Transcript

HTI-2 PROPOSED RULE TASK FORCE 2024 MEETING

GROUP 3: INFORMATION BLOCKING AND TEFCA

August 1, 2024, 11 AM – 12:30 PM ET

VIRTUAL

MEMBERS IN ATTENDANCE

Rochelle Prosser, Orchid Healthcare Solutions, Co-Chair
Sooner Davenport, Southern Plains Tribal Health Board
Derek De Young, Epic
Steven (Ike) Eichner, Texas Department of State Health Services
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Hannah Galvin, Cambridge Health Alliance
Dominic Mack, Morehouse School of Medicine
Anna McCollister, Individual
Katrina Miller Parrish, Patient.com
Kris Mork, Guidehouse
Randa Perkins, H. Lee Moffitt Cancer Center & Research Institute
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, CyncHealth
Sheryl Turney, Elevance Health
Rachel (Rae) Walker, University of Massachusetts Amherst

MEMBERS NOT IN ATTENDANCE

Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Eliel Oliveira, Harvard Medical School & Harvard Pilgrim Health Care Institute

ASTP STAFF

Peter Karras, Acting Designated Federal Officer
Maggie Zeng, Staff Lead
Sarah McGhee, Overall Task Force Program Lead & Group 2 Lead
Cassie Weaver, Group 3 Lead

PRESENTERS

Rachel Nelson, ASTP

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

Peter Karras
Good morning, everyone. Welcome to the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule Task Force Group 3, Information Blocking and Trusted Exchange Framework and Common Agreement (TEFCA), meeting. I am Peter Karras with the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP), and I will serve as your Designated Federal Officer today, acting on behalf of Seth Pazinski. This meeting is open to the public, and public feedback is welcome throughout the meeting. Comments can be made through the Zoom chat feature. Also, there is scheduled time for verbal public comments toward the end of our agenda today. Let's get started with our meeting. I will now begin with rollcall of the HTI-2 Proposed Rule Task Force Group 3 members. When I call your name, please indicate that you are present. Let's start with our co-chair. Rochelle Prosser?

Rochelle Prosser
I am present. Good morning.

Peter Karras
Good morning. Shila Blend has indicated that she will not be joining today's meeting. Hans Buitendijk? Sooner Davenport?

Sooner Davenport
Present.

Peter Karras
Derek De Young?

Derek De Young
Present.

Peter Karras
Steve Eichner? Steve, I do see that you are on. You might be muted. Lee Fleisher?

Lee Fleisher
Present.

Peter Karras
Hannah Galvin?

Hannah Galvin
Good morning.

Peter Karras
Good morning. Dominic Mack?

Dominic Mack
Present.

Peter Karras
Anna McCollister has indicated that she will be joining for the second half of today's meeting. Katrina Miller Parrish?

Katrina Miller Parrish
Good morning.

Peter Karras
Good morning. Kris Mork?

Kris Mork
I am here.

Peter Karras
Eliel Oliveira? Randa Perkins?

Randa Perkins
Good morning.

Peter Karras
Good morning. Zeynep Sumer-King?

Zeynep Sumer-King
Good morning.

Peter Karras
Good morning. Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Peter Karras
Good morning. Sheryl Turney?

Sheryl Turney
Good morning.

Peter Karras
Good morning. Rae Walker?

Rachel Walker
Good morning.

Peter Karras
Good morning. Thank you. Are there any members I missed or any members who just joined us who would like to indicate that they are present?

Steven Eichner
This is Steve Eichner. I am here. Can you hear me now?

Peter Karras
Yes, we can hear you perfectly. Thanks, Steve.

Steven Eichner
Thank you.

Peter Karras
All right. Please join me in welcoming our co-chair for opening remarks to get us into our meeting. Rochelle, over to you.

Opening Remarks (00:02:45)

Rochelle Prosser
Yes, hi. Good morning. Thank you, Peter. Welcome, everyone, to the first round of actual business with the HTI-2 rule. I really thank you for taking the time and making time in your very busy schedules to be here to discuss what we will talk about today on patient and patient access. I expect that it will be a very robust discussion, and I just want everyone to understand that although we are here to discuss about that, the law is what has been already written, and we are working to either approve the law as it is or make recommendations regarding the law, but we have to work within the confines of the guidelines that the ONC has given us. If there is something that we have forgotten or omitted that is of major importance to the section we are discussing today, that can be brought further to a higher level, but we really cannot make major changes to the proposal. It is simply to put the framework behind what the ONC guidelines are. With that, I will give it back to Peter, and we will begin.

Peter Karras
Great. Thanks, Rochelle. So, this is the agenda. We are going to get into information blocking enhancements, and then the discussion, and then we will open up the Task Force recommendation worksheet, and then have our scheduled public comment toward the end of today's meeting. Let's go on to the next slide. This is a repeat of the overall Task Force charge for HTI-2, which we have seen for members to review and provide recommendations on the proposals during the public comment period. With that, we can go to the next slide. This just highlights the topic for today's discussion. With that, I will turn it over to Rachel Nelson from ONC to dive into our information blocking enhancements topic. Rachel, over to you. Rachel, if you are talking, you might be on mute.

Information Blocking Enhancements (00:05:17)

Rachel Nelson

Okay. Accel, could you advance the slide, please? Today, we are actually going to talk about one enhancement to the information blocking regulations that is proposed in the HTI-2 notice of proposed rulemaking. It is the proposed new protecting care access exception. Next slide, please. I am going to give you a couple overviews of it. We do have slides that present a lot of detail of the proposed regulation text, but we may not read all of them here. They are here; you have them handy. I would also encourage everyone to read the preamble discussion of this proposal in the notice of proposed rulemaking if they have not already done so. Please try to find time to do that.

Without further ado, the proposal is an exception that would apply to practices likely to interfere with Electronic Health Information (EHI) access, exchange, or use that an actor believes in good faith could create or increase a risk of potential exposure to legal action, including investigation, that the actor believes could potentially be brought under law in effect at the time the actor engages in the practice against patients, healthcare providers, or those who help make providing or receiving care possible for the mere fact that a person sought, obtained, provided, or facilitated reproductive healthcare that was lawful under the conditions in which it was provided or, specific to the patient protection condition, the mere fact that a patient has health conditions or history for which reproductive healthcare is often sought, obtained, or medically indicated.

The benefits of this proposal at a high level are that it offers actors certainty that practices satisfying the exception would not be considered information blocking, it would assure patients that the information blocking regulations support actors limiting EHI sharing in response to risks that arrive over time while also continuing to support patients' own access to their EHI and other sharing of EHI consistent with applicable law and patient preferences that fosters better care. The exception would also support continued advances in digitization, interoperability, and public confidence in the nationwide health information technology infrastructure. Next slide.

Here is the overview of the exception. An actor's practice implemented to reduce the risk of potential exposure to legal action would not be information blocking when the practice satisfies at least two conditions: The threshold condition and the patient protection condition or the patient care access condition. As we note in the proposed rule, some practices in some situations might satisfy all three conditions, but the minimum for an actor's practice to be covered by this exception is threshold plus at least one of the other two exceptions. To meet the threshold condition, there are three requirements that the practice would have to meet. The actor would have to hold in good faith the belief that a risk of potential exposure exists. There is a tailoring requirement for the practice. It needs to be no broader than necessary.

There is an implementation requirement. There are specific details for this in the proposed regulatory text. The practice would need to be implemented based on either an actor's organizational policy or a case-by-case determination. The patient protection condition is applicable to practices an actor believes could reduce the patient's risk of potential exposure to legal action based on the mere fact that reproductive healthcare was sought or received or that the patient has a health history or condition for which reproductive healthcare is often sought, received, or medically indicated. The care access condition would apply to practices an actor believes could reduce potential exposure to legal action of healthcare providers or other persons who provide care or are otherwise involved in facilitating reproductive healthcare that is lawful under the circumstances in which it is provided. Next slide, please.

This is a snapshot of how the reg text flows. The threshold condition, patient protection condition, and care access condition are shown in their entirety, I believe, on the next three slides, but I am not going to read through them here, unless the workgroup wants me to. I wanted to include those to show that this is the structure and also highlight that there are provisions in here that are not conditions. One is the presumption provision. For purposes of determining whether an actor's practice needs the patient protection or care access condition, care is presumed to be lawful unless the actor has actual knowledge that the care was not lawful under the circumstances in which it was furnished, and we do include in the draft regulatory text a definition of legal action.

For purposes of this exception, "legal action" means any one or more of the things you see listed here: A criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive healthcare, a civil or criminal action brought in court to impose civil, criminal, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive healthcare, or an administrative action or proceeding against any person for the mere act of seeking, obtaining, providing, or facilitating reproductive healthcare. Next slide.

Again, this is the text of the threshold of the condition pasted on this slide. We are not going to take time to read it because I want to leave you guys time for discussion. Next slide. Patient protection conditions. Next slide. The care access condition. Next slide, with a couple of additional details that are of interest. So, in case folks are wondering what "reproductive healthcare" means for purposes of this exception, we propose in the rule to adopt, in a different section of our regulations, the same definition of reproductive healthcare that is now used for purposes of the Health Insurance Portability and Accountability Act (HIPAA) regulations in 45 Code of Federal Regulations (CFR) Parts 160 and 164. We do discuss this proposal in the same section of the HTI-2 Notice of Proposed Rulemaking (NPRM), where we discuss the protecting care access proposal.

Just as a reminder, "healthcare provider" is defined in Section 171.102 of the information blocking regs, along with other defined terms for purposes of the information blocking regulation. We do propose in HTI-2, as we talked about last week, to clarify the wording of the healthcare provider definition, but not to change its scope, and on this slide, you also have a pointer to which section of the NPRM we discussed the healthcare provider definition wording update, and also, as a reminder, "person" is defined in Section 171.102, currently codified, by cross-reference to the definition of "person" in 45 CFR 160.103. That is the same definition of "person" that is used for the HIPAA privacy rule. Effective June 25th, 2024, that HIPAA privacy rule definition includes clarification of what "natural person" means in context of that definition of "person." On this slide, for your convenience and future reference, there are URLs to where you can find the current text of 45 CFR 171.102 and the other regulatory section mentioned in this slide, 45 CFR 160.103. Next slide.

That was all I was planning to prepare for you today. Again, I wanted to leave lots of time for the workgroup to discuss, but I am happy to go back and talk through the detailed slides that I skipped over in this presentation. Am I turning this back over to Peter or Rochelle?

Discussion & Task Force Recommendation Worksheet (00:15:39)

Rochelle Prosser

It would be me. Thank you so much, Rachel, for that wonderful overview. At this time, we will begin the Task Force recommendation worksheet, but before we begin that, does anyone have any questions before we go to the recommendation worksheet? Yes, I should see lots of hands. Peter, I will let you control the questions on who came first.

Peter Karras
Sure. The first hand up I see is Rae Walker.

Rachel Walker
Hi, thank you. I would appreciate a quick clarification as I am familiarizing myself with this. In the section as it is phrased about legal action against patients, with the way this is written, does that definition include legal action against patients' parents or legal guardians?

Rochelle Prosser
That is a great question. I had that question myself.

Rachel Nelson
In the preamble discussion of the proposed rule, you will find that we do talk about what "patient" means in this context, and in this context, it means the person who is the subject of the EHI, so, the person receiving the care. In this context, "patient" does not mean "individual" in the same sense as it is used in the HIPAA privacy rule or in the same sense as we used it in the privacy exception. I am trying to be very careful here and make sure that I am only saying exactly what we have said in the rule, because procedurally, I cannot say more than what is in the published rule, but in the published rule, we do address what "patient" means here, and it means the subject of the EHI.

Rachel Walker
So, if I understand it, in the concern on the part of whatever actor was seeking to engage in withholding this information, to not be information blocking, a concern around the risk for parents or legal guardians is not explicitly spelled out in this rule the way it is currently written.

Rachel Nelson
I would have to do a word search to confirm whether the word "parent" appears anywhere in this rule. What we talk about in this rule in the care access condition is persons who facilitate the provision or receipt of care, not just the people who provide the care, but also persons who make receipt or provision of the care possible.

Rachel Walker
Okay, thank you.

Peter Karras
The next hand up is Katrina Miller Parrish. Mike, did you want to jump in?

Michael Lipinski
Yes. Can we go back, just so they can see the care access condition?

Rochelle Prosser
I think that would be Slide 16.

Michael Lipinski
I think that might help.

Rachel Nelson
Fifteen.

Rochelle Prosser
Yes, 15.

Rachel Nelson
We were in the ballpark, though, which is pretty good at that point for slide numbers.

Michael Lipinski
"Other persons involved in providing or facilitating reproductive healthcare."

Rochelle Prosser
So, I am looking at this, and I am unclear as to whether those other persons involved would be parents, because parents are not necessarily providing care. Parents would be the person bringing them to care, not necessarily providing that care. We are also responsible to pay for that care, but not necessarily provided under the provisions. Correct me if I am wrong, but we are to provide food, clothing, and shelter. Access to care…

Michael Lipinski
I do not think that is the word you want to focus on.

Rochelle Prosser
Yes. Could I have some clarification?

Rachel Nelson
I would encourage you all to read the preamble. I know you have limited time and are very focused on the reg text, but the preamble is part of the package deal, and our preamble discussion is where you would find different wordings than just "provide" or "facilitate" in talking about things like making the receipt or provision of the care possible.

Rochelle Prosser
Okay. For the sake of time, let's make time for our workgroup to go back and look at the preamble, and we can carve out some time at the beginning of our next meeting before we start on the next list in case there were any questions there. So, I will send it back for questions, Peter.

Peter Karras
The next hand raised is Katrina Miller Parrish.

Katrina Miller Parrish
Thanks. I was looking at what I think is the next slide, the one that had the references to 45 CFR. I was having trouble finding the exact definition, so, just in case everyone was having that level of trouble, it looks like the first one is just referring to "healthcare provider" and the second one is referring to both "reproductive healthcare" and "person," so if anyone wants to find those definitions, they are in there. What would be great in the future is maybe creating a slide with those definitions just so we do not have to go search around for them, and then I agree on the preamble. If we are really referring to the preamble, it would be great to actually have that on a slide to be able to start off with that understanding and then work through it. I will admit that I had a lot of trouble trying to find the right text, as Rochelle and others are aware, so I would appreciate any actual text and confirming links so that we know we are finding the right information to review. Thank you.

Rochelle Prosser
That is great feedback. Rachel, you have yourself off mute.

Rachel Nelson
Do you want me to go on mute any time I am not responding? I did not take that as a question so much as a process improvement suggestion.

Katrina Miller Parrish
Correct.

Rochelle Prosser
Okay, no problem.

Peter Karras
The next hand is from Dominic Mack.

Dominic Mack
Yes, good morning, everybody. This question is coming from a provider, but is it presumed that the patient is in agreement with the exception? I look at it from a provider's point of view, because this is for legal protection of the patient and the provider, but I see where there could be an issue if it did come to a legal action where the patient was not informed and we are on two different pages. So, just like in behavioral health, does it presume that the provider has told the patient, "Hey, your records will be secure, we will not share them"?

Rachel Nelson
So, the patient protection provision is subject to override by the patient. If you are just holding it back to protect the patient and the patient says, "I hear you, but do it anyway, it is my risk to take," then you cannot meet the patient protection condition at that point. As noted earlier, you only have to meet one or the other for the exception to apply in the withholding of the information, not the information blocking.

Dominic Mack
I guess I did not see in there where the patient consent was part of the prerequisites.

Rachel Nelson
Go back up. I thought we managed to fit the whole thing. Go back up to the patient protection slide, No. 14. That is where the definition of "patient" was. "When implemented for the purpose of reducing the patient's risk of potential exposure to legal action, the practice must affect only the access, exchange, or use of whatever specific electronic health information the actor, in good faith, believes could expose the patient to legal action because it shows or would carry a risk of supporting an inference that the patient obtained reproductive healthcare, inquired about or expressed an interest in seeking reproductive healthcare, or has any health condition or history for which reproductive healthcare is often sought, obtained, or medically indicated," and then, the second requirement to meet this condition is that whatever you are doing, when it is implemented for the purpose of reducing the patient's potential exposure, must be subject to nullification by an explicit request or directive from the patient that the access, exchange, or use of the electronic health information occurred despite the risk to the patient that the actor has identified.

Dominic Mack
All right, got it. Thank you.

Rochelle Prosser
Thank you for your clarification, Dr. Mack. All right, if there are not any further questions, I will ask Accel to show the spreadsheet, and we will begin working through the legal clauses. Thank you for this robust discussion. It is very good. Dr. King, I hope you had some of your questions answered from our first meeting last week. Sheryl, would you like to take yourself off mute and comment?

Sheryl Turney
Sure, thanks. I did want to mention that with all the comments that were going in the chat and everyone speaking, the patient should really be an authorized individual that the patient has identified, which could be a caregiver, and also what is allowed by law, and we all need to recall that in many states, there are laws that limit the ability for parents to have access to minors' information if they are above a certain age, and it is not consistent from state to state. I do not know that changing the definition of "patient" here is the intent. I think it always has been to go back to HIPAA in terms of what is defined in terms of the patient, and that always includes the authorized caregivers and/or those allowed by law.

Rachel Nelson
We were specific to right access. I just want to clarify that when you say that, you are referring to right of access, who has the ability to exercise the individual right of access.

Sheryl Turney
Exactly.

Rachel Nelson
I do want to step in and clarify two points, just as reminders. If you are operating under HIPAA or under a state law, and that law that applies to you forbids you from disclosing particular EHI to particular people, do not do it. We do not need to explicitly address that scenario within the exceptions because it is required by law, and I can provide links to a couple of relevant FAQs in the chat if that would be helpful. If you are required by law to withhold something from someone, then you do not need to get to this exception. You just need to follow that law.

Rochelle Prosser
If you could provide those links, Rachel, I am sure that, as we are going through this document, we will have some further discussion later on. Thank you for that.

Rachel Nelson
I appreciate you guys making a plan to look into the preamble. The other thing that we do address in the preamble is that meeting this information blocking exception would mean that your practice was not information blocking. Whether you are meeting your obligations, if you are a HIPAA-covered entity or business associate under the HIPAA privacy rule, is a separate situation, so meeting this exception would not do away with your obligations to provide the individuals access under the HIPAA privacy rule. That was just a second point of clarification that I did not want us to miss.

Rochelle Prosser
Thank you for that, Rachel. I appreciate it. All right. Without further ado, we can begin the first rule. I do not know about you, and I am a younger person, but this print is very small. Ah, thank you. All right, so, the first one, if we can go back to the left, is Rule No. 171.206, and Hannah, I see you are already in. So, this one is looking at patient access and the exception. We have pretty much gone over it, and you are welcome to go into this workgroup document and draft. I see that we have some questions in Column G. For those that have put their initials up, I would like to go in order and start discussing your questions regarding the patient. KMP, Katrina. Go ahead.

Katrina Miller Parrish
That is me. From your intro, I understand that we are basically looking at the regulations according to the law, which I would believe are really focused on reproductive care access, so I think my comments would be backlog, considering that there may be other situations where this kind of care access protection would be important, and some other comments supporting that as well. Really, that is where I was going with that, and I understood that that may not be what we are focusing on right now.

Rochelle Prosser
When we say “reproductive,” and Rachel, correct me if I am wrong, there are other use case scenarios for family planning which would come under reproductive health, such as if you are an oncology patient and you need to have access to reproductive services to either prevent pregnancy or cause pregnancy after you have finished, so that would be part of that care that would have to occur for you to receive treatment for another chronic disease condition that would require you to access reproductive services. So, that is one area, and IVF fertility would be another. Rachel, please keep me honest if there are any others.

Michael Lipinski
While I talk, Rachel, can you see if you can grab…? Yes, that is exactly it. That is too funny. Grab it from Office for Civil Rights (OCR)’s rule. So, just for clarity, because I know this came up originally when we were doing the presentation to HITAC on the entire rule about this definition of reproductive healthcare and if that includes gender-affirming care and other possible ways to interpret it, as you just mentioned, Rochelle. So, to be clear, we had only proposed the definition that has already been codified for reproductive healthcare by OCR, so it is a cross-reference to their definition, and I would encourage you to look at what they said in the preamble. I was wondering if I could bring up at least the citation, and I will

throw that in the chat, to when people brought up gender-affirming care as well in their role, because obviously, you would not be surprised that it could come up in that role.

I do not think we are going to say more on that, just to be honest with you. It is not our definition, so we will not control the interpretation of that definition. That will be OCR. You can make a comment to your views on that, of course, but we did not propose to independently define reproductive healthcare. We only proposed to take the definition, and this is part of the entire consistency between our rule and the HIPAA privacy rule on reproductive healthcare. So, I will grab at least the relevant part of their preamble where it was addressed, because they essentially said they were not going to a list of all types of care that could fit under reproductive healthcare, and it is best just to look at the definition of it, and if you do have concerns of what is included in that definition, feel free to raise them, but I just want to be clear on what we actually propose.

We did not propose a definition for purposes of information blocking. We proposed to essentially incorporate the definition that was codified by OCR in their regulations so that there would be consistency in that definition. Rachel, I do not know if you were able to grab it yet. Oh, it looks like you did. Awesome. It is in the chat. I can grab the on-point preamble part, and I will turn it to you right now while I do that.

Michael Lipinski
The preamble was going to take me another minute versus just digging into current 160.

Rochelle Prosser
Thank you for that. I appreciate the consistency, and I think Katrina does as well. For the purposes of the group, trying to have that consensus and uniformity between where the law originated, what other definitions are currently, and what we are moving forward in this proposal helps to streamline and at least start something along the lines of ensuring that we protect patients in their most vulnerable circumstances, and although we are not giving an exhaustive list, it may be better for the blanket coverage where we are not asking folks to pick holes and target. And so, I just want you to think about that in a broader context as we move forward, and where we see, if there is an issue, we can always discuss it at a higher level other than here. I see a few hands, so I will open it back to the floor. Sheryl?

Sheryl Turney
Thank you so much, Michael, and I wanted to add to that point. One of the challenges that payers have had, which I do not has been resolved and which I do not believe the definition resolves, is that when it comes to claims data, we can use Current Procedural Terminology (CPT) codes or something to come up with an alignment as to what that definition means, but when it comes to clinical data, which is really a big part of this, there is not that clear alignment. So, I just think that we need to note somewhere that the definitions are going to be used and will have to be interpreted, and as far as I know, there is not yet any large-language model that says how you would discern either maternity, substance abuse, or gender-affirming in clinical notes today. We have asked and looked around and have not found that, so everyone's interpretation may be slightly different, and that has to be at least taken into consideration related to the participants in the data sharing because I think most entities are going to err on the side of caution, so, hopefully, that does not fall under information blocking, but it falls under protecting the needs of the patient.

Rochelle Prosser

Thank you for that, Sheryl. Rae?

Rachel Walker
Thanks. On the same lines, I suppose I can see the value here of aligning definitions and not trying to pick out exceptional cases. I just want to clarify with this threshold condition that includes with it that the institution would have clearly spelled out their reasoning and particular policies for protecting certain groups of patients might be. The definition of reproductive healthcare can be so culturally specific beyond what the federal government requires, so does that leave room for institutions to operationalize these definitions in a localized way that might be, as some might say, more expansive than one might strictly think of under the current federal definition of reproductive healthcare, which is also still quite abstract, to the point that was just made about clinical data.

Rochelle Prosser
Where ONC would look more to the regulations and the context of the law, what a healthcare facility does or does not do within the confines of the law within their operation and approval by their legal system, they are entitled to go as far or as simply as they would want. I do not know if there is a better answer for that. My understanding is that the ONC is not going to tell a healthcare provider or facilitate how to write a policy as long as it does not interfere with the broader federal regulations and the laws that are there to protect the public and other entities. I am trying to be as social on that as possible without also getting myself into trouble. Would the ONC like to comment, or shall I move on? Michael? All right, well, they are muted, so I guess they are in agreement. Kris?

Kris Mork
Thank you. I am building on the commentary provided by Rae. I was going to say something similar after expressing my disappointment that we are absolutely limited to reproductive health. As someone with a target on their back because they seek gender-affirming care, I am disappointed in that restriction, and I see an opportunity here. I do not think we need to just cite that definition that is on the screen that is all matters relating to the reproductive system. I think there is room to include language that says exactly what Rae did, that we do not see a prohibition on interpreting that broadly.

As a concrete example, take vaginoplasty and metoidioplasty. These forms of gender-affirming care interact with the reproductive system, and therefore, for any institution that chooses to make use of this exception under that definition, we consider that based on our understanding of this definition to be something they are allowed to do. We are not saying they have to, but we are saying that if you nail down that definition for yourself, you have met the intent and can be presumed to be in compliance with the rules of this exception, and therefore, you do not face penalties for information blocking.

Rochelle Prosser
I see what you are saying, Kris, and I will happily disclose that I live in Florida, and so, I can uniquely understand the challenges of what you are discussing, but I also do believe that some of the definitions of the care that you are discussing also lie in other realms that would then be covered explicitly under the reproductive care without specifically having a target on your back because you are saying we are moving that into gender-affirming care, because that happens in many instances, either in newborn care where the parent needs to decide what sex this child is going to be, should there be a birth defect, and also in allowing the child to develop between the ages of 12 and 14, if they had a chronic condition that would preclude

them from having that gender-affirming natural transition from their own body because they had either a chemoactive agent or some other medication that would preclude them and prevent endocrine function. So, I worry that, in not keeping it broad in general, it will, by reason of omission, put a target, and I do not think that is what ONC wants to do, so we want to at least align it, broadly in this context, to provide those individual challenges, should they arise.

Kris Mork
I think we are substantively saying the same thing. The definition that is laid out there can be interpreted many ways. An institution that chooses to limit it just to what we stereotypically think of as reproductive health is in compliance with the rule as stated, and I think it is safe to note that an institution that has a much broader interpretation… So, to include chemotherapy that may interfere with reproductive function, as long as it touches in some way on the reproductive system, if your policy adopts a broad definition, however it defines it, without necessarily putting in examples like oncology or gender-affirming care, as long as you have a sound basis for doing so, you are presumed to be in compliance with this exception. I guess that is what I am looking for, to make it easy for those institutions or actors to say, "I am applying this exception, I am covered, and I am safe" because you have written down, for example, in the preamble, that the intention is that you can interpret this broadly.

Rochelle Prosser
I think for the ability to really come and say definitively for what you are asking, I am not sure that the ONC can come and make that position because there are so many different broader use case scenarios, and for the purposes of just getting this across the threshold to get it on the books so we can at least say, "Okay, that is the law that we are going to point ourselves to" as we begin to think about or reimagine crafting healthcare policies that are either protective or omissions to either cloak, hide, or protect, again, I do not think the ONC can definitively say what you do as a healthcare facility, but as long as it follows the context and law of your state, your legal counsel, and the healthcare facilities under your license, then you would be able to go ahead and craft it however you choose based on those regulations. We still have to follow the context of the law. We cannot say, "Okay, we are going to break the law." We have to make sure we fall within the legal definition of that. We cannot say, "Okay, the policy is here, so we are not going to follow the law." That would put ONC and everyone else in jeopardy. We still have to follow the context of the law.

Kris Mork
I do not intend to be saying we should break the law. I am seeing that there is a legal definition of "reproductive healthcare" that includes anything that relates to the reproductive system, and therefore, looking at that definition, we could be explicit that we understand that to mean that not just the small set of things that people normally think of fall under that, that it is okay for an institution, under its state laws, to apply a policy that is as expansive as possible without telling them what that policy is. I am okay with being discreet about it, but we are making it clear to them that that is a freedom they have under this legal definition so that everybody is on the up and up there.

Rochelle Prosser
On that, I think we can concur.

Kris Mork
Cool!

Rochelle Prosser
All right.

Michael Lipinski
I just want to say this one more time. We appreciate all comments. I already see them on the screen. I just want you to again be aware of the guardrails of our proposal. When a final rule comes around, we only propose to adopt a definition that another agency defines. We do not propose to define "reproductive healthcare" ourselves in this rulemaking for the purpose of information blocking.

Rochelle Prosser
I agree. I am trying to walk a fine line here, Michael. Thank you so much. Lee?

Lee Fleisher
Not to get too wonky, but I will for a second, because you keep saying "law." I assume this is in reg or statute.

Rochelle Prosser
Statutes and regs, yet.

Lee Fleisher
But the definition is not in statute, it is in the reg from the OCR, correct?

Michael Lipinski
Correct. That is semantics, but statutes and regulations are both considered law for purposes of our general counsel.

Lee Fleisher
Right, but having overseen the implementation of Emergency Medical Treatment and Labor Act (EMTALA), I am just concerned because reg could change. Have we considered any concerns about being this explicit or tying it to another regulation over time? That is why, as opposed to any kind of statutory, and is there a larger statutory authority with regard to information blocking, or was it really given at the discretion of the secretary?

Michael Lipinski
So, our statute is pretty clear for information blocking. There is a definition that Congress gave us in the Cures Act, and our job is to interpret the terms of those definitions, such as what a healthcare provider or an interference is, for example. More specifically, the statute gave it to the secretary, which was delegated to ONC, but still has to be signed and approved by the secretary, to identify reasonable necessary activities that would not be information blocking, and to that point, we call them exceptions. This is one exception that we are proposing. There is no additional statutory legislative history on this point, obviously. The *Dobbs* case came after the Cures Act and, I think, HIPAA. Just a word on the process so people understand how regulations are developed, before they are even proposed for the public to comment on under the Administrative Procedure Act, they do go through a vetting process in the department, and even all of the

federal government, including the Department of Justice, which reviews our regulations before they are put out. So, it is just part of the process.

Lee Fleisher
So, Michael, I have lived through that, and having watched regulations change, is there an opportunity, just like in EMTALA, where reproductive health is specifically called out, but being a little broader, to include reproductive health? That is my comment because you make a comment as part of the notice and comment rulemaking in this area, so that is why I wanted to bring it up. This is not statutory; it is regulatory.

Michael Lipinski
Right, and regs can always change. The interpretations of the statutes can change as well.

Lee Fleisher
[Inaudible – crosstalk] [00:52:54]

Michael Lipinski
Right, exactly. So now, our interpretation of all these terms, like what interference is, is subject to the court, and they do not have to defer to our interpretation anymore, so there is that. As you pointed out, regulations can always change. All the exceptions are done via the regulatory process, so any administration can propose rulemaking to change exceptions, or propose new ones, or remove them. That is the process that has been set up through statute. I hear your position. Like I said, I welcome these comments, and I am not discouraging you from making any of these comments, I am just giving you the legal guardrails that we will be under, just to level-set expectations. Under the Administrative Procedure Act and case law, when you propose something, if you have not proposed something else, there is substantial legal risk to finalize something you did not propose because the public has not had an opportunity to comment on that. There are these concepts of logical outgrowth, and that is why I am emphasizing that we did not propose our own definition of "reproductive healthcare" for the purpose of information blocking.

Lee Fleisher
Right. I am actually saying something different, Michael. You specifically anchored on reproductive healthcare.

Michael Lipinski
Yes, for the exception. It is very limited.

Lee Fleisher
It is very limited, and we have heard comments today, and there could be logical outgrowth for additional comments. I realize there is some risk, and I assume the HITAC comments are part of the official record, such that logical outgrowth could be construed.

Michael Lipinski
I do not represent a general counsel, so I have to be clear about that. I am not allowed to give legal advice or guidance. But just because you get a comment on something that you should do, that does not mean that everybody… The entire public did not know about your comment and then comment on it, so, logical outgrowth is really based on what was proposed. What could you foresee, based on what was proposed

by the agency, on what comments came in, based upon which you changed your view? Like I said, a lot of lawyers looked at our rule.

Rochelle Prosser
Let me help you out, Michael. Lee, for your question, if you feel that there is something that needs to be taken to a higher level that we just cannot address here due to the confines of what the goals and purposes are for our meeting in this workgroup, we are welcome to bring it to Eliel and the other leaders on the HITAC commission, but just understand that in this context of where we are within this workgroup, we really have to stay within the boundaries of what is presented in our definitions and approving those definitions.

Michael Lipinski
No, you are not. You can make any comment. Any comment can be made on a rule. We get comments all the time about being too narrow, overly broad, or ambiguous in what we proposed. All those comments are welcome. That is why I am saying these comments you have on the screen are very much welcome. I am just trying to give you what we did and did not propose. We will give you alternative parts of the rule, like alternative proposals. We have the main proposal, and the alternative proposal puts out a bunch of different options. Sometimes it is how many days we should apply to a certain set of circumstances, like under the infeasibility exception. In that case, the public has knowledge that we could go in any one of these directions because we have told them that this is a possibility.

While we have a main proposal, there are all these other proposals. I was just trying to explain that part to you, like how the rulemaking process works and what we will likely be looking at in a final rule and can be in what we can do in a final rule, even based on comments, because it is not something we proposed. So, that is all I was trying to get at. In terms of interpretation of the definition that we propose, **[inaudible] [00:57:55]** obviously can make any interpretation of their own definition. I was just pointing out that we did not propose adopting the OCR's definition of reproductive healthcare or creating our own definition. Then, we could be talking differently. That is all I was trying to point out, what we actually propose. The definition that you see in the chat is not a definition we came up with, it is a definition that has obviously already been codified, and for various reasons, we thought it best to propose adopting that same definition.

Rochelle Prosser
Thank you, Michael.

Michael Lipinski
But yes, comments like "Hey, you missed this" or "We are not sure this is in scope" are always welcome. I want to be clear about that.

Rochelle Prosser
All right, thank you. Hannah?

Hannah Galvin
Thanks, Rochelle. I have two quick comments. I also was very confused, and I think part of it had to do with the reference to the definition of reproductive healthcare in 45 CFR 160, and it was not until I searched the rest of the HIPAA legislation and found several paragraphs about reproductive healthcare, the prohibition, and the rule of applicability where reproductive healthcare is really carved out in HIPAA. Just the fact that

there is a definition along with all the other definitions in 160 left me very confused about why we are carving out just reproductive healthcare here. So, I might suggest to FUP and ONC to also reference that 45 CFR 164(C), the part where HIPAA is actually carving out those regulations around reproductive healthcare, because just as a reader of this rule, I was very confused about the definition at the top. But I am no lawyer by any means, so I do not know how things should be referenced.

Secondly, just to call this out, I know we have talked about gender-affirming care. Thank you, Rachel. I appreciate that. I really appreciate the discussion about gender-affirming care and echo that. The other thing I want to call out is about immigration, and I put some of those comments in the document itself, and Rachel, since you live in Florida, you are probably very familiar with this. There has been evidence of immigrants not seeking care after laws have been passed requiring them to disclose their immigration status, and I understand that there is no legal precedent to go on around information blocking, but I did not want to lose the chance to advocate on behalf of needing more protections around other areas in addition to this narrow definition. That is all I have. Thank you.

Rochelle Prosser
Hannah, I thank you for bringing those points up, and thank you, Rachel, for referencing the preamble. I think I have spent a week and a half going through line items on all of these areas, and I want to allow the ONC to lead where applicable so that we stay within the scope. The comments are valid. As a new immigrant coming to this country who becomes a citizen or is in the process of becoming a citizen, there is that misconception or misunderstanding of what is covered and what they are allowed or not allowed to do as they come from different countries, so, thank you very much for bringing that up. Another area that may have different governance is the native Indians and what their treaties say in terms of what law they will follow within their lands and borders, and I would defer to Sooner on that to discuss more to see where it is or it is not applicable and to provide comment in that space to ensure that as we look for equal protections under the law, we are taking in all populations, whether newer or older. Sooner, would you like to comment, or shall I continue?

Sooner Davenport
No, thank you. I believe I was in a listen-only mode last week, so I think I asked a question similar to this about the question at the time, which was about acknowledging tribal law, because that is critical to acknowledging the public health jurisdiction or the health system of the tribe or Indian Health Service, which gets more complicated, and sometimes it is the Indian Health Service (IHS) versus the tribe. I believe there was follow-up that there is something addressed in the Cures Act which better defines that because the issue that does come up is that tribes will bring forward their standard or their law, and then, what happens a lot with Indian Health Service or with states is they will say, “Well, we do not need this, we need this other document or this other process to validate this.”

So, I think that is where we see that often in terms of defining what the system is and what it looks like as well. And so, I think once we do that, then yes, we can look at some of those other questions, especially for this topic specifically. I will say that for the reproductive health, they tend to follow how Indian Health Service defines reproductive care, so that closer look would need to be through that lens to inform what occurs there. Is that helpful to the group, Rochelle?

Rochelle Prosser

Yes, that is very helpful, thank you. Rachel or Michael?

Rachel Nelson
I would find it helpful to let you guys distill that into writing. I sometimes can process things easier when I see the words than when I hear them, and that is a me thing, but I would appreciate you all accommodating that. I will just note that I can give you a citation to the Cures Act final rule. It was our regulation where we said an information blocking actor subject to a state or tribal law that expressly prohibits a certain access, exchange, or use of EHI can comply fully with a state or tribal law without implicating the information blocking regulation, and I can probably find a better chunk of discussion once I see in writing what your question is so I can better process it because we have said in a couple of different places how tribal laws factor into things like "required by law" for purposes of the information blocking exception and the information blocking definition where the information blocking definition itself says "except its practices that are not required by law."

So, we interpret "required by law" in the Cures Act final rule, which is probably the first place I am going to give you a link to, but I did just want to note that I am about to share something that may be helpful, but it may not exactly answer your question because, again, it is a me thing, and I am not sure I fully understood it.

Rochelle Prosser
That is fine, Rachel. I appreciate that. Bringing up that section will help us craft it a little bit better, and Sooner, with your comments there, they are very applicable. Would you like to lead or place a comment under this section so that we can add that or put reference to it? Hannah, I ask you to do the same, where you are referencing Rule 45, if you could provide that in the comment section on this spreadsheet so that we can have consistency, or at least have a point of reference to help us guide under HIPAA. Can you raise your hand or voice your assent? I will need a yes from Hannah and Sooner. You are both on mute. Go ahead, Sooner.

Sooner Davenport
Yes. Is this something we will be discussing in the future? I am a little unclear on that.

Rochelle Prosser
Yes, we will discuss it at our next meeting, just to have the rest of the group know where we are pointing.

Sooner Davenport
Yes, I can do that. Thank you.

Rochelle Prosser
Thank you, Ben. Hannah, was that a yes?

Hannah Galvin
It was, yes.

Rochelle Prosser
Okay, thank you. All right, Ike, go ahead. I am ready.

Steven Eichner
Thank you. I have two points. I am a little concerned about impacts on public health reporting, especially in regards to pregnancy status, which is a variable we often collect in association with infectious disease and other health status components, as well as things like birth defects, because that information is really vital for controlling disease and managing things in that space. Outside of public health, thinking about it from a patient safety perspective, looking at things like pregnancy status where there might be referral for radiological treatment or something else that would be at risk, it would be good to catch that earlier rather than later, so, thinking about those impacts of blocking that information. There are also some technological impacts in terms of looking at actually operationalizing that information exchange where a field like pregnancy status might be required from the data exchange standpoint. If you are blocking the exchange of that information, what then becomes the technological change for populating that field? So, that is a technology impact that would need to get worked through, and potentially even looking at changing some of the implementation guides we supported where there is not an option to say "nonreportable."

Rochelle Prosser
Rachel and Michael, would you like to take the first stab, or would you like me to answer?

Rachel Nelson
If you feel like you can, please go ahead.

Rochelle Prosser
I certainly can. So, first of all, Ike, I want to thank you for your questions, and yes, they are valid, but for the sake of protecting information where it is going to be used against you, I do not believe that the ONC is saying in this instance here that we are not going to provide the data to fill the fields. What we are looking at is if we are going to share that with an entity that is going to use this information for a purpose or manner that will be hurtful to the general public, who is affected by the disclosure of that information. So, without being a contrarian on the group, I do not think that we are saying you cannot collect that information and you cannot populate that field, I think, that that information and the access to that information for very critical care, where necessary. It is what is included behind that.

I agree, you do not want to know that somebody is pregnant when you are providing a radiological event where they will be hurt, but then they can go further with that test to check and see if there is seaming in there. Depending on the age, that becomes information searching for punitive purposes. So, in those instances there, we do have to provide privacy and protection for the general public where it would be applicable.

Steven Eichner
I understand that there is nothing in regulation that says it cannot be collected. The regulation is about blocking the disclosure. That is exactly the issue, that from a public health perspective, looking at identifying what constitutes the definition of a nonmedical risk to the individual, it enables a provider to not report information that is required reporting under state law, and that interferes with public health operations.

Michael Lipinski

That is not what it does. There is no preemption, and we make that clear in the preamble. So, if there are other laws that you have to comply with, yes, you will not be an information blocker, but you will be subject to that other state law that requires reporting of certain information. We do not have that. HIPAA is different. There are different things going on there with their law and preemption, but our law has no specific preemption granted. As Rachel notes, these are voluntary exceptions. What it does is not double penalize you, where you could be an info blocker for not providing it and because of state law. What it does is take away the information blocking double penalty.

Steven Eichner
It does complicate things a little bit on the enforcement side. If individuals are then claiming an information blocking exception, it puts an additional burden on public health to then potentially have to pursue it legally, so that may be something we want to be cognizant of going forward.

Rochelle Prosser
I think that providing that legal premise of why they need it would then provide clarity on the use case scenario in the case for what you are saying there, Ike, but for the purposes of what the guideline is or the rule that is ahead presented in front of us to provide uniformity between the different government entities in terms of what the definitions are, I think that the scenario that you are bringing up may or may not apply, because again, as I was saying with Kris, we are looking at exceptions to the rule, as you are saying, in this case here, and so, where legal action will have to preside, then that would fall under a use case or one by one.

Every hospital has their own policies and guidelines on how they provide care when it comes to diagnostics and what conditions are other conditions that are there. They have to follow those hospital policies and procedures first in order to protect the public, and that would also include any information sharing that would have to occur for the public health monitoring. Although what you are saying can have an issue in terms of sharing, I do not think that we are using this purpose to prevent the natural course and order of sharing information for public health, such as “This is a birth” and “This is a birth defect,” all those other things that should actually be there because there are other laws governing that. I hope that answers your question.

Peter Karras
Rochelle, I just wanted to do a time check. We are scheduled to go to public comment in about a minute. Kris, I see you have your hand up.

Rochelle Prosser
Thank you. Go ahead, Kris.

Kris Mork
I was going to respond to the excellent comment that Ike brought up. The way the exception is constructed, you must make your policy as narrow as possible to provide the intended protections, and crafting it in a such a way that precluded you from sharing information for public health use is unlikely to survive that “as narrow as possible” scrutiny. Perhaps there is a place in the response to the comments that have been made where ONC can make it clear that the intention is that you still have to report for public health because any policy that denied that would not ascribe to that notion of being a limited case exception.

Rochelle Prosser
Thank you for that very relevant point. With that, I will turn it over to Peter to open up public comments.

Public Comment (01:17:32)

Peter Karras
Sure, thanks, Rochelle. So, we would like to open the meeting for public comment at this time. If you are on Zoom and would like to make a comment, please use the hand raise function that is located on the Zoom toolbar at the bottom of your screen. If you are joining today by phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. I will pause for a moment to see if we have any members of the public with any questions or comments. I do not see any raised hands at this time, but I will wait a little bit more and just throw out a couple of reminders that the next Group 3 meeting will be on Thursday, August 8th, from 11:00 a.m. to 12:30 p.m. Eastern. I will remind you that all HITAC meeting materials can be found on HealthIT.gov. I am not seeing any raised hands at the moment and Accel has notified me that we do not have any folks on the phone who wish to comment, so, Rochelle, I yield back the rest of the time to you.

Next Steps (01:18:46)

Rochelle Prosser
Thank you, Peter. I just want to thank everyone on the call today. As you can see, this is why you were chosen to be here. This was such a wonderful, robust conversation. For the next steps, our takeaway today is that when we meet on the 8th, we will meet from 11:00 a.m. to 12:30, but before that, I would like to have a moment where we carve out five or 10 minutes to revisit this to allow those on the call to go through the preamble and have a little bit of clarity before we move to the next topic. We have a lot to do, and we only just scratched the surface. I really thank you for having an openness and willingness to have this topic discussion. I encourage you to go to the working document and add your comments there, and I really look forward to our meeting next week, and hopefully we can move forward in these rules so that we are able to bring them to the full meeting on 9/5. So, at this time, I will turn it over to Kris. If there are any questions from the panel, please raise your hand. Otherwise, I will return the rest of the time, and thank you, Rachel, for the links. All right, Peter?

Peter Karras
Thanks, Rochelle. The meeting is adjourned. I do not see any other hands raised or any questions coming through.

Rochelle Prosser
Thank you for coming, everyone. I look forward to seeing everyone next week. Take care.

Adjourn (01:20:46)

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT
No comments were received during public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Katrina Miller Parrish: Person means a natural person (meaning a human being who is born alive), trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Katrina Miller Parrish: Faciliatator

Michael Lipinski: The rule will publish on Monday. At that time, citations will be readily available.

Katrina Miller Parrish: Thanks Michael!

Rachel Nelson: FAQ "Would it be information blocking if an actor does not fulfill a request to access, exchange, or use EHI in order to comply with federal privacy laws that require certain conditions to have been met prior to disclosure?" https://www.healthit.gov/faqs?f%5B0%5D=term_parent%3A7011

Rachel Nelson: FAQ "If an individual requests that their EHI not be disclosed, is it information blocking if an actor does not disclose the EHI based on the individual's request?" https://www.healthit.gov/faqs?f%5B0%5D=term_parent%3A7011

Anna McCollister: Hi all - Just letting you know I'm on.

Rochelle Prosser: Welcome Anna

Rachel Nelson: FAQ: "If an actor, such as a health care provider, operates in more than one state, is it consistent with the information blocking regulations for the health care provider to implement practices to uniformly follow the state law that is the most privacy protective (more restrictive) across all the other states in which it operates?" https://www.healthit.gov/faq/if-individual-requests-their-ehi-not-be-disclosed-it-information-blocking-if-actor-does-not

Rachel Nelson: 45 CFR 160.103 "Reproductive health care means health care, as defined in this section, that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes. This definition shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care." https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-160/subpart-A/section-160.103

Katrina Miller Parrish: Appreciate the consistency and referring back to already established definitions.

Michael Lipinski: https://www.federalregister.gov/d/2024-08503/p-556

Michael Lipinski: https://www.federalregister.gov/d/2024-08503/p-560

Michael Lipinski: https://www.federalregister.gov/d/2024-08503/p-567

Rachel Nelson: If anyone wants to browse the information blocking statute, its text is available here: https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section300jj-52&num=0&edition=prelim

Rachel Nelson: Another way to say it might be: ayone can make any comment they like. Which comments we could act upon in a final rule is constrained by administrative procedure law.

Rochelle Prosser: Thank - you for that clarification Rachel

Rachel Nelson: Hannah - we discuss that relationship in the preamble.

Lee Fleisher: Thank you Rachel for referencing the statute. This is helpful and how the APA constrains what falls within logical outgrowth

Rachel Nelson: Information blocking exceptions are voluntary. They do not override other law that requires a disclosure.

Rachel Nelson: https://www.federalregister.gov/d/2020-07419/p-1707

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

RESOURCES

HTI-2 Proposed Rule Task Force 2024
HTI-2 Proposed Rule Task Force 2024 Group 3: Information Blocking and TEFCA - August 1, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO, on 9/10/24.