regarding the prioritization process, the leveling process, how the draft versions are assembled. So, we are going to be coming back to you later this year, hopefully, with two additional presentations.





One on the recommendations for adjustments to the prioritization process because we hope that that will be incorporated into the next cycle. And then, further recommendations later on in the year in September. So, again, just pointing out that this is not our only chance to expand USCDI. And the vision that we have of why and how quickly to expand USCDI will, certainly, evolve over time. So, with all of that introduction, let me go ahead and talk about the recommendations. We break them down by the task. So, recall that the very first task was to look at the data classes. You can go to the next slide. Look at the data classes and elements that were included in Version 1 and the applicable standards that applied to those and make any recommendations about those. So, part of what ONC does with each version is they look at the applicable standards and how they've been updated and then, they suggest that those standards be advanced in the next version of USCDI to the latest version of that standard.

So, that was our Task 1A. And we did have a couple of recommendations related to that. So, on the next slide, the first one was, some of you may recall that within Version 1, there is a data class and element called assessment and plan of treatment. And this came to us from the common clinical data set. This was not new in Version 1. And when this was added under the HITAC to the data set, there was not a specified technical standard to constrain this. It was a section. It was felt that this was important. But today, as increasingly we have standards tied to the individual classes and data elements, it was really pointed out that the scope and definitions of assessment and plan of treatment were unclear. It was unclear whether this required both an assessment and a plan of treatment or whether those are the same thing or whether they're separate. So, the group is suggesting that this be clarified, hopefully, in time for Version 2. But if not, at some point in the future. But this was a clear recommendation related to a Version 1 data class and element.

Now, what I'm going to do, if it's all right with everybody, is present all of the recommendations and then, take questions and discussion at the end because I think we want to get through all of this. The next slide, again, was from our Task 1A looking at the diagnostic imaging data class and the imaging order data element. And, again, the recommendation here was to request additional clarification though that's sort of the scope of this data element. Does this include only radiology or does it include other kinds of images that are used to support diagnostic processes such as visible light photographic or video images say from a diagnostic endoscopy? I think, in general, the ONC team that's been supporting USCDI has a clear sense of how they see the scope of each of these coming down. We did discuss this at some length sort of what would be the pros and cons of an expanded or restricted scope. And I think really the key is we want clarification, again, knowing that USCDI will march ever forward.

The things that are out of scope now will come in scope in the future as they're demanded by the industry. But there is a real need for clarification on this one. On the next slide, our third recommendation with regard to the Task 1A, again, the data elements and classes from Version 1 has to do with laboratory. And here, again, clarifying the scope. What distinguishes something as a laboratory test as opposed to another kind of diagnostic study. I think, again, this reflects a general feeling that people want more, certainly people on the task force, want more in USCDI. They want more data to be clearly defined, to be required for access, exchange, and use, whether that's in the context of information blocking, in the CMS rules, in the TEFCA. Any particular part of rules and regulations that point to USCDI, I think, there's a general feeling that more is better. And we're really caught in this tension between wanting to introduce and support more data classes and elements and really more specific data, as in this case.





There was an argument that let's just throw everything into this kitchen sink and get all of those diagnostic studies in. But the reality is that there is some difference between laboratory tests where they collect the specimen and process it and other diagnostic studies. And I think the industry is really hungry for greater clarification on that. On the next slide, again, within the laboratory data class, thinking about the values and results, here was one where there was a broad perception that it would be valuable to include a specification of a standard, a technical standard to support values and results. And Clem McDonald, who is really our guiding light in terms of a lot of standards and the work that's been done historically, made a strong argument that we specify UCUM, the Unified Code for Units of Measure, as the applicable standard as it is widely used. So, the task force felt that was a good idea and is recommending that as well.

On the next slide, again, another Task 1A recommendation from Version 1 having to do with problems. And, again, it's a great reflection of the many stakeholders that have provided input. This one came, specifically, from CMS as a recommendation. But, certainly, others chimed in and are in agreement that this was a really good idea to include, basically, to allow ICD-10 to be used as a supporting data standard for problems. This is to say on a problem list. This was already included for encounter diagnoses. And this was an acknowledgement of the fact that this is used generally for billing. And this is in addition to SNOMED, which is included in Version 1. The last Task 1A recommendation on the next slide also has to do with problems. No, I'm sorry. This one is procedures. My mistake. And here, again, the same concept as we discussed before. Clarifying the definition and scope of procedures whether this includes diagnostic as well as therapeutic procedures to be clear.

And I think this has come up also in a lot of our work to implement the information blocking rules where we're clarifying different types of notes. Do procedure notes include surgical notes? I think there is a real desire within the industry for ONC to be very crisp in its definition within USCDI because we've found that organizations really have to make distinct decisions to configure their systems to support these guidelines. It ends up that diagnostic and therapeutic procedures could be differentiated. And I think there was a sense that this would be important to clarify this. So, those were all of our recommendations related to USCDI Version 1 and the elements and classes that were included in that. And then, our Task 1B took us on to recommendations related to what had been proposed by ONC in Draft Version 2. So, let's go on to the next slide and the one beyond that. So, now we are looking at the modest expansion that was recommended, the few data classes and elements that were proposed for inclusion in Draft Version 2 and making comments on those.

So, the first couple have to do with the care team members. Clearly, capturing a patient's care team is important as well as the characteristics of those care team members. So, one of the data elements included in this data class is the provider identifier. And the recommendation is that this should include the identifier code system. That was not specified. And, of course, in order to utilize an identifier, you have to know what the reference data set is. So, this was a recommendation. On the next slide, having to do with both the provider identifier and the provider name, there was a strong feeling that we should lose the term provider and exchange that for the term care team member. And this was really based on a broad observation and robust discussions of the fact that a patient's care team includes many people who may not be licensed clinicians and that limiting this to providers is too restrictive. We want to capture the fullness of a patient's care team. And those that have identifiers, that's great. But the mother-in-law may not have an identifier but she still belongs on the care team if her role is central to the patient's care.







On the next slide going right along here, now switching back to diagnostic imaging, this is a data class. And what happened in Version 2 was that there was this transition where the diagnostic imaging data class was created. And both the diagnostic imaging narrative, which had been included as a clinical note type in Version 1 was put into that new data class along with two additional elements, the diagnostic imaging order and the diagnostic imaging report. And there was a rich discussion about both diagnostic imaging and laboratory, which we'll be getting to about the role of narrative in the result. And I think the bottom line here is that everybody agrees that the narrative portion of a result report, whether it's coming from the laboratory, from pathology, from imaging is critical to understanding the meaning of a report. But that narrative should not be seen as separate from the report itself. The report without the narrative is incomplete. The narrative without the discrete data elements that are included in the report would similarly be incomplete.

And by identifying these as distinct data elements within the data class, there is a concern that vendors or other stakeholders might be confused and might think that it's okay to include one or the other. So, the idea here is not to say that we don't support the narrative but rather that the narrative should be considered a component of the report if and when it is present and should be sent along with that. So, on the next slide, this one has to do with encounter information. And here, again, we spoke about problemless diagnoses a moment ago and the potential or importance of ICD-10. Here, we're talking about the encounter diagnosis. And, again, specifying the reference coded billing diagnoses for encounter we felt was important. Here, again, most encounters are billed using ICD codes, today ICD-10 and in the future, perhaps ICD-11. But the key point here is that the billing diagnoses, whether they were associated with an inpatient encounter, an ambulatory encounter, a home visit, there is almost always a billing diagnosis in ICD-10 terminology.

And we felt that that should be included as a component here. On to the next slide. This has to do with the encounter time. Boy, talk about a rich discussion. Encounter time is included as a new data element under Draft V2. But it was not felt that it was sufficiently specified. And for CMS in particular, there was a need to be able to identify the duration of encounters in certain care contexts, specifically, in the acute care setting. And so, there was a lot of discussion about the need to clarify the scope and definitions of various timing elements so that health IT vendors could assure that they are collecting the time in a consistent way. And here, again, we did not go down to the level of saying exactly what we thought that should be but rather to say that the clarification was necessary so that the duration of certain types of encounters could be captured because these are, in fact, used for quality measures. So, we know that systems are capturing them. We know that these are being used for reporting. And we want those to be fully clarified so that we can all be doing it in the same way.

On the next slide, our next Task 1B recommendation, again, has to do with the narrative, as I discussed. Laboratory and pathology report narratives were included in Version 2. And they sat on their own as data elements within the laboratory class. And here, again, our feeling was that the narrative was of critical importance and that separating it out into its own data element, potentially, caused confusion and, potentially, could lead to a vendor system presenting narrative without the discrete data in the report. And we felt that, in the case of both laboratory and pathology, all discrete data elements, as well as narrative data elements, should be considered a part of the report. So, while we're recommending removing these as distinct data elements, we are, certainly, recommending including them within the definition of the report itself. Next slide. Here, again, laboratory. This is where those would go. The laboratory value results would include the unstructured narrative content as we've been discussing.





On the next slide, we are now ready to move on to Task 1C. And, again, just to remind everyone, Task 1C was, specifically, where the group was asked to look at the data elements that were proposed by the public that the ONC decided were at Level 2. That is to say that they had the technical readiness, they had been tested and used in live data exchange to the point that they were ready to be added to a USCDI version. And there were many of these. And the task force, while appreciating the work that ONC did to narrow things down in their draft V2, there was a general feeling that we should be more inclusive and that there were more data elements that were in Level 2 that really were important to include in Version 2. So, I'm going to try to go through these fairly quickly because I don't want to overstay our time. So, on to the next slide. This is our 14<sup>th</sup> recommendation. Here, again, having to do with care team members, we discussed earlier the importance of the care team. These data elements, the care team member role, location, telecom information, NPI and DEA number were all leveled as Level 2.

And we felt that they should be added to Version 2, again, with the proviso that they be named care team member role, care team member location, etc., as opposed to provider exclusively. But we really felt that this would support comprehensive understanding of a patient's care team. On the next slide, our Recommendation 15 having to do with diagnostic studies and exams. Here, again, we were talking about laboratory results earlier. We were talking about imaging results. Here, the diagnostic studies and exams data class was put at Level 2. And we felt that it was of sufficient value and that it should be included in Version 2. And we, specifically, called out a number of diagnostic studies and exams that we felt should be included in testing because these, in particular, colonoscopy, echocardiography, electrocardiography, and pulmonary function tests are utilized by CMS for quality measures. So, all of the systems that deal with Medicare and Medicaid patients, certainly, do have the ability to capture these.

So, they are in broad use and we thought that they should be included in Version 2. On the next slide, we have encounter disposition as a data element that was not included. Here, again, very important to CMS. And it's already collected broadly by certified EHR's. It's used for many use cases. And we felt that its inclusion in V2 made sense. On the next slide, we're up to Recommendation 17. And this has to do with encounter location. Again, for specific types of encounters, the location is important. For all encounters, it's important. But there are some where it's, actually, required for CMS in their quality measures. We felt that this should include the TIN or CCN as a location identifier where that exists. And that would make the data set richer. On the next slide, moving right along, discharge medications. The idea here is that this would be a flag on the medication list to specify that a medication was included at the time of discharge. And it was on the discharge medication list.

This was felt to be critical for supporting safe transitions of care as well as downstream medication reconciliation workflows and would not require much of a lift from the standpoint of the health IT systems. On the next slide, Recommendation 19 having to do with orders, specifically, orders as a data class with the data elements, types of orders for medical care services. This was, again, at Level 2. We felt that this should be included in Version 2 with specificity that orders for end of life care be included in certification testing. Clearly, orders is a very broad data class. There are other data elements within that data class that are at Level 1 and will be coming forward in the future. But we felt that getting this data class into Version 2 was important and that this specific use case around end of life care orders would be a very good place to start as this moves into USCDI. On the next slide, our Recommendation 20. And there are only a couple of more here. We're almost there.







Patient demographics including the data elements of gender identity and sexual orientation. Again, well tested, well understood, used broadly. So, we're placed at Level 2 but not included in Version 2. We felt that this should be included in Version 2 as we go forward into that version. These are well supported by US core and 60 day implementation guides but they are not finalized. So, this is an example where we are, specifically, saying that these should be included in Version 2 contingent upon finalization of implementation guides by HL7. If those guides cannot be done in time then, we would put this off to a future version. Luckily, we have Andy Truscott on our task force who is the chair elect of HL7. And Andy really offered to help to shepherd this and to coordinate the communications between ONC and HL7 to get this done. On the next slide, our Recommendation 21, Medicare beneficiary ID. That's a data element within the class of patient demographics.

We felt that this should be added to Version 2 but, again, only contingent upon its inclusion in HL7 implementation guide. So, another example where this is a contingent recommendation. Again, this is, clearly, broadly available and widely used. But this is an example of where we think things should be added to USCDI when they have clear definitions, technical specs, and implementation guides. And that's not true for every data element, historically, or even going forward. But for this one, we felt that it was. And our last discrete recommendation has to do with social determinants of health. And it's at the end only because, I think, of the alphabetical order. It's not to suggest that it's the least important. I think we're all well aware of the importance of social determinants of health in determining health outcomes, how important these have been in the context of the pandemic. Five of these data elements were leveled as Level 2 by the ONC. And their implementation guides are well along the path to finalization of IHL7.

But, again, it was felt that including these in a future version of USCDI really should be done only once those implementation guides are finalized. So, our recommendations really include the future collaboration with HL7 to get these IG's done. So, the next slide takes us into suggestions for consideration for Version 3. And the next slide here in the recommendations includes a couple of specific suggestions. These are things that we spent a lot of time talking about that were not ready for inclusion in Version 2 but that we felt were, particularly, important for future consideration. So, just letting you know that these were discussed in depth around encounter information and the encounter disposition when it applies to long term care. We are capturing encounter disposition in other settings. The reason for encounter being the chief complaint as distinct from the diagnosis that was made in the encounter. We talked about orders and the value of orders related to end of life care.

There were some that were not ready for inclusion now but will be in the future. And, of course, advance directives. These are all things that are down at Level 1 and we just wanted to express our support of those. On the next slide, we have the questions for guidance. And I'm going to hand it back to Leslie. So, we've completed presenting our recommendations that we're going to ask you to comment and, eventually, vote on. But we are moving into the next phase of our work and this is what we need your help with.

### **Leslie Kelly Hall**

Thank you, Steven, and thank you, everyone. As you can see, we had a lot of discussion and robust recommendations but still in the eyes of being constrained and responsible around our tasks. That doesn't mean that we have broad questions, which we do because as we are struggling with our due diligence in making recommendations, there is often tension about what is it we're doing. Who are we serving? And we brought up this question in our last meeting. Is there an opportunity for HITAC to give us guidance about





stakeholders? They are different and sometimes competing interests. And these interests then have different end results. Obviously, whatever stakeholders' priorities are put in place, we respond to those first with that top priority. And so, we'd love to hear your thoughts and guidance around stakeholders. Is there a priority for waiting that we should use as we go forward with the recommendations? And then, as you can see, our next task, as Steven talked about, is to evaluate our processes and to evaluate the submission cycle.

These will also be informed by having guidance from you around stakeholders. And although we know that everyone is important and the needs are quite important, they are sometimes diverse. For instance, the data underserved is a class of organizations and people that often don't have natural sponsorship, the patients, public health, tribal nations, underserved populations who don't actively have organizations promoting standards and data elements, except for those of us who are assigned to serve. And so, is there a need to elevate the data underserved as a priority? Providers well integrated into a lot of our policy efforts, obviously. Payers are really emerging and integrating into the HIT ecosystem. The regulatory bodies have considerable influence and needs from quality measurements and beyond. In fact, one of our discussions in the meeting revolved around that CMS came with some great recommendations. And some of those recommendations were particularly around quality improvement.

But some of that also made it in our recommendations had a direct relationship to care. And that was a great example of where there is congruence between a regulatory need and a care need. So, we strive for congruence but when there isn't, we would love to hear your guidance around priorities of stakeholders. And Steven and Denise and Aaron, I would love to hear your guidance about how to get that feedback today as well as then, seek a vote on our current recommendations.

**Aaron Miri**

Sounds good. So, as an order of process, Leslie, what we'll do is we do have a hard stop at 11:55 a.m. for our OCR partners. And so, I do want to give time before that to, actually, hold a vote. So, I would propose that at 11:50, we will pause the questions and comments assuming nothing major and substantial and call for a vote. But we have until that time to be able to go through that. And we could leverage the existing features of raising your hands and our normal functionality to be able to get that done if that's acceptable to you and Steven.

**Leslie Kelly Hall**

Great. Thank you.

**Aaron Miri**

Perfect. So, I will call for the HITAC to utilize our normal processes please. Please raise your hand or indicate, and if you're on the phone line, you can also indicate if you have a question. And we'll just go in the order of folks raising their hands. And first up is Abigail Sears.

**Abby Sears**

Hi. First, I want to acknowledge all of the hard work that was put into all of this and what fantastic work. And it's so important and I can't wait to, actually, get to the next version as well because the more that this stuff is clear around the country, the easier the data will be to flow. And I know how much work goes into this. So, first, thanks for that and for the leadership, Leslie and Steven. You asked a question around the data





for underserved. I think one of my major roles on being on HITAC is, actually, to represent that. We have a broad set of knowledge around the patients' public health and how that data is being captured. I want to just relay a couple of things related to that. It is managed by state. There is continuing to be different data collections required in each state that we go into related to social determinants of health. It is an incredible administrative burden. It is not necessarily adding value to our system overall.

And we are having to contend with about 38 different ways to, actually, collect this data with a provider group that doesn't have the bandwidth or capacity to, actually, do that. And they're doing the best that they can. We have over 700,000 unique patient sets of data around social determinants of health. And we also perform a lot of research. The data that's most important is related to food, transportation, and housing. Those are the ones that, actually, create the most impact when you are doing referrals and working with your community partners. It also is having the biggest impact when we look at the data and the segmentation of the data around outcomes. So, I think that might be helpful for you to know that that's what we're beginning to land on. And we've been collecting a lot of different types and kinds of data. But those are the three areas that are the most useful. And I would also say that our patients tend to be more expensive patients. And 60% have chronic disease diagnosis attached to them. Of that, there is an additional 50% that have a secondary diagnosis.

And in the top eight diagnoses, three of them are significant mental health. So, what I'm, basically, saying is that there are incredible mental health issues and chronic disease issues with this patient population. So, even though it might seem like it's competing, I don't think it is competing because our patients are showing up in all of your hospitals. And they're costing a lot of money because the care coordination is more challenging. So, I'm just trying to make it compelling. The fact that we can get social determinants of health data standardized in this country, the less money we will spend related to capturing it and coordinating the care for this patient population and the better care we'll be able to provide for the at risk population that we're leaving behind from an equity standpoint. And I'll just leave it at that. And I'm volunteering to participate on your task force if you're taking anybody else.

**Steven Lane**

Aaron, you're on mute.

**Aaron Miri**

Steven or Leslie, anything you want to respond to that with?

**Steven Lane**

I'll certainly say, Abby, thank you for those words of encouragement. I think they really reflect the views that we heard on the task force that social determinants are critical and that they warrant being brought forward sooner rather than later and that there were just these five data elements that ONC leveled as Level 2 so we're within our scope for comment. And we suggested bringing all of them forward. But, again, as you say, based on the finalization of implementation guides because having people collect and exchange the data in all sorts of different formats is just going to make more of a mess of this. And we did feel that it was critical to have those guides finalized and in place for this to be added to USCDI formally.

**Aaron Miri**

Leslie, anything you want to add?





**Leslie Kelly Hall**

No thank you.

**Aaron Miri**

Perfect. Next up is Michelle Schreiber.

**Michelle Schreiber**

Hi. Thank you. First of all, to Steven and Leslie, you guys did a masterful job in listening to many points of view and bringing consensus to this. And thank you for a great presentation today. On behalf of CMS, I also want to thank you for the consideration that was given to many of our recommendations. When we tried to make recommendations, it wasn't just about our regulatory requirements or the requirements of quality measurement but also, what's important in clinical care. What is really needed by the provider at the point of care that they should have to make the most informed decisions as well as what is important for the consumer and the beneficiary to have as they're making decisions about their own care? We are fully supportive of social determinants of health and also encourage those to be brought as quickly as possible. But you've heard me say this before and I'll just say it once more, we really encourage ONC to step back and consider what is the USCDI and what should it be. Just how inclusive should it be?

And it may be that it can't be everything we want in standard data elements. But then, what are some adjacencies? For example, what really is required in quality measures, other regulations, other ontologies, for example, that are important in clinical care? Oncology standardized data elements, which I know are being worked on. And so, we do think that there needs to be a philosophic approach and agreement about what the USCDI really should be. So, thank you and thank you to Leslie and Steven for all of your work.

**Aaron Miri**

Fantastic, Michelle, thank you.

**Steven Lane**

I'll just comment, Aaron, to that. CMS was really, through Michelle, an active participant in our discussions. And it was really a dialogue that CMS proposed a number of data elements that made it up to Level 2, many that were in Level 1 that they were proposing and advocating for. Some of those are included in our final recommendations. Some of them they decided to take back and provide more detail on. So, I don't want it to appear that CMS was driving the boat here but they were definitely on board.

**Leslie Kelly Hall**

I echo those comments, especially around the congruency. When those recommendations really aligned with care, regulatory need, patient advocacy and others, I think we did a good job of balancing all of those issues.

**Aaron Miri**

Excellent. And I would say, Michelle, I appreciate the social determinants of health emphasis there from a CMS perspective. I think it's very important. We're leveraging extensively patient reported outcomes in our clinical practice and enterprise. And it's proven over and over and over again of being able to intervene for depression screening, whether it's PHQ29, GAD, [inaudible] [01:01:41] for ortho or whatever it may be,





all of those are invaluable. And that goes further than when you talk about areas of need from food insecurity and others. So, thank you for echoing that. Next in cue is Steve Posnack.

**Steve Posnack**

Thank you very much. I want to dollop the praise as well for Leslie and Steven. I know how hard it is to manage a task force. And thank you, everybody, for their contributions. As before with the meaningful use common data set, which is the initial data set that we have and then, on to the common clinical data set and now, we stand with the USCDI, one of the intangible aspects of it is around standards policy and things that get settled. And one thing I would appreciate some additional dialogue on would be around Recommendation 5, which I would note is settled standards policy since 2012. And that SNOMED CT would be the single co-system used for clinical problems. That is one where I would just appreciate any dialogue from the task force or further explanation around that recommendation as it would be inconsistent with the direction that the nation has been on for the past nine years.

**Steven Lane**

I'm happy to comment and then, perhaps Clem or others would want to add in. But really, I think when that first recommendation was made, it was a perfect aspirational goal that SNOMED CT is very detailed and very helpful for many purposes. In reality, we capture problems as diagnoses and we bill for them and then, we add them to the problem list. They're not different things, diagnoses and problems, in the reality of utilizing electronic health records and sharing data. So, the thought was that SNOMED CT, certainly, meets a number of goals that many systems had to create mappings to take their ICD coded diagnoses and find the appropriate SNOMED CT and include that. But the thought here was really that if ICD-10 is available to allow that to be used as well so that the mapping is not required on receipt. If we are using ICD-10 and we map it with SNOMED CT and we exchange CT and then, that comes in and then, you have to map it back to ICD-10 that just seems like a waste of energy and a potential loss of signal that rather we should include ICD-10 as well.

And, again, I don't think this says that there is anything wrong with SNOMED CT or that anybody made a bad decision back when they made that decision but times have changed. The systems have advanced and this should be included when available.

**Leslie Kelly Hall**

One of the things that those of us in patient advocacy brought up is that there needs to be a continuum that goes from the problem all the way to the bill so that people can decipher and have no surprises. And by using ICD-10 from the get go, we have a way then to track and to review, to analyze whether it's the patients themselves, quality measurement, internal process review, continuity was important. So, this was brought up from, actually, every stakeholder in support.

**Aaron Miri**

Good deal. So, I do want to note some of the comments that have been in the public chat box here, one from Jonathan Nebeker. And I would ask if he wished to expand upon it to please voice in. But his comment here agreeing on the need for a clear framework and how USCDI fits into the larger picture. I will take a shot at sort of explaining what is happening on the provider side. And even when we went into effect with the information blocking for USCDI Version 1, explaining what is USCDI to my surgeons and my physicians and my clinical staff took a bit. They're like what is that. And I had to explain this is the framework to which





certified health IT vendors are certified against. There is a new version coming out and what data elements. And then, naturally, the clinicians gravitated towards elements that weren't in USCDI Version 1 going, "What about this and what about this?" And for the right reasons. So, I think maybe, from that degree from the CIO hat perspective, and I definitely defer to Steven and Leslie for their comments on this, it's one of those things that this is the engine that fuels going forward.

And it fuels how these systems talk to each other and how that is used and explained and communicated in the provider and clinical communities probably could get better. But I think as folks get used to it and they understand the data elements and data classifications and the importance, much like Dr. Lane and Leslie were doing earlier in their presentation that will help illustrate and illuminate what USCDI, actually, means from boots on the ground. But Steven and Leslie, I don't know if you want to comment to that.

### **Steven Lane**

Well, I'll ask the person who is running the slides to back us up three slides. And I'll say that this is part of what we are going to be focusing on in our next body of work is really working with the team on the task force to develop a set of guiding principles that we think should be applied going forward. And clearly, that is dependent on a clear vision of what is the role of USCDI in our ecosystem. And, again, this has been a lively part of our discussion already that we keep saying we're going to get to that. Well, now we're getting to it. These are some of the things that we've come up with that we hope to include as recommendations for future versions, Version 3 and beyond. But I think, clearly, that will be part of our discussion is where does this sit and how, if at all, can the task force and the HITAC weigh in on that and impact ONC's vision of that.

### **Jonathan Nebeker**

Aaron, this is Jonathan and I'll take you up on your suggestion. And I also noticed some comments from Steve Waldron. And I think that we are now at an interesting inflection point in the evolution of EHR's and other information systems where we can start taking advantage of a more mature and useable set of data because of terminological advancements and implementations. We have a number of means with CMS to coordinate on this issue and we strongly supported them in this. But there is a growing potential for connectedness across all of these terminologies. And ICD is really the odd man out on this. And I think we need to start thinking about, within the regulatory framework, where does USCDI fit but also within the knowledge of network framework, how does USCDI or should it have a role in advancing the connectedness of the knowledge networks and how things might fit into ontologies to drive decision support, to drive quality measurement, etc. And maybe we say USCDI is not what we're supposed to do.

It just fits in the regulatory framework and it doesn't really have a role in advancing more useable, more connected, more ontologically reasonable data. And I guess that phrase was not properly said but I hope you know what I mean that we can use the data to reason across as in ontologies. And so, I think we're at an inflection point. We need to address both issues and decide what USCDI is going to do.

### **Aaron Miri**

Okay. Leslie, anything you want to respond to that with?

### **Leslie Kelly Hall**







I think that the task force had lots of discussion on this item in particular. And I think everyone is bringing up the main point of connectedness and being able to have a knowledge network and a continuity of information. And recall that the task force is not saying to eliminate SNOMED. It's to add ICD-10 when available for continuity of information. And so, I think that we're not in conflict with these recommendations or with these comments that have been made. This is an and/or and not instead of. Steven, would you like to comment further?

**Steven Lane**

Yes. And I think we're having a discussion with Steve Posnack in the chat as well. I agree. The notion is since the systems are using ICD to codify diagnoses for billing, for orders, etc., often using the same diagnoses on the problem list, don't limit the ability of sending that and exchanging that and requiring only the use of the mapped SNOMED CT codes.

**Aaron Miri**

All right. Good discussion. I see a raised hand here with Clem McDonald.

**Clem McDonald**

I'll comment on the last discussion. Firstly, ICD-11 is a less discordant coding system than ICD-10. And there is a lot of interest in corners for that. So, that might reduce the problem. The second thing is there are some other vocabularies. One is called HPL, which has gotten a lot of purchase in research areas, especially in genetics, which is very otologic. So, I wouldn't give on strong ontologies at all. And I would just support what was said. We're going to keep them both.

**Aaron Miri**

Okay. Steven and Leslie, anything you want to add?

**Steven Lane**

Looking at the time and sensitive to our need to take a vote, Clem, I know that you have a suggestion for data element inclusion that goes beyond the scope that the task force was given. Did you want to bring that to the table before a vote is taken?

**Clem McDonald**

If I may. I've been a fly in the ointment or a nuisance to the committee as bringing this up all of the time. It's tonometry, which is intended to protect against glaucoma and reduce blindness. And the assumption made by the activities prior to our meeting there really was no electronic transfer of tonometry so it wasn't really in scope. But it turns out it's a huge amount. There is a big project developed by the American Academy of Ophthalmology, which carries now 60 million patients and 350 million patient visits since 1914. And as of 2017 where I've got good data, there are 14 million patients with interocular pressure recorded. And it's such an easy thing. It's two numbers that fit right into a typical message structure of observations. And I'm sorry. I really was a metal to poor Steve. But it's like at least get it out because it's a little, itty, bitty thing. It's two numbers and it could prevent blindness and it is being widely used. So, there was a misconception that there was no electronic transferring of it until we came up with this new information.

**Aaron Miri**

Good deal.





**Steven Lane**

And just to put some context around that, Aaron, this would relate to our Recommendation 15 regarding diagnostic studies and exams. You'll recall that we advised that colonoscopy, echo, electrocardiogram, and PFT's be included for testing. I think Clem's suggestion we could not include because the tonometry data elements were leveled by ONC as Level 1 and were, therefore, out of scope. Clem's argument is that they were misleveled and that they should have been Level 2. They should have been available for us to recommend. And I believe he's suggesting that they be added as a tested component to our Recommendation 15. But just to be clear, we could not, as a task force, make that recommendation to you today.

**Clem McDonald**

But you guys can.

**Aaron Miri**

Sure. So, I want to stay close to time here. We've got about 2.5 minutes left before a vote and we do have one more hand raised with Mr. Andy Truscott. Andy, if you want to ask your question really quickly in cue and then, we can get to the vote.

**Andy Truscott**

Yeah. I'll be quick, Aaron. Thanks. I think on this ICD SNOMED discussion, for adoption, we're going to need to proceed with ICD. But I think we should be very cautious about allowing that exception to be long lived. And we've been trying to encourage SNOMED for so long now that this feels like it could send the wrong message by doing otherwise. So, that's my core point in that. Second, I agree with Clem entirely on this particular issue. And third, I think we need to be careful when we're using the concept of core for USCDI that we still focus upon what is core as opposed to we could also include lots and lots of other things as well, which are useful, needed, and absolutely should be focused upon but not necessarily within the core data.

**Aaron Miri**

Well said, sir. Steven or Leslie, anything you want to add?

**Steven Lane**

Just thanks to Andy for his tremendous participation in the task force and his willingness to step forward and take on extra work.

**Andy Truscott**

You're welcome.

**Aaron Miri**

Leslie, anything you want to say really quick?

**Leslie Kelly Hall**

No. That's it, thanks.







**Aaron Miri**

Perfect. Thank you, Andy, as always for your clarity of definition. Okay. So, I think we are at the point that we're ready for a vote. And so, I would ask to look at this in entirety. I would say that this is a vote on all of the recommendations. I realize there are suggestions for out of bounds and out of scope things. But given our charge, we stayed to what we were charged with as a task force and then, look at anything for future versions as necessary. But to the degree based upon the recommendations of this task force, I would like to move this forward for a vote. I look for a second, please.

**Andy Truscott**

I second.

**Denise Webb**

Aaron, are you making the official motion or are you calling for a committee member to make the proposed motion?

**Aaron Miri**

No. I'm, actually, making the official motion to vote.

**Denise Webb**

Okay. Thank you.

**Aaron Miri**

Andy, I think you just seconded it.

**Andy Truscott**

I did.

**Aaron Miri**

Okay. So, I'm looking now at the whole HITAC for up or down. So, all of those in favor of all of the recommendations for this task force, say aye.

**Group**

Aye.

**Aaron Miri**

All those not in favor say nay. Any abstentions? Okay. I believe USCDI Version 2 task force recommendations have been approved. Well done Steven and Leslie. Okay. So, now that that is done, we are going to move on to our next section and I'll give it to Denise.

**Steven Lane**

Aaron?

**Aaron Miri**

Yes.





**Steven Lane**

Just to be clear, we cut off. We just had a little bit more we wanted to cover in our last two slides. So, if you can go forward one slide. I think we still have –

**Aaron Miri**

Sure. We have to save time so we've got about four minutes.

**Steven Lane**

No, this will take less than that. I just wanted to be clear to people that what we're focused on now is our Tasks 2 and 3. And we have as a task force suggested that we want to do Task 3 first because there is an opportunity for us to provide input to ONC for the prioritization process that they will be using to evaluate Version 3 submissions. And they will be republishing their prioritization scheme up before our September timeframe. So, we would like to come back to you over the summer with our recommendations related to Task 3. And then, you'll hear back from us regarding Task 2 and its sub tasks in September. So, we wanted to get that out in front of you. On the next slide is simply a list of the currently scheduled meetings. We are continuing on week by week hoping to get to a point that we can take a little bit of a summer pause along with the HITAC. But our task force is very engaged in working hard to try to bring you these recommendations.

**Leslie Kelly Hall**

Just one other thing, Steven, on I think it was the slide prior. We talked about the suggestions for consideration in V3. And we talk about some of the biases that we have, which includes things like having more broad consideration of a total data class. For example, facility level data, patient demographics that are widely used. And instead of a more piecemeal approach, taking a look at entire classes of service. So, those are some considerations as we go forward on our next task.

**Aaron Miri**

Definitely. That is a lot to bite off and chew. So, I really appreciate both of you two steering us through this all. Okay. So, we are at the point now to transition. So, Denise, I will turn it over to you if you would like to kick off the next section.

**Denise Webb**

Absolutely. And, again, thank you, Steven and Leslie, for providing your leadership to our task force. We will next have Tim Noonan present on the proposed modifications to the HIPAA Privacy Rule. And so, I welcome Tim to the mic to provide his comments.

**Tim Noonan**

Hi there. Can everybody hear me all right?

**Denise Webb**

Yes.





## Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement (01:20:13)

### Tim Noonan

All right. Thank you. Hi, everyone. I am Tim Noonan. I'm the deputy director for Health Information Privacy at the Office for Civil Rights. OCR is the federal agency responsible for administering and enforcing the HIPAA rules. We do this through rule making and guidance, investigations, and enforcement actions and outreach like today's presentation. And so, let me begin by thanking everyone for inviting me to speak on OCR's proposed modifications to the HIPAA Privacy Rule. I have information on some resources at the end of these slides where you can view and download our NPRM, how to provide comments, as well as our last press release announcing that the public comment period is open through May 6. So, about three more weeks, a little less than three weeks for the comment period. Next slide, please. So, our NPRM solicits public comments on proposals to modify the HIPAA Privacy Rule to improve health information sharing for more effective healthcare, empower individuals with their own health information, and list unnecessary burdens on covered healthcare providers and health plans.

And this effort started back in December of 2018. We did a request for information. And that's where we sought input from the public on how the HIPAA Privacy Rule could be modified to promote information sharing, parental and caregiver involvement, and reduce regulatory burdens. We had a great response to the request for information received, over 1,300 comments. And the comments we get are never half a page or one page. They're always 12 or 15 pages and really detailed. We ended up with nearly 4,000 pages of comments. And we read them all. It's a lot, by the way, and we appreciate it but we need it. It's how we can do the most effective and informed rule making is understanding how different proposals or different information will affect the healthcare industry, the regulated community, and individuals. So, we're looking forward to another robust comment period in response to this NPRM. The NPRM is guided by the work that we do and stories that we hear, the comments that we receive, and our experiences enforcing HIPAA through our investigations and compliance reviews.

And the stories we hear are stories of frustration about obstacles to getting timely access to health information, the right of access, the sharing of health information with family members and loved ones, particularly when they're involved in an opioid crisis or other medical emergency. And then, regulatory burdens that don't seem to contribute significantly towards the privacy and security of health information. You'll see in the agenda that I have today that there are eight sections of the NPRM that I want to cover and let's get at it because it's a lot of stuff to cover. I'm curious if we can do this in an hour. Some of my presentations have been an hour and a half. I've cut this down to try and fit the timeframe but I'm interested to see if we can be done also. Next page, please.

So, the individual right of access is the largest section of our NPRM and so that's where I'm going to spend most of our time today going through these proposals. I'll be discussing some proposed new definitions, shorten the timeframe for code entity to respond to a right of access request, personal health apps, unreasonable measures on access and identity verification, viewing and capturing images of protected health information as part of a right to inspect, directing protected health information to a third party, and the effect of the SIOUX decision, and a way for individuals to ensure that protected health information is shared among providers and plans as well as some changes to fee limitations and requiring the posting of





fee schedules. Next slide, please. So, we're proposing some definitions for electronic health record, clinicians, and health related information on an individual.

And so, the HITECH Act included a definition of electronic health record, which we proposed to incorporate directly into the HIPAA Privacy Rule to help define the scope of the right to direct an electronic copy of protected health information in an EHR to a third party. Because the HITAC definition of electronic health record includes within it the terms clinicians and health related information, which previously were not defined within HIPAA, we're proposing to clarify those component terms by making reference to several existing, commonly understood terms already in the HIPAA rules. So, we propose that clinicians are healthcare providers in a direct treatment relationship with an individual. So, physician, nurse, pharmacist, other allied health professionals and their staff or their workforce members. And then, as you see, we propose to define health related information as individually identifiable health information, which is an existing defined term in HIPAA.

And then, accordingly, the electronic health record would include electronic records consulted by any covered healthcare provider or workforce member of such covered healthcare provider so long as the provider has a direct treatment relationship with individuals. For example, an EHR would include lab test reports created by workforce members of a large health system who are licensed clinical laboratory personal and who perform clinical lab tests for patients treated by the health system or electronic billing records created, gathered, managed, and consulted by workforce members of a healthcare provider that has a direct treatment relationship with an individual. It would be included in the term EHR because healthcare billing information is health related information. Next slide, please. Here, we're proposing to define a new term to the privacy rule, personal health application, by drawing on the definition of a personal health record contained within the HITECH Act.

So, more and more, individuals are using personal health apps to access and manage their protected health information. And so, we're proposing to revise the right of access. To clarify that, it includes the right of an individual to access electronic copies of their protected health information. And one of the mechanisms by which a request for access can be fulfilled is by transmitting electronic copy to an individual's personal health app used by the individual. To support this proposal to address the use of personal health apps and the right of access, we're proposing to define personal health application as an electronic application used by an individual to access health information about that individual in electronic form, which can be drawn from multiple sources provided that such information is managed, shared, and controlled by or primarily for the individual and not by or primarily for a covered NT or another party such as an application developer. So, what does that mean? To put it another way, a personal health app is a service offered directly to consumers.

The covered entity does not manage it, share it, control the information, nor does the app developer manage the information on behalf of the covered entity or use it to manage access for the individual. So, instead individuals, and this would include their personal representatives, would be using the personal app for their own purposes such as to monitor their own health status and request their own protected health information. So, an example is individuals might want to request weight, vital signs, or other health information from their healthcare providers to store in their personal health app. And in this case, the personal health app is not acting on behalf or at the direction of the covered entity and, therefore, they wouldn't be considered to





be a HIPAA business associate. And, importantly, they wouldn't otherwise be subject to the privacy and security obligations of the HIPAA rules.

And so, by defining personal health app, we think this will help individuals, consumers make greater use of their right to access health information and get rid of some of the confusion about whether the personal health app considered a third party, which we'll get to in a little bit when we talk about the facts and decision. Next slide, please. Currently, a covered entity has 30 days to act upon a right of access request with the possibility of one 30 day extension. And we're proposing to reduce the timeframe to act on a right of access request to within 15 calendar days with the possibility of one 15 day extension. And we believe shortening the timeframe for responding is consistent with advances in technology and will strengthen the individual's rights with respect to their health information and enhance care coordination. In developing this proposal, we noted that at least eight states have statutory requirements to provide patients with copies of their health records in less time than the current 30 days provided in the HIPAA Privacy Rule.

For instance, California, Colorado, Hawaii, Louisiana, Montana, Tennessee, Texas, Washington have requirements that range from 10 to 15 days. And some of these are large populous states. And so, we believe we've been supporting the right of access through our right of access enforcement initiative and we've been highlighting just how important OCR thinks the right of access is and the need for covered entities to ensure that they have policies and procedures in place to take timely action on the right of access requests. Since announcing our right of access enforcement initiative in 2019, we have completed 18 investigations with settlements. And in each case where **[inaudible] [01:29:57]** timely action, some instances it took over a year for the entity to provide the individual with the requested records. And really, it was as a result of an OCR investigation. It's that whole thing about you don't want to make a federal investigation out of something.

Well, in some instances, that's the only way to get a covered entity to respond to an individual's request. So, we're also proposing to require covered entities to develop and implement a policy to explicitly prioritize urgent or other high priority requests. And the idea here is to try and limit the use of the 15 calendar day extension. We're not proposing to define what constitutes an urgent or high priority request. We think the covered entities are in a better position to do that. And we're not suggesting that covered entities have to ascertain the purpose of a right of access request. But if an individual does share the purpose of their request, if they state they're going into surgery and they need these records in order to facilitate the surgery that could be an instance where a covered entity could highlight that as an urgent request and try to complete it inside of the 15 calendar days that we're proposing. Next slide, please. We're proposing to modify the privacy rule to expressly prohibit a covered entity from imposing unreasonable measures on an individual that's exercising their right of access.

And we propose to clarify that while an entity may require individuals to make requests for access in writing as is currently provided, it would not be permitted to do so in a way that impedes access. And to help this, we would define unreasonable measures for covered entities. We're proposing to include in regulatory text a non-exhaustive specific examples of reasonable and unreasonable measures that some covered entities have imposed that we've discovered as the result of our enforcement program. For example, requiring individuals to complete a standard form containing only the information that the covered entity needs to process the request would be a reasonable measure as it does not cause an individual to expend any unnecessary effort or expense. But in contrast, some unreasonable measures that we've seen are filling





out request forms with extensive information, which goes well beyond what is necessary to fulfill a right of access request.

Requiring notarization of the individual's signature if the individual has to go to a notary and get the official seal before they'll act upon an access request. Or other limitations like only allowing written requests in paper form, only requests that are made in person at the entity's facility, or directing people to only go to the online portal and that's the only way to put in an access request. Those are examples of what we think would be unreasonable. And as is the case with all of the proposals that we're talking about, we do invite comment on these proposals. And we ask specific questions in each section that get a little more granular about some of what we're proposing. Next slide, please. The privacy rule generally requires the covered entity to take reasonable steps to verify the identity of a person requesting protected health information before disclosing the protected health information to help ensure that unauthorized persons are not obtaining protected health information.

And we don't mandate any particular form of verification such as viewing an individual's driver's license at the point of service. But we, generally, leave that to the discretion and professional judgement of the covered entity of how to best implement verification measures. Verification measures may be done orally or in writing. And in many cases, it just depends on how the individual is requesting or receiving access such as in person or by telephone, by fax, email. And so, despite guidance that we've issued in the past about complaints and hearing stories of covered entities imposing the burdensome verification requirements like I mentioned before, requiring a notary in order to facilitate an access request, we're proposing to clarify it within the regulatory text that unreasonable verification measures are those that require an individual to expend unnecessary effort or expense when a less burdensome verification measure is practicable for the particular covered entity.

Again, what we want to do is try to eliminate some of the barriers that have cropped up over the years that we've discovered in our enforcement program. Right of access complaints is one of the largest sources of complaints that OCR receives on a yearly basis. And we receive about 28,000 HIPAA complaints a year. So, we're drawing from a lot of information that we've received through our enforcement program where some of the friction spots are and we may help with that. Next slide, please. Here, we're proposing to strengthen the existing access rate to inspect and obtain copies of protected health information by incorporating a portion of access guidance we developed in 2016 into a new provision of the privacy rule. And so, what we're proposing is to add a new right that would, generally, enable an individual to take notes, video, photographs, or use other personal resources to view and capture protected health information in a designated record set as part of the right to inspect protected health information in person.

And so, under this proposal, covered entities would be required to allow individuals to take notes, videos, or photographs using their personal resources after arranging a mutually convenient time and place for it to occur. We're proposing to extend the right to inspect situations where mutually convenient times and places include points of care where the protected health information is readily available for inspection by the patient. For example, by viewing x-rays, ultrasounds, or lab results in conjunction with the healthcare appointment with the treating provider. We are not requiring a covered entity to allow the individual to connect a personal device such as a thumb drive, flash drive, to a covered entity's information systems. And we're not expecting them to tolerate unacceptable security risks, which would violate the HIPAA Security Rule in order to accomplish a non-secured mode of data transfer to the requester.







So, for example, a covered entity could establish reasonable policies and safeguards to ensure that an individual's use of personal resources minimizes disruptions to the covered entity's operations but is used in a way that enables the individual to copy or otherwise memorialize only the protected health information in the designated record set. Potentially, we believe strengthening this ability to inspect and take photos and videos could reduce the number of right of access requests that covered entities receive and the number of right of access complaints that OCR receives as the individual would now have the opportunity to get the desired information more immediately. And so, for example, an individual who is looking at their own x-ray, MRI, sonogram while in the exam room could use their smart phone to take a photo of the image. Next page, please. The privacy rule requires the covered entity to provide an individual with access to their protected health information in the form and format requested if readily producible in that form or format.

Or if not, in a readable hard copy form or other form and format as agreed to by the parties. And if the individual requests electronic access to protected health information that the covered entity maintains electronically, the covered entity must provide the individual with access to the information in the requested electronic form and format if it's readily producible in that form and format. Or if not, an agreed upon alternative format. And so, where EPHI is rarely producible in the electronic form and format requested by the individual, the healthcare provider must provide that access, including through when the individual requests access through a secure standards based API for the individual's personal health record. And so, what we're proposing to provide is that if other federal or state law requires an entity to implement a technology or policy that would have the effect of providing an individual with access to his or her PHI in a particular electronic form or format then, such form and format would be deemed readily producible.

So, in other words, if an entity is already required to provide something in this form and format by virtue of another law, all we're saying is that under HIPAA then, we would deem that it's readily producible because it's already required by another law. Next slide, please. The right to direct EPHI to a third party. So, this is part of the January 2020 SIOUX decision. So, in January of 2020, a DC district court vacated a small part of the HIPAA right of access with regard to directing protected health information to a third party. And the court held that, in part, an individual's right to direct health records to a third party is limited as follows. An individual may only direct protected health information in an electronic health record to a third party in an electronic format. So, there is no longer a right to direct paper health records to a third party or to direct copies of electronic protected health information that is not in an EHR. The court said this went beyond the HITAC authority expressly provided in the HITECH Act.

The court also said the right of access fee limitations do not apply when exercising the right to direct protected health information in an EHR in an electronic format to a third party. We'll talk about that when we get to the fee limitations. But the court said that the fee limitation provision did not go through notice and comment and, therefore, that's why that was struck. So, with this proposal, we're proposing to revise the right to direct protected health information to a third party consistent with the SIOUX decision. So, what we're proposing is that an individual may only direct PHI in an EHR. So, both the HITECH Act and the SIOUX opinion provide that this right only extends to electronic health records. And as I noted earlier, the HITECH Act definition of EHR requires that the record be consulted by clinicians or staff. And so, what we're proposing is that the interpretation of this obligation is that it only applies to healthcare providers because they are clinicians and their staff.





Moving on, an individual may only direct PHI in an EHR in an electronic format. So, the protected health information being directed to a third party can only be an electronic format. There is no right to direct paper records to a third party. We're also proposing to specify that the request be clear, conspicuous, and specific, which is taken directly from the language in the HITECH Act. And so, the request could be oral or in writing. This would change the current requirement that a request to direct an electronic copy of PHI be in writing signed by the individual and clearly identifies the designated person and where the copy is to be sent. Again, this is the express language from the HITECH Act that the request be clear, conspicuous, and specific. And that's why we're choosing to incorporate that in as the proposal because that's consistent with what the SIOUX court said that our rule making authority should have been more consistent with the express provisions in the HITEC Act. Next slide, please.

In response to the request for information and in other ways, we've heard stories about health information not being shared among an individual's doctors. For example, an individual that's in a car accident and has sustained traumatic injuries may be receiving multiple treatment from multiple specialists like an orthopedist, a neurologist, physical medicine and rehab but the doctors are not sharing their records and medications with one another. Presently, there is a permission for healthcare providers to disclose health information for treatment. But, importantly, it's not a requirement that providers share PHI with one another. It's just a permission. And so, in order to address instances where a patient or the patient's family wants to ensure that the healthcare providers that are involved in an individual's care are receiving all of the health records that the individual or family wants received where we created this proposal.

We're proposing to create a requirement within the right of access for a covered healthcare provider or health plan to facilitate an individual's request to direct electronic copy of PHI in an EHR to a third party designated by the individual. So, that's a mouthful. Let me break it down a little bit and you'll see how it applies. If an individual makes a clear, conspicuous, and specific request, oral or in writing, to his covered healthcare provider or health plan, the requester recipient, the blue square on the slide, to obtain an electronic copy of PHI in an EHR from one or more covered healthcare providers, and that's the disclosure, the purple octagon on the slide, the requester recipient would be required to submit the individual's request to the discloser as identified by the individual. This proposed requirement is limited to directing electronic copies of PHI in an EHR back to the requester recipient. So, as I just discussed the SIOUX decision, this is an example of an individual directing protected health information to a third party, in this case, the covered health plan or covered healthcare provider, the blue square.

It is limited to directing the covered healthcare provider to send an electronic copy of PHI in an EHR to the requester recipient, again, in line with what the HITEC Act says and what the SIOUX court says. This proposal would require that the requester recipient, the blue square, submit such access request to the discloser on behalf of the individual as soon as practicable but no later than 15 calendar days after receiving the request from the individual. And then, the discloser, in turn, the normal right of access timeframes would apply. So, it would be what we're proposing, in general, the 15 calendar days to respond to the request. So, an example is if an individual from California was involved in an automobile accident in Virginia and is being treated by a variety of specialists, orthopedist, neurologist, physical therapists in Virginia, the individual or their family could ensure that the Virginia treating doctors receive an electronic copy of the individual's records from their primary care physician in California to assist the Virginia treating physician in providing care to the individual.







The Virginia doctor would be required to forward the request within 15 days and the California doctor would be required to respond to the request within 15 days under the right of access rule. And so, this proposal is not intended to replace or frustrate the prompt transfers of protected health information that covered healthcare providers and health plans already make. Instead, this is creating a new required disclosure for covered entities but in a manner that we believe respects individuals' preferences and puts the individual in control over the disclosure of protected health information through their exercise of the right of access. Next slide, please. Fees. So, the privacy rule permits a covered entity to charge a reasonable cost based fee to fulfill a right of access request for copies of PHI. And the rule limits the allowable fees to the costs of labor for copying, supplies for creating the copy, and postage and mailing. And so, what we're proposing here, as shown on the chart, would be five categories of access requests and allowable fees.

So, the first row is no fees permitted when an individual inspects protected health information in person, including taking notes, photographs, or using other personal resources to view or capture the information. If you recall, I talked about beefing up the right to inspect earlier. The current privacy rule contains no provision permitting fees to be charged for inspecting PHI. And we believe that the covered entity does not incur labor costs for copying and is unlikely to incur costs for supplies when providing an individual with an opportunity to inspect their protected health information in person and when the individual is using their own personal resources to capture that information. And so, therefore, we're proposing to expressly provide that the covered entity may not charge a fee to an individual who is exercising the right to inspect PHI in person. The next row is no fees permitted when an individual uses an internet based method to obtain an electronic copy of PHI.

So, we believe that access through an internet based method occurs without the involvement of the covered entity workforce members. And thus, a covered entity does not incur any allowable costs or expenses. We did request comments on the cost of providing access through an internet based method, including any internet based methods described in the ONC Cures Act Final Rule. But for here, we're proposing to prohibit covered entities from charging a fee to provide access through an internet based method. While covered entities currently using patient portals and API to provide individuals and their designated third party recipients with electronic access, we propose that the term based method would apply to portals and API's as well as similar successor technologies. We do not intend the free access to apply to situations where the individual is simply using an online portal to submit a request for copies of protected health information be sent to them in a manner that would require the covered entity to incur costs for supplies, postage, or labor as well as part of the reasonable cost based fees.

So, when a doctor adds a health note about an individual to the electronic system that provides view, download, transmit capabilities for individuals, the patient shouldn't be charged for the costs associated with allowing access to the VDT system because entering individual patient record information into the system is part of the normal course of providing care and is not presumed to introduce any labor costs. The next row, reasonable cost based fees remain the same for a non-electronic copy of protected health information through a non-internet based method. So, no change here as this is the current rule when providing non-electronic. And what are we talking about? Paper. For non-electronic, we're talking about paper copies of protected health information to an individual, covered entities would remain subject to the current access fee limits. This would include only labor for copying PHI in a non-electronic form, supplies for creating the non-electronic copy and then, actual postage for the mailed copies.





The next row is access requests by an individual for an electronic copy of PHI through a non-internet based method. So, here we're proposing a reasonable cost based fee that could be charged that is limited to the cost of labor for making electronic copies of the PHI or, if applicable, preparing a summary or explanation as agreed to by the individual. We understand that such methods may include copying protected health information onto electronic media such as a disk, flash drive, and mailing it to the individual. The costs of the electronic media and the postage would not be allowed for providing electronic copies of protected health information. And why is that?

The HITECH Act at Section 13405E provides any fee that the covered entity may impose for providing the individual with a copy of such information if such copy is in electronic form shall not be greater than the entity's labor costs in responding to the request for the copy. So, given this express limitation in the HITECH Act and the decision from the SIOUX court, we're proposing to add this limitation to the HIPAA rules to limit the fees entities are permitted to charge for electronic copy of PHI in an EHR based on the plain reading of the statutory requirements. Access requests to direct an electronic copy of PHI in an EHR to a third party. So, here, again, we're talking about another aspect of the SIOUX decision. Remember, I said the court held that the reasonable cost based fee limitation in the current HIPAA rules does not apply to this right because applying the HIPAA right of access fee limitations to this type of access request, in the court's opinion, didn't go through the notice and comment period as required by the Administrative Procedures Act and it was too great of an expansion of what we were trying to do.

So, accordingly, we are now making this proposal and putting it through notice and comment in compliance with the Administrative Procedures Act. A reasonable cost based fee would be limited to the costs of labor for making electronic copies of the PHI and, again, if applicable, preparing a summary or explanation as agreed to by the individual. Under this proposal, the allowable fees would include, for example, labor involved in transferring electronic copies of protected health information from an EHR onto electronic media when requested by the individual. But it would exclude the cost of the electronic media and the labor involved in shipping or mailing the media and the cost of shipping and postage. Finally, what haven't I spoken about? What about sending paper copies of health records to a third party? As we discussed earlier, under the HITECH Act and the SIOUX decision, the right to direct protected health information to a third party is limited to protected health information in an EHR in electronic form.

So, in order to request sending paper health records to a third party, an individual or their personal representative would have to sign a valid HIPAA authorization and covered entities responding to a request based on authorization would not be subject to the access fee limitations. So, you can still send records to a third party but it's not part of the right of access. It's now an authorization. And covered entities are not required to fulfill this. So, if an individual were to send an authorization to send paper records, for instance, to their attorney, the covered entity is not required to follow it because it falls outside of the right of access request. It's just an authorization. They can fulfill it and they can charge more for it now. It's not limited by the reasonable cost based fee limitations. But they're not required to do so. And that's just the nature of how the authorization component works in relation to the right of access piece. Next slide, please.

To increase an individual's awareness of the cost of copies of protected health information and to make the access fee requirements more uniform, we're proposing required covered entities to provide advance notice of the approximate fees for copies of protected health information requested under access right and with an individual's authorization. So, individuals should know how much it's going to cost when they make an





access fee request, what it would cost if it's under the right of access. In addition, as I mentioned with the paper records, if they want to send paper records to a third party, they should know in advance how much it's going to cost to try to limit the sticker shock that sometimes occurs when they get billing invoices for several hundreds of dollars that they couldn't reasonably anticipate. We believe readily available public information about access fees would serve to promote compliance of the privacy rule because, certainly, covered entities would want to avoid posting fee schedules that show noncompliance with the HIPAA rules on their websites.

So, what we're proposing is that the covered entities would be required to post a fee schedule online and state it on the website and make the fee schedule available to individuals at the point of service upon the individual's request. And this notice must include all types of access available free of charge and fee schedules for all of the categories that we've listed, copies of health information to producible electronic and non-electronic forms or copies of PHI and EHR and then, directing it to third parties. With respect to fee schedules available at the point of service, we would expect a covered healthcare provider would make the fee schedule available on request in paper or electronic form at the point of care or at an office that is responsible for releasing medical records. And for covered healthcare providers or health plans, the point of service could include a customer service call center that handles requests for individuals or any location at which PHI is made available for individuals to inspect.

Finally, we're also proposing to require that covered entities provide an individualized estimate to an individual of the approximate fees to be charged for the requested copies of protected health information. And, again, this goes to transparency. We think it will help greater compliance and it will help the consumer. Last year, the department did some work with surprise billing and this is an **[inaudible] [01:55:45]** of that albeit limited to right of access but just limiting the surprise that sometimes befalls individuals and consumers when they're making a request and really don't know how much it's going to cost. And also, I think it will help the covered entities that sometimes have excessive flat fees beyond what's permissible. It's not a reasonable cost based fee. And so, having it posted should ensure that they're bringing themselves into compliance and, ultimately, reducing less investigations and less time being spent with OCR investigating covered entities and covered entities responding to OCR. So, hopefully, this will be beneficial for everybody.

The next slide. That was right of access. That was, hopefully, exhilarating for everybody. Next, is notice of privacy practices. So, the privacy rule requires a covered healthcare provider that has a direct treatment relationship with an individual to make a good faith effort to obtain a written acknowledgment of receipt of the provider's notice of privacy practices. And if they're not able to obtain a copy of the notice of privacy practices, they may have to document their good faith efforts. And so, we've heard anecdotally and in public comments to the 2018 RFI that this acknowledgment requirement imposes paperwork burdens that are perceived as unnecessary and that create confusion for individuals who may erroneously believe they are signing an authorization or a waiver of some kind as well as provider front office staff who, in some instances, have declined to permit an individual to receive medical care services because they would not sign a notice of privacy practices.

So, to alleviate paperwork burdens and reduce confusion for individuals and covered entities, we're proposing to eliminate the requirement for a covered healthcare provider with the direct treatment relationship to an individual to obtain a written acknowledgement of the receipt of the MBP and document





their good faith efforts. Now, to ensure that individuals are able to understand and make decisions based on the information that's contained in a notice of privacy practice, we're proposing to replace the written acknowledgement requirements with an individual right to discuss the notice of privacy practices with a person designated by the covered entity. Next slide, please. So, we're proposing to modify the content requirement of the notice of privacy practice to help improve the patient's understanding of an entity's privacy practices and their rights with respect to the PHI.

First, we're proposing to modify the required header of the notice of privacy practices to specify to individuals that the notice provides information about how to access their health information, how to file a HIPAA complaint, and the individual's right to receive a copy of the notice and to discuss the contents with a designated person. The required header would also specify whether the designated contact person is available on site. It must include a telephone number and email address so that the individual can directly reach the designated person. The header content requirements will also apply to all covered entities and not just the covered healthcare provider with the direct treatment relationship because we want to ensure there is a consistency in how notice of privacy practice's content is being presented to individuals.

We believe that providing this information at the beginning at the top of notice of privacy practices would improve patients' awareness of the privacy rule rights, what they can do if they suspect there is a privacy rule violation, and how to contact a designated person at the covered entity to ask questions or perhaps address it at a more local level. Additionally, to ensure that individuals are fully informed of their access rights, we're proposing to modify the requirement and make as a required element that the notice of privacy practice address the access right and describe how the individual can exercise the right of access to obtain a copy of the records at limited cost or, in some cases as we discussed today, free of charge and the right to direct a covered healthcare provider to transmit an electronic copy of PHI in an EHR to a third party. Again, the third party designation as allowable by the HITECH Act and SIOUX. And, again, it goes to just how important OCR reviews the HIPAA right of access.

It continues to be a large source of complaints to OCR. And so, we want to make it clear to the covered entity as well as the individual their right to access records and the covered entity's responsibility in fulfilling those requests and taking timely action within the specified timeframes. Next slide, please. We believe that more can be done to encourage healthcare providers to disclose protected health information when family members and other caregivers of individuals are attempting to assist with health related emergencies. And this can include substance use disorders, including the opioid public health emergency, serious mental illness, and other circumstances where individuals are incapacitated or otherwise unable to express their privacy preferences. We're proposing to facilitate disclosure of PHI needed to improve care for individuals experiencing these certain healthcare emergencies by changing the standard from one that is based on the professional judgment of a covered entity to one that is based on a good faith belief that disclosure would be in the best interests of the individuals.

The proposed change includes a presumption that a covered entity has complied with the good faith requirement absent evidence of bad faith. This can help improve care coordination by expanding the ability of covered entities to disclose protected health information to family members and other caregivers when they believe it's in the best interest of the individual who is unable to agree or object because of incapacity or other emergency circumstances. A good faith belief may be based on, for example, knowledge of the facts of the situation. This could include any prior expressed privacy preferences of the individual such as





those contained in an advance directive or the representations of person or persons who reasonable can be expected to have knowledge of relevant facts. The extent of disclosure of protected health information would still be limited to the level of involvement of the family member or caregiver of which the staff is aware.

So, for example, a licensed healthcare professional could draw on their experience to make a good faith determination that's in the best interests of a young adult patient who has overdosed on opioids, disclose information to a parent who has been involved in the patient's treatment and who the young adult would expect based on their relationship to participate in or be involved in the patient's recovery from the overdose, or front desk staff at a doctor's office who has regularly seen a family member accompany an adult patient to appointments could disclose information about upcoming appointments when the patient is not present based on the staff's knowledge that the person's involvement and the good faith belief about the patient's best interest. So, again, it's limited to the level of involvement of the family member or caregiver. That's the existing law and we're not looking to change that. The stories we've heard, particularly, with the opioid epidemic where family members find out that their loved one was in the thralls of opioid emergency and they found out too late.

The patient had passed away and there is all sorts of evidence that family involvement helps in achieving better healthcare outcomes. And so, we think by moving the standard from professional judgment to one of good faith, good faith is perhaps a little more easily understood term. And it still puts the discretion, the decision making in the hands of the healthcare provider, not the bureaucrats in Washington, certainly, not me but with the healthcare provider for when they think it's in the best interest. Next slide, please. We're proposing here to expand the ability of covered entities to disclose protected health information to avert a threat to health or safety when harm is serious and reasonably foreseeable, instead of the current standard, which requires serious and imminent. So, replacing imminent with reasonably foreseeable. This proposed standard is expected to improve the ability of covered entities to make timely disclosures to prevent harm. The reasonable person standard involves consideration of whether a similarly situated covered entity could believe serious harm is reasonably likely to occur.

And it doesn't require a determination that a majority of covered entities could have such a belief. And so, we're seeking to prevent situations where covered entities could decline to make disclosures or protected health information that they believe are needed to prevent harm or lessen the threat of harm due to concerns about their inability to determine precisely how imminent the threat of the harm may be and the fear that they could incur a HIPAA penalty for an impermissible disclosure of protected health information. So, this proposal modification would permit covered entities to disclose PHI without having to determine whether the threat or harm is imminent, which may not always be possible in some cases. Instead, they may determine whether it is reasonably foreseeable that the threat and harm might occur. So, for example, a healthcare provider could timely notify a family member that an individual is at risk of suicide, even if the provider cannot predict that a suicide attempt is likely to occur imminently.

An Emergency Room doctor who sees an elderly patient with COVID-19 could contact the patient's nursing home to alert them of the potential exposure of other residents and staff based on the serious and reasonable foreseeable threat of infection with COVID-19 in a vulnerable population without delay caused by the need to assess whether the threat is sufficiently imminent to permit the disclosure. Next slide, please. We're proposing to modify the definition of healthcare operations to clarify that the term includes care and





coordination for individuals. So, the current definition is sometimes read to cover only population based activities with the result that some entities believe that health plans are not permitted to use and expose protected health information to coordinate care for individuals. The privacy rule expressly permits certain uses and disclosures of PHI without individual's authorization for treatment and certain healthcare operations. And the definitions of both treatment and healthcare operations include some care coordination and case management activities.

In fact, the preamble to the 2000 Privacy Rule states that certain activities may be considered either healthcare operations or treatment, depending on whether population wide or patient specific activities occur. And if patient specific, whether the individualized communication with the patient occurs on behalf of a healthcare provider or a health plan. So, what does that mean? A telephone call by a nurse in a doctor's office to a patient to discuss follow up care is a treatment activity. The same activity performed by a nurse working for a health plan is not treatment because health plans don't provide treatment but it would be a healthcare operation. So, the current privacy rule contemplates that health plans would, as part of healthcare operations, conduct care coordination and case management activities, not only at the population level across multiple enrolled individuals but also at the individual levels for a patient including providing for their care across the different settings.

Despite this guidance, we've heard stories that this hasn't been well understood and it's not been applied at the individual level. So, we're proposing to clarify expressly in the definition of healthcare operations to encompass all care coordination and case management by health plans whether at the individual level or population based. This would provide clarity to covered entities and individuals regarding which privacy rule standard applies to which care coordination and case management activity and thereby facilitate those beneficial activities. This recognition that health plans conduct individual level care coordination and case management also will support the proposal that we're going to talk about next here to modify the minimum necessary standard to promote uses and disclosures for care coordination and case management for individuals. Next slide, please.

Covered entities, generally, are required to limit their use, disclosure, or request for PHI only to the minimum necessary to meet the purpose of the use disclosure request. And the minimum necessary requirements are designed to be sufficiently flexible to accommodate the various circumstances that the covered entity encounters and to avoid creating unnecessary barriers to information sharing. Currently, disclosures of PHI by or to or used by covered healthcare providers for care coordination or case management for individuals are considered treatment disclosures or uses, which are accepted from the minimum necessary standard. And the exception for treatment was intended to avoid creating a barrier or delay in providing patient care. That makes sense. However, case management and care coordination is also listed under the definition of healthcare operations. And when case management or care coordination is considered a healthcare operations activity under the current rule, it is not accepted from the minimum necessary standard.

Because health plans, generally, don't perform treatment functions, any care coordination or case management activity conducted by a health plan is, generally, considered to be a healthcare operation subject to the minimum necessary standard. So, the current imposes greater restrictions on disclosures to and requests by health plans than on disclosures to and requests by covered healthcare providers. And so, we're proposing to add an express exception to the minimum necessary standard for disclosures to or requests by a health plan or current healthcare providers for care coordination and case management for







individuals. The exception would only apply to those care coordination case management activities that are at the individual level. And covered entities would still be required to meet the minimum necessary standard in other instances as outlined by the privacy rule. So, this is really in conjunction with the previous slide and what we're intending to do with the definition for health plans and just facilitating the greater coordination of health information.

And we've heard stories from the health plans as well as individuals and frustration with the barriers and the delays that are caused by making minimum necessary determinations. So, that's why this is being proposed and seeking comment on it. Next slide, please.

**Denise Webb**

Tim, just a time check. We have just a few more minutes. We'd like to leave some time for questions if possible.

**Tim Noonan**

Yeah. I'm winding up. We're hitting the lightening round so this should be pretty quick. Thanks. Care coordination and disclosure to third parties. The privacy rule permits a covered entity to use or disclosure PHI for treatment, payment, healthcare operations. Treatment is defined to include the coordination or management of healthcare by healthcare provider with a third party. So, the current definition of treatment already contemplates disclosing PHI from a healthcare provider for the coordination or management of healthcare by the healthcare provider with a third party. We've issued guidance on this. However, we continue to hear stories about that not being well understood. So, this is an example of us seeking to elevate what's contained in our guidance and putting it expressly into regulatory text to make it clear and give covered entities greater clarity on availability and use of this permission.

And so, some examples are a covered entity can disclose the PHI of a senior individual experiencing chronic illness to senior center attended by the individual so they can check on his health periodically and to ask the senior center to give reminders about effective disease self-management. Or a doctor can disclose PHI of a patient to a community counseling program and to support and coordinate care. Next slide. Health communication relay services. This facilitates telephone calls between individuals who are deaf, hard of hearing, or deaf/blind and have a speech disability and others. It's a federally mandated service that requires federally regulated common carriers to provide individuals in the general public with this service. And they use a communication assistant who facilitates transliterating conversations sometimes interpreting through USA and ASL. We've had a longstanding FAQ that provides covered entity's permitted to disclose an individual's PHI to a TRS communications assistant when communicating with the individual without the need of a business associate agreement with the TRS provider.

However, changes in the advancement of the technology we recognize is done so seamlessly, the individual may not be aware that a TRS operator is being used or there may be instances where a workforce member needs the service in which the individual is not involved at all. And so, we're proposing to expressly permit covered entity's to disclose PHI to TRS communications assistants to conduct covered functions and that a business associate agreement would not be required. Next slide.

This last section involves express permission that allows the use and disclosure of protected health information for armed services personnel. And it's recognizing that US Public Health Service Commission





Corps and the National Oceanic Atmospheric Administration Commission Corps, respectively, are in similar instances where decisions need to be made about medical qualifications to perform their responsibilities and being medically ready for deployment. And so, we're proposing to expand the armed forces' permission to facilitate coordinated care to these two branches as well so that they enjoy the same permission and can perform their jobs without an unreasonable delay. Next slide. Here are some resources I referenced at the beginning. So, the comment period runs to May 6. We have a web page where you can access the NPRM and additional information. We also have a fact sheet that provides specific examples to each of the sections that I talked about today. And then, there is a site at regulations.gov to access the NPRM and provide comments.

Next slide. This is just contact information for OCR. Next slide. And these are ways to connect with us and get information via our list serve, Twitter accounts, or access our general web pages to find out additional information. All right. I did it in less than an hour. I wasn't sure that could done.

**Denise Webb**

Great job, Tim.

**Aaron Miri**

Well done.

**Denise Webb**

That was a lot of information to absorb. My head is spinning a little bit. I'm thinking there are a lot of things I'm trying to figure out. So, let's go ahead and see if we have some questions or comments. And it looks like we have Jim Jirjis in the cue presently if you want to go ahead, Jim.

**Jim Jirjis**

Hey, Jim Jirjis. A quick question for you. Has the OCR considered additional measures that could be adopted to ensure the privacy and security of health information as it travels to third parties, such as personal health apps, outside of HIPAA protections? Or does OCR think they're limited by the 21<sup>st</sup> Century Cures? Because I'm sure it's no news to you that there is a lot of angst about ne'er-do-wells that might miss use that info.

**Tim Noonan**

Oh, yeah. There is always somebody that's going to ruin a good thing. So, our position is we're limited by the express jurisdictions set forth in HIPAA and the HIPAA rules. So, covered entity and business associate. And so, the health apps that direct consumers, something that's offered by Amazon or Apple directly to the consumer, they're not a business associate relationship with the covered entity, it's our view that we don't have express authority over those types of entities. And there was a lot of attention last year in congress on this issue. So, I do think it's something that we're going to see a legislative solution for. But in terms of OCR's jurisdictional authority, we're just limited. We just don't have direct authority over those third parties. Now, the FTC has some limited jurisdiction and that could be an interesting conversation to have with them. Their jurisdiction is a bit limited. It's when someone makes a deceptive, unfair statement, it's not true, it's not accurate and they have much more general, I believe, privacy and security language.







It, certainly, isn't as express as the HIPAA security rules. And we work with the FTC to identify instances in the past where we don't have jurisdiction but it might be something that they can pick up. But our view is that we would need greater legislative authority before being able to directly address the applications that are direct to consumer and don't have any relationship with the covered entity.

**Denise Webb**

Thank you, Tim. We'll go to John Kansky next and then, Aaron.

**John Kansky**

Hi, thanks. I've got a page worth of questions and comments here but I'll boil it down to just one comment, which I think falls under the category of doesn't go without saying. So, I can go all the way back to the formation of TEFCA and how that's architected. And the HIPAA requirements in here were clearly making sure that we enable a channel for interoperability that flows through the patient through a PHI enabling patients to control the flow of their information and get it when necessary from Point A to Point B. I just want to make sure that absolutely let's pave that channel and let's continue to advance and enhance the existing channel, the ecosystem that exists that is not controlled by the patient. That's not a bad thing. We need to enable the patient as a means of moving their information to support interoperability. And we need to support the system, I guess I would call it, to continue to advance and make that a better way to enable interoperability. We need to do both. Thank you.

**Denise Webb**

Thank you, John. Aaron?

**Aaron Miri**

Tim, thank you very much for the presentation. I appreciate it. And I can hold a lot of my questions and comments and respond to the NPRM formally. But generally speaking, I have a request and then, I have a question for you. So, the request would be is it possible for OCR to put out a crosswalk that helps the community understand the differences between information blocking and some of the times and some of the things that are required there and what this is requiring? Most importantly, around the 15 day statutes and those kinds of things that are being proposed. And I realize these are all proposals so nothing is codified. But it would help folks, I think, understand the two, especially since in the provider community, we've been very focused on to make sure we confirm to what final rule is related to information blocking and so forth and so on. So, that's just a request. And my question for you would be I noticed a lot of focus in the NPRM regarding covered entities.

And I can appreciate that. But a lot of times, a lot of the immediate actions are dictated by a vendor or some sort of certified health IT vendor that we utilize. And a lot of those vendors are conforming to information blocking deadlines and timelines, which does not allow for expedited release of information just because of those timelines and the way that USCDI Version 1 was written. And elements are not yet adopted as final. So, my question to you would be is there going to be any consideration for certified health IT vendors that intersect with the CE's and the responsibility there to conform to these types of timelines?

**Tim Noonan**

Great question and great thought. Once we do have something that's finalized, I do want to create more guidance and make things clearer. And we've got a great relationship with ONC. So, I think putting together





a final document that incorporates information blocking and right of access and, hopefully, making it easily understood so folks can talk about it around the dinner table would be of great benefit. So, great suggestion. I agree. With respect to your question, it's a little challenging. So, again, our authority is a bit limited. We don't have direct authority over business associates with respect to right of access. Our authority is limited to the covered entity. And so, that's why so much time is spent talking about the covered entity. It's the covered entity's obligation to ensure that there is timely action on a right of access request. And the fact of the matter is a lot of them do use business associates. And the failure could be the business associates mechanisms or some of the technological challenges that are occurring.

I will say we receive 28,000 complaints a year. Right of access is a huge component of it. We resolve probably 98% of our cases with technical assistance where we remind a covered entity or, where applicable, a business associate of what the HIPAA rules require. And the cases get elevated for investigation and potentially as an enforcement action when, after receiving our technical assistance, the matter isn't resolves. So, the individual files another complaint. Because we notify them at the same time. We've provided the covered entity with technical assistance on January 7 and we invite the complainant to refile if the matter isn't resolved. And so, after being out on notice that there is a problem with the right of access process, the individual is waiting on their records and sometimes, when we get the complaint, it's six months' old. I've been waiting on my records for six months so you're not even close to the timeframe to take action.

And so, to me, once you get notification of that, it ought to be resolved right away. So, my point is we do exercise great discretion. We recognize there can be some challenges. And our immediate instinct isn't to jump to enforcement and start chasing somebody down with a monetary settlement or pursuing a civil money penalty. We provide technical assistance, as I was saying, 98% of the cases that we provide and, particularly, when there is an ongoing conversation. If the covered entity lets us know what's going on and what's being done to address the situation and can give us some comfort, some assurance that it's going to be fixed and individuals' rights are not going to be impeded, those are all factors that mitigate against us proceeding to enforcement. So, those are my thoughts on that. I recognize the challenges with some of the electronical implementation requirements but, again, we try to communicate directly with the covered entity because that's where our jurisdiction is and clear obligation.

And we do exercise enforcement discretion so we're not unfairly going after somebody that has legitimate challenges. And we took that into account with the COVID-19 public health emergency. That, certainly, created additional challenges to try to fulfill some of these rights in a timely manner.

**Aaron Miri**

Thank you.

**Denise Webb**

So, for the committee, we are at time. And I would like to thank you, Tim. I don't imagine you can stay on until the end because I was going to suggest we have a couple of hands still up from Les and Cynthia. But I suppose you're stepping away at this point, right?

**Tim Noonan**





Regrettably, as is often the booked, I'm double booked or triple parked. So, I do have a 1:00 that I have to

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**Denise Webb**

Well, we really thank you for your time. You really provided us a lot of detail to think about. And I want to just remind all of my colleagues on the committee that while we are not making any recommendations or providing any input to OCR since that's not in our scope, each of us as individuals can put in public comments. And we have until May 6 to do that. So, I would encourage everybody to do that. And if Les and Cynthia wanted to put something in the chat, we can at least pass that over to Tim. So, thank you, Tim, for all of this valuable information that can help us all kind of think about what sort of comments we want to provide before the public deadline.

**Tim Noonan**

Great. It was great speaking with all of you. Thank you for the invitation. And I look forward to speaking again sometime. Thanks, everybody.

**Denise Webb**

All right. So, we are going to transition to a short break. And if everyone can return at five after the hour that would be great.

**Aaron Miri**

That's about seven minutes. Yeah.

**Denise Webb**

All right.

**Break (02:25:20)**

**Operator**

All lines are now bridged.

**Interoperability Standards Priorities (ISP) Task Force Update (02:32:34)**

**Mike Berry**

Great, thank you. Welcome back, everyone, to the April 2021 HITAC meeting. We just finished a very short break. And I hope everyone feels refreshed and ready for the second half of our meeting today. I will turn it over to Aaron and Denise to welcome our next presenters.

**Aaron Miri**

All right. Yes. That was a very thought invoking discussion so I hope everybody got a good little break in there. But now, we are ready to go to our next exciting topic here, which is our interoperability standards priorities task force with Arien and David.

**Arien Malec**

All right. Thank you. And we have some exciting updates today for the ISP task force. Next slide. So, these are the attendees or members of the task force. We've got a pretty diverse group that represents multiple





perspectives on standards evolution. Next slide. Our goal is chartered by the Cures Act to periodically assess the status of standards and look for ways to evolve standards implementations specifications, etc. Next slide. And our goal is to make sure that the ISA includes interoperability needs related to standards evolution to drive the next turn of the crank for standards evolution. Next slide. So, we have evaluated a number of potential topic areas. I'll just briefly summarize them here. Clinical administrative data and standards harmonization burden reductions is, basically, taking the output of the ICAD task force's input into this task force, data sharing between federal and commercial healthcare entities, primarily, looking at a broad range of topics, including veterans and service members receiving care in the community, etc.

Vaccine and immunization registry reporting so let's meet the lessons of COVID in this important area. Health equity standards, in particular, looking at SDOH. And also, improved capture of some of the base data that's associated with evaluating care for health equity. Broader use of EHR source data for real world evidence compared to effectiveness or looking at some of the work that the UK did in response to COVID with the recovery trials. We've got substantial amount of data flowing through EHR's that I think are arguably behind the UK in terms of using that infrastructure for evaluating questions and getting to real world evidence that informs care. Public health situational awareness. So, evaluating in the context of a natural disaster or public health emergency, healthcare system readiness, ED capacity. Basically, looking at capacity constraints in a region. Next slide. So, syndromic surveillance looking at how, again, the system responded in early and emerging parts of COVID-19 to syndromic surveillance and assessing the status of disease outbreaks and also assessing the status of control.

Care plans and chronic disease burden management. So, ensuring that individuals have access to their plan of care and that their interoperable standards were taking plan of care such as discharge instructions for longitudinal plan of care to the patient, to the individual, accessed using the tools of their choice. Adverse event reporting. So, making sure that we have an overlap an interoperability, imagine that, between EHR source clinical data and the source of adverse event reporting that are intake into FDA using more of the clinical trials reports. So, as an example, clinical trials reporting using major terminology, which is not used in EHR's. So, how do we solve for the impotence in mismatch there? Patient device linking. So, in particular, how do we use mobile devices as an individual controlled token for identity management? And then, also how do we associate wearables and other medical devices with the individual? So, some of the basic work here is using the EDI and then, on into more advanced topics.

Contact and exposure notification. So, contact tracing and exposure notification. Two different topics. Contract tracing, how do we better support the public health response system with data for contact tracing? And then, exposure notification. How do we use mobile tools and interoperate with testing and other sorts of infrastructure of facilities to make sure that we drive better exposure notification for public health and for individuals? And then, we decided to table vaccine credentials given other work that's going on with this topic. Next slide. We put all of this into a prioritization framework really making sure that we were looking at overall ONC priority. So, looking at attributes, including COVID-19 response, health equity, 21<sup>st</sup> Century Cures enablement, and the prior ONC roadmap, prior to 21<sup>st</sup> Century Cures and COVID time ONC roadmap. Potential impact of the work. So, some of this work is foundational in the sense that it unlocks a number of interoperability areas.

Some of these areas are general purpose in the sense that they can be used in multiple use cases. And some of them solve very specific use cases. Availability and applicable policy levers. So, in some cases,





you may have great standards but weak policy levers or policy levers that require more coordination versus less coordination. So, going from well defined, single point policy levers. So, for example, EHR certification would be an example of a well-defined, single point of policy lever to areas where new policies or regulations are needed or significant coordination is required between multiple actors. So, for example, if we need to line up states, localities, federal government, multiple federal actors that would be a harder set of policy levers. And then, current burden on target audience looking at both settings of care as well as the individuals. And in some cases, the job may be getting done appropriately and the burden is low for physicians and for patients.

In other cases, the job isn't being done. The burden is low for physicians in other settings of care but the burden is high for patients. And in other cases, there is substantial work that's required by all of the actors with high burden. So, ranking that from low to high. And then, we used a prioritization scoring methodology that overweighs high versus low. So, it sort of creates separation. So, we arbitrarily used a 9-3-1 scale, which is a pretty typical way of driving separation here. We are prepared to do more fancy things like waiting but we ended up getting reasonably good separation just using this overall framework. Next slide. The areas cluster into a top set, which is health equity standards, real world compared to [inaudible] [02:40:55] and recovery, EHR data use standards as our top group.

And then, a group of four or maybe five if you include syndromic surveillance around care plans, vaccine immunization, registry reporting, data sharing between federal and commercial healthcare entities, and clinical administrative data burden reduction. And then, a cluster at the bottom of areas for various reasons had overall lower prioritization. And so, our proposal and the work that we're already doing is to focus our work on the first two projects looking at health equity and real world and comparative effectiveness data use. And then, work on the next group, care planning, vaccine immunization, registry reporting, data sharing between federal and commercial actors, and clinical administrative data standards and burden reduction. Given Micky's announcement earlier today on some of the task force work for public health, we probably should work with ONC to look at the overall prioritization of the public health actions relative to some of the other areas.

It may be better for us to focus in digging ground that is not already being dug. But, again, we're happy to continue the work in this area. This is how the overall prioritization shook out. And I'm happy to take, at the appropriate time, comments from the committee in terms of the prioritization framework or any surprise that this creates. But we're going to turn it over to David who has been doing most of the work in lining up our speakers and experts to provide testimony. So, David, over to you.

### **David McCallie**

Thanks, Arien. I will make one comment on the prioritization work. The voting for the priorities that you saw there on that slide were taken before we had any specific input. So, I would take it as a preliminary priority. My guess is that as we gain expert input and understand the opportunities in more detail, we may want to come back and re-swivel our priorities because I think at the beginning, some of these areas the task members were not very familiar with. So, look at it as our guide to figure out what we should start focusing on that we may revisit it. Next slide. So, what we have been doing is scheduling at least one and, in some cases two, outside experts to come address our regular Thursday meetings and then, spend the rest of the meeting time questioning the experts and discussing the material that was brought to us. So, I'll give you a little bit of the status report on how far we are working through our issues. Our first expert was a group from





Audacious Inquiry talking about the Saner Implementation Guide that is being proposed to address the need for real time public health situational awareness.

Saner is currently being piloted at a couple of HIE's and with a couple of hospitals. And we were very impressed that they were thinking about this the right way. They want to prove that it works in the real world before advancing it too far. The gist of what they proposed to do is use FHIR and FHIR API's to allow a query to be sent to a critical resource and get unattended feedback about the current status of that resource and many other things. But that would be the essence of it. So, that's No. 1. It was our first session. The next session, we had Bob Dieterle from Project Gravity give us a detailed presentation on the HL7 project that is, essentially, focused on defining improved standards for capture of SDOH. And we had asked about race, ethnicity, and gender but they have decided to defer that to the USCDI work and focus really on social determinants. We got a detailed presentation on this from Bob. It's impressive work. I think the whole task force was impressed with the scope and depth and thoughtfulness of the SDOH work.

So, I think we'll come back and put considerably more energy into that. The schedule that we have for tomorrow, our next meeting, is addressing the better leveraging of EHR data. We have what will hopefully be a great panel. We have George Hripcsak from Columbia talking about OHDSI and their work on mapping OMOP to FHIR. Then, we have Russ Waitman from University of Missouri taking about the PCORNET and his experiences in aggregating clinical data for research. And then, finally, Chris Chute and Melissa Haendel will be talking about the N3C massive COVID database that they are assembling to answer some of these questions about the proper way to manage COVID. And we'll use those discussions to draw from that. We have asked them to tell us what they think could be done to make their work easier or faster or closer to real time, scale up, scale out. Then, we're still working on the data sharing across federal and non-federal boundaries.

Frankly, a lot of progress has been made since we first thought about this space. And it may turn out that it's less of a priority than we realized. The good news is that progress has been made. The bad news is there is still some to do. But it's pretty arcane. We have a session coming up on the 29<sup>th</sup> to focus on CDC modernization, which we hope will rope together a number of the public health data flow concerns that we've raised in our priority list. You saw several things about things like syndromic surveillance and vaccine registry, data flow, and such. We're going to try to bundle all of that into a single session. And as Arien mentioned, the fact that Micky has announced this morning that creation of a specific task force to focus on public health data flows, we were hoping to get ONC's guidance on whether we should defer discussions on this topic to avoid conflict with the new task force to be determined.

And then, finally, on the list of things that we are currently scheduled is we have, I believe, this has now been set for the 29<sup>th</sup>, a presentation from the ICAD task force that Arien mentioned a few minutes ago on what recommendations they generated regarding better synchronization between clinical and administrative data with burden reduction. We will schedule some other domains as we get further into our priority list but this is where we stand at the moment. Arien, do you want to add anything to that?

**Arien Malec**

No. I think that was a fantastic overview. And I think we have a pretty tight timeline. So, we're looking to get as much input as possible and then, turn around to writing recommendations for the committee's consideration.





**David McCallie**

One more comment. I did include in an appendix a couple of slides from SANER and a couple of slides from Gravity and a couple of slides that go into our initial list of potential priority areas in more detail if anybody wants to dive in. But we figured that could be on your own time instead of taking up the meeting time.

**Aaron Miri**

Excellent. David and Arien, thank you very much. Great job with the presentation. So, we'll go into questions now from the HITAC. In the cue, we have Steven Lane.

**Steven Lane**

Thank you. I just wanted to tell you, David and Arien, how much I miss you guys and the ISP task force. I can see you are doing tremendous work and the detail of analytics that really need to be done to move this work forward. Clearly, the work of the task force is foundational to our ability to move interoperability forward. It has to be based on a really deep understanding of the standards and the data that we're sharing. So, I just wanted to say hats off and thank you so much for this great presentation.

**Arien Malec**

Thank you, Steven.

**David McCallie**

The feeling is mutual, Steven. If you want to come back and just be a volunteer, we'd be happy to have you.

**Aaron Miri**

All right. Next in the cue is James from the DOD.

**James Ellzy**

Yes. I just wanted to let everybody know that if you do need some names for the DOD VA interaction, I'm happy to provide those.

**Arien Malec**

Thank you. That would be helpful.

**Aaron Miri**

Excellent. Any other questions or items from the HITAC? I don't see any in the comments or chat section here. So, I think everybody was pretty impressed with you guys' presentation. So, we really thank you for that and great work. And we look forward to seeing continued work there. With that, I know we can get a couple minutes back of time here. Let me transition over to Mike. Actually, Denise, I read ahead in the agenda. My bad. It's all yours.

**Denise Webb**







Oh, no. That's all right. It looks like we're way ahead of time here. So, our next topic is public health data systems. And Micky is going to speak to us about that and what he has in store for us as a committee. And so, if Micky is available, let's see. I think he is. There you are, Micky. We welcome you back at the podium.

## Public Health Data Systems (02:52:08)

### Micky Tripathi

I've been here. Great. Thank you. Thanks, everyone. And thanks for the great presentation. I was able to see David and Arien and so I really appreciate all of the hard work there. And we're happy to work with you figuring out the priorities as it relates to this specific task force. So, the public health data systems work that we're doing is part of an executive order that is, specifically, focused on the evaluation of public health data systems looking at the systems as they exist today, what we have learned from the pandemic experience, and what we continue to learn and then, recommendations for the future. And it's related, specifically, to public health data. It's ensuring a data driven response to high consequence public health threats, I think, is the name of the executive order. And then, there is a public health data systems portion of that. And that's the portion that ONC is co-leading with CDC. I have the privilege of co-chairing that with Dan Jernigan from the CDC.

And as a part of that work that's there, the work group is up and running and underway. And we want to use various vehicles to get industry expertise and input into the process. And so, the HITAC is one obvious place that we wanted to go to be able to get people to be able to help provide input from the field and with all of your experience and expertise, some of the key questions that we're going to be addressing. The CDC will also be engaging some public health organizations as well in parallel. So, we're trying to do as much as we can to get as much public input and public feedback and expertise into this process as possible. So, why don't we go to the next slide, Mike? So, the overarching charge here, as I said, is to inform HHS's responses to President Biden's executive order. There it is. Ensuring a data driven response to COVID-19 and future high consequence public health threats. I forgot the COVID-19 apart. Sorry.

But it's very much focused, as I said, on what did we learn today but also with an eye toward the future. And so, the specific charge that we have is to identify and prioritize policy and technical gaps associated with the effectiveness of interoperability and connectivity of information systems relative to public health and to focus on a variety of things. Surveillance systems, infrastructure improvements, health equity, clinical engagement, long term services and support systems, research, and empowering individuals, and identifying characteristics of an optimal future state for information systems relative to public health and their use. And I know that sounds like a huge charge. But with lots of these charges that we present to the HITAC, we'll have a set of more detailed questions that will at least provide some starting point thoughts on some of the concepts that we are thinking about underneath this. And, again, just to provide a little bit of guidance. So, that will be upcoming as further guidance to the task force.

And the importance of this, as I said, is really input to this ONC/CDC work group that's working on this. And I think the input of the HITAC task force will be invaluable in being able to provide all of your expertise and experience from everything that you know, both from being in healthcare as well as from the current experience that we're going through with the pandemic. So, let's go to the next slide, Mike. I think there is just one more slide if I'm not mistaken. So, any questions from the HITAC members? I can answer any general questions right now. There will be more forthcoming. As a task force, it will be HITAC members as well as we can draw from other experts who are not HITAC members in keeping with the recommendations





of our task force. So, we'll have all of those considerations as we think about the composition of the group. And did we have a slide on the timelines? I forget, Mike.

**Denise Webb**

That's what I was just going to ask, Micky, if you could share a little more with the committee on the timeframe.

**Clem McDonald**

Micky, I've got a couple of questions if you did open for that. This is Clem. So, there are two questions. One of them is the nature of how they responded over the many years, it has been a very cubbyhole organization. And they have to recognize that and try to maybe break it down if they're going to be successful in the more generic activities and a more efficient way of connecting their stuff. I don't know if that's going to be offensive or not. And the second thing is there's a real problem with the separation. And I'm not trying to be anti-constitutional but there is a problem with the separation of state and national public health. The data can't flow smoothly. They don't [inaudible] [02:57:36] identifiers and all kinds of complex things, which should really be reviewed as part of this effort before they spend a lot of money making it just stay like it was. That's all.

**Micky Tripathi**

I think those are great comments, Clem. And I think as a part of those further set of directional guidance, we have a bunch of questions that are related to a number of those issues that you talked about. And in general, I think the way Dan and I have been thinking about this is how do we think about what you may characterize as public health data systems today, which just in the name has a certain siloization just embedded in that name. And how do we think about that moving toward a public health ecosystem that thinks about it being a part of an ecosystem rather than just being something that's isolated and siloed. And the jurisdictional issues that you're pointing to, I think you're absolutely right. There is a technical and architecture component to this but there is also a policy architecture component to this as well that's at least as important in defining the shape and capabilities of our nationwide public health system.

**Clem McDonald**

Okay. Thank you.

**Denise Webb**

All right. So, if anyone has questions, please raise your hand. And I do see that Aaron does have his hand up.

**Aaron Miri**

Yeah, absolutely. So, Micky, thank you very much. This is such an important charge and we really appreciate you coming to the HITAC and asking for our feedback and participation in the committee. I was just curious that I understand the urgency and the nature of it. Obviously, I don't think we have a timeline slide up. But probably something in the relatively near future to turn around. Is the charge focused primarily on boots on the ground and how do we activate the public health infrastructure, syndromic surveillance infrastructure, to help prevent a COVID-19 or other type outbreak? Or can we roll them into research and other activities that help augment? As you know, a lot of that data is either case data from contact tracing or vaccination data, immunization data could feed future efforts of vaccination in coming up with new





therapies and new drugs and others. So, I'm just curious where the boundary is and if this is really meant to be immediate boots on the ground or something also to, I guess, mitigate future events.

**Micky Tripathi**

That's a great question. So, let me just answer the question first on the timeline. To your point, there is some urgency around this because we are responding to an executive order. And so, the timeline here is that we want to have a public hearing on May 13, I think, as we know and as I talked about before with the HITAC. We'd like to get the task force meetings as soon as possible. Realistically, if you think about the lead time of identifying members, vetting all of that, we're probably looking at by the end of the month if we could get the task force launched. And we're hoping to get final recommendations by mid-July. And that will help to be the input to the work group. So, I think anyone who is considering volunteering for this, you just need to take into account your ability to meet that kind of timeline where I expect there would be weekly meetings starting from the launch of it all the way through mid-July with a fair amount of work in between. But I know that many HITAC members have, thankfully, been very eager to dive into public health.

And so, we really appreciate that and feel very lucky that we can tap into all of your enthusiasm and your expertise and experience on this. On your other question, Aaron, it is broader. I think that one of the challenges that we have here is how can we be as broad as possible but be practical in terms of a concrete set of recommendations in this time period. So, we don't really have that many constraints on it per se. And as you'll see from the more detailed questions, I think Dan and I are trying to cast the net as widely as possible. But just, again, trying to recognize that we have to be practical as well. But it is very much future looking. It's about what are we experiencing today but now do we think about it going forward. And how do we test the definition of public health? I think we're very open to that, too, as well. We conceived of it in a certain way but we shouldn't be constrained by that preconceived notion of how we thought about public health up until now.

**Aaron Miri**

That's great. Thank you.

**Denise Webb**

So, I don't see any hands up. Any other questions or is anybody on the phone that can't raise their hand?

**Aaron Miri**

Denise, I'm going to guess they're all writing an email to Mike saying they want to participate. So, that's probably why they're not raising hands.

**Mike Berry**

I, actually, had several. So, just to back you up there, Aaron.

**Denise Webb**

Oh, good. Eager committee members. That's great. All right. If there are not any other questions, where are we on our timeline, Mike? We're ahead of time. So, yes, we are. Thank you, Micky, for telling us about our new charge. And we're all enthusiastic about that. It's very important. Are we able to go to public comment early? Or before we do that, is there any other discussion or comments that the committee wants to bring out?





**Aaron Miri**

That's what I was going to propose. Denise, maybe we can take five minutes and let folks ask questions about the day, comments, further questions. I know there were a few folks that were in cue for the OCR discussion that didn't get a chance because we ran out of time. Maybe they want to state that for the record or elaborate on it so we can follow up. So, that's what I would offer.

**Denise Webb**

That might be helpful because I do know Les had put a comment in the chat. I don't know, Les, if you want to share with the group what you were pondering about in terms of the OCR rule.

**Les Lenert**

Yes. We talked about two of these issues already. If there are any changes that are contemplated for public health operations and what key changes might mean for real world evidence coming into play in healthcare because the HIPAA rule is at the center of access to data for real world evidence? And then, also the issues of data for public health operations continue to be of profound significance to our ability to manage the pandemic efforts. And I wanted to hear if any of the proposed changes impacted those.

**Denise Webb**

And also, that might be a fair topic for the new task force as well in terms of the policy side for public health and data access.

**Aaron Miri**

Yeah. I would agree. I would totally agree. And that's going to be an interesting intersection point between this NPRM being finalized here in a couple of weeks and then, that new task force and what does that mean going forward. I think there is a lot of evidence in the news of various public health agencies only being able to communicate in fax machine, which is just arcane but it is what it is. So, what does that mean when it's electronic only, potentially, for right of access.

**Les Lenert**

We had some discussions back in May about the interoperability issues related to HIE's and data from vaccination registries and for test results central registries for regions. And the regulations need to be able to support the rapid dissemination of both vaccination status and test results through HIE's. And we also talked a little bit about whether there would be any advantages in an emergent situation removing any remaining barriers, if there are any, for research based on HIPAA. So, I think that we had some great discussions on this back in May and June. It would be wonderful to pull those back into this committee. But I'm hoping also some of the NPRM addresses the issues that we raised back in May and would allow us to move forward.

**Denise Webb**

Well, hopefully, too, Les, you'll put forth through the public comments your comments as well. That would be great for all of us, actually, to do that.

**Aaron Miri**





I think on the same lens, real quick, Denise, I would also say to add to that the signature requirement that was mentioned. A lot of times, especially in the research world, that's lost upon what the definition of electronically and what an electronic signature is and what's acceptable. Can you use DocuSign? Do you have to use some other format? Do you have to use a topaz pad? There is varying understanding of that. So, I hope in the final rule that there is clarity on exactly what constitutes an electronic signature as acceptable because it really does depend on who you ask and how you ask it and what time of day it is and what the position of the moon is in the sky for you to get a straight answer. So, those things need clarity.

**Denise Webb**

And state law, certainly, comes into play as well there.

**Aaron Miri**

That's exactly right. Yes, exactly.

**Denise Webb**

So, I do note Cynthia had had her hand up. Cynthia, did you want to share what your thoughts were on that presentation from Tim?

**Cynthia Fisher**

For the presentation from the Office of Civil Rights on HIPAA, there are two things. One is the 15 day turnaround. One could understand for the paper form. But now that we are going to be electronic health digital form, which is real time, and I think Carolyn made a comment as well, would support that patients would be able to have readily available, same day access. And in fact, one could imagine, just like any other industry or in our economy that once it's in digital, it's immediate in real time. So, if a patient does want to request into their personal health information mobile app or into another third party app that it would be immediate. That it could happen even before they left the hospital or a physician's office one could imagine. And so, I'm thinking since we're going to digital, it would be wise to looking at living in the digital world rather than 15 days because people go across facilities after they have a broken ankle. They may go to a surgeon. That's another hospital or in another place in a different office.

And just having all of that access for them and their care team is huge. And then, secondly, we've been remiss to also include that we're adding USCDI billing information. And there are two things problematic right now. We know we have the price transparency rules, which you all know is near and dear to my heart for patient rights having a right to know a price before they get care so they can get that \$250.00 MRI at the same facility rather than pay \$4,400.00 for the same image from the same place. And so, being able to have the visibility into prices in a standardized format, which right now the parser organizations are telling us there are over 500 different types of file records being posted up by the hospital, which only about one-third in this country are making an effort to comply with these new rules. So, as we go into the insurance rule for coverage being price transparent and the hospital rules, I'm looking at this is also a patient's right to information both through the Office of Civil Rights because HIPAA does tell us we have the right to past, present, and future pricing and payment information.

And I think we as a committee, as we are working for standards in billing, we should come to the front of the train, not the caboose and that is let consumers drive down the prices of healthcare by easily getting ready access in a standardized format to prices. And I would say that since the EHR's are utilized to up





code and charge for the patients on a revenue stream, we should look at how do we, actually, reduce the cost of care by empowering the patients to get access to this critical information before they get care. So, that's my input to our committee. Thank you.

**Denise Webb**

Thank you, Cynthia. On your first point, I just wanted to mention, if you recall, Aaron had requested of Tim the importance of having a crosswalk or a mapping between ONC's 21<sup>st</sup> Century Cures Act rule related to information blocking and these changes that will be forthcoming in the new HIPAA rule. And if you think about the interoperability provision around the content and manner exception, it does define electronic access use exchange as the patient having access without any special effort. And if that is available then, the 15 days doesn't make any sense at all because by definition in the information blocking rule, that's immediate access. And if that is available and it's not provided to the patient then, that would likely constitute information blocking. So, we definitely need to clearly understand the intersection between what's going on with the changes in the HIPAA rule and what we're all subject to in the information blocking provisions as healthcare provider organizations or covered entities.

So, thank you for bringing that point up. And hopefully, we can get that from OCR eventually here as they finalize their rule.

**Cynthia Fisher**

Yes. And I would just say that there is also a bridge if we all think about that is getting access to this information for the patient of their electronic health record. And expansively, we do not, as patients, have that readily accessible right now with those cost estimator tools on the price transparency rule. The hospitals have been, essentially, making it difficult because the patients can't get a price without giving away their personally, individually identified information along with their insurance information. So, even if you don't have insurance or you want to just search comparative prices, you can't unless you spend five minutes or ten minutes entering your own personal information. So, nowhere else in our economy do we shop by having to give away all of our personal information. So, I think that's really important that when we look at the bridge into the Office of Civil Rights with HIPAA rules that having immediate and ease of access to this information is critical.

And then, one more thing on information blocking is we are all using the standard of the ICD-10 codes, which is really a proprietary code by the American Medical Association. And what we're finding is the parsers in the price transparency world are not getting access or responses to be able to use the coding to be able to parse and compare data on pricing. So, that in itself by the AMA not enabling that is in itself information blocking to be able to share comparative price information like we see on Kayak or Expedia and the airlines or Orbitz. We could, actually, get expediently there with third party apps comparing prices for consumers in healthcare market. But that's being blocked. And one could beg why do we have a standard with a proprietary intellectual property of these codes when we don't have a standard that's open source and free to anybody to innovate in our country and allow readily available access to the patients and American consumers of healthcare.

So, I think it behooves us as a committee to make sure we are doing our best to allow timely access to health information for the people who need it most and that's the consumers and the payers, we the patients. Thank you.





**Denise Webb**

Thank you, Cynthia. Steven, you're in the cue next.

**Steven Lane**

Thank you. Yeah. I just wanted to comment in response to Cynthia's point about the value of immediate digital access. And clearly, this being propagated through the ONC rule and information blocking and the question of whether HIPAA being set at 14 days is appropriate. And I just wanted to point out from the provider perspective that, as we've grappled with our system changes to support information access, there have been categories of data and thinking about historical behavioral health notes or pediatric data, from the past where a lot of organizations have not felt comfortable making that available for immediate access because they don't have the ability to go back and assure that providing that data might not meet one of the established exceptions, specifically, regarding risk of harm and privacy. So, I just think it's clear that immediate digital access is the goal. I think that most organizations have understood that and are providing that on a go forward basis.

But there is still a role for release of information requests that go through more of a deliberate process that take some period of time for review that cannot be managed entirely through automation. And I don't think it necessarily would take 14 days but it takes more than immediate time to ensure that that data release is optimized for the patient and their needs. So, I just wanted to throw that out, Cynthia.

**Cynthia Fisher**

Well, one could imagine, Steven, that if it's digitally available within the healthcare system or health network, it would be digitally available to the patients. And we really need to be working to that front to give Americans the best of quality of care. And I really think that we have the ability to provide better healthcare in this country because it is digital. And we're not letting the patients get access real time when it's real time available in the files. And I think we can do this. It's very exciting that we have the ability.

**Denise Webb**

Thank you. Carolyn Petersen is next in the cue. Carolyn?

**Carolyn Petersen**

Thanks, Denise. And thanks, everyone, for this really rich, informed discussion. I think just to circle around, I totally agree with Cynthia in the sense that the 15 day period plus an additional 15 day period at the organization or provider's discretion is really excessive at this point in time. At the same time, I also agree with Steve about the notion that there are some kinds of data where perhaps there might be some reason for additional review or some other concern to be addressed before release. Mental health information is one category that comes to mind. Potentially, information about children where there have been situations of family abuse or custody issues and there is a need to ensure that information is going to correct parties and perhaps not to other parties. I think in that situation, we might be thinking about looking for some clarification, something along a 72 hour rule perhaps that creates a space where those processes can occur but still ensures rapid deployment of that information to patients on request.

But I do think this is a really important discussion to have. And I'm glad we're advancing it.







**Aaron Miri**

Great point, Carolyn. And I want to echo that for a second. In terms of implementation of the information blocking rule that was a great topic of debate among the medical staff and the clinical staff and the compliance team to make sure that the patient is not inadvertently harmed by release of information. So, it's a matter of safety checks and balances to make sure exactly to your point. Clarity would be definitely helpful there. So, you're right.

**Denise Webb**

So, at this point, there are no other hands up. Are there any committee members on the phone that can't raise their hand? All right. So, it looks like we're a little bit early. Would it be possible, Mike, to go to public comment early?

**Public Comment (03:19:54)**

**Mike Berry**

We sure can. Operator, could we please open up the line for public comments?

**Operator**

Yes. If you would like to make a comment, please push star 1 on your telephone keypad. A confirmation tone will indicate your line is in the cue. You may press star 2 if you would like to remove your line from the cue. And for participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. One moment while we poll for comments.

**Mike Berry**

Great. Thank you. And while we're waiting, I just want to remind HITAC members to email me by close of business tomorrow, if possible, if you're interested in participating in the public health data systems task force. My email is on fire at the moment. So, I'm not sure how many are left at might want to join. But please do so by tomorrow if you could. Also, the next HITAC meeting is going to be on May 13. And as Micky mentioned, we will include the public health data systems hearing during that May 13 meeting. So, we'll extend the meeting likely to all day. So, we'll update the calendar hold that you have currently to reflect the proper time once we have the agenda fully built out. So, you might want to plan accordingly. And just a reminder that all HITAC material could be found on the HITAC page on HealthIT.gov. All right. Those are my public announcements for this afternoon. And I'll check with the operator to see if we have any comments.

**Operator**

There are no comments at this time.

**Mike Berry**

All right. Thank you all. Aaron and Denise, back to you.

**Aaron Miri**

They're probably all emailing. They went for part of it, too, Mike. This wasn't public comments. All right. Denise, does this sound better? I just switched my thing.

**Denise Webb**





Oh, yes. That's much better. I was just going to jump in on Mike's public announcements. Just to remind our committee that now that we have voted on the USCDI task force's recommendations, the next step on that is the HITAC will be advancing the letter to the national coordinator endorsing those recommendations and making those recommendations to ONC next. So, I just wanted to just remind everybody that that is our next step on that.

**Aaron Miri**

Yeah. It looks like there was a public comment in cue and just dropped out. So, we'll just give it just a second here to see if they come back.

**Denise Webb**

Okay.

**Aaron Miri**

But while she does that, let me just say to the group here that there is some phenomenal work going on in the provider community and across the entire healthcare industry, especially as related to vaccinations. Seeing the numbers creep up of how fast we're vaccinating folks gives you a lot of hope and a lot of optimism for the future. And that's everybody here and everybody listening's work and hard work. With that said and done, those also come at a tremendous loss of lives and a provider impact and clinician impact. And mental health is definitely a public health item to think about. So, as we go forward with the Public Health Commission, I would definitely ask us to look at mental health as being a part of that. And the mental health and wellbeing of everybody, especially our provider community, is front and center. And so, if you're not a clinician yourself, if you see one, give them a high five, give them a hug if you've been vaccinated or an elbow bump because they have really put in some serious efforts.

And that's just tremendous. So many physicians and clinicians on this committee, my hats off to all of them. But that's just to ground us in what we're doing and why this is so important. It makes a difference for everything that we're doing.

**Denise Webb**

So, Aaron, we have our person back to provide public comment.

**Operator**

Now joining, Nancy Spector from the American Medical Association. Please go ahead, Nancy.

**Nancy Spector**

Thank you. I'm speaking to the earlier report and recommendations by the USCDI task force. And the AMA has some significant concerns about the overlap between the current data class procedures and the proposed new data class for diagnostic studies and exams and even the new proposed data element for diagnostic imaging order. And there are several others who have posted comments on the USCDI website raising the same concern. The task force is recommending that there is a need to clarify the definition and scope of procedures due to its recommendation to add diagnostic studies/exams. But the problem is that procedures include diagnostic and therapeutic services. So, there is no real separation and distinction between procedures and diagnostic studies/exams. And even the terminology of diagnostic can be confusing because procedures can start out as diagnostic and then, change over to therapeutic.





For example, you can be having a diagnostic colonoscopy that can turn into therapeutic if polyps are identified and removed during that procedure. And there is the same when you have bronchoscopies and other scope procedures. There is that same dynamic. Another example can be a primary care physician doing a routine periodic screening EKG for a person over the age of 40. But in that same visit, if that patient happens to mention some recent episodes of chest pain then, that EKG becomes diagnostic and not just screening. So, we really do believe that adding the data class diagnostic studies/exams, no matter how it's intended to be used, will cause confusion for the classification of these data and the subsequent interpretation if they're exchanged among users. Thank you.

**Aaron Miri**

Okay. So, we have those comments. Are there any other comments in cue?

**Operator**

There are no more comments at this time.

**Aaron Miri**

Okay. Denise, anything you would like to add?

**Clem McDonald**

This is Clem.

**Denise Webb**

Go ahead, Clem.

**Clem McDonald**

Well, my question is can we dialogue with the inquirer because they're in the FHIR world and I think HL7 there is a distinction and a definition distinguishing those two kinds of procedures. Though, I agree at the edge, there are some mixes. But what's the implication of that? We don't do anything? That's what I would want to ask the person on the phone. And maybe we don't have that option.

**Aaron Miri**

Yeah. I'm pretty certain that we can record it and there is a way to file that so we can talk about it. Okay.

**Final Remarks and Adjourn (03:27:06)**

**Denise Webb**

All right. Any other final comments from committee members before we conclude? All right. I think we're ready to close the meeting, Aaron. I want to thank everybody for their thoughtful comments and questions today and all of our presenters and the ONC and Accel staff for supporting us for this meeting today. And our plate just got fuller after today with our new task force. So, please get your names in. I guess many of you have already. And, again, I'll remind everybody we have until May 6 to submit our own personal comments or organization's comments on the proposed HIPAA rule changes.

**Aaron Miri**





That's right. So, I'll just quickly say thank you as well to the ONC. Thank you to all of you listening and to this entire HITAC crew. You all are amazing. Great feedback, great dialogue. Keep up the good fight. Please encourage all of those you know to go get vaccinated. And also, try your best to help your organizations really steer towards the underserved and try to make it more equitable where you can. So, we really appreciate all of your efforts and be safe please.

**Mike Berry**

Thank you, everybody. We are adjourned. See you next time.

