Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

GROUP 2: ONC HEALTH IT CERTIFICATION UPDATES – NEW AND REVISED CERTIFICATION CRITERIA

May 3, 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
Jim Jirjis	HCA Healthcare	Member
Anna McCollister	Individual	Member
Aaron Miri	Baptist Health	Member
Kikelomo Adedayo Oshunkentan	Pegasystems	Member
Naresh Sundar Rajan	CyncHealth	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
Seth Pazinski	Office of the National Coordinator for Health Information Technology	Acting Designated Federal Officer
Sara McGhee	Office of the National Coordinator for Health Information Technology	ONC Program Lead
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
Grace Cordovano	Enlightening Results	Presenter

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

Seth Pazinski
Hello, everyone. Good morning and welcome to our HTI-1 Proposed Rule Task Force under the Health IT Advisory Committee. Thank you for joining today. My name is Seth Pazinski with ONC. And I will be serving as the designated federal official for today's meeting filling in for Mike Berry. I just want to remind folks that all task force meetings are open to the public and your feedback is welcome. You can do so in two ways. One is throughout the meeting, you can put comments in the Zoom chat feature or you can make comments verbally during our public comment period, which will be taking place at 10 minutes towards the end of the meeting. So, you can save your comments for then as well. I am going to start the meeting with a roll call of the task force members. When I call your name, please indicate that you are present. I will start with the co-chairs. Steven Lane.

Steven Lane
Good morning.

Seth Pazinski
Good morning. Steven Eichner.

Steven Eichner
Good morning.

Seth Pazinski
Good morning. Medell Briggs-Malonson.

Medell Briggs-Malonson
Good morning.

Seth Pazinski
Good morning. Hans Buitendijk

Hans Buitendijk
Good morning.

Seth Pazinski
Good morning. Jim Jirjis.

Jim Jirjis
Good morning.

Seth Pazinski
Good morning. Anna McCollilster.

Anna McCollister
Good morning.

Seth Pazinski
Good morning. Aaron Miri.

Aaron Miri
Good morning.

Seth Pazinski
Good morning. Kikelomo Adedayo Oshunkentan.

Kikelomo Adedayo Oshunkentan
Hi. Good morning.

Seth Pazinski
Good morning. Naresh Sundar Rajan.

Naresh Sundar Rajan
Good morning.

Seth Pazinski
Phil Southerland.

Fillipe Southerland
Good morning.

Seth Pazinski
Good morning. And Sheryl Turney.

Sheryl Turney
Good morning.

Seth Pazinski
Good morning. All right. We have a full roster today. And with that, I will turn it back over to our co-chairs, Steven Lane and Steve Eichner to get us into our agenda.

HTI-1 Proposed Rule Task Force Charge (00:02:10)

Steven Eichner
Thank you, Seth. And good morning, everybody. Good morning task force members and a special welcome to the general public. And welcome to our presenters as well. We have another good meeting laid out for us today where we are going to continue working in DSI as we started last week. And we are going to continue to work through that. We have some great presentation materials to go through with Kathryn and Jordan to help find additional information. There have been a couple of contributions into the worksheet that we are using to begin to develop recommendations. Please do continue to use that worksheet and make recommendations. We will go through them a little bit as we have time today. Steven, do you have anything to add?

Steven Lane
No. Again, as you say, thank you to all of the task force members and members of the public who are joining us today. We have got a lot to cover so we want to jump right in.

Steven Eichner
From a logistics perspective, Steven Lane is going to help identify raised hands and track things in chat. And I am going to be doing other aspects of the meeting. Please if task force members do have questions, please do raise your hand electronically or make a question in the chat window. Comments made to everyone are included in the minutes and the official records of the meeting. Information included through hosts, panelists, or direct conversations with individual task force members are not. We have reserved 10 minutes towards the end of the meeting for public comment. We will ask Seth to recognize the public where the public can ask questions electronically and we can respond. That being said, we will go ahead and shift into a quick overview of our task force charge and then, into the content. As a quick overview for the task force charge, the task force has been charged to evaluate and provide feedback on the NPRM broken down into specific charge areas such as certification program, ECR, shifting from USCDI Version 1 to Version 3 in a regulatory environment, and other aspects.

Those are available in the presentation for you to peruse at your leisure. Let us go to the next slide please. These are a continuation of the comments. All comments are due to HITAC and to ONC by the end of the 60 day public comment period so we are time limited in the development and submission of our comments. We're making good progress. We still have a way to go but I believe that we will be able to get there in a timely manner. Next slide. This is, again, a continuation of the specific areas that we are making comments on, again, across the three work groups. While folks here are focused on Subgroup 2, as a reminder, you are welcome to attend any of the group meetings. They are all at 10:30 Eastern Time, Tuesday, Wednesday, and Thursday, generally speaking, for the next month and a half or so. The public is also welcome to attend all meetings. Links are available in the ONC/HITAC calendar. Next slide please.

We are now going to shift into our continued discussion of decision support interventions and predicted models to continue the discussion that we had last week. Steven, do you have anything to add?

Steven Lane
Simply that we have a very full plate today and we are going to blast through a lot of rich material before we take questions.

Steven Eichner
Thank you for that. Given that, we are going to turn the floor over to our presenters and, hopefully, learn quite a lot.

Decision Support Interventions (DSI) and Predictive Models (00:07:08)

Jordan Everson
I am going to take it from here. This is Jordan Everson. And we are going to dive right back in where we left off talking about source attributes for predictive decision support here. Next slide please. Before doing that, a reminder that the materials in this presentation are based on the proposed rule. And while we have tried to be accurate to the proposals, this is not a legal document and please review the proposed rule. And also, ONC must protect the rule making process and comply with the Administrative Procedures Act. That

means we can present information in the proposed rule. We cannot interpret the information or clarify or provide for the guidance unless this communication is produced at taxpayer expense. Next slide. As I said, picking up where we left off with source attributes for predictive decision support interventions and as a reminder, source attributes in the proposal would be available via Link Out or Drill Down from certified health IT for review from the module. Next slide.

We developed a list of several source attributes specific to predictive decision support interventions. And in developing that list, we are guided by a few key concepts and goals. First, we looked for attributes that were most commonly included in existing reviewed reporting guidelines of which there are many reporting guidelines both for the peer reviewed literature and for clinician facing model information. We focus on attributes that would be most meaningful and interpretable in the context of health IT users and developers that were focused on health equity, fairness, and issues of bias, and on attributes that were intended to show the model would perform effectively outside of this specific context in which it was developed so information like external validation and local validation. Our goals here were to minimize the number of attributes to base them on those existing model reporting guidelines to the extent feasible, to balance prescriptiveness and flexibility, which is a topic we will come back to in some of the requests for comments.

We also sought to align with existing reference material, notably the NIST AI risk management framework and the White House blueprint for an AI bill of rights as well as White House executive orders. And we sought to support emerging industry led efforts towards score cards and other information around this such as those pursued by the Coalition for Healthcare AI and the Health AI Partnership. Next slide. This is the list of the 14 proposed source attributes, specifically, for predictive decision support interventions. And these would be in addition to those that we have discussed previously that apply to both evidence based and predictive decision support interventions. And the logic here is that if a health IT module enables or interfaces with predictive DSI's, we are proposing that the module must make information about additional source attributes available to provide transparency on how the predictive DSI was designed, developed, trained, evaluated and should be employed.

These 14 attributes fall into 4 categories, intervention details, intervention development, quantitative measures of intervention performance, and ongoing maintenance and use. We are going to walk through each of these in at least a little bit of detail. And so, I will not read through each of them right now but thought to group them together for you all. Next slide. An important note here is that the proposals around source attributes would not require disclosing or sharing intellectual property existing in the developer's health IT. The proposed requirements would not provide information about or report any details of the specific code, pipelines, physical processes, or algorithms used to generate model predictions, which might be considered intellectual property. Next slide. I noted that in developing these, we tried to balance between prescriptiveness of the information provided and flexibility to meet the varied use cases to which predictive models might be applied.

And we have included a request for comment on whether there are items contained within the proposed source attributes that we should explicitly require as elements of source attributes information. So, these are items currently listed as should within the preamble description. And the question here is are there should components that would become explicit requirements within the regulatory text and specific attention to three source attributes. And this will make more sense as we walk through those where we have multiple should components. One is intended use of the intervention. Second is input features of the intervention,

including description of training and test data. And the third is the external validation process if available. Next slide. So, here we're starting to walk through the specific source attributes in detail. So, the first is the output of the intervention, which is a description of the value that the model produces as an output, including whether the output is a prediction, classification, or other type of output.

And the intention here is that users evaluating the model can decide whether to use the output and ensure that the output is directly relevant to the way in which the user intends to use it so that it is not predicting something that is not directly relevant to a given use case. The second attribute is intended use of the intervention, which is a description of the intent of the model developers and how the model is meant to be deployed and used. Here is an example where we have included several should statements and requested comment around these. And the should statements are whether the model was intended for specific or general tasks, who the intended patient population is, who the intended users of the model are as well as the intended action of the user, the role of the model, which could be conveyed through a taxonomy like that developed by the International Medical Device Regulators Forum, the American Medical Association, or the Consumer Technology Association, each of which have produced separate but related taxonomies.

And lastly here, the logic underlying the model, including the exact question the algorithm is supposed to answer. Each of these are included in the description, the preamble, but are not listed individually in regulatory text in the proposed rule. Next slide. The next source attribute here is the caution out of scope use of the intervention, which is a description of task situations or populations to which the model developer cautions a user against supplying the predictive model. I will note, in prior comments, you had concerns about models being used in inappropriate situations. And this would be within the construct of the source attributes, a place where information around that could live. And this would include known risks, inappropriate, settings, inappropriate uses, or known limitations. And these descriptions should inform users about tasks or populations related to the intended use of the model in which the model may not perform as expected.

Another source attribute is around input features of the intervention, including descriptions of training and test data. And this is another where we include several should statements and request comment. Exclusion and inclusion criteria that influenced who was included in data sets, statistical characteristics of the demographic and other key variables in training and test data, the source in clinical setting from which the training and test data were generated, the extent of missing values, and other attributes related to data quality are all items that should be included within this source attribute. Next slide. Further in the intervention development category, we have the process used to ensure fairness in development of the intervention, which is a description of the approach the model developer has taken to ensure that the model output is fair. We know there are many such approaches that one could take. And we are not prescriptive about what process a developer might take to ensure fairness but do propose that information around these processes be provided through source attributes.

And an example would be to say that in pre-processing the data, the developers employed a disparate impact from move or transformation across race or ethnicity groups based on a well known approach simply an example of which there are many potential approaches. The next attribute here is external validation process if available, which is a description of how and in what source, clinical setting, or environment a model's validity and fairness has been assessed other than the source, training, and testing data. And this is another one with a list of items that should be included. Who conducted the external testing. Was it the

model developer or developer of certified health IT or an independent third party? What was the setting from which the external data was derived, the demographics of the patients and external data, and a brief description of how external validation was carried out. And here I will note we include this if available phrase, which indicates that if this information is available and was performed by the developer, it should be included in source attributes.

But if this information is not available, it should be clearly indicated as not available for user review. Next slide. This slide, actually, covers seven of the source attributes. And there are those related to quantitative measures of intervention performance. First, we have three source attributes related to validity of prediction corresponding to validity in test data and, if available, external data and local data. And this is a presentation of the measures or set of measures related to the model's validity. You can think, as an example, sensitivity and specificity. And that is validity tested and data derived from the same source as the initial training data and data from an external source and then, data local relative to its current use. In other words, from perhaps the health system it is being used in. Importantly, this proposal would not prescribe specific performance or validation measures. Simply, that information must be included in some cases if available.

We have a parallel set of source attributes around fairness of the prediction, in test data, and if available in external data and local data. And, again, these are the presentation of measures related to fairness derived from data that is the same source as the training data and data from an external source and then, data local relative to its current use. And this, again, is a place where there are numerous approaches to measure fairness. And we are not prescribing a specific measure. We have included several examples here as in the proposed rule. Many of these are case specific of what the best measure might be. And lastly here, we include references to evaluations of use of the model on outcomes if available. And this would be bibliographical citations or links to evaluations showing the use of the model on objections such as reduced morbidity and mortality, length of stay, or other important outcomes. The information that might be generated from clinical trials or other studies of the model. Next slide.

The last category of source attributes focuses on ongoing maintenance and use and includes the update and continued validation or fairness assessment schedule, which is a description of the process in frequency by which the model's performance is measured or monitored in the local environment and corrected when risks related to validity and fairness are identified. And information here should include how often performance is evaluated and how often the model is updated giving an insight into the likelihood that the model may have degraded or drifted since it was last updated. And then, in this section, we include the validity and fairness in local data, which I described on the prior slide, again, measures of validity or measures of fairness generated in local data within the local context. Next slide please. Beyond the list of 14 source attributes we have included in the proposed rule, we have also included a request for comment around numerous other source attributes that we have considered but have not included within the current proposals.

And we have listed these and several more within the proposed rule. And I do suggest taking a look at the information included there. These items include things like information on ability to explain and interpretability of the model and predictive decision support. And of note, some of this is information that we would also include within the intervention risk management proposal that Kathryn will describe in a few minutes. I am not going to read through each of these but you can see there are alternative quantitative measures, specific information or online or unlocked models, as well as other information about how the

model was developed. Next slide. Another important request for comment that we wanted to highlight is that we have solicited comment on whether we should require developers of certified health IT with health IT modules certified to B11 to make source attribute information publicly available. For example, on a website similar to the existing API documentation requirements.

And here, we are asking for comment on whether this information would be beneficial for potential users or purchasers of models or associated technology or software and would help inform them prior to procurement of health IT and procurement of predictive DSI's integrated with certified health IT. And we also solicit comment on whether having this information available would improve public confidence in predictive DSI's, for instance, by enabling research on that underlying source attribute information. Next slide. A further request for comment, we are aware that patients want to know if AI is being used in their care and understand how and why it is being used. We understand an emerging trend is for healthcare providers to inform patients about the use of these technologies, including predictive decision support in making decisions about their care.

And we have solicited comment on whether existing program requirements in the communications condition and maintenance of certification are sufficient to ensure open and transparent discussion regarding the use of predictive DSI's in patient care, including discussion between users of certified health IT and patients so really asking if the communications condition is sufficient here. And we are interested in knowing if additional requirements around the technical capability for users to access underlying source attribute information would be beneficial to patients understanding the use of these decision support interventions in the course of their care so an important request for comment around patient access to this information. Next slide. We also solicited comment on testing or assessment tools that might further support transparency and trustworthiness, including consensus metrics and technical standards. We did identify numerous reporting deadlines but they are numerous and are not all in consensus so looking for additional metrics and standards that may be achieving consensus.

We are also interested in comment on development and engineering of algorithmic impact assessments and development of documentation of data sets used such as data sheets for data sets and data cards as well as similar information. Next slide. So, we proposed 14 source attributes. We have also proposed the ability that health IT modules provide the ability for users to author and revise attributes beyond what is proposed to support the ongoing evolution of what source attributes are important to users to make informed decisions. We have, essentially, positioned the 14 proposed source attributes as a baseline or floor from which users may modify or add to fit their specific needs. This authoring and revising proposal pertains to both evidence based decision support and predictive decision support for which we have proposed additional source attributes already. And it would mean a health IT module would need to support the technical ability for a limited set of users to create or edit attribute information alongside the source attributes proposed.

An example would be that if a hospital develops its own predictive DSI and thinks that there are specific pieces of information relevant to its users, they could add those pieces of information to the existing list of source attributes. Next slide. We have also proposed, and this is a general proposal, again, for both predictive decision support and other types, in the 2015 edition proposed rule, we proposed to adopt functionality that would require health IT modules to be able to record at least one action taken and by whom it was taken when a CES intervention is provided to a user. And we proposed, at that time, whether

the user viewed, accepted, declined, ignored, overrode, or provided a rationale for the action taken. We also proposed that the health IT module would be able to generate either a human readable display or human readable report of the responses and actions taken. In the final rule, we noted that many commenters stated that current systems provide a wide range of functionality. And so, we did not finalize that proposal at that time. Next slide.

In this proposed rule, we are proposing that health IT modules certified to B11 must be able to export such feedback data, including but not limited to the intervention, action taken, user feedback provided, user date and location so that the exported data can be associated with other relevant data. In the course of developing the rule, we heard some that the tool was not as widespread today as it perhaps could be and so having included this. We have arose that such feedback data be available for export by users for analysis in a computable format so that it can be associated with other relevant data such as patient information like diagnosis, other inputs into the DSI, in the outputs of the decision support. In addition to quality improvement of decision support, we believe such a structured export would facilitate research associating feedback data with other relevant data in linking the DSI to patient health outcomes. Next slide.

And that concludes the quick run through of the source attribute information for predictive decision support. And here, I will hand it over to my colleague, Kathryn, to continue through the intervention risk management proposal.

Kathryn Marchesini
Great. Thanks, Jordan. To focus a little bit on the intervention risk management proposals, we realize that model development is not as straightforward a routine but just a technical process. We understand that the experience and judgment of developers, as much as their technical knowledge, greatly influenced the appropriate selection of inputs and processing components in also dealing with the training and experience of the developers. And so, in addition to skilled modeling and robust validation and model risk cannot be eliminated, there are other tools that should be used to manage model risk effectively. That is part of why you will see on the proposals here the overall, big picture perspective is we propose that developers of certified health IT with health IT modules that enable or interface with predictive DSI's that they employ or engage intervention risk management practices. We are also proposing that the summary information regarding these intervention risk management practices be made available via a publicly accessible hyperlink.

We view our proposals for risk management of predictive DSI's as complementary to the proposals that Jordan just walked through on the predictive DSI source attributes. Next slide please. As mentioned, the proposed source attribute information requirement is meant to provide the users and the implementers with sufficient information, you heard Jordan speak to that really, to understand how the model was designed, developed, tested, as well as including the model's purpose, the known limitations and the intended use. And you will see some of that here. Correspondingly, as mentioned the proposals for the intervention risk management you will see in the middle here, sometimes are referred to as governance. This would provide users and implementers and the wider public in some instances, including patients, with the information on how the developers of certified health IT with the health IT modules that enable and interface with predictive DSI's how they analyze mitigated and governed risk throughout the technology's lifecycle. Next slide please.

So, while we believe that the transparency regarding the technical and performance dimensions of the predictive DSI is needed, as mentioned, we believe that the transparency regarding the organizational as well as sometimes referred to as sociotechnical competencies that were employed by those who actually developed the predictive decision support intervention. We see this as foundational for users to determine whether their predictive DSI is **[inaudible] [00:30:41]**. I know we talked about that last week. In addition to the proposed requirements, you will see for source attributes previously here on the slide the proposals to required developers. To the extent a developer tests yes, they would need to do intervention risk management practices as I mentioned earlier. But you will see here this is just, I would say, a brief overview of the requirements. I will dive a little bit more in the following slides. Generally speaking, it focuses on intervention risk management practices that includes three areas. The risk analysis as well as risk mitigation and governance.

The other piece you will see is the requirement that summary documentation be publicly accessible as well as detailed documentation. That proposes a requirement upon ONC request. Next slide please. Before diving into some of the specifics, I know that the NIST AI risk management was mentioned earlier but also I wanted to flag here about a lot of the proposed terms and definitions heavily rely on the NIST management framework. In some cases, that is connected to the ISO. But we tried our best to make sure that we had consistency across terms. Next slide please. As far as some additional background, you will see here, I will not necessarily read all of it, but it is really trying to focus on the fact that we tried to find the balance between prescriptiveness but also providing opportunity for industry to further opine on some of this regarding how best to approach methodology around risk management. You will also see similar to the source attributes requirement, there is some intersection between the topics of an effort.

So, there is definitely some synergy there. So, I would encourage you to read more about that. And then lastly, the intent is that this is something that would happen throughout the technology's lifecycle. Next slide please. At a very high level, you will see here, as mentioned, the risk analysis, the risk mitigation, and governance. And so, we propose that developers of certified health IT analyze potential risk and adverse impacts with predictive decision support intervention for the following characteristics. And they were listed on the prior slide and we will touch a little bit on them on the following. But this deals with validity, the reliability, the robustness, fairness, intelligibility, safety, security, and privacy. The thought being to the extent there was risk to that that was identified, the developer would need to implement practices to mitigate those risks associated with the predictive DSI. Lastly, governance. We proposed that a developer of certified health IT establish policies and implement controls for predictive DSI, including how data are acquired, managed, or used in a predictive decision support intervention.

I will touch a little bit more on the following slide. Next slide please. Here, again, I will not necessarily read the slide but know this is the background because I know you all want to get to discussions. But the categories that are proposed as far as where the predictive decisions support intervention if there is risk related to the lack of or failure of validity as well as the reliability and robustness. Again, I will not necessarily read this here. Just know that we did our best to connect with the underlying NIST definitions as well as risk to fairness and intelligibility. I know there is a strong interest here. And I know that Jordan spoke to some of this as well as part of the source attributes. I just wanted to make that connection here. Next slide please. Also, risk related to safety as well as security. We understand that there is often some intersection between safety, security, and maybe even sometimes privacy. People may use different terms or see it from a different perspective.

So, we did try to capture all of those here. Next slide please. Lastly, the risk to privacy. Again, you will see in the proposals these terms defined. We are interested in the feedback that the group has for your discussions. Next slide please. The thought being after the risk analysis, there would be risk mitigation. And I am sure folks are very familiar with mitigation of risk. Again, we are not prescriptive to where the methodology of the approach that an organization or developer uses. We do provide resources or potential places or activities that could be leverage. The key thing being is that the underlying activity of risk mitigation is performed. Next slide please. Last but not least, we propose to require, as mentioned, governance. This really gets into the health IT developer established policies and implement controls for predictive decision support intervention governance. And as mentioned earlier, this includes how data are acquired, managed, and used.

I will spend a little time here in that the governance should encompass the models, the software, and the data developed or provided by other parties as well as internally developed interventions. You will see here also we talk about what we mean by policies and what we mean by controls. And so, as mentioned, we tried our best to seek to strike a balance between the prescriptiveness and the sufficient description to enable robust reporting of information on the intervention risk management practices. There is also, as mentioned earlier, the proposal to provide a summary of the risk management practices publicly accessible. I just wanted to share that as well. Lastly, I know this probably isn't as visibly appealing as it should be but this is just a very high level crosswalk of where in our proposals we see the connections between the source attributes requirements and then, risk management requirements and how that connects back to the concept of FAVES**.**

I just wanted to share that. Next slide please. I will just briefly touch on some of the last area to focus on oversight and implementation as it relates to the proposals. Next slide please. Again, you will see here this is a snapshot that we are going to be focusing on the discussion around oversight. And this really is how the proposals would be implemented in terms of ONC's role as part of the broader existing health IT certification program. Next slide please. Many of you are probably very familiar with the existing health IT certification program. You will see here the proposed new requirements conformance will be found through the existing, real world testing program. You will see some information there about dates. As a result, there would be a requirement, as mentioned, about the publicly available part of the intervention risk management but also as part of the real world testing program, the plans, and the results are also publicly available on an annual basis. Next slide please.

Again, this is just a little bit more detail provided really focusing on the summary information for the intervention risk management and their availability as well as the requirement on certified health IT developers with health IT modules that are certified to the proposed regulation and the requirements that would be associated with that under the existing ONC health IT certification program. Next slide please. With that, hopefully, you will have enough time to discuss these topics. We tried our best to provide you an overview. With that, I will turn it back over to the co-chairs.

Steven Eichner
Thank you so much for that wonderful presentation. I know that there are a bunch of questions in chat. I do invite task force members to also raise their hands so they can ask questions orally as well. Steven, do you want to help us go through the questions in chat?

Steven Lane
We did not discuss this specifically, but one thought was to allow Grace to go ahead and add her commentary before we open up to full questions because I think some of the items will be addressed there.

Steven Eichner
Absolutely. That would be fantastic. Grace?

DSI Proposals: Patient & Carepartner Perspective (00:41:27)

Grace Cordovano
Thank you, everyone. I just wanted to say thank you to ONC and to the task force for giving me the opportunity and some time today to speak from the patient and care partner perspective on some of the DSI proposals. And while I was going to go into some applause moments in my presentation, I think Kathryn and the team at ONC really deserve a round of applause for all of the work that they have been doing to bring so many important aspects of what is future facing to the surface for our discussion. Next slide please. From the patient and care partner perspective, really the success of the DSI arena in healthcare has to be rooted in inclusive co-creation and symmetry to access of information for all stakeholders, including the patient and care partner voice. There is mention of utilizing health equity and social determinants of health data but that is not enough. We really need diverse patient representation as part of the decision making process and guidance process here.

Patients really do need to be included as well as care partners as subject matter experts, co-creators, and users of predictive DSI. And I encourage everyone to dream bigger than the status quo, which is currently that the physician or the clinician is the one that is going to be using DSI and benefiting from it. I would like you to imagine a world where patients will be asking for these technologies and selecting their coordination of care according to who has these DSI's. So, the way that the rule is currently written, it seems that we are still looking at the conventional status quo, which is that the clinician or the provider is the end user of DSI. Patients really face an asymmetry of what is available with FAVES information. We have access to none of this or very little. And I encourage, again, clinicians are not the only ones as we think to the future and the DSI arena who are going to need access to this information. More information and transparency is key.

Each component of FAVES information also should be inclusively defined from the patient perspective through a co-creative process. Anna posed a question in the chat. How do we protected against the use of poorly defined measures that may not reflect what patients think are important? I think that's a grave, genuine concern. And I think what we need to do is make sure we have diverse representation and all voices included when we define each of these components. What is fair and fair to whom? We need to be readily available to patients as end receivers and end users of DSI's and really going back, again, round of applause for the amazing blog series that was put together across the last year, the five part blog series on AI and ML, patients can help reduce the risk of "market for lemons." Next slide please. From the patient and care partner perspective, ONC's role in really advancing transparency, trustworthiness, and predictive technology in healthcare as well as transparent risk management for and governance of really is truly appreciated and amazing.

And it is going to be fruitful in building shared accountability and partnership and advancement of the field collectively from a multistakeholder patient partnership approach. I really want to point out that some key

things that really jump out as important from the patient and care partner perspective includes requiring developers of certified health IT modules to make all source attributes information publicly available. Also, to provide technical capability for patients to be able to electronically access source attribute information as well as how important it is to provide these feedback loops and the ability to generate a human readable display. If we're going for transparency, all stakeholders need to have all access to information. Next slide please. I want to take this opportunity to highlight some concerns from the patient and care partner perspective, the biggest one being that patients currently have no access or way to access, request access, to predictive DSI outputs.

Again, in the rule, it is mentioned that these outputs are being used to guide decision making on care or coordination of care. So, I would like to understand does that mean we are going to formally call these outputs EHI? And are they part of the designated record set? As the proposed rule reads right now, it is unclear if patients and their care partners are really considered to be users by virtue of perhaps their engagement with patient portals, API's, or patient facing tools. So, I just want to make sure that we are clear in the language that we are using and not inadvertently excluding patients as active proactive users of health IT of the future. I would like to better understand who and what body are really defining the specifics of the FAVES components. Who is identifying what is "minimum necessary attributes?" The voices at that table will matter and dictate what the priorities are so we have to make sure we have equal, equitable, diverse, inclusive representation in these foundational decision making processes.

And if we do not have that, we do have a risk of introducing or exacerbating existing bias in equities and harm. Again, I already mentioned this. Are these DSI outputs considered EHI? And are they part of the designated record set? This also relates not just to a right of access piece but also how we think about exporting and sharing information. Does this make the priority different if we recognize that these outputs are indeed EHI and part of the designated record set? One of the biggest concerns that patients and their care partners and patient communities have is what are we doing about errors that may already exist in the medical records. We know that the data that is in our EHR's are powering the future of predictive DSI's and AI and ML powered innovations. Will there be greater emphasis on ensuring curation of medical records by patients and enabling more avenues and opportunities for correcting records or errors that may be in records or addendums in records?

And then, we have a number of opportunities to share from the patient and care partner perspective feedback. What does that look like? Will there be a portal here for reporting complaints similar to maybe the information blocking rule complaints or others' concerns or bias or discrimination? How would we collect that data upfront instead of waiting long term and saying, "Oops. We missed a few things?" Next slide please. I am going to wrap with some high level recommendations from the patient and care partner perspective. I recommend that ONC more specifically clarifies the role and expectation of patients and care partners as true stakeholders and co-creators in the future of responsible DSI. I recommend ONC ensures diverse representation of the patient voice and work groups and task forces centered around the future of DSI work such as consensus around FAVES definitions and defining priority of minimal attributes.

Lastly, ONC defines if outputs of predictive DSI that are used to make decisions about an individual's care or coordination of care meet the definition of EHI and if they are part of the designated record set. Thank you so much.

Steven Lane
Thank you, Grace. I do not know if Ike fell off the audio here.

Discussion (00:49:28)

Steven Eichner
I am still here. Thank you, Grace, so much. I personally agree with you wholeheartedly on a number of those factors. I do think that patient perspective, patient involvement is consistent. I am not quite sure where things fit in terms of ONC and technical standards and FDA's component on safety standards. I think that is irrelevant and I do think it needs to be addressed in both forums. Patient access to the information is critical and timely access as well. If I know that the DSI tool is going to be used to evaluate like here, I personally would like to know about that several days before my appointment so that I have enough opportunity to understand what tool may be used so that I can have a constructive conversation with my care team because there may be things that I have particular concerns about. If I do not know what tools are being used to evaluate it, I do not have a context as the questions to ask. So, I think that becomes a relevant component as well.

That being said, I think we are ready to shift into question and discussion. And I do welcome task force members to raise their hands and we will circle through the questions in chat. Aaron.

Kathryn Marchesini
Steven, I was going to just add to the patient, this is Kathryn, if it would be helpful just to draw some attention in the NPRM if that is of use.

Steven Eichner
Sure. Absolutely.

Kathryn Marchesini
I completely agree. I guess to draw your attention to that patients want to know if AI is being used in their care. We do, actually, solicit comment on whether existing program requirements in the communications conditions and maintenance certification requirement if that is sufficient to ensure open and transparent discussion regarding the use of predictive DSI's, including discussion between users of certified health IT and patients. And I just wanted to caveat we, actually, don't explicitly define users. Grace, to your point, if there is public comment on that, definitely let us know. But I just wanted to share that. We also speak to multidisciplinary approaches and ways to engage the patient perspective trying to learn more about that.

And then, the other thing just to full circle on the designated record discussion, you will find language in the preamble that speaks to if a patient requests access to their information held by a healthcare provider, the designated record set could include, for example, the underlying data used to generate recommendations about their healthcare or the underlying information about any use of predictive DSI generated as part of the healthcare decision as well as other information. And you will see some footnotes there that touch on the Office for Civil Rights, the HIPAA frequently asked questions that does a parallel arm with test results and underlying genetic information. Based on this conversation and Grace's remarks, I just wanted to make sure people were familiar or aware of that and where to look as you are contemplating your recommendations and deliberating on your discussions.

Steven Eichner
Thank you so much for that addition. I think we will go back to questions now. Aaron.

Aaron Miri
Thank you very much. I appreciate the questions. I appreciate the overview here and setting the stage. To me, there are a couple of things that I think we should consider and work through. One is, of course, origin. We talked about that extensively in the chats here of the algorithm of the DSI. Where is it coming from? What is the purpose? I understand we cannot peel the box back per se in terms of intellectual property. But increasing the trustworthiness is going to be important and really understanding that synthesis and origin of DSI where that algorithm came from is critical. I do think that there is also the notion of private and public algorithms. I will give you an example. An agent that could be used to derive a DSI algorithm such as a chat GPT publicly known does have vulnerabilities. I just posted a link showing how chat GPT was hacked, the public version. I will tell you that our health system here, Baptist Health, we are experimenting with a private version of that algorithm builder in building our own DSI algorithms based upon Baptist Health data.

And I can tell you there is a lot of opportunity here to shine the light so that the public transparency, if we chose to take that into a course of care, right now it is an alpha version, but take into a course of care, for instance, outputting a treatment option, how do we notify that patient? And how do we differentiate between a public DSI algorithm built on publicly available open source code versus private code? How does that work and also how does that fall into the rules then of my third part, which is HIPAA and/or information blocking if a patient requests for us who maybe uses a private algorithm generator such as chat GPT to build an algorithm and they want to know the data that went into that, who is responsible? I would take it the health system is. But is that called out specifically in 21st Century Cures where those pieces are? The answer is I do not know. So, I think there are a few dimensions here that we need to look through and think through to make sure that we are being 100% transparent with technology and these algorithms and, as I am always saying, not being creepy with technology. Thank you.

Steven Lane
Creepy. Hans. Oh, sorry. Do you want to respond?

Jordan Everson
Yes. I thought really quickly to respond with one clarifying point is that the source attributes we walked thorough today for predictive decisions are in addition to the **[inaudible] [00:55:41]** source attributes that include bibliographical citations, the developer of the intervention, funding of the intervention, and release, and if applicable revision dates for the intervention. And so, I think some of what is already in regulation would address at least some of the concerns you mentioned, Aaron.

Aaron Miri
Jordan, I will respectfully push back a little bit. I do believe we are missing geolocation data and other location that's specific to the DSI algorithm and ensuring that we do not have some nefarious actor in a third world country trying to insert themselves into a course of care. And I believe Grace said this in her chat there and then, suddenly codify an archaic process into workflow because we cannot peel back the veil of transparency. I think there is other componentry here that we need to think about beyond some of the existing source data. So, I appreciate your perspective. You are right. It will give us some bread crumbs.

But I think more needs to be done to ensure public trust because the minute that trust is violated, I cannot see us coming back from that.

Steven Lane
Anna's hand is up.

Anna McCollister
Hi. There are a number of things that I am concerned about. Aaron just referenced the comment that I made about the incorporation of measures that patients that are currently out there that are developed in a very analog, "open" process for clinical guideline development that do not reflect the interest of patients think are important. How do we keep that from being incorporated behind a black box into an algorithm that spits out an appropriate treatment for a patient that may not be appropriate? In a very analog case, the couple of times that I have been hospitalized in recent years, especially in the ER with diabetic ketoacidosis, the ER doctor who is not an expert in endocrinology and is not accustomed to somebody like me who understands a lot about diabetes, diabetes treatment, and measures always wants to give me more insulin than I need because I am very insulin sensitive. So far, I have not been completely incapacitated and passed out in the hospital so I have been able to actively advocate and refuse the insulin that the ER doctor used based off of clinical guidelines.

In that case, insulin can be very easily deadly. This is the kind of thing that in an analog environment can already be very deadly. How do we keep measures such as hemoglobin A1C, which is highly unreflective of reality with disease as being the ultimate measure for inpatient emergency care, for instance, or static glucose levels, which are like a snapshot of where you are at the time rather than the trend line about where you have been and where you are going? Again, this is just diabetes. This is just the thing that I live with. But it is and has been a very deadly scenario in an analog environment. I do not think it is appropriate for us to permit those kinds of things to be hidden behind a black box under the guise of intellectual property. I do not know exactly what the answer is but that stuff has got to be exposed somehow, some way to people who could challenge the inputs and what is being defined as good health and appropriate health.

It cannot just be done by engineers and consulting doctors at a hospital system or at a health IT company. And then, secondly, I think transparency is a baseline. I need to dig into what Kathryn just posted in terms of the real world testing thing. I have not yet done that. But for a patient who has a lot of other stuff to deal with and in addition to trying to work jobs, care for themselves, care for their families, whatever the scenario, asking them to dig into details of what particular decision support tool or some of these is just not appropriate and it is not fair. And I think that we have to think beyond transparency and more into how do we actively challenge these models and how do we actively challenge them on an ongoing basis to see if they, actually, are producing results that make sense? I will stop there. And I thought Grace's comments were excellent and raised some really important points that I hope we consider.

Steven Lane
Thank you, Anna. Does anyone want to respond to Anna before we go on? Great. Hans, your hand has been up and down and up and now, it is up.

Hans Buitendijk

I think it is up, yes. Thank you. I really appreciate the background provided. There is a question that I have that was also voiced in the chat. And I have a couple of further comments from Grace and Aaron as well. And it goes to the transparency and who, actually, has that transparency. The focus of the proposed rule is around the certified HIT. And the HIT that is most likely and typically going to be certified are, in many cases, actually, consumers of such DSI. Particularly as we are looking at AI, ML, and going up that path from the simple algorithms into these more predictive models, there is more external use, which we already see that currently clinical decision support capabilities are being added outside the EHRR being referenced.

What is the approach that both from the perspective of DSI provided by services, capabilities that are really not developed by the certified HIT but that are included, accessible, etc., through that certified HIT, how do we engage that community and that set of developers where we, ultimately, are going to depend on to provide all of the information that is being asked for and that the HIT has been certified needs to make available? How do we get them engaged? They are HIT. They do provide capabilities there. They are not necessarily currently intended or indicated that they need to certify by which we could get access to this documentation as well. Yet, that is going to be extremely relevant in the context of a number of comments of having a library available, where is it, etc., to do that, which means we need to go to the source, not to the intermediary only. What are the thoughts on how to engage them and have that information more easily available as we are trying to get the transparency that we are trying to get?

Steven Lane
And I think that is a question for the ONC.

Hans Buitendijk
Correct.

Steven Lane
Do you want Hans to restate that in no more than two sentences?

Seth Pazinski
That would be great.

Hans Buitendijk
That is always a challenge. How do you intend to engage the CDS DSI developers in enabling this data to be transparently available along the lines of whether it's library or otherwise but to the actual intermediary and consumers of that and going back to the source, not only the intermediaries?

Seth Pazinski
Sure. One thing we include in the proposed rules and request for comment, and this is not exactly answering your question, but whether CDS hooks or other tools could be ways in which information around these source attributes were transported from developers that are not developers of certified health IT into the health IT module. So, that is one related question would be getting this information transported. I think the broader one is how to engage or motivate folks to provide this information at all who are not developers of certified health IT. Towards that end, we have included language around the need to clearly indicate that information is missing when it is not provided by these developers. And we have the intention that this will drive folks to say if this information is missing, I cannot verify that the tool is trustworthy and perhaps not

use it. And there is, in essence, a market based incentive there. I think this does also intersect with other policies from other parts of HHS, including FDA that I think all play distinct roles in the ecosystem.

Kathryn Marchesini
And just to add to Jordan's comment, in addition, there is a section in the preamble that talks about other parties. And I would say consistent with the ONC's prior discussion regarding third party developed evidence based DSI's under the current requirements, we anticipate that developers of certified health IT would obtain the information on the predictive DSI's from, as mentioned, the model developers, the owners, or the creators in most instances. And I would say this is consistent with what ONC has historically expected noting that in the 2014 edition proposed rule that it would be the third party from which the developer of certified health IT would get this information. I just wanted to add that as well.

Hans Buitendijk
And maybe to react to that, I think that still focuses very much in the intermediaries, the certified HIT, less so on the actual original source. And I think it behooves everybody to identify opportunities of how they can be better engaged so that that information is available that is available in the standard fashion whether CDS looks at the right one or not. There are a couple of different ways that we can look at that. But to really identify ways, whether it is ONC or the combination of ONC and CMS in other areas, ONC and FDA, how can we ensure that the sources are providing the relevant information as they are making their capabilities available so that this is not a highly challenging event to pull that all together. There has to be an easier way to do that for everybody involved, whether it is providers to patients, anybody that is using it to understand what is being used.

Steven Lane
Thank you, Hans. Medell, you have been very patient and your hand is up.

Medell Briggs-Malonson
Thank you so much, Steven. And I want to thank all of our presenters today for the amazing context and also, Grace, for your excellent recommendations. I have two questions for the ONC. And this is expanding upon what Hans just mentioned. And I just want to make sure that I am hearing this very clearly. I want to bring up the scenario of when providers themselves, so let us say health systems, are developing their own predictive DSI. At my organization here at UCLA Health but I also sit on some additional University of California wide efforts that are looking at data insights and innovation, there has already been a movement of developing, of course, our own predictive DSI's. And there is always caution in how those DSI's are being developed. How will this proposed rule be applied to provider organizations themselves in terms of making sure that we are identifying all of the source attributes and, of course, all of that information is as transparent as possible to the internal organization of users that will be using it as well as to the patient? Does this apply to that group as well? So, that is my first question for ONC.

And then, the second question that I have is when we are thinking about FAVES, in general, and we are thinking about the transparency and really making sure that all of the end users and will say all of the end users, whether it be health IT module owners, the providers and clinicians, and patients, if we are trying to make sure that everyone is very aware of this content, when there are elements that are not available or when there are elements that are available but yet, they have various different report outs, has ONC considered having a model or having recommendations of what would be a strong DSI in terms of all of the

various different elements or what may not be as strong? What I am concerned about is, especially our providers, clinicians, and patients may see the attributes but they are unable to interpret if that DSI is appropriate or not and if it truly is, for instance, representative of themselves, if they are a patient or the patient population they are serving and how to, actually, apply that in an appropriate way that will not cause increased bias as well as increased adverse outcomes or harm.

I have just those two questions for ONC.

Kathryn Marchesini
This is Kathryn. I will take the first question and my colleague, Jordan, may be best suited for the latter. In short, the proposals, much like the existing regulatory authority of ONC, the proposed requirements would be on developers of certified health information technology. The question about what role or how the healthcare provider organization plays as it relates to these proposals, I mentioned earlier I would say there is some language about other parties. To the extent a predictive decisions report intervention was enabled or interfaced by a certified health IT module, if that was developed, for example, by a healthcare provider organization, the proposal much like the current requirements around third parties and other parties, the expectation would be that the certified health IT developer would get any necessary information from the other party.

In this case, it could be the healthcare provider organization. The other thing just to draw you attention to is in the preamble, I failed to mention there are a few other very important requests for comments or requests for information towards the end of the risk management section. And one of those includes users of certified health IT, particularly around healthcare provider organizations. That might be something of interest. A lot of the conversation is around what else can ONC do to help the users. There are also two other requests for comments that are there. One is focusing on the ethical, legal, social implications of JADA **[01:11:42]** realizing ONC's authority. We thought it was helpful to at least have the conversation. And the department is interested in receiving any comments on that. And then, also we understand that there is concern around the underlying data quality, appropriate use, as well as the technical standards and the quality of data and things of that nature. Again, it is not part of some of the proposals but you will see language in there and requesting for comment.

I just wanted to add that in. I guess, I will turn it over to Jordan to answer your second question.

Jordan Everson
As Kathryn indicated, we do have a request for comment around what HHSY could consider doing to help providers gain the competencies to make use of this information that we are proposing to make transparent. Your question is very much one on our minds as we develop that request for comment is how can we ensure folks have the information they need to determine if a DSI is a strong DSI. Within the contracts of the proposed rule, we are not proposing that ONC would play a role in saying what a strong DSI is or would look like. We are really proposing transparency around that. And, of course, I would point towards FDA's role in reviewing decision support that is a medical device and the safety and effectiveness of that decision support as a separate authority.

Steven Eichner

We are running short on time because we need to go to public comment in just a moment. But I do want to recognize Steve Lane and we will address a couple of comments in the chat as well. Steven.

Steven Lane
I just wanted to raise a couple of things that have come up in the chat. One is when we talk about the users of the certified health IT, do we include in that the patients' caregivers who are using the health IT by way of the portal or an API? That is a directed question to ONC. Are patients considered users of certified health IT?

Seth Pazinski
I think we have intentionally not defined users of certified health IT. Certainly, we know that today, in some cases, they are and in some cases, they focus on health systems and healthcare providers.

Steven Lane
So, we are just going to leave that as a hanging question. The other question has come up here repeatedly as to what portion or components of the DSI might be considered EHI for the purposes of information sharing.

Kathryn Marchesini
I guess, this seems to somewhat relate to the question earlier or the comments that Grace shared about the designated record set. I would maybe encourage looking into that particular area as it relates to existing HIPAA interpretation given the connection between the designated record set and EHI.

Steven Lane
I guess I was looking into it by asking you the question.

Kathryn Marchesini
Okay. There are, I would say, links to that. And I am happy to put those in the chat for easy reference.

Steven Lane
That would be great because I think that is a key question that we have been going back and forth. We have public comment coming up in two minutes. The one task force member who has contributed to the chat but has not taken the mic yet is Sheryl. And Sheryl, I wanted to give you a chance, especially since you weighed in on a detailed comment by Julie Moss and wanted to see if you wanted to mention that.

Sheryl Turney
Thank you, Steven. I know I have been fairly quiet on the raising of my hand so far. I will be adding some of these comments also to the Google Doc over the weekend. You will be able to see them there. Really, my focus is on what we need to do to ensure that the certification process as it applies to decision support not only fulfills the requirements that are needed to ensure that there is sufficient data utilized but that there is knowledge about that data. And the whole concern is it is quite cumbersome to identify what was tested, what was not tested. If there was at least a publicly available data sandbox that had a minimum required amount of data that we would be able to utilize to say yes, these decision support systems have exercised that, I think it would provide more validity around the depth of the testing and also the scope of the testing

because, at the end of the day, this is a rapidly developing field. And without having specific requirements, it can do much more harm than good, especially related to, as I mentioned, rare and orphaned conditions.

And there are already examples where we use decision support based on cost information and I will bring it up again on Vitamin D testing. It is a very common thing. They say the normal person does not need it. But if you are a Vitamin D resistant rickets patient and that test is used to modify your medication, it is needed but they have to fight to get that test paid for. And it can be quite expensive. There is an example in today's world that already exists where patients are being harmed. And so, how do we prevent that same exact scenario going forward? These are the things that we need to ensure. We cannot plan for everything but we need to plan enough so that we are not adding burden and we are not adding harm to those patients that are underrepresented. And I do not believe that in the Bill of Rights for AI that they just released that it properly addresses it with the reference to disabilities because without knowing what data was used for testing those models, the model cannot take into account how it is going to address the data that it does not know about.

It is extremely important that we are very cautious and careful and, quite honestly, I think we need to take some time to ensure that the governance around the certification of these models is important and taken into consideration. My comments will be along all of those lines but thank you for the opportunity to speak up.

Steven Lane
Thank you so much, Sheryl. And we are going to go to public comment now.

Public Comment (01:19:53)

Seth Pazinski
Thank you, Steven. We are going to open up the meeting for public comment. If you are on Zoom and you would like to make a comment, please use the raise hand feature, which is located on the Zoom toolbar on the bottom of your screen. If you are participating just by phone today, you can press star nine to raise your hand. And once called up, press star six to mute and unmute your line. We will give folks a few seconds to cue up if any of the public has any comments.

Steven Lane
And I particularly invite Julie if you are interested in adding to any of the discussion, feel free to raise your hand and jump in. I will bring everyone's attention to one of the very first items I put into the chat, which was some new resources that the ONC has put together and posted. Specifically, these are Word versions of the NPRM as well as a very impressive public comment template. We thank the ONC for putting those together.

Seth Pazinski
I am not seeing any hands raised at this point so let us conclude the public comment period. Then, I will turn it back to you, Steven, to continue discussion. We still have about six minutes left on the call.

Steven Lane
Thank you, Kathryn, for providing the links that you put into the chat there. They are very helpful. I do want to point out that, actually, maybe we can pop back to the spreadsheet again. We were displaying earlier

the spreadsheet and we will display it here briefly. Again, we are still on the very second row, the first meaningful row, in the spreadsheet, the first item that we are addressing here in Group 2. We have captured a number of member recommendations and I will give justification to hers. And then, we have captured a few things in the task force discussion. I did copy and paste in there the recommendations that Grace provided in her last slide and a little bit about our discussion today but, obviously, there has been rich discussion. Sheryl, you mentioned that you were planning on getting back to the spreadsheet. I really encourage everyone to do that. And also, do not be shy about editing what you have already put in there if you want to tighten it up or refocus it based on the discussions that we have been having.

Again, we want to drive towards specific recommendations so I think especially in Column G, if you want to go back to your member recommendations and refine those in any way, a number of us have put some recommendations in there. Maybe if you modify it and put a little notation there modified and the date or something. And then, what we are going to do is, hopefully, have time to come back and work through these in detail. Sometimes, some of that working through falls to the co-chairs because we do not have the time. What we may do is take your recommendations and perhaps modify them slightly, rephrase them into draft recommendations to reconsider with the task force.

Steven Eichner
And this is from a process standpoint, please feel free to insert comments tagged with your initials or first name, not necessarily at the bottom of the particular cell. If somebody else has made a comment on a related issue and you want to add additional information or share a different perspective or reemphasize the point, please feel free to do so. For convenience, please do put it close to the original comment just to help us link the information together.

Steven Lane
Are there any comments from the task force members or from the ONC, frankly, any of you? We have just a few minutes left. I want to specifically give a chance to task force members who have not had a chance to speak up, Phil, Adedayo, Naresh, Jim, anything you guys want to add? If not, that is fine. Again, we do not have to burn every minute of our hours here. I really want to thank everybody for your engagement. I want to especially thank the members of the public who came and participated. Obviously, public comment is open. And those of you who are investing the time to be here are going to be well prepared to contribute to and provide public comment through the ONC process. And as I said, they have made that easier for us all by posting a template to facilitate that.

Kathryn Marchesini
Steven, this is Kathryn. And I just wanted to say thanks for allowing us to share a little bit about what is in the proposed rule. I did also want to circle back. My audio cut out when you were asking a follow up question about the users and I did put in the chat a link to some language in the preamble that talks about the user and who ONC sees as users, generally speaking. I know elsewhere in some of the rule, end users are referred to. But you will see in this proposed section some of that discussion regarding users.

Steven Eichner
Seth, can you make sure to cut that out of the chat and make sure that you share the email with the task force members?

Steven Lane

Great suggestion. I will ask the ONC team to capture those links and include them with the next email out. Preparing for our next meeting, do we have that last slide that shows the upcoming meetings? There we go. You guys are good. This group is meeting again in a week on May 10. We have three items to touch on. ONC certification criteria, discontinuing the year themed additions, that should be fairly uncontroversial, requirement for health IT developers to update their previously certified health IT, and assurances, conditions, and maintenance of certification requirements. We look forward to diving into those next week. That will be followed by a week off for this work group as we will provide a brief update to the HITAC and then, we will be back again on May 19 to dig in further. We do have SME's coming for the ECR discussion as well as the patient requested restrictions. We will be having a lot of lively discussions.

With that, thank you all. We will end on time. We really appreciate your participation and we will see you next week.

Adjourn (01:27:37)