ONC | HealthIT ADVISORY COMMITTEE

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

April 12, 2023 11 AM – 2 PM ET

VIRTUAL

Speakers

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

Name	Organization	Role
Thomas Cantilina	Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
Ram Iyer	Food and Drug Administration	Federal Representative
Meg Marshall	Department of Veterans Health Affairs	Federal Representative
Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Nara Um	Federal Electronic Health Record Modernization (FEHRM)	Federal Representative
Micky Tripathi	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Sweeney Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Seth Pazinski	Office of the National Coordinator for Health Information Technology	Director, Strategic Planning and Coordination Division
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Kathryn Marchesini	Office of the National Coordinator for Health Information Technology	Presenter
Mike Lipinski	Office of the National Coordinator for Health Information Technology	Presenter
Rachel Nelson	Office of the National Coordinator for Health Information Technology	Discussant

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

Michael Berry
Good morning, everyone, and welcome to the April 2023 HITAC meeting. I am Mike Berry with ONC, and we are always glad when you can join us. This meeting is open to the public, and your feedback is welcomed, which can be typed in the Zoom chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled at about 1:50 Eastern Time this afternoon. So, before we get started with our meeting, I would like to welcome ONC's executive leadership team to the meeting, and with us today is our National Coordinator Micky Tripathi, Steve Posnack, the Deputy National Coordinator, Elise Sweeney Anthony, the Executive Director of the Office of Policy, and Avinash Shanbhag, the Executive Director of the Office of Technology. I would like to begin rollcall of our HITAC members, so when I call your name, please let us know if you are here. Let's start with our co-chairs. Aaron Miri?

Aaron Miri
Good morning.

Michael Berry
Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning.

Michael Berry
Shila Blend?

Shila Blend
Good morning.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Sarah DeSilvey?

Sarah DeSilvey
Good morning.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Cynthia Fisher? Lisa Frey? Hannah Galvin?

Hannah Galvin
Good morning.

Michael Berry
Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Michael Berry
Valerie Grey? Steven Hester? Jim Jirjis?

Jim Jirjis
Good morning.

Michael Berry
Bryant Thomas Karras?

Bryant Thomas Karras
Hello, everybody.

Michael Berry
Ken Kawamoto?

Kenasku Kawamoto
Good morning.

Michael Berry
Steven Lane?

Steven Lane
Good morning.

Michael Berry
Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
Arien Malec?

Arien Malec
Good morning.

Michael Berry
Anna McCollister?

Anna McCollister
Good morning.

Michael Berry
Clem McDonald? Deven McGraw?

Deven McGraw
Hello, everyone.

Michael Berry
Aaron Neinstein? Eliel Oliveira?

Eliel Oliveira
Good morning.

Michael Berry
Kikelomo Oshunkentan?

Kikelomo Adedayo Oshunkentan
Good morning.

Michael Berry
Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Michael Berry
Alexis Snyder?

Alexis Snyder
Good morning.

Michael Berry
Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
Sheryl Turney?

Sheryl Turney
Good morning.

Michael Berry
And now, our federal representatives of the HITAC. Thomas Cantilina? Adi Gundlapalli is with us, but he will be joining on audio shortly. Ram Iyer? Meg Marshall?

Meg Marshall
Hi, good morning.

Michael Berry
Michelle Schreiber?

Michelle Schreiber
Good morning.

Michael Berry
Ram Sriram?

Ram Sriram
Good morning.

Michael Berry
Nara Um? All right, thank you, everyone, and before we begin opening remarks, I would like to introduce Sarah DeSilvey so that she can announce a new role that she has. Sarah?

Sarah DeSilvey
Good morning. In line with HITAC policies, I need to announce a new role that I have. I am working now with Yale Center for Outcome Research and Evaluation, assisting with CMS health equity measurement in my role as an expert in social risk and social care informatics. I just wanted to make sure that everyone on HITAC was aware of that, and thank you for the opportunity to disclose that at this time.

Michael Berry
Great. Thank you so much, Sarah. And now, please join me in welcoming Micky Tripathi for his opening remarks. Micky?

Welcome Remarks (00:03:53)

Micky Tripathi
Great, thank you, Mike. Welcome, everyone, and thank you so much to the HITAC and to everyone else listening in for attending today. We have a big day today with the release of our draft rule yesterday, and we very much look forward to describing that to you as part of the agenda. I know we have some other

parts of the agenda from various workgroups that we are also very much looking forward to. I will just focus my remarks on the draft rule itself, just to give a few highlights of that, and then allow the team to dive into some of the details.

It has been almost exactly three years since the publication of the CURES Act final rule in 2020, and there have been a lot of market developments over that time, and we have learned a lot about what we have been able to see in the market with respect to implementation on a variety of fronts, things like in the information blocking provisions, certification, FHIR APIs, TEFCA, a wide number of things that have taken shape and certainly moved forward in the last three years. And so, we think it is very appropriate and necessary for us to continue to make sure that our rulemaking is keeping pace with the market and helping to further all of the aims that we have to be able to have the kind of open architecture, health IT industry, and information exchange capabilities to be able to support patient needs.

So, I think of the rules and the specifics of the rules, which the team will go over in a little while, and I like to map them to our ONC policy priority areas, and just as a reminder, there are four policy priority areas. One is to keep the digital data foundation that we have all been working really hard to build over the last decade, and there is always more work to do, and there is the foundation that we want to keep rising. So, there are elements in the rule that are related to that.

The second is making interoperability easy. What are the ways that we can focus on technology enablement to make it easier for providers, patients, and others, to be able to share information? The third is promoting information sharing, using those digital tools, building on that digital foundation to actually share information. Finally, ensuring appropriate use, making sure the information that is being shared on the other end actually has some guardrails around it so that we at least have some degree of understanding and appropriate guardrails, to the extent that we can, over how that information is used.

So, let me just describe some of the highlights of the rule that map to some of those policy priorities, and again, it is a 550-page rule, and I recognize there is a lot of other stuff in there that Elise and the team will go over in more detail in the structured and comprehensive part of the agenda. So, going back to building the data foundation, the rule moves us forward in the USCDI to move us from USCDI Version 1 to USCDI Version 3. As many of you may know, the incremental benefit of USCDI Version 3 is pretty significant in a variety of ways, but most importantly in the dimension of health equity.

So, there were a number of data elements added there that followed from Version 2 and are now encompassed in Version 3 related to social determinants of health, sexual orientation and gender identity data, as well as tribal affiliation, just to give a couple examples of the data elements that are in USCDI Version 3 and that we are proposing be required to be supported by electronic health record systems. Insurance information is also included in that, which is an important aspect of the health equity dimension as we think about the mixture of insured and uninsured that exists across the country.

So, we are very excited about that. The USCDI is kind of the de facto minimum data set of the country, and we try to be very judicious and incremental in adding those data elements year on year because we know that there is a lot of work on the part of providers and technology developers to be able to support those, but it is an imperative for all of us, I think, to keep moving forward with that and continuously improve the

quality of data that is exchanged and the value of that data once it reaches its destination for the recipients of that information to be able to make the best use of that information.

As we think about making interoperability easy, we are continuing to bolster the FHIR API requirements to achieve the goal of access without special effort, as the 21st Century CURES Act directed us to, and some of the nuts-and-bolts examples of that with FHIR APIs are that we are going to further the SMART on FHIR framework, which puts requirements on authentication for authorization and token introspection to help us keep building that foundation toward APIs that are able to interact with each other without special effort, and also things like standardizing the representation of endpoints or service-based URLs to be able to have a better ability to discover endpoints and to be able to automate the discovery of endpoints.

On TEFCA, we have a newly introduced exception in the information blocking framework that will allow actors to leverage TEFCA to assist them with compliance with information blocking rules. So, there are a wide variety of ways that actors can be in compliance with the information blocking rules, and we just wanted to highlight and give some assistance to those who are participating in TEFCA to be able to leverage TEFCA to be able to streamline that approach and allow the information sharing that they want to be able to conduct.

On the public health front, we are introducing a technical standard for electronic case reporting. Up until now, deriving all the way back to 2015, the electronic case reporting requirement in electronic health record systems has been a functional requirement, so that has led to a variety of ways that it has been implemented. Advances in the maturity and the hard work of HL7 workgroups and the public health community at large to develop an implementable and feasible technical standard for both IHE-type approaches, HL7 V.2, C-CDA, as well as a FHIR-based approach now is at the level of maturity that we believe it is important to include that as part of a technical requirement for electronic case reporting. That will help the public health community be able to do much more with the electronic case reports for public health and pandemic response.

We also have RFIs in key areas such as lab interoperability and advanced FHIR capabilities such as CDS HOOKS, subscriptions, and SMART Health links, which gives us the SMART Health cards, the QR codes that many people are familiar with, because it is certainly our intent to build on the FHIR foundation that is now in place from previous rules to get us to those higher-level capabilities, and we very much welcome industry feedback on the maturity of those different kinds of advanced functions and what we can do to be able to advance those so that they are available across the landscape.

In the area of promoting information sharing, we are refining our information blocking requirements in a number of ways, but one that I will highlight is to encourage the use of standards-based information exchange mechanisms where available. So, to the extent that an actor is going through the manner options in providing that information, the encouragement there is to say that one can exhaust the options if one has gone through offering a wide variety of standards-based approaches, and that encourages everyone to try to share information in standards-based approaches and allows the streamlining of that discussion to allow the information to be shared in ways that help to encourage and motivate convergence on open industry standards and information sharing using open industry standards.

Finally, in the area of ensuring appropriate use, there are a couple of things I would like to highlight. One is there are certainly mounting concerns about privacy and the sharing of sensitive information, and that has certainly been heightened over the last nine months, and we have a number of things that are in there that speak a little bit to that. One is there is the requirement on FHIR APIs to allow a revocation of authorization of access to an API within an hour of a patient's request. So, the idea there is that a patient is granted a request to their record through a certified API, and they have changed their mind and decided they do not want that access to an app to be allowed anymore, and the requirement is that within an hour, we want the certified API holder to be able to turn off the spigot, to be as responsive as possible to a patient's request to be able to restrict the flow of information through that API to that particular app.

There is also a growing interest in being able to restrict sharing of certain types of data under certain circumstances, and we know that this has been a longstanding, difficult issue in healthcare IT. It is a very complex area, as we know, because at its heart, it is really not a technology issue. It is a convergence of technology, policy, and medical record documentation practices, a very dynamic landscape in terms of what is considered to be very sensitive data, a wide variety of things, so we know that there is no easy way to tech our way out of the growing concerns that people have about the sharing of sensitive information, but we have included a proposal for data filtering to support patient-requested restrictions, but really, what we are looking for there is comment from industry on ways in which technology and standards can help, if at all, to address some of these concerns regarding the sharing of sensitive information, and we very much appreciate the complexity, which is why the approach has a variety of options when you look at the rule to think about, perhaps, different ways of using technology to help further the concerns there or being able to address those concerns, and we very much welcome comments on all of those options, as well as any others that we have not thought about, and in general about the applicability and feasibility of using technology to address some of those concerns.

The other area that I will point to, which will be the last area that I highlight, is we have a whole new area, which is really an extension of an area that we have had in certification in the past, but we have now updated it and directly focused on the growing use of algorithms in electronic health record systems. So, as we all know, decision support interventions, as we call them in the rule, are a growing part of the landscape. They are rapidly growing, even in the last couple of months. ChatGPT was just publicly released in November and had over 100 million users in a very short couple of months.

So, even outside of the healthcare space, obviously, that use has been growing, but there has been a longstanding history in electronic health records in general with computable guidelines and a variety of ways of having decision support. We have now entered the realm of what we call predictive decision support interventions that are increasingly available in electronic health record systems, either because they are being trained on the data that is in the systems, or they are being built with tools that are made available through certified electronic health records systems, or the results of algorithms from wherever they come from are being made available into workflows that clinicians and administrative users are using to make decisions.

So, we have gotten proposals for the creation of mechanisms for transparency on the use of algorithms that are incorporated in electronic health record systems, so we are very much focused on working with our federal partners, like the FDA and the Office of Civil Rights, on the various types of authority that we have and making sure that we are collaborating closely with them and having our various authorities complement

each other, so the ONC proposal here is not about evaluating algorithms that are in electronic health records as it relates to safety, quality, or any other dimension, it is really focused strictly on providing transparency in the way of key information that characterizes the algorithm so that the user, the customer of the electronic health record system, has information about the algorithms that the technology developer has incorporated in the electronic health record so that that user can then assess the applicability of that algorithm to their particular local circumstances. So, it is not about evaluating the algorithms themselves, it is about making sure that users have as much information as they can about the algorithms so that they themselves can make those determinations with as much information as possible.

It is important to mention health equity. We specifically call out being able to represent if there are health equity issues and being able to tie algorithms to standards related to health equity types of data elements to assure that the providers/users have a sense of where there might be unintended consequences, perhaps, in the area of health equity through the use of algorithms, but it certainly applies broadly to safety, quality, and other issues as well, the goals of this in terms of being able to provide that information to users. The second element of the provisions related to algorithms is about requiring some type of risk management process or governance type of process on the algorithms that a certified technology developer makes available in their system.

So, we do not try to dictate what that risk management process looks like. What we want is to be able to have a thoughtful, formalized process for the determination of algorithms that are made available to customers in the certified technology system and to have that be something that is publicly available to just summarize what that process is. So, again, the idea is kind of two parts. One is transparency to the customers on the algorithm that are in place in the certified technology system and some information about those algorithms, what some people think of as the model card type of approach or nutrition label type of approach, and then, the second is some type of governance process used by the certified technology developer for how they do determine which algorithms to incorporate into their system.

So, hopefully that gives you a sense of how all the various things that are in the rule map to our policy priorities. As I said, Elise, Mike, and the team will provide a more structured, comprehensive view of the rule, but I wanted to make sure that everyone was able to see how the rule very much addresses the policy priorities that we have in the administration that we are very excited about moving forward. So, thank you very much for your attention today and for the discussion that we are going to have. Let me turn it over to Aaron and Medell.

Opening Remarks, Review of the Agenda and March 9, 2023, Meeting Notes – HITAC Vote (00:19:39)

Aaron Miri
Thank you so much. That was a very interesting overview. What an exciting day that we have here today at HITAC. I cannot think of a better topic for us to go through and really dig into details and ask questions, so, thank you, Micky, for that wonderful overview. I also want to give a shoutout to all the work the HITAC has been doing related to the annual report. A lot of you will recall we have had in our annual report year over year the questions of how we get better transparency into AI algorithms, so we really appreciate the administration, ONC, and others listening, looking at the HITAC's working, and seeing how we can incorporate that in future rulemaking. So, once again, HITAC, congratulations to all of you. You were

listened to, your opinions and thoughts helped shape this rule, so we look forward to a robust discussion today. Medell?

Medell Briggs-Malonson
Thank you so much, Aaron, and also, Micky, thank you so much for those opening comments. Today is going to be a really great meeting, and we have a lot to discuss, and we want to make sure that HITAC is there with their insight so, as Aaron just mentioned, we continue to help to guide where we are going next as well. It is also our pleasure to have an 8:00 a.m. start time, especially for those of us on the West Coast, so thank you for that as well. And so, Aaron, I will turn it back over to you so we can go through the agenda.

Aaron Miri
Absolutely, let's get to the agenda for today. So, we have a busy agenda today. Obviously, we are going to go through the ONC proposed rule at 11:30, then the standards workgroup USCDI 12:45, then some updates after that, and public comment around 2:00. Medell, over to you.

Medell Briggs-Malonson
Great. Why don't we go ahead and proceed to our first order of business? That is approving our March 9th, 2023 notes. Do I have a motion to approve the March 9th, 2023 notes as written?

Hans Buitendijk
So moved, Hans.

Medell Briggs-Malonson
Wonderful. I have a motion by Hans. Is there a second?

Kikelomo Adedayo Oshunkentan
I second it.

Medell Briggs-Malonson
Great. I also have a second on the table. So, all in favor, say aye.

Several Speakers
Aye.

Medell Briggs-Malonson
All opposed, say nay. Any abstentions? Great. So, the motion has been appropriately carried, and the March 9, 2023 meeting notes are approved as written. Thank you so much to the HITAC. So, I would like now to introduce Elise Sweeney Anthony, who is actually going to take us through our most recent ONC proposed rule. Elise?

ONC Proposed Rule – Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (00:22:02)

Elise Sweeney Anthony

Hi, good morning, everyone, or good morning on my side anyways. It might be earlier on Medell's side. 8:00 a.m. still seems pretty early, but we appreciate all the West Coast team does to participate in these calls. I know it is not easy sometimes. All right, today we are going to talk about the ONC proposed rule. We had a great overview from Micky on some of the high-level priorities that underpin this rule overall, and we are going to walk through some of the specifics. Go ahead to the next slide.

I will start to walk through our wonderful disclaimer, so bear with me as I read through it. "The materials contained in this presentation are based on the proposals in the health data technology and interoperability certification program updates algorithm transparency and information sharing proposed rule. We will talk about our new naming convention of how we refer to it in shorthand in a little bit. While every effort has been made to ensure the accuracy of this restatement of those proposals, this presentation is not a legal document.

The official proposals are contained in the proposed rule. ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the proposed rule as it is contained in the proposed rule. ONC cannot interpret that information, or clarify, or provide any further guidance. ONC cannot address any comments made by anyone attending the presentation or consider any such comments in the rulemaking process unless submitted through the formal comment submission process as specified in the *Federal Register*. This communication is produced and disseminated at U.S. taxpayer expense." All right, so, we'll start walking through everything now. Next slide.

So, we started with the concept of what? What are the three things that folks are going to want to know about this rule? Going to the next slide, the first thing is the title, which I mentioned a little bit. In the past, we have had different titles for all of our different rules. Most recently before this rule was the CURES Act final rule. What we have done with this rule is start a new convention, and that convention is based on a prefix title of Health Data Technology and Interoperability. The suffix of the title as we call it would depend on what that particular rule covers. The acronym overall will be HTI, and then, the numbering will reflect which rule it is in the ONC series. In this case, this is Rule 1, so it is HTI-1 proposed rule, and then, when we get to the final, HTI-1 final rule.

Now, there are a couple things I just wanted to note here. As folks are aware, there are other rules in the unified agenda, which is kind of the list of the rules that are coming from the federal government by ONC. So, ONC-issued rules would have this Health Data Technology Interoperability title. There is a second rule we are working on as well, so, as you can imagine, my team and myself are pretty busy, and actually, yesterday and today have been exciting times for us to be able to release this rule and start to get the thoughts from the public and the opportunities for commenting to occur. I am going to start the presentation, but I am also going to turn it over to Mike Lipinski, who is the head of the Division for Regulatory and Policy Affairs in the Office of Policy and responsible for all of our regulatory development, and then, also to Kathryn Marchesini, who is our Chief Privacy Officer. She is going to talk a little bit more about the algorithm transparency provisions that we have in the rule. Jump to the next slide.

All right, what is in the rule? Micky talked a little bit about some of these pieces, so I am not going to spend so much time on this, basically because I want to make sure that we get through the deck overall. I know that HITAC members may have questions, so I want to leave time for that as well, but I will also note at the

end the task force process that we will be starting up in terms of going through the rule and getting the input from the HITAC so that it can be part of the public comment process as well. So, there are some areas you will see that we will kind of scan over, but do note that we created these as resource slides. They are available on the HealthIT.gov website, and by "resource slides," I mean that they may be a little text heavy in certain situations, and that is because we want to make sure that they are accessible and usable even if we are not talking over the deck, that they make sense when you are actually reading through them, so bear with us on that as well. Next slide.

So, what is the why? The why is really important, and Micky talked a lot about the ONC priorities and how those are built in, and you see those spread across the slide in different ways. Looking first at the 21st Century CURES Act, the 21st Century CURES Act is an ongoing implementation. As we look at things like the EHR reporting program, we have been working on that in a number of different segments, starting with a request for information that we released some time ago that gave us some initial feedback on what folks were thinking about in terms of the EHR reporting program.

And then, as we moved through, we also worked with a contractor, Urban Institute, who provided some feedback on the measures themselves, and now to what you see in the proposed rule. In addition, there are other aspects of the CURES Act as well. If you think about the information blocking section in the CURES Act final rule, for example, we released definitions that related to how to define actors, as well as created the reasonable and necessary areas that are not information blocking, and we refer to those as exceptions.

s we look at what is happening in the landscape, as we try to understand, which we continuously do, what is happening on the ground, what information sharing looks like when it is actually happening, as well as what information blocking looks like and the different ways that can occur, we have provided some updates to the information blocking section as well, so we look forward to sharing that with you. And then, APIs. Micky talked a lot about APIs, and this is a really important part of what we do at ONC and also what the CURES Act called for us to do, and that is supporting the access, exchange, and use of information without special effort, and those three words, as the HITAC knows, are really important to the work that we do, supporting that information flowing without special effort.

And then, when we look at the Biden-Harris administration executive orders, we have listed two here in terms of the importance of making sure that our work aligns with the administration goals, including as it relates to data-driven response related to COVID-19, as well as racial equity and supporting underserved communities. And then, if you look all the way to the right hand of the slide, we talk about the HITECH Act, which continues to underpin the work we do, including around the certification program and interoperability advancement, and when we think about interoperability advancement, we do that at ONC in many different ways, whether it is working with standards-developing organizations, our work around USCDI, our work around TEFCA, or our work as it relates to proposed rules and final rules. Next slide.

So now, we are going to talk a little bit about some of the high-level things that we have done as it relates to the certification program, and then I will turn it over to Mike to talk about some of the specific certification criteria. Next slide. The first thing is around the edition list concept, and for folks who have been around the health IT certification program for many years, you are familiar with the concept of editions, whether it was the 2011, 2014, or 2015 edition that we released, and those editions mark different sets of certification

criteria that developers who are coming to be certified to would have to comply with, and those were edition-based.

What we are doing now is moving to an editionless framework, and that framework really focuses on making sure that certification criteria is updated at the right time as it relates to what is happening in the field and what the needs may be. In some cases, there may be a need to have a new certification criteria or a revised or updated certification criteria, but what we are saying here is that the developer would be able to update just that certification criteria or capability that it relates to, as opposed to updating the entire product per se as it relates to an edition. So, this is an update to our framework, and some of the benefits are listed here, and you will see that we noted that across the slides. You will see a proposal-and-benefits framework, but I do encourage folks to definitely read the rule. As Micky said, it is 500-plus pages, so there are many things in the rule, and this slide is comparatively fairly short, so we tried to highlight some things, but reading the rule, and particularly the preamble, which provides some of the reasons why we are doing what we are doing, is extremely helpful as well. Next slide.

So, when we think about certification criteria now, we are thinking about it in terms of the particular criteria and the standards as well, and in that respect, we want to make sure that the capability or the certification criteria and standards are being used at the right time. So, in some cases, they may no longer be applicable because new, revised, or updated versions of that criterion are now available, so it is important for health IT developers to be aware of that, and we are providing a more transparent and kind of certain approach to how we are handling that through our approach to an editionless system and also how we are going to look at updates over time.

In addition, in some cases, when we are thinking about new standards, we want to make sure they are adapted at the right time as well, on a going-forward basis, so that takes us to the next slide. On this slide, there are two ways we are approaching that: Making sure that the right certification criteria and standards and the capabilities related to them are available at the right time, and that is in regard to what we call the update-and-provide approach. So, one, a health IT developer who is certified under the program has to update their certified health IT modules at the right time as we designate. On the other side of it, you have to provide it to your customers at the right time as well, and those are two parts to a very important equation of how we make sure that health IT is operational on the ground when it needs to be operational and that we are supporting that interoperability that Micky talked about earlier as well.

So, that is the certification criteria part of it. On the assurances side, I will walk back for a quick reminder. The condition and maintenance of certification requirements are one of the things that are laid out by the CURES Act in terms of things that should be part of the health IT certification program, and there are different conditions in the maintenance of certification requirements. As it relates to the assurances one, what we have said here is that a health IT developer must assure that it is not interfering with the customer's timely access to interoperable health IT. There is also a maintenance-of-certification requirement that has three key components: 1). Updating, as I mentioned, updating to make sure that the revised certification criteria, the new certification criteria, is in place, 2). Providing, making sure that is provided to customers, and 3). Timeliness, and actually, we are going to put together a fact sheet that kind of sums up this approach so that you will have that accessible.

We have two fact sheets available now, and you will see that we will add a couple more over time, and this is going to be one. We are going to talk in that fact sheet, but also, I will discuss it here, in terms of the timeliness component, which is really important to this concept of the editionless approach that we are taking, but also in terms of what is necessary to maintain certification. In general, what we say is that for an existing customer, the technology or the capability has to be updated in a timely way, and for the most part, that is about 24 months after the end of the effective year. So, if a final rule becomes effective in, say, November of X year, which is just hypothetical, then, starting at the beginning of that year, you would have two years, so you would have two-plus years, depending upon the timing, to make sure that that health IT technology has been updated and provided, which is a key point.

In the case of new customers, we generally say 12 months is required, and I should note that when I say "new customers," I mean new to that capability, because you could have a customer who has been working with a health IT developer on other capabilities, other certification criteria, but not on a particularly new one that they have now decided they want to add to their suite for operations purposes, and in that case, in terms of adding to their suite, that capability would be a new capability, and for that, they would be under the rubric of a new customer.

So, there is lots of nuance to this, but we wanted to provide this approach at a high level. We think it is going to be very helpful to provide certainty across the landscape, but also provide certainty not just to health IT developers, but also to customers as well in terms of when they can expect that updates to the technology would be rolled out. With that, I will go to the next slide. Now, I am going to turn it over to Mike. Mike is going to talk a little bit about the certification standards functionality updates, as well as information blocking, and then we will go over to Kathryn, and after that, I will come back and talk a little bit about the process for the task force, as well as some of the resources that we have available. Mike?

Mike Lipinski

Thanks, Elise, and good morning, everyone. I am going to jump right in. I am going to be talking about the topics you saw on the agenda, which will be the standards and functionality in the rule, the insights condition, which is the EHR reporting program, and information blocking. Let's go. Next slide. So, this is a high-level slide indicating the standards that we have proposed in this rule, as well as the criteria changes, including a new criterion or iteration, so, with the CDS, it will be the DSI one. I do want to point your attention to what I will call the infographic on the screen there on the right of the slide, which is that we will be looking to actually ultimately adopt newer versions of CORE and the C-CDA companion guide that will better align with USCDI Version 3. It is my understanding and our understanding that those versions will be available during the comment period sometime in May. Now, again, the comment period will not begin until April 18th and run for 60 days.

All right, let's start talking a little more about all the various standards and criteria. Next slide, please. I think many of you are familiar with USCDI and ONC as the standard steward here, and the developer of the standard as well. Version 1 was the baseline standard used for certification via the CURES Act final rule. Obviously, I have a Version 2 inversion, and we can move to the next slide to talk about the version that we are now proposing as the new baseline for certification, and just from a timing perspective, obviously, it was three years ago, as Micky mentioned, when we got the CURES Act final rule that established Version 1 as the baseline, and the end of last year, so we are already three months past when all certified health IT that was affected by the new standard USCDI Version 1 had to be updated. So, we are already in a position

where we have given more than the two years to update to Version 1, and now we would obviously like to continue improving the interoperability of data and its availability for access, exchange, and use, and we are now proposing Version 3 as the new standard baseline. Let's move to the next slide.

Again, this is just reiterating the proposal. I think the benefits are obvious here in terms of more data being standardized and available, and as you can see, it is obviously a theme in why we are doing things, including the name of our rules going forward. You have the data, you have the technology, and then you have interoperability. And then, listed here is obviously the criteria. You are looking at the same criteria plus a new one, D-14, that were affected last time by the USCDI adoption. I am going to move to the next slide.

Okay, minimum standards. We updated the minimum standard code set. I think a lot of you are familiar with the code sets that change frequently throughout the year, maybe even monthly in some cases, which is RxNorm, quarterly, and semiannually, which I believe is the case with SNOMED. So, this time, we are proposing to update all criteria that are affected in regards to the minimum standards code set. So, last time, we did not do that, we just focused on the USCDI. This time, you will see this have an impact on, for example, the public health criteria like the immunizations criterion or electronic case reporting that uses LOINC. Again, this is obviously going to improve interoperability by raising the baseline with the standards that are in use. Let's move to the next slide, please.

You heard Micky talk about API, and I think we think this is going to have… Obviously, it is based on the implementation of our first go-round with the APIs using standardized approaches with FHIR and USCDI and the conditions of certification that we established, the maintenance requirements, and so, we think this is going to help the market a lot, both from a privacy and security perspective, but also from an access perspective with the URL publications. I think this will hopefully make them more easily and readily available for third parties to have access to them and connect, so we are really looking forward to getting feedback on this proposal and hopefully moving forward finalizing each of these individual proposals here. Let's move to the next slide, please.

Case reporting is another one where we are trying to move the needle from a standardization perspective, including implementing not just interoperability, but, again, with the executive order that Elise mentioned about public health. So, here, if you recall previously, we focused on just the data set trigger and then the USCDI, but now we are going to be looking at standardizing this through two ways, either through CDA or FHIR, and that includes particular IGs in this case, so I believe that would be the ECR, electronic case reporting, IG for FHIR as an option, and then, the one that we are doing is testing now for the ability to transmit the case report electronically to a system capable of receiving such a case report, which was not part of the current criterion. Again, that is not a standards-based approach, but we are seeing the ability that that can be done with our proposal. I will move to the next slide.

So, you heard Micky mention this at the outset. This is a new proposed criterion, which really focuses on the ability to capture patient preference or, in this case, their preference related to sharing, and then tagging that data for future use and disclosure. The key point, though, is complexity, as Micky mentioned, the intersection of policies and technology here. If you are familiar with a lot of ONC's work, including their regulatory work, we have dabbled in here in terms of doing requests for information and trying to get feedback in various other ways, whether it is in the pediatric setting or the behavioral health setting. So, in

the rule itself, you will find many permutations of considerations and proposals here, and we really are looking forward to getting the comment on all that.

Hopefully, we have done a good job laying out all the intersections and questions that need to be answered and matters that need to be addressed in terms of laying that out for you to give comment on. Again, I want to reiterate Micky's and all of ONC's sentiment. We are really looking forward to all the feedback we can get on what we have laid out here. There is obviously an intersection with information blocking. We have a separate request for information under information blocking related to being able to essentially capture, in some respects, patients' preference because there are obviously certain exceptions where it permits a provider or an actor in particular, under information blocking, to acknowledge and adhere to a patient's request not to share information as a reason why that would not be information blocking. Okay, let's jump to the next slide.

These are other requests for information in the rule. Obviously, on FHIR itself, there are a lot of permutations of requests for information and feedback. They are listed here on your screen, but there are two other large areas of interoperability that we are hoping to get feedback on, and those are obviously lab interoperability, something that ONC has cared about since the beginning of what I will call the Meaningful Use program, the EHR incentives program, and various proposals we had tied to some of the measures there, and some other proposals we made in subsequent years through regulation that were not actually adopted, but we are looking again for feedback here, and Congress is also very interested.

In the last Appropriations Act, they asked us to do a study and report on lab interoperability, so the information that you provide in response to this request for information can help inform that as well. And then, on pharmacy, similarly, we are asking for feedback related to pharmacy interoperability, but particularly to real-time benefits capabilities. Congress again asked us to include such functionality in the base EHR definitions from the 2021 fiscal year appropriations law. So, again, there are a lot of requests for insight from you all on your thoughts about interoperability and what we can do from an agency, both through regulatory processes and other means. I will move to the next slide.

So, we are going to shift now to the EHR reporting program that we are referring to as the Insights condition because that is what we are hoping it will do. The reporting of this information will help provide a lot of insights into various things in terms of usage of certified health IT, into the sharing of data, into interoperability, and just the functionality of various EHRs that are in provider settings. So, let's jump into that. The first couple slides are just going to be more refreshers for you all. You obviously are very familiar with it in terms of providing feedback, that is going to be noted, but Congress laid out a lot of specificity to the EHR reporting program, and then, also specifically said it should be a condition of certification.

And then, as I mentioned earlier, we are hoping this will provide information, similar to other transparency initiatives, including the algorithm one that my colleague Kathryn will be talking about, that will be able get information and make that available to the public regarding what is being reported. So, let's jump into the next slide quickly, just to remind you all of the information and how we approached this. So, we had a contractor that did a lot of outreach and work for us in terms of getting feedback and provided us some draft measures. We provided that to you all for feedback through the task force, and then we took all that, including the public health feedback, and did some additional research, and what you will see in the rule

and what we will briefly cover on the next screen is what we came up with in terms of the first iteration of measures in our focus. So, we can move to the next slide, please.

Here are the areas, the measures, and then, the related criteria. Personally, I think it is a very good slide in terms of trying to make the connection for you and lay out the focus. So, there are nine measures, as I mentioned, and they essentially cover four topic areas, which are listed on your left there, and I will briefly mention them. There is individual access, clinical care, and information exchange standards adoption and conformance, and these align with what was specified in statute, and then, obviously, public health information exchange. And then, the criteria from a certification perspective, meaning the products being certified to, are listed on the right that align with the measures. Let's move to the next slide.

This is really essentially laying out the three criteria in terms of identifying who would report. Ultimately, these are the minimum qualifications that would be needed to be met to report, but even if you not meet them, as a developer, you will have to attest that you do not meet these criteria for reporting purposes, so that is your high-level second bullet on the screen. And then, we are going to make, similar to other reporting requirements under the program, a web-based approach available for submitting that information, and again, from a transparency perspective, making that information publicly available. I think we can proceed to the next slide.

This is just focusing on the frequency of reporting. I think the key points are that the information is going to be submitted every six months here, and it will be phased in over two years. I think this was mentioned earlier, but the one thing that I want to mention before we move on to our next slide and next topic, which is going to be information blocking, is a specific presentation just on the insights and conditions. So, if you have a strong interest in this proposal, this condition, these nine measures, I highly encourage you to attend that presentation. It will be recorded, so you will be able to attend it. If you are unable to make the specific time in which we are doing it, you can go back and listen to the recording at another time, but we will go in depth on this particular proposal and condition. Now we can move to the next slide.

All right, information blocking. Before I jump into the proposals here, I just want to do a quick summary of where we are from an information-blocking regulatory guidance approach and so forth. Obviously, we have this proposed rule. As Elise mentioned, there is another rule we are planning to go through rulemaking on this year, and that may include additional proposals related to information blocking. We continue to look at where we can issue guidance as well as respond to stakeholder inquiries that come through a portal or web-based process in which you can go online to submit inquiries, and we respond to those.

Also worth mentioning is the OIG final rule related to developers and health information networks. That is now with the OMB. It was accepted for review by OMB last Friday, so if you were not aware of that, it has now reached that stage, and we are hopeful that that will get through quickly and publish in the near future. Lastly, there is this concept of advisory opinions in which we are to be able to give binding guidance about particular facts and circumstances and then make that public on our website, for example, so that others can see it and see if they have similar situations that compare to that and know what type of actions they can and cannot take that would implicate information blocking and/or particular exception.

So, that advisee opinion authority has to be provided by Congress. It was in the last fiscal year administrations budget and is in this year's fiscal administrations budget request as well. I mention that

because when we go talk about the proposal on this rule, some of these proposals could have been addressed through some form of binding guidance, but we have to go through a regulatory process to address some of these matters, particularly when we think that they rise to a level… And again, they will not be with as much specificity, but hopefully more helpful to actors based on the feedback we got in terms of, again, the Congress instruction identifying reasonable and necessary activities.

With that, let's just focus on the specific proposals in this rule. Next slide, please. Here, you will see a quick summary. We are looking at the definition of "offer." It does not have an impact on the health IT developer certified health IT definition, which is one specific actor which built in the "offeror" definition, including for self-developers, so we had to tweak it for self-developers too. So, those are more a flowdown of defining what an offer is, so that is the key proposal in this rule, but it obviously impacts other more procedural proposals we had to make with the definition of health IT, including, like I said, for self-developers.

There are exceptions that we addressed. We are not creating any new exceptions, we are creating new conditions under current exceptions, so that will be the infeasibility exception, and then the manner exception, you heard Micky reference the TEFCA condition, and I think that is a nice consideration of feedback in the past, and Congress's instruction in terms of having ONC focus both on information blocking and TEFCA and how we can make sure they are relating and working together, just like we do with HIPAA. And then, obviously, I mentioned some requests for information. We will not really spend time on that, so let's move to the next slide, please.

So, the "offeror" definition. What are we trying to address here? We received a lot of inquiries, some indicating and highlighting "not our intent" with the definition of "offer," and so, we are trying to address that here. There were a lot of inquires about "If I do this, am I offering health IT?" It is impactful in two ways. It is impactful for actors that may not be currently covered under the program. For example, a health plan may find that what they are doing may bring them in as an offeror of health ITs, and/or a provider doing certain activities may find that that changes their status for that particular activity from being just a healthcare provider, which has a different knowledge standard, as you know, and different potential penalties compared to a developer of certified health IT in which the offeror piece fits. So, it is not a separate definition. "Offeror of health IT" is part of the definition of "health IT developer of certified health IT," and so, that is why what an offer is matters.

So, the way we had to approach this is besides just clearly defining what an offer is, it is an exclusion approach, so we have to exclude certain activities that would not meet the definition of "offer," and therefore not change your status if you are a healthcare provider and/or bring you under the regulations if you are a particular entity that is not one of the identified actors under the program. So, it really falls into two key areas that we are identifying for exclusions. Those are donations and other types of subsidized arrangements, but the key piece of that to remember is we do not use the word "control," we use more specific regulatory language without conditioning or limiting the interoperability of that tech, access, or exchange that you are providing, but essentially, colloquially, I will say you are not maintaining control over their use of that subsidized tech that you are providing to them, or the donated certified tech that you are providing to them, in either instance.

The other one is implementation use activities. You might be surprised, although some of you on this call may have the same questions, but we got questions about "Does providing you a user account login

credentials mean I am offering health IT?" or "If I just make the patient portal available, am I offering health IT to patients?" It is the same with APIs. So, those are some of the activities we try to address for purposes of exclusion in this rule, and I highly encourage you to take a look at the specifics and certain activities that we have identified, and let us know if there are certain activities that you also think should not fall under the definition of "offeror." So, let's move to the next slide.

So, this is really a clarification trying to provide the utmost clarity. Surprisingly to us, we received some inquiries when the COVID-19 public health emergency began of "Oh, there is a public health emergency. Does that mean the uncontrollable events exception applies because it mentions disasters and public health emergencies? Does that mean we do not have to worry about it and we can just invoke this and not have to worry about information blocking?" That was not our intent. We have tried to clarify that. We have used the words "do too" in there, but apparently there were differing views of that from the public. While we still maintain that you would have to show a causal connection, we actually are proposing to change the wording to provide even more clarity, which is "because of." So, to make it as clear as possible, we propose to change the rec text that you really need to demonstrate that because of a particular emergency or disaster, that is why you cannot provide access, exchange, or use.

Moving on to the next slide, third-party modification use condition, again, maybe this is not "plain language" for some on the outside, but we had to use very technical terms because we are using and leveraging other defined terms under regulation, for example, "business associate" in particular. We are bringing in the same definition as is used under the HIPAA regulations. The bottom line is what is happening here is trying to provide more certainty than the infeasibility under circumstances, or if you had to use a separate exception to document or demonstrate why you were not providing access to a particular entity who wanted to modify the records.

So, we are talking about deleting or creating something in the record. Just for clarity, as an example, if you had an EHR developer that is an actor and maintains the EHR record for a healthcare provider, if the healthcare provider or, as we make clear in the preamble, another separate business associate on behalf of the healthcare provider made a request to do that to the record, that the EHR company, who is an actor, and a business associate is maintaining, this proposed exception would not apply in that circumstance. That does not mean that any other exceptions could not apply. The security exception may still apply under that circumstance. The infeasibility under the circumstances condition of the infeasibility exception may still apply, but this particular proposal would not apply to that specific circumstance.

What it would apply to is outside parties that do not have that relationship, including third-party apps on behalf of patients, as well as potentially other healthcare entities who wanted to write to your record. You could quickly point to this proposed condition and not have to determine whether or not, under all the factors of infeasibility in the circumstance or another exception applied in that circumstance. So, it is to address those particular facts and circumstances. Let's move on to the next slide.

So, this is what we are calling the manner exception exhausted. So, the manner exception is the new name for the content and manner exception, and it is really a three-part test, and you are going to see that a lot of the parts are parts that are coming from either the manner exception itself or the infeasibility under the circumstance exception, and those are the first two parts. I guess I should start with the problem we are trying to address. In a lot of instances, entities or actors who have a lot of financial technical resources

express concern that they are getting a lot of requests to build unique interfaces or one-off interfaces, and they are worried that they do not have a certainty that if they do not respond in the affirmative to all these requests, and you can imagine the amount of requests they are receiving, that they may or may not meet the infeasibility under the circumstance because it is a weighing of all these factors, and these factors include the financial and technical resources available to them, and there are a few others, like if they have control over the technology or if they provide it to others.

So, what we have done here, which is consistent with one of the other factors under infeasibility under the circumstances, was "Were you able to provide it through the content and manner exception?" The one thing about the content and manner exception, though, is each of the various alternatives you work your way down through in the prioritization has to be agreed upon by the requester.

So, what this one does is says there no longer needs to be that agreement in this particular condition. They have to offer it, and because of lack of time, I am not going to go into the alternative proposal about two or fewer alternatives, but they have to go down and offer each of those, and then, the third factor also has to be met, which is that they are not providing the same access, exchange, or use of the EHI to a substantial number of individuals, entities, or similarly situated. So, think in terms from a software perspective, the general availability manner or means, and if they are not doing that, if it is a one-off custom build, for example, and somebody else is asking for access to that or for you to build that same custom build again, then this could be a potential condition that you are looking at to use to not meet that request.

There are a few quick terms on that third part of the test. "Currently provide" gets to that general availability. It is not something you built in the past and they are saying, "Oh, you have done this in the past." It has to be something you are currently providing. You are going to see that substantial number, and we are requesting comment about that, because what is a substantial number for one potential actor, particularly a developer or large hospital system, could be far greater than it is for a small system, a rural provider, or a one-off niche developer of certified health IT.

The one thing I do want to emphasize is "similarly situated." While these terms are used in both the licensee exception and the fees exception, here, we make clear that "similarly situated" is not necessarily particular classes by themselves. The best example I can give you is "Oh, I provide this imaging approach availability access to other healthcare providers, maybe specialists," and then a patient app shows up and says, "I would like access to that too." You cannot say, "Oh, you are not similarly situated because you are not a healthcare provider, you are a patient-facing app." I want to be clear, and we make this clear in the preamble, that that is not our concept of "similarly situated," so that would not be a basis for denying that particular request on those grounds. Okay, can we move to the next slide?

This is a tough one that Micky mentioned in the beginning and that I also mentioned earlier. Really, I think there are three key things, beside what you see on the screen, that need to be remembered here. It has to be within the TEFCA permitted purposes, so it goes beyond the required purposes, but both parties need to be in TEFCA, too, the one who is requesting it and the actor who is having that request made of them for access, exchange, or use, so it does not apply to non-TEFCA party requests, and then, it has to be consistent with the TEFCA connectivity services, the framework services that are available.

So, for example, if it was a permitted purpose in a large amount of EHI also, then the services still have to be able to support what is required for exchange under TEFCA. So, if, in your framework, that cannot be exchanged, then you would not be using this particular condition. With that, I think we can move to the next slide, and I will turn it over to my colleague Kathryn. Thank you.

Kathryn Marchesini
All right. Good morning, everyone. In Micky's introductory remarks, he provided some background in this area and previewed some of the DSI and algorithmic transparency proposals, so I will do a little bit more of a deep dive there, but I wanted to share that we heard loud and clear at the HITAC hearing last March around health equity and elsewhere that there is a lack of trust among clinician users, given the limited information available to determine an algorithm's quality. So, we understand that there is substantial growth of predictive models in this area, including the use of models that are poor quality, as well as that they have demonstrated that they lead to bias, discrimination, errors, and overall widening health disparities, potentially even misallocation of resources and other negative outcomes.

And so, I will talk through the proposals, but the primary role we are proposing ONC to play is to support the optimization of predictive algorithms in healthcare and hopefully to shed some sunlight on the quality of the predictive algorithms. Specifically, you will see on the next slide that we are proposing to update and modernize our existing certification criterion for clinical decision support, CDS, for include a new definition for predictive decision support interventions, or predictive DSI, for short.

Our proposals really are looking at a couple things. One, it is really trying to incorporate the contemporary emerging software functionalities that aid decision making in healthcare, including AI and ML. We are also looking to make sure that there are new requirements that are factored in regarding enabling information transparency, and we see that as a prerequisite for trustworthy AI. This includes transparency around the actual data elements for the predictive algorithms to use, as well as the predictive DSI, how that was designed, developed, and trained, and I will talk a little bit more about that later, but also, as you heard from Micky earlier today, talks about how the certified health IT developers or others that develop the predictive technology manage risk, as well as governance of the models themselves. Next slide, please.

Overall, I would say increased transparency or increased transparent information of predictive models and algorithms used in healthcare leads to improved trustworthiness. As I mentioned, our primary role is really making sure that the technology that enables or interfaces with certified health information technology provides information that users of that technology can use to make determinations as to whether or not that particular technology is used for their purpose. You will see here that we really focus on trustworthiness as well. We use that term in a catchall way to explain what we see on the slide here, fair, appropriate, valid, effective, and safe phase. It is really trying to look at the consistent way that developers can convey to the users information about different aspects of the technology, and we will talk a little bit about that later, and you heard Micky speak to some of this as well. We also propose areas that really encourage and advance the aspects related to health equity by design. I know that is an interest of the group here, and so, I will talk a little bit about that on the next slide as well. Next slide, please.

So, to jump into some of the specifics, the predictive algorithms are used across a wide variety of use cases, and so, at ONC, we are fully aware of that, and we are trying to make sure some of that is incorporated into future uses of technology. You will see here on the slide that the proposed definition is

not tied to specific uses regarding the purpose. So, for example, we are describing the implementation of models to support or inform decision making across healthcare as predictive, whereas others have used terms such as augmented intelligence, automated decision making, or augmented decision making to describe such tools that we are trying to capture through our definition.

As you will see here on your slide in blue italics, as well as on the left, generally, it would include a human in the loop. There is some type of expert judgment that we are factoring in. But, of note, as mentioned, the definition really is focused on the relationships learned in the training data, and it is not specific to, for example, if it was used for treatment, payment, operations, research, or public health, for that matter. The other thing to focus on is that it is not tied to a level of risk in terms of the application or use of the technology itself, and so, there could be technologies that meet the definition that is proposed, and it can be presented in a wide array and state of mechanisms or mediums through the certified technology. So, for example, it could be an alert, it could be an order set, it could be a flow sheet. It does not necessarily focus on a specific kind of mechanism or functionality per se.

The other area of focus on this slide here is that the scope would include, for example, simple statistics or regression models, as well as machine learning models, including large language models and generative AI. The other point, which Micky touched on earlier, is that the proposed definition is not tied to who developed the technology. In many cases, we understand that certified health IT is a key component, as well as data source, for predictive models. It is also often providing the data to help use, train, and build such models that are also serving as vehicles to influence day-to-day decision making. And so, this is just a contrast to ONC's existing certification program in terms of evidence-based decision support, where there is a lot of focus on rules-based engines of that nature. Next slide, please.

So, these proposals would include, as I mentioned, requiring certified health IT modules that are certified to the criterion that enable or interface with predictive DSIs to enable users to review information about additional source attributes, particularly relevant to health equity, among other purposes, and you will see those listed here on the slide. We were referring to this as "data transparency." There is an existing requirement that we are building off of, as many of you may be familiar with, under CDS, particularly around source attributes, so this is adding to that. The other area that Micky also spoke to earlier, some of the key focus areas of the proposals, the two prongs, if you will, is requiring developers of certified health IT modules that are certified to the criterion to also provide information related to additional source attributes and the technical and performance aspects of the DSI.

And so, as Micky alluded to, this is your nutrition label, your model card, really trying to provide information in a consistent way, as you can see listed on the slide, around intended use and the date it was maybe trained on. There are kind of four big categories. The other piece to the proposal focuses on the behavior or the activities that the organization that developed the DSI took into account as it relates to risk governance of the actual model and the technology. And so, in both of the cases, there is the encouragement to share information. In the first example around the source attributes requirement, which Micky spoke to as well earlier, some of that information would be available to the user, whereas the organizational risk management is something that would be made available to the general public. Again, this is just a note that would be summary information. More detailed information would be required, and the proposal speaks to that, but it would really just be for ONC purposes. Next slide, please.

This is the bird's-eye view of some of the aspects, a few more details around the DSI proposals, particularly related, say, to the predictive DSIs to raise some additional proposals in the DSI section. Similar to the content on the prior slides, the functional requirements, which you will see titled as technical and performance, through the proposals, if finalized, would provide assurance regarding the functional requirements. Some of you may be familiar with source attributes in that the certified health IT enables the technical capability to provide the information to users and certified health IT developers that they have. And so, you will see here that it is for the users, it would be through the EHR, and there is not a prescription as to where. The focus is on plain language, direct display, drill down or link out, and I spoke to some of the other equity considerations on the prior slide. You will also see there some advanced enhancements for those that are interested in some of the additional details.

The other aspect we spoke about is governance, and some of this is very tied to our proposals related to risk management. And so, I know I touched on this loosely, but basically, this is really getting at model risk and understanding that there are errors along the way in the software development process in which model outputs could potentially lead to recommendations, for example, that are not fair. So, the idea is that there would be an area in which, as you will see on the slide, the developers would allow providers and others to have information about how they have managed the risk. You can see the eight types of risk there, everything from validity to fairness, privacy, and safety, and also the overall management of data.

I know there is interest and questions about where the data came from, and the curation, and the evaluation, and things of that nature, so you will see some discussion in the proposals where some of that conversation, or at least ONC's framing of that conversation, happens. Lastly, from an oversight perspective, how would ONC understand or be aware of whether or not developers meet these requirements with overall conformance? As a result of the proposals, this would happen through ONC's existing health IT certification program as part of the real-world testing activities, the thought being that in addition to current activities, information related to these proposals would be included in that as well. Next slide, please.

The last piece is just a different way of looking at the information. As I mentioned earlier, we referred in the proposals to predictive DSIs and models that are faves as high quality. So, we believe that overall, through the proposals, it encourages industries and others to have rigorous internal processes, as well as information sharing as relates to their practices in the technology, as well as the transparency around that and how they can be helpful for potential implementors as well as users to more easily determine themselves if they are actually faves.

And so, you will see different perspectives here where we have tried to identify areas which, from a patient perspective, really focus on how the proposals could impact patients as well as providers, developers, and industries, but overall, the intent is that the resulting information transparency would enable users, including clinicians, hospital administrators, nurses, and things of that nature to scrutinize these technologies. It would increase public trust and confidence in these technologies as well, but also, we are hopeful that patients would be able to understand and to have more confidence and trust that, as a result of what we are proposing, it would allow them to benefit from healthcare providers using trustworthy predictive models for decisions related to their care, as well as connections related to being able to access some of that information. I will turn it back over to Elise.

Elise Sweeney Anthony

All right, thank you so much, Kathryn, and thank you, Mike. So, we are going to go through a couple of components regarding the charge and some resources, and then we are going to open it up for questions. I do want folks to keep in mind that there are some questions we may be able to answer based upon what is in the rule itself, but in other cases, we suggest, as always, that folks submit comments, but that is the best route for us to get the feedback because that is the way that we are able to consider it in terms of the final rule. We are not able to consider comments that do not come in through that comment process, but to the extent that there is something in the rule that touches on it, I will try to point you in that direction as well.

All right, to that point, resources are on HealthIT.gov. If you go to HealthIT.gov, you will see two fact sheets that we have released so far. We plan to release additional ones as well, so that is a great plug for me to suggest that folks sign up for our listserv because you will get announcements when we release new aspects of fact sheets as well as it relates to webinars. We have three webinars that are scheduled right now, the NPRM overview, and then, one on the DSI and algorithm transparency proposals, and then, one on insights that Mike had talked about earlier. We also have some of our SMEs, our subject matter experts, who have been working hard to understand the landscape and to build out these proposals on these webinars as well, and in fact, for the Q&A that we have after I finish here, we will have some of our ONC experts on the line as well who can answer some of the questions that come up. Next slide.

So, how to submit a comment: We want to make sure that folks are aware of this because I know that we have a number of the public on the line as well, so I just want to emphasize, please do check out Regulations.gov, and you will see that there is an e-rulemaking portal where you can submit comments. And then, we will talk about the HITAC in terms of submission of public comments as well. The public comment template: This is not out yet. Right now, what is available at the *Federal Register* website is the public inspection version, but once we have the final *Federal Register* version, we are going to put together the public comment template.

I want to emphasize that it is not required that the public use the public comment template, but we put it together as a resource, in case helpful, so it kind of pulls the different sections of the rule, and then you can comment under each section, as it were. So, it is something we have done in the past. Many in the public have indicated that it has been helpful, so we are going to do that again, but again, we are going to wait until the *Federal Register* official version is out, and then we will map it to that for purposes of use. Next slide.

All right, the task force. Next slide. We are really excited about the task force. The HITAC has been charged regarding review of the ACI-1 proposed rule, and the task force is going to be the vehicle by which the recommendations and the rule is reviewed and then brought to the full HITAC for review and vote. So, the overall charge is listed here. In the interests of time, I am not going to read it per se, but this is available on HealthIT.gov, as is this deck. Next slide.

What I did want to highlight is this specific charge that talks about some of the areas under the new and revised standards and certification criteria, as well as the condition and maintenance of certification requirements, the RFIs, etc. Next slide. And then, here, the task force would be one task force divided into three groups, and that is so we recognize that all of the HITAC members do this in their spare time. We know you do have day jobs, and there may be specific areas where you would like to contribute your time as part of the task force work, so the groups for the task force are listed here. This is Group 1, with a focus

on information blocking, and then, Group 2 focuses on health IT certification updates. You can see it related to the new and revised certification criteria, and then, we also have Group 3, which also focuses on certification program updates with a focus on insights, conditions, standards, updates, and the RFIs. Next slide.

Okay, here is the roster for the task force. We are going to be working with the team, and I really want to thank the chairs of the HTI-1 proposed rule task force for their contributions and really supporting this work. It is always so helpful to ONC when the comments come in from across the public, including from the HITAC, and I know it is a lot of work to get that done across the entire task force, and particularly with the co-chairs' leadership, so I want to thank the co-chairs and all of the task force members for that. Mike Berry will be working in the coming days with the co-chairs in terms of the groups and organizing the groups and the members in each group as well. Next slide.

So, the proposed meeting schedule: You can see that the task force meetings will begin on April 25th, 2023, and from there, you will see they will be meeting in sequence over time to get to the point of having the comments in by the end of the public comment period. Next slide. I think that is it. All right, with that, we are going to go ahead and open for questions. I guess I will turn it back to you, Aaron and Medell.

Aaron Miri
Thank you, Elise. I appreciate the comments very, very much. First of all, I want to credit you, Elise, Kathryn, Mike, and the whole team there for breaking this down into plain English for us, so we really appreciate that explanation and your working through it. First of all, I want to say that all the comments in the public chat will be part of the record, and they will be notated there so you can go back and follow up. There is a lot of great conversation in the chat window there, and good questions that were asked, so we want to go back and reference that. Just know that it will be part of the official record, and you can go back and look at that. With that, I will invite the HITAC to please raise hands. I will say that we have a hard stop at 12:45 p.m. Eastern Time to go to the next section. However, if there is time at the very end, I do promise we will go back to try to answer any additional questions there going forward. In the order of hands raised thus far, let's go with Dr. Jim Jirjis first.

Jim Jirjis
I have more of a comment here. First of all, the rule really addresses a lot of feedback that people have given over time, so, congratulations on including that, and inclusiveness health equity traction is just wonderful to see. The other comment is particularly around the FDA algorithms. It is very delightful to see such collaboration and coordination across HHS entities. I have no questions, just kudos.

Aaron Miri
Wonderful, Jim. I appreciate that very much. Dr. Briggs-Malonson?

Medell Briggs-Malonson
Thank you, Aaron. I am just going to amplify what Jim just mentioned. I just wanted to say congratulations on putting together this proposed rule. The alignment across all the various different partner agencies is very comprehensive. I did have one question. Is there going to be a planned sub-task force for DSI in particular? We know that DSI is so incredibly important right now and is being accelerated throughout our industry, and it has the potential to not only improve overall health outcomes, but also to mitigate health

inequities, but, of course, it has to be developed appropriately or it can actually worsen health inequities. So, is there going to be a task force from HITAC that is specifically looking at DSI?

Elise Sweeney Anthony
Mike Berry, feel free to jump in, but the way it is set up now, DSI is part of the task force review for HTI-1, but it is part of the groups. So, if that is something that the HITAC chairs would like us to consider, we are happy to look at that as well. Just to make sure I am understanding, are you suggesting, Medell, that there is a separate group formed specifically focused on DSI and not on transparency?

Medell Briggs-Malonson
That is correct, Elise. At least, looking at the three groups that were presented just now, it did not seem like there was a particular sub-task force focused solely on DSI and all the various different components of transparency, trustworthiness, as well as the various different inputs and how it is going to be presented to all the various different stakeholders, and we know this is an area of significant interest throughout the nation, and we want to make sure that if this HITAC is able to be there to provide input on how best to make sure we are identifying those factors that are going into DSI, that we do have some dedicated time in order to do so. So, my recommendation is, if possible, to have a completely separate group to focus on DSI.

Elise Sweeney Anthony
Okay. We will take a look at that. Our expectation is that it would take a fair amount of discussion in one of the groups where it is designated, but we can look at whether we can have it be a fourth group. I think we also want to be cognizant of the time constraints for the HITAC members in terms of participation in multiple groups, but we absolutely are looking forward to feedback, and whether that is part of an existing group or a fourth group, we are open to it, so we will follow up on that as well.

Aaron Miri
Great comments, Medell. Thank you for that. Anna, you are up next.

Anna McCollister
I just wanted to second Medell's comments. I feel like the algorithm question and how that is managed is one that is going to be of significant public interest, particularly amongst patients. It is such an incredibly complex issue, with many facets, and it feels distinct from the other categories that we have discussed, but it seems to be more its own sub-task force. I think there is going to be a lot of interest in that, so there should be and needs to be a lot of interest in this, and I do not want that to get lost in some of the other elements, which are equally important, but may be less abstract or obtuse to public participation.

Aaron Miri
That is a great point, Anna. We also faced this a few HITAC sessions ago with the pediatric care continuum task force, which was sort of a sub-topic, but it was very important, so we broke that out as its own tiger team to look at that and bring recommendations back, so it is a very good point, and I think the ONC team has a great plan to look at that and see where it belongs, but great feedback, Anna. Ike, you are up next.

Steven Eichner
Thank you so much for that. Anna, I wholeheartedly agree with you about the importance of considering looking at algorithms. That was the reason I wanted to talk for just a moment, A). Just to get a little more

information from Elise about how algorithms are addressed in the proposed rule and, without making public comment, thinking about for all the… I happen to have a rare disease. Things that work well for everybody else work really badly for me personally many times, and I would hate to have medicine applied by disease. If I go to an ER and someone says, "Here is the standard protocol for X," and they try the standard protocols for me, it could literally make me permanently immobile for the rest of my life, and that is not undoable, so I am really sensitive about these kinds of pieces, and I want to point it a little bit more about what is in the draft rule, and then figure out how we explore it as part of task force.

Elise Sweeney Anthony
Thank you. I will turn it to Kathryn to jump in on that question.

Kathryn Marchesini
So, to the extent a specific task force or…?

Steven Eichner
The question at the moment is what is in the base rule as a starting place, recognizing that comments on the existing rule are part of the comment period, but where are we starting from the draft?

Kathryn Marchesini
I guess there are kind of two areas. One is there is a section focused on building out source attributes, additional categories specific to the technical and performance aspects of the technology, so, intended use, preferred ways to use such technology, as well as really getting into the specifics of the algorithm itself, and then, other areas like the data it was trained on, how it was evaluated, if it was learning data, how it was in terms of evaluation, and also, looking at the maintenance area. So, I would say there is a framework of categories, and we also asked for comment on consideration if there should be additional areas that we should require source attributes.

Also, we spoke to the risk of categories, so we identify in the proposed regulation around identification or risk analysis, risk mitigation, as well as governance, so I would say the frameworks are there. So, to the extent there are specific comments on what is proposed, I would say that is a great place to start a conversation. The other thing I did not touch on is we at ONC know that there are a lot of other aspects that may contribute to concerns around the use of this technology, things dealing with the quality of the data, data standards, the fact that users in healthcare organizations also have a role related to responsible use and trustworthy use in addition to the ethical, legal, and social implications of the initial use of the data. So, we have requests for comments on those other areas that are of interest, and if there are areas that ONC or even the department address some of the concerns around that as well. So, hopefully, that is a little bit more helpful as you are thinking through.

Steven Eichner
Yes, because there may be places where following methodology or an algorithm is actually not necessarily the best practice.

Kathryn Marchesini
Right. So, the proposal actually leaves that open. It is not too prescriptive on the methodology that is used. Think of categories. It is more of trying to identify the consistent types of information or level of information

that should be provided on the particular type of technology. There is some language in there about additional frameworks or other approaches that could be used, but the proposal leaves that open to industry for input, but it is not that prescriptive.

Steven Eichner
Okay, thank you.

Aaron Miri
All right. Great questions, great comments there. Thank you, Kathryn, for that. Any other questions or comments, HITAC? You guys were chatty in the chatboxes there, so I figured you have more questions. I am not seeing any. We want to give one more minute, though. This is a very important rule, and I am sure people are still digesting and reading the rule, all 500-plus pages, and memorizing key passages, and every "whereas," "thou shall," and all those things. All right, Dr. Steven Lane, you are up, sir.

Steven Lane
Thanks. There was more rulemaking that came out this morning, and some new FAQs. Are we going to have time today in the agenda to talk about those?

Elise Sweeney Anthony
Well, I can start, and then I can turn it over to Kathryn. The rulemaking was not an ONC rulemaking, it was an OCR rulemaking, so we would not be able to comment or present on that rule. Kathryn and Rachel Nelson from our rulemaking team also put together a blog that talks about our intersection with other federal, state, local, and tribal laws, including HIPAA, so I can turn it to Kathryn to talk about that, but the focus of this presentation was really on HTI-1, but we are happy to come back if there are any additional questions on the FAQs that ONC released. On the OCR rule, I would definitely direct folks to where they have a page, and they have a fact sheet and a press release on the rule that they released today. I will drop that in the chat. Kathryn?

Kathryn Marchesini
Just at a very high level, as Elise mentioned, you can read in the blog that Rachel Nelson and I worked together to compile that we are really trying to explain the intersection of HIPAA and information blocking, realizing that there is a proposed rule, but you will see us really trying to focus on the fact of how the information-blocking regulations work in concert with HIPAA and really that ONC designed our regulations with the understanding that many actors would need to continue to comply with the HIPPA rules. And so, what you will see is even in addition to what is being proposed, the information-blocking regulations accommodate and adapt to proposals, whether it is federal law, state law, or other things of that nature. At a very baseline point, if another law that applies to the actor prohibits the sharing of EHI in a particular circumstance or for a particular purpose, then not sharing the EHI in particular circumstances would not be information blocking.

Two other areas are really trying to focus on the fact that if another law applies to an actor, if it permits the actor to share the information only if specific requirements are met. So, some of you may be familiar with the preconditions and the privacy exception. The information-blocking regulations allow for actors to take reasonable and necessary steps to ensure that the actor shares EHI only when those requirements are met. Lastly, if there is a federal or state law that restricts or prohibits the sharing of EHI, if that changes, the

information-blocking regulations are built to automatically accommodate actors and their overall needs to comply with those laws as soon as the changes are in effect. So, what is being proposed today is just proposed, and it is not finalized, but we wanted to try to have the conversation because in the current state of how information-blocking regulation works, it would be applicable to existing federal, state, tribal, and community laws as well. I will turn it back over to Aaron.

Aaron Miri
Absolutely, Kathryn. Thank you. Steven, I hope that answer helps, and also, it is bringing up a good point that perhaps, in the future, once a rule is finalized, we could also consider inviting the OCR here to do an update and talk more about this once there is a final ruling and it is appropriate to do so. We can always talk about that. We did that before, historically, if you recall, when considerations were being made around privacy and security, so there is always that option. All right, we have about four minutes left. Any other questions from HITAC members or folks that are curious? Steven, is your hand still up? Do you have another question?

Steven Lane
Yes, back up. There was also the issue of the new FAQs. Can we take a couple of minutes to discuss them? Looking on the website, there are four FAQs flagged.

Elise Sweeney Anthony
Yes, and I think that is what Kathryn was just walking through. The FAQs pretty much walk through what Kathryn just mentioned in terms of the intersection between information blocking and other laws, whether that is HIPAA or other federal, state, local, or tribal laws. So, that is what the FAQs focus on specifically. There are four FAQs. Three FAQs focus on that, and those are noted in the blog as well, and I see Rachel came on, so I will give Rachel the opportunity. Do you want to add more there or talk about the suite of all four FAQs?

Rachel Nelson
I think I was only double muted.

Aaron Miri
There you are.

Rachel Nelson
Sometimes it is double, sometimes it is triple. So, three of the FAQs are mentioned in the blog, and they are specific to the intersection with federal privacy law and with other privacy law. The fourth FAQ talks about enforcement timing and gives a little bit more expectation. It puts in writing in an FAQ some things that have already been said, for example, in the Office of the Inspector General's proposed rulemaking that came out a couple years ago for which a final rule is still targeted at this point for later this calendar year. I do not really have much more to say except…

Elise Sweeney Anthony
I think you went out a little bit. I do not know if you are back, Rachel, but I will say that the FAQ process is something that we have in place, and we build on them over time. We look at questions that are coming into us through the portal, areas where we think additional clarification could be helpful, and they are really

focused on information blocking. I think we dropped the link in, so you will see where they are noted. In this case, we thought it would be really helpful to release the three FAQs that are noted in the blog, and also the additional one on enforcement. We do hope that those are extremely helpful to the landscape and will make sure that we drop the notes in there, but Steven, let me know if that does not answer your question.

Steven Lane
That is great, thank you.

Aaron Miri
Fabulous. All right, one last go-round. We have about half a minute left, so we want to give everybody every full second to ask questions.

Elise Sweeney Anthony
As we round that out, I will take the opportunity to say thank you. I know it is a tremendous amount of work that is coming up in terms of the three groups and the task force's work on the rule, but I cannot emphasize enough how important it is to get that feedback, and also from the public who is also on the line. I know I say this every time we do a rule, but it is so important that we get feedback on where we may have gotten it right or where we may have gotten it wrong. All of that really helps us to build out a solid final rule that can really be implementable and effective on the ground, so we look forward to all of the work that the HITAC has coming. Also, in terms of the groups, as I said, we will have our SMEs join in and be able to do walkthroughs or overviews of the provisions as part of the process for you to provide recommendations, so we hope that is helpful as well.

Aaron Miri
Thank you, Elise. I appreciate it. Kudos to your team, and I really appreciate all the hard work the ONC team does. You guys are magic. Thank you for making it understandable for us and getting us to the goal. I really appreciate you. All righty, with that, hopefully everybody stretched and ate their Wheaties. Time for another good topic as we get into the Interoperability Standards Workgroup recommendations for the draft USCDI Version 4. This is going to be going up for a HITAC vote, so pay attention and get out your pencils because it will be a good time to talk about it. With that, let's send it to Sarah and Naresh. You are up.

Interoperability Standards Workgroup Recommendations on Draft USCDI Version 4 – HITAC Vote (01:44:18)

Naresh Sundar Rajan
All right, thanks, Aaron. I can kick us off from my end. Next slide, please. Here is the agenda today. We will go through the overall update around our work plan and charge and then leave us at our USCDI motion for recommendation of Level 2 data elements. Next slide, please. I just want to take a minute to thank all the team members who were involved in this process. There were a lot of meaningful discussions, diverse stakeholders, including ONC staff, specifically Al and Carmela helping us as new co-chairs, myself and Sarah here, with the ways of doing operations around going forward with IS WG. There are also a lot of discussions that we have gone through so far with respect to Level 2 data elements which needed subject matter expertise on how to arrive at a consensus around that. We will go through each one of them on the next few slides. Next slide, please.

To reiterate here, specifically, the overarching charge was to review and provide recommendations that were drafted in USCDI Version 4. Specifically, the one charge that we had was to evaluate the question force and provide recommendation back to HITAC, the straightforward data elements that were presented or proposed in the draft V.4, and then, Level 2, additional data elements that were not present that we fully discussed. Next slide, please.

So, here is our work plan and how we approached this in the past six weeks or so. February was around discussions of existing straightforward data elements that were proposed, and then further discussions with SMEs in the month of March, which included physical activity, treatment and permission, care experience preferences, facility information, diagnostic imaging data, etc. Further details will be coming through on the next slides through Sarah. Next slide. On the whole, we have had a total of 15 recommendations on the straightforward data elements, 18 Level 2 recommendations as part of the work, and one future consideration for recommendation on a data element specifically, and we will go through that. In total, there are 34 data elements with specifically eight different classes that you see here and one new class, which is the facility information as part of V.4 that is going to be recommended, which has different data elements altogether. Next slide, please.

Here are the SME presentations that happened in the month of March. Again, we would like to take a minute to recognize those who have taken an enormous amount of effort in explaining each one of those domains or classes, the data elements' needs, and recommendations around the workgroup members, and here is the list of folks that have actually helped us a lot in getting it to final consensus. With this, I will move forward, handing it to Sarah, our co-chair, who will get into the next steps of recommendation report format. Sarah, all yours.

Sarah DeSilvey
Naresh, thank you so much. I am going to remain off camera because I come to you from rural Vermont, and bandwidth concerns apply. I am going to be going into the draft USCDI V.4 recommendations. Of note, all the recommendations in USCDI draft V.4 were approved by IS WG, but an important thing to know about the content and individuals on our committee is that they all have different areas of expertise, so we have experts on laboratory, experts on clinical science, different perspectives, public health, clinical health, patient perspectives, care planning, and pharmacy, so one of the jobs of the IS WG is to give nuance and subtlety, including recommendations integrating with existing standards.

The full nuances of these recommendations are contained in the formal report, the transmittal letter, to HITAC, so this is a brief summary as we go forward. Highlighting really specific areas of nuance, again, just to make sure everyone is aware prior to the vote, in addition to reviewing the new rule just covered, we do hope you have had time to review the full recommendations that were sent because they really offered the breadth of what we had to say. Next slide, please.

The formal report that we sent over has background. It initially goes over all the USCDI V.4 data element recommendations and then elevates those Level 2 data element recommendations, and again, there is one recommendation for future consideration. Next slide, please. What we are doing is highlighting the recommendations here. There will be opportunity for questions, led by Medell and Aaron, at the end, and I do want to highlight that we have representatives from each of our areas of expertise on the call, so if there

are specific recommendations that need to bring forward their information, such as laboratory, pharmacy, public health, or patient perspectives, we can do that at that time.

So, Recommendation 1 is recommending that ONC add allergies and intolerant substances, nonmedication, with clarification that this extends the existing elements to cover nonmedication substances. This is a critical absence, just to note that this needed to be elevated. Next slide, please. Again, I am going to be running through them, and we will have questions at the end. We recommended that alcohol use be added, referencing the specific LOINC codes mentioned at submission. We also recommended SNOMED CT as an applicable vocabulary standard. Next slide, please. We also recommend the substance use reference of specific LOINC codes mentioned in the submission. The definition itself clarifies substance use that is nonmedical versus medical, so we did not addend this submission with that information, but it is important to note that this is the nonmedical use of substances. Next slide, please.

Recommendation No. 4 was recommending that ONC work with CDC, CMS, state, tribal, local, and territorial agencies to identify and evolve appropriate vocabulary standards for facility information/facility type. These are really critical. We have had long conversations regarding the facility information, and part of the job of IS WG is to lean into areas of opportunity for future recommendations in future versions of USCDI. Next slide, please. Recommendation No. 5 was recommending that ONC include the following applicable standards for facility information/facility identifier. This includes the CCN, the PTIN, NPI, and CLIA. Again, these are all submitted and supported by our experts in the public health and CMS/CDC ecosystem, and were advanced without concern by the IS WG. Next slide, please.

Recommendation No. 6 is recommending that ONC specify that vital signs average blood pressure includes, at minimum, the following LOINC codes as applicable vocabulary standards. Again, extensive information about the utility of average blood pressure for assessing given new blood pressure management recommendations. This was carried forward. Next slide, please. Recommendation No. 7 is recommending that ONC reference the following code systems applicable standard for laboratory result interpretation, and this is the observation interpretation from FHIR, so this is part of the original APHL submission. We just wanted to make sure that this was referenced. I want to note that there are extensive development and recommendations in the laboratory sections. Almost all of these, and I would say all, are really binding us to CLIA, and these are therefore making sure that we follow the guidance of CLIA in what we are recommending EHRs gather as part of USCDI, and great thanks to the sub-group that led these recommendations. There is a whole set of them. Next slide, please.

We recommend that ONC add language to the definitions of the following data elements, that they are required by CLIA. Again, this is the note: Reference range, results unit of measure, and specimen source site. Next slide, please. We recommend that ONC specifically, in its definition of laboratory specimen identifier, recommend that it is intended to include the accession number assigned to the specimen, again, required by CLIA. So, this was, again, a nod to the immense group of the subcommittee that worked on laboratory elements. Next slide, please. We recommend that ONC rename the proposed laboratory specimen condition and disposition data element to specimen exception annotation. It is again in alliance with CLIA. This renaming was at the recommendation of our colleagues at ONC, and this was carried forward by the IS WG, because the need to do so was clarified by the laboratory subcommittee of the IS WG. Next slide, please.

Because such extensive development was performed in the laboratory element of all those separate laboratory elements that we discussed in that laboratory group, IS WG needed to ground itself by stating that ONC just will not use procedures/time of procedure to represent the collection date and time for laboratory tests because of specific requirements for laboratory timing, and examples are contained in the recommendations for the laboratory subcommittee that we just reviewed prior. Again, this is just to make sure that those necessary elements for laboratory processing are documented according to standards. Next slide, please.

Recommendation No. 12 is recommending that ONC make the following changes to medications/medications instructions data element, including specific components included in structured and codified, signature patient directions, route of admin, quantity, timing, and special instructions. I do want to note that akin to laboratory, there was a lot of development in the medication elements in USCDI this year, recommendations both in USCDI V.4 and in Level 2 elements we are recommending, and in recommendations for future work. You will see that throughout our recommendations to HITAC. Next slide, please.

Recommendation No. 13 is recommending that ONC make the following changes to the medication adherence data element, including two specific components, adherence codes and reason for patient nonadherence. This, again, is very critical from a patient-centered perspective to make sure that we center the patient voice in reasons for not taking medication. We are very grateful for our patient advocates and patient voices who helped us get this right, and again, thankful for our pharmacy experts who led a subcommittee on all these elements, so, thank you, pharmacy friends. Next slide, please.

We recommend that ONC rename the goals data class to goals and preferences to really better contain the elements that are now grouped under this. The change will better accommodate the range of concepts therein, including patient goals, SDOH goals, and the new data elements of treatment intervention preference and care experience preference. Again, this is in line with other accelerator work across the ecosystem to make sure we had representatives come and ensure that we were in line. Next slide, please. Recommendation No. 15 is recommending that ONC add health status assessments physical activity and references specific LOINC codes of the base measures mentioned at submission. This is just clarifying it is not representing the entire IG of the amazing work of AHA leading a physical activity accelerator, but really leaning into those assessments that are appropriate in the health status assessments section of USCDI. Next slide, please.

That was the completion of the USCDI V.4 elements that came to us. Again, our work was really referencing subtlety and nuance and alignment with other standards, given the vast perspectives and expertise in IS WG. I am now going to go forward with the Level 2 data elements as the second part of our charge, so these were elements that were not included in draft USCDI V.4 that we are recommending for inclusion based on their status of Level 2. Next slide, please.

Recommendation 16 is recommending that ONC rename the patient summary and plan data class to patient care plan, and the assessment and plan of treatment data element to care plan summary, and there is also a further refinement that ONC should work with interested parties to quickly develop those core structured data elements beyond a narrative summary into care plan data class in order to help meet immediate needs. This makes a critical advance, moving care plan to a more shareable data class. Again,

this is really centering the work of patients that are care planning and patients under care, really trying to make sure those critical elements of patient voices and patient care plans are part of USCDI. Full recommendations are, again, in our full spec that we sent over to HITAC, and there is a link in the chat. Next slide, please. Again, thank you to the subcommittee that worked on that extensive work, advanced directives, care plans, pharmacy, and medications.

Recommendation 17 is recommending that ONC include advance directive in USCDI V.4 with an immediate priority focusing on establishing an onramp for access to currently available unstructured advance directive documents such as PDFs and scanned images. We also recommend that we include advance directive as a care plan type in the care plan data class as per Recommendation 16. This is to enable access to structured data from advance directives. Again, you can see a really core focus on ensuring patient voices and patient priorities are throughout USCDI in this recommendation and others from the IS WG. Next slide, please.

Recommendation 18 recommends that ONC add the following clinical notes to USCDI V.4. This is operative note and emergency department note. We do note that we do not want a proliferation of all possible note types, but we really leaned into the critical nature of both of these notes for a public health perspective, follow-up perspective, and safety perspective, so we are recommending them and their associated LOINC identifiers. Next slide, please. Recommendation 19 is recommending again that ONC add the following data elements, definitions, and value sets from the amazing work of the Gender Harmony Project to USCDI V.4. These include elements of gender identity, sex for clinical use, recorded sex or gender, name to use, and pronouns. Next slide, please.

Recommendation 20 is recommending that ONC change the name and definition of sex to become an example of recorded sex or gender, e.g., recorded at birth. Next slide, please. Recommendation 21 recommends that gender identity remain in the patient demographics information data class. When added, name to use and pronouns should be in the patient demographics information data class. Gender identity, name to use, and pronouns should be self-reported by the individual. So, this is clarifying, really, best practice regarding documenting these elements, not just where they belong and how they should be documented, but stating very clearly in line with the evidence that all this information is best self reported. Next slide, please.

Recommendation 22 recommends that ONC add metadata capturing source for the data elements sex for clinical use and recorded sex or gender and a method of collecting values for each data element. There are some questions regarding these. I do want to note that the extensive research and documentation work of the Gender Harmony Project within HL7 has source documents for all of this, and there is further information also in our full recommendation, just for reference and grounding in the literature there. Next slide, please. Recommendation 23 is, again, complicated. We recommend that ONC change the name of laboratory test performed date/time data element to specimen collection date/time and add specimen collection date/time as a data element to USCDI V.4. Again, this is due to the extensive work of the laboratory subgroup.

I think I actually might have misstated and said this is the one that we were advised to go forward with this way because of recommendations from ONC. This data element represents the most clinically relevant timepoint in which to interpret the result. In the case of observations taken directly from a subject, it's the

actual date and time an observation was obtained, so again, these are all critical elements for ensuring laboratory documentation correctly. Again, there is further information in the full recommendation of the transmittal letter sent over to the HITAC. Again, these were all led by that laboratory subgroup. The last element to note is the intent is that one element will be a subset and the above data elements would be combined. Next slide, please.

Recommendation 24 is recommending that ONC change the name of lab test report date/time data element to laboratory result report date/time and add laboratory result report date/time as a data element to USCDI V.4. So, as we were mentioning above, we really are trying to clarify the specific laboratory timestamps that are important for documenting from safety and from specifics for every single element within the laboratory request. That is part of us noting that procedure date and time did not apply to laboratory elements, so this represents the most recent timestamp associated with completion of all components. Again, these were all led by our laboratory subgroup. Next slide, please.

Recommendation 24 is, again, part of that laboratory subgroup, recommending that ONC add laboratory test kit device name and manufacturer to USCDI V.4. ONC should initially include the device name and manufacturer component of the test kit device and address the barriers to including the full UDI in the next USCDI version. This is one of those areas, as we have noted, akin to facility information, where we are identifying what we can state now and asking ONC to lean into the opportunities to fully make sure that we align with best practice in future versions of the USCDI. Next slide, please.

Recommendation 26 is recommending that ONC add provenance/author in USCDI V.4. This is relevant for patient-generated health data and patient-reported outcomes. We recommend that ONC include author in USCDI V.4 for the following USCDI and draft USCDI V.4 data elements that represent self-reported data. Again, in these instances, self-report is best practice and supported by the literature and requirements. We also recommend the following Level 2 elements that capture important patient-generated health data and further advancing those Level 2 elements to USCDI V.4. Next slide, please.

Recommendation 27 is to recommend data elements that may be used to capture patient-generated health data and to support bidirectional exchange in USCDI V.4. This is Recommendation 27. So, we did review possibly combining these, but we are asking that these remain separate as two different recommendations. This includes family history, reported medication, and everything on the list. Again, further information is in the full recommendation. I apologize for going fast. We have a lot to cover to allow for questions at the end. Next slide, please.

Recommendation 28 is recommending including the following three diagnostic imaging data elements in USCDI V.4. These include imaging reference, requested procedure identifier, and accession number. There is a comment to the ecosystem and what the ecosystem can do. This is important to note, so while not all HIT systems currently capture, maintain, or share information to access and view DICOM images, the requirement to exchange it when available… Again, there are some extensive comments on this regarding the proposed rule earlier in the chat. The requirement to exchange it when available would significantly advance the ability for individuals and providers to access and use diagnostic images and data files utilizing broadly available technology and would support current implementations of DICOM image file access and use with or without side networks, such as Carequality and the Trusted Exchange Framework. Next slide, please.

This is a recommendation that ONC add facility information and facility address to USCDI V.4. Facility address is part of a core set of facility-level data elements needed to link data to a specific physical place, service, or resource. Again, these came from our colleagues in the public health ecosystem and were supported by the IS WG. Next slide, please. Recommendation 30 is to recommend that ONC add medications, medication prescribed code, and medication route to USCDI V.4, as they are important data elements for quality measurement and public health.

We do want to note that we had extensive conversation in the IS WG regarding many different status types of medication lists, whether they be discharge statuses or other statuses, and we want to make sure that we recommend that ONC work with stakeholders to define elements for documenting data elements for medication administered statuses. So, again, akin to other work, what we are saying is we are not ready to advance this data element right now, but please lean in, ONC and stakeholders, to ensure those critical elements within medication statuses are available for future versions. This is the second part of this recommendation. Next slide, please.

Recommendation 31 is to recommend that ONC add vaccinations/vaccination event record type data element to USCDI V.4. It came from our colleagues in the CDC and CMS ecosystem. Next slide, please. Recommendation 32 is to recommend that ONC add orders/orders for end-of-life care data element to USCDI V.4. Next slide. Recommendation 33 is to recommend that ONC expand the definitions of the following health status assessments data elements to include not only the specific assessment questions, but also the responses or results of the assessments. This is, again, brought forward by our colleagues at CDC and CMS with full support of the IS WG, so this would apply to functional status, disability status, and mental/cognitive status. Again, they align with existing work across the ecosystem, including PACIO Project IDs. Next slide, please.

Our last recommendation is a recommendation for future consideration. I do want to note that you saw throughout the recommendations that some of the recommendations for future work were bound to the recommendation itself within the context of that rec. That was at the request of the IS WG because it provides critical context for how we wish the recommendation for future work be applied. This one is unique, so, next slide, please.

This is a recommendation separate from other ones, so Recommendation 34 is recommending that ONC reevaluate organization/organization identifier as a Level 2 data element for consideration for addition to future versions of USCDI, which would include updating the definition or the applicable standards to include NHSN org ID as one of the applicable, widely used national standards in, really, a hope that ONC would collaborate with CMS to evaluate moving the CCN from the currently proposed facility information data class to this organization data class. So, these just came out of our conversation regarding facilities, and we are asking that ONC work with stakeholders again to lean into this work to prepare for future versions of USCDI. Next slide, please.

We are on to discussion. Thank you for tolerating my rapid-fire review of the recommendations from IS WG. Again, Naresh opened us out, and I am going to close us out by saying a sincere thank you to welcoming Naresh and me as your co-chairs and a sincere, even deeper thank you to the amazing wisdom and

expertise of the IS WG committee that worked extensively, deeply, and brilliantly over the course of the last couple months. Now, back to you, Medell and Aaron.

Medell Briggs-Malonson
Thank you, Sarah, and I also have to extend a sincere congratulations and thank you to both of you as the co-chairs of the IS WG, both Sarah and Naresh, and thank you to the entire workgroup. You all were able to truly put forth your expertise in this area in such a short time period, so we are very grateful as the HITAC for you all doing this work and presenting this back to us. And so, we know there are several different questions already in the chat, and I am sure many other people want to ask their questions as well, so we will go ahead and get started, and the first hand that I see is Steven Lane's, and Clem, I know you have a question as well, so please do raise your hand and we will get to you right after Steven.

Steven Lane
I just want to give incredible thanks to the co-chairs of this workgroup. This was a rapid-fire process through a lot of changes. They did a wonderful job stepping up, both brand-new co-chairs, and the group got through all of the recommendations and put together these suggestions with consensus, and I just fully support the co-chairs and the recommendations and everyone on the workgroup.

Medell Briggs-Malonson
Thank you, Steven. Hear, hear. Thank you for those wonderful words. Clem, you are up next. Clem, if you are speaking, we cannot hear you right now. Clem, while we are getting everything working, we will come back to you in just a moment, as soon as we figure out how to unmute you. Any other questions? If not, we can go to some of the various different questions that were actually in the chat. And so, just to begin with, Hannah, I know that you had a question. There was some activity. Did you want to ask your question coming off the mic, and then we can have several different discussions? I know Eliel had some additional questions related to your additional one.

Hannah Galvin
No, that is great. Thanks, Medell. Sarah, I heard you mention sex at birth, and I just wanted to clarify around the terminology, and Steven helpfully put in the link to the Gender Harmony Project just to understand and make sure we are all clear about what we are meaning by "sex" and "gender" and whether sex is just biological sex, or whether there is a specification, or whether the group is asking ONC for additional specification for either sex at birth or legal sex, or just leaving it as biological sex. That was my question. I had thought that I understood you to say that there was some ask for additional specification around sex at birth, but I may have misheard.

Medell Briggs-Malonson
Sarah and Naresh, did you want to answer that question? Eliel and I both have a related question to that as well.

Sarah DeSilvey
I can answer that our recommendations are fully in line with the Gender Harmony Project recommendations, which determine variations on what elements of sex are required. There is recorded sex at birth, which, in some instances, will be the same as legal sex, unless there are variations, and there is also advancing sex for clinical use, which would drive the use of specific sex documentation that is required for things such as

organ-required imaging or hormonal-required laboratory analysis. Mark, do you further wish to come forward as the lead of this submission in order to clarify better questions for Hannah, Medell, and possibly Eliel?

Medell Briggs-Malonson
Is Mark here as a panelist?

Sarah DeSilvey
Mark is here. Maybe he is not here as a panelist. He writes that he does not know how to talk.

Naresh Sundar Rajan
I can possibly answer the question to the link page. The question expands into more how the importance of the data element would actually relate to the link page. So, our recommendation is to go with the standard of nomenclature, but then, on the linking side, if you think about weightage, for example, as part of matching, you can weight by the importance of the data elements or by the specific data elements that flow in, and by the classification further. So, it is a bit of an extension beyond metadata at this point in time, beyond USCDI's scope, I would say, but then, that is a known issue, so it is not just for this gender perspective, but it is also existing in other areas of the classes in USCDI, if that makes sense.

Medell Briggs-Malonson
That was just my quick comment, and I want to go to Eliel, and we are trying to unmute Clem as well. The Gender Harmony Project has done some amazing work. And then, the two various different terms of sex for clinical use versus recorded sex or gender… Based off the various different rules that are used, especially within a lot of our electronic health record systems and other health IT platforms, just making sure that there is some clear definition of when to use which may be helpful.

Both myself and my organization have done a large amount of redesign of our systems in order to provide equitable, affirming care to all of our various different patients and the gender diversity that does exist, and as we know, there are various different clinical decision roles as well as lab values that are reported that are mapped directly to various different fields, so as we continue to support all of our patients, especially in terms of that inclusive, affirming care for our gender-diverse patients in particular, making sure that the public in these standards also have clear definitions for which of the various different fields or terms may be used in order to drive various different aspects to provide both safe care, but also clinical excellence as well, so that was just one of my comments also. Eliel, you are up next, and then Clem and Arien.

Eliel Oliveira
Thanks, Medell. I guess I will just add some more detail and example of why I am asking this. I think we are going to hear about the lead projects in a bit, and one of the ones we worked on was a mobile platform for patients to get access to their medical records, and in order to do that, we needed to do some linkage and matching with the health information exchange, which, as you know, is ingested from electronic health records, and we were promising that we were going to use FHIR standards in that process, but in the collection of gender used in the FHIR standards, we would not be able to match with the way that the health information exchanges store gender, so we are not able to get one match done until we manually have to do some mapping to be able to allow that to happen.

So, I am saying all that to make a point that, like you just said, Medell, in order to allow for linkage to take place, I think we need to be crystal clear what the element is that needs to be collected for gender or sex across organizations nationally and not changeable. Otherwise, we create a very big challenge in terms of linking individuals, and I agree with the weights being put in different elements that are being used for matching, but if we are not clear enough of what is the element that we all have to do uniformly, it is just going to create a lot of challenges down the road.

Medell Briggs-Malonson
Great observations, Eliel, and there are some additional chats directly from Sarah and Mark saying some of the definitions and trying to make sure there are the appropriate linkages that are there, but thank you for bringing that up. Clem, you are next. We have been waiting. Maybe I can ask the HITAC admin if we can unmute Clem. Just one moment, Clem. You are still on mute. We can hear you now, Clem.

Clem McDonald
I want to get my hand down.

Medell Briggs-Malonson
We will take care of that for you, but now we can hear you.

Clem McDonald
Okay, but I do not have anything to say.

Medell Briggs-Malonson
Okay, thank you so much. Arien?

Arien Malec
Thank you. Hopefully you can hear me. I am having some technical difficulties at home. I just want to remind the full committee that we covered these topics in depth in our last update, and, as many people have mentioned, the Gender Harmony workgroup has done a really fantastic job at putting together an ontology for what can be a very complicated situation, but the general answers are that the sex assigned at birth or sex recorded at birth is the general immutable observation that is implied is often used in a patient-matching context. In an HIE context, it generally assigns to the administrative sex that is attached to the person, but when it wants to be immutable, it really wants to be the observation that was made at time of birth. Again, sometimes that can be a complicated situation, but often can serve as a relatively stable, immutable identifier.

And then, as many people have mentioned, where we really need to get to is a place where we think in some of the complicated situations that we use sex for clinical use, which can differ in different clinical contexts. The standard examples are an imaging exam that may be looking for anatomical differences versus a laboratory exam that may actually be more sensitive to, for example, the hormonal milieu of the individual.

So, where we really want to go to for clinical use is thinking about sex for clinical use as the primary clinical marker that is being used, and then, I agree that this would merit some additional specification, but in the areas where we are looking for an immutable observation for patient matching, what we are really looking

for is the administrative classification of a human being that was made at the time of birth. It is pretty crude in some circumstances, but it does serve the purpose for which we are looking, so I just wanted to make some clarifications for the full committee and remind folks that the Gender Harmony workgroup has done a really fantastic job. There are a lot of very in-depth presentations, and if you look back, I think, a year ago at the Gender Harmony presentation that was done for the Interoperability Standards Workgroup, you will see a lot of the reflection there, so, thanks to the full committee, and thanks to the task force.

Medell Briggs-Malonson
Thank you, Arien, for those important, important insights because you are exactly correct. We are trying to move past just the basics that we have done historically and really make sure that we are providing the best care and outcomes to all of our patients, and especially, again, our patients that tend to be more gender minorities or have other various different aspects that we have to make sure that our systems are supporting them. So, I really appreciate that, and again, I cannot express my gratitude for the work that has been done by the Gender Harmony Project and, of course, IS WG. So, I am just going to see if there are any other questions or any other comments because we definitely need to take a HITAC vote on all of these amazing recommendations. So, any additional comments or questions?

Well, one additional comment, while people are thinking of any other questions, is that I also do want to say that the Level 2 recommendations, especially around the care plan and ensuring that we are incorporating our advance directives into that space, is so incredibly critical. Oftentimes, we put advance directives as almost a peripheral item when we are inviting care, but advance directives and end-of-life care are incredibly important for just the overall plan of care for both patients and their families, so we really do appreciate those recommendations of really making sure that we are structuring that a lot more for interoperability because it does make a difference, especially during those critical time periods where providers and others have to make decisions. So, I just wanted to, again, just say thank you for that. All right, I am not seeing any additional hands raised for questions or comments, so I think it is time for us to go to an official vote. So, I would like to call for a motion to approve the IS WG recommendations as written in their official report and as presented today. Do I have a motion?

Steven Lane
I would welcome the opportunity to make that motion, Medell.

Medell Briggs-Malonson
Excellent. I have an initial motion by Dr. Steven Lane. Do I have a second?

Naresh Sundar Rajan
This is Naresh. I second.

Medell Briggs-Malonson
Absolutely. We also have a second by Naresh. I really appreciate that. Now, let's go ahead and call for the vote. So, all in favor of approving the IS WG's recommendations say aye.

Several Speakers
Aye.

Medell Briggs-Malonson
Any nays? Any abstentions? Well, the IS WG recommendations to the HITAC have been fully approved. Thank you so much, again, to the amazing co-chairs, to this amazing workgroup. We greatly appreciate all of your work on this. And so, at this point in time, let's see where we are in our wonderful agenda. We are just going right on along. Next up is Avinash Shanbhag, who is going to give us some of our ONC Office of Technology updates. Avinash?

ONC Office of Technology Updates – Health IT Innovation (02:24:38)

Avinash Shanbhag
Thank you very much. I am just checking my audio is working well and you guys can hear me. Excellent. Well, thank you very much for having me here. My name is Avinash Shanbhag. I serve as the Executive Director of the Office of Technology, and I know this has been a very exciting day for you all, but do not worry, this is also going to be as exciting, if not more than, our proposed rule. So, I wanted to talk today a little bit about the work of innovation that we are doing within the Office of Technology at ONC. Next slide, please.

So, just for the agenda, I wanted to talk a little bit about our role in health IT innovation as a gauge to emphasize the importance of advancement health IT innovation in all the work that we do, and then I will talk a little bit about the work that we have done thus far through our Leading Edge Acceleration Projects, which we started in 2018 to give you a little bit of a snapshot of the work that has happened, and then focus a little bit on our exciting opportunity that we just recently announced of a new 2023 LEAP area of interest notice of funding opportunity. With that, next slide, please.

Hopefully, this will be a very quick, high-level overview. If there are any additional interests in knowing more details, we can certainly work with you all and come up with them at a later time, but at a high level, one takeaway I can give you all is ONC is very supportive of health IT innovation. I think you have all heard in our proposed rule a lot of things that have been put into our proposed rule that have come in our CURES rule previously have really been based on innovation work done by all of you, by the community of stakeholders. I want to mention that here. As part of the 21st Century CURES Act, innovation has been an important focus area request and part of ONC's mission, and again, that is something that we have worked along with you all to work over the last several years.

Again, previously, part of the HITECH Act, if folks remember the Strategic Health IT Advancement Research Project, the SHIAR program, that was started as part of the HITAC program really did a lot of very important innovation work, some of which has resulted in standards of practice that are not innovation, they are just actual standards activities that are now being implemented by industry as the normal processes. So, again, innovation has been an important area, and health IT innovation really helps drive the market towards ensuring that we have new technologies available for patient access and patient care. Next slide, please.

At a high level, within the Office of Technology, when we invest in innovation, the work is led by our strategic initiatives branch led by Stacey Bircham, and a very important part of that activity is our Leading Edge Acceleration Project. As I mentioned, we have had this program launched in 2018 as part of HITAC, and over the last five years, it has been strongly supported by our national coordinators. This is an area of innovative new solutions that, today, get tried and tested so that in the future, they become the standards of practice, and at a high level, each year, ONC publishes what we call an area of interest.

So, each year since 2018, we have published two areas of interest, and then, based on the input and responses we get from industry, we award two awards per year, four awards for two years, and really, the work that has happened has really helped shape a lot of work, and some of this work is very early innovation work, as Dr. Oliveira mentioned. As we go through the slide, some of the work that has happened here is early innovation work that really helps drive and identify some of the areas where standards are not as mature, but that really helps us realize where we need to lean in more as it comes to standards activity, as the group here working on USCDI very aptly identified. Next slide, please.

This is really a birds-eye view of the various LEAP activities that have occurred since 2018, and I am going to go very quickly over each of these in the time that I have, but at a high level, what I wanted you to take away was, for example, things that were considered innovation in 2018. At that time, we had just invested in identifying new APIs for getting access to a population-level data, and that became the bulk access implementation guide that then became part of the standards requirements for certified health IT, so I just wanted to mention that things that were considered an innovative base of handling in 2018 have slowly migrated into standard activities over the years.

Across the years, we have also not only focused on health IT innovation, but also, as you look through the areas, I will note that we also have focused on ensuring that health IT is meeting the needs of health data outcomes. So, each year, when we invest into these new areas, we also want to make sure that is always a component that makes sure that patient data is also a central part of our team, and the last several years, from 2020 onwards, you will see that we have heavily invested in ensuring that health IT has a health equity by design focus, and also ensuring that algorithms and ensuring the use of data within the health IT environment that is used by algorithms, and we had support that interventions are tested, researched, and identified so that we get an early idea of areas that we need to work on.

For the next few slides, I am going to breeze through and give you high-level views of things of interest, but definitely, there are links and references for the HITAC members to look into and get into details. Next slide, please. Now, just looking back at 2018, just to give you a quick overview, we had invested in pop health on flat FHIR, which really began, as I mentioned, this bulk access implementation guide, really a great way of giving API access to data in bulk that can be used by the research community, by the care community, and by other parties that are interested in accessing data on EHR. In 2018, on the flip side, we also had invested through our lead agency with MedStar in leveraging health IT architecture to advance clinical knowledge, and part of the outcome on that was the early adoption of developing a SMART on FHIR app. As we all know, fast forward five years, this has become a common way of doing it, and the industry is rapidly maturing. Next slide, please.

Moving on to 2019, again, if I pick on the two areas we focused on, we focused on consent and identifying the various areas where consent, both from a technology perspective and an innovation perspectives, are the issues that could be identified, and the team from San Diego Health Connect did a great job in testing out the early standards activity that was going on in concept, but also in identifying and developing the concept. Similarly, on what I think was the project that Dr. Oliveira mentioned, we also wanted to slowly understand how all this technology can be used based on patient engagement and some of the work that was done by the LEAP team from University of Texas at Austin really helped us understand and shape some of the equity considerations and the need for standards in those areas. Next slide, please.

Moving to 2020, again, as we come into 2020, as you can imagine, the CURES rule was published. We also knew that industry would take some time to catch up to build out the FHIR APIs, but knowing that there will be several years after which there will be these APIs already available, we had funded two areas of interest. One was to enable registries to be able to be also accessible to these FHIR APIs because, again, expanding the scope of accessibility to health data in all the different databases, such as registries, is really a very important source of knowledge that can be leveraged by the industry. This project is still ongoing for planned completion for 2023.

Similarly, one other area we looked at was to fund a project that leveraged these bulk data to develop some kind of a learning platform that would allow the research interests to be used to be leveraging these new technologies, and the result was that was the Cumulus platform that the SMART team from the Boston Children's Hospital has been developing working with Yale University and Yale New Haven Health, and again, these are some of the early indications of just knowing some of the challenges, using these technologies that we can learn from and hopefully ensure that as the standards mature and these technologies mature, the rest of the industry can benefit from them. Next slide, please.

In 2020, we actually had a couple more areas of interest. That was a year where we also invested through MedStar Health Research **[inaudible] [02:35:03]** and Health Lab. The idea of developing tools based on these APIs were, again, as we have mentioned, with certified health IT and through the use of API, there is a floor that has been set now to be able to access data, and now, really, what we also wanted to do was to start coming up with new innovative projects that could start test driving and seeing how those data could be leveraged, how those APIs and technologies can be leveraged for meeting patient outcome. So, that was a project that was funded through MedStar, and then, also, we started looking at linking our patient data with data for long-term services and social services needs, again, knowing that clinical data, administrative data, and other data all needed to be connected and interoperable to be able to be supporting whole-patient care, so that was a project that we had funded through the Missouri Department of Mental Health. Next slide, please.

In 2021, we did focus, again, through the work that you all did, on both health equity, so one of the projects was on ensuring that there was a referral management program that could exchange data from community health centers and the providers' clinical systems to the referral management program that was essentially interoperating with social determinants of health data. That has been funded through University of Texas at Austin, and it really helps connect the dots for understanding how social determinants of health data can be leveraged for clinical care. At the same time, knowing the interest in AI and machine learning, we have a project that was funded through DARTNet Institute to start looking at figuring out how EHR data could be leveraged by large AI/machine learning models, and just understanding what could be the models needed, and some of the work is still going on for plan completion in 2023, but some of the outcomes around use of semantic ref technology is something that we feel excited about that could be leveraged in the future as AI/machine learning models become much more prevalent. Next slide, please.

And now, we are in 2022, so these are the projects that are still ongoing. As I mentioned, these are LEAP projects that are all multiyear projects, but hopefully, as you see, as we move into the later years, we are focusing much more on now connecting interoperating the data and really looking at the whole patient's requirements and needs. So, one of the areas that we have funded in 2022 is this project with

AllianceChicago to address health equity and SDOH data through tools and EHS. Again, it is a very broad project, and the feedback is looking to an identifying base by which they can leverage all the health information technology advancements that have been made over the past several years in ensuring equitable healthcare. Similarly, we have another project that we have funded in 2022, which was to use equity-enhancing, patient-generated health data for clinical care and research. It really gets into both patient-generated data, which we heard through the USCDI discussion the desire to have self-reporting data be captured. Again, this is an area where we think the work from USCDI could be helped by some of the early innovation work done by this project, and we are very excited about that.

So, this was really through 2022, so, at this point, I wanted to quickly move over and give you the high-level view of what exciting areas we want to fund in 2023. Can I get to the next slide, please? This is just a summary of all the projects. One thing I will note here before I move on to my description of what is up in 2023 is to stand up and give you a view of how things that were innovative in 2018 have become the standard of practice in 2022. So, again, things that we feel are difficulties and/or areas that are not mature are the things that we want to learn from LEAP, and they drive some of the work that happens at ONC through our engagement with the standards community, through our engagement with organizations and other agencies that are working to support those things. So, I just want to make that picture, that LEAP projects are really helping us understand the current state of affairs and things that we want to engage on.

Now, let me go to the next slide, please. This is the most exciting this. This is really our most recent announcement that we published, actually on Monday this week, so this week has been a busy week for ONC. Here, we have identified two areas of interest that we think are ripe for innovation. The first is our exploring the use of advanced FHIR, and I think as you all saw in the proposed rule, we have several requests for information on advanced FHIR, and one of the key areas is the feel that industry as a whole is ready to take that leap and use cool technologies, cool, new, advanced FHIR features such as CDS HOOKS, subscriptions, and SMART health links, and we are really impressed in learning more about both how it can be leveraged, but also learning to make sure that we understand, we keep those technologies, run them through the paces, and understand how they can be used. So, that is one of the goals of this area of interest, is to just learn the challenges and understand where those advance FHIR feature capabilities need to be further hardened.

Another area of really important need for us is to assess and improve the data quality of elements that are there in the health IT space, and we pick on USCDI because that gives us a scope to start with, but we know that data quality is immensely important if you want to start using the data for any sort of clinical decision support, let alone going into AI/machine learning, and this is an area of active interest. We feel this is an area of interest that is ripe to be explored in the next two years. So, this is exciting.

I will just mention that we just now announced it this week. The application submission date is June 12th, 2023, so, everybody who is listening, if you are interested, if there are areas you want to focus on, please do submit within the time of submission, and we really are hoping that this will be the driver for the next several years of work as we expand the LEAP activities. Thank you very much. I hope this was a very quick update on the LEAP program. I wanted to make sure that I gave enough time to the HITAC members both for any questions, but more importantly, if you had any questions from the proposed rule that you did not get time for. I am going to turn it over to the co-chairs, Aaron and Medell, to open up the floor for any questions related to this activity and other activities that you all heard today. Thank you.

Aaron Miri
Wonderful. Thank you, Avinash. I appreciate that presentation. Great stuff with the LEAP funding opportunities. It is great to pursue those and see what we learn, so, fantastic. I appreciate that. All right, first up is Dr. Steven Lane.

Steven Lane
Avinash, hi. Can you say more about the data quality initiatives that you are looking for? How are you defining data quality, what dimensions of data quality, and what kinds of tools you are looking for? Have you developed any preconceived notions of what that is going to look like?

Avinash Shanbhag
Thank you, Dr. Lane. To be fair, these are the exact type of questions we want these innovative projects to look into. So, what we have done is typically, and again, these are the typical ways in which we define these LEAP projects, we kept the scope pretty broad so that we would really like innovative responses coming from the stakeholders, and we know where there are various facets of data quality and various models of data quality being used, checked, and leveraged, and we certainly appreciate important responses from industry and from responders on various aspects. I think what we have done in terms of keeping the scope is, as I mentioned, we start with USCDI data elements as the broad scope of data elements, but in our cooperative agreement that we put in our notice of funding request, we also expand it so that if there are any additional elements of interest, we certainly would appreciate those responses to be taking care of that. So, again, it is a fairly open-ended funding request, and again, the idea being we want to learn from the industry, get the best practices, and hopefully mature it over the next several years, and that is the same thing for **[inaudible] [02:44:45]** public, is we list a few, but again, we know that the list is infinite. I hope that helps.

Aaron Miri
Good questions. Other comments and questions from the HITAC members? We have less than four minutes before public comment, so I am looking for hands raised, questions, even about the rulemaking process, the prior topic we were talking about. Feel free. I want to make sure folks have opportunity here. Okay, everybody is still digesting the rule. Sounds good. Mike and Medell, if you are open to it, perhaps we transition to public comments to close them out, giving the folks in the public a chance to ask questions.

Medell Briggs-Malonson
I think that is a great idea.

Avinash Shanbhag
Thank you. I appreciate it.

Medell Briggs-Malonson
Thank you, Avinash.

Public Comment (02:45:50)

Michael Berry
We can absolutely open up our meeting to members of the public if they have a comment. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are just dialing in on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. Let's pause for a moment to see if anyone raises their hand, and while we are waiting, I will just remind everybody that the next HITAC meeting is scheduled for May 17th, 2023, and that meeting materials for today and for every HITAC meeting can be found on the HITAC pages of HealthIT.gov. Someone just raised their hand. Adele Stewart, you have three minutes. Go ahead.

Adele Stewart
Thanks so much for the opportunity to ask a question. I would actually like to ask this of our ONC friends on the call. During the presentation on HTI-1, the new proposed rule, it was mentioned that the manner exception will now apply to TEFCA, and in another monthly RCE coordinating meeting call, they had mentioned that the proposed SOPs that have been released thus far do not necessarily limit the scope of information that could be exchanged for a given purpose, but just define how the purpose could be implemented. I have not had the chance to read the full rule yet, but I wanted to know if the manner exception would apply to any data exchanged within the required purposes or if it is limited to what would be defined in the SOPs. Thank you again.

Mike Lipinski
I think that is me. I think I am up on that one. I thought I might have mentioned it, but maybe it did not get caught. I know we went through it quickly. So, you have your required exchange purposes, and we talk in this exception twofold, that it can be the extent of our definition of EHI, so that is broader than TEFCA, and it can also include the permitted purposes. But, recall this is going to be limited to the agreements that are in place and the connectivity services that are in place. Now, you can offer the EHI, or at least make the attempt to offer more EHI than needed because that is what they wanted, and say you are going to use what we refer to as the TEFCA means, which includes the framework and the QHIN services, more broadly to capture all that. If it was from one QHIN going into a different QHIN, then you would have multiple agreements in play there. I am just laying that all out.

But, if that was not a supported permitted purpose under one QHIN or for that much EHI, then obviously, that does not give you an out in terms of using the condition that we are proposing. You cannot just say you tried to. You are part of TEFCA, I am part of TEFCA, and the means still have to be supportive of it. So, it is obviously trying to encourage the broader use of TEFCA than just the required purposes, so, hopefully that is helpful, but yes, it could be used for more EHI and for beyond the required purposes, but it is still contained by the permitted purposes of TEFCA. I hope that helps.

Aaron Miri
Thank you, Mike.

Michael Berry
I am not seeing any other hands raised, so I will turn it back to Aaron and Medell.

Final Remarks and Adjourn (02:49:54)

Aaron Miri
Okay. We have a few minutes left, HITAC, so I definitely want to give every opportunity to folks. If you have questions, comments, concerns, or any of the above, please raise your hand on any topic here. We have a few minutes left; I just want to give everyone an opportunity there. Okay, if I do not see that, then we will begin to wrap up proceedings, Medell, if you are in agreement with that.

Medell Briggs-Malonson
I agree as well.

Aaron Miri
All right. Well, I will start it here in the trinity to close it up for us. I just want to thank everybody for the great discussion and robust topics today. It is always a wonderful HITAC when we have these new rules drop and we try to sort through and understand the different nuances of a great discussion, and as I was saying earlier at the beginning of this, it is great to see the HITAC's work included in these rulemaking opportunities. It is excellent, and shows just how contributory your efforts are, that it actually comes out and helps govern the health IT space, which is exciting. As Mike said, just a reminder that the June meeting will be in person, so be on the lookout for that. For all the new HITAC members, I would definitely encourage you to please pay attention to the instructions in your email. There is a series of steps you have to follow, and so, be prescriptive because you are working with the federal government, and you want to follow every step as appropriate. That is my soapbox moment there. I look forward to seeing you next month. Medell, over to you.

Medell Briggs-Malonson
Again, thank you so much to all of our ONC colleagues for all the work that they have done, and also with presenting to us, and just really simplifying it for us so that we have a clear overview of the new proposed rule. Again, we want to thank the IS WG for all of their work and their leadership in this space, and to all of the HITAC members, you all are exceptional. It has been a wonderful meeting with lots of engagement, lots of great questions, and so, we are off to a really good start. Yes, we look forward to seeing everyone in June in person, but we may be able to see each other next week if any of you all are at HIMSS, so maybe we can have a small little HITAC reunion there as well. It is wonderful to have everyone here today. Thank you so much for a highly productive meeting, and we will all reconvene next month. Thanks, everyone. Have a great day.