Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

April 25, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Steven Eichner	**Texas Department of State Health Services**	**Co-Chair**
Steven Lane	**Health Gorilla**	**Co-Chair**
Medell Briggs-Malonson	UCLA Health	Member
Hans Buitendijk	Oracle Health	Member
Hannah Galvin	Cambridge Health Alliance	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Member
Jim Jirjis	HCA Healthcare	Member
Elaine Johanson	Food and Drug Administration	Member
Hung S. Luu	Children's Health	Member
Meg Marshall	Department of Veterans Health Affairs	Member
Anna McCollister	Individual	Member
Clem McDonald	National Library of Medicine	Member
Deven McGraw	Invitae Corporation	Member
Aaron Miri	Baptist Health	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Kikelomo Adedayo Oshunkentan	Pegasystems	Member
Naresh Sundar Rajan	CyncHealth	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Daniel Healy	Office of the National Coordinator for Health Information Technology	ONC Program Lead
Sara McGhee	Office of the National Coordinator for Health Information Technology	ONC Program Lead
Dustin Charles	Office of the National Coordinator for Health Information Technology	ONC Program Co-Lead
Michael Wittie	Office of the National Coordinator for Health Information Technology	ONC Program Co-Lead

Name	Organization	Role
Kathryn Marchesini	Office of the National Coordinator for Health Information Technology	Presenter
Jeff Smith	Office of the National Coordinator for Health Information Technology	Presenter
Jordan Everson	Office of the National Coordinator for Health Information Technology	Presenter

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

Michael Berry
Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task Force meeting. I am Mike Berry with ONC and I would like to thank you for joining us today. On behalf of ONC, I would like to thank the cochairs and the task force members for dedicating their time and expertise to provide a recommendation on our proposed rule.

Today's meeting is of the full task force. The task force members are divided into three groups who will generally meet on Tuesday, Wednesday, and Thursday each week during the public comment period. All of our task force meetings are open to the public and your feedback is welcomed, which can be typed in the Zoom chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled towards the end of the meeting.

I would like to begin roll call of our task force members. When I call your name, please indicate you are here. And I will start with our task force cochairs. Steven Lane.

Steven Lane
Hello. Good morning.

Michael Berry
Steve Eichner.

Steven Eichner
Good morning and welcome.

Michael Berry
Medell Briggs-Malonson.

Medell Briggs-Malonson
Good morning.

Michael Berry
Hans Buitendijk.

Hans Buitendijk

Good morning.

Michael Berry
Hannah Galvin.

Hannah Galvin
Good morning.

Michael Berry
Raj Godavarthi. Adi Gundlapalli. Jim Jirjis. Elaine Johanson.

Jim Jirjis
Jim Jirjis here. I did not hear you.

Michael Berry
Hung Luu. Thank you, Jim. Hung Luu.

Hung S. Luu
Good morning.

Michael Berry
Meg Marshall. Anna McCollister. Clem McDonald. Deven McGraw.

Deven McGraw
Good morning, I am here.

Michael Berry
Aaron Miri. Oh, thanks, Deven. Aaron Miri. Eliel Oliveira.

Eliel Oliveira
Good morning, everyone.

Michael Berry
Kikelomo Oshunkentan.

Kikelomo Adedayo Oshunkentan
Good morning, all.

Michael Berry
Naresh Sundar Rajan.

Naresh Sundar Rajan
Morning. Here.

Michael Berry

Fil Southerland

Fillipe Southerland
Good morning.

Michael Berry
Sheryl Turney. All right. Thank you, everyone. Now, please join me in welcoming Steven Lane and Steve Eichner for their opening remarks.

Opening Remarks/Task Force Introductions (00:02:24)

Steven Lane
Again, thank you all for joining us this morning. It is really a treat to kick off a new task force with so many friends, and dedicated HITAC members, as well as the ONC team. We have a lot of work to do. Obviously, we have broken the work into three subsets and most of you have been assigned to one of the subgroups to meet together over the next couple of months. A few people have volunteered for more than one workgroup, which is welcome, and a couple of you have volunteered for all three, for which we really appreciate the input and the thoughtfulness here.

There is just a lot of meaty substance in this proposed rule and I know that ONC has asked for a lot of specific input so we will have a lot of opportunity to dig deep, to provide that input, and likely impact the final product that we anticipate will come out later this year. Again, thank you all for being here. Steve, do you want to add to that?

Steven Eichner
There is not much to add. You did a wonderful job. I would just like to reemphasize, or restate, my gratitude for all task force participants. We do have an awful lot of stuff to go through but it is really interesting and I hope we can provide some valuable input back to ONC and our federal partners, and really continue to make a difference in improving health information exchange and interoperability. I look forward to the challenge.

Steven Lane
I think we are going to have some review here of our charge and our timelines and then dig right into the decision support interventions and predictive models space. We thought it would make sense to take advantage of having the entire group together. This is really a new domain for the ONC to be making rules about, and the team from ONC has come to get us started on that. We actually have quite a lot of material to cover, the background for that. We are hoping to get through that. Certainly, if people want to dig in and ask questions that will be fine. We gave ourselves plenty of time to do that. Then, group two, the Wednesday group, will be picking it up and developing the specific feedback about that. I believe, Mike, that discussion will continue tomorrow, correct?

Michael Berry
Yes, that is correct.

Steven Eichner

This is Steve Eichner. To add on to that, if for some reason we do not have sufficient time today for questions and answers we will continue the Q&A component during tomorrow's meeting. It is a public meeting. Both task force members and the public are welcome to attend.

Steven Lane
I think that is a really good point, which is to say that we have laid out the schedule for all of the workgroups, noting which topics will be discussed in which meetings. Even though you might have committed yourself to the Thursday group, if there is a topic that is being discussed on Tuesday or Wednesday that is near and dear to your heart, you are certainly going to be welcome to join and serve as a task force member, with all the rights and responsibilities thereof, during a meeting of a workgroup other than the one to which you have been assigned. We do hope people will show up for their assigned workgroup simply so we have the full input of the group and have a quorum for those meetings.

Steven Eichner
As an add-on to that, the ONC team has worked diligently to make a lot of information available through the Google Sheets interface, with things broken out by subgroup or by task force group. Everybody does have access, both read and write access, to all of the material for all subgroups. We do ask that if you make a comment on a subgroup worksheet, that you also then attend the relevant meeting for that particular topic, regardless of subgroup, so that if there is a question or additional information needed, you are available to help fill in the gaps. Thanks.

Steven Lane
One other point, just to help with any confusion, Ike, you and I have done this before. I am happy to go by Steven. I think Steve Eichner is happy to go by Ike, just so we know whom we are speaking to. Perhaps in the written materials, I think, Ike, you are happy to go as Steve and I go by Steven. Again, so we can keep that straight.

Steven Eichner
Absolutely. Both Steven Lane and I, Steve Eichner, are always available via email and like to help answer questions, chat, do whatever we can to help you, the task force, help everyone produce better content.

Steven Lane
With that introduction, Mike, do you want to get us to the charge and the timelines so we can walk through it?

Michael Berry
Sure. Can we go to the next slide? Next slide.

Steven Lane
There we go.

Michael Berry
All right. Go ahead, Steven. Take it away.

Steven Lane

I was just going to say I think we went through the roster for roll taking, but we did want to give everyone a brief chance to introduce ourselves, where you are from, and what your specific interest is in the work of this task force. We can just run down the list. Steve, you want to start us off?

Steven Eichner
Gladly. My name is Steven Eichner. I am the health IT lead for the Texas Department of State Health Services. My role at the SHS includes working across programs and with external parties on a wide range of activities related to health information exchange. I have also got subject matter expertise in rare diseases and the benefits of health information exchange for small populations.

Steven Lane
I will go next and then we will run alphabetically from there. Steven Lane. I am a practicing family physician and clinical informaticist with a deep interest in interoperability, privacy, and information security. For six or months now, I have served as the Chief Medical Officer at Health Gorilla. Medell?

Medell Briggs-Malonson
Good morning, everyone. My name is Medell Briggs-Malonson and I am a practicing emergency physician. I also serve as the Chief for Health Equity, Diversity, and Inclusion for the UCLA Health System, where I actually provide the oversight and strategic planning for all initiatives that advance equity and justice within our organization and communities. My other area of expertise is the intersectionality between building equitable infrastructures in health IT in order to support health justice as well as data justice. Lastly, I do serve as the cochair for the full HITAC committee. Very happy to be on this workgroup. Thank you.

Steven Lane
Thanks, Medell. Hans?

Hans Buitendijk
Hello. My name is Hans Buitendijk. I am with Oracle Health, Director of Interoperability Strategy, focusing on anything interoperability from standards to regulations. In that capacity, I am active within the EHRA, where we will be talking a lot about these topics as well. I am active in HL7, to develop the variety of standards that are referenced and in national network activity as well. Looking forward to the discussion. I guess I am one of the ones with an interest in all three, so will attend them all. Upfront apologies because there might be some background noise when I talk at times There is some construction going on nearby but I will try to minimize that.

Steven Lane
Thank you, Hans. Hannah?

Hannah Galvin
Hello, I am Hannah Galvin. I am a practicing pediatrician and the Chief Medical Information Officer for Cambridge Health Alliance, a public academic health system in the Boston area. I am also the cofounder and co board chair of Shift, the independent healthcare task force for equitable interoperability. In that capacity, I am very specifically interested in the RFI around granular data segmentation and the patient restricted ability to restrict data. transmission in this rule. However, I am interested in multiple aspects of this rule, including the information blocking pieces and the decision support pieces as well. In my capacity

in Shift, I will certainly be commenting as well, so I did want to call that out. Looking forward to this very much.

Steven Lane
Thank you, Hannah. I do not think we have Raj here or Adi. Is that true? Okay. Jim Jirjis, are you with us?

Jim Jirjis
Yes. Thank you, Steven. Can you hear me?

Steven Lane
Yes.

Jim Jirjis
Thanks. I am Jim Jirjis, a physician internist trained in infectious diseases as well. I am the Chief Health Information Officer for HCA and I have been for about 10 years now and have been along for a few years on this ride with HITAC. I am very interested in going deep and making sure that what is in the rule and what our comments are really serve the goals of reducing provider burden, increasing patient access, and true interoperability. I delighted to be on this task force.

Steven Lane
Thanks, Jim. I do not see Elaine from FDA. Hung Luu?

Hung S. Luu
Yes. My name is Hung Luu and I am the Associate Professor of Pathology at UT Southwestern Medical Center. I serve as the Director of Clinical Pathology for Children's Health, a pediatric healthcare system in North Texas. I bring the perspective of a laboratorian and also I always keep in mind the pediatric point of view to all of the standards and regulations. My special interest is in laboratory data interoperability and how we use big data to improve healthcare. Thank you.

Meg Marshall
Thank you. I do not think Meg Marshall from VA is here. Anna. You might be on mute, Anna.

Anna McCollister
Sorry about that. Yes, I was on mute. Hello, I am Anna McCollister. I work as an independent consultant focused on patient health technology and ways to inform data use, data access, data governance with the perspectives and interests of patients. I helped start a patient hacker movement in the Type I diabetes space and I have done a lot of advocacy and work focused on data access, interoperability, data standardization, and making it possible for individuals to be able to use data streams and data for the things that matter most to them. In addition, I have done a lot of advocacy and patient discussions and policies around the use of real-world data for health research as well as the development of better digital biomarkers to replace blood-based biomarkers.

Steven Lane
Wonderful. I do not see Clem with us. Deven?

Deven McGraw
Hello, everyone. I am Deven McGraw. I am the lead for data stewardship and data sharing at Invitae, which is a clinical genetic testing company. I came to Invitae after they purchased a startup that I cofounded called Citizen which helps patients leverage their rights to get their health data under both HIPAA and the information blocking rules and to then have that data under their control. I was formerly Acting Chief Privacy Officer at ONC and also worked at OCR as the Deputy Director of Health Information Privacy, so all things HIPAA. Many things in this rule are interesting to me, like others. Similar to Hannah, I am very interested in the data segmentation and right of restriction issues, although I tend to look at those issues through the policy lens. I have less knowledge of the technical pieces. I am excited to have so many experts on those aspects of it as part of our workgroup. I am also very interested in the information blocking provisions and particularly around the incentives to utilize TEFCA. I have many questions about that, so I am looking forward to that discussion, too. Thank you.

Steven Lane
Thank you, Deven. I think Clem has joined is now. Clem, do you want to introduce yourself? You are on mute.

Clem McDonald
I have joined you now. Thank you, Steven.

Steven Lane
Great. You want to tell people where you come from?

Clem McDonald
Sure. I am the Chief Health Data Standards Officer at National Library of Medicine. My history has been a deep interest in electronic medical records and the standards needed to support them.

Steven Lane
Wonderful. Thank you. Eliel.

Eliel Oliveira
Good morning, everyone. My name is Eliel Oliveira. I am the Director of Research and Innovation at the Dell Medical School, which is at the University of Texas at Austin. I lead a health informatics team, where we manage several informatics projects related to social determinants of health, health equity, **[inaudible] [00:17:50]**, population health, and of course most importantly, anything that has to do with data aggregation for research purposes is part of our purview. I also serve as a board member for the Health Information Exchange in Central Texas called HIETexas. I am PI, the principal investigator, for one of the ONC LEAP projects which right now is worked on a closed loop social services referral system. I have been running previously projects in the past. Thank you for having me.

Steven Lane
I must say, the expertise in the room is pretty overwhelming. Dayo?

Kikelomo Adedayo Oshunkentan

Hello, good morning, all. I and the Chief Medical Officer at Pegasystems, which focuses on low-code platform technology powered by AI and workflow automation. My background is that I am boarded in internal medicine with extensive knowledge in the payer and provider space. I worked as the medical director for a large health payer here in the States. I also worked as a healthcare consultant. I have a keen focus on high quality and cost-efficient payer delivery models as well as a deep expertise in proficiency in hospital medicine and physician alignment and accountability for delivery of quality metrics. My keen focus in terms of joining this committee is because I am a staunch patient advocate also, dually, a provider advocate. My hope is to decrease the provider burden as I still practice. There are a lot of things that we can improve upon still. Also, data interoperability as well as information sharing and health equities are also my passion. I look forward to working with you all and gaining some insights from you and your experiences as well. Thank you.

Steven Lane
Thank you. Naresh?

Naresh Sundar Rajan
Thank you, Steven. Good morning, everyone. This is Naresh and I am currently serving as Chief Data Officer for CyncHealth, a statewide health information exchange for the state of Nebraska and state of Iowa. My areas of expertise relies on interoperability and specifically provider payer for public health and patient data exchange across the states and boundaries with proper data governance and policies in place. With respect to interoperability, we work with on a daily basis exchange of the millions of records, which actually complies with USCDI coding standards. I am really looking forward to the conversation around clinical decision support systems and other topics. Thank you. .

Steven Lane
Thank you so much. Fil, you are next.

Fillipe Southerland
Hello. Good morning, everyone. Glad to be part of the group. Fil Southerland, Director of Healthcare Solutions at Yardi Systems. We have about half a million **[inaudible - crosstalk] [00:21:00]** long-term post-acute care space. I have a software development background. I had a startup back in the late 2000s that was acquired by Yardi. I am generally interested in how this rule will impact the overall interoperability landscape, and particularly interesting in the algorithm transparency rule.

Steven Lane
Wonderful. I do not think Sheryl is with us this morning. Mike, can we do a brief introduction of the ONC staff who is supporting us here?

Michael Berry
Sure. I think everyone is on. We have several people that are program leads that are supporting each of the groups. I think group one is Dan Healy. Dan, if you would like to introduce yourself?

Daniel Healy

Hello. Good morning, everyone. I am Dan Healy. I am a policy coordinator in ONC's Office of Policy and Compliance Administration branch. My background is in health systems research, primarily. It is great to be with you all today and I am looking forward to the discussions and the conversation. Thank you.

Michael Berry
Great. Thanks, Dan. And for group two, Sara McGhee is going to be supporting that group. Sara, would you like to introduce yourself?

Sara McGhee
Hello. Good morning, everyone. I am Sara McGhee. I am on the Regulatory and Policy Affairs Team. I am an attorney by training, but I have been working in policy for quite a while. Many years ago, I actually worked for Texas Department of State Health Services when it was HHS. It was nice to meet all of you. I am looking forward to this task force and working with everyone.

Michael Berry
Great. Thanks, Sara. We have two ONC folks helping us with group three, that being Michael Wittie and Dustin Charles, if you would like to introduce yourselves.

Michael Wittie
Sure. I am Michael Wittie. I am in the Strategic Coordination Group at ONC. I am an epidemiologist and informaticist by background. I was the program lead for the contract that developed the draft EHR reporting, now Insight's condition measures. I am very interested in that. I also have a background on CVS coordination and development. I am interested in everything.

Steven Lane
You are in good company. I do not see Dustin on the list. Am I missing him?

Michael Berry
Dustin is not on at the moment. He is one of the program leads for group three. Of course, there are many other people, including myself, that support this task force and the HITAC in general. We are going to meet a couple of the ONC presenters further along in our agenda. I will turn it back to you, Steven.

Steven Lane
Great. Thank you, everyone, for taking the time. It was a little more than 20 seconds per but just amazing expertise and insight. I am looking forward to our discussions. With that, let us dive in, Steve and Ike, unless you have something else you want to add.

Steven Eichner
I have nothing to add.

Steven Lane
Great. All right. Ike, do you want to take us through our charge and timelines?

HTI-1 Proposed Rule Task Force Charge and Timelines (00:24:30)

Steven Eichner

Absolutely. Let us go to the next slide. We have an overarching charge, which is looking at evaluating and making comments upon the broad NPRM. We have specific charges going through looking at specific ONC proposals, such as reviewing all certification criteria within the certification program, looking at establishing new baseline versions of the USCDI, shifting from version one to version three, and then looking at implementing the EHR reporting program with some new insights. All those charges are broken out and applied a little bit differently to the different subgroups, again, depending upon what is in each subgroup's portfolio.

Next slide. This again continues the specific charges, looking at recommendations on a range of ONC proposals, looking at things like OHI case reporting, clinical decision support, API interfacing, FHIR interfacing, new patient certification criterion, looking at additional assurance criterion, and maintenance of certification components. Then, we are also looking at several requests for information on program standards and information blocking.

Next slide, please. We can go through and, as I mentioned earlier, these are broken out by the different groupings. What is on the slide right now are those specific charges that are for group one, looking at information blocking, looking at RFI for additional exclusions. We are offering health IT, looking at information blocking and exceptions under TEFCA. We are looking potentially at additional TEFCA reasonable and necessary activities related to information blocking that would allow or permit information not to be shared. We are looking at additional information about information blocking and the infusibility exceptions to keep reviewing and revising the existing conditions for uncontrollable events. We are looking at third party seeking a modified use. We are looking at a new condition for a manner for an exception exhausted. Again, another RFI looking at health information technology capabilities for data segmentation and user-patient access and information blocking.

Next slide, please. Looking at group two. Looking at DSI and predictive models, looking at electronic case reporting, looking at the ONC certification criterion for health IT and discontinuing same year additions in order to see a shift from a methodology that uses say the 2015 edition to another methodology for identifying what providers need to be compliant with at what point in time. A requirement for health IT developers to update their previously certified HIT, and then a little bit looking at that consistency measure so that providers can easily understand what version they have and what version they need to be using to be compliant with existing systems.

Looking at group three, focused on ONC health IT certification program updates. Looking at Insight condition and maintenance of certification, the USCDI standards we mentioned earlier. Looking at updates to the C-CDA companion guides. Looking at modifications to standardized APIs for patient and population services. Making recommendations regarding FHIR US Core Implementation Guide, STU, and then, several other requests for information.

Next slide. We have divided the order task force into three different workgroups, or three different sub task forces.

Steven Lane
Ike, the do you want me to share your voice and we can throw it back?

Steven Eichner
Sure.

Steven Lane
Good. I do want to point out that Sheryl Turney has joined us. Apparently, she was able to get in by phone on the public line and they are trying to get her switched over to be a panelist. Sheryl, welcome. You are one of the lucky folks who got assigned to group one and you have heard what the specific charge for that group is. You can see we tried to spread the groups out so that they are roughly the same size, but as we said, you are welcome to hop between them if you want to do some additional work. You can see here, group two. Again, I am not going to read the names, but there are the assignments there as well as group three. As we mentioned, Ike and I are going to try to attend all of the meetings. Hung has agreed to lead group three. We really appreciate that, especially as we pull together the recommendations towards the end. Next slide.

Fillipe Southerland
Can I just ask on that, Steve? If we do have an interest in attending the other group meetings, will we be receiving invites for all groups or do we need to reach out to you as cochairs to receive that information?

Steven Lane
Mike, how do you want that to be done?

Michael Berry
We have not sent invites to everyone for all groups. If you are interested in participating in another group, whether it is a one-off meeting or more, you can email me and we will make sure that you are added to a specific meeting. Just let us know.

Steven Lane
I got a message from Jim Jirjis. He wanted to be on group two as well. Maybe, Mike, if you guys can facilitate that, that would be great.

Michael Berry
Sure.

Steven Lane
Excellent.

Steven Eichner
This is Ike. The reason we did not email invitations for everyone for each meeting is that we did not want to overwhelm or harass too much. There are quite a large number of meetings across three task force subgroups over the next several months. Again, everyone is welcome to participate and please let Mike know if you are interested. I am sure they would be happy to send you invitations for one or all of the task force member meetings. They are also available on the HITAC and ONC calendar of events.

Steven Lane

What we are going to do next is go through the week-by-week timeline that we have proposed. I suspect we will be able to keep to this, but there is always flexibility built in. All of this culminates with our presentation to the HITAC on Thursday, June 15. What we have heard is that is going to be an in-person meeting. We will be well known to one another by then and it will be great to be able to get together in person for the delivery of the recommendations. The ONC team, do you guys want to quickly run us through the timeline slides?

Michael Berry
Sure, happy to. Can we go to the next slide? I will just note that all of these documents are on our website for any member of the public who wants to follow along to any task force meeting. Today, the full task force is meeting, as you can see. Group two will meet on Wednesdays except for one of the meeting dates, that meets on Wednesdays. You can see the topics assigned for each group. Group three will meet on Thursday. What we did is we just broke this out by week. It is pretty easy to follow along.

We can go to the next slide. This is getting into May, the three groups meet. Keep going, please. You can see all of the topics that were on the slides that Ike went through previously. They are all on this list. The plan is to get through all of the topics pretty much by the end of May.

We can go to the next slide. As you can see, this is a very fast-moving task force because it has to operate within the public comment period. We have a lot to get through in a little bit of time. When we get to week seven, that is when we did send meeting invites to the full task force. All task force members got those invites. If group one, two, or three needs to meet one more time then we can turn one of these full task force meetings into a specific group meeting or a combination. The goal is to get wrapped up during week seven into week eight. It would be great if we could have all materials on the slides and recommendations ready for meeting 21, which is on June 8th. We have a placeholder meeting, number 22, on June 13th, if needed. That is cutting it awfully close for the recommendations to be delivered to the HITAC.

As Steven mentioned, we are planning an in-person HITAC meeting in Washington, DC, and we will publicize that on our website. The HITAC members will be sent an email probably this week, once we finalize our logistics, which we are very close to doing so. And we can go to the next slide. Steven and Ike, I will turn it back to you.

Steven Lane
Thank you so much. I want to open it up to any questions or comments from the members before we dive into the material itself.

Hans Buitendijk
Steve, this is Hans. Maybe one question on just the logistics on gathering our feedback, the spreadsheets, otherwise, how we plan to use it, maybe now or later so that we know where to look, where to update, and how far we can go.

Steven Lane
Really good question, Hans. Thank you for that. I think you have all been sent the link to the spreadsheets. Is that right, Mike?

Michael Berry
Yes. That was part of their homework assignment.

Steven Lane
You should be able to get in that. Most of you have been on task forces before and know the drill. We want you to add your input, positive, negative, correcting, supplementing for each of the line items in the spreadsheet. When you do, please preface your remarks with some indication of your name, at least your last name. Maybe a first initial would help, too. We will do carriage returns between comments and try to collect that information. Then, we will use that to guide our discussions as well as to develop the final recommendations. If anybody has any trouble getting to the documents, please let the cochairs and/or Mike know, and we will get that addressed. Thank you to those of you who found the raise hand function. That is really helpful when we are doing these big meetings. Eliel?

Eliel Oliveira
Yes. Thank you, Steven. I maybe missed a bit. I am looking at the document, the doc was sent by email, and we have the roster and then we have the groups assignment but I do not see my name and a few other people's names under the group's assignments.

Steven Lane
Eliel, I see you in group one.

Eliel Oliveira
Okay.

Steven Lane
I am looking at Slide 12 from today's materials.

Eliel Oliveira
Okay. That is good to know. Again, I guess I am looking at the PowerPoint that was sent by email and that does not seem to have all of the details. Thanks, Steven.

Steven Lane
Okay. The version I am looking at, maybe we can pop back up to Slide 12 real quick before we dive into DSI. There we go. This is the slide that I am offering to. Everyone should be able to find themselves. Again, Jim has asked to join group two so we will tuck him in there as well. As you can see, people are in one, two, or three groups. We are happy to accommodate if people want to do extra work.

Eliel Oliveira
Thank you.

Steven Lane
More than welcome to. Fil?

Fillipe Southerland
Yes, Steve. I was curious. Are we allowing guest speakers in?

Steven Lane
Absolutely. Thank you for that question. As usual, we will bring subject matter experts to discuss topics, as appropriate. As task force members, you are welcome to recommend either areas of expertise or individuals to come. Some of us have already started doing that. I think that can be very helpful. Of course, we are going to have to be mindful of the time available. Let us actually slide up to Slide 10 and just be real quick remind people of the assignments. These are the multiple task items that we are going to address in group one. Then, down on Slide 11, you can see groups two and three. We have a lot to get through. Certainly, let the leads know if there are individuals that you want to invite to the meetings and we will get on that.

Fillipe Southerland
Great. Thank you.

Steven Lane
Not seeing any other hands. I would say, let us slide back down to Slide 18. Kathryn and Jeff are going to walk us through the background materials around the DSI proposal, which are extensive. Then, if we have the time, we will jump into the proposals themselves.

Clem McDonald
Steve, one last question about the assignments for the various groups.

Steven Lane
Yes, sir.

Clem McDonald
Can we expect to get information packages of the things we are supposed to review?

Steven Lane
Yes. The team has worked on that. In the spreadsheet, if you scroll over to the right. Mike, I do not know if the team has the spreadsheet handy and can just pop it up really quick since we are going there. There are numerous columns that include that information. One of the things that I have specifically asked ONC to do is to pull out, in a really handy, readable, highlightable, copyable format, the specific sections of the 556-page rule that apply to each of the topics so that people can assure they have read all the necessary information, both from the preamble and the body of the rule itself. I know that can be a real challenge. I am sure that there is somebody on here who has not read every single page of the proposed rule to date and will want to be doing that in a just-in-time way. We want to assure that we support people in that.

Clem McDonald
What you propose, Steve, would be a gift.

Steven Lane
Yes. Mike, can you give us any update on how that is coming along? I know they are working on it.

Michael Berry
You want us to pull up the spreadsheet. Is that right, Steven?

Steven Lane
No. I mean, yes, feel free to pull up the spreadsheet, but the question specifically had to do with, as we were discussing in the email, the idea of pulling out the sections of the rule and putting them into a Word document, ideally, because that is going to people the most flexibility, that they can download and manipulate themselves to facilitate their review. Today, we obviously have the original published PDF version, and the three-column view, neither of which is optimized for individual review.

Michael Berry
Right. We are working on that. And **[inaudible] [00:42:38]** team, if you can let me share, I will pop the spreadsheet up quickly so that everyone can see it.

Steven Lane
If that is going to take a while, oh, okay. Here we go. Great. There we go. This is the spreadsheet. Again, the team has a lot of experience now. We have done this a number of times. As you can see, we have got the item to discuss, the date for discussion, which group number it has been assigned to. I think in Column D, that is often where we put the name of the person who first starts the discussion. I am not sure how important that is, frankly. Unless, Mike, you feel otherwise, or Ike, I would not worry about that one. The topic, the summary from the proposed rule, obviously takes up a lot of space here. And then they have the specific page numbers, where are the references. Our hope was to go from those page number references to actually have a little Word document that is sitting there that you can open up and get to just what you are looking. Otherwise, the hunting and finding and reviewing can be challenging.

Member recommendations is where we want you to put your name and your ideas. Feel free to be brief. You can put URLs in there as needed. Justification, again, I think the recommendations usually stand on their own. If you need to put in some other references etc., feel free to use Column I. As we discuss these items, and pull together ideas, we will pop those into J. Here again, this is a great place to list any subject matter experts that should be invited. If you want to just pop it in there, as opposed to sending emails, that should be fine. Then, we will then craft our final recommendations in K. During that last week, we will pull that into more of a **[audio distorts] [00:44:54]** document and pretty it up along with slides for a presentation to the HITAC.

Hung, if you are interested in joining the presentation and presenting the recommendations from group three, that would be welcome. We will have a party there on June 15th. I do not think there is anything to the right of K, is there, Mike?

Michael Berry
No.

Steven Lane
Great.

Michael Berry
I will just add, Steven, that these are broken down into the groups down at the bottom here. There are three tabs so that you can find the topics depending on which group they are assigned with. If somebody is

working in a specific group, you really only need to focus on what is in that group. Obviously, you can toggle back between the tabs to see what else is going on if you would like.

Steven Lane
I can see we have a little bit of a data entry issue there, at least in one of them. The group number was in the task force member column. We can clean that up a little bit. It was on the second tab. Yes, that one. No big deal. Not to worry. Any other questions? Clem, your hand is up. You are on mute, Clem. Okay. We can come back to Clem when he gets off mute. Let us jump back to the slides. We are a bit behind our aspirational schedule, I think. Let us jump in. Kathryn, are you going to take it away here?

Kathryn Marchesini
Yes. Thank you, Steve.

Steven Lane
Hold on. Hold on, Kathryn. Clem was off mute momentarily. Clem, diid you have a comment?

Clem McDonald
Yes. Some of those topics we have been through before, the USCDI Version 3. Are we really going to rehash that again? **[Inaudible – crosstalk] [00:46:51]**

Steven Lane
No. Specifically, it is the recommendation to change the standard for data exchange in various ONC rules from USCDI Version 1 to USCDI Version 3.

Clem McDonald
Oh, okay. All right. I get it.

Steven Lane
We are not going to be rehashing the USCDI itself. Okay. Anything else, Clem? You are good? Great. All right, Kathryn, take it away.

Decision Support Interventions (DSI) and Predictive Models (00:47:20)

Kathryn Marchesini
All right. Thank you, Steve. Good morning, everyone. I am Kathryn Marchesini, the Chief Privacy Officer at ONC. Thank you, HITAC members, for inviting my ONC colleagues. Jeff Smith, and then later on Jordan Everson, and I are going to share ONC's proposals, I would say, that intersect with data technology and decision support. Also, thank you for setting aside the time today and in future sessions as you are thinking through your comments.

Next slide, please. Before we dive in, you will see here a standard ONC disclaimer. It is really just focusing on this is not a legal document or advice and you should review the underlying relevant laws and regulations for the particular proposals and the requirements.

Next slide, please. You will see a roadmap of how we plan to discuss what as it relates to the topic and the proposals related to decision support interventions and predictive models. Over the first three meetings, we

have tried to divide the content up into manageable areas. I know we are going to do a lightning round today, for providing an initial overview and then setting up some initial background of the proposals and how it fits into the current state of the ONC health IT certification program.

Next slide, please. Jumping in, you will see here at a very high level, some of what is in the proposal. ONC's proposal is an update to long-standing requirements for decision support and transparency about that decision support. The proposed rule, as you will see on the slide, revises the existing clinical decision support certification criterion by proposing a decision support intervention certification criterion. We will talk a little bit more late, but it is a renaming and an update. We are looking at overall leveraging ONC's authorities. As many of you are familiar with, it is regulating certificated of health IT, also known as or commonly referred to as EHRs, to bring transparency into the relative quality of the predictive models as well when those are used for decision making. That is a broad definition and I talk about that as it relates to healthcare. The proposal also includes a definition of predictive decision support intervention.

This includes AI, ML, as well as driven decision support as well as talking about, you will hear the acronym FAVES, fair, appropriate, valid, effective, and safe. That is, I would say, shorthand, or what we equate to as a high-quality model, and also whether or not it is trustworthy. Overall, you will see here the proposals are intended to compel a certified health IT to display information that would enable users to determine the quality of the predictive decision support intervention. It is really trying to, I would say, encourage. I hate to use the word compel, but really to require developers of certified health IT to employ, engage, and report public summaries of information as it relates to risk management practices. This is often referred to as governance. Overall, this is going to be leveraging the existing ONC health IT certification program as it relates to real world testing.

Next slide, please. I would say today and future meetings, you will likely hear about transparency, FAVES, and trust. You will see here, I would say, the birds eye view. The proposal is really focused on improving transparency, enhancing trustworthiness, promoting consistency, and incentivizing the development of wider use of FAVES as it relates to a broader topic regarding predictive DSIs, but also advancing ONC's overall approach to health equity by design. We are hoping, or the intent is, that the resulting information transparency to enable users. That includes healthcare providers, clinicians, hospital systems, health systems to scrutinize and look into the technology so that they are able to make informed decisions. Overall, this would increase the public trust and confidence in these technologies.

Next slide, please. At a very high level, what technology are we talking about? You will hear the term predictive decision support intervention, and you will see on the slide the definition that is proposed. Of note, just to call attention, the definition focuses on technology that makes estimates, thinking outputs, are based on relationships learned in training data. This is different, I would say, in contrast with the current certification criterion scope that contrasts with evidence-based decision support interventions, which supports decision making relying on predefined rules based on experts and the consensus, particularly around recommendations. For example, computable clinical guidelines.

This is not to say that predictive support would not be based or could be based on evidence, but it really is focused on learning that happens throughout the process based on data. The other thing to pinpoint is the definition does not depend on the who, the what, the where, and the why of the model in that it can be developed by someone other than the certified health IT developer. It is not use case dependent or

determined or tied to a specific purpose. This can be used for treatment, payment, healthcare operations, public health, research. I say that for purposes of terms defined under HIPAA for those that are familiar with that. You can see some examples on the slide, but the technology also is not dependent on how the output is displayed or presents itself in the EHR. It can be an alert, an order set, flow sheet, of that nature.

Next slide, please. I talked a little bit about the definition. The other thing to focus on that the proposals include is, I would say, the premise that transparency is a prerequisite for trustworthy artificial intelligence. You will see three pillars, if you will. You will see here data transparency, predictive DSI transparency, which is technical and performance, as well as organizational transparency. Again, at a very high level because we will touch on this in later discussions, for data transparency, just to call attention, when a technology includes the use of race, ethnicity, language, sexual orientation, gender information, and SDOH, as well as health status data elements, that is going to be as part of source attributes, we will talk a little bit about that later, for the actual decision support intervention.

This information about that would be provided to users. The thinking is that this would greatly improve the possibility of identifying and mitigating any potential risks of employing not only evidence based but also the predictive decision support interventions for patient care. This includes those related to exacerbating racial disparities as well as promoting bias. The other area that is of interest you will see in the yellow. This is about the actual predictive model and the technology itself. This is really getting at the technical and the performance aspects or dimensions of the technology. The next meeting of this group, tomorrow, we will spend a lot of time talking about that, but generally speaking, there are 14 areas across four categories that really focuses on the details so that the user understands what was the intent for the model when it was designed, what data was used, how the model is maintained. The proposed requirement is that this information be in plain language. That is just some big-picture thinking and we will talk more about that tomorrow.

The last area or grouping focuses on organizational as well as, some refer to this as the sociotechnical dimensions or competencies. The organization here is referring to the developer, particularly the certified health IT developer. The proposed requirement is that there are intervention risk management practices that are employed by the developers for the functional requirements as it relates to the health IT module that enables or interfaces with the predictive decision support intervention. To the extent that there is a technology that meets this definition of predictive decision support interventions, and it is enabled or interfaces with a health IT module, and we will talk a little bit about the intersection with the USCDI, if there is such technology, this is a snapshot of what the requirements are the intended efforts or outputs of that leading to trustworthy algorithms, particularly around predictive decision support.

Next slide, please. You will see here, I touched on loosely the concept of FAVES. These are areas related to, not only is it helpful for the individual and the users, the organization that is using the technology to make decisions. I talked about the scope. It is not just about treatment. The benefit is so the user will have the information to make an informed decision about whether or not to apply technology to a particular use case if it meets their needs. The other area to highlight here is really looking at the outputs and the activity, how it intersects with the work that industry, and academia, as well as the public sector are doing to develop means to communicate measures that they might be working on and other areas that they are diving into.

We try to strike a balance to where the proposals are not overly prescriptive, but really trying to start the conversation about how to implement this in other areas of certification criteria, adding onto our existing requirement.

Lastly, for the overall healthcare industry, it is really focusing on promoting the transparency necessary to encourage the development of a dynamic marketplace and really focusing on high quality models. As mentioned before, for shorthand, for FAVES. Again, we will talk about that in a little bit on the next slides. With that, I will turn it over to my colleague, Jeff Smith, to share some of the background and context we included in the proposals related to decision support interventions and predictive models. Jeff?

Steven Lane
Kathryn, before we pass the baton, Ike has his hand up and we have a thoughtful common in the chat. Maybe we will just touch on those before we move on. Ike?

Steven Eichner
Thank you. Thank you for all of your hard work. This is going to be a complicated question, I think. I am sorry about that. I happen to have a really rare condition, one of about a thousand people identified worldwide. The nature of the condition means that a lot of things that you might do for a person without the condition are really contraindicated for me. What controls have we built into the system to identify where these supports should not be used in making a recommendation for a particular individual? For example, an intramuscular injection for me would literally fuse that joint and I would never be able to move it again. That is not exactly an outcome that I or my PCP, or any other healthcare provider, really wants for me. How are we building into the system controls to identify where these things should not be used?

Kathryn Marchesini
That is a great question. I guess, initially, you will see in the proposal under the source attributes, which we will talk about tomorrow, there is an area, or an element, or factor regarding out of scope. There is also the intent to include what assumptions, or factors, or aspects, or problems that the tool was designed to solve. I think maybe a little bit of what I heard in your comment had to do with maybe some potential unintended consequences or areas where, to your point, it should not be used. I will just share that the intent of the proposal is not about right now. It is not about the ONC, about the safety and effectiveness of the technology, which is a little bit different than the FDA's approach as it relates to medical devices. However, it is not to say that information about that could not be provided as part of the requirement. And so, I will see if my colleagues, Jeff Smith or Jordan Everson, have anything else they wanted to add on to that question.

Steven Eichner
Again, not a solution because I do not have enough expertise to do that. Looking at something in the space of, from a regulatory standpoint, "Hey, these tools should not be used in these circumstances," or built into the framework, not as a matter of looking at specific safety requirements because that, as you pointed out earlier, may be attached to a particular instance of a particular tool. But from a systemic way, looking at systemic support for enabling a non-use at the patient level becomes highly important. I work carefully with my PCP on making good medical decisions in that space. If I show up at the ER, I am not working with a medical team that I work with on a more regular basis. They are not familiar with my medical history or my

medical background and might be in a position where they are more likely to use DSI and computer supports.

I, as a patient, need protection built into the system that says, "Hey, based on this patient's core diagnosis pieces, these things do not do well," or, "Do not rely on this recommended algorithm to use recommendations because this particular patient's fundamental measures are so outside of the norm for getting a predictive value that you are not going to get a usable result."

Steven Lane
Ike, I think you are making a good point. I think this gets at the component of the predictive DSI transparency that is built into these recommendations. Obviously, group two is going to have a chance to clarify this and comments. I am a little sensitive to our timing, I see a couple of hands going up. Would anybody object strongly if we let the ONC team get through the presentation and hold the questions to the end? Clem, Hans, can you live with that, I hope? Yes. Let us go ahead, Kathryn and Jeff. Let us power on through this because I think some of the questions that are coming up may be answered by your presentation.

Jeff Smith
Okay. Thanks, Steven, and thanks all. Given the amount of time, I think what I would like to do is for whoever is running the slides, can you skip ahead six slides? What we are going to be skipping through is a series of slides that articulate a series of blogs that we authored going back to the summer of last year. Can we get two more slides? There we go. You can stop there. Go back one more. Perfect. The blog series that we published is vital for your understanding of where some of the background and context that we do include in the preamble. The preamble, as long as the DSI section is, is really important to give everyone a clear understanding that we are operating based on the best information and the latest peer reviewed evidence that we were able to uncover and contextualize that within the authorities of ONC.

If you did not read those blogs along the way, shame on you for not keeping up with our tremendous ONC buzz blog. More importantly, I think it would give you important context as to the aspect of the space that we are focused on, which happens to be around decision support and the use of AI and ML technology towards supporting that decision support. I am just going to start here with this. I am happy to go through as much as we can, but also I recognize that we have folks with questions. Steven and Ike, can you just let me know what I need to stop? I will keep my eye on the clock. It looks like we have about 12 minutes.

I think for those of you who have been longtime admirers and fans of ONC's certification program, or those of you who have just been regulated entities, you have probably known that we have had a certification criterion all the way back to ONC's health IT certification program in its inception, focused on CDF. It was actually mentioned in statute as part of the qualified electronic health record definition, and it essentially said that a qualified health electronic health record is a record of health-related information that has the capacity to provide clinical decision support. It is actually in statute.

We took a number of steps to translate statute in the HITAC act into meaningful use related initial certification criteria. What we ended up putting into regulation eventually was based on the Health IT Policy Committee's recommendations way back in 2012. We included requirements that health IT modules support CDS that does a number of things, including displaying source for citation of CDS, is configurable based on the patient context, is presented at a relevant point in clinical workflow, and includes alerts

presented to users who can act on those alerts. Then, it is integrated with the EHR. Those were the recommendations that the HITPC, Health IT Policy Committee, recommended to us back in 2012.

You can go to the next slide. Since 2012, a heck of a lot has happened, but not much of anything has happened in relation to our CDS criterion. Obviously, a lot of the background that was covered in those slides went into detail on how predictive models are increasingly being used and relied upon to inform a wide array of decisionmakers, including clinicians, payers, researchers, and individuals. Also, one of the key things that we describe and discuss across those blogs is the role that certified health IT plays has become a central component both as a data source of these predictive models and as a delivery mechanism. Again, we talk at some length around the centrality of certified health IT, in both supporting the development and design of predictive DSI as well as serving as a vehicle to influence day-to-day decision making.

Next slide. One more. We have a series of slides here, and I do not think we will be able to get through them in the nine minutes that we have got, but we can go as far as we can. I think a lot of folks had initially asked a question around why change the name. What is DSI? How does it compare to CDS? All very good questions. I think the big takeaway is we are trying to modernize a certification criterion that is a decade old and recognize that certified health IT plays a role in a greater variety of use cases. The DSI concept expands on CDS to reflect the various and expanding forms of decision support that certified health IT and modules enable or interface with. Increasingly, these use cases support across many aspects of healthcare, not just clinical workflow but early detection of diseases, automated billing procedures, facilitating scheduling, and public health disease surveillance, among other use cases.

Part of this reframing, part of this renaming, is intended to really acknowledge this expanded set of use cases that certified health IT supports and adjust it for the future, where we anticipate certified health IT will continue to support numerous kinds of use cases outside of the traditional CDS workflows.

Next slide. Here are some updates. I would say, the traditional A9, and we do apologize in terms of using the Code of Federal Regulations citations, but I think it is going to be something you will get used to. A9 is the CDS criterion. We are proposing to move that to B11 and this is important for a handful of reasons that we will get into. I think it is really important to know that if you are familiar with the structure of A9, you will be very familiar with the structure of B11 because we used A9 as the base. We built on top of it and we built around it, B11.

We talk about how the new criterion and modules that certified to the new criterion will still be expected to enable evidence-based decision support as well as linked referential decision support based on a defined set of data elements. This has always been the case. Historically, we have required health IT modules to support CDS that uses problems, medications, allergies, demographics, labs and vitals. We are now proposing that health IT modules also support to individuals on support CDS based on procedures and unique identifiers for implantable devices. We are also looking to expand on the existing set of source attribute information. We currently require that health IT modules provide users access to information, bibliographic information, about the CDS. We also require that health IT modules provide users with developer information on the CDS or on the intervention, and funding sources, and the release or revision dates of the CDS if applicable. That is all existing today.

What we are proposing is that moving forward across all DSI types, the health IT modules would also enable users to know if the intervention uses specific demographic data, if the intervention uses any social determinants of health data, and if the intervention uses any health status or assessment data. Across all of these data, we focus on USCDI. If you have a question of what is health status or assessment or social determinants, we point to the USCDI as their data elements. Again, this is meant to provide users with transparency on what data elements are being used in that CDS. This is, of course, something that a user is required to look at, but this is something a user may look at if they would like to be able to look at it. Again, this builds on existing requirements for bibliographic information, and software, and funding source.

Steven Lane
Hey, Jeff?

Jeff Smith
Yes.

Steven Lane
Jeff, before we go on to the proposed new requirements, why don't we pause because I think we have a couple of task force members with questions and we want to be on time for the public comment. Clem, you had your hand up for quite some time. Did you have a question you wanted to put out? If not, Hans?

Hans Buitendijk
Thank you, Steven. Yeah, a question that I have that ties a little bit to Deven's question as well. I will point to her for that part. With DSI that spans a variety of HIT that potentially can offer that, and the examples to that being used go into **[inaudible] [01:15:08]** operations, other topics where that can be value to that. What is ONC's intent from HIT that should be certified to these capabilities beyond EHRs? There is a clear understanding in that space, but there is also HIT that are not considered EHRs where this would apply. How are we looking at that? I think, Deven, your question might be tied to that as well with other places in that space.

Jeff Smith
It might be helpful to jump down to a slide. Can you go forward four slides? One more. Hans, this is something that I think, obviously, we will spend more time on this slide and the concepts contained in this slide. We do provide additional information in the preamble. I think the easiest way to try and answer that question is to point out that we regulate certified health IT and certified health IT modules. We really do not think in terms of the EHRs. There is going to have to be a conceptual common ground knowing that obviously there are entities out there that are very much thinking to themselves, "We are an HER company," or, "We provide EHRs." At a basic level, we have health IT modules that are certified to certain criteria. I think the answer to the question, understanding the scheduling software use case.

The real nexus that have in the certification program and that we are proposing for this, and the predictive decision support intervention definition is that the health IT module, if it enables or interfaces with a predictive model, and I will boil it down to that for just a little bit. If it enables or interfaces with a predictive model then the predictive model, or the DSI, would be subject to our requirements. There is some further caveats there because we do not regulate algorithms out in the wild. We regulate certified health IT. When we get into the conversation around source attributes, it is important to recognize that we look at the world

in terms of which predictive DSIs are developed by certified health IT developers themselves and predictive DSIs that are developed by other parties.

The requirements that we are proposing would be, in some ways, absolute for developers of certified health IT that develop predictive DSIs. Then, we would rely on essentially existing requirements around CDS. If you are a health IT developer that uses CDS but developed by a different organization, or maybe it is developed by the, sorry. Anyways, this slide is going to be one that we will probably want to focus on quite a lot and get your feedback on. I will stop there.

Steven Lane
Yes. Thank you. We actually are going to transition to public comment. If we have time left, we will come back to Clem, Deven, and Hannah in that order.

Public Comment (01:19:01)

Michael Berry
All right, everybody. We are going to open up our meeting for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press star-nine to raise your hand and when called upon press star-six to mute and unmute your line. So, let us pause this for a moment to see if any members of the public raise their hand. I am not seeing any hands raised. I will turn it back to you, Steven.

Steven Lane
All right. Sheryl, I know you have been very patient. Did you have anything you wanted to toss in since I cannot see your hand raised?

Sheryl Turney
Thank you, Steven. I did want to say that, with the point that was brought up earlier, and I will definitely want to talk about this in the small groups, it was a concern of mine as well ensuring that predictive models address rare and other conditions because we have looked to what are the factors for health equity. What are the factors for specific types of conditions that already, in the way that we look at cost data, which has decision modeling around it. They have pretty much done away with paying for testing Vitamin D. But if you are a Vitamin D resistant rickets patient, you need that Vitamin D test and they do not pay for it today. There is no variation that happens in the decision support, unfortunately.

I do think that we have examples in today's world that show that this is an area that we particularly need to pay attention to. We need to make sure that the right guardrails and governance is there around that. To the extent that it impacts certified health IT, I know this is not the area where we are going to be implementing what should be there and what should not be but there should be at least some guardrails relative to the governance of how these things are implemented that we should be able to recommend. With that, I am very happy to be part of this group and look forward to our recommendations.

Steven Lane
Thank you, Sheryl. Again, we have eight minutes left. We are going to end on time. We have three hands up. Clem?

Clem McDonald
Very quickly, I think we should not put decision support on too high a pedestal. It is not perfect. There are all kinds of issues and problems. We are talking as thought it is a done deal and all we do is someone cooks up a rule and everything is going to be perfect. It will not be. Just be wary.

Steven Lane
Thank you for that wise observation. Deven?

Deven McGraw
I am trying to get a handle on what the incentives are to purchase a module for a certified EHR vendor that has been certified to these criteria. What are the incentives for the HIT developers to certify modules, whether they are home grown, self-developed or whether they are addons from additional vendors. It could be that my knowledge of where the incentives are to utilize certified modules and the authorities that ONC has is a little rusty. Given that not every piece of a certified, where is the incentive for certification, I should say. I think, Jeff, you have got the answer to my question. The prior slide did not really answer it because it did not say to me that any certified EMR vendor would be necessarily required to certify a module. Maybe they are. If so, I would like to have that underscored. Where is the customer incentive to actually purchase a module? I am not aware of any financial incentives to use DSI that has been certified, for example. I will stop there. Thank you.

Jeff Smith
Great question, Deven. To the first question on whether or not health IT developers are required to support predictive DSIs, the answer to that is no. We have constructed the criterion to be conditional. If there is a developer who is certified today to A9 and they have no ambitions or plans to enable or interface with predictive DSIs, then they will not have to go through many of the requirements that are predictive DSI specific. There is no obligation to certify to B11 and do so supporting predictive DSIs. We can get into the conditional nature of the criterion, but that was built in because we do not want to force that.

To your other question around incentives, also a good question. I may have glossed over this in our haste, but I mentioned that clinical decision support a part of what was the original statutory definition for qualified EHR. We have translated the statutory definition for qualified EHR into what we call the base EHR definition. As of today, you cannot be a certified health IT module, or you cannot meet the base requirement for certified health IT without being certified to the clinical decision support criterion, which is today A9. Moving forward, we propose to include B11 as part of the base EHR definition. Therein lies the incentive. It will be a baseline requirement for any module or product that wants to meet the baseline EHR definition.

Deven McGraw
Got it, but there are not any **[inaudible] [01:25:04]** requirements on the part of users of the IT to use those if they are going to deploy predictive algorithms. They do not necessarily have to use what is offered in there. We do not have any incentives for them to use what is certified versus something else.

Jeff Smith
Well, certainly, there are requirements under CMS payment policy, to use a base EHR definition.

Deven McGraw

To use a base EHR, but not particular to decision support **[inaudible] [01:25:38]**.

Jeff Smith
The decision support is part of the base EHR definition. Again, we would **[inaudible – crosstalk] [01:25:47]** –

Deven McGraw
Well, that is right, but are there –

Jeff Smith
There would not be requirements for users to use predictive DSIs, for instance.

Steven Lane
Yet, Deven, it seems that there may be some market advantage to be offering certified predictive DSI. Time will tell.

Deven McGraw
Of course. This was helpful clarification on where this sits in terms of both users incentives to use it as well as developers incentives to provide it. Thank you.

Steven Lane
Hannah, you have been very patient with your hand up. Anna and Hans, I have noted your questions. I think we may end up coming back to them tomorrow. Hannah, do you want to get your question out there?

Hannah Galvin
Thanks. I will be very brief. While we think about transparency, as someone who implements these types of models, I would think about how we are transparent to those who are implementing the models, the ASCMIO or an implantation team, versus the transparency to a provider at the bedside. What does a provider at the bedside need to know? To Ike's point, I have a patient in front of me with a rare condition and I need to understand how the model was built and is it appropriate for the patient, versus the transparency of is there bias in this model. We may need to dig deeper. What type of population was this tested on? What type of transparency is needed in both situations? It may be the same or it may not be the same thing. Keeping provider burden mind, there only so much that a provider at the bedside can dig into a model.

I would also keep in mind, I did go back and review the slides to my previous question. We are encompassing more advanced neural networks in this process. As we think about bias, just thinking about the data that is being fed into those neural networks it is not necessarily understanding how that is being used. That is a start to understand what pieces of data are being fed in, but it is not quite the same thing as understanding the algorithm. When we do have a black box problem there in not understanding how the data is being used, there is only so much that we can understand in terms of potential bias of the potential algorithms. I think there are some pieces there that I want to further understand how the decision support capabilities will be required to provide that information to better assess bias for those who are implementing this as part of a certified health technician.

Steven Lane
Thank you so much, Hannah. I will let that be the last word today. We are going to pick up this topic, as well as Anna's and Hans' raised hands, when group two meets tomorrow. Any of you who wants to continue the discussion there, let us meet then. I anticipate that everyone will have a chance to review the slides in detail to spare us the time of making ONC go through those. We will pick up the conversation and questions at that time. Anything to add, Ike or Mike?

Steven Eichner
No, sir. I look forward to seeing folks tomorrow and continuing our work.

Steven Lane
Excellent. Everybody have a great day.

Steven Eichner
Thank you.

Adjourn (01:29:25)