Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

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

May 10, 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
Wendy Noboa	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
Michael Lipinski	Office of the National Coordinator for Health Information Technology	Presenter
Kate Tipping	Office of the National Coordinator for Health Information Technology	Presenter

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

Wendy Noboa
Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task Force. I am Wendy Noboa with ONC, and I would like to thank you for joining us today. Just as a reminder, all Task Force meetings are open to the public, and your feedback is welcomed, which can be typed in the Zoom chat throughout the meeting or can be made verbally via the public comment period at the end of our meeting. Now, I will begin rollcall of our Task Force members. When I call your name, please indicate that you are present, and let's start with our cochairs. Steven Lane?

Steven Lane
Present.

Wendy Noboa
Steve Eichner?

Steven Eichner
Present, good morning.

Wendy Noboa
Good morning. Medell Briggs-Malonson? Hans Buitendijk?

Hans Buitendijk
Good morning.

Wendy Noboa
Jim Jirjis?

Jim Jirjis
Present.

Wendy Noboa
Anna McCollister?

Anna McCollister
I am here.

Wendy Noboa
Aaron Miri? Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning, I am here, thank you.

Wendy Noboa
Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning, present.

Wendy Noboa
Fil Southerland?

Fillipe Southerland
Good morning, everyone.

Wendy Noboa
Sheryl Turney? Thank you, and good morning, members. Now, please join me in welcoming Steve Eichner and Steven Lane for their opening remarks.

HTI-1 Proposed Rule Task Force Charge (00:01:22)

Steven Eichner
Good morning all, and welcome to this meeting of Task Force Subgroup 2 for looking at the HTI rule. We are excited to have our Task Force members here. We want to welcome especially any members of the public that are in attendance. We will have a public comment period a little bit later in the meeting and do encourage the public to take advantage of that opportunity. We are really interested in hearing a wide range of viewpoints, and anything you have to offer or questions you have would be most welcome. What we have on the agenda this morning is a good presentation around some of the other elements that we have been asked to comment on regarding HTI-1, really focusing on naming conventions, so we will get there in a minute. Steven, do you have anything to add?

Steven Lane
No. Let's jump right in. Let's make the most of our time.

Steven Eichner
So, let's go on to the next slide, please. We are going to do a really quick review of our charges. Again, the Task Force has been laid out to help ONC by responding to the HTI-1 proposed rule and provide feedback in a number of very specific areas. Today, we are focused on renaming all certification criteria to move away from the edition naming to a new framework. Next slide, please. We are also going to be looking at establishing additional assurance criteria and maintenance of certification requirements today. Next slide, please. Again, continuing through the rest of our charges and things that we are going to be looking at in today's discussion. Next slide, please.

We are now going to shift into presentation mode and ask Kate and Michael to begin their presentation on certification criteria. Steve Lane is going to help us by tracking some of the questions and hand raising in the chat. I see we are going to try to hold questions until the end of the presentation, and then come back and circle up. We do always encourage members to make recommendations in the worksheet. We will spend a few minutes looking at the worksheet a little bit later today. Again, welcome, Michael and Kate.

New Regulatory Approach for Certification Criteria ("Editionless") (00:04:20)

Michael Lipinski

Good morning. I know it is pretty early on the West Coast, so I appreciate those out there who have joined us today. We are going to talk about the proposed approach on, essentially, editionless certification and editionless criteria, so let's just jump into that. Next slide, please. I am not going to read the disclaimers, but generally, we are going to do our best to recite the proposals in the rule, but there is always the potential to misstate something, and the official proposals are in the rule. That is generally the main point, and also, importantly, since it is a proposed rule, we cannot really interpret or clarify anything right now, so what we would do is take your comment on that and then use that comment in terms of whether we believe there needs to be further clarification in terms of what the proposal was or how that potential proposed requirement should be interpreted. Okay, let's move to the next slide.

As I mentioned, if you are familiar with our history, we have taken different approaches to the naming convention when it comes to our criteria, and there is a whole in-depth and rich discussion of this in the rule, so I am not going to spend a lot of time on the history, but generally, we have changed the names. We have tried to do it to make it, in some respects, connected to what is now the Promoting Interoperability program, but also, from a recency perspective, so you would understand which year those criteria standards were adopted. We still currently have the 2015 edition, we did not update in the CURES rule to that, but yes, 2015 was when that set of criterion standards was originally adopted. They have been updated a bit through the CURES rule, but not all of the standards and criteria.

So, what we are trying to do now, since, obviously, we have had different discussions in the rules about how the program is for health IT, not just EHR technology, and that, while it was in the beginning and still does, it is not just to support the Promoting Interoperability programs. That is not the sole purpose of the program or potential use of the program. So, now, also from a recency perspective, these are the criteria that you need to either meet the base EHR definition, like the other program, and be clear about what you need to meet that program from meeting the certified EHR technology definition that they have in reg for the Promoting Interoperability programs, so we just feel it will be much easier to understand and administer the program this way, in which we are setting essentially… And you can see this in other standards.

CMS has done this with procedures and the codes and standards that are applicable to that by setting time periods, so, essentially, that is what we are doing here with the standards and criteria in this rule. There are some benefits that I have already mentioned, but they are outlined here on your slide. I am not going to read directly from the slide. You have had the time to take a look at the slides as well, and are probably reading them as I am speaking anyways, so we can move to the next slide.

So, the two big things that we are doing in relation to the standards is that, like I was mentioning, there is a time band, which I guess is the way to best express it, and we started doing this with the last rulemaking, if you recall, the CURES Act update, which I believe we called the 2015 update, where we set that by such date, product… It was under real-world testing where we generally set the timing requirements, that products that were previously certified to certain criteria that had identified certain standards would have to be updated to the new standard that we adopted in that rulemaking by a certain date, and what we did was allow a flex period up until that originally adopted standard was no longer valid for certification purposes, and we are still taking that same approach here, so you would be able to use a current adopted standard,

or you could switch quickly to a new adopted standard. This is a policy and process that we have employed in other places.

The best example would be the base EHR definition, so when we used to have the 2011 and 2014 edition, you could jump to the 2014 edition before the time you had to, so you could do it early and implement early, or you could continue on the 2011 edition until you had to move, based on the adopted timing requirements to the 2014 edition. Same philosophy here when it comes to the standards and similar, like I said, to what we did in real-world testing. We have embedded it in standards now, for example, with the USCDI in 170.213, and we also have proposals that I will talk about related to the assurances provision. So, I see some questions in the chat, and this is my first opportunity to present to the Task Force. I am willing to work with you. How do you generally handle things? Do you want to do questions as we go?

Steven Lane
No, Mike. Sorry, my bad. As Ike said, we are going to hold questions until the end.

Michael Lipinski
All right, I might have missed that in the beginning.

Steven Lane
We sort of stack up our questions so that we can keep track of them. You can respond to any of them if you want to, but you are not required to be distracted by them.

Michael Lipinski
All right, great. That is super helpful, and it also tells me that depending on how many questions stack up, I will know how fast I need to move so that we can get to the question.

Steven Eichner
And we will also do you the favor that Steven is monitoring the chat, so if something really pertinent pops up, he can bring it to your attention, but you do not necessarily need to focus a lot of attention on the chat while you are presenting.

Michael Lipinski
Great. Next slide, please. So, like I was foreshadowing, there are two forms of compliance there. They are embedded into the criteria, like the example I gave you with USCDI, but now there is a condition of certification that we are proposing under the assurances. Again, similar to what we did in the real-world testing, we have now changed where we are putting that. We are putting it under the assurances condition of certification. We have removed it from the maintenance one; granted, in all of the ones that were generally in the maintenance other than the EHI export one, the timeframe had passed. It was December 31st of 2022. There are generally three requirements: Update, provide, and timeliness, which is where we are going to spend most of our time.

In terms of update and provide, we do not set independent timeframes for them. Essentially, from the assurance perspective, which goes to what I was saying before, we say you can update early. If you are cloud-based, you can go all the way to the end and then turn the switch, so to speak. I know it is not quite like that, but the point is I am trying to give you an illustration of how you can do it. You can update first and

have a planned rollout, or maybe you can do it quicker, depending on how nimble your software is to roll out. Let's go to the next slide because I am sure this is where a lot of questions will come up, and we will spend some time on it. Hans, we are not quite there yet.

So, in the rule, revised certification criteria is an important aspect in terms of how that is when you are certified to a revised criterion, that is when the timeliness and the update and provide kick in, so we tried to be clear, so, again, to the point of clarity, what criteria fall under this. So, you have the definition above on the slide, and then, we have identified what criteria meet the definition, and therefore would implicate the assurance condition and maintenance of certification requirements that we are proposing.

Okay, now I think we will get into timeliness, but granted, I did not put these slides together, so I am not 100% sure what the next slide is. Next slide, please. All right, yes. So, here it is in a nutshell. It is a lot of words and a lot of thought in terms of trying to figure out what this actually means, so we are really going to spend time on a visual representation of this. We have tried to put some slides together to visually represent the various scenarios that may implicate this timeliness proposed revision and how it would play out, and we can talk about things such as what a new customer is. We do give a very generalized definition of what that is. We do not provide more, but if you think that is needed, we welcome comments on what is a purchase or licensing relationship. We are really leaving that flexibility up to the developer, and how you structure that as to when that clock is going to start on when the actual relationship starts. Okay, next slide.

The first one is easiest to at least illustrate, although I think by the end of this, you will see that they are all easy to illustrate. So, let's say the final rule is effective this November. That would give all developers 26 months to both update and provide their technology. That is a simple illustration of this. That does not apply to everything in the rule that we propose, and we will talk about that, but this is a simple illustration of how it would work. Next slide, please.

So, this is the new customer illustration. And so, with this one, if you recall back from the slide before, the relationship is established in October of 2025. Now, if you recall on the prior slide, from the 24 months from the calendar year after the effective date of the rule, it would expire on December 31st of 2025, but here, you will be given additional time. Really, the minimum is 12 months with a new customer. I think a really important part of this, which I am not sure if we tease out on these slides, though we are working on a fact sheet to do it, and it is almost done and will hopefully go out this week, is that "new customer" means new to the capability. So, if you had a product certified, and then you added a new capability to that product, and then rolled it out, that would be new for them. So then, the 12 months would kick in and it would be in this timeframe. Now, remember, you still have the 26 months, so it is whichever essentially provides you more time, unless the original timeframe begins to expire. Next slide. If we can go to that, we can try to tease it out even further.

Steven Lane
Mike, I will just slip in. You said at least 12 months and, looking at the slide, it looks like it is at most 12 months.

Michael Lipinski
No. Here is a good example. At most, it could be 26 months.

Steven Lane
I see.

Michael Lipinski
The operative word is by whichever timeframe expires last. So, we are trying to show you here that you establish a new customer within that original… Let's assume it is November 1st of this year. Boom, you kick out the 26-month timeline. We are showing you that. You establish a relationship with either a completely new customer or you create a new product that has functionality that is new to even your existing customers, so it is new to them. You can see here an example of how you would still get the full 26 months because it is whichever timeframe is last. However, if you do not establish that relationship, which is something I think we want to try to hone in on in terms of consideration of when and how you establish new customers and new relationships, in the previous slide, you saw that you would have gotten 12 months at minimum because it would have started October of 2025.

So, obviously, if you were within the 26-month period, you would only get three months, but what we are saying is it is whichever timeframe expires last, so in that instance, you would get 12 months. Yes, there is a potential for only getting 12 months, and this is not the only way that you may get a lesser period than, in this example, 26 months. Generally, it is 24 or more. I think the example we give in the rule is if we dropped the rule and it as effective in January of 2024, you would get that whole year plus two years, so, almost three years. We are going to talk about this next. There is a condition and caveat beyond the one we are just talking about here in terms of a new relationship that could be established, not within the original 26-month period in this example. Next slide. We can come back to these to spend some more time when we get into the question part. So, there is the "unless expressly stated otherwise" in this part.

So, this example shows you our proposal for USCDI Version 3, which has its own timing that is less than the full 24 months. So, this is an example where that would kick in, and if that rule, again, dropped on November 1st, which is the timeframe we are trying to use to give you a basis or starting point, you would only have 14 months until the end, and that is for all customers, so that would be previously certified, nothing new to them. You would have until that timeframe to update to USCDI Version 3. That could create a potential problem if you have a new customer toward the end of that period, and you are welcome to comment on that, but that is generally how that would work. Does that take us to the end, Kate? Yes. So, we are at the end of this, so I am happy to go back and go other slides some more. I know it was fairly quick. I am not sure how much time you guys generally have overall. I know you all have other things to discuss as well, but again, I am happy to go over the questions and any particular slide again.

Steven Lane
Thank you so much, Mike. I have been monitoring the questions, Ike, so, whenever you want to go ahead, I am good.

Michael Lipinski
I can do the one on if it affects SVAP. If you have a particular reason why you think that, we can go into deeper detail, but no, because we are not… So, as an example, we never proposed to adopt Version 2 of USCDI in reg, so right now, we are proposing Version 3, it will be the new baseline, and, again, it is not going to kick in until, first, we adopt it, as it is only a proposal, and then you would have a time period in which to update. So, you had to do Version 1 by the end of last year. You could go to Version 2 with SVAP

now or in the next year or so if you wanted to, and that would not change, but if there is more to do that, I am happy to…

Steven Lane
Now, I recall that Version 3 has not yet been added to SVAP. Is that right?

Michael Lipinski
Not to my knowledge, no.

Steven Lane
But theoretically, the SVAP process will just continue to march forward, and folks can leverage that for their existing certification, and when this new process goes into place, there will still be SVAPs done with USCDI and other standards as they move forward.

Michael Lipinski
Yes.

Steven Lane
Maybe it is just me, but I am thinking it would be nice to have some kind of a graphic that clarifies…

Michael Lipinski
SVAP?

Steven Lane
Well, where SVAP fits, and also where… Each of those individual graphics is nice to build the picture, such as the 12-month, the 26-month, and how USCDI V.3 comes earlier, but like you guys did with the info blocking, it is nice to have a compiled graphic where, as you build up the story and people understand it, then you can see it all in one place. To me, at least, that would be helpful.

Michael Lipinski
Okay, I will definitely take that back. We are always open to however we can best convey our policies and proposals, so I will definitely take that back and talk to some of the standards folks. Obviously, a lot of them are out at HL7 this week.

Steven Lane
They will be right there with Hans, who has the next few questions.

Michael Lipinski
On SVAP, I think we are looking at more standards, too, right now for SVAP, just for awareness. Hans?

Discussion (00:24:19)

Hans Buitendijk
You want to jump to me? I have a little bit of background noise based not on HL7, but the hotel where we are at. I have a couple questions. I want to make sure I understand something. You explained that the HTI

versioning in this regard changes from the edition to the HTI-1, but potentially, with a number of these updates, like the example that you used of USCDI Version 3 being on one timeline and other things being on another one, which may stagger over time, etc., how are we looking at these designations? HTI-1, HTI-1.1, HTI-2? I am just trying to get a better sense of how we are going to manage this. I have a little context there. Generally, the idea to move away from the way that editions have been named and addressed with the confusion around which year you are talking about, the target, when it is published, etc., is very helpful.

As new line items effectively in certification criteria start to travel along different timelines, then maintaining overview, getting updates out to clients, etc. is actually also going to complicate matters a little bit, so it is a balancing act between naming and other things getting easier and making sure that, at any point in time, the progression, whether it is from a developer or from a client perspective, that we maintain good overview insight on the workload that they have to keep up with the changes in total, not just one at a time, which might look very doable, because there are now going to be many threads to manage as opposed to "one thing," albeit big. So, that is where some of those concerns come in. How are we going to think about this?

Michael Lipinski
Obviously, I think you know what I am going to say here. This is a comment you should make if you see where there could be significant rub based on these proposals. Obviously, from a policy perspective, ONC thought it was important to get USCDI Version 3 out sooner, hence why it did not fall into the full timeframe that any other standard would have received, and it is not the only one. I do not know if we were to adopt the patient segmentation one…

Hans Buitendijk
Demographics?

Michael Lipinski
Yes, I think maybe that one, too. This is not the only one. So, if that creates a development rollout concern, I think that is something we would definitely want to hear in comment, so I am very open to that.

Steven Eichner
Hans, this is Steve Eichner. I agree with you, not just from a pure, technical standpoint, but also from a communications standpoint. Putting on two different hats for a second, as a provider, how do I tell if I am current? If we are looking at the 2015 edition, but the 2015 edition **[inaudible] [00:27:38]** or not, but if each criterion is on its own developmental phase, what is the source of **[inaudible – crosstalk] [00:27:49]**.

Michael Lipinski
Right. I wish they were here, but they are both out. Rob Anthony, who is the director of certification and testing, and Jeff Smith, who is the deputy director, have been thinking about this, and we actually heard it in internal comments from certain interested parties about beginning to know that for various reasons. You can see from an enforcement perspective that it is important to know as well, like if the developer is certified to what it should be at that time, as well as from participating in programs, knowing that I have product that meets the cert definition at that time. So, there is a lot of thought and work going into how we would operationalize this regulatory policy through the CHPL, for example. I am not in a place to speak to that, so I do not want to misspeak, but we can try to circle back on that when they are both back in the office, which

I think will be next week, or at least Jeff is in next week, but Rob will be out for a week after that, but we can circle back on that and see what we can say publicly about that.

Steven Eichner
It may just be a space for a comment.

Michael Lipinski
Yes. Obviously, it should be a comment, too, because it is not in the regulatory proposal, but it is something that we are contemplating how best to demonstrate that and represent that on the CHPL.

Steven Eichner
Hans, do you have a follow-on, or shall I jump to Fil and come back to you?

Hans Buitendijk
It was a follow-on to clarify, and this may indeed also be just a comment, but you might be able to address it, on the intent as proposed. Is the intent that we are looking here because we have a transition of the old edition approach to the new HTI approach, that that is the reason why there are some of these that have a different timeline, so it is part of a transition, or is it, indeed, in the way you heard the questions raised, that the intent is that on an ongoing basis, this may occur, and therefore, that would put a different context in how we may want to make some comments at that point in time? That would be great to clarify. Is it a transitional thing only as intended, or is it an ongoing potential and we have to keep that in mind in our comments?

Michael Lipinski
Maybe I am not quite following. So, for example, the USCDI proposal with the shorter timeframe is not in any way tied to the simple fact that we are just going to an editionless approach. It is more a policy proposal.

Hans Buitendijk
Okay, so we need to keep in mind that this is not a traditional proposal. It can happen at any point in time. That is helpful.

Michael Lipinski
Exactly. That is why we have “unless otherwise stated” in this part, and just to be honest, it is policy driven, what the agency wants to see by a certain timeframe. It is a proposal. As I always say with any of our rules, the whole point of the APA is to get public feedback and consider that public feedback before finalizing any policy proposal.

Hans Buitendijk
That clarifies. I appreciate that, thank you.

Michael Lipinski
No problem.

Steven Eichner
Fil?

Fillipe Southerland
Good morning. I am curious: What is the enforcement or monitoring mechanism for tracking when the vendor gains a new contract, so how would we have insight into that? Would that be public information, the last time the vendor had received a new contract? Would there be an attestation process?

Michael Lipinski
That is a good question. I do not recall us making that a reporting requirement. Hans may know better than me. I am a little removed from the daily ins and outs of the certification program and what is required in the quarterly reporting, but it could be a good point for comment. I am not sure if that is something we are trying to monitor from an enforcement perspective, so there is that. We are happy to take comment on that piece. Obviously, if you ever got on a CAP, a correction action plan, you would have to identify all your customers that are affected by whatever the nonconformity is, but I do not think we require updates on customers on a regular basis, but again, I am not on day-to-day activities between the certification body and the developer, so I cannot speak with certainty to that. I do not ever recall it being one of the quarterly things that they have to report, and we did not propose that in this rule.

Fillipe Southerland
Okay, thank you.

Michael Lipinski
To be honest, I think it would be more a reactive thing. Some of what you are talking about is more proactive and about the auditing on that, but to give you an example, if somebody said, "I did not get the product rolled out, I established my contract with this developer on such-and-such date," then that would be reactive, and we would look into it and determine whether or not that contract would establish if they did it within the time period they should have under the rule, so it would be more of a reactive approach. That is how I was thinking about it.

Steven Eichner
One of the things that I think this approach in the timelines does impact is looking at both the effective rate of change and the length of time between a standard being developed and actually in place from more of a universal perspective. If we are looking at a year-and-a-half or two-year development cycle for an HL7 standard, and then balloting it and going all the way through, that process can easily take a couple of years, and then looking at including that in federal reg, and then fully implemented and fully vetted and going through the entire process, you are potentially looking at about a five-year timeframe from birth to full implementation, and that may be a little bit long.

We are looking at some changes, not necessarily universal. I think it depends a little bit upon what the standard is for a variety of reasons, looking at some of the rapid response and rapid changes that were needed by public health to better respond to things like the COVID-19 public health emergency, and thinking about where there are potentials for shortcuts, and I am not looking for an answer for this, but looking at where there are opportunities not to shortcut because it is something you want to do, but looking at accelerating a process for adoption because there is an imperative to do so to meet a particular need.

Michael Lipinski

Right. So, we could spend a lot of time philosophically about how we approach things. ONC has created the whole ISA, and we also have a process for how we even determine maturity and levels of elements that go into USCDI, for example. While I think we have an approach that we think is viable before we propose in terms of maturity and adoption of a standard before we even propose it for adoption under 3004 and even inclusion in a certain criterion, we are not technically beholden to it, so I think you are raising some of that, about where is the standard at and the timing of all that. And then, once we think it has reached a place where we are proposing it for adoption, I am going to take what you said, and also the flexibility of the language in our proposals. It can go either way.

If there is a strong need to get a particular standard that we think is either… Maybe even if it has not been fully adopted, like we are obviously going to explain our rationale when we make a proposal, but I am going to do a couple hypotheticals. We need that functionality out quicker, so we are going to propose a shorter timeline, or we think from a policy perspective about the benefits of getting that out sooner, so we propose it. Granted, like Hans is raising, I think there may be other considerations that we have not considered, either with that particular standard in the rollout or with its relationship to other functionality and rollout and a burden it could create by enforcing some kind of artificial separation in updating and rollout, for example.

Alternatively, it could go the other way. We may think that the industry needs a push to get this standard out in the functionality that it supports, but when this rule is going to drop, maybe we do not think that is a sufficient amount of time, and we can use the "unless expressly stated otherwise" in this part to give even more time for that particular standard rollout. So, I guess what I am trying to point out is that there is a lot of flexibility in the regulation text of how we have proposed it to support different policy positions and use cases, but also, I wanted to just emphasize that we have a strong approach before we even get to proposing a standard. I will stop there.

Steven Eichner
Thank you. Hans?

Hans Buitendijk
Thank you. I generally agree that having the framework that allows a level of flexibility is helpful to have that available. At the same point in time, I think that is where some of our comments and deliberations will be around how to phrase it and how we can manage it. How do we ensure that the flexibility does not create uncertainty and ambiguity otherwise? Because that can easily come with that, and I think that is the balancing act that we clearly see. There were challenges with the classic edition approach, and now we are going to look at the other one, and that definitely has a number of very interesting opportunities, and this is more for the comments than for a particular question for Mike, but we need to make sure that vocabulary standards play into that as well.

There are tracks that you could say can move relatively independently from each other, but actually start to have vocabulary terminology updates in there as well. At what point in time are they meant to go first? Because they typically impact multiple streams, and to date, that has been the new floor of the version, not that you could not get there by way of SVAP or adoption already, but the floor actually was at the same time that everything else happens. If everything is moving at different timelines, what does it mean if I am going to put it into one stream that is dependent on it, but not yet the other? So, vocabulary is going to be one of those cross-cutting issues that is going to provide some dependencies that need to be kept in mind

as well among efforts, total workload, transparency, etc. So, I just wanted to bring it up as part of the considerations that we need to look at.

Steven Eichner
Fil?

Fillipe Southerland
Another point I wanted to call out from Workgroup 3 that was also identified was that including the USCDI as essentially a forcing function for other certification criteria will continue to exasperate the issues for specialty EHRs around USCDI, where there is additional burden, potentially, where the EHRs are developing functionality that they are not the source for, and that potentially becomes even more front and center with this new methodology.

Steven Eichner
Okay. Mark, do you want to elaborate on your comment in chat?

Steven Lane
Mark is not on the audio yet.

Steven Eichner
Okay. Steven, do you want to bring it to attention, or is he coming on?

Steven Lane
I always invite Mark to chime in when we go to public comment, but the comment in the chat is that Mark is reminded of the USCDI Task Force and HITAC's recommendations from two years ago around USCDI V.2 to move more strategically and less incrementally, so I think that is a comment on the pace of change of USCDI in particular.

Steven Eichner
I wanted to bring that in at the moment just because it fit in well with Fil's comment. Do we have other comments or questions from Task Force members?

Steven Lane
So, I had a question, and it relates to the slides, I think Slide 14, which we sort of glossed over, having to do with the revised certification criteria themselves.

Michael Lipinski
Sure, we can go back to that.

Steven Lane
Of course, most of this discussion has been about the timing, how to get there, and how to deliver them, but these revised certification criteria are obviously extensive, and this is sort of the what that we are talking about. We have been focused on the when, how, and for whom, etc. How deep are we digging in the work of our Task Force into this list of revised certification criteria? Are we being expected to go through and

provide comment on each of these? Are these broken up into the various items that we are going through with our different workgroups? I am just trying to put this all together in my head.

Michael Lipinski
Is Mike Berry on, or Vera? I do not have a good understanding of all the different… I want to feel like these criterion are in another Task Force, but I am not sure. Wendy?

Wendy Noboa
Hi, Mike. I am here for Mike Berry. I can take that back and get clarification for you, Steven, just to make sure that we get you an answer.

Steven Eichner
And building on that idea, looking at things like electronic case reporting specifically, which is actually also being modified by the current HTI rule, what is the interplay with the two sections of the rule in terms of looking at what becomes the floor? What is the expectation for implementing the standards that are included in the HTI draft or ECR, if that makes sense?

Steven Lane
That may be another component of the question to talk to Mike and the team about.

Michael Lipinski
From my perspective of what I am talking to today and that I think Hans, Fil, and some others have hit on is I think you need to be considering… I know it requires a fuller understanding of all the proposals. You cannot just understand what I am talking to today to give probably a fully informed view on whether the timing proposals make sense or create problems because you need to know what the burden is with each of the criteria identified here. So, obviously, we know DSI has a lot to it in terms of just the changes to the criterion itself, let alone the algorithm transparency piece, and then, on the case reporting, I am just saying something I have heard in the past from comments, and I am not saying they are going to make the same comment again, but they could, is that if there are two standards identified, they may have to do both standards, not an "or," but an "and" for them, depending on who their clients are.

Steven Eichner
This is Ike. Part of the reason I brought up ECR in particular is that there is an "other" section of the HTI rule that is also setting specific characteristics about the ECR reporting standard and I was not quite sure about how the two aspects of the rule interplay and what that would mean for actually adopting the language that is laid out in the ECR section.

Michael Lipinski
My vague recollection of things, and I see Sara is on, and I am hoping to hear from her or Kate, is that each of these criteria are going to be discussed in depth as part of the whole HITAC review. I am not as familiar what each of you have in your scope.

Steven Eichner
Yes, I was just filling you in on the backside. This is why that particular topic is perhaps more relevant than others. There are not modifications to many of the other certification criteria.

Michael Lipinski
Right. That one is much more extensive in the bigger chain.

Steven Eichner
Exactly. Hans?

Hans Buitendijk
That may be helpful because in a couple of these, like F5, which I can make larger on the screen, for case reporting, has larger changes, and we have talked about it and are going to talk about it. G10, by adjusting USCDI Version 3, immediately gets pulled in as well because that is being used to support and demonstrate that you are supporting a USCDI version, whichever one it is. So, I thought we were going to touch on most of this list with different areas. If they did not change, other than a name change, there is probably not a lot of discussion.

Steven Lane
Yes, and that is fine, Hans. I appreciate that. Again, our whole discussion today has been about the timing of changes, and as far as I can tell, it is about the timing of changes that are proposed in this particular rule, and then, there will be additional rules, as you said, in HTI-2 and HTI-3, where there will presumably be additional updates to certification criteria because those all seem to happen in the rule, and then there will be a timing discussion. We will just no longer be calling them year-themed editions, they will be rule-themed editions, presumably. Does that make sense? Are you guys all seeing it the same way I am?

Michael Lipinski
I do not want to speak for Hans because I know he has no problem speaking for himself, but he raised the point that the operative language that we are proposing for an assurance because it is irrespective, which I think is what Hans is pointing out, and I would too, of this particular role. It would be applicable under any rule. It would just apply differently depending on what the proposals are in that rule. So, I think he had some thoughts about that, potentially, or at least wanted to identify that as a point.

Hans Buitendijk
Yes, and on that particular part, it also goes back to one of the earlier questions that we had about timelines and how they fit because the slides that Mike stepped through on 6 and 17 through 19 are nice examples that help illustrate how the language works, which is really helpful, having then the total picture to understand which timelines are what criteria on and making sure that we understand that. I think that goes back to an earlier question that we have on what the timelines actually are.

Now, at HL7, I had the chance to run into Avinash because he is here, and he said work is in progress on that, so it is not quite there yet, but work is going on there, but that will be very helpful to understand how the list on Page 14 that we see and whatever other aspects there are all fit together because that will really illustrate that picture of what is staggered, what is together, where we might have some friction between the two, and if we are all talking about the same intended timeline or not, so I think that is where it all starts to tie together. Is it just a name change in a timeline? No big deal. If it is a major change to a large uptake of standards and other ones, we need to look at that more carefully.

Steven Lane
Thanks, Hans, and Sara did dig in a little bit, but most of these are on the Group 3 list to go through. Anna, you have your hand up.

Anna McCollister
So, my role on HITAC and these various workgroups is really coming at this from the patient perspective and trying to think through what the implications are of each of these proposed standards, rules, and changes on patients, and more broadly, when I do stuff like this, I like to find ways to get input from other patients and people who are involved in these things so that I am not just representing my own personal perspective. I want people questioning my thinking and adding their own perspectives because it is a learning experience.

This is really, really challenging and remarkably time-consuming, particularly when you look at it within the context of a 500-page rule, which references a whole bunch of stuff that requires a significant degree of technical standards. I am somebody who started two health tech startups, who likes data, who helped start a patient hacker movement, so I am far more sophisticated in these things than most patients. So, when I look at this, I am trying to zero in on the things that would impact patients directly. Whether the timing impacts patients like that, I do not really have that much perspective on. Maybe I should, and if I should, please inform me, but some of these things, like the revised certification criteria… If I were to go to somebody and say, "This thing matters to you, this is going to have input, you need to give input to ONC and comment on the rulemaking," I am a little lost as to where I would even start, both from my own perspective as well as others'.

So, when I look at this list, care coordination is something people should care about. What does patient engagement mean? Can you download and transmit to a third party? What about actually being able to correct mistakes in your medical record? How does that work, or how do you comment on notes that the doctors put in there? Design and perform a standardized API for patient and population services: What does that mean? Does that mean that the certified health vendors are required to make APIs that are accessible through consumer-focused apps, that it is required to make APIs accessible, but write to HealthKit, which are the kinds of things that matter the most to patients?

Anyway, finding my way through this, for me, is super challenging. Thinking about how to actually help others engage in this process is a little baffling. I would love some guidance, frankly, from the other workgroup members and the committee or ONC staff on how exactly to focus efforts and thoughts on this process because a lot of the other folks that are participating in this spend a lot more time as part of their job thinking about these various certification criteria, and that is great and awesome, but we have to find ways that realistically get input from the people who are most impacted by this, and that is the patient, not the EHR provider.

Michael Lipinski
Sure. I really appreciate those comments, that really high-level overview of a regulatory framework, and I am not going to delve into a long diatribe about what regs do or are supposed to do and why you do regulations, comparative statute, and all that stuff. The bottom line, though, is from a regulatory agency, there are obviously policy goals and legal considerations why we put things in regulation for notice and comment, but the key high level is cost-benefits, and benefits are not always economic benefits. They can

be benefits that are sometimes… Well, I should say it this way. They are not always quantifiable. There are qualitative benefits that may not be currently quantifiable. What we try to do, though, is usually, what you are doing is always weighing or at least trying to estimate the costs, and costs are usually symbolic of burden. Anybody who is a regulated actor has to do these things, and there is a cost to that, and then we try to ensure that the benefits outweigh the costs.

And so, part of this whole process we are talking about today is really about how we think it is really important to get this functionality into EHR or health IT and out to the public because here are the benefits we see from it, and then, we say we know this is going to create some type of cost and burden, we have to estimate it, and then we try to figure out an appropriate timeline to achieve the benefits at a reasonable cost and ability for the regulated actor to achieve it. I think that is it at its highest level, and you can apply that to any field, really, any regulation, like EPA, transportation, or us. So, for you, you are looking at what benefits or costs occur for your constituencies. There are multiple constituencies and interested parties in our rules. Some are directly regulated, like developers, some indirectly, like providers, because we are essentially saying they have to have this to participate in another program, and then there are some that get ancillary or direct benefits, like patients, from these proposals, like easier access, more access to their data.

So, I would think of it from that perspective, and you should ask yourself what is most important for your constituencies that you represent from this rule. What do they need most, and how soon would it be great for them to have that, and what type of access, and does this achieve that in a timeline that makes sense to you? That is just my view of feedback to you. We want to hear from everybody because you each have an interest, a stake in this, and you each provide a different perspective that we are trying to balance all of. So, how important is it to get this out to the medical community, to providers, to researchers, and to patients, and also, who is bearing the initial cost and burden and when can they do that in? Usually, in our case, it is developers when we are talking about the certification program. Is that helpful a little bit?

Anna McCollister

I get all of that. I have done public affairs in previous lives for years. I understand the whole process and understand my role, and the role I have chosen is to try to figure out how this impacts various patients with various needs, and I take that seriously. What I am saying is that it is a 500-page rule that is chock full of things that could really have significant impact on patients, and a lot of the input from the timing perspective and the level-of-detail perspective is really a lot easier if you work for the industry and somebody is paying you to actually spend your time digging into the regulations, crafting comments, and participating. I choose to do this, I am not asking for sympathy, I am just asking what would be the best way to actually zero in on the elements, just within that slide that we were looking at, that matter the most? Because the one title description that was on that slide, and I know that a 500-page rule has a lot of details in there, is a substantial burden that we are placing on individuals who have other things to do, like paying mortgage and car payments and stuff, to read through, understand, and assess.

Just looking at the title alone there, I saw some stuff that made me think there are some key things that are missing, but it requires a substantial amount of historical knowledge, of procedural knowledge about how the government works, as well as an understanding of where we are within the technology perspective of what each of these terms means. The notion that we are actually going to get patient input is somewhat questionable.

Just making it possible does not make it realistic to assume that you are actually going to get input, even from more sophisticated patients, and all I am asking for is guidance on which are the ones that are going to be the most impactful from your perspective or from others' perspective on individuals, and what are the kinds of things that we should point people towards **[inaudible] [01:00:57]**, and that does not preclude anybody from commenting on anything, but there are some things in here that are substantial and some that I would not care about, that would only matter if I were an EHR vendor, but if some of the things that are requirements… EHR vendors will have substantial impact on whether or not patients can do what they need to do to stay healthy. I feel like I am just going off on a tangent at this point, and I do not think that is what this workgroup is for, and I do not want to derail our efforts, but it is super challenging to be able to zero in on the things that are really going to matter to me and the constituents that I have chosen to represent.

Michael Lipinski
Let me offer this. I am sure some of your colleagues here may have some ideas, and I definitely want to give them that opportunity. If you have the time, I am happy to talk with you a little bit directly about that.

Anna McCollister
That would be great.

Michael Lipinski
So, I can maybe give you Friday this week, if that works for you, or we can find another time. The comment period is open until the 20th of June, so we do have some time.

Anna McCollister
Yes, Friday works. Send me some times.

Michael Lipinski
No problem, but again, I will leave it to your colleagues. Like you said, a lot of them do this… Sorry, I did not realize I had my headphone up, so you may not have heard me that well.

Steven Lane
We can make you out, thanks.

Michael Lipinski
Fortunately, Anna did hear me, so we will connect, but like I was saying, your colleagues may have some ideas, too. They are very familiar with us and have been providing comment for years, so I will see if they have any ideas too.

Steven Lane
Thank you, Mike. That was very kind of you. Hans, your hand is up.

Hans Buitendijk
I wanted to really appreciate what Anna is mentioning because it is very hard when I have tried to just take my EHR hat off and say, as a patient, what is in all this, what would I really care about when I go to the doc, etc., and I try to flip back on forth on that to help also make sure what, then, from an EHR perspective,

which is my daytime hat, is that balance. Particularly at this point in time, I think it is very hard because of the variety of perspectives that come into this to understand what is more important and which data is most relevant, and that varies depending on the provider you support, the patient's perspective that you support, and if it is a specialty or a particular scenario, and as you add that up, it is becoming very daunting to understand if you add all those perspectives up that are all equally relevant and important in many ways, you get a very big pie. I cannot eat that in one bite. How many bites does it take to eat that? I certainly want to make sure the first bite is the best one I can have. I might not be able to handle the last one in the period of time.

I completely sympathize with that. We have the same challenge. We may have more underpinning on what effort it takes to create something, which is where you will hear a lot of those comments come from, but I want the entire pie for all kinds of reasons because when I add it up, that is where we want to be. The hardest question is about what the fastest path is to get to it. So, I do not have the answer either, but no matter which hat I am putting on, I am being challenged in the same fashion as you are, Anna, and that is a hard one, on what to focus on first, second, and third.

Anna McCollister
Thank you, Hans, and I really do empathize with that, and I appreciate that, and again, I have done two health tech startups and I understand all of the competing interests, time, etc., but I am here as a patient representative. Every second I spend on this, I do not spend on anything that is actually going to earn me income, and I am on here and interested in this stuff because I have an incredibly complex chronic disease that takes a lot of time to manage and stay healthy, and I am one of the healthier ones. So, if we are serious about actually getting input from the individuals for whom this stuff is supposed to be the intended beneficiaries of all of this policy, we are going to have to figure out better ways than asking people to dig through a 500-page proposal and try to have a historical… I do not know what the answer is. Again, I do not want to derail our efforts here by going off on a philosophical tangent about the regulatory comment process, but this is a lot, and any kind of assistance that other family members could provide in the group chat, in direct messages, email, text, or whatever, I would really welcome that because this is a lot.

Steven Lane
Anna, one thought that I have is we have asked the ONC repeatedly, and they have stepped up in their efforts to make it really clear to Task Force members what each workgroup needs to focus on, what is the most relevant highlighting things, including these discussion topics on the slide before us. I think the idea of asking ONC if they have some ability to organize this from the patient perspective and say, "We think that members of the public, patients, caregivers, etc. should particularly pay attention to these areas and provide comment." There are a lot of places where they say, "We are seeking comment on A, B, and C," but putting on a patient hat and saying, "Of all of this, these are the things patients might first focus on," that might be helpful for them to consider, maybe not in this round of NPRM, but maybe for the next one.

Anna McCollister
That is an excellent idea, Steven.

Steven Eichner
To add onto that a little bit, "patients" incorporates a wide range of individuals with individual needs or differential needs depending on, in some cases, the complexity of the patient's medical condition, so that

is another factor to look at. There are some things that are maybe a little bit more in the weeds to people who have regular business and do not require specialty care and the like, but for those folks that do require or utilize specialty care, there are some aspects that may be very highly important or highly relevant to those specific patients.

Anna McCollister
Frankly, in earlier versions, like in the Meaningful Use days, I would take it upon myself at times to summarize stuff, send it out to patient bloggers, get input, explain to them how to submit comments to regulations, and again, this is just a hobby. This is not what I do for a living. This 500-page rule is just a lot, and I am starting to think of how I can do that, and it is just too much. Steven, I love your idea of asking ONC to help with that process.

Steven Lane
Thank you so much, Anna. I think we do need to move on here.

Steven Eichner
We now need to shift to public comment. Can we open the lines, please?

Steven Lane
I think we are a little early for that. We have one more topic to cover before we go to public comment.

Steven Eichner
Sorry.

Steven Lane
If we can go to the next slide, that will remind us. Ike, we wanted to do some prep work for next week. Do you want to walk us through that?

Steven Eichner
Yes. I was going to do that after public comment, but that is okay. For next week, this group gets a week off. Steven and I will be presenting an update on Task Force progress overall to the full HITAC. Steven, do you want to elaborate a little bit more?

Steven Lane
Sure. So, what we are doing this week is asking each of the workgroups to let us know if there is any particular topic that we have been discussing that you think we should highlight for the HITAC so that they can be thinking about them ahead of time before we come back with our final recommendations. I am not suggesting that there is, but I just wanted to give us that opportunity.

Typically, in these HITAC updates, it is fairly perfunctory. We just say, “This is who is meeting, this is how often we have met, this is who our speakers have been and what topics we have covered, and we will be back with recommendations,” but maybe if we could pull up the spreadsheet quickly here and just remind ourselves where we have been in this workgroup to date, again, the Group 2 recommendations spreadsheet, you can be reminded of the topics we have considered. We have a number of recommendations that we put together initially about the DSI interventions. That has obviously been the

hottest topic I would suggest in what we have been discussing, but there are other issues that we have covered, and we just wanted to give this group a chance to consider whether there are any that they think should be highlighted. So, there are some hands up. Hans?

Hans Buitendijk
I am not sure whether I am confusing Group 2 and 3, and I apologize if I am, but perhaps the one that jumps out that might be of potential interest is a heads up on the discussion around USCDI. Fil mentioned it today and we talked about it earlier. I think that is this group or Group 3, the USCDI growth and managing to enable more HIT to be certified to the appropriate subset of that. That seems to be a big potential topic for a heads up, not that we have the final recommendation, but as a candidate.

Steven Lane
Great suggestion, Hans, and ONC team, let's consider that one when we start putting together our slides for discussion. Hans, the sooner that you are able to craft language around that recommendation, maybe we could even put a version of that together for next week.

Hans Buitendijk
That sounds good.

Steven Lane
Anna, you have your hand up.

Anna McCollister
Yes. One suggestion I would like to pose for the Google sheets and comments and stuff is I was wondering if it would be possible, again, thinking back to the amount of work this requires, for some of the support staff from ONC or the Excel Solutions people to actually take comments from members of the workgroup or the committee more broadly and incorporate them into the spreadsheet to reduce the work burden on committee members because it gets to be a lot to read the rule, participate in a meeting, and then submit comments to this, and then go back and check others' comments on top of it. So, it is just a suggestion. I know that is the process that has been used in other things like this that I have done. There was less of a burden on the individuals that were participating in the workgroups or the committees to be able to go in and, in addition to voicing opinions, actually incorporate them into the document. It was just an additional burden.

Steven Lane
I think you make a good point, and I will also take that as a constructive suggestion for the cochairs, that perhaps we should be doing or trying to do a better job capturing the highlights of the discussion into the spreadsheet. The reality is that just keeping track of the discussion, participating in the discussion, and reading the comments is keeping me and Ike pretty busy, so, yes, it would be wonderful if one of the ONC staff could try to summarize some of the discussion points as we go through them.

Anna McCollister
Yes, exactly. Back from the USCDI Task Force that went on for a while, I provided a number of comments, but in addition to the comments, you had to go in and actually incorporate the document by documentation and subject matter expert suggestions, and that is just a lot, and since there is a substantial amount of

support staff, seemingly, for ONC, and I know they have a lot of stuff to do, it would be incredibly helpful if they could take on that burden. Again, with every other advisory committee that I have ever participated in, even ones with the federal government, that is usually the way the process works.

Steven Lane
Thank you for that, Anna. Any other ideas about things we should incorporate next week? Again, it is not a big deal, we do not have to do any of it. And then, what I would hope we will do is keep the spreadsheet handy. After we come back from public comment, we can look back at our spreadsheet and see if we can start turning some of these member recommendations into draft Task Force recommendations.

Anna McCollister
Again, from the patient perspective, I think one of the scariest and biggest parts of this is all the stuff around DSI or AI, so I hope that we can talk about that, and again, that is a thing I have not had a chance to comment on in the spreadsheet.

Steven Lane
Anna, I agree with you. In a sense, I think that is one of the hottest topics that is here. Obviously, the recommendations are largely around transparency. That is the part of it we are dealing with, not the larger issues of if this is good or bad, if it is moving too fast or too slow, etc., but from a patient perspective, transparency is a key issue. How does a patient know that DSI is being utilized? From what is it based? The whole issue of governance… I think there is a lot of patient stuff there, so again, I do not want to push you ahead, but the sooner you and all of us can get into the spreadsheet and put our thoughts into draft recommendations, the better, because again, I do not personally see a lot of problems or gotchas in the way that the rule has been constructed. Maybe I have just not thought about it deeply enough, but it is clearly important. Okay, I think it is time to cut to public comment.

Public Comment (01:17:32)

Wendy Noboa
Yes, that is right. So, we would like to open the meeting for public comment. If you are Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen, and if you are on the phone only, please press *9 to raise your hand, and once called upon, press *6 to unmute or mute your line. I believe Mark Savage already has his hand up, so, Mark, please share your comment. You have three minutes.

Mark Savage
Thanks so much. I am just responding to the invitation to follow up on my written comment. Listening to the discussion about timelines and Ike's comment about meeting national imperatives gave me a little sense of déjà vu to our conversation in the USCDI Task Force two years ago when we were looking at the process and wishing that we were all, ONC and the Task Forces, moving more strategically and less incrementally. It felt like we were moving step by step and were not getting where we needed to get as fast as we needed to get there. Ike mentioned some examples of the pandemic response. COVID is not the end of things. We have to be moving faster. Health equity, maternal health and mortality, and patient-reported outcomes and remote monitoring are all things where, if it takes three, four, or five years to get someplace, we are really behind the curve.

We did put together some recommendations two years ago, so I will maybe summarize the thought in a way that I do not think we put them out there, but to think more in terms of the interoperability roadmap that came out in 2015 not to say what the process is step by step, but to say where we need to be in two to three years and back up from there, and that may help us realize that the processes are not moving us strategically enough to get where we need to be in time. Anyway, that is a version of what my written comment there was about. Thank you.

Steven Lane
Thank you so much, Mark. We are available and open to additional public comment from the rest of you who have joined us, and we really appreciate the public engagement, whether you comment or not.

Wendy Noboa
Yes, absolutely. At this time, there are no individuals with their hands up indicating public comment, so, at this point, if there are no others, we will go ahead and close public comment, and we will yield the time back to the Task Force. Ike and Steven, please proceed.

Steven Eichner
Thank you so much.

Steven Lane
Go ahead, Ike.

Steven Eichner
After you.

Steven Lane
I was just going to invite you to walk us through the spreadsheet more on the recommendations.

Steven Eichner
Sure. Let's go back to the spreadsheet, if we can. This is the spreadsheet as it stands, with everything that anyone has contributed in it up to date. So, we have our proposed rule summaries in there and looking at member recommendations and comments, so let's go down… Steven, do you have a particular piece you would like to focus on?

Steven Lane
No, you go ahead. I just know we need to move from member recommendations to Task Force recommendations, and we have six minutes now. Let's take advantage of it.

Steven Eichner
Right, exactly. There have been a few contributions and recommendations made from Task Force members. We can look at those, but looking at the one that is highlighted right now, we need to track conformance to new vendors. Fil, do you want to explain your recommendation?

Fillipe Southerland

Yes, I am happy to here, Ike. So, what was the question, just on the first and second one, or just on the second recommendation?

Steven Eichner
Just to add a little explanation.

Fillipe Southerland
Okay. So, on the first one, this references understanding better how ONC would track the new client specific timelines for vendors.

Steven Eichner
Okay…continue, please.

Fillipe Southerland
The second one would be around the impact of the USCDI essentially having interplay with other certification requirements and looking at how that might cause additional burden and disincentivize adoption of the certification program for specialty EHRs. Going back to Hans's point, as USCDI becomes more integral to the certification process and evolves to include additional data points, we might have the inadvertent, unintended consequence of disincentivizing participation in the program, unless we can get some guidelines around how we might make the USCDI more adoptable for EHRs that do not track certain data points.

So, I certainly understand ONC's perspective that we do not want to dilute and piecemeal the USCDI, but what happens when the vendor is not a source data point for USCDI? As a specialty vendor, I have gone through that process, and it is a significant development issue that we have faced and delayed our implementation by six months to a year, which resulted in a lot of meetings with the various organizational stakeholders to sell the fact that we would have to fully comply with USCDI, including data elements that were not in our sector.

Steven Lane
Fil, I really appreciate your comments and your taking the time to put them in as recommendations in the spreadsheet. Can I just ask you to go back to these and rephrase them as "recommend ONC…"? The first one is "We recommend ONC clarify how they will track, etc." I think the more we can have the discipline to do that as we put these in initially, the easier it will be for us to get to the endgame here.

Steven Eichner
Yes, because what will happen is we will take the recommendations that are being developed in the worksheet, and then, in the next few weeks, we will transfer them into a regular Word kind of document, and because we are presenting these as recommendations, as kind of a comment, we need to phrase them in a manner that says, "We recommend this action, we recommend clarification about this subject, we recommend that the final rule be modified to include X or not Y," or things like that, so it is really phrased as recommendations. Hans?

Hans Buitendijk

Just a quick note. I found the comment around USCDI in Group 3. I plan to go back into that later today or tomorrow, update that, and link it back to Fil's comments in this sheet that we are looking at, trying to connect them because they are going to be related.

Michael Lipinski
This is Mike with ONC. Can I just jump in real quick, being somebody who has done regulations for 15 or more years? These comments are great, but if I am not hearing you, sometimes they are too generalized, to be honest with you. Fil, for example, what data elements and what criteria are having the…? Do you know what I mean? What particular data elements are you not supporting that are included in Version 3, since Version 3 is finalized and standard now, and what criteria are those? Is it the API one? Which one is it, the CDA, the VDT?

I guess that would be helpful too to better understand it, because I either talk to somebody in standards who… Because I do not even know which specialty you are talking about. There are so many specialties that have different… We have gone through that in the past with the base EHR definition, pathologists versus pediatrics, and the list goes on. So, I think that is valuable too, to know a little more specificity, because you probably know it, obviously, because you just pointed out that you went back to your client to talk about "Hey, we do not really support this, but we are going to need to to get certification," so I think that is always helpful. It does make it generalized.

Steven Eichner
Sorry, we need to cut you off because we are out of time. As we said earlier, next week, this group gets a break, and we will be back in two weeks to continue our work on Group 2 activities. Everyone is welcome to attend the HITAC meeting as well as other Task Force meetings in the meanwhile. Steven, do you have anything to add?

Steven Lane
No, that is great. Thank you, everyone, for your participation today. We really appreciate it and hope to see you at the HITAC meeting.

Wendy Noboa
Steven and Ike, can I just make a comment really quick?

Steven Eichner
Absolutely.

Wendy Noboa
We do actually have you guys scheduled to meet next week on Friday, outside of your normal tempo, on the 19th.

Steven Lane
Ah, good reminder. That is the ECR discussion to boot.

Wendy Noboa
Sorry to cancel your holiday.

Steven Eichner
No, thank you.

Wendy Noboa
I just wanted to make awareness on that, and we will be sure to clarify that in any communications that go out for this week, just in case somebody missed it.

Steven Lane
Well, this has been a good week for mea culpas on the part of this cochair, so, thanks, Wendy, for keeping us straight. All right, we will hopefully see you all at HITAC, and we have our meeting next week.

Steven Eichner
We will see you next week. Take care.

Steven Lane
Bye-bye.

Hans Buitendijk
Thank you.

Adjourn (01:29:00)