ONC HealthIT ADVISORY COMMITTEE

Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

GROUP 1: INFORMATION BLOCKING

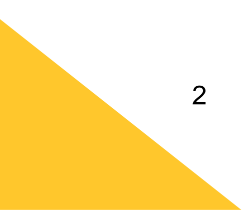
May 16, 2023 10:30 AM – 12 PM ET

VIRTUAL

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

Speakers

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



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 Mike Berry with ONC, and I would like to thank you for joining us today. I am also joined by several ONC subject matter experts who we will meet shortly. 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 toward the end of our meeting this morning. I would like to begin rollcall of the task force members, so when I call your name, please indicate if you are here. I will start with our cochairs. Steven Lane?

Steven Lane

Good morning, I am here.

Michael Berry

Steve Eichner?

Steven Eichner

Good morning, and welcome.

Michael Berry

Hans Buitendijk?

Hans Buitendijk

Good morning.

Michael Berry

Hannah Galvin?

Hannah Galvin

Good morning.

Michael Berry

Adi Gundlapalli?

Adi V. Gundlapalli

Good morning.

Michael Berry

Deven McGraw?

Deven McGraw

Good morning.

Michael Berry

Eliel Oliveira? Fil Southerland? Sheryl Turney? All right, hopefully they will be joining us shortly. Thanks to everyone, and now, please join me in welcoming Steven Lane and Steve Eichner for their opening remarks.

HTI-1 Proposed Rule Task Force Charge (00:01:19)

Steven Lane

Well, good morning, everybody, and thank you so much for joining us today, both members of the task force and members of the public who are with us today. I am always excited to see members of the public joining us. There are some new ones today, which is wonderful, so I want to remind the members of the public that they are welcome to participate in our meeting in real time by utilizing the chat feature in Zoom, and we will be having 10 minutes set aside for verbal public comment at the end of the meeting at 11:50 Eastern Time. So, you are looking at our agenda for today. We are going to be focusing in today on the infeasibility exception proposal regarding uncontrollable events, as well as a new condition of third parties seeking modification of use, which I am particularly interested in, and we will be talking a little bit at the end about our plan for our HITAC presentation tomorrow. I do not think, Mike, that we distributed to this group the slides for the HITAC presentation. Are they already posted on the public web?

Michael Berry

Yes. I can put a link to the slides in the chat.

Steven Lane

Great, wonderful. All right, I actually think we are going to get through all of this pretty well today and we are ready to dive in. Ike, do you want to add anything to that?

Steven Eichner

I do not have anything to add to that wonderful introduction other than, again, echoing your welcome to members of the public and expressing gratitude both for their attendance and participation as well as to the attendance and participation of our task force members.

Steven Lane

Great. We invite task force members to use the hand-raising feature, and, in fact, members of the public as well. If you have something that you think you want to share in public comment at the end, go ahead and raise your hand at any time. That will allow us to have a sense of how many comments there will be, and if we need to make more time, we will just cut to public comment early. All right, let’s go and review our charge briefly, especially for those who have not been here before. So, the charge of this task force, of which this is but one workgroup, is to provide recommendations back to the HITAC regarding the recent proposed rule, the HTI-1. We have a number of specific charges within there. I am not going to read every one of them, but today, our focus includes enhancing information sharing under the information-blocking regulations, so we are going to be focusing on a couple of the exceptions there.

On the next slide is the remainder of our charge that the task force has been working through in the three workgroups, and I think we are making good progress, I must say. A lot of review has been done and some draft recommendations have been put together. I do want to remind task force members to ideally have the spreadsheet open in another screen if you can, and review as we go along, and contribute to the notations there, both the recommendations as well as capturing any highlights in our discussion. Ike and the ONC team will try to capture those highlights in real time as we go along.

Just as a reminder, we are on the Group 1 recommendations tab, and today being May 16th, we are looking at Row 6, so that is where we want to be on the spreadsheet, Tab 1, Row 6, "capturing recommendations." I do see that Hans has already added a member recommendation for today's discussion, which we will certainly have a chance to touch on. Just a reminder that the presentation to HITAC tomorrow is an interim update, giving them a sense of where we are and how far we have come, but the final recommendations will be presented in person at the HITAC meeting in D.C. on June 15, and we are hoping that many of you will be there to deliver the recommendations. Let's go to the next slide.

Here, again, are the topics that were assigned to us here in Group 1, and we are focusing on the three that are highlighted regarding infeasibility exception and conditions. Next slide. Fil, thank you for joining and pointing that out. We do have from Mike the link to the presentation for tomorrow's HITAC meeting, which you are all welcome to review. It would be nice to have that ready. If we have time at the end, we might fly through that with the group, just to get any final feedback, and we have a comment from the public already queued up here, which we will bring up and perhaps work on even before the public comment period as needed. All right, now we have Cassie, Dan, and Rachel to talk us through the first of the information-blocking infeasibility exception topics.

IB Infeasibility Exception Proposal: Revise Existing Condition: Uncontrollable Events & IB Infeasibility Exception Proposal: New Condition: Third Party Seeking Modification Use (00:07:13)

Daniel Healy

Great. Thank you very much, Steven, and thanks, everybody, for being here today. For those of you who have joined us previously, it is great to be with you again, and for those of you who are new, welcome. I will start out, and I know we have limited time, so let's jump right in. Next slide, please. This is a brief disclaimer before we jump into the rest of today's presentation and discussion. I would just note that 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, also known as HTI-1. While every effort has been made to ensure the accuracy of the statement of those proposals, this document is not a legal document, and the official proposals are in the proposed rule. Please also note that other federal, state, and local laws may also apply.

Another note: ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the proposed rule as it is contained in the proposed rule. ONC cannot interpret that information or clarify or provide further guidance, and this communication is produced and disseminated at U.S. taxpayer expense. Next slide, please.

So, here we have our agenda for the discussion today, and as noted, what we are here to discuss are two elements of the information-blocking infeasibility exception, first, revising the existing condition of the infeasibility exception that involves uncontrollable events, and second, the proposed new condition, third party seeking modification of use. So, I will be going over the first several slides during our presentation today, providing some context and background and overview of the policies, and then I will turn it over to my colleague Cassie Weaver to continue her presentation and discussion. Next slide, please.

So, again, we will start out with some background and context here. Next slide, please. As we mentioned, these are the two proposals we are going to be discussing. First, ONC proposes to revise the uncontrollable events condition of the infeasibility exception to information blocking in Part 171.204A1, and then, second, ONC proposes to renumber the infeasibility conditions infeasible under the circumstances condition from Paragraph A3 to A5, and to codify A3, a new condition that we are also set to discuss here, third party seeking modification of use. Next slide, please.

Okay, first, we will start off with some background on the first topic of discussion, revising the existing condition relating to uncontrollable events. So, to begin, we created an exception under which an actor's practice of not fulfilling a request to access, exchange, or use EHI "due to" the infeasibility of the request would not be considered information blocking, and in the preamble of the CURES Act final rule, we specified that there may be situations when complying with the request for access, exchange, or use of EHI would be considered infeasible because an actor is unable to provide such access, exchange, or use due to unforeseeable or unavoidable circumstances that are outside of the actor's control.

As examples, we noted that an actor could seek coverage under the infeasibility exception if it was unable to provide access, exchange, or use of EHI due to a natural disaster or war. Importantly, we noted that the actor would need to produce evidence that ultimately proved that complying with the request for access, exchange, or use of EHI in the manner requested would have imposed a clearly unreasonable burden on the actor under the circumstances, and we have citations, if folks are interested, to the places in the rule preamble where these discussions take place.

In addition, as part of the revisions to add clarity to the infeasibility exception in the CURES Act final rule, we established the standalone uncontrollable events condition of that exception, and under the uncontrollable events condition, an actor's practice of not fulfilling a request to access, exchange, or use EHI as a result of a natural or human-made disaster, a public health emergency, public safety incident, and the other categories that one can see here will not be considered information blocking, provided that such practice also meets the relevant condition contained in the regulations. Next slide, please.

So, for some additional context around this uncontrollable events condition, the fact that an uncontrollable event that was specified in the regulation occurred is not a sufficient basis alone for an actor to meet the uncontrollable events condition of the infeasibility exception. Instead, the use of the words "due to," as we noted, in that condition was intended to convey, consistent with the proposed rule, and does convey that the actor must demonstrate a causal connection between not providing access, exchange, or use of EHI in the uncontrollable event.

So, to illustrate, a public health emergency was listed as an uncontrollable event in the regulation, so if the federal government or a state government were to declare a public health emergency, the mere fact of the declaration would not suffice for the actor to meet the condition. To meet the condition, the actor would need to demonstrate that the public health emergency actually caused the actor to be unable to provide access, exchange, or use of EHI for the specific facts and circumstances in question. One additional note on that: The emergency need not be the only cause of a particular incapacity, but the actor needs to demonstrate that the public health emergency did, in fact, negatively impact the feasibility of that actor fulfilling access, exchange, or use in those specific circumstances where the actor is claiming infeasibility,

just to provide some additional context there on this first condition that we are discussing today. Next slide, please.

Here, we get into the background on our second topic of discussion today, the new condition of third party seeking modification of use. So, here, I am going to turn the mic over to my colleague Cassie Weaver to continue on with this portion of our presentation today, so, Cassie, I will turn it over to you.

Cassie Weaver

Thanks so much, Dan. I appreciate that. So, I am going to dig into this new proposed condition for the infeasibility exception in just a minute, but first, I want to walk through this slide so that we are clear what we are talking about. So, here you can see in black the current infeasibility exception and the current conditions. So, we are starting with B because it applies to all of the conditions in this infeasibility exception as it stands today, so you have to meet the requirements in B and all of the requirements and at least one of the conditions from Paragraph A, so there is no change to Paragraph B. We are changing things, however, in Paragraph A.

So, as Dan just discussed, we are proposing one change that is really more of a clarification to A1, A2, the segmentation does not have any changes proposed, and then, A3, we are proposing to redesignate at A5, but we are not proposing any changes to the substance of that condition. And so, then, in between, obviously, we have a new A4 and a new A5 that we are proposing. One of those is the manner exception exhausted condition, which we either talk about next week or have already covered. Now I cannot remember, but I think we will talk about it next week. And then, the other is this third party seeking modification of use condition, which is what I am going to get into here in just a minute, but before I do, I just want to remind folks what “infeasible under the circumstances” currently requires because right now, to meet that infeasible under the circumstances condition, an actor has to… Oh, thanks, Steven Lane. Yes, we will discuss the manner exhausted condition next week.

Today, to meet the infeasible under the circumstances condition, an actor has to demonstrate six separate factors that led to its determination that complying with the request would be infeasible under the circumstances. So, those factors, just quickly summarized again, refer to the reg text, though this is not the actual reg text. They are the type of EHI and the purpose for which it would be used, the cost to the actor, the financial and technical resources available to the actor, it has to be a nondiscriminatory practice, the actor must consider if it has predominant control over the relevant technology, and also demonstrate why the actor was unable to provide the EHI in an alternative manner, and those alternative manners are the ones listed in our current content and manner exception. So, just keep that in mind as we go forward here because it is relevant as to why we propose the two new conditions. Next slide, please.

So, here is background for this third party seeking modification of use. I will get into the details of it again in a few minutes, so just bear with me while I talk about why we are proposing it. Basically, we are looking to reduce actor burden and uncertainty by creating this condition whereby practices specific to declining certain requests for third-party modification of use of EHI that is held by or for a healthcare provider could be excepted from information blocking more efficiently than might be the case under those other conditions in the infeasibility exception or under other exceptions. So, in these instances, an actor may be concerned about the accuracy or reliability of data that a third party would like to add to an individual’s designated

record set maintained by the actor, or an actor may be unable to complete a third party's request to modify or add EHI in the specific way that it was requested.

So then, rather than working through all of the alternative manners, or establishing that the practice meets the security exception, or working through all those six factors of the infeasibility exception, we propose that this third party seeking modification of use would apply in certain situations where the actor is asked to provide the ability for a third party or for its technology, such as an application, to modify EHI that is maintained by or for an entity that has certified health information technology and maintains within that technology any electronic health information as defined in our regulations. So, we also propose that the request to enable use of EHI in order to modify it be limited so that it does not apply when the request is from a healthcare provider requesting such use from an actor that is its business associate, which I will also explain more as we go on. Next slide, pletirase.

Here is some more context for this third party seeking modification of use. It is available for the actor, is asked to provide the ability… I just said this on the previous one, but for a third party or its technology, such as an application, to modify EHI that is maintained by or for the entity that has deployed the health IT as defined in 170.102 and maintains within or through use of that technology any instances of any EHI as define din the information-blocking rights at 171.102. It is not available when the request is from a healthcare provider requesting, directly or through another business associate of that same healthcare provider, that modification of use from an actor that is its business associate. Next slide, please.

So, let's get into these actual proposed revisions and new conditions. Next slide. First, the uncontrollable events proposed update, which Dan really covered most of already, but again, here, we are proposing to revise this condition by replacing "due to" with "because of" to make clear that a causal connection is needed to use this exception. In our view, this really is not a substantive change, it is more of a correction, and conforms to the preamble, not just in this proposed rule, but also in that CURES Act final rule. We want this exception to be used in situations where it is really needed. It makes clear that the actor has to demonstrate the causal connection, not just state that it exists. Just the fact that an uncontrollable event specified occurred is not a sufficient basis alone. Next slide, please. And here is the new reg text for this. Again, the only change here is in the text that says "due to," which we have changed to "because of a natural or human-made disaster," and then an ongoing list with the rest of the uncontrollable events. Next slide.

And now, the third party seeking modification of use proposed update. Again, here, this is to reduce actor burden and uncertainty. It will allow an actor to turn down without information blocking a request to enable one or more third parties to modify EHI, which includes, but is not limited to, creation and deletion functionality, and it could be considered infeasible, but this exception is not available if the request is from a healthcare provider requesting such use from an actor that is its business associate.

Again, this just has less documentation requirements compared to those six factors and "infeasible under the circumstances." There is no need to look to see if another exception applies to the request, such as the security exception, so if you are an actor who has security concerns but the practice would otherwise meet these conditions, you can meet this condition of the infeasibility exception rather than the slightly more onerous requirements of the security exception. I want to emphasize here that where this condition or this exception is not applicable, all the other conditions of the infeasibility exception are still applicable, including the "infeasible under the circumstances" condition, and every other exception in the information-blocking

regulations is still available. So, just because you are unable to meet this condition does not mean that you are unable to meet some other condition or exception. Next slide, please.

Here is the proposed text for A3. An actor's practice will not be considered information blocking due to the infeasibility of the request when the request is to enable use of EHI in order to modify EHI, including but not limited to creation and deletion functionality, provided the request is not from a healthcare provider requesting such use from an actor that is its business associate. If you look at the preamble, we go through the way that we are using the word "use" here in order to get to this modification of use, so I recommend you read all of the preamble, but if you are wondering about that, please do take a look there. And then, I see some comments and questions are already coming in. I think our next slide will say "discussion" on it, but maybe we should leave it here because it might help us to be able to look at this for some of these questions.

Let's see. "Does modification of EHI include the ability to add new instances of data elements or only to modify data that has previously been entered, for example, correcting an erroneous entry or modifying a medication dosage for an existing medication?" I do not believe that we get into that specificity in the preamble about the actual data. I can tell you that we do say that "use" here encompasses the ability to read, write, modify, manipulate, or apply, so "use" would cover all of those, and in particular, this condition focuses on requests to create and delete EHI held by or for a healthcare provider, so I think if you apply that to that question, it would not just be "modify" in that sense, but "modification of use" would be adding as well.

Michael Lipinski
I just want to confirm that, too, what Cassie said. "Create" is the same as adding something because you are creating something in the record, so you are adding something to the record, so it covers all this.

Cassie Weaver
And then, the next question… Oh, I like that abbreviation, TPSMU. "Does third party seeking modification of use include a provider requesting that their business associate EHR allow a specified app to add data to or modify data already existing?" So, this exception specifically excludes business associates of any actor, which does not mean that the provider has to allow it to occur, it just means if the provider does not want to allow the business associate to add data, then they need to seek another exception or have a practice that is not information blocking. Go ahead, Mike.

Michael Lipinski
To add a little more to that, we have made it pretty clear here it says "business associate." We have adopted the same definition of a business associate as HIPAA does for purposes of this. This is not changing anything with what the status… So, the bigger picture of status quo prior to this proposal is all requests of use are in scope for information blocking by all entities, and so, then, does an exception apply in all those circumstances? What normally would have to occur is… Let's just use an EHR vendor as the best example, which we do use in the preamble as an example too. They would either have to meet the request or use an exception why they did not, so, either the infeasibility under the circumstances, which Cassie alluded to as a six-factor test, and there are certain things you cannot consider, too, such as competition, how much you make, what your profit would be. There are also other exceptions that could apply, such as privacy and security. That is the current landscape.

But then, when you look at all the situations, what we are saying is for anyone who is not an associate of the healthcare provider who is asking for modification of use, then you can use this exception. You do not have to go through all the other exceptions. When it comes to a business associate of a healthcare provider, all business associate agreements have to comply with requirements under HIPAA too. So, they have preconditions, like a privacy exception, of how they determine what the access/use of that business associate is going to be. This is not changing any of that, but if one of them was that I need you as, say, a clinical decision support app to write to the record, this condition could not be used if that app that the healthcare provider or the app acting on behalf of the healthcare provider, as we say in the preamble, asks to write to the record the EHR developer maintains as a business associate. It cannot use this exception that we are proposing, but there are still all the other exceptions, so we have not changed anything in that respect. The same dynamic still exists that existed prior to this proposal. So, that hopefully provides some clarity, but obviously, we can take additional questions on that.

Steven Lane

Why don't I go ahead and just verbalize my question? Because I have really been struggling with this. I am trying to figure out whether this change provides the opening that providers have wanted to be able to use apps to write data into their EHR database. For me, that is the core question, and I appreciate that the EHRs could try to dodge this responsibility using any number of other exceptions, but what I am hoping this will do is help to open the door to write access to the EHR data, which EHRs have largely been blocking forever. So, one question about this business associate issue is if I am a provider and I develop an app in house that wants to write to the EHR database, is that different than if I am a provider and I purchase an app from an app developer who then presumably would be my business associate? Does purchasing the app from a business associate change my ability to claim that I want to utilize that app to "use my EHI" that is maintained in my EHR? So, is there a bright line between in-house-developed apps and purchase apps? Let's start with that question.

Michael Lipinski

No. So, we recite some of this in the preamble for this proposal, but the whole basis has not changed why we did the original CURES Act rule and final rule, including saying that we were not going to permit business associate agreements to be an exception by themselves under the rules. So, it covered "write" as some people understand "write" to be. I understand there is a difference of opinion in what "write" means in a technical sense comparatively, but it was always in scope of the definition of "use." That has not changed.

What we are saying is part of that scope, which is modifying a record or adding to a record, doing anything to change the record or add information to the record, in this particular scenario, the entity that is requesting it, which could be a healthcare provider that is not affiliated with the other healthcare provider that is an actor or an EHR company who is a business associate of the actor, in that situation, third-party apps, patient-facing apps, or any other outside party, such as a public health agency who wanted to somehow write back to the record with immunization data, as an example, are a no-go under this exception for that actor. That is the proposal.

Cassie Weaver

If they want to use it.

Michael Lipinski
If they want to use it. They do not have to.

Cassie Weaver
It is voluntary. They do not have to do it. They can allow the third-party app.

Michael Lipinski
They could do that. They could let the writing happen to the record in the context of everything under applicable laws. They can do all that stuff.

Cassie Weaver
They can send the blood pressure.

Michael Lipinski
If they did not want to, this would be available to them in those circumstances if it was finalized as is. Prior to this, all those entities I just mentioned, plus business associates of the healthcare provider, were all similarly situated. So, if I was the entity who was being asked to have information written to the record, I would have to use a different exception as to why if I did not want to allow that to happen, so I would have to use the infeasibility under the circumstances, or I would have to use the security one, or potentially the privacy exception. So, all we are doing is carving out that particular set of requests from certain entities, but the other piece, which is what we have always been trying to address, as we mentioned it in the congressional report to Congress, in the preamble of the CURES Act proposed rule, and again here in this rule, has not changed. That is what we have heard and what Congress has heard as a concern, is that certain EHR vendors, or maybe even healthcare systems, were not permitting…

Generally, the one example use case is the one I have given you, and it could be for population analytics, it could be for a lot of different reasons, like a healthcare system wanting to use a different vendor or different app to write to the record and having difficulty doing that with their EHR vendor, so that has not changed. We were trying to address that with the CURES rule, and if anything, that is why we said that we are not including situation in this proposed exception. But again, the BA agreements decide the scope of each business associate's access to the record in the first place, so I think that is almost essentially a precondition before you would even get yourself to an information-blocking stage. That "other business associate" in their business associate agreement would even have to be written in there in the first place, that on behalf of the healthcare entity, they have the ability to write to the record. So, it should not be overinterpreted that any business associate that they have, even previously, has some ability to write to the record under info blocking.

Steven Lane
Michael, I think you are saying… Again, I am really trying to understand, and I am trying to listen to you really carefully, so I have not been able to follow the chat, and I think there are some people putting really great thoughts there, which I will have to get back to, but does this change make things better or worse for providers who want to use apps to write to their EHR database? When I first read it, I thought it made it better, and based on what you just said, I think it makes it worse, and that is what I cannot understand.

Michael Lipinski

Well, I am not going to opine in that way on the provision.

Cassie Weaver
Can we do harder or easier, Mike?

Steven Lane
Harder or easier, sorry.

Michael Lipinski
I think it is designed to address a certain situation, which we have heard from actors, under the rule that they have had difficulty…

Steven Lane
Provider actors or EHR vendor actors?

Michael Lipinski
I think we have heard it from both because do not forget that the EHR vendor is the business associate of a provider.

Steven Lane
Exactly.

Michael Lipinski
So, I think we have heard it from both, and to provide them more certainty that we did not think in that situation… Certain certainty could be provided in other ways. I am saying something that is public. It is in the budget request for advisory opinions, so that is another way to do certain situations, and you can actually apply the facts to them in that case, and you can look at intent, and you can actually give better guidance on the situation, but here, we think that based on these facts as we have laid them out in the preamble, we are providing a potential exception. So, I am not going to say it is harder or easier, better or worse. I do not think it has changed the situation at all for what I think you are asking about, which is a healthcare provider being able to use another business associate to write to the record. I do not think that has changed. My colleagues can weigh in, too, but we were very careful in how we crafted this not to change this situation, so I think it is status quo for that situation. That would be the way I would characterize it.

Steven Lane
But it also does not change the ability of the provider actor to use their own in-house-developed app to do the same thing. What you are saying is the EHR vendor could write into their BAA, which is a requirement of their sale of their EHR, that they are just not going to allow write access.

Michael Lipinski
Right, and in the CURES Act final rule, we talked about that situation, about a business associate agreement, and that we would look at that because we said sometimes there are uneven bargaining positions by both the developer and the… It is not just the provider who is the one initiating the BAA, and those would be open for OIG to investigate to determine whether or not the terms themselves are an

interference. So, that is still the status quo, too. That has not changed. There just has obviously not been any investigation or enforcement yet into these, but the policy related to that has not changed.

Steven Lane
Okay. If no one else is going to raise their hand, I am going to keep asking questions until I understand this.

Cassie Weaver
Can I just add one thing based on some of the chat? We have previously issued an FAQ that said that provisions in a business associate agreement could implicate the information-blocking regulations.

Michael Lipinski
Yes, that was the example I was trying to get to, and I am sorry if I did not provide the clarity Cassie just did, but that is what we said. The business associate agreements themselves are not some type of exception or bar to a potential information-blocking claim in that we said there could be any bargaining power in there for the terms themselves that are subject to investigation as to why those terms were reached. That could be an interference under the information blocking. So, that was to your question, Steven, about an EHR vendor putting certain provisions in their contract. It will obviously be very fact-specific because it depends on what type of access you are saying. Is it an API access, is it a proprietary API, is it a certified API? All of that comes into play, but generally speaking, they are all within scope for investigation under the policies. I see there are a lot more hands.

Steven Lane
Yes, thank you for humoring me. Ike, your hand is up next.

Steven Eichner
Thank you so much. I can see this is a really complex issue. One thing I think we may want to explore making a recommendation about is looking at refining the language about not just a business associate, but within the scope of the business associate agreement, so that there is a bound in that space. I guess the other issue there is looking at unintended consequences of looking at modifying a record that may have other effects on the functioning of the EHR, not from a pure data perspective, but looking at modifying a data table or modifying a structure that may then result in the EHR not being able to function because a field got relabeled or some other condition that was a result of that data insertion. I am just wondering how we best address that kind of scenario. I am not sure there is a question there, but I do think at least including the refinement about the business associate agreement and the scope of the exception being tied to the nature of the agreement is at least a minimal thing we could do, and I entered that as some text in the worksheet.

Cassie Weaver
Thanks.

Michael Lipinski
You can obviously respond if I mischaracterize what I am hearing from you, but I am going to try and do an analogy for folks. So, segmentation: We have a segmentation exception by itself, which says if you cannot unambiguously segment part of the record, then it is infeasible, and I think what you are raising is if it is even infeasible to write to the record, and I think it can be circumstantial, but I think you are giving an

example where you think it would not be because of all the potential problems that could occur, which I think we acknowledge, but we do not specifically offer a condition under infeasibility about that generally, for the reasons we discussed.

Steven Eichner
Right, and here is what I perceive to be a rub, which is that I think it is feasible to write to the record. The challenge is looking at modifying the record in a way that does not have any unintended downstream effects. So, again, it is hitting that balance point. It is great to do it, but if you suddenly inserted an unexpected value into the data set behind the scenes and the software that was normally accessing the data was expecting values in certain ranges and was doing error checking on the input side of it, you are suddenly ending up with weird data coming out.

Michael Lipinski
Yes. So, this proposed condition of the exception would address any potential of that happening from anybody who was not a business associate. Now, when it comes to a business associate of the healthcare entity, that could probably still happen, Steven. I am not going to say it could not, but it is approached differently under info blocking, but for anybody else trying to do that, that would not be a concern under this new proposed condition.

Steven Eichner
Right, exactly, but again, taking that as a case, and thinking of it, perhaps, from a language in terms of looking at any investigation in that space as a subsequent action, we would say, "Hey, this is a consideration here." That might be an approach. Again, I think it is important to provide the ability to write access to the data so that you can have a unified patient record. That part makes a great deal of sense to me, it is just that not having an unintended consequence on software performance is the other end of it that we have to figure out some way of balancing against.

Cassie Weaver
One thing we do mention in the preamble, too, is that again, where this does not seem to quite fit a given scenario, there is the health IT performance exception, there is the security exception. I know that is not necessarily satisfactory for each set of facts or circumstances, but sometimes it helps to keep that in mind. Deven, I see you have had your hand up patiently for a while.

Steven Lane
Yes, Deven, go right ahead.

Deven McGraw
That is okay, no worries. This is a lot of discussion on this, and it has been very interesting. I found this exception a little hard to wrap my brain around because as always, the double negative stuff really gets to you. "It is not information blocking except when it is not…" But, I am going to raise something that Mel Solis raised in her comments, and it is something that she talked about on an Interoperability Matters call that I was on, and I think it is an important point because the definition of healthcare provider as an actor extends beyond those providers that are subject to HIPAA because HIPAA is only those providers who bill electronically, so you are going to have some providers who are contracting with data holders, like an EHR provider, for example, that is not their business associate. They are not business associates because they

are not covered by HIPAA. So, I just wondered if ONC had any reaction to a potential comment from us that this be extended to contractors that are data holders that are not business associates because they are working for providers that themselves are not covered entities.

Michael Lipinski

I think that is a good comment. I will not go into too much because of the process, but I think that is a good comment. I think you should make that comment. I think we are looking at that in another exception, too. I do say that we also have to consider from the whole scope of all of it, too, and we are, and we did get comments on if the definition should have been limited just to HIPAA, and obviously, we chose not to. We just went with the statutory definition, but when I say "the whole big picture," it is also investigation and enforcement as well, so that is a consideration for the department, too, what our abilities will be in that space. But, yes, that is a good comment, so, thank you.

Cassie Weaver

I think we are mostly caught up in chat, but if someone from the task force does have a question in the chat that they feel was not answered, feel free to ask it again verbally now so we can try to get to it.

Steven Lane

Ike, I know you have been monitoring the chat more closely than I have been able to because I cannot do that and listen carefully at the same time. Was there anything else in chat that you thought needed to be raised, either from panelists or members of the public?

Steven Eichner

I have been tracking, and I think we have picked up everything.

Steven Lane

Okay. I want to try to capture the insights that have been developed here through our discussion in this Column I, and I tried to write down what I came away with, but I invite others, Deven in particular, to jump in and add text here so that we can at least try to capture what we have discussed. I will also point out to task force members that we have said that we want to use Column I in the spreadsheet to capture the names of SMEs that we will be inviting to future meetings, and the ONC team as well, you guys have been capturing a number of SMEs for some other workgroup discussions, and if we can keep a listing of those in the spreadsheet, that would be really helpful for all to know where to go to reference for that. All right, Fil, your hand is up.

Fillipe Southerland

Thanks, Steven. I am curious: One the scenario where, if there is a write request to the EHR where the EHR has not developed the API ability to receive programmatic write requests, what does that fall under if there is simply no ability that has been developed to write into the EHR? The regulation requires the ability for the EHR to allow read access to all of the data, but there is not a specific requirement to provide write.

Michael Lipinski

Right, so you are talking about the certified API. Obviously, a lot of vendors have proprietary APIs that do and maybe do not have write access, but again, you would be in the infeasibility under the circumstances, potentially, so that looks at what resources you have. That one looks at if you could build an interface based

on the request. I am trying to consider some of your comments and your thoughts in conjunction with other proposals. We also have the manner exhausted proposal too now, so…

Cassie Weaver
Which we have not presented yet.

Michael Lipinski
Yes, we have not presented on it yet, but that looks at what functionality you are providing as a developer, but the infeasibility under the circumstance would generally be the one I would be thinking of in that situation, but again, keep that thought in mind also, the new proposed manner exhaustion condition that will be discussed at a later date.

Fillipe Southerland
Okay.

Steven Lane
I am hoping that someone is writing in this field here. It looks like some people have their cursors in there. I am still trying to digest all the great thoughts in the chat here. Deven, are you writing, or can you summarize and I will write the insights that you have developed here?

Deven McGraw
I would be happy to, I just do not find I do it as effectively while I am simultaneously also trying to listen, but I do remember the issues on which I am actively engaged, and when I go to do my homework, I will put it in.

Steven Lane
I see that somebody added Fil's question, which is when the EHR does not have write access, does the infeasibility exception apply? And it sounds like either infeasibility and potentially infeasibility under the circumstances. That is what I think I heard there. Cassie, you have a poker face on.

Cassie Weaver
That is good. Mike is always telling me that I am smirking, so I am glad I have a poker face. I think I would repeat my line that the other exceptions are available, including the other conditions of the infeasibility exception, and if something cannot be done, then it would probably be infeasible. If you look at the conditions, you could probably find one.

Steven Lane
Okay. As you and I shared a bit in the chat, Cassie, I will just restate that my enthusiasm when I first saw this was that I thought that this actually provided benefit to providers who wanted to force their EHR vendors to allow them to write to the record, the old FHIR write access, and at the end of this discussion, my sense is that that is not the case, that if anything, this actually was a gimme to the vendors who were trying to find ways to avoid providing that functionality, and if I have that wrong, please disabuse me of that opinion.

Cassie Weaver
Blink twice. No, I am just kidding.

Michael Lipinski
So, Steven, without endorsing your characterizations of it, I think that is a fairly accurate understanding in terms of the proposal.

Steven Lane
Great, thank you. I will stop celebrating.

Michael Lipinski
But I do not want to lose sight of what exists today, and I do not want to belabor the point you raise, but there is information out there we are still hearing about, both studies, surveys, and general feedback, specifically back from even questions from Congress from constituents about this particular situation, so I will just leave it at that. We still receive questions, comments, and concerns about this particular situation from various avenues.

Steven Lane
Ike, your hand is up.

Steven Eichner
This is actually a question for you, Steven. I wonder if there is an opportunity to make a recommendation in the space, perhaps not in this particular rule, but looking forward, if there is a way to advance your goal of improving provider access in a manner that is compatible or supported by APIs in that space to facilitate that kind of access as part of, perhaps, a longer-range increase requirement on EHRs to both help provider providers write access but also help alleviate concerns about breaking or impacting the data behind the scenes, as it were.

Steven Lane
Good point. I want to apologize to the members of the public. I said in this meeting, and I have said in prior meetings of this task force, that there was an open invitation to raise your hand during the course of the meeting so that we could keep a count of the number of public comments that we were going to need to process, and apparently, the ONC and Excel has another opinion. They would rather wait and have people raise their hands all at once at 10 minutes before the end, so, my apologies for giving the wrong instructions. Having said that, we are at half an hour before the end, and we seem to have exhausted our discussion here. Hans, you saved the day.

Hans Buitendijk
No, the reason I waited for the hand up is because with the discussion so far, it has been focused very much on the specific proposals and updates, where we did not have a lot of specific feedback. It was very clear. Good point raised between a good relationship where there is a BAA and where there is a contract. I think that is a very helpful question to get further clarification on, but otherwise, what the proposals provided with "because of," etc. was very clear on the last topic. In the end, I am not sure whether the updates and the clarification, not just focusing on the BAA part, really fundamentally changes the arguments, the rationale, and the evidence that needs to be provided whether you can or cannot provide write, so I am not on the same page that I would say it favors one or the other. There is still the fundamental

question on why something can or cannot be done. That still remains the same. There is some clarity in some areas, but beyond it, I am not sure how much it changes what was already there.

The reason I waited is there is another question around feasibility that was not brought up, but where there is continued question and concern around, so it would not be a reaction to a specific proposal, but currently, how exceptions and particularly when infeasibility comes into play, where you typically are in more complex scenarios and alternatives that need to be evaluated that you may need to in combination with other considerations, other exceptions, as well as if you receive one request first, at some point in time, you are going to get a similar, if not the same, request later.

For example, there are some updates that would be requested for updates to data, like we talked about. The 10 days is challenging because that is an overall approach, and you need time in order to go through the considerations why things can or cannot be done, under what context, and what not, so the 10-day response time from the moment that you receive the request rather than from a point where the evaluation or the information and the understanding of what is being asked for has been sufficiently worked through remains a challenge. How do we do that in 10 days when things get more complex?

So, that is where we would have a consideration based on the time that the evaluation is collectively done with the requester and that then goes back to the circumstances, the facts, and the intent to address whether the time spent on it was inappropriately long or whether it was appropriately correct because of the complexity of the issue. So, in the context of infeasibility, that is where we remain to have some concerns and would like to recommend that that time window is not starting at the time of the request, but at the time of a mutually acceptable way to go through and review the evaluation so that it can be informed at that point in time and to finalize the response.

Steven Lane
So, Hans, thank you for that, and before we go to the raised hands, I guess I would just ask if the workgroup would like to embrace Hans's recommendation.

Deven McGraw
No.

Steven Lane
Okay, perfect, Deven. Go.

Hans Buitendijk
That is very clear!

Steven Lane
Your hand is up, Deven. Go right ahead.

Deven McGraw
My hand is up. I appreciate that 10 days may be too short, so I am not necessarily disagreeing that that feels a little cramped, but if we are going to extend it, I think we should seriously think about where there

still needs to be a deadline because I think otherwise, requesters with legitimate requests could be left on the back burner indefinitely without some sort of expected timeframe.

Hans Buitendijk

I completely appreciate your concern, Deven. It is one of those… Ten is too short, what is too long? What is a reasonable way that that works, you can get a good response from everybody, and it is satisfactory? So, I have no concerns with your concern that there needs to be a backboard, but the 10 days is short.

Deven McGraw

So, it is not a full disagreement, it is just that we still need an outer boundary.

Hans Buitendijk

I think there can be clarity there across the variety exceptions when it gets complex and is unattainable.

Steven Lane

Mike?

Michael Lipinski

I was going to actually comment on that too, so I appreciate your points, Deven and Hans. So, what we have committed to as an agency, not within a particular period of time, but we are working on it, is when do you actually have an actionable request, though that is not necessarily the term of art yet, that you know you have something of which you can act upon to attempt to respond? So, that is one thing, and then, that would probably indicate when, for example, in certain circumstances, the "10 days" starts.

The other piece that I would note about that is there was a discussion… This is not the first time someone has raised the issue of 10 days. It was raised in comments on the proposal originally, and we responded and kept it at 10, noting also in our discussion with the OIG that it is an attempt-based statute as well, and this is an exception. It is really essentially trying to find a safe harbor as to your actions and why, even though you did not do something, that you did commit an interference, that you did have bad intent, or maybe not bad intent, but you still met an exception and your intent really did not matter in that example. So, I just wanted to keep that in mind. It is not something that was not raised in the proposed rule that we addressed then. We continue to appreciate the comments. I do think some of it is contingent on knowing when you have something that is actionable that starts the clock, so we are looking at that too. Thank you for that time.

Steven Lane

Okay. Are there others on the workgroup who want to chime in on this? Ike, you had some recommendations as well, in addition to Hans, regarding the 10 days. Do you want to comment on those?

Steven Eichner

If that was to me, no. I do not have any recommendation looking at the 10 days.

Steven Lane

So, you have a couple of recommendations that you put in Column G, "Recommend that ONC consider revising the draft rule to reference any disaster emergency declared by the appropriate governmental entity.

This could include public health emergencies, but would also include response/recovery periods associated with natural disasters that impact the ability of providers' information systems or data."

Steven Eichner

Right. Just to elaborate that, in the sense of a hurricane or other natural event that is not necessarily specifically a public health disaster, that may very well have an impact on a provider's ability to respond to an information request. If they have no electricity to their system, they cannot respond unless they have a backup that is outside of the affected area, and obviously, that disaster could also include a public health disaster, but I think that is perhaps a little more accurate in terms of looking at the impact. Again, in the same situation, just because there is a natural disaster, a publicly declared disaster, it does not automatically mean there might be an exception, but it provides, perhaps, a better basis.

Steven Lane

Does anyone feel that they would like to either support or conflict with that recommendation? Because this is what we want to do. We want to bring recommendations together here that we will then include in our report to the HITAC. It does not seem unreasonable, Ike.

Steven Eichner

I guess the question for our ONC representatives and presenters is without the modification to the rule, what available exception might apply to a healthcare provider in the situation that I just described, if they were a provider in, say, Tampa, Florida, and a hurricane comes through, and they have no power for three weeks?

Michael Lipinski

That is covered. I do not know if somebody on the team can quickly bring up the reg text while I am talking, although I can remember… Maybe it is not in the reg text, Rachel, that we describe an uncontrollable event, or if it is in the preamble, but it is war, it is natural disasters, which a hurricane would be… You just have to show that it is because of. So, in the example you are giving, Ike, it is "because the hurricane knocked out all our electricity, so we cannot respond." It was just what we were getting questions on, and we still feel that, as drafted, it was clear enough if you were in an enforcement perspective, but we are in here doing changes to infeasibility, so we felt like we had enough comments to address it.

What came to us is COVID-19 public health emergency. That is uncontrollable, and we do not have to respond. We said it was "due to" in the current reg text, so that was to say that it is a causal connection. That may be true. Maybe you have an influx of patients in such and such hospital because there were waves in different parts of the country, so you could not respond because of COVID-19, but it was not a blanket that everybody did not have to respond because of COVID-19 public health emergency. That was the point we were trying to make. That exception did not provide that. So, to your point, we can go through tons of examples. The hurricane comes through, knocks out all your power, but does not knock out the neighbor down the street, so there are two different facts and circumstances. While you could use this provision, they may not be able to use it because it did not prevent them from responding. Does that make sense?

Steven Eichner

Exactly.

Michael Lipinski
That is how it is drafted.

Steven Eichner
That is exactly my point. Where I guess I was going overall is if we adopt this language, it then seems like there are two very similar exceptions that could potentially be confusing for the provider community, and if there is a singular exception that would encompass both, that would seem to me to be a more logical approach. Does that make sense?

Michael Lipinski
I guess I will speak for ONC. None of my colleagues have jumped in. I was hoping we could get the reg text up, just so you can see it again and understand what the change was. I feel that contextually, that might help everybody.

Steven Lane
Rachel has bene trying to paste text into the chat, but I think bringing it up is a good idea.

Cassie Weaver
It is in the PowerPoint, or at least the new proposed text, anyway.

Steven Lane
Why don't we pop back to the PowerPoint? We are going to be cutting to public comment fairly soon here.

Steven Eichner
It may just be a misunderstanding on my part.

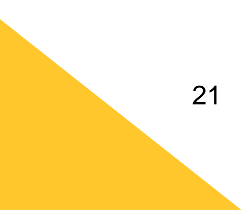
Michael Lipinski
I could share my screen if that is feasible. I do not know if it is. Can I do that? I am not sure. I guess I could try and see what happens. I am trying to do that. All right, perfect, I can.

Steven Lane
I think the reg text was on Slide 21.

Michael Lipinski
All right. Can you all see my screen right now?

Steven Lane
There we go, yes.

Michael Lipinski
All right. So, you should be seeing this right here. I will highlight it for you. So, this is what exists now, and all we are doing is where it says "due to," we are changing it to "because of" because of what we have discussed today. There seemed to be some confusion. "Oh, public health emergency? That means I can take advantage of this condition." What we have been trying to say is no, it has to be due to it, that is why



you could not fulfill the request, but that apparently was not clear enough, and since we were in here, to be honest, proposing other changes to the infeasibility exception, we thought it was best to address this for utmost clarity, and we are going to change "due to" to "because of" to establish that for any of things, you have to show the cause.

Steven Eichner
Great, wonderful. Particularly as you presented it today, the text was focused on the public health emergency side, and I missed the link.

Michael Lipinski
No worries. That is what we are here for.

Steven Eichner
That is great, thanks.

Steven Lane
So, we are happy to support this change, right, Ike?

Steven Eichner
Yes.

Steven Lane
I thought so. Okay, good. Minor point. It is fascinating, just as a philosophical observation. Not being an attorney and not having spent my life understanding how carefully reg text needs to be refined, this seems like such a minor change, and for some people, "due to" and "because of" would seem to say exactly the same thing, but the fact that this has raised an issue in the public, people have had questions, and making this change makes that better, it is pretty remarkable. All right, let's cut early to public comment. Thank you for raising that slide, ONC. Do you guys want to recite your words?

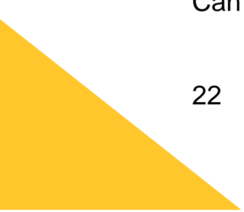
Public Comment (01:15:35)

Michael Berry
Sure, thank you. We are going to open up our meeting for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. So, let's just pause for a moment to see if any members of the public raise their hand.

Steven Lane
We had a hand up earlier. There we go, and now it is up again.

Michael Berry
All right, Melissa, you can go ahead. You have three minutes.

Melissa
Can you hear me okay?



Steven Lane
Yes.

Melissa
Great. I just had two questions, and it's about the new condition for third parties seeking modification of use, and my first question is based largely off of the conversation that was had earlier, which is also in the chat, is whether or not there should be further language tweaks to clarify that we are talking about enabled use or exchange, to make clear that we are also talking about the manner in which the data might be written to the system. And my section question is this particular exception has a carveout to the exception for healthcare providers who are requesting use from the actor that is its business associate, and I am just curious whether there has been consideration about if it should be just limited to healthcare providers. What about health information networks and exchanges, for instance, that have platforms supported by developers, and they might want to use a third party to also write data to their systems because in some of those platforms, it is not strict data exchange. Sometimes it is the ability to also capture or modify data or add data. So those are my two questions.

Cassie Weaver
Sure. I think I can address some of them. I cannot remember if I sent you this link in the chat or not, Mel, but I think the use and the clarity that you are seeking to ensure that includes what you were talking about. We do mean the broadest definition of use. We just are using modifier modification use in order to avoid confusion between this modification use idea and the HIPAA rule's defined term "use." So, by saying "modification use," we are referring to access, exchange, or use, and I found the citation for that that I will drop in the chat right now.

Melissa
Great. And then, one of my concerns with that is for the IBR's definition of use, there is not a proposal to change that definition, and right now, the way that use is defined, it says after there has been an access or exchange, and as an attorney parsing words, I was just worried if the plain language of the regulation might be in conflict with how broad it is intended to be in the preamble to the proposed rule.

Cassie Weaver
Okay, I see what you are saying. I would have to go back and look more closely, but that sounds like something that could be a good comment if you think we have not made that clear enough because we definitely do want it to be, obviously, as clear as possible.

Melissa
Thank you.

Cassie Weaver
Thank you.

Steven Lane
Okay. We do not see any other hands up. Were there any that came in on the phone only?

Michael Berry
No, I am not seeing any other hands up, Steven.

Steven Lane
Oh, there's a hand. That is Melissa again.

Melissa
I just have another question about infeasibility conditions, and if this has been considered, I think there will also be written comments as well, but one of the things I think happens a lot with infeasibility is when actors are cutting other to new technologies or new platforms and it is not feasible for them to bring on new customers or they might have to temporarily disable services, and where there is the health IT performance exception, if you already have an existing contract with folks and you have SLAs in place, it is not a great exception because the health IT performance exception anticipates that your SLAs are in place, and a lot of times they do not actually address something like a new technology or a migration to a new platform, and it is very burdensome to use infeasibility under those circumstances in those situations, and I am just curious if there is room in written comment in the final rule for additional infeasibility conditions that could address when we are having a significant technology change, and that makes it infeasible to satisfy certain requests as the migration occurs.

Michael Lipinski
I was going to call you Melissa, but Cassie knows it is Mel, so I will say Mel. This is Mike. I think she was going to say what I was going to say, but I was probably going to add a caveat to it. We are always interested in comments, and the more facts, like you are doing now, that you can provide, the better. The caveat I was going to offer, and obviously we are doing a lot of rulemaking if you have looked at the unified agenda, but generally speaking, there are legal limitations on what we can finalize in a final rule based on what we have proposed, without getting into too much legal mumbo jumbo that not everybody needs to hear about here, but again, we are always happy to have those comments to take under consideration.

Melissa
Great, thanks, Michael.

Steven Lane
I would like to come back to the recommendation that Hans raised about extending the 10-day infeasibility response. I think your proposal, Hans, of switching it to "upon completion of the evaluation" clearly raised concerns, and I can see why because one could say the evaluation can go on forever, but could we as a workgroup just simply try to extend it a bit? If we say 10 days feels too short, and I was just reviewing some of the public chat on this, is 14 days better? Is 15 days better? Could we settle on a specific recommendation?

Deven McGraw
I think that is the hard part because I agree with Deven. What would that be?

Steven Lane
It will be 10 days if we do not comment, right?

Michael Lipinski
Well, let me say a couple things on that. Again, same thing that I said to Mel: We are always happy to have these comments, anybody in the public should feel free to comment, but there are still all these legal considerations as to what we can finalize in a final rule. Let me just give you an example on this one. I am 100% certain we did not say, "We are considering whether or not we should change the 10 days, and here are a couple options, and we would like to hear from you." So, the point why I say that is the way the APA works, the public has to have notice of what you are potentially going to do from a regulatory standpoint so everybody can comment on it, so, again, please send us your comment. I just want to manage expectations a bit about how the APA works for us, from a regulatory perspective, because no one else knew that that was even open for comment. Do you understand? They did not know that could potentially be changed, so how would they have known to comment?

To your point, Hans had an idea, he does not think it is right, but Deven does not necessarily agree, but she did not know that was even proposed for change, which we did not propose, to be clear. That is not a proposal in this rule. Again, though, comments are always great because we can use them to inform future proposals, and if they are somehow within context, we always talk to our general counsel about whether we are able to do something. That is the other piece.

Steven Lane
So, I think what you are saying, Mike, just so I am clear, is that it would be outside the scope of the task force to recommend at this point that ONC extend the 10-day infeasibility to 14 days, for example. You are saying that that would not be appropriate for our task force.

Michael Lipinski
I leave that to Michael Berry to talk a little bit more about what the scope is. I think you have a charge, so that brings in different laws. You as a person can still make comments outside of HITAC, so I am just giving that more as a public service announcement so people can understand. I know the regulatory process seems like it is behind a curtain and it is hard to understand it if you are not in this every day. I am sure some of the attorneys do. There are court cases that have defined terms like "logical outgrowth," for example.

I am not going to spend a bunch of time talking about that term here, but just the notice requirements and everything in terms of making the public aware of what is in scope for that rulemaking, so that is kind of why I wanted to say it, but we always encourage your comments. We may not be able to act upon them in the final rule, but like I said, they are useful for potential rulemakings. Before there was a rule, there was a report to Congress on information blocking, and then then we had all these listening sessions, and we used all that to decide what to put in the proposed rule. So, that is my point about comments. You may see something from experience, from your own knowledge that maybe the rule has not addressed and should address, so that is why I am still encouraging comments. I was just trying to manage expectations a bit.

Deven McGraw
On that note, Steven, I was actually going to be reacting to your comment. In the context, actually, of what I raised, we can still bring it up to say there is a concern here and we encourage ONC to look at that and explore opportunities to do that because we are not aligned, whether it is 14 days, 15 days, 30 days, or some other criteria that makes it very clear that it is a good trigger, so I think putting a suggestion to address

that for awareness, that these exceptions are being advanced, to look at that as well as they move forward, so I think we can do something with it that is directional, but not with a specific recommendation.

Steven Eichner

This is Steve Eichner. Just to add onto that, I think that concept would be consistent with some of the things we have done with past task forces, again, not necessarily looking at a specific recommendation within the scope of the NPRM in front of us, but looking at some general suggestions about things that might be worth considering for the future.

Steven Lane

Great. Well, we are coming up on our time here. On the slide, you can see that this workgroup has two additional meetings scheduled, on the 23rd and the 30th, the next two Tuesdays, and we will be tackling the issues that are listed here. I really appreciate folks jumping into the spreadsheet, adding specificity from our discussion that you want us to capture and specifically to work on particular recommendations. Hans, it sounds like your recommendation is not going to stand, but we should consider whether we will add a comment about looking at that in future rulemaking. Ike, I think your draft recommendation was addressed through our Q&A, and then you have another recommendation in there that you started to frame. I added to it a little bit, and you might see whether you are comfortable with my edits, and maybe we can bring that forward. Having said that, I really want to thank everyone for their time and attention today. We are at the hour, and hopefully we will see many of you at HITAC tomorrow, and then back here in a week.

Adjourn (01:29:00)