Transcript

HTI-2 PROPOSED RULE TASK FORCE 2024 MEETING

GROUP 3: INFORMATION BLOCKING AND TEFCA

August 14, 2024, 11 AM – 12:30 PM ET

VIRTUAL

MEMBERS IN ATTENDANCE

Rochelle Prosser, Orchid Healthcare Solutions, Co-Chair
Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Sooner Davenport, Southern Plains Tribal Health Board
Steven (Ike) Eichner, Texas Department of State Health Services
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Dominic Mack, Morehouse School of Medicine
Anna McCollister, Individual
Katrina Miller Parrish, Patient.com
Kris Mork, Leidos
Eliel Oliveira, Harvard Medical School & Harvard Pilgrim Health Care Institute
Randa Perkins, H. Lee Moffitt Cancer Center & Research Institute
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, CyncHealth
Sheryl Turney, Elevance Health

MEMBERS NOT IN ATTENDANCE

Derek De Young, Epic
Hannah Galvin, Cambridge Health Alliance
Rachel (Rae) Walker, University of Massachusetts Amherst

ASTP STAFF

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

PRESENTERS

Rachel Nelson, ASTP (Discussant)

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

Seth Pazinski
Hey, 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. I am Seth Pazinski with the United States Department of Health and Human Services (HHS) Assistant Secretary for Technology Policy (ASTP), and I will be serving as your Designated Federal Officer today. As a reminder, this meeting is open to the public and we encourage public feedback throughout the meeting. Comments can be made via the Zoom chat feature. Also, there is scheduled time, for verbal public comments towards the end of the agenda today. I am going to start the meeting off with a roll call, starting with, our chair, Rochelle Prosser.

Rochelle Prosser
Good morning.

Seth Pazinski
Good morning. Shila Blend.

Shila Blend
Good morning, everybody.

Seth Pazinski
Good morning. Hans Buitendijk.

Hans Buitendijk
Good morning.

Seth Pazinski
Good morning. Sooner Davenport. Derek De Young. Steve Eichner.

Steve Eichner
Good morning.

Seth Pazinski
Good morning. Lee Fleisher.

Lee Fleisher
Good morning

Seth Pazinski
Good morning. Hannah Galvin. Dominic Mack.

Dominic Mack
Good morning.

Seth Pazinski
Good morning. Anna McCollister.

Anna McCollister
Good morning.

Seth Pazinski
Good morning. Katrina Miller Parrish.

Katrina Miller Parish
Good morning.

Seth Pazinski
Good morning. Kris Mork.

Kris Mork
I am here.

Seth Pazinski
Good morning. Eliel Oliveira.

Eliel Oliveria
Good morning.

Seth Pazinski
Good morning. Randa Perkins.

Randa Perkins
Good morning.

Seth Pazinski
Good morning. Zeynep Sumer-King. Naresh Sundar Rajan.

Naresh Sundar Rajan
Good morning.

Seth Pazinski
Good morning. Sheryl Turney.

Sheryl Turney
Good morning.

Seth Pazinski
Good morning. Rae Walker. Thank you, everyone, for attending today. Is there anyone I missed or anyone who just joined who wants to indicate that they are present? Then, we will get into our meeting. Rochelle, I will turn it over to you.

Opening Remarks (00:02:17)

Rochelle Prosser

Good morning, everyone. I just wanted to welcome all of us to this third week as we move forward in the information blocking and Trusted Exchange Framework and Common Agreement (TEFCA) portion of the overall HTI-2 Rule. I want to thank everyone for their wonderful contributions and their reports as they have worked through the document. Last week, after our meeting, we were graciously blessed with having the overview of the HTI-2 Rule by Rachel and our ONC partners here on this call. It was a wonderful overview and gave a really good indication of the soup to nuts through the entire rule. I hope that you were able to review it, or go back, and review it over this past week. I am looking forward to hearing the comments now that we have more insight from our ONC Partners. As we move into the third portion, it is now time for us to really hone our craft and start drafting what our comments will be. I will open up and actually volunteer or request that some of you begin to craft that volume for the patient section, as well as, the last part, where we were talking about the specific rules of TEFCA. We are going to open up a few minutes, just to go over some of the parts of TEFCA that had a robust discussion, so that we were not able to get to, but it was definitely part of the conversation. I welcome you, again, this week and I am so thankful for the work that we are doing together. Seth, if we can begin.

Seth Pazinski
All right. We are just going to quickly go over the agenda and the charge, and then, we will get into our presentation by Ben Dixon, on information-blocking enhancements. We will have a brief presentation and discussion, and then, we will jump quickly into our Task Force Recommendations Worksheet, including, as Rochelle mentioned picking up on some of the TEFCA conversations from next week. Then, we will wrap up with public comments and next steps. We can go to the next slide. As a reminder, this slide has the charge. We can go to the next slide. This is kind of where we are in working through our Subgroup 3 discussions. As a reminder, Rochelle and Brian will be presenting an update from the HTI-2 Proposed Rule Task Force at the full HITAC meeting tomorrow. If we can go to the next slide. I believe I will be turning it over to Ben Dixon to give us a short presentation.

Rochelle Prosser
Seth, before we begin, Sooner and Zeynep are here.

Seth Pazinski
All right. Thank you.

Information Blocking Enhancements (00:05:50)

Ben Dixon
Thanks. I will start off just talking generally about some information-blocking enhancements, what we are doing, first, with requester preferences and the exception there. Next slide. Perfect. This is a proposed rule. It goes into the limitations on the amount of Electronic Health Information (EHI) that is made available by the requester, the conditions under which EHI is made available, and when it is made available, and this exception can apply. Then, the reason that we are making this particular new exception, this proposal, is because we want to give more clarity on what conditions are available to honor these requests. Also, with the people who are requesting it, what is going to be made available for them? What are the parameters that are being denied? If something is not being made available, what would be the reasons? Also, people who are holding the EHI, so they have more clarity on what they need to do to make sure that they are not being an information blocker. This is just sort of a part of our goals with all these proposals to give clarity, but also, on both sides. Next slide. Yes. Now, we are going to go into the privacy exception updates. Next

slide, for me. Thank you. This one is the privacy exception. This one is the simpler of the ones I am going to be talking about today, so this is just a correction. There were some typographical errors that came in and these are correcting those. It is not going to change anything major; it is just to get to the actual proposed, what would have been the things that were connected to this definition. It gives more clarity, as I said previously, but also this just sort of gets more into the goal, so people are not confused that a regulation or a rule that they are looking at does not direct them to the wrong thing. It is a simpler update here, but it also goes along with the theme here giving more clarity but also gives people more understanding of how to be in compliance with these.

The next slide, please. This is denying individuals on reviewable grounds. This is just to broaden the existing sub-exception so it would be available to an actor responding to a request for EHI. This is to improve the consistency. It goes along with what I was saying earlier, gives more of an understanding, and is more consistent. Here, it would be for the Health Insurance Portability and Accountability Act (HIPAA) rules, so, people know what they are in compliance with, but also just make things more standardized, just to make sure everyone is in compliance with getting the proper outcome that I think all parties would want. Then, it just sort of makes a simpler version of what unreviewable grounds would be. That is essentially what would be happening here. Next slide, please. This one is the sub-exception, request not to share EHI. This also broadens the sub-exception, the availability by removing the existing limitation on individual requested restrictions on EHI that are permitted by other applicable law. This is just to improve assurance to some actors to make sure that the restrictions are what is being asked of them in this particular sub-exception. This just makes it simpler for everyone to sort of understand what is going on in this particular section, but also, with this particular area, there just needs to be more assurances on both sides of what would be asked of both parties. This is what we think, with this proposal, would be allowed to do, sort of just give both parties actors and people requesting information, what information should be going, but also just understanding what the ground rules are with that, and why things would be going the way they are. Next slide, please. All right. Well, I will toss it back over to Rochelle. Thank you, guys, for giving your time, and I look forward to hearing what everyone has to say.

Discussion & Task Force Recommendation Worksheet (00:11:34)

Rochelle Prosser
Thank you, Ben, that is a lovely overview that you gave of the third section, under the Privacy Rules and the Privacy Exceptions. If Accel will put on the spreadsheet. I would like to just discuss very quickly that there is a subsection under the Task Force Worksheet. Then, we can begin our discussion surrounding this rule. While we wait for the document, last week, we were discussing the section regarding TEFCA and we had a three-part section that outlined three ways. We can either agree with the rule, we could come up with a compromise between TEFCA and QHINs, or we can just stay with the FHI under the TEFCA. I did not see a lot of commentary on that part, but also, there was another section that came before it. Without causing some confusion, I am just going to look at the document here.

Seth Pazinski
Can you zoom in a little bit?

Rochelle Prosser
Pardon?

Seth Pazinski
Can you zoom in a little bit?

Rochelle Prosser
Yes, if we could, Katrina, we could add what we stated in the meeting last week or the overview from part of the homework that was two sections. The infeasibility, yes. Based on what we talked about last week, are there any additional conversations that we wanted to have surrounding the TEFCA or the Qualified Health Information Networks (QHINs)? Either as continuing as part of the Fast Healthcare Interoperability Resources (FHIR), having it separate from FHIR, or continuing on with the FHIR while we wait for FHIR to continue. I did not hear a consensus, but a lot of discussion. I know, Dr. Mack, we had some long-term discussions.

Dominic Mack
Yes. Sorry, for being lazy and not doing my homework, or putting anything in the document. I was definitely not for naught waiting on the QHINs, personally, around that particular rule.

Rochelle Prosser
Thank you, Dr. Mack. Katrina.

Katrina Miller
A quick question, again. I understand that we should be putting our opinions into this document, even though we stated them at the previous meeting. I do not think we are necessarily trying to get to a unanimous vote.

Rochelle Prosser
No, we are not.

Katrina Miller
Right?

Rochelle Prosser
No, we are not. No. Not at this point.

Katrina Miller
Right. Just **[inaudible] [00:15:03]** a weigh in, and then, we will see which direction it goes. Great. I just wanted to make sure.

Rochelle Prosser
Yes, because there could be something that you provide that we have not considered that we need to consider.

Katrina Miller
Yes.

Rochelle Prosser

If it is in the document, then we have at least a record and we can go back to that, and then, say, “Okay, we can adjust here” or “Not adjust here,” but at least we have that conversation that everyone can share, and for those who were not here at the time of our discussion.

Katrina Miller
Great. Thank you.

Rochelle Prosser
Thank you, Katrina. Ike.

Steven Eichner
Sorry.

Rochelle Prosser
Yes.

Steven Eichner
My hand got raised inadvertently. Sorry.

Rochelle Prosser
Lee.

Lee Fleisher
Yes. Based on that conversation, does it sound like we want to draft something that outlines the strengths and weaknesses of the different ones based on the consensus of the committee? It is not a consensus.

Rochelle Prosser
Yes. But just to begin that drafting we can then, based on the comments that are there, see where our heads are at going forward, and then, we can start to begin to draft what that looks like, in a consensus coming together. We are not at consensus at all, as of yet, but we want to be able to see the various opinions of our committee and to see if there is anything that we are missing.

Lee Fleisher
Great. Thank you. I will add comments and I am happy to help with any drafting.

Rochelle Prosser
Dr. Mack.

Dominic Mack
Yes, ma'am. Again, you can call me Dominic.

Rochelle Prosser
Ma’am is my mother.

Dominic Mack
I will not call you ma’am if you do not call me Dr. Mack.

Rochelle Prosser
Fine, Dominic.

Dominic Mack
All right. Let me just ask, I know this is being recorded, and I definitely want to enter into the document.

Rochelle Prosser
Yes.

Dominic Mack
The verbal things that we say at the meeting, how are they registered? Are they considered to be comments?

Rochelle Prosser
Yes, they are.

Dominic Mack
Okay.

Rochelle Prosser
Yes, they are. After I review, have those conversations, and then, craft the homework based on what was said in the meeting, and then, the comments that we have read here. If I am making a comment, it is because I am requiring a little bit more from the group just to make sure that we are moving forward together.

Dominic Mack
Thank you, Rochelle.

Rochelle Prosser
No, you are very welcome. Now that we have an understanding of how to do the documents and how those comments are figuring out, I would like to know who would like to start drafting some comments. I think we had a very robust discussion on the patient definition. If possible, I would really like to have Kris and Sheryl begin to work on that, as well as Anna, on the patient definition. Anyone else that wants to come in and start drafting their thoughts? Sooner, if you would also, please weigh in as well. Rae is not here, but I will send an email to her, as well. The second part, if you can go up in the document a bit, Accel, to the next portion of the rule, right under the patient definition. That one had a lot of robust discussion in protecting access and the exemptions. Lee, you had raised some very good points on how the data would be used and some things that I think are missing when we talk about that. If you and Steve could start to work on that. I would also like Kris and Anna to weigh in and anyone else who would like to volunteer, please let us know in the chat, and we can begin crafting that.

Lee Fleisher
My pleasure if the Accel people follow up since I am traveling.

Rochelle Prosser
Yes, that is fine. We will make sure that we get it in the email that goes out for the homework for those that I have tapped on the shoulder. Thank you for volunteering your time and doing the extra work. Let us begin

the discussion on what we are here to talk about today. The Accel team, can we go down, please, in the document to what we are working on today? Yes, the infeasibility. Let us open it up to the floor. I believe that Hans, we had talked about the 10-day business part. There was a lot of robust discussion as we went through this. Of course, Kirs, we thank you for your comments here. Are there any other comments that we would like to discuss about the infeasibility exception? I will open the floor. Hans or Kris, go ahead.

Hans Buitendijk
Yes, Rochelle, this is Hans. I think the comment that I would make is just a relatively straightforward alignment of date consistency so in that regard it is not a fundamental discussion on the exception, just on alignment of timelines to keep it simpler.

Rochelle Prosser
Okay. Kris, you mentioned in here about how to resolve the tension between the **[inaudible] [00:21:57]**. I know that you are moving. Accel, can you move over a little bit to the right so that we can see the comments that Kris has?

Kris Mork
We discussed those.

Rochelle Prosser
Yes, we did discuss those. There are some of us that are here that were not here last week. I just wanted to have a further discussion before we move on through this document.

Kris Mork
Got it.

Rochelle Prosser
Go ahead, Steve.

Steve Eichner
Yes. There is language in the current text that talks about entities acting as business associates or the activities of a business associate rather than actually being a business associate. It would seem to me that we would want to have it continue to be focused on entities that are business associates that actually entered into an agreement rather than somebody doing an activity because that, to me, is just a little unfair. That would seem to me that a third party could quote-unquote, act like a business associate without actually having entered into an agreement with a covered entity as to being one. That just does not quite make sense to me.

Rochelle Prosser
That is a good point. I would love to open that to the ONC to hear your thoughts.

Rachel Nelson
I think at this point, it would be helpful to make the comments. You all make the comments that you want to make, and we will work with them from there.

Rochelle Prosser

Okay. Steve, if you would please put the comments in and then, we can at least have it on the log and work with that. Go ahead, Kris.

Kris Mork
Did we not have an observation last week that there are occasions when someone is sharing electronic health information, but because of the narrow definition of a covered entity, they are in possession of electronic health information? The rules that we are describing here, we want to apply to them even though they are not a covered entity, and that this discussion of a business associate is to capture that same analog that there may be circumstances wherein an actor that is behaving like a business associate would behave, worthy primary holder of the information, a covered entity. Basically, we are trying to go from we understand the specifics of a covered entity to a business and the business associate, but there may be circumstances, where it is not under that HIPAA law, a covered entity and business associate. We want the same collection of rules to apply, despite the fact that they are not technically covered entities and business associates. Am I misremembering how we got here?

Rochelle Prosser
No, I do not think you are misremembering, at all. We definitely had our ONC partner give us some guidance on that. Thank you for that reminder. Also, all comments are welcome, and this is one of the reasons why I wanted to circle back for those of us if there were any additional questions that we had, or clarity that we needed after the ONC did their wonderful overview of the entire HTI rule after our call. Thank you for that reminder, Kris. All right. Are there any other comments? Let us move on to the next one, please. Kris, Hans, and Lee, would you like to start beginning to draft this one out on the infeasibility and exception? Dr. Mack, if you would like to weigh in, that would be wonderful. Accel, if we can go to the next rule, please?

Hans Buitendijk
Rochelle, yes, I am happy to, on that form statement, to start there.

Rochelle Prosser
Okay.

Hans Buitendijk
Sure. Refining the other parts.

Rochelle Prosser
Perfect. Anyone who would like to assist? Perfect. Please, go ahead and let us know in the chat. We have a new feature that we are using, a timer, to make sure that all of us have an opportunity to have a say just to make sure we can move through the document. The next part of the infeasibility is the manner and exception request, or is it infeasibility? Accel, yes, thank you. It is the manner and exception request for comments. Thank you, Ben, for that wonderful overview of the exceptions. There were a few exceptions to this rule. If you can go up a little bit. Yes. Yes, thank you. We were looking at aligning the exception to make sure we are using the same definition, just for clarity's sake, and including limitations on its use for the FHIR API, and application, as well as the fees for licensing. I noticed there were not any comments on this. If someone could start the new timer for me, please. Thank you. Did anyone on the committee have any comments on this part? Seth, are you seeing anyone? Did anyone need any clarification regarding this or are we all in agreement with the presentation?

Hans Buitendijk
Are you looking at Row 6? I am sometimes not clear where the focus is.

Rochelle Prosser
Yes, Row 6.

Hans Buitendijk
Okay. I do not have any further comments.

Rochelle Prosser
Everyone understood. Well, we have a consensus on that. If we do actually have a consensus on that, that is wonderful. It is quite clear, so we can make that one green. I believe green is where we are in agreement. Unless there is someone else that does not have any comments or is differing. Well, that is wonderful. This is great.

Hans Buitendijk.
If we agree, we can note that, as well. What would be a standard word for that that we drop into the right column?

Rochelle Prosser
Yes. Yes.

Hans Buitendijk
We support these 10 things, whatever it is.

Seth Pazinski
Yes. I would suggest, Ben, that you could just record in Column J where the group recommendations are going to go that there is support for this proposal, and then, mark that Column J green, and then, we can have a standard statement for any of the proposals that there is a recommendation for support on.

Rochelle Prosser
Perfect. As Accel makes the adjustments and updates, thank you so much, we can then move on to the next one, and restart this timer. I will begin to work on that one. The second one is Column 7. If we can move that up a little higher? Row 7. In this one, we are talking about the requester's preference. I see a lot of comments in there. I will actually open it up in order who made the comments. Who is ST? Sheryl.

Sheryl Turney
That is just me. I wanted to add the note here because, in the other work group, No. 2, one of the comments, we have not had a chance to talk about, in that workgroup, yet, but we will is the recommendation I made, that patients be able to add via the patient access API information to their patient portal. Because, today, even though the patient access API rule is out there, it does not require the portals to include it, so patients can add data to their portal that is outside of the facility that provides that portal. If patients like that portal and there are many examples that I have heard already where, “Ninety percent of my data is in my chart, but I cannot add anything to it from another system that I went to, to get a test, or another lab that was outside of it, and then my doctor has trouble seeing that data. I requested it and requested it, and I still do not get it. I want to add it myself,” and there is no way for them to do that. That is where that is coming from.

Rochelle Prosser
Thank you for that. Hans.

Hans Buitendijk
Yes, I would like to react to Sheryl's comment. I understand the challenge. In the rule, though, there is no proposal at this point in time for any write capabilities in the APIs. From the information-blocking perspective, those capabilities are not there. It is about access. I am not sure whether that is in scope or not. If we were to make recommendations, none of the other capabilities under certification or the way that **[inaudible] [00:32:52]** I understand would address that you are information blocking if you are not able to add information to a chart. It seems to be mostly focused on if there is data and is patient-specific then you have the information blocking exceptions in play. I am kind of curious as to maybe a clarification from ONC perspective on the current scope of information blocking, its access to existing data is not about the ability to add data to the HIT command.

Sheryl Turney
Hans, I want to correct something you said. The API would not have to write anything because the patient API already exists. It would need to be made part of the patient portal so that the patient could invoke it and the data would come across as it does in any other app today. Just to correct that one statement.

Hans Buitendijk
That helps clarify. On that note, though, at least on the certified electronic health record (EHR) side as part of HIT, the systems need to have both the ability for access to the portal, view, download, and transmit as well as APIs. Whether that is functionally by way of the portal or not is separate, the discussion, they have those abilities. I am not sure whether it is part of this criteria or how we would address that. A patient API would have to be part of a portal or otherwise. That is the part I am not sure whether I understand the intent of the recommendation.

Steven Eichner
Yes, I think I would agree with that in terms of looking at the information-blocking regs are more about access to data, not access to write services.

Rochelle Prosser
My question is, if the patient has a PDF or a document that is already created and they want to upload that or otherwise share it, it is not necessarily writing, it is just having the ability to push a button and upload whatever they would like for content. I just wanted to know if that is part of that.

Steven Eichner
From a technical perspective, I was looking at "Write", not necessarily creating, but writing as in adding information into the record so you are modifying the record. I was using "Write" on the computer-ish side meaning to add data to the file, not literally writing new text.

Rochelle Prosser
Okay.

Sheryl Turney

To clarify the way the patient portals work, you can always upload a document and a message, but that does not become a part of the record, nor does it go to anyone except for one doctor, and then, it expires after a period of time. The bottom line of it is, I saw it a little differently because in looking at the patient access API rule and the fact that the patient portal is 99% used as an app, but it does not have access to the patient access API. To me, I do not know that it necessarily belongs to information blocking. I think it actually belongs in the section for Group 2 that we are meeting on separately, Hans, but I wanted to provide a reference to it here because it does impede the patient's access, which is what the whole idea behind the information blocking rule is all about.

Hans Buitendijk
I think we want to have a little bit further discussion in the context of Group 2, then given that the patient API in G30 is actually covered with the capabilities in G10, G20, now, and A9 on the provider side. The patient API there is on the payer side. If there are suggestions on how the patient API on the payer side may further integrate with their portals or otherwise, I would keep that discussion separate from how would you further need to enhance and improve on the provider side. I think we have to be careful mixing the two because also, the environments are different, and what is already there or not.

Rochelle Prosser
Very good. Sheryl, I noticed that you had an extra P. I did not want to edit it out from your comment. In your first line, it says, "Related to P Patient, provider, and payer." Would you like to edit your comment yourself?

Sheryl Turney
Yes, I will edit it.

Rochelle Prosser
Perfect. In the few remaining time, Hans, would you like to explain your comment here about what is unclear?

Hans Buitendijk
Correct. When we read this new paragraph and we look at what is already defined and approached in content and manner, we are not sure, and we do not see, actually, anything that is added new that is not already described in content and manner, that already addresses it. It is perhaps more clarification on content than manner, and that is something new and different that always has the potential of creating ambiguous and varying interpretations. The question is, what is really new in 202 (e) that is not addressed or not part of and could be explained easily as part of content and manner? That is effectively the crux of this topic.

Rochelle Prosser
All right. ONC, Ben, would you like to share?

Ben Dixon
Yes. We definitely appreciate the comment on that. We are definitely going to take the comment under advisement just as far as where it should go and also, what information needs to be added. We really appreciate it. You share about that, and we will definitely take it under advisement.

Hans Buitendijk

I appreciate that. I know that I am teetering on the line of what you can say and cannot say. Sorry about that. Yes, if there is anything that can be identified already as this is something in 202 (e) that is not addressed in content and manner that might already help to better understand how we may provide the feedback. If that is not feasible, I understand that, and if that is not the case then we will phrase it in, perhaps, a more general way, the feedback on what this would be.

Rachel Nelson
We can clarify one point, which is that we are going to go back and fix a little problem that happened here in XO. I think it would be helpful for me to say this, and then, Hans, that will give you an opportunity and others in the workgroup an opportunity to clarify for us whether you are commenting about the request or preferences exception, or the privacy sub-exception for, which is 202 E. There is a privacy sub-exception for requesting restrictions on information that the patient requesting restrictions on what EHI the patient is a subject of would be shared with someone else who would be allowed under applicable law to have the information, but the person just does not want as much shared as could legally be shared. That is the privacy sub-exception, 171.202 (e). The requester preferences exception, which appears to me on the screen side by side with the short version of the 202 (e) modification proposal. Requester preferences with the new exception would be 171.30 4, I think. It would be helpful to make sure that we are clear on whether your comment is perhaps meant to refer to the requester's preferences. The requester preference is the one where, whoever I am, I am allowed to access, exchange, or use some amount of EHI. I want less than you could give me. I want it later than you could give me, or I only want it under specific conditions.

Hans Buitendijk
That actually helps clarify and if that could be reflected, the correct linkages in there and especially that, that would be great. It just might be what happened.

Rochelle Prosser
All right, thank you. Thank you very much. Kris was mentioning that her comment from the prior rule has been duplicated here, but it actually applies to this portion of the rule and not the other section. Thank you, Accel. Kris, do you want to just very briefly speak to where the tensions that you are seeing in this based on your comment, if you are able to unmute?

Kris Mork
Sure. I believe that there is language in there under requester preferences that the holder of the information is not supposed to be pressuring. It has been a week since I have looked at it. There is something about not pressuring, basically, the requester to make certain preferences. At the same time, there is an implicit pressure to choose preferences that can be accommodated by the holder of the EHI. If you express preferences that are very hard for the holder to the actor that might share the information to satisfy. Then, they are allowed to say, "Hey, it is going to take us much longer to satisfy these preferences, or maybe it will block things entirely," which creates an incentive structure not to express those preferences, which runs counter to the, "Do not influence the requester in how they formulate their preferences." Although, maybe I have struggled with some of these cross-references that I think we just touched on with some of the rows, what they point to, and the legislation is not quite accurate, so I am actually a little confused now as to exactly which sections I am remembering.

Rochelle Prosser

Understood, yes. I definitely understand that. ONC, did you have any comments on that, or should we just leave it as an overarching comment as a reflection?

Rachel Nelson
Because I cannot, at the moment, put my finger on a sentence that is for sure in the proposed rule that might help clarify the point this comment is getting at, I would appreciate us capturing the comment.

Rochelle Prosser
Okay.

Rachel Nelson
Thank you for raising it.

Rochelle Prosser
Perfect. I see three people that were very vocal in this section. I would love to have you begin drafting the comments for the rule. Hans, would you like to lead or Sheryl?

Hans Buitendijk
I think there might be two parallel aspects, so perhaps we can just have two aspects to it.

Rochelle Prosser
Yes.

Hans Buitendijk
I can **[inaudible] [00:45:39]** the one related to the overlap with manner and exception as soon as the update to the spreadsheet is there. I need to chase that one down to make sure it is related to the correct one.

Rochelle Prosser
Perfect. Sheryl and Kris, you can work together, as I see there is a bit of overlap in that for the comments. Thank you, very much. Accel, if we can move the document up to Section 8 or Row 8? We can restart the timer and we can begin discussing this two-part rule. Sooner, you had a comment on this if you would like to take it yourself. Are you here?

Sooner Davenport
Yes, I am here. It took me a second to find it. Yes. I was looking through. I added it to the privacy exception here, in my comment, but I think it also might be appropriate elsewhere either in addition to, or instead of. I am trying to find where that was, which is why I got lost. I had just mentioned that it might be helpful to include that according to the private rule, covered entities can still disclose to private health authorities to ensure access and necessary data. I was speaking specifically to tribal issues in terms of not always. Sometimes it gets conflated in terms of withholding data to tribal organizations because it is somehow a HIPAA privacy rule violation. That was really the intention there was to hopefully clarify that in the regs. I think that definitely fits somewhere in here, I am just not entirely sure if this might be the best place or if it could also be added elsewhere just because I know there is definitely some nuance there that leads to not getting access to data. Because of that conflation, that also means that tribal health systems that are covered entities can often not get data, either. That was the initial thought, but I welcome any follow-up, questions, or clarifications.

Ben Dixon
Rochelle, you are on mute.

Rochelle Prosser
Thank you. Sorry about that. That is an excellent point, Sooner. We want to really be able to take in that inclusive for those areas that will be using the technology and make sure that we provide full interoperability in case they come into another area off of where they are in the Indian reservations or in the Indian health system. We really want to make sure that there is information sharing. It comes to mind when I think about public health, too, and making sure that the FQHCs also have this ability for interoperability. Is there any comment from the ONC that we wanted clarity on where this would be more applicable since this is a two-part rule?

Rachel Nelson
This particular comment is technically out of scope. It is not about anything that we are proposing. It seems like you are asking HHS to issue guidance that centers more on the privacy rule. In Row 8, I guess. Well, it is either eight or three, depending on whether you are looking at Excel or Column C.

Rochelle Prosser
Right. Row 8, for us.

Sooner Davenport
Well, yes, and I think the concern is that the regulation will be used against sharing, which is why I was asking for further clarification because then, information that is within the scope is going to be withheld because there is no clear understanding.

Rachel Nelson
I think where it is here is definitely a mismatch because the sub-exception for privacy, is just not information blocking to honor an individual's request that information about their health not be shared with someone else. That does not change. We stated this a couple of times in the proposed rule. We can think about where to say it. Just to be clear, clarifying what the privacy rule still allows does not necessarily mesh well with saying that an actor who honors an individual's request not to share all the EHI that the law would allow them to share with whoever it is the individual does not want the information shared with would not be information blocking under the conditions specified in the exception. Also, privacy sub-exception D is actually about unreviewable grounds for denying the individual themselves access to EHI, or in the case of our exceptions, it would be the EHI. It is a general comment, and we hear you. I guess, for whatever it is worth, it is more of a general comment on something that we are not specifically proposing here. We do hear you. We hear the concern and the confusion.

Sooner Davenport
Yes. The reality is that Intensive Therapy Unit (ITU) relies 75% on referrals outside of the health system, and then, that is where we do get into a very real issue of the tribal health system not getting the information back on their patient. That is part of this, really. I think from the perspective, I do not want to speak for every tribe, but it is something I have heard from tribes. Maybe that is outreach and additional conversation. This was definitely an item that falls under tribal consultation that was not held with tribal organizations that I think this is kind of touching on. Yes, we can definitely work on finding the appropriate place since there

are definitely no enforcement mechanisms in place. I think you are right; we definitely have to get more creative there.

Rochelle Prosser
All right. Thank you, Sooner, for your comments. Are there any other comments from the committee regarding Sections D and E in the privacy exception that we went over today? Is there anyone who sought any clarification on what these exceptions and sub-exceptions would be in the manner of the patient being allowed to control what is and is not shared as long as it is within the confines of the law or HIPAA? Let me ask, outside of Sooner, are most of us in agreement with what is written here and outlined here? Yes? No? Dominic.

Dominic Mack
I am just trying to do a thumbs-up, I guess. Yes, in agreement with it.

Rochelle Prosser
All right. Sooner, for us, we have certain states, unfortunately, that are going around and finding ways, unique ways of accessing patient records in a punitive way. We want this, at least, in my understanding, to be able to give more control and more understanding and clarity around what information a patient can share and what control they do not want to have shared. Outside of the fact of the punitive side, I can see where information sharing might be difficult to obtain. We currently have that between primary care providers, certain other specialties, and behavioral health in that they make the referral, but then, they cannot have that information to follow up on. I do hear some of your concerns. I just wanted to put that on the record that patients should have the right to what is covered and what is not shared, but it is also covered in the preamble in the regulatory text, so I do thank the ONC for pointing us to areas of clarity on this. If we have no further comments, I see most of us are in agreement. If we can move to have someone volunteer to agree or draft that we are in agreement. We will move on from this privacy exception. I think most of us agree there should be some exceptionality and sub-exceptions to this. Accel, if you can go to Column J, I believe it was, and put that towards the green, that we mostly support. Sooner, I do understand we need to find a proper place for your comment. Then, once we are done, we can restart the timer and go to Row 9. Is there a way to see it? We are on the Trust Exchange Framework Agreement. This is a little extra. We are actually, moving faster than I had anticipated. We are talking about a bit of the work on the rule earlier. This part of the Trusted Framework Exchange Comment, Accel, can we make that column a little bit wider so we can pull it up a little bit? I am not sure if there is a better way of showing this. To just begin talking about this, on the TEFCA part. Yes, thank you. Rachel, just a quick overview. We have the last 30 minutes to talk before we have to open up for comments. Maybe, we will set the timer, too. Perfect. Rachel, could we just go over the new part for 172? What is actually new in this?

Rachel Nelson
What is? The entirety of Part 172. It is all about TEFCA. The common agreement, etc.

Rochelle Prosser
For our TEFCA folks, Hans and Lee, as we look through this one. I understand this is extra. We are ahead of ourselves. Are there any opening comments on what we are talking about, the new guidelines, and the new portions of Part 172?

Hans Buitendijk

This is Hans. I do not have any particular opening comments. I see mostly it is being reviewed by folks a little bit further. Alignment with what you already effectively see in TEFCA with the updated version to the common agreement and a series of a lot of other documents in there. Of all the topics, this is not the one that I have been delving as deeply into because so far, the initial review looks like it is aligning with everything that is already happening in TEFCA. It might be missing something, and I am going to be looking for that.

Rochelle Prosser
I think I have the same. Again, committee, we are ahead of ourselves, which is fabulous, and so, it allows us a little extra time to move faster or further into the comment. Dr. Mack, you were mentioning about not reading for QHINs, and there is a section here. Keep your hand up. I will get right back to you. Under the fourth bullet point where we propose, it is talking about how it is necessary for the entity to maintain designation as a QHIN capable of trusted exchange under the common agreement. This proposal will establish procedures governing onboarding and supporting reliability and privacy security, but trust within TEFCA would further TEFCA's ultimate success. Dominic, you had mentioned in looking at the choices of waiting for QHINs, waiting for everyone to be enrolled in FHIR or just looking at FHIR that it was preferred not to wait for the QHINs. Just a cursory overview because I know that we have not necessarily looked at this just yet, but just your thoughts on that language.

Dominic Mack
Yes. I understand the importance of the technical requirements and having the functionality for privacy and security, but I was saying that in light of if there are those entities who are able to transmit information, we should not put a barrier that they have to be connected to a QHIN if it follows HIPAA rules, the privacy, and security rules because, to me, that is adding to the information blocking. Those are my comments. I know we would want it to satisfy the privacy and security in HIPAA rules, but if it is able to be done outside of the QHIN. I think the other question was to ONC. I forgot who said it. Is this specifically working on behalf of the QHINs? If that is our mission, that is one thing, but if we are just specifically trying to make sure to lower the barriers to information blocking, I think we ought to strongly consider that. Thank you.

Rochelle Prosser
Thank you, Dominic. Rachel. Just to allow the ONC to respond.

Rachel Nelson
Well, I think the comment is well-taken. I think I would, for what it is worth, map it to a TEFCA manner exception more so than anything in 172. I know we talk a lot of numbers, and I cannot believe I do this because if you told me 20 years ago, I would talk in numbers, write numbers like this, I would have told you, you had lost your mind. I take that comment as being about the TEFCA manner exception. That exception applies within the TEFCA world. A TEFCA manner exception does not apply where the person or entity seeking to access exchange or use of EHI from an actor is not somehow a part of TEFCA as a QHIN participant or sub-participant. If we had had slides ready, I think it would have been helpful. If I had known, we would get so far ahead. It is awesome. Part 172. Let me scroll down to 172 again. I scrolled on myself. The 172 or the whole TEFCA-specific part of the Code of Federal Regulations (CFR) is, "We have proposed to establish rules in 172 to implement," so we turn to this new chapter that is all about TEFCA and "We are proposing everything that is in TEFCA chapter to implement our obligations under specific sections of the statute that was added by the CARES Act to publish a directory of health information of works that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement

and to establish a process through notice and comment rulemaking for health information networks to attest to adopting the trusted exchange framework and common agreement. These regulations would further our obligations to support TEFCA under the law. The provisions included in this proposal would establish the qualifications for health information networks to receive and maintain designations as a QHIN capable of trusted exchange pursuant to TEFCA. As well as establish procedures governing QHIN onboarding and designation, suspensions, termination, and administrative appeals to ONC." Then, the rule dives into the details of what is being proposed in those areas that are specific to our obligations under TEFCA, and for lack of a better way to say it, TEFCA procedures. Which are, again, within TEFCA. We turn to a new chapter in the book and are now, I think, trying to talk about the TEFCA-specific chapter sort of separate from any information-blocking definitions or proposals.

Rochelle Prosser
Thank you. Thank you for that clarification. Accel, can you add an additional five minutes so we can have comments from Lee, Hans, and Kris? Then, I will turn it over to Seth to allow time for public comment. Lee, if you would like to go first.

Lee Fleisher
I do not think I had raised my hand. I apologize if I have.

Rochelle Prosser
It was Steve. I am sorry. Steve. I apologize. Yes, your hand was up. Go ahead, Steve.

Steve Eichner
Thank you. I do think it is important in the TEFCA language that there is recognition of states' public health authorities, the regulations, and the QHINs need to work not only within the bounds of federal law but also, within the bounds of state and applicable law in that space, as well. Pursuing that with some issues. Looking at the standard operating procedures that were just released for public health or public health exchange under TEFCA do not clearly lay out that the QHINs need to take it upon themselves to understand the law and put a significant burden on public health to have to educate QHINs and each and every QHIN because of the way TEFCA is set up there is not necessarily a relationship with a particular QHIN and a particular health department that any provider can report data to any QHIN and route that data subsequently to public health across the QHIN network. We need to recognize that kind of responsibility on the QHINs. I think we need to do it in the regulations, on the regulatory side. Thanks.

Rochelle Prosser
Steve, would you like to add that part of the comment? I think that is a great point as we begin looking at this. Rachel, I know you put yourself on mute. I am hoping you are in agreement that that is what you want me to do.

Steven Eichner
Yes, I would be glad to.

Rochelle Prosser
Go ahead, Rachel. Are you in agreement with having Steve add that to the comments as we are in a new section? Yes? No? Maybe? All right, Hans, if you can take yourself off mute.

Lee Fleisher

Sure. Thank you. Just a couple of thoughts and comments based on Dominic Mack's input. I think it is an important point that is being raised to make sure that some of the requirements do fully consider whether you should or should not or must or must not participate in TEFCA. The way that we have been looking at it is very much that we see it in both the rules and the TEFCA documents itself is that TEFCA remains voluntary. However, voluntary can be incented by and is being incented by Centers for Medicare & Medicaid Services (CMS), for example, in some of the measures that if you participate in TEFCA, that that might have certain benefits, or you can see contracts that may pop up to indicate that in order to fulfill this, you have to be part of TEFCA. I think the different other tools that are out there that can incent, entice, or require the use of TEFCA, but 172 and TEFCA itself are not required to participate in at this point in time. It is still voluntary. Sometimes you could say, "Well, is that voluntary or is it volun-told?" but you do not have to. Information blocking, as I understand Rachel's explanation, and as we have been interpreting it as well, is that participation in TEFCA can help address some of the information-blocking exceptions and approaches that you can take. That does not mean it has to be. Well, yes, you have to be part of TEFCA to be able to claim that, but that does not mean that the general concept is not applicable, whether you are part of TEFCA or not. There are still considerations there, as well. It makes life easier, in that context, specifically to do that. When I was going through 172, and I just brought it back up again, as it is currently stated there, it is indeed, that is why we will not have a lot of comments here, it is effectively reflecting all the updates and the work that has been done at TEFCA and moving forward. I appreciate, understand, and support Steve's comments about how we always need to make sure that all the variety of stakeholders, which are payers, providers, and everybody else who share data that we recognize that they are all opportunities to connect and get a smoother environment around that. I think the comments that I will be considering mostly is in support of the comments that Steve is making, and underscoring that this is a voluntary effort, but that it has substantial benefits to participate in.

Rochelle Prosser

Thank you, Lee. I will look forward to reviewing your comments in the comment section after this time, if you would be so inclined to add. Dr. Mack, I would also like you to be inclined to add your comments here, as well, from a provider's perspective, I think it provides wonderful insights into some of the challenges. Rachel, I wanted to ask a question. Would Sooner's comments be more relevant in this section, under 172 for what she placed in the prior one? I am just wondering if it is applicable here since we found it was not necessarily applicable in the prior rule. That is something, food for thought. Sooner, I would love also to see if you would apply your comments here. I think under here, it might have more relevance. All right, Kris, would you like to take yourself off mute and share your comments?

Kris Mork

Certainly. I was following up on the comment about whether or not we needed to wait for QHINs or other components of TEFCA. My understanding of the exception that is made to information blocking related to TEFCA is that if the actor, the person, or the entity with the EHI is already participating in TEFCA, they are a participant or sub-participant connected to a QHIN. If the requester is also in TEFCA, is a participant or sub-participant, then the actor is allowed to say, "The only way I am going to share information with you is through TEFCA" and making that restriction is not information blocking because there is a valid path for the information to flow, and that creates an incentive for people who are in TEFCA to stay in TEFCA. If my understanding is correct in all of that then I think that is an excellent exception to have made, and I do not think it forces or it delays anybody sharing information because TEFCA or QHINs are not up and fully operational and accessible by enough actors.

Rochelle Prosser
Thank you, for your comments, Kris. I definitely can hear you and I appreciate that. Sooner, you have raised your hand. Go ahead.

Sooner Davenport
Yes. I wanted to double-check. What row are we in again?

Rochelle Prosser
Nine. I believe it is nine. Ben, keep me honest here. Are we in Row 9 of your screen?

Ben Dixon
We are on Row 9, that is correct.

Sooner Davenport
I guess I have a question as to why Indian health services is not listed and why that exception might be. I know it is because the resource patient management system, obviously cannot handle it, but they are in the middle of a health IT modernization and will be implementing and having a new EHR. That was a question that I had and because, it is not just specific to the direct-service sites for Indian Health Service (IHS), a lot of tribal sites that operate their own clinics still use the Resource and Patient Management System (RPMS) provided by IHS for development and support.

Rochelle Prosser
Thank you for that comment, Sooner. This is why I wanted to have you here to be able to bring up portions that we may not have considered. Your points have been very valued, and I look forward to you providing them here, in Row 9, as well. Now that we are at 12:20 p.m., thank you so much for this very wonderful conversation. Moving forward, I would like to now turn it over back to Seth to discuss public comment, if there are no further questions or comments at this time.

Public Comment (01:17:34)

Seth Pazinski
All right. Thank you, Rochelle. We are going to open up the meeting for public comment. If you are a member of the public and you are on the Zoom, you can make a comment by using the hand-raise function, which is located at the Zoom toolbar at the bottom of your screen. If you are participating by phone only today, you can press star nine to raise your hand, and then, once called upon, you can press star six to mute and unmute your line. While we give folks the opportunity to raise their hands, I will just give a quick reminder that the next Group 3 meeting of the HTI-2 Proposed Rule Task Force will be next Wednesday, August 22nd, From 10:00 a.m. to 11:30 a.m. Eastern time. As a reminder, the meeting materials from today, as well as all other HITAC meeting materials are available on healthIT.gov. I am checking and I do not see any hand raised on the Zoom. Accel, can you let me know if we have anyone on the phone?

Accel
No comments at this time.

Seth Pazinski

All right. Rochelle, I will turn it back to you then to take us through some next steps and to close out the meeting.

Next Steps (01:18:47)

Rochelle Prosser
Perfect. Thank you. Our next steps. Tomorrow, we actually have our HITAC Committee, full committee meeting, and we will be providing updates on what we have done, how far, and what we have accomplished here on the HTI-2 third group to the larger HITAC Committee. I do look forward to that conversation because we will hear some wonderful feedback from the full HITAC Committee. As well as we look forward to meeting next week, on 8/22 and then, on 8/29. I just want to encourage all of us to please do the homework and work through it. We are getting through these a lot faster than I had anticipated, but the conversations that we have had have been very informative, to help us move forward. Wherever I can, after these discussions to provide more insights, on the additional counterpart rules or clarity, I will continue to do so in our homework. I thank everyone for all your time. We only just have a few short weeks left before we have to put our recommendations together. I thank you for doing the hard work. There are a few of us who have not provided comments, and I look forward to you providing those comments in the spreadsheet so that we can have your thoughts on record and known. We begin now the task of actually crafting what we are going to do and where we will come to a consensus, so we can take a vote. I believe that would be 9/5. Keep me honest, Seth, on how that works.

Seth Pazinski
Yes, just to give you a little sense of kind of what to expect over the next few weeks here. Group 3 will need to have draft recommendations. We will aim to have those done by the 29th, which would be the last individual meeting of this group. We will be pivoting and encouraging folks to, and we will include this in the homework as well but start drafting the group recommendations. Moving from the individual comments to the group recommendations based on all the discussions over the past several weeks. Then, we will use part of that meeting on the 29th to go through and identify the areas where we will move the draft recommendations to sort of complete by marking them green. Then, we have three meetings the week of September 3rd and the intent will be to, as a collective task force, bring all three groups together to go through all the recommendations and work towards consensus. Whatever we have that has made it across the finish line by September 5th will get packaged up, and the co-chairs of this task force will present that at this September 12th HITAC meeting for a vote to approve. Ultimately, whatever gets approved then goes on to Micky Tripathi, to ONC, and ASTP. I am happy to take any questions on that. I know we have a minute or two, if folks have any questions before we wrap up. Rochelle to close us out.

Rochelle Prosser
Yes. I just want to encourage everyone to continue to read ahead and get ourselves prepared. I certainly do welcome the discussion and where we can move it forward to provide extra time, extra overview, and follow-up I will. I thank you for the hard work that you are all doing. We are moving through this rather quickly. I definitely enjoy the comment process going back and forth. If we do not have any questions at this time, I would like to move to adjourn.

Seth Pazinski
All right, thank you. We will close out today's meeting.

Hans Buitendijk
Thank you.

Rochelle Prosser
Thank you, everyone.

Adjourn (01:23:40)

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Kris Mork: I am here, but in the middle of moving from GA to VA, so I will likely not contribute too much today. And I've certainly not done my homework.

Sooner Davenport: Sooner Davenport. I am here as well.

Katrina Miller Parrish: Did you want us to add what we stated in the meetings?

Katrina Miller Parrish: Understood

Katrina Miller Parrish: Agreed

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 14, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO, on 9/18/24.