Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

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

April 26, 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
Michael Berry	Office of the National Coordinator for Health Information Technology	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

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

Michael Berry
Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task Force. My name is Mike Berry, and I am with ONC, and I would like to thank you for joining us today. All of our Task Force meetings are open to the public, and your feedback is always 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 for the end of our meeting this morning. I would like to begin rollcall of our Task Force members, and this is for Group 2 of 3, so when I call your name, please indicate that you are here. I will start with our cochairs. Steven Lane?

Steven Lane
Good morning.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning, everyone.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Jim Jirjis? Anna McCollister is not able to join us today. Aaron Miri? Kikelomo Oshunkentan?

Kikelomo Adedayo Oshunkentan
Good morning. Rough start, sorry.

Michael Berry
Good morning, Daya. Naresh Sundar Rajan?

Naresh Sundar Rajan
I am here, good morning.

Michael Berry

Fil Southerland? Sheryl Turney?

Sheryl Turney
Good morning.

Michael Berry
Good morning, everyone, thank you. Now, please join me in welcoming Steven Lane and Steve Eichner for their opening remarks.

Steven Eichner
Good morning and welcome, all. Mike, I think Jim Jirjis is just connecting now. Thank you all for joining us this morning to begin the Task Force Group 2's work today, continuing the work that was started yesterday in the overall Task Force meeting. We have some good stuff, of course. We are going to go over the worksheets just a little bit, go back into DSI for vital discussion, and then have some public comment. Steven, do you have anything to add?

Steven Lane
No. Let's get into it.

HTI-1 Proposed Rule Task Force Charge (00:02:20)

Steven Eichner
As a quick refresher, we do have a charge from the ONC. We are not going to go through each of the slides in detail, but just looking at the overall charge, it is to evaluate the content of the proposed rule and provide feedback in select areas to ONC by the close of the comment period. You have the slides, both from today and historically, looking at those charges. We will continue to include them in future presentations for convenience, but we will not be revisiting them in detail, unless, of course, there is a change in the charge. Let's go on to the next slide, just for folks' reference. This group will be looking at a variety of things, including DSI, electronic case reporting, which version of USCDI, and some other things.

So, the way that the Task Force documents its progress and helps build its recommendations is through use of a Google Sheets worksheet that includes both original material and reference to links in the existing rules or the proposed rule, as well as a number of fields for Task Force members to use in presenting recommendations and actually building content. Sarah, are you going to be able to show your screen?

Sara McGhee
Yes, I am working on that right now.

Task Force Topics Worksheet (00:04:13)

Steven Eichner
Wonderful. The way that you get to the worksheets is through a link that ONC is providing through its homework emails, which you should receive on a regular basis. If you need documentation in other formats, please do reach out to ONC. We do recognize that there are some organizations that may have some challenges in granting access to Google Sheets, and there are some workarounds that are in place. Sara, let me give the floor to you.

Sara McGhee
Okay. Can you all see my screen?

Steven Eichner
Yes, ma'am.

Sara McGhee
Okay, excellent. Well, here is the proposed rule summary for the decision support interventions and predictive models proposal. This is a high-level summary that has been taken from the executive summary in the preamble. We also have this link for the *Federal Register*, where you can find the full preamble, and then it looks like there have been some comments already added. I will turn it back to you.

Steven Eichner
Just to add on, at the bottom of the window for the different tabs and different groups, this group will be focusing on the content on the Group 2 tab. You can also see the work being done in Group 1 and Group 3, and also include information or comments in that space. We do ask for every time that you are entering a comment that you enter information just before the comment, such as M. Briggs, as done on the screen, to identify who is making the comment so that as we are looking at discussing it, if there are future questions about it, we can understand who has made the suggestion so we can track it back, and if there is additional information or additional explanation needed, we have a way of getting back to see who contributed the information.

During our Zoom meetings, there is a raise hand feature down at the bottom of the screen. We encourage folks to use it. Steven and I and other folks will be monitoring the chat to help bring things that are of interest to the group at large in the chat, making sure that we are aware of them, so please take advantage of both of those opportunities to contribute. Sara, looking at the meeting topics schedule tab at the bottom, do you want to touch on that really quickly? Okay.

So, what we have here is an additional tab that lays out the full meeting schedule for all Task Forces or all subgroups and all Task Forces throughout the duration of the project, identifying both the meeting dates and what the subjects are going to be for the meetings. We do have a couple of larger group meetings later in the schedule as we move towards finalizing our recommendations. The final document will be a Word document or a text-based document that ONC and Excel will be helping build by extracting data from the worksheet and then converting that into a written document where we can also make comments and finalize text, so that is kind of the workflow that we are going to go through for the duration. Are there any questions or concerns?

Steven Lane
One thing that I would add, Ike, is that, as you have all noticed, Ike is taking the reins here for our Wednesday meetings, as I did a bit yesterday. Hung Luu is going to be leading the Thursday meetings, with the rest of us providing support. Today, I will be trying to monitor the hand raising and the chat, and we will divide and get through this work. I also really wanted to thank Medell for showing up with the first comment in the Group 2 tab of the spreadsheet. In fact, I think it may be the first comment anywhere in the

spreadsheet, so, as usual, Medell got her homework done first, and we really appreciate that, including the thoughtful comment here on this item, the DSI item that we are discussing today.

Steven Eichner
And comments are always welcome on any of the items up until the point at which we want to close discussion on any particular item. It is a little advantageous for us if you make comments on a particular item that is on the agenda for a given week to make those comments at least a couple hours before the meeting so that we have an opportunity to preview them before the meeting, and you are always welcome to contribute. It is a guide, not a requirement, in terms of looking at giving us a couple-hour window to prepare. So, if you can, fantastic, and if not, we do appreciate the comments at any point.

Steven Lane
Another point I would make is that we added that meeting topic schedule tab so that you could be looking ahead at what is coming in subsequent weeks and meetings. If there are topics that you would like to participate in reviewing that are in a different workgroup, you are more than welcome to attend that workgroup, either as a Task Force member or member of the public. Also, if there are particular subject matter experts we should be reaching out to for participation in any of these topic-focused discussions, please let us know so that we can make those contacts and get that on the schedule.

Steven Eichner
To add onto that, we are looking to subject matter experts that are not Task Force members in potentially a couple of different roles, one, to just join a particular meeting as a subject matter expert without a prepared presentation, but also, certainly, if the topic needs this particular expertise or there is a perspective that needs to be shared that might be supported by a presentation, those are also most certainly welcome. The goal here is to ensure that the Task Force members have as much useful information as possible without creating an undue burden on folks who are willing and able to share that information.

Steven Lane
Also, I have a response to the question submitted by Ian Sefferman, which Mike just got to. Thank you for your interest in the sheet, but the Google docs that we use for these Task Forces are kept to the Task Force members themselves. They have edit access, and while the public is welcome to view them during the course of the meeting or in the subsequent recordings, we do not provide access to the public.

Steven Eichner
I guess we are ready to move on to our next agenda item, which, I believe, is getting back into DSI.

Steven Lane
Where we left off yesterday was that we had a couple of open questions or hands raised. Anna and Hans both finished the meeting with their hands up, and here is Hans at the ready with his hand up again. Why don't we try to complete that discussion?

Decision Support Interventions (DSI) and Predictive Models (00:13:14)

Hans Buitendijk
All right, thank you, Steven and Ike. To pick up from the questions, my question was in line with some of Deven's questions as well. Maybe I will rephrase it a little bit this way. I think it was very clear from the

explanation that Jeffrey provided that an EHR that is currently certified to 9A is expected to certify to 10 or 11B with the DSI update, though I still get the numbers mixed up a little bit. The question was really around if you have other HIT that provides **[inaudible] [00:14:04]** capabilities, are they, in some way, through other incentives, compelled to certify to this capability? That is where I think there were still a few open questions, to make sure we understood the context, which may, in turn, help understand what other kinds of comment or recommendation we made, want to make, or not, and that is if you have HIT that is otherwise not considered a base EHR or does not want to consider that, they cannot always be certified to these modules as they see fit, but there are only market drivers at this point in time, not regulatory or other incentive drivers, that would compel them to do that.

So, if you have either a patient-focused app that might do some DSI, if you have a healthcare operations capability that may include some DSI. If an EHR is interacting, let's say, initiating some CDS Hooks, and connects with another capability that does some DSI and particularly some AI that it then takes back, there may be some clarification there, but other than that, ONC, as much as the certification is enabled for HIT, beyond EHRs, there is no current other known incentive beyond market values to actually certify to this and also other capabilities. I just want to make sure that context is clear, as it might lead to some recommendations or considerations as well. Did I get that right? Other than there is an EHR CDS Hooks connected with an AI capability, there are some particular parts that you do have some things, but not on the other AI capability. I think that is the part that was still left from yesterday to clarify.

Steven Lane
Mike, do you want to take that, or any of the ONC team, just to confirm what I think Hans said, which sounds correct to me?

Jeff Smith
This is Jeff. I think I track your comment, Hans, and I think the answer to your question may become clearer as we walk through some of the slides and are basically able to add scope around the nexus of our regulatory authority or proposed regulatory authority. I think you are broadly correct that the module that certifies to A9 would be required to update to B11. If that module enables or interfaces with a technology that meets the predictive DSI definition, it would then be subject to additional transparency requirements. However, if there was another health IT system, and I think the patient-facing app is maybe a good example, that was not enabled by or interfaced with the health IT module, then this patient-facing app and its predictive DSI would not be required to adhere to our transparency requirements. So, I think it is understandably complex, but I hope that as we walk through some of the slides, we can get a little more clarity. And then, the last thing I will say is that in the deck we are going to walk through, we have just a couple of clarifying disclaimers that we need to keep in mind as we move forward.

Hans Buitendijk
That helps, and I am looking forward to the rest of the presentation to help fill that in as to who will actually be responsible for what if you take the patient app, the EHR, or other HIT that provides DSI capabilities, and depending on how they are connected, to understand who really is required to be certified, who can do it voluntarily, but is not otherwise required by ONC or otherwise, like CMS or another program, and has no obligation to certify other than the market drive. So, as we go through, I will keep track of my clarifications and questions that are left.

Steven Lane
Hans, perhaps you want to add your understanding, perhaps in Column I, under Task Force discussion, just so we have that captured. I was thinking of doing that for you, but you are so good with words. I also wanted to add one comment, which is to say "just market forces" is, I think, to understate the power of these guidelines in the way that we have seen with the CARIN Alliance and the voluntary engagement around standards for privacy, specifically around patient-facing apps. I think there is going to be a real opportunity for the market to pick up these guidelines and requirements, and to be able to say that the DSI that they are implementing in their product, even a noncertified product, does meet these guidelines.

I think we should be prepared for that in such a way that ONC should be prepared for that specifically so that when those claims are made, there is some way for the market to be assured that they are valid. I do not know offhand… Again, this is not what the CARIN Alliance is about, but in the CARIN Alliance, the way it is done is that the CEO of the company signs something, and it is as official as something can get without being an actual law, but I think we should just be thinking ahead, about how to leverage this for the benefit of the larger industry beyond certified health IT. Was that you, Jim?

Jim Jirjis
Hey, I had a quick comment. I just wanted to remind everybody that these rules are around the certified technology as stated today, but do not forget that the FDA has released a guidance document, for example, that is broader, and it uses its authority to regulate medical devices and has defined some of these predictive decision support models within their guidance document. In that guidance document in particular, 100% of patient-facing apps would be considered devices that would need to be regulated by the FDA, so this is not the only lever, and it seems like this lever is targeting currently defined certified technology, but there are other nonmarket levers in the government, like the FDA. I just want to remind us of that. Remember, in Micky's coordination activities, he has been working closely with the FDA in drafting this.

Steven Eichner
This is Steve. Just to add onto that as part of today's presentation, and maybe Kathryn, Jordan, and Jeffrey can address it at the appropriate point in their presentation, look at what integration or connectedness mean in the context of the requirements, what is a component of certified technology, and what might be auxiliary, whether it is an integrated module or a connected piece of technology. Down the line, that would certainly add some clarity or add some opportunity or guidance for the Task Force to be able to contribute content or comments in the right space.

Jeff Smith
Yes, absolutely. We will spend some time on the slide that we have, and I am happy to try to provide clarity on that point. So, I am going to take the wheel today. My colleague Jordan Everson is on tap to speak to some of the source attributes, if we get that far, and a quick scan of the attendee list reveals that Kathryn is not currently on. I know she has had additional obligations today. So, if we could go to the next slide, that would be helpful.

Just real quick, we had a different disclaimer slide that was a little outdated, and in fact, it was a disclaimer slide for presentations based on final rules, not necessarily on proposed rules, and this disclaimer should have been offered yesterday, so I will spend just a moment on this so that we are all clear. We are doing our best to try and provide a synthesis of what we have proposed in the Health Data Technology and

Interoperability proposed rule. Because we are in the throes of the rulemaking process, we have to comply with the Administrative Procedures Act, and so, we can only really present the information as it is contained in the proposed rule, so this means we cannot really interpret information, clarify, or provide further guidance than what is in the proposed rule. Of course, we are not going to read you the proposed rule, so, what we are going to try and do is provide you key concepts and do our best to explain those concepts, as well as leverage the content that is in the proposed rule, but I cannot stress enough, especially for as complicated a subject as this, how important it is to actually read the proposed rule.

The other thing I will say, just again, so everybody is clear, is when you make these wonderful comments and you ask these good questions, make sure that those actually get submitted to the *Federal Register*, either through the HITAC process or through your individual process. Everybody as individuals can submit comments to the *Federal Register* as well as through other organizations and associations, and I know many of you are part of those. Make sure that your comments get through the *Federal Register*, otherwise we really cannot consider and respond to it, because that is the Administrative Procedures Act process.

So, I think, last but not least, my editorializing on this slide is that it might be better to consider subsequent sessions an opportunity to provide commentary to your other Task Force members and to react to that commentary than for ONC to react to the commentary. Obviously, if we can clarify questions based on what is in the proposed rule, we will do this, either during the meeting or, if needed, as follow-up. So, just know that those are the ground rules for the APA. Go to the next slide. Okay, we are at HITAC meeting, Task Force No. 2. Go to the next slide, please.

All right. Yesterday, we tried to provide and paint a picture of the policy rationale for what it is we are trying to do, and just to summarize, we are really trying to drive transparency into an opaque market for how predictive DSIs, as well as other DSIs that do not leverage predictive models, drive transparency into the market for how they work and for how they ought to work. And so, we have a series of slides today that we will go through that try to provide, I would say, not a 30,000-foot view, but maybe a 10,000-foot view of the certification criterion that we are proposing, and then we have a set of slides that are going to go down to probably the 200- or 500-foot view. We are going to zero in on the source attributes and really try and do our best to paint a picture of what it is we are proposing to require and what it is we are not proposing to require. Go to the next slide, please.

This is a slide that we went through pretty quickly yesterday. Hopefully, this slide and the next will provide some context to CDS and the role that it plays in the certification program. Briefly, we have had a CDS criterion as part of certification since beginning because it was named in statute that gave rise to the certification program. We had an initial CDS criterion that was pretty straightforward insofar as it just described what the CDS was supposed to do. The CDS was supposed to implement rules according to specialty or clinical priorities, automatically and electronically generate and indicate, in real time, alerts and care suggestions based on clinical decision support rules and evidence trade, and track, record, and generate reports on the number of alerts responded to by a user. This was very early days in the certification program, think 2010 or 2011, as part of that initial suite of requirements.

Later, the health IT policy committee recommended in 2012 a series of updates to that initial criterion, and they essentially said that the updated criterion for CDS should display source or citation of the CDS, so, where this CDS comes from and what evidence base exists for it. They recommended that the CDS be

configurable based on patient context, is presented at a relevant point in clinical workflow, includes alerts presented to users who can act on those alerts, and is integrated with the electronic health record, not a standalone. Go to the next slide, please.

So, we took those recommendations from the health IT policy committee in 2012, and we turned that into regulation text, and that is what you would find if you went to 170.315 A9 in the Code of Federal Regulations, and I think we will talk a little bit about the differences, but generally speaking, we have had that criterion in place going back almost a decade now, and while there have been some changes on the CMS side, and those of you who have been here long enough remember when there were requirements that there be at least five alerts or something like that on the CMS programmatic side, our criterion has remained fairly unchanged for a number of years.

And so, I think one of the things to think about as we delve deeper into this subject is that the decision support intervention itself does not get certified, the health IT module supporting the decision support does, and that is going to be a really important distinction as we move forward. The current CDS criterion for health IT module is, as I mentioned yesterday, part of the base EHR, and the base EHR is referenced in CMS payment policy, so, pretty much every hospital and clinician that participates in Promoting Interoperability and MIPS respectively has to include technology that supports CDS and is certified to A9, and we are really proposing to update the base EHR definition to include B11, which is the new DSI criterion.

So, current requirements for health IT modules are, essentially, if you boil down the regulation text, that modules enable interventions based on specific data elements, and when meds, allergies, and problems are incorporated from a transition-of-care and overall summary record, we currently also require that health IT modules enable "evidence-based" decision support interventions based on a set of data elements, we require health IT modules to identify, for a user, diagnostic or therapeutic reference information, which is part of the linked referential CDS that is currently in A9, and finally, we require that health IT modules enable a user to review "source attributes," and these include bibliographic citation, developer details, funding source, and release and revision information, if available, and those source attributes, according to the preamble text, currently in regulation ought to be available to end users via direct display, drill-down, or link-out, and we will get into a little bit of that later on. Next slide, please.

Okay, here is one of the high-level flybys that we are going to do in terms of what we are proposing to require for health IT modules certified to B11. So, first, we propose that source attributes must be available as a plain-language description to users via direct display, drill-down, or link-out from the health IT module. This would make a historic expectation explicitly required. I know that we had some questions on what "plain-language description" means, and I will say that we will get back to you on that. There are some government sources, like .gov definitions, for what "plain language" means, but we can get back to you on some of those questions a little bit later.

We would also require that if a decision support intervention is developed by a developer of certified health IT, all attributes are required unless otherwise noted, if available. We note that for decision support interventions that are developed by other parties, the health IT module clearly indicates when any attribute is not available for the user to review. We note that "other parties" could include health systems, third-party software developers, and medical education publishers, etc. Next, we note that health IT modules must

enable users to author and revise source attributes and information beyond the source attributes listed, and we think that this would provide flexibility to users to design DSI information unique to their circumstances.

And then, we would require health IT modules to enable end users to provide feedback regarding the intervention and make available such feedback for data for export and in computable format, and we note that this information should include the intervention, the action taken, user feedback provided, if applicable, user, date, and location, and we think this would go a long way toward supporting quality improvement for all DSIs.

Steven Eichner
Jeff, Hans has been asking some really thoughtful questions in the chat here. I wonder if we can try to address them.

Jeff Smith
Sure, let me open that out. Hans, do you want to go ahead?

Hans Buitendijk
Sure. I think it is progressing the way we talked about. The first question is if you have the module that is calling, if you will, some other module to actually provide the DSI, thinking of using CDS Hooks or otherwise to invoke that however, the one that is calling, which we will assume is the EHR, has to be certified or whatever, but the other module is being called to actually perform that. The EHR clearly needs to be transparent on what it uses and provide the information about that, but the module that has been called, which actually is also supporting DSI, which is where I want to make sure the language is interpreted correctly by me, has no certification obligation in the way that you are describing it, only the one that is certified for one reason or another and is calling somebody else to further support that. Is that accurate? I think I heard that, and I want to make sure that is accurate.

Jeff Smith
I believe that is accurate. Yes, that is accurate. When we get four slides from here, we can confirm that, but yes, I believe what you just described is accurate in terms of how we envision the responsible parties, the certified health IT developer, and other parties.

Jordan Everson
Jeff? Hi, I just thought to quickly reiterate the note here that for DSIs that are developed by other parties, transparency within certified health IT would indicate if a piece of information was not available, so, kind of a clear signal that information we expect to be available is not here for that DSI developed by another party that is then interfaced with or enabled by the certified technology. The other thing I would highlight with the example of CDS Hooks is we do have a request for comment here about whether standards like CDS Hooks could be used to provide that transparency information into the certified health IT and would be very interested in thoughts around that particular goal.

Steven Eichner
This is Steve. Just to follow onto Hans's questions, from a passthrough perspective, what would be the expectation of the attributes from the original source being included as the content provided for the attributes in the certified technology component? In other words, would the certified technology component

be acknowledging the existence of the third-party module as being sufficient, or would it need to incorporate the details from the third-party module?

Jeff Smith
So, the way that we have envisioned this is, as Jordan mentioned, if they were working with another party on the DSI, the health IT module would be responsible for indicating to the user that the information is unavailable, and just to be clear, our current expectation, as stated in the preamble, going back to the 2014 edition, actually made this statement, that essentially, we at ONC are not requiring for these other parties to provide the source attributes, and if we want to scope it just to current requirements, bibliographic citation.

So, if the health IT module today works with another party for CDS, and that CDS is delivered through the health IT module or called from the health IT module, the health IT developer is expected to work with that other party to get the bibliographic citation, and if it is not there, it needs to indicate that it is not there, and historically, we have posited that the lack of information in and of itself may be an indication of the CDS's quality and should, at some level, give pause to the user as to whether or not they ought to use the CDS if there is no bibliographic citation, and we provide background and point to the original source of that preamble language in the DSI preamble.

Steven Eichner
Thank you for that explanation.

Jeff Smith
Of course. Hans, you have your hand up.

Hans Buitendijk
The other part, Jeff, that you described which I want to clarify is then that if an HIT developer has EHR software that needs to be certified to this and they do everything that they need to do, but somewhere else, they have a product that they also develop, like in healthcare operations or otherwise, that does not have that requirement to be otherwise certified, they are using DSI, not interacting with the EHR per se, or maybe there is a variant there, but they are developing other capabilities that are used as HIT, but not as part of the EHR that is certified. Does this require that the moment you need to be certified to this in one area of EHRs or if you are a more general-purpose HIT and provide DSI, you now need to certify in other areas as well? Is there a ripple effect that the moment you get certified in one, you have to do it everywhere in the organization?

Jeff Smith
We do not speak to that specific scenario, so that might be good, Hans, to put down on paper, and we can look at that as this process proceeds, and if we can provide clarity on that question, we will.

Hans Buitendijk
Okeydoke, great. **[inaudible] [00:41:26]** already was clear enough. That is great.

Steven Eichner
Thank you, Hans. Medell's hand is up.

Medell Briggs-Malonson
Yes, thank you so much, Stevens. I just wanted to expand upon some of the comments that were in the chat, and I am driving, so I cannot see all the chats. I just wanted to respond to what Jim mentioned because that was one of my concerns as well. It seems like the charge of the proposed rule right now is to increase transparency for core safety and to improve overall outcomes, but if a certified EHR, for instance, does actually interface with a third-party DSI tool in which there are then no citations that come forward, it seems like that would be a loophole for various different organizations using the certified EHR to say, "Hey, we are using this DSI tool, but we do not have any of that information available, but we are going to continue to proceed."

So, one piece for consideration is that since we are trying to add accountability for the safety of these systems, if you are part of a certified EHR and you are interfacing with a third party, it is still your obligation to ensure that that DSI does abide by all the various different criteria as if we ourselves, as the certified end product, were the ones that created that DSI. So, that is just something to consider, that we need to ensure there is accountability to support the transparency that we are all trying to achieve with this proposed rule. So, I just wanted to put that out there for consideration.

Jim Jirjis
Steve, could I comment on that? Then I will resolve my comment.

Steven Lane
Yes, go ahead, please.

Jim Jirjis
I have not been close to the FDA thing, like many of us have, but to me, Medell, it seems like there are other levers in government, for example, FDA's device. So, these third parties that are providing algorithms for clinical decision support are considered devices regulated by the FDA, who would be requiring this same information to be made available. This rule is simply making sure that that is able to be expressed in the workflow. I do not know that certified technology, unless we redefine it, is ever going to cover the third parties, but the FDA will, and to the extent that they comply with the FDA and provide that background data, this rule just makes sure the pipes are in place for the clinicians to see it and benefit from it in the workflow.

Medell Briggs-Malonson
Absolutely, I understand that, and I think just making sure that there is that clear connection of saying we know, for instance, that this DSI that is developed by the third parties is compliant with all the various different FDA regulations or any other regulations instead of just saying that information is not available, so, just ensuring that there is that seamless connection so that the users do know and can have confidence that this has been vetted very thoroughly by all parties that need to vet this technology.

Steven Eichner
Medell and Jim, this is Steve. Thank you so much for your excellent points. I do not want to call off debate, but I do want to remind folks to please enter those comments into the worksheet so that we can track them and include them as appropriate in recommendations.

Jim Jirjis

Thank you.

Jeff Smith
Okay, great. Can we go to the next slide, please?

Steven Eichner
Just to add, ONC can take our recommendations that we provide in writing as they are looking at developing a final rule. Comments that we make orally as part of this discussion are not considered comments that they can consider in making modifications. So, this is really good stuff; we just need to make sure we are getting it back to ONC in a method they can consume.

Jeff Smith
Exactly, thanks, Ike. All right, sorry, let me pull this back up. So, yesterday, we did describe our definition for predictive DSI, and we wanted to flag here for you just what that definition is. We also wanted to flag for this group that we have a very specific set of requests for comment. So, we described and defined predictive decision support intervention to mean technology intended to support decision making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis. The request for comment we have, and again, I am happy to listen to deliberations on this, but I just wanted to flag this as an area for this group to potentially look into, is whether or not the predictive DSI definition needs to be modified in various ways.

I will note that our definition would not include simulation models that used modeler-provided parameters rather than training data, and it also would not include unsupervised machine learning techniques that do not predict an unknown value among other technologies. So, we have questions about if there are prominent models used to support decision making in healthcare that are not effectively captured under this definition, and if so, is it feasible and appropriate to include such models in the scope of this proposed rule. This is one of those foundational points of information that we would like feedback on. We described in the proposed rule how DSI as a concept is meant to be more broadly inclusive than what traditional CDS has included, but at the same time, we want to make sure that we are appropriately scoped for this definition, so I will leave that there and see if there are any questions we can answer.

Steven Eichner
Hans, your hand is up.

Hans Buitendijk
Yes, a clarification question by way of an example. So, do typical, traditional CDS flags drug-drug interaction and other algorithms that have been used that have been embedded but are not interacting with a dynamic AI capability still fit under this definition, and does it intend to be, as well as the full range where you either dynamically or otherwise are using AI in the way that we currently understand it to learn and come to a prediction that is then offered as a recommendation? My understanding is it is meant to provide the full range in those examples. Is that understanding accurate?

Jeff Smith

Sorry, let me come off mute here. Yes, I believe so. I think we actually have a slide where we can talk just a little bit about scope for various kinds of DSIs that are in our criterion. We currently have evidence-based decision support interventions, and we have linked referential decision support interventions, and we are proposing to carry those forward while also adding predictive decision support interventions, and the way to think about this is to think about which data the DSI uses and whether or not it meets this definition. I can recognize that this is a little bit of a nuanced area. We have another slide here in a few that can delve deeper into this. Jordan, do you have additional thoughts on Hans's question?

Jordan Everson
Well, I thought to revisit this slide from yesterday about the predictive DSI definition, which really is intended to capture these predictive models, ranging from relatively simple models using regression techniques and others to quite complex models using neural networks and random forests, and that would be inclusive of large language models that are really trained to produce the next word in a set of training data where, really, it's a supervised learning task, and so, that is what we are focused on here, and it is quite separate from the Boolean logic that I think underlies existing evidence-based decision support interventions.

Hans Buitendijk
And that would be helpful, and it would then lead to a comment: Where is that line drawn? Because if we say a drug-drug interaction is intended to represent the traditional evidence-based Boolean type of logic, then it still used pretty much everything in here that was based on research and otherwise that fundamentally does the same thing. The difference is that now, a machine is doing it versus a research process. That is what I am trying to understand. Is it meant to be totally separated, or not? But that would be a follow-up question. This way, the lines are becoming very blurred because in the end, they are trying to do the same thing. What would be the next best step to take?

Jeff Smith
Right. Well, we spend a fair amount of time, and I do apologize for not having the slide from yesterday easily presentable, but we have a similar slide from yesterday that tried to articulate in a little bit more detail, by way of slide, the definition, but certainly, I think the preamble goes into sufficient detail, and one small comment, Hans, to the last thing you said is that if the intended use of the CDS is achieved by a machine, whereas previously, it was achieved by a human, then I think that would be considered predictive decision support intervention that would meet that definition, but at any rate, take a closer look at that and provide us some thoughts because we do intend to cast a fairly wide net, but we want to make sure there are some lines of clarity. Okay, next slide, please.

So, here is an interesting aspect of the criterion in the way that we have constructed it. We have established this as a conditional. The predictive DSI aspects and requirements are conditional. So, a health IT module certified to B11 is not required to enable or interface with predictive DSIs, but developers of certified health IT must make one of the following attestations. They may indicate that yes, the health IT module enables or interfaces with a predictive decision support intervention based on any of the data expressed in the USCDI. So, essentially, this is asking the developer to look at the definition and determine whether or not they enable or interface with technology that meets that definition and that technology uses any of the data expressed in USCDI.

There is, obviously, as part of this attestation, a no option: No, that IT module does not enable or interface with a predictive decision support intervention based on any of the data expressed in the USCDI. So, if the developer attests yes to this statement, the developer and its certified health IT module are subject to applicable predictive DSI requirements. If the developer attests no to the statement, the developer would still be subject to applicable general DSI requirements, but they would not be subject to the predictive DSI requirements. All right, next slide, please.

So, trying to provide this in a slightly different format, developers of certified health IT should attest yes if any of the following are true: The developer, which, remember, is a certified health IT developer, self-develops predictive DSIs for use in their certified health IT or the developer's health IT module enables or interfaces with predictive DSIs developed by its users or customers, such as a healthcare organization or medical center, or the developer's health IT module enables or interfaces with predictive DSIs developed by another party, such as a separate software developer, and the predictive DSI is based on any of the data expressed in the USCDI standard. Okay, next slide, please.

So, I know there is a lot of text on this slide. I apologize. The clip art was meant to help focus the mind on some concepts that we are thinking about here, but Hans, I think this is where some of your questions may potentially be answered, or maybe some of your questions will morph into additional questions. The construct of "enabled by" or "interfaced with" are terms of art. "Enables" means that the developer of certified health IT has the technical capability to support a predictive model for DSI within the developer's health IT module. These could be user, third-party, or self-developed applications, standalone applications used within or as part of the health IT module, and we do provide this example.

For example, if the calculations for predictive DSI occur within the health IT module, either a two- or three-way standalone app used within a health IT module or an app developed by a developer of certified health IT for use within a health IT module, we would consider this enabling. So, this also includes instances where predictive DSIs are enabled by default or instances where they can be enabled by users. So, I think the big takeaway here is that "enables" is really about the certified health IT being supportive of or a container within which a predictive model or DSI can be used, either as an app or as part of the health IT module.

In terms of "interfaces with," we articulate that this means that the health IT module facilitates either the launch of a predictive model or DSI or the delivery of a predictive model or DSI output to users when such a predictive model or DSI resides outside of the health IT module. Again, for example, scenarios where the calculations for predictive DSI occur outside the health IT module and the predicted value or output then gets sent through or to a health IT module or to or through an app used within or as part of a health IT module would be considered to interface with, and then, a health IT module would also interface with a predictive DSI in scenarios where an application is launched from a certified health IT module, including through the use of single-sign-on functionality. So, really, the big idea is that "interface with" is about the certified health IT being a door through which actions can be taken to launch or deliver a predictive model or DSI output.

Hans Buitendijk
And that predictive output would still come back to the initiating health IT, correct?

Jeff Smith

Well, that is a good question. Under the concept of "interfaces with" as a means to launch an application, that would be interfaced with. So, I do not think that we have designed this in a way that has a closed-loop scenario, so there could be instances. I think we have discussed it, and in the preamble, there may be examples where, under this construct, you could have a health IT module that launches into another system or application that has a predictive model or DSI, and if the output of that does not come back through, that is not required for the interface construct, so it is an either/or, not a both.

Hans Buitendijk
So, if I then read the definition and the example of "enables," "enables" reads like it is a closed loop because it indicates to or through a standalone app, which means it is not mine, I use somebody else's, but something comes back and I continue to use it versus an interface that is a one-way street, where I initiate it and it goes somewhere, but it does not come back to me to further manage or present.

Jeff Smith
Correct.

Hans Buitendijk
Okay, I will jot it down, but it might be a helpful clarification to make that distinction between a two-way street and a one-way street.

Jeff Smith
Okay, I think that is a good way of framing that, and Jordan, please tell me if I have gone over what our initial intents here were.

Jordan Everson
My only comment would be in the instance where a standalone app is embedded in the health IT module but perhaps not part of the module itself, I am not sure the two-way street quite applies to that instance. So, I think it is worth a close read of the description and preamble because we have tried to summarize it here, but this is a nuanced topic.

Hans Buitendijk
Definitely, because depending on the architecture, that is a blurred line at that point in time, whether it is embedded. It is somebody else's module and I am communicating with it wherever it lives. In the cloud, next door, or wherever, it is not mine, but I am communicating with it and I am getting something back. That is fundamentally the difference. Everything else might be a packaging thing.

Jordan Everson
I will note that whether it is "enables" or "interfaces with," the same requirements apply in terms of transparency, so this is not distinguishing in that regard.

Jim Jirjis
Even if it is a one-way street, Hans, like if I am a provider in certified technology and the certified technology is linking me in a one-way street model to another application, wouldn't the requirement still apply to provide transparency around what it is linking me to, even though the EMR is not getting a response back?

Hans Buitendijk
I completely agree. The thing, then, is making the distinction between "enable" and "interface" gets a lot of attention for effectively no difference because the requirements are still the same on what you need to document, so it might be helpful, but in the end, it does not matter which technique is being used, so I would then be cautious about overemphasizing it because it leads to the conclusion that you may have to act differently when you do not, but that is a clarification, not a further discussion right now, that you can think about.

Steven Eichner
This is Steve. To me, one of the confounding components is looking at the developer's health IT module versus system versus another descriptive word. That is a little big confounding, just as you start looking at encapsulating services.

Jeff Smith
I will just say that one of the motivating factors behind this is that there are numerous arrangements and data flows that we are aware of, and there are probably dozens of others that get into nuances that we are not aware of, and I think what these descriptions fundamentally try to do is say if the health IT module has the technical capability to support a predictive DSI within it or whether the health IT module facilitates the launch or delivery of a predictive model or DSI output, then in both of those scenarios, or maybe in all three of those scenarios, we would consider that to be enabled by or interfaced with and subject to the predictive DSI transparency requirements.

Steven Eichner
Can you define or restate the definition of health IT module? That might be really helpful, both for me personally at the moment, but also in future presentations on it.

Jeff Smith
Yes. So, a health IT module is any certified piece of technology. So, at this point, we have 50-some certification criteria, and a piece of software that is certified to any of those criteria is a health IT module.

Steven Eichner
Maybe this is the intention, but it feels as though we are looking at, in some ways, the Russian dolls about putting things in buckets and buckets and buckets, and how things are encapsulated depends, to a certain extent, on how things are actually implemented by an IT developer as to whether they are integrated or a separate package. For a parallel example, I guess, look at something like the ability to report data in the required formats to a cancer registry. Many vendors offer that as an add-on module, not necessarily as part of their core base HIT or their EHR, so I am trying to envision, from a development standpoint, how core the HIT has to be for this to apply.

Jeff Smith
I think that is going to be a good area for the group to opine on. We do not really tackle the definition of a health IT module in the proposed rule. Going back several years, I think we have had a longstanding nomenclature to refer to any technology that is certified regardless of whether it is certified to a single criterion, like registry reporting, or whether it is certified to a host of criteria. Many larger developers are certified to numerous certification criteria. In both circumstances, we refer to those as health IT modules.

Steven Eichner
Okay, thank you.

Jeff Smith
Okay, next slide, please. This may be a potentially difficult slide for folks to get their heads around, but this is one way to think about my earlier statement that we are not certifying the DSI itself, but we are certifying health IT modules. At some level, what we tried to depict here is the scope of DSIs that health IT modules would have to provide transparency requirements on, and whether you think about transparency requirements as the bibliographic source or enabling users to see which data elements were part of the DSI, I will just broadly refer to those as transparency requirements.

So, in the attestation slide, we did talk about how, for predictive decision support interventions, all DSIs that use any USCDI data element would be within scope, and you can see the attestation there. For evidence-based decision support interventions, all DSIs that use problems, meds, allergies, and intolerances, demographics, labs, vital signs, and procedures according to the USCDI standards would be within scope, and I will just note a small error on this slide. We are proposing a few additional data elements, which include the unique device identifier of implanted devices there. And then, the scope for linked referential CDS is actually the same as it is today. All DSIs that use problem meds and demographics would be subject to the transparency requirements for linked referential CDS.

Steven Eichner
This is Steve. Just to ask for quick clarification, any of the USCDI elements in the related classes or all of the elements in the related classes?

Jeff Smith
It would be any. So, just to give you a hypothetical example that may or may not exist in reality, if there is a predictive DSI that does not use any of the data elements that are part of the USCDI, then that predictive DSI and the health IT developer that enables or interfaces with that predictive DSI would not be subject to our transparency requirements. However, if the predictive DSI uses any data element within the USCDI, then a health IT developer that has a health IT module that enables or interfaces with the predictive DSI would be subject to those transparency requirements.

Steven Eichner
Okay, and again, a clarifying question. Is this whatever version of USCDI is officially adopted in regulation, whether it is 1.0 today or 3.0, depending upon the final final rule, and subject to change down the line, or how does it fit in with other changes in the USCDI?

Jeff Smith
What you just stated is correct. To get really granular on this, that would be USCDI V.1 until the expiration date of V.1, at which point it would be USCDI V.3. So, just to give you another hypothetical example, if the predictive DSI was based on health insurance data, then it would not be until USCDI V.3, which includes health insurance data.

Steven Eichner

So, is it the version of USCDI that is adopted in regulation or in SVAP?

Jeff Smith
In regulation.

Steven Eichner
Hans, you have a question.

Hans Buitendijk
To follow up on that same question, Ike, based on Jeff's answer, if hypothetical USCDI Version 3 is adopted in the final rule, as proposed, and then SVAP comes around with USCDI Version 4, then, at that point in time, if you adopt USCDI Version 4 with FHIR US CORE, 6.0 or 7.0.0, whatever is current at that time, then are you not obligated to upgrade to now cover USCDI 4 in your DSI efforts? It is still with the base one for the duration, or when the base one is in effect. Is that the intended proposal? If you certify by way of SVAP to the next version of USCDI 4, 5, or whatever, then do you need to up your DSI accordingly as well?

Jeff Smith
That is a great question, which I will have to get back to you to confirm. My understanding of SVAP and the way that it works is that if you are to certify using SVAP, and we can use Version 2 or Version 3, then you are certifying to all that would come with that version of USCDI. I will have to get back to you on that, but my interim comment is that the version of USCDI that this policy pertains to is the version that is in regulation; however, if you avail yourself of SVAP, I believe our policy around SVAP and the ability to use SVAP voluntarily for certification purposes would then position you to need to support those additional data elements for this and for other criteria that mention USCDI. So, I think if you put this into context of transitions of care for G-10, you would not be able to certify to USCDI V.2 and then not support those data elements in Transitions of Care V.1 or API G-10.

Steven Eichner
Or potentially enable a developer to utilize elements from USCDI Version 4 for SVAP. It is a two-way street.

Steven Lane
Hans, we are going to run out of time if we drive this one to the ground.

Steven Eichner
Yes, and I will try to beat that one. Hans, can you make sure there are some notations…?

Hans Buitendijk
I already started to ask more questions because there is more nuance to it than what we just talked about.

Steven Eichner
And thank you, Steve, for keeping us on. Thank you, Jeff.

Steven Lane
Let's see if we can get through the presentation and not have to carry it over to next meeting.

Jeff Smith
All right. Next slide, please. This is kind of the last slide on the 10,000-foot overview, and then we will dive into source attributes, and even though there are many source attribute slides, hopefully they will be really self-explanatory. They are more granular, so hopefully there will be fewer questions. So, here is the proposed implementation timeline and real-world testing implications. We propose that health IT modules certified to A9 would need to update and provide their customers with technology certified to B11 and comply with these new requirements by December 31st, 2024, and we note that health IT modules may be certified to A9 and/or B11 until December 31st, 2024. We do propose to modify the base EHR definition to include B11, and we note that A9 will expire January 1st, 2025, and B11 would replace A9 in the base on and after January 1st, 2025.

We also note that developers of certified health IT with health IT modules certified to B11 would be required to submit real-world testing plans and corresponding real-world testing results consistent with other B criteria that are listed in the real-world testing condition and maintenance of certification at 170.405A. So, this means that real-world testing for all DSI types, whether they be predictive, evidence-based, or linked referential, would be alive, if you will, for the 2023 plans, and measures demonstrating conformance to the requirements, of course, self-identified by the developer would be expected, and then, the annual cycle of real-world testing plans and results should be publicly available for CHPL.

Now, I will note here that our proposal for plans beginning in 2023 comes before the requirement of the December 31, 2024 deadline, and essentially, what this means is that for plans that would cover 2024, I believe those need to be submitted in December of 2023. So, what we are trying to do is say that if you certify on the last day of the year, you still need to incorporate those in your plans for the year, so I am happy to dive into that if it is confusing, but at any rate, we also propose to add A9 to the list of applicable criteria for real-world testing, effective as of the final rule, until it expires, so that means if you have modules certified to A9, you would need to include those in real-world testing plans effective as of the final rule.

Steven Lane
Thanks, Jeff. Hans has a nice comment, which is that it would be good to have a visual that stacks up all of these dates next to one another so that it all makes sense. Let's go on.

Jeff Smith
Yes, next slide. All right, next slide. So, here is going to be how we operate over the rest of this meeting and the next and final meeting on DSI next week. We are going to use these tricolumns as a means to try and provide the roadmap for where we are going to go. So, today, we are going to talk about the technical and performance-related proposals, and then, next week, we are going to talk about the governance-related proposals as well as the implementation and oversight proposals, and there is some overlap because part of our governance and risk management proposals overlap nicely with oversight and implementation, so we will get into those during next week's call. Go to the next slide, please.

Today, we are going to talk a little bit about the technical and performance requirements around source attributes, and these are, again, essentially transparency requirements, and we will go into more details on what this means, but generally speaking, we have some requirements around source attributes that are intended to provide the ingredients, if you will, of a hypothetical nutrition label for algorithms. This is a concept that I think is well understood and well cited in the literature, and is an area we would love to get

your feedback on. We also think our proposals are supportive of health equity by design, and we identify that race and ethnicity, language, sexual orientation, gender identity, social determinants of health, and health status data elements need to be identified if they are used in a DSI.

And then, also, there are specific source attributes that are focused on validity and fairness of prediction in test and local data, if available, that we think could be very helpful to the overall effort of supporting health equity, and then, last but not least, if we have time, we will talk about the additional enhancements that would enable clinicians to author and revise source attributes, as well as this feedback loop capability that would enable users to provide feedback on how the DSI performed, and then provide export of that feedback data for quality improvement. Next slide.

Okay, so, as I said, there are a number of trends that we are monitoring and have been monitoring for the last couple years now that largely are academic and industry-led. Most recently, there are certainly some more government-related activities, and we will talk about those, but really, academia and industry have been leading the way to develop and demonstrate technical and performance standards of predictive algorithms in healthcare, and certainly, there have been longstanding reporting guidelines for research around AI and ML. We talk about and cite extensively the notion of model cards and data sheets for data sets, AKA algorithmic nutrition labels, that provide information on the model details, development processes, performance, and maintenance requirements, and this is really to identify issues related to things like model drift when I speak to model maintenance requirements.

We hyperlink to certain things, but certainly, you will notice our section of the NPRM is rife with footnotes, so just know that a lot of what we have sought to propose is based on the best available evidence that we have got, leveraging a host of really excellent papers and initiatives. We also note that government and academia and industry are coalescing on the need to manage risks at the organizational level, so, not just how the algorithm performed on training and test data and then in the real world, but what governance and risk management practices that were employed by the developer of the AI model. Again, we cite extensively the NIST risk management framework, and my colleague Kathryn is going to talk more about that in next week's meeting, but we also look at the Office of the Comptroller of the Currency, who has been pretty far ahead of the rest of the federal government when thinking about how to manage risks in the financial sector's use of AI. Next slide, please.

So, when we put together the list of source attributes that we will show you on the next slide, I wanted to emphasize that we did not make these up out of thin air. The source attributes that we are proposing really are a culmination of what we identified as the most commonly included types of information that exist in the literature and is used for reporting guidelines, again, mostly academic, mostly research-focused, but increasingly, this kind of information is being reported in evaluations of models in clinical contexts. We thought that the attributes that we identified would be most meaningful and interpretable in the context of health IT users and developers. We, of course, focused on health equity, fairness, and identifying issues of bias, and the source attributes were intended to show that the model would perform effectively outside of the specific context in which it was developed, so we have a number of source attributes that are meant to capture the performance in local data if available.

Steven Eichner
Unfortunately…

Sara McGhee
Jeff?

Steven Eichner
Sorry.

Sara McGhee
Oh, go ahead. I was just going to mention the public comment.

Steven Eichner
Sara, that was what I was going to say. We unfortunately need to bring this to a close so we have a couple of minutes for public comments, but we can continue this at our next call next week.

Public Comment (01:25:06)

Michael Berry
All right, thanks, Steve. 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 are on the phone only, please press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. So, let's pause for a moment to see if any members of the public raise their hand.

Steven Lane
And also to acknowledge the five members of the public who have hung in with us throughout this meeting.

Michael Berry
Thank you. I am not seeing any hands raised, so I will turn it back to our cochairs.

Steven Eichner
Thank you, Mike. I think we had a really good discussion today. I wish we had a few more minutes to talk things through today, but we will need to push that off until next week. Please do look for a homework assignment email from ONC. Included in the homework will be recommendations or suggestions to visit the worksheet, become familiar with the worksheets, and begin to draft recommendations and comments, especially looking at the DSI. We will send out the presentation materials for next meeting as soon as they are available and continue our discussion. Steven, do you have anything to add?

Steven Lane
There is one more resource that we anticipate coming from the ONC to support your review of the relevant sections of the NPRM, and I am anticipating we will probably have that available before our next meeting in a week.

Steven Eichner
Is that a new print resource or a new electronic resource?

Steven Lane

You will get it electronically. If you want to print it, that is up to you.

Steven Eichner
Are there any questions from the Task Force, or any closing comments?

Steven Lane
I will just say thank you to everyone for your participation and thoughtful comments. This is meaty stuff, and again, as much as possible, if we can all do all of our background reading before the meetings, come to the meetings prepared with thoughts, feel free to draft those thoughts into the spreadsheet so that we can go through them, all of that will lead us to a better place.

Steven Eichner
Again, thank you all. Mike, do you want to close us out?

Michael Berry
Sure. I appreciate everyone joining us today. If you are interested in participating in tomorrow's Task Force meeting, Group 3 will be meeting, so I am sure we will see some of you then. At this point, we stand adjourned.

Steven Eichner
Thank you so much, everybody. Have a great day.

Hans Buitendijk
Thank you.

Adjourn (01:28:04)