ASTP | Health IT Advisory Committee

Health Information Technology Advisory Committee

HTI-2 Proposed Rule Task Force 2024 Virtual Meeting

Group 3: Information Blocking and TEFCA

Transcript | August 29, 2024, 11 AM – 12:30 PM ET

Attendance

Members

Rochelle Prosser, Orchid Healthcare Solutions, Co-Chair
Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
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
Kris Mork, Leidos
Randa Perkins, H. Lee Moffitt Cancer Center & Research Institute
Naresh Sundar Rajan, CyncHealth
Rachel (Rae) Walker, University of Massachusetts Amherst

Members Not in Attendance

Sooner Davenport, Southern Plains Tribal Health Board
Dominic Mack, Morehouse School of Medicine
Anna McCollister, Individual
Katrina Miller Parrish, Patient.com
Eliel Oliveira, Harvard Medical School & Harvard Pilgrim Health Care Institute
Zeynep Sumer-King, NewYork-Presbyterian
Sheryl Turney, Elevance Health

ASTP Staff

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

Presenters/ Discussants

Mark Knee, 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 meeting on Information Blocking and Trusted Exchange Framework and Common Agreement (TEFCA). I am Peter Karras with the Assistant Secretary for Technology Policy and 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. Public feedback is welcomed throughout the meeting. Comments can be made via the Zoom chat feature. Also, as a reminder, there is scheduled time for verbal public comments towards the end of today's agenda. I will now begin the meeting with roll call of the HTI-2 Proposed Rule Task Force Group 3 members. When I call your name, please indicate that you are present, and we will start with our cochair. Rochelle Prosser?

Rochelle Prosser
Present. Good morning and afternoon.

Peter Karras
Good morning. Shila Blend?

Shila Blend
Good morning, everyone.

Peter Karras
Good morning. Hans Buitendijk? Sooner Davenport has indicated that she will be absent for today's meeting. Derek De Young?

Derek De Young
Present. I do not know if I am muted, though.

Peter Karras
I can hear you, Derek. Welcome. Steve Eichner?

Steven Eichner
Good morning.

Peter Karras
Good morning. Lee Fleisher?

Lee Fleisher
Good morning.

Peter Karras
Good morning. Hannah Galvin?

Hannah Galvin
Good morning.

Peter Karras

Good morning, Hannah. Dominic Mack? Anna McCollister? Katrina Miller Parrish has indicated that she will be absent for today's meeting. Kris Mork?

Kris Mork
I am here.

Peter Karras
Hello. Eliel Oliveira? Randa Perkins?

Randa Perkins
Present.

Peter Karras
Zeynep Sumer-King has indicated that she will be absent for today's meeting. Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Peter Karras
Good morning. Sheryl Turney? Rae Walker?

Rae Walker
Good morning.

Peter Karras
Good morning. Thank you, everyone. Is there anyone I missed who just joined the meeting that would like to indicate their present?

Rochelle Prosser
Dominic sent email stating that he is traveling back to the US today and would try to make it unless he is already on the plane, so it looks like he will not be able to make it today.

Peter Karras
Great. Thanks, Rochelle. Please join me in welcoming our co-chair Rochelle Prosser for opening remarks and to kick off today's meeting. Rochelle, over to you.

Opening Remarks (00:02:44)

Rochelle Prosser
Good morning, everyone, and thank you so much for these past weeks as we have worked really diligently to get to today's point where we actually discuss the recommendations and prepare this document to go over to the larger group next week, when we meet with all the other sections of the HTI-2 group and come together. So, I thank all of you for all your hard work. I have been diligently looking at your comments, working through the documents, and making sure we are all included in the documents where it matters, and I thank you all for your hard work. It has been a tremendous task to come together within these past few weeks, and I look forward to working on this document and completing this task, so thank you, all of you, for all your input and hard work. Next slide, please.

All right. So, right now, where we are in the agenda is to begin looking at the Task Force recommendation sheet, but we have done the call to order and finished the opening remarks, and after we go through the recommendation worksheets, we will begin the public comment and then have the next steps and adjourn. Next slide, please, and I will give it to Peter.

Peter Karras
Great. Thanks, Rochelle. We can actually just move on to Slide 9 and specifically get through the portion of our discussion today. This is going to be the breakdown. We will have dedicated time towards these topic areas, starting with TEFCA, and then we will go into the information blocking enhancements by various sections and subject areas. With that, we can turn it over to Ben to do the screenshare of the recommendation sheet.

Ben Dixon
All righty. Can everybody see the sheet?

Rochelle Prosser
Yes, Ben. Thank you so much.

Ben Dixon
Perfect. Just let me know in the chat or give me a holler if you guys need me to zoom in or move over.

Task Force Recommendation Worksheet (00:05:19)

Rochelle Prosser
Absolutely. Thank you so much. So, we have had an opportunity to look and add some comments, and where we agree, we have made those sections green. So, on those areas, I will not be bringing that up to the group because we came to a consensus unless there is something that the group wanted to add that we have missed. So, for the purposes of the group, for Line No. 2, on this one, if you could make it a little bit bigger for me, Ben, that would be appreciated. I just want to read the proposed rule, to amend the definition of "healthcare provider" under 172.102 so that it is explicitly clear and references 42 USC Section 300.JJ3, and for that purpose, the definition terms of "laboratory" and "pharmacist" have had meetings established for these terms respectfully. Basically, we are adding in "laboratory" and "pharmacist" for the laboratory doctor as part of the "healthcare provider" definition.

The second part is that we propose for the information blocking regulations under 45 Code of Federal Regulations (CFR) Part 171 both "health information technology" and its short form, "health IT," have the same meaning as "health information technology." And then, the third section of this element in terms of definition is to come to agreement on what the business day will entail, and we believe it is Monday to Friday, not including the weekends. All right, we can go to Section J, under Line 2. So, basically, we agree that we will cover that, and Kris, do you want to unmute and say your caveat here?

Kris Mork
Say my caveat here?

Rochelle Prosser
Yes. You were talking about how "the actors and the entity" is different than "the actor is not a covered entity." In each case, examples of the actor and not covered entities would help.

Kris Mork
So, I am not entirely sure. I was trying to capture what I saw in the commentary and what I remembered from the commentary.

Rochelle Prosser
Okay. Ben, can you go over a few sections to where Kris's comments were, just to help her with her memory? There we go, Section G.

Kris Mork
So, DM had provided some comments about how exemption terms such as "non-covered provider" should be clarified. It is not clear what subset of providers this is referencing, etc. To my recollection of the conversation, all of the language is about actors more generally, which can include both covered and non-covered providers, but if there is confusion about that distinction, the recommendation to account for that commentary would be to make it more clear how there can be non-covered providers in addition to covered providers as actors.

Rochelle Prosser
Okay, thank you so much. Can we go over to Section J, please, Ben? All right. So, basically, from the "We further recommend that the ONC summarize the scenarios in which the proposed rule treats an actor as a covered entity different than an actor that is not a covered entity. In each case, examples of actors and not-covered entities would help." Would it be best to have that as part of the fact sheet to say the recommendation to add a clarification fact sheet on what a covered entity versus non-covered entity is, and is that found elsewhere in the Cures Act or in another applicable rule or existing law that references the HTI? I am not sure if that is already spelled out in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule.

Steven Eichner
This is Steve. Recommending a fact sheet is something we can do, but that is more of a parking lot issue than it is modifying the regulation. In other words, it is a suggestion about communication, not a suggested regulatory change. I do think that something that is related to this that is a regulatory change would be specifying in regulation what is a non-covered actor non- Health Insurance Portability and Accountability Act (HIPAA)-covered actor. For example, public health serves multiple roles. How information blocking applies to public health in its different roles is still a little bit of a question. As an example, public health serves as a laboratory and can serve as a health provider in some circumstances, but much of our registry and public health surveillance work is not HIPAA-covered.

Rochelle Prosser
I see. I was looking at the definition terms of "healthcare provider" to include those that are not traditionally added into the space, like the laboratory physician or the pharmacist. Although they are doctors in their own right, they are not necessarily seen in the traditional definition of a healthcare provider, so we were looking at the ability to include them, and that would fall into the covered and non-covered entity. I am looking to ONC to help with this. Mark, thank you for the definition. Do you want to take yourself off mute and discuss that?

Mark Knee
Yes. Sorry, can you hear me now?

Rochelle Prosser
Yes.

Mark Knee
Just to be clear, we are talking about information blocking here, right?

Rochelle Prosser

Correct.

Mark Knee
Okay. So, just to be clear, I am here for TEFCA, but I did work on information blocking before, and I just wanted to share this resource that we put together. It is like a table that breaks down the healthcare provider definition, which I think may get at what you guys are asking about. It is available on our website. So, I just wanted to share that. I think it is a useful resource.

Rochelle Prosser
That was you speaking earlier, correct, Ike?

Steven Eichner
Yes.

Rochelle Prosser
Would that suffice, or do you actually want further clarification here within to remain with the statement from "We further recommend examples in the rule"?

Steven Eichner
I think that may suffice. I thought your point was that, from a comment perspective, keeping our comments focused on rule modification is a better use of our time than looking at things that are outside rule modification.

Rochelle Prosser
Okay, that is a fair point, and it is well taken. So, I guess by a raise of hands for this part here, for the comment section, "We further recommend that ONC summarize scenarios which propose rules that…" Basically, the language is asking for examples within the rule of what is a covered entity versus not a covered entity. For those that want to keep that language here and ask that we recommend examples under the definition section, please raise your hand in approval of leading that language here and making that request.

Lee Fleisher
Can I ask a question?

Rochelle Prosser
Surely.

Lee Fleisher
I have seen a lot of questions & answers (Q&As) in guidance. I have not seen any in regulation, so I am a little concerned about this recommendation. Sorry for being a minute late, but I would certainly be comfortable with "in regulation or urge ONC to develop guidance which includes those examples." As a friendly amendment, I would be more comfortable with that.

Rochelle Prosser
Okay, so we have two things on the table, to say that we include definitions of examples within the regulation, or to have ONC put guidance around the rule as an example, maybe a fact or guidance statement, for what a covered entity is or is not. So, that is what I am hearing here as what we are clarifying. We are asking to either put it into it as a definition and example within the rule or as guidance. Are we clear? That is what I am hearing.

Lee Fleisher

That is what I suggest. I love ONC's belief, but I get concerned when you put examples into rules per se, as opposed to into guidance. You have to do rulemaking if one of the examples is not precise enough.

Rochelle Prosser
All right. So, the first one, for the covered entities, only got three hands, so, based on the numbers, we would look now to… Rae, do you want to put your hand down?

Steven Eichner
Rochelle, this is Steve. I looked quickly at the guidance sheet that ONC just shared. It does not include definitional terms for things like public health. It is a very, very narrow piece in terms of what is defined. It does an excellent job of describing those elements, but it is pretty narrow in band. Again, it is unclear. Are those examples, or is that the entire catalogue of what constitutes entities that are subject to information blocking? Because I think that is something that the community at large is really after at the end of the day. "Am I in the pool or not?"

Rochelle Prosser
I can see where that begins, but also can see ONC's point in saying that for those healthcare providers that we did not provide clarity around, let's standardize the meaning of "healthcare provider" and include all areas where healthcare providers are and other areas where they are not seen as a healthcare provider and include them.

Steven Eichner
Right. I guess part of the issue here, broadly speaking, is what we mean by "healthcare provider" as an individual versus "healthcare provider" as an entity or facility, and what role that particular individual is playing in that particular component.

Rochelle Prosser
So, are we actually splitting hairs here? That is the question I am asking, because an entity could be a developer or a company, but it could also be a healthcare provider. I am wondering if guidance would be better. Mark or anyone from ONC?

Mark Knee
Can you explain one more time what the guidance that you are talking about would cover?

Rochelle Prosser
So, right now, we are looking at standardizing the definitions for "healthcare provider." Ben, can you move to the left, please? I am trying to move my own screen. Yes, all the way to the definition part. No. 1, they are trying to standardize the terms of what a healthcare provider is, and within that definition, we come to covered and non-covered entities that are also added to the definition of healthcare providers, and an example that they give is laboratory, where there is an actual healthcare provider laboratory doctor that reviews the labs and signs off on the results to ensure that we have compliance and accuracy. And then we have the pharmacist, which is also a part of the care team, but they also are a healthcare provider, so we just wanted to make sure that these entities and these individuals, even though they would be seen as an entity such as the laboratory, are actually seen as having a healthcare provider there, and we wanted to standardize across all areas of government to just make sure that ONC has the same definition as United States Department of Health and Human Services (HHS) and elsewhere. Does that help clarify?

Mark Knee
Yes, I think so. Again, if Ben has thoughts, I welcome them. I will say I was not running point on this in drafting, but I would think that that comment would be welcomed. It seems like that might be something that could be addressed in the preamble as a clarification that certain types of entities would be covered under the definition. It

sounds like that is a fine recommendation to make, as long as it does not cause any misalignment with the existing definition. It seems like it is more of a clarification, if I am understanding, which would probably go in the preamble.

Rochelle Prosser
Okay. Can we go back to Column J, please? By a vote of hands, putting a guidance from the ONC regarding the difference between "entity" and "non-covered entity" to provide more clarity under the definition of "healthcare provider." For those that are in favor of guidance and changing the language here, "We further recommend that ONC summarize these scenarios," and the word instead would be "We recommend that ONC provide guidance on the scenarios of a covered entity than an actor that is not a covered entity." If you are in agreement, please raise your hand.

Steven Eichner
I have a friendly amendment. Use "guidance in rule," and ASTP can interpret that as they see fit, correct?

Rochelle Prosser
Correct.

Mark Knee
This is Mark jumping in again. I think this is what Ike is getting it. I am just noting that "guidance" is very broad and can mean different things, and I think what you are trying to get at is that ONC should clarify this point in the rule. Is that right, or are you saying that you want additional guidance, not sub-regulatory guidance, to be released to address this? Because those are two different things.

Lee Fleisher
My amendment was deferring to ONC on whether or not it was rule or sub-regulatory guidance in the formal sense of sub-regulatory guidance.

Steven Eichner
My friendly suggestion was to include the recommendation as regulatory guidance. ASTP may or may not interpret that and go forward with that. They may then interpret it as other forms of guidance, but my recommendation would be on the regulatory side so that there is greater clarity and reliability for the affected partners rather than just broader guidance.

Hans Buitendijk
Should sub-regulatory guidance be considered regulatory guidance, or would that be different? I agree with the commenter, which I think was Lee, as I am on the phone and cannot see, but I believe that the flexibility on where it goes in the rule, whether in the preamble, sub-regulatory, or somewhere else, is appropriate there to avoid the examples becoming limiting. They are extensive, but they might not have the full depth defined there either. So, that is where I also add caution to how much can be in the rule versus in preamble versus sub-regulatory clarification or other guidance.

Peter Karras
I just want to flag that we are past time on the section, but from what I am hearing, it seems like "guidance" tends to be the word of choice, leaving it up to interpretation by ASTP so as not to be too specific in terms of the solution, the type, or in what location the guidance would be provided.

Rochelle Prosser
That is my preference. I will just go out there and say it. That would be my preference. That way, we can make sure it is inclusive, and yes, I am aware of where we are on the timer with this. I just want to make sure we get this

particular language right for the sake of going forward and providing the appropriate recommendation. So, guidance with ONC flexibility to determine where it would sit, whether it is in the actual rule, the preamble, or as actual guidance, as Lee has mentioned. From the number of hands from before, it looked like everyone was looking for it to be a guidance so that ONC could determine the flexibility.

Hans Buitendijk
My verbal hand is on that line, as I cannot raise it.

Rochelle Prosser
Perfect, all right. So, I think we have consensus here, and then, we will work on this tomorrow, just to clean it up more, to add regulatory guidance as ONC clarifies. Perfect. Can we reset the timer and move on to the next line, Row 3, please, Ben? Can we go all the way to the left, please? Accel, can you please reset the timer? Thank you. Can we go to the actual rule itself, just a little bit further? So, we are on Section 171.104 with the terms of "interfere with" or "interference," and we are saying the update is that the term "interfere" or "interference" is currently defined in Section 171.102, and informed concerns and questions that interested parties have brought to our attention.

We propose that Section 4(a)(3) add Section 171.104 to the information blocking that would codify certain practices, acts, and omissions that constitute interference for the purpose of information blocking definition as codified in Rule 171.103, and the proposed codified practices are not an exhaustive list, but additional practices described in the purpose of Rule 171.104 that are likely to interfere with, prevent, or mainly discourage access, exchange, or the use of electronic health information may also be considered to rise to the level of interference. The proposed codification to these practices is intended to provide actors and those who seek to engage in electronic health information access, exchange, or use with actors certainly that these specific practices constitute interference. The codification of these practices may also help regulate entities and other interested parties to consider the likelihood that any practice or act might contemplate or engage may also meet the definition of "interference" and "interfere with" as defined in Rule 171.102 for the purpose of information blocking regulations under 45 CFR Part 171.

So, with that, can we move to column G, please? Sooner is not here, but she is saying from the Indian Health section, "Is this an appropriate section to include with the compliance and laws? It is not considered information blocking, therefore 171 overrides federal, state, and tribal law. Predictions: Patient privacy that might potentially limit the sharing of information." To answer that, her section is covered under the Cures Act, under which most of the information blocking under the HTI-1 and the HTI-2 rule has originated out of. So, with that said, let's go to Section J, and we can begin the timer please, Accel. So, for the purpose of the group, Dominic, who is not here, had said he agrees with the rule change, the language is broad and encompassing, allowing for proper interpretation by governing bodies, without being too descriptive and running the risk of conflict with state, region, and tribal policies. And then, Kris, the language is "The workgroup supports to propose language from ASTP and ONC." With that said, by a show of hands, do we all agree with the proposed language to ensure that it is broad, but not too broad? One, two, three, four, five, six…

Hans Buitendijk
My verbal hand is up.

Rochelle Prosser
Seven, thank you. So, Ike, Sarah, Rae, Naresh, or Maggie, would you like to comment? I have seven hands. Is it seven?

Steven Eichner
I agree. I just had not raised my hand.

Rochelle Prosser
Eight. So, three have not said, and thank you, Rae, for putting up your hand. Does anyone else want to put a comment? All right. I would say that that is a majority. Sheila, Hannah, and Naresh, who disagrees? All right, we know who agrees. Raise your hand if you disagree. Let's all lower our hands. What about those that disagree and say that they are not? Okay, your hand is up, Hannah. I have Derek, Ike, and Hannah, and I do not see any other hands in disagreement. Derek and Ike?

Derek De Young
No, I just did not lower it fast enough.

Steven Eichner
I am in the same boat.

Rochelle Prosser
As a yes?

Steven Eichner
Yes. I did not lower my hand fast enough.

Rochelle Prosser
Okay, that is a yes. So, Hannah, you said no?

Hannah Galvin
No, I had my hand up.

Rochelle Prosser
All right. Naresh is the only one I do not have a yes or a no from. Naresh, could you take yourself off mute and say yes or no? Okay, he is not voting. So, by that, I would say we have a majority, so we will let the rule stand in Column 3, so can we make this section green, please? Thank you, perfect. All right, so, let's go into Row 4, and Accel, can you please reset the timer? Under here, I actually want to break it up a little bit as we talk about each bullet point because there is more to discuss and unpack here. So, for the first bullet point, in proposing a new protective care access exemption, that would be under specified conditions.

So, I am talking about Rule 171.206, proposing a new protective care access exemption that would, under specified conditions in Section 4(b)(3)(b) through (d), and the draft regulatory text of the proposed Rule 171.206, apply to acts or omissions likely to interfere with the access, exchange, or particular electronic health information that an actor believes could create a risk of exposing patients, care providers, and other persons who assist in access or delivery of healthcare to potential administrative, civil, or criminal investigations, or other actions, or certain biases. All right, so they are saying patients should be able to say yes or no as to what they wish to access. That is the first part. The second part in accessing the protective access exemption under 171.206 is not intended to override any provision of another law that is independently applicable to the actor. So, we want to make sure we are setting this clear. A patient or other person has the right to block, share, or request to share, but as long as they are covered within the confines of other preexisting laws. So, I just want to make that clear.

The third bullet is that practices that propose protecting access care exemption 171.206 would accept from the information blocking definition would be those implemented based on the actor's good-faith belief that sharing electronic health information indicating that any person bought, received, provided, or facilitated the provision of a receipt of the reproductive healthcare that was lawful under circumstances in which it was provided could result in

a risk of potential exposure to legal action for those persons, and that the risk could be reduced by practices likely to interfere with particular access, exchange, or use of specific electronic health information. So, that is a lot. In Line 3, we were saying that under reproductive health, we want to make sure that for those that wish to withhold or wish to share and are doing so on the basis of protective measures to ensure the confidentiality, HIPAA, etc., that they would be covered and not be considered information blocking.

Finally, Section 4: For the purposes of protecting care access exemption, we would propose to rely on the same definition of "reproductive healthcare," which can be found in 45 CFR 160.103, that is used for the purposes of HIPAA. In addition, we discuss in Section 4(b)(3)(b) how we would interpret whether care is lawful under the circumstances in which it is provided. So, this is where we will align with HIPAA under this regulation for reproductive healthcare, and everything that is covered and included within reproductive healthcare. Finally, to satisfy the proposed new protective care access of 171.206 exception, an actor's practice would need to satisfy threshold conditions and at least one of the two recommendations. So, from a legal point, they are shielded, or from a health policy point, they are shielded. I just want to go over that.

And finally, we are looking at it under 171.206(a)(b), Section 1(a), Section A(2), Section A(3), and etc. going down into B, C, D. We want to look at it from an organizational standpoint under policy or a case-by-case determination, and not to be seen as punitive if an act of God occurred because we are in areas where acts of God occur, and if we go under the confines of a certain time to return the information or provide the information and it is not possible to do so, that is not to be considered information blocking for the purpose of the rest of this document, and just summarizing it thusly.

So, without further ado, let's go to Section G. Under there, we have had a lot of agreements and a lot of protections, and ONC was very helpful in helping us work through the different areas, and I think we came to a general consensus under J, if we could move to Section J, and Accel, if you could start the timer. We came to a general agreement that we agree to the legislative changes and the definition and broader definition of what reproductive care is under HIPAA, but Dominic and Kris, you had some revisions and additions to add, and Laurie LAF. I just want to make sure I say the name. Is she here? LAF? Ben, do you know who LAF is? If you want to take yourself off mute, you can tell me.

Ben Dixon
I do not.

Rochelle Prosser
Okay. And Kris, you wanted some examples, recommendations, or guidance under gender-affirming care as part of the reproductive system in some manner.

Kris Mork
I think my recommendation would be to the preamble language, that there be something about noting, and I think the following recommendations are politically sensitive. I like the terminology that Dominic has put in there about how if you, in good faith, adopt an expansive interpretation. Basically, in the preamble, recognize that if your organization, in good faith, uses a broad definition of reproductive care because it affects the reproductive system in any way, from ONC's perspective, that good-faith interpretation is something that is covered by the protecting care access exception. But I do think that it should be explicit in the preamble that ONC understands there is considerable latitude, and anybody who uses a good-faith interpretation is covered by this. I recognize that we are trying to encourage people to read between the lines that there is some flexibility there, but to make it clear, it is okay to do that.

Rochelle Prosser

Okay. So, my suggestion in coming to consensus with the group, and Mark, feel free to chime in… So, you are saying that the preamble is the best place to look rather than the HIPAA privacy, Kris? I just want to make sure I am hearing you correctly.

Kris Mork
I think so. The definition of "reproductive care" that we are working with is nailed down. That does not get to be changed. We looked at it in the discussion, and the definition that was pulled from that legislation said that reproductive care was essentially healthcare that affected the reproductive system in any way. I do not remember the exact language, but it was basically just saying that if it touches the reproductive system, it is reproductive care. Do not touch that definition, but acknowledge that that definition is one that if you, in good faith, apply beyond just fertility treatment and abortion, you do not even need the specific examples. If you treat this as broadly as it was written, you are in good faith.

Rochelle Prosser
Okay. So, let's go back to your suggestion, because what I am hearing is that you are in agreement with using the broader definition and alignment of what reproductive health is, and you think that is good enough, and you are saying that ONC should make an example to suggest that gender-affirming care would be considered as all-encompassing under the broader definition of reproductive care. Is that what I am hearing you say?

Kris Mork
I think what you said is maybe too broad. I do not think ONC should say that gender-affirming care is necessarily reproductive care because there are some organizations, and I will avoid them if I make this stance, but if they say that gender-affirming care does not affect the reproductive system, fine. We do not get to control or dictate their interpretation of that definition taken from elsewhere. But if somebody does treat some forms of gender-affirming care, and I was very specific about saying "some forms" or "many forms," like any sort of hormone therapy, which has an effect on the reproductive system, there are other things that do not, like forms of breast augmentation or reduction surgery. It might get difficult to include that under reproductive care, especially under augmentation. We acknowledge that, so it is not all forms of gender-affirming care, but many of them do touch the reproductive system somehow, and as a provider, if you choose to adopt that broad definition and therefore restrict access using the protecting care access exemption, then you are okay. That is all.

Rochelle Prosser
Okay. I need Lee's help. Lee is LAF. He is stating as part of that suggestion, and Dominic's recommendation that they add explicit language to any actor who, in good faith, adopts an expansive interpretation of reproductive care, is covered by protecting care access exception. Lee is stating that we should be very careful, and link it to the statute, and certainly not the term "politically sensitive." So, he is asking us to remove the term "politically sensitive topics" from that and say that we want to be careful in how far we bring that broader definition to narrow focus under examples, and I am having a lot of lightning in my area, so I apologize if you hear the thunder. So, we want to be careful. We want to make sure we remain within the confines of the definition of HIPAA and what has already been predetermined under the rule. And so, I open this up to a bit of assistance on the revision. I agree with you, Kris, and also Rae, in terms of the gender-affirming care.

I think that if we add language to say that we agree, but if we bring in language that any actor in good faith adopts an expansive interpretation of reproductive care is covered by protecting care access exception, I would like that language in, and then remove the examples. I live in a state where this is targeting, and I would hate to see that the legislation goes down by death by a million cuts because we are giving pathways of examples. So, I open it up to the floor. Accel, can we add an additional five minutes in this section, please? This is a hot topic. By a show of hands, do you disagree with adding this specific language: "Any actor that, in good faith, adopts expansive interpretation of 'reproductive care' is covered by the protective care access exemption"? Is there anyone who is

not in agreement with adding that language? Okay. By a show of hands, for those who are in agreement to add language that "Any actor who, in good faith, adopts an expansive interpretation of reproductive care is covered by the protecting care access exemption," raise your hand if you agree to adding that language. Hans, are you in agreement or disagreement? Ike?

Steven Eichner
I am abstaining at the moment.

Rochelle Prosser
Okay, Hans, are you abstaining?

Hans Buitendijk
I am double muted. I am abstaining.

Rochelle Prosser
Abstaining, okay. Okay, so I have six in agreement, two abstaining, and no disagreement at this time. Could everyone lower their hands, please? Mark, I am going to ask your countenance here. From an ONC or TEFCA position, would it be an issue in the recommendation to add "Any actor in good faith adopts an expansive interpretation of reproductive care is covered by protecting care access exemption"?

Mark Knee
Hi, Rochelle. Thanks for the question. Did I interrupt you?

Rochelle Prosser
No, that is the thunder that just went on. I jumped. I am so sorry, I apologize.

Mark Knee
Oh, boy. I hope you are all right. One clarifying point is that this is totally separate from TEFCA. This is the information blocking piece. If I am following the recommendation you guys are thinking about, the workgroup recommends that ASTP/ONC add explicit language that any actor who, in good faith, adopts an expansive interpretation of reproductive care is covered by the exception. If that is the recommendation, that is fine. ONC will have to consider the breadth and scope of the recommendation and whether it strikes the right balance, but I think it is a fine recommendation. I do not know if Ben has any thoughts as well.

Ben Dixon
When we had the discussion on this, Rachel, who is the point person on it, said that we would definitely take it under consideration to have that broader, and I think it is a fair interpretation, but I cannot really go further than that comment on it being broader, since that would be out of my zone, but it would be a fine comment, and we could definitely take that into consideration.

Rochelle Prosser
Thank you very much. For those that abstained, is there a reason to abstain that you wish to share with the group in the last 30 seconds before we move on? Hans or Ike?

Hans Buitendijk
Not at this time, thank you.

Rochelle Prosser

All right, thank you. Understanding folks on the group, we can add this recommendation as is, but understand that this may not go forward, once we come together with all of the group, to ONC when we finally go to the final draft. If you are okay with that, then we can move on to the next section. Thank you, timer, and thank you, Accel. I would say that there is majority approval with two abstentions at this time. Thank you very much. Ben, when you are finished, let's go on to Item 4 or 5. Peter, where are we?

Peter Karras
It would be 5.

Rochelle Prosser
Thank you. Can we move down to Line 5? All right, the infeasibility. From the consensus, we came to an agreement under Section 174.204 under infeasibility that it would be a 10-day segment from the rules. We had a few choices within there, up to 30 days, and we said a 10-day response is reasonable. I am just reading if there is anything else underneath there. Can we go to Section G? It is basically the timeframe in this section. How long are we going to give a provider to respond? Hans made the suggestion that infeasibility under the circumstance should follow the same 10 business days from determination to inability, and I think that was the general consensus. Can we move to Section J, and Accel, can we start a five-minute timer, please?

So, the language here is that we came to an agreement. However, Dominic was mentioning that he is not clear as a non-covered provider. I think that is synonymous with our questions in Section 1 on covered and uncovered entities, so I think we have addressed that in the prior definitions. His comment is "As described in HIPAA policy, but ONC may need to clarify the definition to fit the TEFCA rule." This is more specific to you, Mark. Basically, a non-covered provider under HIPAA… ONC may need to clarify this definition under TEFCA specifically if it is not clear. Do you mind providing some insight to us here before we move on, Mark?

Mark Knee
Sure. I am just trying to read the comment. So, the question is about defining non-HIPAA entities. Is that the question?

Rochelle Prosser
Yes, a non-covered provider as an entity under HIPAA. Is this one along the lines of what we discussed in Section 1?

Mark Knee
Okay, I think that is a fine comment. I am trying to think. I think you are probably right. I am assuming that if there is not that definition, we may have that definition included within the common agreement and the standard operating procedure (SOP)s, so I think it would be easy to include if that is the case. It is defined somewhere, I believe, so I think that is a fine comment to make.

Rochelle Prosser
All right. So, as long as we understand that ONC will provide that clarification definition under the TEFCA rule, are we all good to go ahead and say 10 days is an appropriate time for an entity, provider, or otherwise to say they are either able or unable to provide the feedback? By a show of hands, one. It is two things we are voting on: To provide a clear definition by ONC under the TEFCA section as described in the HIPAA policy that a non-covered provider is part of and covered in part and parcel within the TEFCA rule and definitions where it is not clear. Mark is saying it is written elsewhere in the SOP, just to bring it forward. So, that first part is to provide that definition. So, by a show of hands, can we put a clarifying definition for ONC?

Hans Buitendijk

Rochelle, I have a question on the question you asked. I am only wondering here about the direction in which we go here, and it can be clarified, that we may need to clarify the definition to fit the TEFCA rule, which is the other way around. I just want to make sure: Is the direction in which we asked to clarify the correct action? Since TEFCA is following rules, I am not sure whether, in this context, it sets a rule. I just wanted to make sure.

Rochelle Prosser
I think it is to fit the TEFCA rule. As Mark has mentioned, it is already written in the SOPs, it is just not high enough for the reader to say, "Okay, this now fits." Would you agree with that, Mark?

Mark Knee
Just to clarify, I can look right now to see where it is, but the bottom line is this regulation should be looked at to stand on its own. If there is a gap there and there is not a definition that would be helpful for you all to understand what we are talking about in the regulation, I think that is a very reasonable thing to make a comment on. My comment was kind of out of scope in a way because even if we have the definition of a non-HIPAA entity in the other TEFCA documents, like I said, the regulation needs to stand on its own, so your comment would be fine for something to include here.

Rochelle Prosser
Okay, thank you, and thank you, Hans, for asking for that clarification. All right, so, the first recommendation is to add something that would allow the TEFCA rule to not only be included and fit within the rule, but also stand on their own as what a non-covered provider is. By a show of hands, do we agree with adding that recommendation here? Okay, I have six. All right, everyone, lower your hands, please. Those who are not in agreement with adding the language here for definition clarification of a non-covered provider, please raise your hand. I do not see any hands. Those who want to abstain from making a definition, raise your hands. I see Ike.

Steven Eichner
I do not have a hand up.

Rochelle Prosser
Oh, you do not have a hand up, okay. So, we will adopt the definition, and thank you, Mark, for providing that non-HIPAA Qualified Health Information Networks (QHINs) definition.

Mark Knee
Yes, I put it in the chat. I found it. In the link, there is a TEFCA glossary which includes the full range of all terms used in TEFCA, so if we feel like a recommendation like that is necessary, it would be pretty easy to incorporate.

Rochelle Prosser
Perfect, all right. So, the next question becomes are we all in agreement with adopting 10 days for this rule? Raise your hand if you are in agreement that 10 days is long enough.

Steven Eichner
For clarification, this is 10 business days.

Rochelle Prosser
Yes, 10 business days, thank you.

Steven Eichner
Are you using the business days definition?

Rochelle Prosser
Yes.

Steven Eichner
Furthermore, we should use the business day modification up above.

Rochelle Prosser
Correct. Sorry, am I sharing my screen, or do you see the actual document?

Hans Buitendijk
We are still seeing the spreadsheet.

Rochelle Prosser
Okay, thank you. Those that want to agree that 10 business days is appropriate, please raise your hands. All right, six, and Hans, you were in there, correct? All right, lower your hands, everyone. For those that are not in agreement with 10 days, please raise your hands. The only reason why I ask, Shila, is because you did not have your hand up. Are you abstaining? All right, she may have stepped away. We have a majority for 10 days in the rule. Wonderful. Okay, Accel, please reset the timer. Ben, once you are finished typing, can we go to Line 6? How much time do we have left, Peter?

Peter Karras
We need to start the public comment by 12:20.

Rochelle Prosser
All right, perfect, thank you. I think we should be able to. We already came to agreement on Item 6, so we can skip over Row 6 and go to Row 7. Row 7 is stating the requester preference exception -that the requester preference we propose - slightly modify the header to ease the reference individual request not to share electronic health information. More importantly, we revise the Subsection 171.102 sub-exemption to remove the existing limitation that allows exception to be used only for individual requests and restrictions on EHI sharing that are permitted by other applicable law. The proposal would extend the availability of 171.202(e) sub-exception to an actor's practice of applying restrictions the individual has requested on access, exchange, or use of an individual's electronic health information, even when the actor may have concern that another law applicable to some or all of the actor's operation could compel the actor to provide access, exchange, or use of electronic health information contrary to the individual's express wishes.

Basically, we are trying to say, and correct me if I am wrong, ONC, that it is going to be the preference of the patient or the person asking as the individual, regardless of whether there is another law that would be harmful, but we also want to defer to that individual's privacy and preference, so if they want to share it, fine, and if they do not want to share it, that individual takes precedence. That is my understanding. If we can move to Section G, we have our comments from the members, and we had a lot of robust conversation along the lines of mental health and HIPAA concerning diagnoses that would be punitive under certain industries or regulations, and we thank the ONC for their wonderful and clear direction and guidance on that. Based on these, we would have them as revisions or additions for further clarification, but not necessarily to be modified under this rule, but your comments are very, very valid and welcome. Accel, you have started the timer. Ben, can we move to Section J? Thank you, Derek.

For the purpose of this group, the group recommends consolidating the existing content and manner exception to cover both the content and manner in which electronic health information is provided, reducing redundancy and simplifying the regulatory framework. Additionally, ASTP should provide clear guidance to prevent healthcare providers or IT developers from unintentionally steering requesters towards easier or more convenient options for

sharing electronic health information, ensuring that requesters can make fully informed decisions without undue influence. That is a lovely summary. Go ahead, Derek.

Derek De Young
I tried to convey both Hans and Kris's comments from Column G, but I apologize, I did not see the email that came out yesterday to try and get that recommendation in there. So, I tried to do it quickly, and this is what I have done.

Rochelle Prosser
This is fine. ONC, for content and manner, and that would be Ben and, for TEFCA, Mark, can you please provide your thoughts on the words "content and manner exception" just to ensure that we are in compliance with the rule? Do you have any comment at this time, for or against?

Mark Knee
Can you clarify the issue? I guess you could use whatever terms you want. I believe that the exception is now the manner exception. I believe content was phased out because of the timeframe related to the change in the content standard. I guess there could be some confusion there, but I think they would generally know what you are talking about either way.

Rochelle Prosser
Ben, are you in concurrence with that?

Ben Dixon
Yes. We obviously will take this comment under advisement, like all the others, and we do appreciate it. It is something that we will work on.

Derek De Young
Hans, I do not know if you wanted to chime in, but I was trying to pull that out of your comments.

Hans Buitendijk
Yes. Mark confused me for a moment, but if I heard him correctly, "content" is removed.

Rochelle Prosser
Removed, yes.

Hans Buitendijk
I do not believe that, with the word "removal," the intent of what we are talking about here would still then not align with it. I believe the intent is, as Derek summarized, that we want to avoid potential duplication and ambiguity between two exceptions that are actually trying to achieve the same thing. So, if we make this recommendation and then, as ONC contemplates and looks at it, with the emphasis that we are trying to reduce duplication and ambiguity, then from that, they might be able to find the right spot to achieve that. That was really the intent, because, as we have been experiencing and working with the content and manner to date, and this is being presented as a new, separate one, to us, it really sounded like you were trying to describe another flavor of the same concept. That is where the comment came from.

We are trying to add, if you will, another example, flavor, or aspect to it that really follows the same as what is happening in what we are working with as content and manner. So, if we address that, then ONC can work through it and help make it as clear and unambiguous as possible because there was not a pushback on the intent behind it, it was just the placement and the risk of ambiguity and duplicity.

Ben Dixon
Okay. So, you would just like more clarification? What you are recommending is more clarification on what the differences are and to put it in a preamble as a regulatory explanation of what the difference is?

Hans Buitendijk
Either that, or combine them if there is truly no difference. Since we do not see it in that way, that can be clarified one way or the other so that the ambiguity is not there. That is what we are trying to get to.

Ben Dixon
Okay, perfect. I completely understand, and thank you for giving me that clarification.

Hans Buitendijk
[Inaudible] [01:13:39] how to phrase it.

Rochelle Prosser
Mark, thank you very much for providing this link in the chat to Title 45, Subtitle A, Chapter D, Part 171, Subpart C, and Section 171.301 for further clarification. Do you just want to give a very quick synopsis of what we would be looking at there before we go to the next part and our time is up?

Hans Buitendijk
It clarifies my surprise that Mark raised that "content" is gone, and I apologize. In our discussions from an EHR perspective, for some reason, we still referred to it as "content and manner." That is all. I can clarify.

Rochelle Prosser
All right. So, Hans, can I have you go back in and clarify or update the "content and manner" part to the proper language and assist Ben so that we can make this clearer? Knowing that "content and manner" has been removed, we are in agreement on what the intent and understanding of the overall arching confine is, and we just want a little bit of clarification.

Hans Buitendijk
I think it is as easy as removing the word.

Rochelle Prosser
All right. So, from the group, can I have a show of hands? Are we in agreement with providing this recommendation to ONC regarding this law? Please raise your hands. Oh, okay. Steve? One, two, three, four, five, six. I have six at this time. Anyone else? Okay, seven. Thank you. All right, we have seven. If we can lower our hands, is anyone in opposition to adding this recommendation? Please raise your hand at this time. All right, I have no hands raised. All right, Line Item 8 has already been adopted and agreed to by all of us within the workgroup, so we will move over. Line 8 looked at just the administrative updates.

Peter Karras
Rochelle, just to jump in, I do want to leave time for public comment. However, if we do have some time at the end, we can definitely yield back to use the remainder of what we have.

Rochelle Prosser
That is fine. We would be stopping at Line Item 9 anyway, so that is fine.

Public Comment (01:16:39)

Peter Karras
Great, thank you. All right, at this time, we would like to open the meeting for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand. Once called upon, press *6 to mute and unmute your line. I will pause for a moment to see if we do have any comments from the public, whether by phone or via raised hand. I am not seeing anything, but I will wait a few more moments. I see no comments via phone or hands raised. While we are waiting, just a reminder that next week's Task Force meetings will be a series of three full-group Task Force meetings starting on September 3rd, and then going on the 4th and 5th, and a reminder to everyone that all HITAC meeting materials can be found on HealthIT.gov. I am not seeing any raised hands or comments, so, Rochelle, I can definitely yield back some of the time over to you before closing up.

Next Steps (01:17:51)

Rochelle Prosser
All right, thank you. Could we have five minutes before I go through the closing comments to just go back to the spreadsheet and look at Line Item 9? Just quickly for Line Item 9, we are at 10. Yes, right here, thank you. Okay, can we go over to the recommendation? We are talking about QHINs. There are three things that we had to decide. 1) Do we want to continue with FHIR and QHIN together, separate the two, or go with FHIR? 2) What is the threshold that would be appropriate within that? 3) The TEFCA network exchanges. So, can we move to Section J? Okay, group, we have to come together. So, we agreed that a threshold of five percent or under was good. We also agreed that the QHIN would take precedence, but I need some additional volunteers to assist me with that.

I know Lee will be meeting with me afterward to provide workgroup recommendations for this section, and Hans, I would love your input and to talk to anyone else who can provide that. Kris, do you have time to meet with us tomorrow so that we can address this? Right now, we support most of the scenarios, but I think there is a little bit more that we would like to say in what that recommendation is. 11:00 a.m. So, we will pass by this one and go to No. 10. Please, Ben, just scroll right down. Okay, I think this is the administrative updates. We are on No. 8. Let's go to 10, please. Oh, that is Line 10. Yes, I think we agreed on the administrative updates.

Ben Dixon
Yes, we did.

Rochelle Prosser
Okay. So, if you could just send me your availability, Ike, Hans, Kris, and anyone else that would like to meet with me tomorrow on Row 9, I am more than happy to meet with you at a time that we can all agree to come together. With that, I will begin closing remarks. So, in our upcoming meetings, again, as Peter had mentioned, we will be meeting on September 3rd, 4th, and 5th, finally delivering all our consolidated recommendations to the HITAC committee on the 12th. Next slide. I just want to thank you all for the hard work. We have come together on pretty much all of the rules, except for one, which will have some clarification in terms of writing what we agree, and I do thank you for all your hard work, and I look forward to all of us coming together on the 3rd, 4th, and 5th next week to finalize to the broader group how we would move forward with the HTI rule. I thank all of you, and I would like to give one minute back to adjourn the meeting. Peter?

Peter Karras
Thank you so much, Rochelle. This concludes our meeting. Thank you, everyone, for joining. Have a great rest of your day.

Adjourn (01:22:16)

Questions and Comments Received Via Zoom Webinar Chat

Hannah K. Galvin: My apologies - I need to jump off. My comments are in there as well as references. Thanks!

Rochelle Prosser: Thank - you Hanna~

Mark Knee: https://rce.sequoiaproject.org/wp-content/uploads/2024/08/TEFCA-Glossary_August-2024.pdf

Mark Knee: Non-HIPAA Entity (NHE): a QHIN, Participant, or Subparticipant that is neither a Covered Entity nor a Business Associate as defined under the HIPAA Rules with regard to activities under a Framework Agreement. To the extent a QHIN, Participant, or Subparticipant is a Hybrid entity, as defined in 45 CFR § 164.103, such QHIN, Participant, or Subparticipant shall be considered a Non-HIPAA Entity with respect to TEFCA Exchange activities related to such QHIN, Participant, or Subparticipant's non-covered components. Source: Common Agreement Version 2.0 and Participant/Subparticipant Terms of Participation Version 1.0

Mark Knee: https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-171/subpart-C/section-171.301

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 29, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO, on 9/30/24.