

## **Transcript**

# HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

### **GROUP 1: INFORMATION BLOCKING**

May 23, 2023 10:30 AM - 12 PM ET

**VIRTUAL** 



## **Speakers**

Name	Organization	Role
Steven Lane	Health Gorilla	Co-Chair
Steven Eichner	Texas Department of State	Co-Chair
	Health Services	
Hans Buitendijk	Oracle Health	Member
Hannah Galvin	Cambridge Health Alliance	Member
Adi V. Gundlapalli	Centers for Disease Control and	Member
	Prevention	
Deven McGraw	Invitae Corporation	Member
Eliel Oliveira	Dell Medical School, University of	Member
	Texas at Austin	
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
Michael Berry	Office of the National Coordinator	Designated Federal Officer
	for Health Information Technology	
Daniel Healy	Office of the National Coordinator	ONC Program Lead
	for Health Information Technology	
Rachel Nelson	Office of the National Coordinator	Presenter
	for Health Information Technology	
Cassie Weaver	Office of the National Coordinator	Presenter
	for Health Information Technology	
Mohammad Jafari	Individual	Presenter
Michael Lipinski	Office of the National Coordinator	Discussant
	for Health Information Technology	

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

#### **Michael Berry**

Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task Force. I am Michael Berry with ONC, and I would like to thank you for joining us today. We have a number of ONC subject matter experts joining us today, and we have an external subject matter expert. Mohammad Jafari is joining us, and thank you, everyone, for participating today. All of our Task Force meetings are open to the public and your feedback is welcomed, which can be typed in the Zoom chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled at the end of our meeting this morning. I would like to begin rollcall of our Task Force members, so when I call your name, please indicate that you are here, and I will start with our cochairs. Steven Lane?

#### Steven Lane

Good morning. Welcome, everyone.

#### **Michael Berry**

Steve Eichner?

#### Steven Eichner

Good morning.

#### **Michael Berry**

Hans Buitendijk, Hannah Galvin, and Eliel Oliveira are all unable to join us today, but hopefully they will be back next time. Sanjeev Tandon is joining us today in place of Adi. I do not see him on yet, but he should be joining us shortly. Deven McGraw?

#### **Deven McGraw**

Good morning, everybody.

#### **Michael Berry**

Fil Southerland?

#### Fillipe Southerland

Good morning, everyone.

#### **Michael Berry**

Sheryl Turney?

#### **Sheryl Turney**

Good morning, everyone.

#### **Michael Berry**

Good morning, everyone, as well. Now, please join me in welcoming Steven Lane and Steve Eichner for their opening remarks.

#### HTI-1 Proposed Rule Task Force Charge (00:01:28)

#### **Steven Lane**

Thank you, everyone, for joining us this morning. We have come a long way together in this Workgroup No. 1 for our HTI-1 Task Force. We are very excited to be covering the new material that we will be touching on today. Let's review the agenda here briefly. We are going to review our charge and talk about specifically the new condition manner exception exhausted, and then speak about a request for information included in the NPRM regarding health IT capabilities for data segmentation and user patient access, an area that is near and dear to my heart, and I know many of you as well. We will then have public comment 10 minutes before the noon hour, Eastern Time, and we really do want to encourage members of the public to take advantage of the public comment period. In addition, you are welcome to utilize the webinar chat as we proceed through the meeting and enter ideas there. We may or may not have time to take them up during the course of the meeting. So, with that, Ike, do you want to add to our welcome at all?

#### Steven Eichner

Just again reemphasizing Steven's welcome to Task Force members and members of the public. I will be keeping my eyes on chat so that Steven can focus on some other things, and I will bring things to his attention as we need to.

#### Steven Lane

Excellent. Well, let's go ahead, then, in the slides, and just review the charge, and remind ourselves where we are today. So, this is the overall charge of the HTI-1 Task Force. I am not going to reiterate it, but I will point out that today, we are focusing on enhancing information sharing with regard to the information-blocking regulations and looking at some advances and refinements related to that. Next slide. These are the other charges for the Task Force writ large. I also will remind everyone who is attending that these materials are available and posted on the public internet, and Ike or Mike, if you have a chance, just grab that link to today's meeting and drop it in the chat for the benefit of our attendees. Next slide.

So, our group, Group 1, was asked to focus on a number of items. These are they, and we are now down at the last two of this list, having been through all of the preceding nonhighlighted bullet items today. We are focusing on the manner exception exhausted, again, and the request for information around data segmentation. Next slide. So, we are now going to have Cassie, Dan, and Rachel walk us through these two items. We have an invited subject matter expert who is also going to provide some input, especially on the data segmentation question, and then we will go on and discuss all of this, but again, feel free to put items into the chat. Ike will be monitoring that, and we may break into the presentation with questions, if that seems appropriate, or we may hold them to the discussion at the end. So, with that, Cassie, Dan, Rachel, do you want to walk us through the proposed changes in the rule?

### IB Infeasibility Exception Proposal: New Condition: Manner Exception Exhausted (00:05:07)

#### **Daniel Healy**

Absolutely. Thank you, Steven, and thank you, everybody, for joining us this morning. Next slide, please. I know we have a full agenda today, so I will jump right into things. Before we get started with the content of the presentation, I am going to give a little bit of a background and a couple disclaimers that some of you may have heard before if you have joined us previously, and then I will turn to my colleague Cassie to talk

about our first discussion item today, and then come back when we talk about the segmentation request for information, but first, a brief disclaimer. The materials contained in this document are based on the proposals in the Health Data Technology and Interoperability Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule.

While every effort has been made to ensure the accuracy of the restatement of those proposals, this document is not a legal document, and the official proposals are contained in the proposed rule. I would also note that other federal, state, and local laws may also apply. I would also note that ONC must protect the rulemaking process and comply with the Administrative Procedure Act, and that during the rulemaking process, ONC can only present the information that is in the proposed rule as it is contained in the rule, and ONC cannot interpret that information, clarify, or provide further guidance. Lastly, this communication is produced and disseminated at U.S. taxpayer expense. Next slide, please.

So, as I mentioned, I will start off with a brief overview and some background of the topics that we will be discussing today, and then we will jump into the content. So, as Steven mentioned, we have two topics on the agenda. The first is a new proposal relating to the information-blocking and infeasibility exception. It is a new condition as part of that exception, the manner exception exhausted proposal. And then, the second topic for today's discussion is a request for information on health IT capabilities for data segmentation and user or patient access. Next slide, please. Again, we will start out with some background. Next slide. Here, I will turn it to my colleague Cassie Weaver to start the discussion on the first part of what we will cover today, the manner exception exhausted proposal.

#### **Cassie Weaver**

Thanks, Dan. Good morning, everyone. I am sure you are tired of seeing my face at this point, but we really are nearing the finish line here and looking forward to the feedback we are going to get from you all. So, I remember last week, we talked about some other proposed updates to the infeasibility exception, and today, I will finish that topic for us with one final new proposed condition, the manner exception exhausted condition. So, this proposed condition would apply where an actor is unable to fulfill a request for access, exchange, or use of EHI after having exhausted the content and manner exception in 171.301, which we have proposed in this proposed rule to rename the manner exception, including offering all alternative manners in accordance with 171.301B so long as the actor does not currently provide to a substantial number of individuals or entities similarly situated to the requester, the same requested access, exchange, or use of the EHI. Next slide, please.

I am going to just really quickly review the content manner exception. So, what does it mean to exhaust it? So, first of all, it means the actor and requester either could not reach agreeable terms on fulfilling the request in any manner requested, or that it was technically infeasible for the actor to provide the access, exchange, or use in any manner requested. As a reminder, when the actor does provide the requested access, exchange, or use in any manner requested, and they are not restricted by the fees and licensing exceptions and can come to any agreement with the requester, though other laws may restrict charging of certain fees and things like that.

If they are unable to reach agreement or cannot technically do it, then the actor moves to the alternative manners, in which case those restrictions in the fees and licensing exceptions do apply, and the actor must fulfill the request in an alternative manner agreed upon with the requester, and those alternative manners

prioritize the interoperable manners based on HHS adopted and available open-source standards, beginning with certified health IT, and then other open-source standards published by the federal government or as standards set in organization like NIST, and finally, in a machine-readable format, along with the means to access.

So, why are we proposing to add this condition to the exception? For one thing, actors have expressed concerns that a requester could simply refuse to accept any of the alternative manners because the language in that exception does say that the requester has to agree to the alternative manner. And so, then, if the requester has refused to accept any alternative manners and fulfilling the request would require substantial technical or financial resources, or could result in an outcome that does not further interoperability.

And so, for actors with significant financial or technical resources, that uncertainty could result in their investing in nonstandard, nonscalable solutions that they do not support, even after they have offered to provide it in the same manner that they generally make available to their customers or affiliates, or through alternative open-source standards. So, this proposed new condition would help to reasonably allocate resources and relieve some of that uncertainty and confusion. Also, because we do not have authority to give advisory opinions, if an actor does work through those alternative manners and it is unable to reach an agreement with the requester, we can advise any actor, based on those facts, whether it would be acceptable to use, for example, feasible under the circumstances or another exception, and so, this proposed condition would also help to fill that gap. Next slide, please.

So, just a review of the proposed new layout of the feasibility exception. First is the uncontrollable events condition, which we updated just to clarify, but did not make substantive changes to, and we talked about that last week. And then, there is the segmentation, which we did not propose to change, and then we proposed to renumber the conditions so that feasible under the circumstances will still be the last condition in the feasibility exception, except now it will be No. 5, and then, we are proposing to add No. 3, third parties seeking modification/use, which we discussed last week, and No. 4, manner exception exhausted, which is what we are talking about today. So, just to reorient ourselves, that is where we are. Next slide, please.

So, in order to satisfy this new proposed condition, an actor would be considered unable to fulfill a request for access, exchange, or use when three factors are true. First, the actor could not reach agreement with the requester in accordance with 171.301A, the manner requested condition, which we have proposed to call it in this rule, otherwise it would be 171.30A... It is not A now because that is the manner...anyway, the manner requested condition, or it was technically unable to fulfill the request for EHI in the manner requested. The second of the three-part test is that the actor offered all alternative manners in accordance with 171.301B, alternative manner, which, again, is as we have proposed it in this proposed rule. The citation might change, but it is not substantively different from the electronic health information requested, but could not reach agreement with the requester, and third, the actor does not provide the same access, exchange, or use of the requested EHI for the substantial number of individuals or entities that are similarly situated to the requester.

Actually, let me step back to the second one. We did put in an alternative proposal for No. 2 here, which is rather than say the actor offered all alternative manners, we proposed to say "as few as two alternative manners," which would mean that an actor could offer it in two of those three alternative manners and would

not have to offer it in all three. So, we are looking for comment on that, which one would make more sense. So, this third one...I already really went through the first two, just talking about the content and manner exception. The third proposed factor is really allowing for a reasonable limit on the use of the condition without having to take into consideration the financial and technical resources available to the actor. This factor as a whole serves a similar function to the 171.204A5, which is currently A3, feasible under the circumstances.

There are those six-factor tests there, and in general, this third factor covers a lot of those same sorts of things that the actor needs to consider. Here, the practice is nondiscriminatory, whether the actor currently provides the same manner, and currently provides the same access, exchange, or use of EHI to its companies or customers, suppliers, partners, other persons with whom it has a business relationship. This provides a basic assurance that the actors would not be able to misuse this new proposed manner exception exhausted condition to avoid supplying some particular requesters with manners of access, exchange, or use of the requested EHI that would be more generally characterized as generally available already than as new, unique, or unusual.

We structured the factor this way to align with the concept of whether the manner requested, including any involved interoperability elements, is in a stage of development or overall lifecycle that would roughly approximate the general availability phase of the software release lifecycle, or something analogous for nonsoftware interoperability elements. "Same access" simply means same manner. "Substantial number" is there because what may be a trivial number to a large health IT developer of certified health IT might be an important or consequential/substantial number for a small HIN or HIE. We did propose in the alternative that we would seek comment on whether we should instead construct the factor with a simple fixed threshold of more than one or more than another specific number between 1 and 10, as opposed to "substantial."

We recognize the fixed threshold would offer more simplicity to actors and potential requesters while still assuring that an actor's practice would not fail to meet this factor on the basis of a single instance of a particular access, exchange, or use manner. "Similarly situated" will be familiar to our information-blocking actors, as we also used it in the fees and licensing exceptions. It would serve here as it does there, to indicate that different specific individuals or entities within a class of such individuals or entities who are similarly situated to one another should be treated in a consistent and nondiscriminatory manner. Next slide, please.

So, let's do the proposed revisions. I am just going to leave this up while I talk to this slide a little bit more and offer some examples from the preamble that I think really will help illustrate this for everyone. So, to illustrate the situation, we see and believe this new condition is necessary to remediate, for example, an actor that developers or offers certified health IT, may be uncertain as to whether an exception covers its practice of denying a requester's demand for access, exchange, or use in a particular manner that relies on unique specifications instead of interoperable standards because the actor has capabilities and resources that it could potentially divert to the requester's preferred manners. In such cases, the actor may also lose the opportunity to pursue other innovative endeavors or fulfill other customer requests. Those opportunity costs would arise, in other words.

Healthcare provider and HIN/HIE actors with substantial technical or other resources would also currently face demands from requesters who are interested only in their own preferred mechanisms, however unique and nonscalable. We are concerned that actors currently appear to experience such uncertainty even if the actor, to continue the illustration, is offering the requester interoperable manners of access, exchange, or use based on open consensus-based industry standards, and diverting resources to build the new manner would mean the actor would need to delay for months or more deployment of innovations that will reduce burden on clinicians using the software.

In these cases, we currently cannot advise these actors whether or not the requester's demand is feasible in the actor's unique circumstances, again, because we requested and had not received advisory opinion authority from Congress. Therefore, this new proposed condition, we believe, is necessary to let actors reasonably allocate resources towards interoperable standards-based manners rather than allowing requesters who, for whatever reason, do not build their products for compatibility with open-consensus standards or other industry standards to attempt to force use of nonstandard, nonscalable solutions by simply refusing to accept access in any other manner. So, I think if there are no questions right now, we can move on, but this would be the end of the manner exception exhausted portion of the presentation. Deven, I see you have your hand up. Go ahead.

#### **Deven McGraw**

Can you hear me okay?

#### **Cassie Weaver**

I can, yes.

#### **Deven McGraw**

Okay, great. So, I am trying to figure out, particularly around the alternative, where you do not necessarily have to exhaust all three options, but might be able to potentially exhaust two. In the context of health information exchanges or other types of actors that do not adopt certified technology, you are already arguably down to two, so if you get to pick two, does that mean that the third option, which is sort of the catchall negotiation option, is off the table? And then you might be held over a barrel by the actor, who says it is this particular way or now way.

I have a few concerns about that. I very much get that you do not want the requesters to put the actors in the awkward and untenable position of having to do bespoke solutions for everyone that asks in order to adopt mechanisms for exchange, but particularly in the case of HIEs, who customarily have served a very narrow class of requesters for very narrow purposes... I am trying to think through what you guys were thinking in terms of dropping down to fewer than all three alternative manners when you already have some classes of actors for whom one of those alternative manners is off the table.

#### **Cassie Weaver**

Mike, I see you are on video, so I will let you answer.

#### Michael Lipinski

Roger that. I think this is a lot to process in terms of what exists today. We did this in the info-blocking presentation last week, and I understand not everybody can make every presentation that we give, but we

thought it was important to start there. So, let's start with the content and manner as it exists today, that exception. Putting aside the content, as we all know now that it is all EHI, the first thing we talked about in that discussion in the preamble, and for that exception, is that we wanted parties to come together and reach agreement on how the EHI was access, exchange, or used, so the whole first part of it is try to reach agreeable terms, and if you do, that is reasonable/necessary and you are out of information-blocking altogether, but what we said is if you cannot reach agreement, there is this alternative manner process. But actually, the most key piece on the alternative manner process as it exists today that I do not want folks to lose sight on is it has to be agreed to by the requester.

So, if you look at every one of those provisions, and it has a priority of order, and we talked in the rule about how we are trying to promote interoperability, also the use of certified health IT, and we are trying to improve certified health IT so it can make more EHI accessible to those providers and developers that use it, we can get closer to interoperability and help support their ability to comply with information blocking. So, we start there, and then we have standards, and then, the last case argument in the rule was that we wanted to try to get the EHI out so that if it is in a machine-readable format, that is also an okay approach, but remember, each one of those has to be agreed to by the requester, so that does not mean that the actor can just say, "I am going to offer you this, this, and this, and I am done." They do not get the benefit of that exception unless it is agreed to by the requester, and then the fees and licenses apply, the exceptions in all those cases, right?

So, if they still do not reach agreement after all that, then it kicks over into the feasibility exception, and if you remember, under the circumstances as exist today, one of the six factors, and there are two factors you cannot include, which are competition and whether it changed how much you can charge, one of those factors is why the EHI was not provided through the content and manner. So, that is just one consideration of the whole evaluation of the various factors under that situation. So, I am going to stop there, just in that little summary of how it works today and to make sure everybody understood that piece before we talk a little bit more about what is being proposed here because the biggest thing about what is being proposed here is that there is no longer "I agree" from the requester, to take it that way. It is going to be like "this way, or that's it," as long as they meet every one of the proposed conditions.

#### **Deven McGraw**

That is helpful, Michael, thank you very much. I think that when we get into discussion phase, we may consider a potential comment around whether, particularly if you think about actors for which one of those alternative manners just gets completely off the table because they do not use certified health IT, whether that puts them off the hook too much, but that is for comment.

#### Michael Lipinski

Well, that is the purpose of this, to tease this out and get the best comments so we can consider what is the most appropriate final policy based on public comment. So, most importantly, does everyone understand it? I do not want to color anybody's opinion on it. I do want to talk about potential consequences, unintended or otherwise, to what is being proposed because I think that is most important, that everybody here understands, and then you express your views on whether you agree, disagree, or what can be changed.

The reason why it is set up as it is today... What if I want it this particular way? You are offering it to certain people, it is a proprietary way, maybe, but let's say they have ill intent, but we do not know that yet, but just as a hypothetical fact pattern, they are like, "I am not going to give it to you that way because you will create competition for me, and I am actually providing that service to my providers, and then you may siphon off some of my business." So, you say no, and you offer it all these other ways, and you are like, "As the requester, I am not going to agree to those because I can access it that way. I know I can access it that way because I do it for a different use case already. I just want to expand the use cases I offer to the provider, and you are not letting me do that because you will not give me that access, so I say no to all that." Like I said, it kicks you over into the "under the circumstances," and that is the key one because remember, one of the factors is are they providing it to their business partners, so that is one of the current factors now in "under the circumstances," and also their resources, their technical resources, and the cost to them.

So then, it looks at it to see if there is any pretax. Why are they saying no there? Is it for one of the forbidden reasons that would create competition? So, that is how that all gets evaluated. On the flip side, you heard from Cassie today that that creates a lot of uncertainty because if the actor is acting in good faith, I may be forced to say no to them, but it is not a competition thing for me, but I am not sure how this would play out in an evaluation by OIG, so do I have to completely change my business model and take away all my resources, because I have a lot of resources, and I have to take them away from doing other innovative things to meet all these particular one-off interface requests or connections, so that is what we have heard feedback on and what we are trying to address with this proposal.

#### **Deven McGraw**

That makes sense. Thanks, Michael.

#### Michael Lipinski

No problem.

#### Steven Lane

lke?

#### Steven Eichner

Thank you. Mike, you made an excellent point at the last one. That was what I was going to get to, not so much with a question, but with a comment. It feels as though we are developing a really complex framework here that is going to be difficult for smaller healthcare providers or smaller technology providers to understand or meet, and we are running some risks of spinning off a whole series of one-off solutions without necessarily getting a collection of those interfaces for purposes behind them, which limits the ability for other actors to reuse or request a duplicate of somebody else's access, and then the potential for the data provider to not recognize the similarity between two different providers' special requests, really creating a complex framework in that area, and I am just a little concerned that we are creating a big rabbit warren here.

#### Michael Lipinski

Just a couple points back on that, and also, I am not sure if I even answered Deven's one point, but I think I did. I can confirm she was right. Under the alternative, if you are an HIE, you probably do not have certified

HIT, so you are already at two ways. I think our biggest concern there, as Cassie mentioned too, is if you limit it to two where folks that do or could have certified health IT, it could actually work as a disincentive to not adopt certified health IT and/or to donate certified health IT, if you limited to if I could work around having to even do the certified health IT one when I could possibly adopt it or purchase it. So, that is more the rationale that was going on there.

But to your point, Ike, there are a couple things. This is trying to simplify it, even though it may not seem that way, in that in the example I gave, it is trying to get to that. If you are offering it to a bunch of people already and it is not a one-off and you made it custom for someone, and that is why we are asking is it the same manner you offer to a substantial number of people, because if you are, then you are going to have to offer to them or you are not getting this exception, and you are likely also not meeting the current under the circumstances exception. The other piece to this all is obviously, the actors that are covered here are so diverse, and I think that is the other piece. So, versus creating exceptions for somebody who has certified health IT, exceptions for different technologies was not the way we approached developing the exceptions, we approached them in a way, as I think you all know, to cover all the actors, so that was the other situation.

#### Steven Eichner

Just to glom onto myself, I guess the other difficulty is looking at what constitutes a potentially different request in terms of saying "I want one additional field."

#### Michael Lipinski

Right, that gets to "is it the same?", and then there are a few things, like if they are similarly situated. Those are two obviously interpreted words where we try to clarify our intent in the rule, but that may not even be sufficient from your perspective, so that is definitely something we are hoping to hear.

#### Steven Eichner

We can put it in comment. It is really looking at clarity and predictability, and really thinking about smaller providers that do not have a whole host of resources to even contemplate whether an exception may or may not apply, let alone how to actually fulfill a data request.

#### Steven Lane

Okay, Ike. Your hand is still up. Have you completed your input here?

#### **Steven Eichner**

Yes, sorry.

#### **Steven Lane**

Great, no problem. All right, I invite workgroup members to enter your suggestions in the spreadsheet. Thank you, Cassie and Daniel, for going through that. I personally think this is fairly noncontroversial and probably helpful, moving us slightly in a better direction. I thank you guys for that, and I would really like to move on to our second topic.

#### **Cassie Weaver**

Great, thanks. I am going to hand it back to Dan at this point.

### Request for Information: Health IT Capabilities for Data Segmentation and User/Patient Access (00:34:27)

#### **Daniel Healy**

Great. Thanks, Cassie, and I will speak a little bit about today's second topic, our request for information. Next slide, please. So, I will start out with some background, and I just would also note that the text we have on the slides today is pulled from the RFI, but it does not represent the totality of the RFI or all the examples that we have therein of different situations that we will talk about, so I would always encourage everybody to read the RFI in full, but just to start out with some background, we noted that ONC believes that data segmentation is integral for enabling access, exchange, and use of EHI, and that while there are initiatives like security tagging capabilities and other initiatives that are present and represent an initial step toward further enabling appropriate access, exchange, and use within EHI, in accordance with applicable law and patients' preferences, there are additional challenges to data segmentation that remain, and I will talk about a few of those in some of the examples that we give in the RFI here.

But broadly, we have received public feedback indicating that there is a significant amount of variability in health IT products' capabilities to segment data, including the ability to enable differing levels of access to data based on the user and the purpose. There may be many situations in which segmentation of data may be required or requested, including use cases where a special handling or other restrictions on access, exchange, or use of particular EHI or portions of EHI is either required by law or consistent with a patient's express preference regarding their own or others' access to their EHI. Next slide, please.

And so, here, we have pulled out from the RFI the four bullets on various areas that we note in which we are seeking comments, and as you can see here, in the RFI, when we talk about segmentation, we are speaking relatively broadly. I just wanted to note that because I know there are sometimes various technical meanings for terms like segmentation or other terms, and just wanted to note that as we can see here in the RFI, we are seeking comment across a variety of areas, and we have those four areas laid out here, so the first is that seeking comment on steps we might consider taking to improve availability and accessibility of solutions that support healthcare providers and other information-blocking actors' efforts to honor patients' express preferences regarding their EHI.

We are also seeking comment on the capabilities of health IT products to segment data and support providers and other actors in sharing information consistent, again, with patient preferences and applicable laws that are relating to access, exchange, and use and disclosure of EHI. We are also seeking comment on experiences with the availability and utility of certified health IT products' capabilities to segment data in some of the various use cases that we will mention today, as well as others that are included in the proposed rule. And then, lastly, we are seeking comment on how greater consistency in provider documentation practices could enhance the feasibility of some of the technical segmentation solutions that exist, as well as on barriers to those technical feasibility solutions that are presented by local, state, and federal regulations that may apply to various situations.

So, that is an overview of the areas in which we are seeking comment on this particular RFI, and for the next couple slides, I will just talk briefly about some of the examples that we give in the RFI relating to some of the things we have heard and some of the specific examples that are illustrative of some of the things we are seeking comment on. Next slide, please. So, as I mentioned, through public forums and other

correspondence with ONC, some interested parties in the healthcare community have conveyed that their certified health IT lacks capabilities to differentiate the timing of release of certain EHI, based on patients' individual preferences.

Some interested parties have also indicated that their certified health IT may have little or no ability to restrict a patient's personal representative's access to only some of the patient's EHI, looking at that EHI electronically through a portal or API, or to hold back only some pieces of the patient's EHI in response to the patient's request, while, at the same time, honoring the patient's preference for the rest of their EHI to be shared with another of their healthcare providers. There are a couple examples, one of which is a patient's expressing a preference for delay of the availability of certain information to them, such as through the patient portal or, for another example, an actor choosing to honor a patient's request that that actor withhold certain information from particular access, exchange, or use consistent with the individual's right to request restrictions under the HIPAA privacy rule or the information-blocking privacy exception as well. Next slide, please.

So, we seek comment and we seek to support actors' efforts to honor patients express preferences that the law allows, as well as actors' needs to comply with all applicable tribal, state, or federal laws that may restrict or place specific preconditions on the permissibility of information access and sharing in certain situations, and below, we have some other examples that we note in the RFI where some of these considerations may come into play. First, we note that there could be a scenario where a healthcare provider needs to prove or validate consent of the patient regarding EHI that is subject to specific types of restrictions related to confidentiality of substant use disorder, patient records, or other federal, state, or tribal law with specific consent requirements. Prior to sharing that information with another healthcare provider who is treating the same patient for other clinical concerns.

A second example we note is that a healthcare provider needs to identify and segment from particular access, exchange, or use data that is subject to varying state laws requiring special handling or access restrictions in such situations, of which we note some examples of that type of data here, behavioral health information, certain diagnoses or genetic testing information, for example. And then, thirdly, an example where an actor's practice meets the conditions of the preventing harm exception for withholding EHI from access, exchange, or use, for example, such as access by the patient or a patient's personal representative, where some, but not all, of the EHI an actor has for a particular patient would be involved in that situation where the preventing harm exception would apply. So, those are some examples we have. Steven, I see your hand up, so I will pause there.

#### **Steven Lane**

Thanks, Dan. I did not mean to interrupt you, I just wanted to get in line to make some general observations once you have presented. My bad.

#### **Daniel Healy**

No worries. I think we have one more slide on this, if we could go to the next slide. So, we wanted to just include a few more examples here that we note in the RFI of things that we have heard from at least some healthcare providers and their patients as well around challenges or technical limitations that they have encountered as they work to provide patients or their representatives with electronic access to the information that they want, when they want it, and some of the examples of those challenges include a

certified EHR, and I think we mentioned this before, currently in use that, as implemented, is only capable of offering all-or-nothing release of EHI test results for patients immediately to the patient portal without offering the ordering clinicians or other healthcare professionals the ability to flag or withhold individual test results for an individual patient from the patient portal.

Another example may be that a current certified EHR is designed and implemented such that any test result the patient and healthcare provider want to have available to the patient in the portal must be manually pushed to the portal, result by result, by the ordering clinician. And then, a third example, we note that existing segmentation tools or modalities, for example, some segmentation capabilities that are applied by broad data class rather than the level of an individual data point may not provide enough flexibility to address more complex use cases, such as honoring a patient's request to have immediate access to most of their EHI, but to have electronic access to some EHI, such as some test results that may be complicated to interpret or indicate the potential of a certain diagnosis, released only after those results have been explained to the patient in real time by a healthcare professional, if that is the patient's express preference.

So, I think this was all the slides that we had on this, and wanted to go through some of these examples, and then, that being said, broadly, I would just also point back to the previous slide, I think it was maybe 21, where we discussed the various areas in which we are seeking comment more broadly in this RFI, knowing that there are a lot of specific examples and scenarios as well, but wanted to just provide those as an illustrative sample of what we have in there. So, I will pause here. I know we are going to have another guest speaker as well on this topic, so I will pause here for comments or questions before we turn to the next portion of our discussion today.

#### **Steven Lane**

Thank you so much, Dan, and I apologize for the premature hand raise earlier. I like using the hands as a queue, but that is just me. So, as a clinician, and someone who really believes in the importance of privacy, and has had the pleasure of working in a healthcare organization that really took all of the information-blocking implementation very seriously, and was working with a vendor that was very collaborative and developed a lot of tools, I can tell you that even in that situation, this stuff is really hard. There is no question that providers and other actors want to be able to respect patient preferences and to comport with applicable law, both federal and state, and of course, the state laws vary tremendously in what they can require.

So, I think it is very exciting that this is in the NPRM. I look forward to seeing some proposed rules about this, and upgrades to the health IT certification requirements. I think this is a great opportunity to really clarify what is going to be needed, and I will just observe that this ability for being able to respect patient-or provider-specified delays, being able to respect delays in workflows required by state law that may require certain actions to occur before information can be released, either to a portal or via API, is going to be really important. One thing that has really frustrated me is when I go through all the trouble to document and implement an information-blocking exception, say, for harm or for privacy, then that has no impact on how that data is then shared out to other entities that have a valid right to receive it, and that they do not receive with it the metadata that says that this was blocked for harm, for example, or for patient preference and privacy, so then, when it is received at the requesting organization, those constraints are not traveling with it.

So, I think this is great, I think we really need to get a lot of detail in here, I am sure you are going to be getting a lot of public comment on this, but I do look forward to our workgroup collecting some useful feedback as well. I do want to pass it on to our invited subject matter expert, Mohammad Jafari. I can think of no one I know who has given more thought to this than Mohammad, who also really understands the existing technical tools that are available to support data segmentation, both their past, present, and future, so, not seeing any other hands or comments, Mohammad tells me that this presentation will take about 10 minutes, so let's pass it on to him, if that is okay with you, Dan.

#### **Daniel Healy**

Yes, and apologies if I... I think we may have a couple other slides just to mention.

#### Steven Lane

That is fine. Go ahead and close them out, then.

#### **Daniel Healy**

If we could go back to the previous slide there... So, we just wanted to mention this proposal, and I think I will turn it over to my colleague Rachel Nelson here just to talk a little bit about this proposal because we noted it was of interest to the workgroup, so I will turn it over to Rachel to talk about this portion of the presentation here.

#### **Rachel Nelson**

In the interests of time, I will talk fast. This is more of a preview of coming attractions on a related topic, as Dan just noted. In another section of the HTI-1 proposed rule, Section 3C10, if you received the slides for today, that link should actually take you there. There is a proposed certification criterion, a primary proposal, and several proposals in the alternative, and we are really looking for comment from folks on that proposal and the alternative proposals. So, tomorrow, the proposed criterion of supporting technical capability for honoring a patient's right to request a restriction on certain uses and disclosures of their PHI will be discussed in Task Force Workgroup 2, which is open to the public, but just recognizing that it is outside the charge of this particular workgroup, we wanted to remind everybody that is here, including members of the public, that a deeper dive into that proposed criterion will occur tomorrow at the publicly open Task Force Workgroup 2 meeting. Next slide.

There are just two slides on how to submit a comment. I think a lot of folks here already know this, but you are welcome to snag a copy of these slides from today's materials or from last week's information-blocking public webinar slides, which are available right now. If you know folks who are interested in commenting, maybe they are patients or patient advocates, and they want to comment, and they are not sure how, feel free to share the slides, and with that, unless there are questions or comments about how to submit a public comment into the rulemaking process separate from the HITAC process, I am going to hand it over to guest SME Mohammad Jafari.

#### Steven Lane

Sorry, Rachel, before we pass it to Mohammad, can you briefly clarify something? Tomorrow, we are going through an actual proposed new criteria and looking at the options there. I know that the ONC had originally intended that we would do that before we had this conversation, so, to clarify as much as possible, what is today's RFI asking for is separate from the commentary on the new proposal?

#### **Rachel Nelson**

In very simple terms, recognizing we made that proposal for new certification criterion specifically focused on supporting patients' preferences related to their right to request restriction on uses and disclosures of their PHI under the HIPAA privacy rule, and it cross-references a very specific HIPAA privacy rule section, 45 CFR 164.522. What the RFI is asking about, which is part of why there are so many different example use cases that we list in the full RFI, is thinking about other use cases. You might need to adjust timing; you might have folks not wanting to see things quickly, but they want to see them. If you look at what the proposed criterion would require in terms of functionality that the certified module would have to have, the RFI says, having proposed that, what other use cases to look at, what other functionalities would be useful, and ask for information on what else might help you do the kinds of things that I think have even been talked about today, such as filtering what a patient sees according to the patient's own preferences as opposed to letting them see what other people said.

#### **Steven Lane**

Yes, so this is a "What else do we need?", and it is initially what we are going to talk about tomorrow, which is a little awkward, I acknowledge, so let's jump in, and again, Mohammad is going to be with us tomorrow as well, so we will start the conversation a little bit in reverse order today, and I am sure by the end of the week, we will be good. Let's bring up Mohammad's slides.

#### **Mohammad Jafari**

Thank you, and thanks, Steven, for inviting me to this meeting. I appreciate the opportunity and I thank you for your kind words. I am going to go through some very broad comments quickly, and hopefully will have some time to discuss them. My apologies if I am not very familiar with the operating details of the meeting here. I just prepared something that was very broad, but some of the details may be more of interest here, so we can hopefully have that conversation later or tomorrow. So, the first thing I wanted to discuss and bring up is the coupling between patient preferences and patient consent and data segmentation. If there is any way you want to prescribe anything or require how these two concepts are very related and they are tightly coupled, patient preferences basically are where the granular policy rules are reported, and data segmentation creates those segments and the granular breaking-down of the data, and I think the discussion of these two assessed requirements is being kind of... I think someone needs to go on mute.

The second point I want to raise is about the importance of interoperability and standard tags. Even though the mechanisms behind segmentation and labeling could be proprietary, it is important for the outcome and how the labels are reported to be interoperable and standard. Otherwise, we will lose interoperability between the policy expression and the policy enforcement. For example, a consent that is captured or reported by one organization may not be able to be enforced by another organization if that disconnect exists and the labels are not interoperable.

The third point I wanted to raise is that because in the reality of the system, data often flows in different forms. We need to be mindful of that in requirements for segmentation to make sure there is no back door or loophole. If data is segmented when it is released in FHIR, but it is not segmented when it is released with V.2 by another provider, then that could create a loophole for the enforcement of the policies that we have in mind.

The fourth point is about incremental implementation. This is both about the requirements and the burden of the requirements on implementers, but also about certifying products and how people can make decisions about adopting them. As Steven mentioned earlier, this stuff can be complicated and hard, and it is important for us to be mindful of the fact that if we provide a stepwise incremental level of maturity that I will suggest in a bit, I think that could help planning, and that could also help having a vision about where things will go as they mature in the future.

Lastly, I want to mention the link between sensitivity classes and clinical concepts. I think sensitivity classes are very much dependent on the clinical concepts that are the content of the data elements that we are segmenting, and I think lack of consistency or a consistent understanding of what constitutes each sensitivity class and what would cause data to fall within a sensitivity class could lead to another loophole. For example, if one provider considers a certain type of mental health data and another provider does not, then when data translates between these two systems, there could be an opportunity for the data that was considered sensitive in one system to be linked in another system. So, there needs to be some level of guidance. Next slide, please.

So, based on that, I wanted to have some very broad recommendations. I think a cohesive view of granular patient preferences and data segmentation as components in one system is something that I think would be very helpful in working in terms of articulating the requirements and the criteria. I think while there is the standard terminology that is **[inaudible] [01:02:46]** at HL7 right now is very broad, and there are codes that are outdated, there are codes that could be replaced with newer codes. It is important to have some standard code set, and that could be a subset of the existing set of codes that could be identified.

This is something that could also tie into the stepwise incremental implementation or requirement in the sense that we can choose, for one level of maturity, a smaller set of tags, and then, for a more advanced level of maturity, a more expansive set of tags. I think confidential tags that are stricter than normal are essential, the sensitivity tags that correspond most burdeningly to the existing regulations, and also general expectations of privacy by the patients, and also the common obligations or frames that would address most of the current common use cases.

The third point I want to make is tying back to the fact that the sensitivity classes are very much tied to clinical concepts, and having some sort of a guidance on that in order to guarantee a level of consistency and understanding of these sensitivity classes across different providers is also key in consistent enforcement of policies. Next slide, please. With respect to the diversity of methods of communicating data, I think the framework for data segmentation could be cross-paradigm in a way that it would span different protocols and different forms of data sharing. The guidance for requiring that in one of these methods should be replicated on the others in order to make sure that the data is consistently segmented across different protocols.

Finally, I think I spoke already about the maturity model and its importance both in planning the requirements, the rolling out of the implementation, and also a guidance on adoption of technology by vendors who create products with these capabilities. So, with that, I will stop, and hopefully I did not rush through this too fast. Thank you.

#### **Steven Lane**

Thank you so much, Mohammad. I am curious if you are planning on covering the same material or different material tomorrow.

#### Mohammad Jafari

To be honest, I was not quite clear what the difference would be between today and tomorrow, but I am happy to adapt and take your advice.

#### **Steven Lane**

Okay, maybe we can come back to that at the end, or you and I can follow up separately. Deven made a really good point in the chat that the consent policy requirements, in many situations, do not need to follow the data when it goes from one site to another, and I appreciate that legal point. It is very important. As a clinician and a privacy advocate, my feeling is that when the patient, a provider, or a state or jurisdiction goes to the trouble to identify particular requirements within a setting, it makes sense to document that and send that along with the data, even if those requirements do not need to be followed at the recipient because as a recipient, it would seem advantageous to at least be able to "right-click" on something or have it highlighted in such a way as to identify the fact that it was restricted or identified for special treatment at the source, even if you do not have a legal requirement to adhere to that. That is my opinion. I am curious, Deven or others, whether you feel differently about that or if that is something that we should be encouraging. Deven, thank you for raising your hand.

#### **Deven McGraw**

I do not necessarily feel differently unless the tags, through some technical functionality, have additional triggers that restrict further disclosure or things like that in some sort of automated fashion versus just providing metadata. In multiple discussions we have had on this topic, which frankly go back decades, there was a desire to create some sort of automated technical functionality for data that was subject to restriction, either through a patient preference that was agreed upon to be honored or had to be honored, or through some sort of state or federal policy requirements that it was more than just a metadata tag, but created a functionality for that data to then be able to script it.

So, if you are just talking about tagging data, that is one thing. If you are talking about those tags translating into something else, then it does create some competition where there are some automated tools that end up creating some restrictions around data sharing that were not necessitated by law or policy, so there is that to think about. This topic is so incredibly meaty, and again, one that dates back to the original health IT policy coming out of the HITECH Act, if not even earlier than that, and lots and lots of discussion and lots and lots of efforts to move something forward without a lot of success, so it is a topic with a lot of complexity. Having said that, I think it is always a good idea to try to figure our way through this hornet's nest, and it feels like we continue to inch ever closer to something that will work, even though it is taking us a long time to get to where we are, and it may take even more time to get some deployment. I will stop there. I am starting to just muse philosophically, and I do not know if it is terribly helpful. Thanks.

#### Steven Lane

Thank you so much, Deven. Sheryl, you made a good point in the chat. Do you want to speak up?

#### **Sheryl Turney**

Thank you, Steven, and I apologize for my voice. I am still recovering. I do think we need to be a little cautious here because when you consider the fact that certified health IT will exist in the future mostly likely as well in the framework of TEFCA and other things, I do think that there needs to be some education for the patient regarding what limitations mean, and also, I agree with the comment that Deven just made about the tagging being extremely important, and understanding how other entities who have received that data who might be HIPAA versus non-HIPAA might be impacted by these rules. I do think this is something that maybe deserves a little bit more conversation and maybe some recommendations around patient education.

#### **Steven Lane**

That is a great point, thank you. Fil, you made an interesting point in the chat about consent duration and the challenge of managing revocations of consent or, conversely, removal of restrictions, and I am struck by the fact that as patients move through the healthcare ecosystem, they might place a restriction or a restriction might be placed on data in one setting, and then the patient and the data move to another setting where they would then want to remove that restriction or revoke consent that they had previously given to access, exchange, and use of data, and in an ideal world, those changes that happen in Organization B would be communicated back to Organization A and any other organization that had that data such that those restrictions would follow the data wherever it is so that there would not be this leaky boat traveling around with restrictions being applied in one setting and not in another. I know that is a lot to ask, but in an ideal world, that would seem to be what we want. Now I am musing philosophical. Do you want to add to that, Fil?

#### Fillipe Southerland

Well, as you were talking, Steven, another thought occurred to me. Are we going to have situations that start to occur where maybe, as the patient, I am unaware that I have previously restricted information or inadvertently restricted it so that there is not proper sharing between providers, and do we need some way to provide transparency throughout all the various actors that are involved in my care at any given time so that I can essentially audit the consents and revocations that I have put out there so that I do not inadvertently restrict sharing.

#### Steven Lane

I could not agree more. It reminds me of early on in my clinical organization when we were implementing, and we had only this blunt instrument of individuals completely opting out of health information exchange or opting into it, and we kept a list of all the patients who had opted out and the circumstances of the optout, and then, our goal was to go back to those people every year and say, "Do you still want to be opted out of this? You could die because you made this choice." I do not know that we actually ever fully implemented that, but that was always what I was advocating for because, as you say, restrictions have all kinds of consequences, some of which can be life-altering, and I think a lot of people do forget when and for what reason they restricted. Ike, your hand is up.

#### Steven Eichner

It is a little out of bounds for the comment, but it is still very much related to what Fil just mentioned, which is transparency. One of the things that I am not sure why we do not have is greater transparency not just on patient consent, but on disclosures of patient information that, if the transaction is occurring electronically, why is a record of that transaction not available to the patient through their portal, both to

who it was disclosed and some indicator about the purpose? Because that would do a bunch of different things. It would help remind patients that, oh yes, I did consent, oh yes, this is a disclosure purpose that I actually agree with, and understanding how my data is actually being used. I think that is a missing piece.

#### **Steven Lane**

That is a really good point, Ike. It speaks to how complicated this is. Deven, I love your comment that we are slowly moving forward. This stuff is so complicated, and in order to make progress, we need to decide what to do and then make sure that the vendors do it in a consistent way, and I love the way ONC has proposed this. Here is the new certification criterion that we are proposing. Let's get that right, and then, what are we going to do in the next iterative round of improvements?

#### Steven Eichner

Just to follow up, I see the note in chat saying that it is not currently a functional requirement, but we do require folks to be able to track how their information is being exchanged, so I am not sure why we do not include, especially for transactions that are going beyond the bound of a certified HIT module, why that transaction is not recorded. It would seem to me to be logical that it would be.

#### **Deven McGraw**

Yes, that is all related to some HITECH changes in the accounting-of-disclosure rule that, again, previous iterations of this committee dug into pretty deeply, and there were some conclusions reached there, but it continues to be actually on the agenda for this committee in terms of the statutory priorities that we are supposed to look at, as I recall, so it could be something to speak to ONC about a future workstream.

#### Steven Eichner

Right. It may be referred to the annual plan, and that might be a good thing to do from a Task Force recommendation space, but I do think, with all the other advancements we are making in information exchange, being accountable certainly is a component of it.

#### Steven Lane

Right. So, again, I really encourage workgroup members to utilize the spreadsheet to capture your ideas. We have a better rhythm going now with the ONC team taking notes and capturing ideas that we are then going back and adding, for those of you who did not put them in. Mohammad, thank you so much for your presentation. I am hoping that for tomorrow's presentation, you can talk a bit more about the existing technical standards, if they are not already covered in the ONC presentation, because I think that will help all of us to orient our commentary.

#### **Mohammad Jafari**

Definitely, thanks.

#### **Steven Lane**

Great. With that, let's cut to public comment. I am really thrilled to see we have at least one hand up in the public comment space. Mike, do you want to do the official invitation?

#### **Public Comment (01:18:44)**

#### **Michael Berry**

Sure. We are going to open up our meeting for verbal 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, press \*9 to raise your hand, and once called upon, press \*6 to mute and unmute your line. I see that Mark Savage has raised his hand. Mark, you have three minutes.

#### Mark Savage

Thank you very much. Steven invited me to flesh out a little bit the comment I dropped in the chat about the PCAST report in 2010. This is more of a general historical or philosophical observation. I know we are now talking about segmentation, metadata, and use cases that are feeling very immediate, but it did flash back that we were talking about those issues back in 2010 and earlier as well, and there may be some useful thinking back there or not.

I have not really reflected on that, but I am just reminded that this is an issue that has been with us since the beginning, and thinking of some examples now that sort of fall into this category, the Gravity Project, in its SDOH implementation guide, looked at race and ethnicity, sexual orientation and gender identity, and we realized that it was very important to track the source of the value there, the metadata. Was the individual the source of the value? Was the clinician? Was perhaps a batch file the source of the value? And so, we adjusted the FHIR implementation guide in order to be able to capture and exchange that information, and now we are also looking at the same kind of issue around reproductive health data, a critical use case at the moment. So, yes, we are thinking about it now, but it suddenly dawned on me that we had been thinking about it back in 2010 as well. Thank you very much.

#### Steven Lane

Thank you, Mark, and again, it really highlights the point that we are at an important point in the history of this discussion, where ONC really is proposing new certification criteria based on the latest technical standards, so, much work has been done by many people over time to bring us to this point. We have both an opportunity and a responsibility to make sure that we take this next step as well as we can, and also prepare ourselves for the subsequent step. Okay, I do not see any other hands up from the public. Did you get anything on the phone, Mike?

#### **Michael Berry**

No, we do not have any other public comment, so I will turn it back to you.

#### Steven Lane

Great. I also do not see hands up from our workgroup, so maybe, Mohammad, I can invite you, even though it was not on the slides, maybe you could give this group a little preview because I am sure most of us will also join the discussion tomorrow of the technical standards that are available to support this. I think part of what we heard from ONC is that they have heard from commenters about the variability across certified health IT. I have certainly seen this myself. I have been in many provider meetings where people say, "Yes, you can do that because you use Vendor E and I cannot do that because I use Vendor C, and therefore, it is an uneven playing field, so you cannot hold me to the same information-blocking standards that you hold yourself to," and that is a really awkward situation. It seems like we need to have a level playing field in

terms of the technical capabilities. So, can you speak to those technical capabilities a little bit about where we have been and where we are?

#### Mohammad Jafari

Right. So, I can refer everyone to the introduction of the FHIR DS4P that has been released recently, in the past couple months, but to provide a quick summary, I think the first data signature standard that I came across when I started working in the industry was the C-CDA data segmentation. There were requirements there about tagging data at the document level, and also, there are labeling capabilities at the section level. The FHIR data segmentation for privacy IG takes that to the FHIR space. Those capabilities are now included in FHIR. I think FHIR came with capabilities for data late in Build 10, but what the IG did was to organize and update the categories for terminology and value sets for each of the tag types, for example, confidentiality, sensitivity, interoperability labels, and so on.

So, the most recently updated value sets are included in that IG. They are all referenced to the HL7 terminology, so they are all standard codes within the HL7 terminology. And then, the same capabilities have also been added to V.2, including labels on the V.2 messages, so I think Version 2.9 is the one that was added. There was a project that sort of languished at the Security Working Group that wanted to develop a cross-paradigm IG to create a level of harmonization and consistency for all three in terms of data labeling. I think that project never took off. That is an idea that stayed in the working group, but I think there is also implementation guidance in the FHIR DS4P IG, and there is also referencing out to many external resources there, so if I were to cite a major recent standard, I would cite that standard. I think it says D1. It is not a normative standard, but that is the major source of both implementation guidance and terminology.

#### **Steven Lane**

Maybe I will go out on a limb and just ask you, since you are a subject matter expert here, given your deep knowledge of these standards, which of them do you feel would be appropriate to require for certified health IT at this point in history?

#### **Mohammad Jafari**

Right, and that is something I try to address a little bit in my slides as well. So, there are three references in the current NPRM. There is the HCS standard, which is an abstract standard just describing the concepts of data labeling, and it does not go far enough to provide any implementation or concrete implementation guidance. And then, there are the C-CDA DS4P and the FHIR DS4P that have been mentioned. C-CDA is an older standard and FHIR DS4P is a newer one. I think the value sets in the FHIR DS4P are definitely relevant, and I would think they should be included also because of the importance for interoperability of the actual tags, but I would also advise that we would choose a subset of the terminology that has been defined there because there is a wide set of values, and it would create a lot of confusion. Some of that may not be very clear to implement. So, I think defining a subset of what is defined as the terminology specification the FHIR DS4P standard would be the most pertinent piece and the most ready to implement, I would think.

#### **Steven Lane**

And have you or others defined such a subset that you would specifically advocate?

#### **Mohammad Jafari**

There is a recommendation that I helped craft for SHIFT. There is also a new HIE standard, though I think I am mixing up the acronyms, for privacy consent and FHIR. I think there is a subset that is also identified in that IG, but that IG is now just open for comment. It was just released as a draft, basically. It has not reached any status yet, but there are other folks who are also trying to define a subset that would be most relevant to the use cases without wading into the wider set of values that are in the terminology.

#### **Steven Lane**

So, given that, probably the best we could do would be to recommend that ONC work with relevant stakeholders to define that subset.

#### **Mohammad Jafari**

Right, which was one of the alternatives basically mentioned in the NPRM, to require a modification or subset of existing standards.

#### **Steven Lane**

Perfect. Well, that brings us to time. With no hands up, I feel like we have done our work. I thank you, the public, thank you, Mohammad, and thank you, workgroup members for joining us today. This workgroup has how completed all of our bullets and will work on recommendations at our next meeting, so I again encourage all of you to have your way with the spreadsheet between now and then, and I hope to see many, if not all, of you tomorrow at our Workgroup 2 meeting, where Ike will help to lead us through a discussion of the specific recommendations in the NPRM. Have a great day.

Adjourn (01:29:24)