HTI-2 PROPOSED RULE TASK FORCE 2024 MEETING

GROUP 3: INFORMATION BLOCKING AND TEFCA

July 25, 2024, 11 AM – 12:30 PM ET

VIRTUAL

MEMBERS IN ATTENDANCE

Rochelle Prosser, Orchid Healthcare Solutions, Co-Chair
Hans Buitendijk, Oracle Health
Steven (Ike) Eichner, Texas Department of State Health Services
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Hannah Galvin, Cambridge Health Alliance
Katrina Miller Parrish, Patient.com
Kris Mork, Guidehouse
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
Rachel (Rae) Walker, University of Massachusetts Amherst

MEMBERS NOT IN ATTENDANCE

Shila Blend, North Dakota Health Information Network
Derek De Young, Epic
Dominic Mack, Morehouse School of Medicine
Anna McCollister, Individual

ONC STAFF

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

PRESENTERS

Rachel Nelson, ONC
Michael Lipinski, ONC (Discussant)
Bryant Thomas Karras, Washington State Department of Health (Discussant)

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, or HTI-2 for short, Proposed Rule Task Force Group 3 Meeting on information blocking and Trusted Exchange Framework and Common Agreement (TEFCA). I am Peter Karras with ONC. I will serve as your designated Federal officer today acting on behalf of Seth Pazinski. Just a note, this meeting is open to the public.

Public feedback is welcomed and encouraged 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 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 do call your name, please indicate that you are present, and we will start with our Co-Chair, Rochelle Prosser.

Rochelle Prosser

Present.

Peter Karras

Shila Blend has indicated that she will not be in attendance for today's meeting. Hans Buitendijk?

Hans Buitendijk

Good morning.

Peter Karras

Good morning. Derek De Young? Steven Eichner?

Steven Eichner

Good morning.

Peter Karras

Good morning. Lee Fleisher? Hannah Galvin?

Hannah Galvin

Good morning.

Peter Karras

Good morning. Dominic Mack has indicated that he will not be present for today's meeting. Anna McCollister? Katrina Miller Parrish?

Katrina Miller Parrish

Good morning.

Peter Karras

Good morning. Kris Mork?

Kris Mork
Present.

Peter Karras
Eliel Oliveira? Randa Perkins?

Randa Perkins
Present. Thank you.

Peter Karras
Zeynep Sumer-King?

Zeynep Sumer-King
Present.

Peter Karras
Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Peter Karras
Good morning. Sheryl Turney? Rachel Walker?

Rachel Walker
Good morning.

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

Cassie Weaver
Do you see the chat?

Peter Karras
I do. Yes. Noted, Eliel. Thank you for that. Hopefully, the audio issues will get sorted out. With that, please join me in welcoming our Co-Chair, Rochelle Prosser, for opening remarks and to walk us through our agenda for today's meeting and task force charge. Rochelle, over to you.

Opening Remarks (00:02:59)

Rochelle Prosser
Thank you, Peter. Good morning, everyone. I just want to take a moment to thank you for joining us on the third portion of the HTI rule. I think this is probably the most difficult part and the one that we most likely will have the hottest topics of discussion. So, I welcome you to the task, and I appreciate all of the remarks that

you will have to share. I am a 30-year ICU nurse. I also am a data scientist. But, most importantly, I am a patient advocate and focus on the health and welfare of cancer patients but all patients that need access to records and the ability to address their needs in a timely fashion.

So, this portion of the rule is very important to me and many others, and I know that we will have many stakeholders also represented here on the call but also in our audience as we move through providing recommendations and moving this rule to actual laws. I thank you for your time. For those that are new to the task force, I appreciate you sharing and taking a moment out of your day to assist us in bringing this to fruition.

I would like an opportunity for all of us here on the call to just take a moment, maybe one minute or so, to introduce ourselves based on the roll call so that we all know who we are and who is here. We know that Shila is not able to be here, and she represents North Dakota Health Information Technology Network. But shall we start with Hans, please?

Hans Buitendijk
Good morning. My name is Hans Buitendijk. I am part of the day with Oracle Health focusing on interoperability; other parts of the day working in a number of different industry groups like Electronic Health Record Association (EHRA), Health Level 7 (HL7), Da Vinci, CommenWell, Carequality, etcetera, to help move the interoperability forward. I am also a member of HITAC and looking forward to the discussion on this particular part of HTI-2 and see how we can advance some of the challenges and opportunities.

Rochelle Prosser
Thank you, Hans. Derek is not available yet to the call. So, we shall move to Ike.

Steven Eichner
My name is Steven, Ike, Eichner. I am the Health IT lead for the Texas Department of State Health Services where I am engaged in a wide variety of health IT-related activities. Also, like Hans, I serve as a member of HITAC in addition to my work with DSHS. I also work extensively with the disabled community and have one of the rare diseases out there.

Rochelle Prosser
Thank you, Steve. Lee Fleisher, was he here?

Peter Karras
He was not.

Rochelle Prosser
He is not. That is fine. Hannah, would you like to go next?

Hannah Galvin
Yes. Hi. I am a practicing pediatrician and the Chief Medical Information Officer for Cambridge Health Alliance, which is a public academic health system in the Boston area. In addition, I am the Board Chair and Cofounder of Shift, The Independent Healthcare Task Force for Equitable Interoperability. Clinically, I

work mostly with underserved populations. So, I look forward to representing their needs here and in all of my work in HITAC. Thanks.

Rochelle Prosser
Thank you, Hannah. Dr. Mack is not available today at this moment. So, Anna, would you please introduce yourself?

Peter Karras
I believe Anna was not present during roll call.

Rochelle Prosser
Okay. Peter, based on the roll call, can you say the next person?

Peter Karras
Sure. Katrina?

Katrina Miller Parrish
Good morning. Hi, everyone! I am Katrina Miller Parrish. I am a family physician, clinical informaticist, and now the President and Chief Medical Officer for patient.com, which is an app and online service in development where we really want to make healthcare easier for anybody. So, I am very interested in all of these topics. I have worked on the plan side, the provider side, and on, basically, just the family medicine side working with electronically medical record systems; interoperability; optimization of process, standards; and all those kinds of things. So, I am happy to be here and help as much as I can.

Peter Karras
Next up is Kris Mork.

Kris Mork
Hello, I am Kris Mork, they/them. I am a Director at Guidehouse. I have been supporting data science and interoperability initiatives for public health for some time. In the field of data modernization, we do a lot of support for both state and local public health authorities as well as with the Centers for Disease Control and Prevention (CDC) directly. Thank you.

Peter Karras
We will circle back to Eliel. I know he had some audio issues. So, we can move on to Randa.

Eliel Oliveira
I am here, Peter.

Peter Karras
Great, if you want to go for a quick introduction, I am glad the audio issues were sorted out.

Eliel Oliveira
Yes. Thank you. So, again, my name is Eliel Oliveira. I am with the Harvard Pilgrim Health Care Institute. One of the key things that we handle as part of my position there as a Senior Program Director is the FDA

postmarket drug surveillance program called Sentinel. That is one of the key projects that we have on our therapeutics and epidemiology division.

I also serve as the Chief Executive Officer (CEO) of Connxus, which is the health information exchange in central Texas based in Austin where I live, and I have been collaborating with ONC for quite a bit of time building their standards and piloting solutions in real settings. So, I have a lot of experience in research. I was previously at the medical school at the University of Texas, UT Austin, where we piloted a few of the projects here with ONC. Nice meeting you, everybody.

Peter Karras
Thanks, Eliel. Next up is Randa Perkins.

Randa Perkins
Good morning, everybody. I am Randa Perkins, Family Medicine Doctor and Chief Medical Information Officer over at the Moffitt Cancer Institute in Tampa, Florida. I am also a representative with the National Comprehensive Cancer Center Network. So, I work with a lot of my peers at other cancer institutions focusing on, really, the patient, provider, and clinician interaction with the primary EMR, those hurdles, and everything in between. Thank you.

Peter Karras
Thank you, Randa. Next up is Zeynep Sumer-King.

Zeynep Sumer-King
Hi, everyone. Zeynep Sumer-King. I'm from the New York-Presbyterian Health System in New York State. We are a 10-hospital and ambulatory care health system with Columbia and Cornell as our medical schools and our faculty. I am the Vice President for Regulatory Affairs and Global Services here and have spent the last decade and a half really engaged in New York State's health information exchange, advancing deployment and policies that encourage health information exchange and sharing with patients and other stakeholders. Now at New York-Presbyterian, I am deeply involved in our health information technology and exchange activities and also on the HITAC. I am looking forward to working with all of you.

Peter Karras
Great. Thank you. Next up is Naresh Sundar Rajan.

Naresh Sundar Rajan
Good morning. Hi, everyone. This is Naresh. I am currently serving as Chief Data Officer for CyncHealth. CyncHealth is a statewide health information exchange evolving into more of a health utility for the state of Nebraska and state of Iowa. My background is in informatics and computer science altogether with interoperability for **[inaudible] [00:11:59]**, specifically analytics, interoperability, and how information just gets exchanged across entities like health information exchanges, payers, providers, as well as public health policy decisions. So, I will take it there.

Peter Karras
Thank you, Naresh. Sheryl Turney. I do see that Sheryl is on. Sheryl, if you can hear us, you may be on mute.

Sheryl Turney
Can you hear me now?

Peter Karras
We can hear you now, Sheryl.

Sheryl Turney
Sorry. Sheryl Turney. I am a Senior Director at Elevance Health. I am also the business **[inaudible] [00:12:41]** for interoperability and data use at Elevance health. I also was a member of HITAC for the prior six years and retired in December. I am happy to be working with you guys again. But, also, I do focus on the needs of the patient, as you may be aware. Elevance Health puts the patient first. I have family member with a very rare tumor and bone disease. Basically, that is what fuels my passion. So, I am really happy to be here.

Peter Karras
Thank you so much, Sheryl. Rachel?

Rachel Walker
Good morning, everyone. I go by Rae. I use they/them pronouns. I am a nurse scientist and inventor. My clinical background is in disaster relief and acute and community based care particularly related to cancer patient navigation and aging in place. I am now the Associate Director for the Center of Personalized Health Monitoring at the University of Massachusetts, Amherst, which specializes primarily in mobile health applications, sensors, and AI and founder of Health Tech for the People, which focuses on AI ethics and community-led and equity-centered approaches to the design of health technologies.

Peter Karras
Thank you, Rae. Is there anybody else?

Lee Fleisher
Yes. Lee Fleisher.

Peter Karras
Great.

Lee Fleisher
Thank you so much. It is a pleasure to be here. Lee Fleisher, I am Professor Emeritus of Anesthesiology and Critical Care at Penn and a health services researcher. I am a member of the HITAC and most importantly the former Chief Medical Officer and Director of the Center for Clinical Standards and Quality at CMS, which oversaw the penalties related to information blocking. It is a pleasure to be here.

Peter Karras
Thank you, Lee. Is there anybody else that did not get a chance to introduce themselves? Back to you, Rochelle

Rochelle Prosser

I just wanted to acknowledge one of our co-chairs. Dr. Bryant Karras is also on the call in the public comment section. But I just wanted to acknowledge that he is here. I want to thank everyone for their introductions. As you can see, we have today a community of very well-versed and very invested individuals, businesses, and facilities here all working together to move forward to assist in the prevention of information blocking, adhering to the guidelines of TEFCA, and making sure that we propose a rule that will satisfy as many people as possible.

We understand that the work is heavy, and we know that we are not going to be able to please everyone. But the fact that we have started and are moving forward on the work of many that have gone forward before us, I really appreciate your inputs and your willingness to return to the table as well as the new members and presenters here. So, at that point, I will turn it over to Cassie and Rachel to begin the information blocking elements.

Information Blocking Enhancements (00:16:17)

Cassie Weaver

Thank you so much. Hi, everyone. My name is Cassie Weaver. I am a policy analyst here at ONC, and I am also an information blocking subject matter expert. The definition section today will actually be presented by my supervisor, Rachel Nelson. So, Rachel, would you like to take away? Rachel, if you are speaking, you are muted, I think.

Rachel Nelson

Sorry about that, I was worried about something else that was going on with my display and did not notice that I had it double muted. With no further ado, we have proposed some definitions in the rule, and we are just going to walk through them. There may be other definitions touched on in the rule that I am not going to talk about today because they are connected with a specific proposal, and we will discuss those in context of the proposal. Next slide, please.

First thing in alphabetical order, we propose to add a definition of "business day." For purposes of information blocking regulations, "business day or days" mean Monday through Friday, except for public holidays specified in the US code or declared a Federal holiday by a Federal statute or executive order. This would give actors and other interested parties certainty as to which days count as "business days" for purposes of those provisions of different exceptions that reference business days. The same days would count as business days under information blocking, as we proposed in HTI-2. It would count for purposes of the ONC health IT certification program regulations that reference business days. Next slide, please.

We propose to update the wording of the information blocking regulations healthcare provider definition. It does not really change what the definition is, but it would explicitly reference the definitions of laboratory and pharmacist that are in different paragraphs of the same section of ONC's authorizing statute that is cited versus the healthcare provider definition today. The benefits of this would be enhanced certainty for laboratories, pharmacists, and other interested parties of precisely what laboratory and pharmacist mean within the definition of healthcare provider for purposes of the information blocking regulations. Next slide, please.

I think this is the last of our definitions that we are proposing. Health information technology or health IT, we just simply propose to codify so it is explicit and out there in print. For purposes of the information blocking regulations, health information technology and its short form, health IT, as we use them within these regulations, have the same meaning as they do in ONC's authorizing statute. The benefits of this are enhanced certainty for actors and for other interested parties that that is in fact what health IT means when we use it in the Information blocking regulations. Next slide, please.

So, we do not propose to change the definition of "interfere with" or "interference" that is sitting right there in 45 Code of Federal Regulations (CFR) 171.102. You can go look at it today. That is the definition that is in place. We are, again, not proposing to change that definition. I am going to hand it over to Cassie after introducing it. ONC proposes to add a new section, 171.104, to the information blocking regulations that would codify that certain practices, which could be acts or omissions, constitute interference for the purposes of the information blocking definition.

This would give actors and those who seek to interact with them, to access, exchange, or use of Electronic Health Information (EHI), confidence that certain practices of the following general kinds will be interference for purposes of information blocking definition. Actions taken by an actor to impose delays on other persons' access, exchange, or use of EHI; nonstandard implementation of health IT and other acts to limit interoperability of EHI or the manner in which EHI is accessed, exchanged, or used by other persons; improper inducements or discriminatory contract provisions, omissions, and failures to act when action is necessary to enable or facilitate appropriate information sharing, such as where access exchange or use of individual's EHI is required by law or where it is permitted by law and not subject to restrictions requested by the individual to which restrictions, perhaps, an actor might agree in some circumstances.

The proposal would not set a fixed universe of practices that could constitute interference leaving important room for case-by-case assessment across variations in health IT and future innovations. So, before I hand this back over to Cassie to take the next piece of the discussion, I just want to emphasize that last point. These are certain things that constitute interference, but it does not set the universe. This is not the whole entire catalog of things that could constitute interference. With that, I will hand the presentation back to Cassie.

<u>Cassie Weaver</u>

Thank you so much, Rachel. Just to clarify a few things here. As Rachel said, this is a non-exhaustive list. There are certainly other practices that can constitute interference, and we are talking about an interference, not information blocking. So there is multiple parts of an information blocking claim that need to be assessed, including the knowledge standard, whether or not it is required law, and also whether or not an exception applies. None of those other factors is being taken into account in this list of interferences. These are just practices that constitute interference. An exception may still apply. It might be that the interference is required by law. It might be that the actor does not have the requisite knowledge standard, in which case these would not constitute information blocking because they would not satisfy all of the aspects of information blocking. So, these are just proposed as a list of interferences. Next slide, please.

This is the actual proposed red text here. I can run through what the various examples are if folks would find that helpful. I would just basically be reading this off the screen, again, because I cannot go beyond what we have proposed. But here you can see that these are practices that we say are likely to interfere

with the access, exchange, or use of EHI and that includes delay in patient access to new EHI, including diagnostic testing results, so that clinicians or other actor representatives can review the EHI; delaying patient access to EHI in the patient portal when the actor has the EHI and the actor system has the technical inability to support the automated access, exchange, or use of the EHI via the portal.

As I am reading these, I think some of you might recognize them as coming from guidance we have offered previously, including through our frequently asked questions (FAQ), and that is on purpose. We are trying to move some of that from guidance into regulatory text to provide clarity and certainty to actors. The third on the list is application programming interface (API) access, which would involve delaying the access, exchange, or use of EHI to or by a third-party application designated and authorized by the patient when there is a deployed API interface able to support the access, exchange, or use of the EHI. No. 4: Nonstandard implementation: Implementing health IT in ways that are likely to restrict the access, exchange, or use of EHI with respect to exporting EHI, including but not limited to exports for transitioning between health IT systems.

No. 5 is contract provisions: Negotiating or enforcing a contract provision that restricts or limits otherwise lawful access, exchange, or use of EHI. You can see in No. 6 that we have sort of a series here that you would step through. Noncompete provisions found in agreements: This includes negotiating or enforcing a clause in any agreement, which if you read the preamble we note that any agreement means that the actor does not itself have to be party to the agreement if the actor is negotiating or enforcing the clause in the agreement,prevents or restricts an employee other than the actor's employees, a contractor, or a contractor's employee who accesses, exchanges, or uses the EHI in the actor's health IT from accessing, exchanging, or using EHI and other health IT in order to design, develop, or upgrade such other health IT.

I want to note here that we also included a specific request for feedback about this asking if this is clear enough and if we should mention that such other health IT could include competitors' health IT. So, if you look in the preamble for this part, please note that we do have some specific requests about how we could frame this differently. Next slide, please.

So, No. 7, improperly encouraging or inducing requesters to limit the scope, manner, or timing of EHI. Medical images requiring that the access, exchange, or use of any medical images occur by exchanging physical copy or copies on physical media, such as a thumb drive or digital versatile disc (DVD), when the actor and the requester both possess the technical capability to access, exchange, or use the images through fully electronic means.

No. 9 contains a list of omissions. As you might remember, information blocking can be an act or an omission, an act not taken. So, here we have the following omissions listed as interferences in this proposed rule: Not exchanging EHI under circumstances in which such exchange is lawful, not making EHI available for lawful use, and not complying with another valid law enforceable against the actor that requires access exchange or use of EHI.

No. 4 is specific to certified API developers as defined in the certification program section of the Federal regulations, which is failing to publish API discovery details as required by the maintenance of certification requirement in 170.404(b)(2). No. 5 is API information source as defined again in Part 170, which is our

certification program: Failing to disclose to the certified API developer the information necessary for that certified API developer to publish the API discovery details required by the voluntary certification program.

And then just to wrap up since we started with A, the B here says, "The acts and omissions that will constitute practices that are likely to interfere with the access, exchange, or use of EHI for purposes of 171 include acts and omissions beyond those listed in Paragraph (a) of this section. Before I stop, I want to see if Rachel or Mike has anything that they wanted to add to what I have said to make sure that I have covered it all.

Michael Lipinski
I definitely think that you covered it all. Thank you.

Cassie Weaver
Great. Thank you, Mike. Could we go to the next slide, please? This comes from the preamble. This is not in regulatory text, but we propose in the preamble that it would not be interference for TEFCA Qualified Health Information Networks, known as QHINs, for TEFCA participants, or TEFCA subparticipants to comply with required provisions of the common agreement, the incorporated TEFCA terms of participation, and TEFCA standard operating procedure, respectively. Note that we say required provisions, not optional.

The benefits of this is intended to provide insurances to Information Blocking (IB) actors who choose to participate in TEFCA that complying with the requirements of TEFCA as a QHIN participant or subparticipant would not be considered an interference for purposes of the information blocking definition. We believe providing this assurance supports the policy goals of the Cures Act and supports information blocking by advancing interoperability and expanding secure access, exchange, and use of electronic health information. Next slide, please. I think we are done presenting the proposals for this part of the rule. We can move to the task force recommendation worksheet.

Discussion & Task Force Recommendation Worksheet (00:31:43)

Rochelle Prosser
Thank you, Cassie, for the overview and the proposed rule changes. If we could ask Accel to show the recommended worksheet. As they bring that up, we have an internal worksheet that we will be using to log and track the updates and comments as we add or make recommendations from this panel to the rest of the group to vote on for the HTI-2 rule information blocking and TEFCA rule.

For the members of the group, we will go over this document, which is a Google document. The Accel team has asked you provide an additional Google-driven email so that you are able to access this document and provide comments. What I will do is go over how we would use this document going forward. After today, we will ask you to provide your comments in certain sections of the document in preparation for the next eight weeks, as we move through the rule.

So, Section A just lets you know what rule we were actually on. Column B lets us know the date that it was actually proposed for discussion. Of course, Section C is the task group. This document will contain all three groups. Hopefully, we will have it filtered just for ours; but if you wish to see other comments, you are able to see it there. Column D has the task group topic. In there, it will give you a short definition or the title of the specific rule we are discussing. Column E will say exactly what the proposed rule summary is. We

will find the elements based either on the law, the statute, or what we would propose the new language to be. Column F would be the rule page number and link if we had those available.

For the purposes of the group, Column G, going through the rest of the document, is where we begin to provide our information. So, the member of the task groups under Column G will assign their member recommendations based on their analysis and review of what the proposed rule summary is. In Column G would be where you would state either your thoughts for or in objection to whatever that rule is. In Column H, if we can move to the right a little bit, Accel, we would provide the justification for the recommendation to what our comments were. Column I: The rest of the panel will propose the discussion either to bring in an subject matter expert (SME). Or if they have relevant information toward the rule or the recommendation, they could be invited to speak on the panel.

Column J is my responsibility here, basically, stating what the recommendations are from the workgroup recommendations. We will agree either to move it forward or to say that this will be something that we will act on in a future iteration of the HTI-2 rule for information blocking. So, I will open up the comments for anyone who has questions on how to utilize this document. Cassie or Peter, did I go over the document and cover the elements appropriately?

Peter Karras
From my vantage point, yes, but I will defer to the program leads and SMEs on any other process points.

Cassie Weaver
Yes. I agree, as well. I am noting here that we have actually moved the exceptions that involve practices related to actors' participation in TEFCA. There is an exception already existing in regulation that we have some adjustments to, and we will discuss that at a later date. But, unfortunately, I have it listed here in this column, and I need to get that moved. So, do not let that distract you. The first two bullets here and the second box are what were discussed today.

Rochelle Prosser
Perfect, thank you. For the rest of the committee, do you have any questions? No 1, are you able to access the document? If not, please notate in the chat so that we can ensure that you have access to the document. If you have any questions, now is the time to pose your questions so we can explain it to you. If there are no questions, I will give it back to Cassie and Peter. Or do we want to begin discussing some of the topics within this rule? We did a high level. Yes, Sheryl, thank you. Go ahead.

Sheryl Turney
Sorry, I think I have to unmute myself twice because of audio on the phone. One thing I would recommend, though, just based on the way that we have done it before, when members are putting in recommendations, put their initials and the date. That way, as we are reviewing them, we can see what has popped in in between. It will help us for the maintenance of this spreadsheet going forward.

Rochelle Prosser
That is a great recommendation. Thank you, Sheryl. Anyone else? Go ahead, Hans.

Hans Buitendijk

Rochelle, this is Hans Buitendijk with one additional comment. I think it is less so in information blocking as we saw in the other two sections. But where appropriate, splitting the rows into criteria level or paragraph level sections would be helpful to organize it a little bit further. I think this is much closer to that. But it might be as we provide comments, to avoid getting very lengthy discussions and recommendations in the next columns, to split that up in some logical fashion. Otherwise, it will be hard to keep track of the different aspects. But in this topic, it is going to be less likely than in the other two.

Cassie Weaver
Agreed. I have tried to do that, and I will make sure I am checking ahead to make sure we have done that so that everything is boxed out to as small a detail as makes sense.

Hans Buitendijk
Thank you.

Bryant Thomas Karras
That is particularly true, since this is a shared spreadsheet over each of the different task forces referring to a row number becomes problematic when new rows get inserted and the row numbers are going to change over the course of the 60 days. So, in cross-referencing other sections, make sure that you are doing it in a way that will survive any changes to the spreadsheet structure.

Hans Buitendijk
I think one of the first columns and this is shared, so it likely will be on it already. But using the section references, 174 dot-whatever, 404, or whatever it might be, is very helpful because then we can quickly go to the row that has that as the identifier. Then we get a little bit more flexible in inserting or combining over time.

Rochelle Prosser
Thank you, Bryant and Hans, for your recommendations.

Bryant Thomas Karras
It is not our first rodeo.

Rochelle Prosser
No, it is not. That is right.

Hans Buitendijk
We learn as we go, which is fine.

Rochelle Prosser
Perfect. Is there anyone else that has any comments or questions on news? Accel, if we could scroll down to the bottom of our comment section, I just wanted to show the team where we would add any new recommendations that the group has to add. We will add it at the bottom section here. I think the best use case was we anointed that as an additional section where we can say if we can vote on those later on for additional uses. We may not necessarily be able to add those now in the information blocking, but for those future versions of the information blocking, we can add them here and then vote to see if they are necessary

additions for future iterations. But we would house them at the bottom of the spreadsheet. And I will not say the row because the row, as Dr. Bryant mentioned, will change. With that, I will give back the time back to Peter.

Peter Karras

So, we are tracking a bit early. Public comments does not start until 12:20 p.m. So, we do have some time. Rochelle, Cassie, and Sarah, do you want to think through if we want to get into the spreadsheet and start looking at some of the proposed rule sections, see if there is some immediate feedback from HITAC members? It is up to you all. We can always end early, but we do have some time.

Rochelle Prosser

Go ahead, Katrina.

Katrina Miller Parrish

Thank you. I am glad to have the time to ask a quick question. So, for the definitions, I was wondering if the timings are elsewhere. So, for instance, when we are talking about a delay, is that a delay of hours, days, not sure, or not sure if that is not defined, and it is kept open. I am just wondering on that timing question. Thank you.

Rochelle Prosser

Back to our ONC counterparts to answer more intuitively to that question?

Michael Lipinski

Do you want me to jump in? Or do you guys have this?

Katrina Miller Parrish

Feel free.

Michael Lipinski

Okay, we use the term "delay" through multiple exceptions, not just in what we are proposing to codify as an interference. We actually use it combined with an adverb, adjective "unnecessary delay." So, it is not specified by a day number or anything like that. It is really facts and circumstances. So, for this particular interference, we specify the facts and circumstances where there could be a delay. But there is no minutes, hours, or days specified anywhere. Other rules or programs do have certain time frames for providing data, for example, the promoting interoperability program. Or if you were going to go to Health Insurance Portability and Accountability Act (HIPAA), it has a lot of days' timeframe but nothing specified under information blocking.

Katrina Miller Parrish

Gotcha. Now is that unnecessary language in here somewhere? I am not sure I saw that.

Michael Lipinski

Do you mean the particular interference?

Katrina Miller Parrish

Yes.

Michael Lipinski
I do not believe so. Right, Cassie?

Katrina Miller Parrish
It is because it is not described.

Michael Lipinski
Right.

Cassie Weaver
Yes. It is just delaying patient access to new EHI. It does not include unnecessary.

Katrina Miller Parrish
Thank you.

Michael Lipinski
So, you have the definition of information blocking, which has the terms "interfere with, prohibit," and the last word is escaping me now. But in any event, it is interfering with access, exchange, or use. So, then we have from the get-go, from the Cures Act Final Rule, to find instances that we believe are interferences, including a fee. Any fee, we said, was an interference. Then we created a reasonable fees exception, which would be fees where you could charge that would not be considered an interference. Similarly, timing-wise, we have said an unnecessary delay can be an interference. Now in this particular example, we are explaining more specifically when that would be an interference.

Katrina Miller Parrish
Thank you.

Rochelle Prosser
Thank you. I see, Kris, you have your video on. Would you like to comment?

Kris Mork
Absolutely. One of the pieces that you presented on Slide 13 had to do with nonstandard implementation of electronic health information exchange. I am wondering if it is worth considering enumerating examples of noninterference to say here are some standards that if you faithfully implement the standard then that is prima facie evidence that this is in fact standard implementation to provide some clarity to people who are trying to implement things in a way that keeps them on the correct side of what we are trying to accomplish.

Rochelle Prosser
Excellent point. Would that then be an add, Michael, or just a recommendation?

Michael Lipinski
You could make those comments. There are certain requirements for us regarding APA, the Administrative Procedure Act, in terms of what we can do with the Final Rule. We can always issue guidance. So, I think

all of this is always welcome. If you have looked at a lot of what is in our rules, hopefully, you see a lot of proposals and even what was finalized in the HTI-1 Rule was in response to comments that we received over time that leads to a rulemaking. So, always, comments are helpful.

Rochelle Prosser
Thank you, Michael. Steve?

Steven Eichner
I think one of the things that strike me. I am sorry, Bryant.

Rochelle Prosser
I am sorry. Bryant had his hand up first.

Bryant Thomas Karras
No, let Steve go.

Steven Eichner
I think one of the things that struck me is thinking about the image access and the way it may interact with fees may be indirect. But thinking about what happens on bandwidth demands for advancing exchange of fees as a potential source for increased costs and subsequent potential need to charge fees just to provide services, something we may want to think about down the line. It is an interplay with the two exceptions with perhaps unintended consequences.

Rochelle Prosser
We will add that into consideration. Bryant?

Bryant Thomas Karras
This is perhaps a meta-question trying to think about where to make comments in the spreadsheet on things that have applicability over multiple different locations. There are sections in there that say "the lawful request," and it is used multiple times. I am wondering if we need to make a recommendation in the transmittal to specify which law supersedes. I think that there is going to be potential conflicts between different states' stance on the legality of requesting data for potentially controversial medical information, reproductive care. Gender-affirming care is going to potentially be hitting a lot of conflicts between which applicable state law supersedes, and I am wondering if recommendations can be made in this to try to make sure that there is not a misuse of the TEFCA infrastructure and of data blocking as a tool for getting information that should not be had.

Rochelle Prosser
Yes. I do agree with you, Bryant. There are plenty of use case scenarios in the media and elsewhere where information was used to gain access in manners that are very unpleasant. I do support the initiative that our leader, Micky Tripathi, has done to protect those vulnerable entities in providing privacy in the absence of actual law. So, I would love to hear from the ONC side and Casey, Michael, or Rachel on how we can address that. I am not sure if we can address it here, or if that would be a transmittal upgrade to the pecking order on the hierarchy of the laws and how we would be able to address those here.

Michael Lipinski

I will give you a few thoughts, and then I will leave it to the team. I actually have to jump to another stakeholder call at noon on information blocking. So, we use that term in various statements in the rule. A lot of times to have access to EHI or, generally, electronic protected health information (ePHI), you have to have a right to access it. The media cannot just show up and ask for somebody's EHI without an authorization and so forth. So, that is, generally, what we use the term for. I will let Rachel speak to it more. But when we talk about lawful access, we usually look at exceptions and try to address those, whether the privacy exception or the new promoting care access exception, because I heard about references to some state laws for reproductive healthcare.

There is no preemption for information blocking, federal preemption in the statute, just to be clear about that. But we talk about what we are trying to achieve in the exception, and I do not want to jump ahead. You guys are going to have plenty of time to talk about the Protecting Care Act exception. Rachel will walk you through that one. But I just wanted to add those few comments in regard to what I was hearing. But, Rachel, I see you might be off mute. So, if you have some more thoughts, feel free to jump in.

Rachel Nelson

Well, the main thing I will highlight is something that we have said a couple of times. We have said it in FAQ. We have said it in a couple of rule preambles now. If the actor is operating under a law, if you are subject to a law that says you may not disclose this information, when compliance with that law is required by law, then you would want to look at the information blocking definition where it says "except as required by law." Where actors operate, I just want to remind everyone, it may be helpful if you are thinking of this. I want to remind you when actors operate under multiple jurisdictions there is a provision in the existing privacy exception, subexception for precondition not satisfied that provides for the actor to set up their policies and procedures to follow the most privacy protective.

I think the words we use we use in the regulation are the most restrictive of the laws under which they operate and have those policies and procedures, not the information blocking for purposes of the information blocking regulation as long as you meet the rest of the conditions of that privacy subexception. So, I just wanted to add those couple of points there because I think what I heard was something that, undoubtedly, people who want information are going to try to make it seem like, oh, you are information blocking if you do not give me this. But just to remind you that the information blocking statute does not say you have to disclose information when another law, say HIPAA, forbids you from disclosing the information. So, please, do not disclose information in violation of HIPAA.

Michael Lipinski

I am going to drop. But those are all really good points, Rachel. There was the blog that Micky put out after the HIPAA Reproductive Health Rule went final that talks a little bit more about what you are saying. We also have the FAQs, which we referenced in the HTI-1 Final Rule about using the most privacy restrictive law if you practice in multiple states. So, those are also good resources for everyone as well. Thank you for your time. Thank you for spending the time reviewing the rule and providing comment as well. Thank you.

Rochelle Prosser

Thank you for joining us, Michael. We had a hand up. I am finding you here.

Zeynep Sumer-King

I had my hand up. I put it back down, Rochelle. But I will just chime in. I think it is probably for discussion later on down the line. I am so grateful for the protect and care access exception that has been included, and we are really happy that that has been codified. But here at my hospital we have had a months-long discussion on something that is sort of on the flipside of this. Our state has subregulatory guidance. It is not a statute about positive HIV results being released and strongly recommending, which in New York State means requiring counseling with that.

So, a lot of providers have been holding back positive HIV results in New York. I do not know if we could put that on an agenda in the future. I would love to hear thoughts on the considerations around that because we do not want to be information blocking. But our HIV providers, in particular, are fiercely protective of their patients and want to do the right thing in terms of counseling. So, I just wanted to see if there is an opportunity in the comments process to tuck that in there.

Rochelle Prosser

You know, Dr. King, that is one of my passion points as a HITAC member ensuring that protecting the public and ensuring that those vulnerable populations that were unidentified and unprotected, as we move forward, receive the same protections that were afforded to them of those populations that you are specifically identifying way back in the 80s. Those same provisions are now transferred to the current 21st Century Cures Act, and that is one of the things that I certainly did try to champion on the HITAC committee before this new iteration came out. I do believe that they were covered and insured that that blanket information, coverage, and protection was part of that recent rule by Micky Tripathi.

I see that Rachel has unmuted herself, but I just wanted to let you know those things were addressed with emphasis and dissent on my side to ensure that we cover people with the afforded protections that they deserve. There are times and elements in making things public that will cause harm and will cause definite retreat from sharing. We need to do that in a responsible way and in an ethical way. But first, we need to protect the individual as we move forward through those data sharings, and some things should not be shared in a more public way. So, I certainly applaud you bringing up this issue as a point for physician communication with their patient. Know that your thoughts have been heard and are certainly championed here, and I will go to Rachel. Go ahead.

Rachel Nelson

So, I was not planning to say much. I was just going to say I do not steer the process ship here, but I do think it is up to you if you want to find a way to give us section of recommendations or questions that are more future looking. Maybe they are beyond the scope of anything that we have proposed in this rule. Maybe you do not even think we should do it in rule. It is just a discussion you would like us to have or something you would like us to put out something on. I am being deliberately vague because I do not want to suggest to you that there is only one kind of resource or one kind of communication vehicle that we could have. At least from my perspective, if you all want to work out a way that you have sort of a separate section that is like we know this is outside of the scope of what you proposed in this rule, we just want to make you all aware of it. Or we want to document in this venue what we would like to hear you talk more about. That would be okay with me from working on this on an everyday perspective.

I need to jump off for another commitment. The scheduling is a little wonky. Most of you, I think, already know this. You can submit feedback as well as questions to us on an individual informal basis anytime you want to, healthIT.gov/feedback. We are a small but mighty group. We cannot always respond to things quickly, even when there are things we can give you the answer to. But I just wanted to leave those parting thoughts. I defer to the HITAC team to figure out how to make that process work smoothly and keep it flowing smoothly.

From the IB team perspective, we welcome your thoughts, including informal thoughts and asks, and including informal venues. With that, I will apologize for having the conflict. On this occasion, it could not be helped. I am going to try to make sure that I am here, definitely blocking out the whole time that you are scheduled for, on the day that we are going to be slated to do the talk about the protecting care access exception, even though I really cannot say anything beyond what is in the rule itself.

Rochelle Prosser
Thank you, Rachel. I appreciate you making time to be here today, and we understand that there are competing priorities with the updates that recently came down from the ONC. We applaud your championship and your spirit in being with us today. So, Dr. King, maybe we could talk about to the chat. Before Rachel left, she provided some links in the chat on the background for the National Coordinator's blog. I also want to acknowledge that, Hans, with your wide range of sensitive information, maybe we can create a subgroup to create recommendations that are outside the scope of the information blocking team, but we can add a part or comment section for the transmittal letter on things to add for future topics. I encourage anyone on this group to assist or be the champion to add that. We can certainly put a section at the bottom of this spreadsheet. With that, Hans, if you would like to unmute and say your comments, please?

Hans Buitendijk
Thank you. On the topic of this boundary or touching between information blocking, sensitive data, and how we manage that, which then gets into other areas that are not quite in the rule, but touch upon how do we actually manage it because the information blocking looks at the intent. It looks at what is not being shared, that should be shared. Very sensitive data has both the element of what should not be shared and what can be shared but is not because people are, for understandable reasons, conservatively withholding that data because it is hard to actually manage at the level of detail that we need to.

I think there is opportunity there to consider as an alternative for HITAC at least that there are the annual reports. Eliel is one of the co-chairs on that. Would that be the better place to touch on those? I am not sure whether it is really going to work back into feedback on the rule, but it is touching on a number of other areas where there are opportunities, needs to address that intersection, and the ability to manage sharing of data automatically but then share the right amount. That is a big topic in its own right. There does not seem to be a lot in the rule that can tap into that. There is not much in terms of proposals to change of how data segmentation or others standards could or would be used for the infrastructure to be put in place. So, it is just a consideration that perhaps that is the place to bring up the needs and for urgency to address that.

Rochelle Prosser

I absolutely concur, Hans. We have many members of the current sitting HITAC board, and we will take that under advisement. Thank you, Dr. King, for spearheading this wonderful conversation on this specific topic. I am sure we can hear other people cheering in the background. But as a healthcare provider myself, I certainly do understand the struggle and the need to be able to protect our patients in the most appropriate way in the communications sphere as well as ensure that what needs to be private remains private. With that, I am going to check to see if there are any other final comments. We are at 12:11 p.m. Peter, what time do we have left before we begin public comment?

Peter Karras
We have about nine minutes left, but if there are no other questions or comments, we can move to public comment. It is completely fine to move to public comment a bit early if there are no other questions or comments from HITAC members.

Rochelle Prosser
I do not see any hands at this time. I have looked through the chat, and I think we have tried to address as much as possible the questions.

Public Comment (01:08:00)

Peter Karras
Great. 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 six to mute and unmute your line. I am seeing a hand by Sooner Davenport. Feel free to ask your question or state your comment.

Sooner Davenport
Can you hear me?

Peter Karras
We can.

Sooner Davenport
Hello, my name is Sooner Davenport. I work for the Oklahoma Tribal Epidemiology Center at the Southern Plains Tribal Heath Board. I just had one question or consideration during this discussion. There was a discussion about different laws and jurisdictions, specifically how that might also include Tribal Law and Tribal public health practices. Often, because Tribal governments are so different, even though they are a public health authority, often what constitutes a law is not often standardized because, again, everything functions so differently. So, I am not sure where that has been addressed or if it is something that has been considered, especially when we are talking about perceptions of what is sensitive information. That is something in the work that Tribal health boards do with health systems that we are often advocating for. Thank you.

Peter Karras
Thank you, Sooner. Does anyone from the ONC team care to respond?

Cassie Weaver
This is Cassie. I think I am the remaining policy person standing. I would have to double-check, but I do believe we talked about Tribal Law in the ONC Cures Act Final Rule preamble but welcome comment, especially from someone working so closely with the community on how we could better address it.

Peter Karras
Thanks, Cassie. I am not seeing any other hands raised at the moment. Do we have anybody on the phone, Accel team?

Speaker
No further comments.

Peter Karras
Thank you. With that, I will turn it back to Rochelle. But before I do, just a reminder that the next Group 3 meeting will be August 1 from 11:00 a.m. to 12:30 p.m. Eastern Time. And a reminder to everyone that all HITAC meeting materials and be found healthit.gov. With that, I will turn it over to Rochelle for closing remarks.

Next Steps (01:11:04)

Rochelle Prosser
I want to thank all of the members and the public here on this call today for coming to listen to the proposed rule changes and updates for the information blocking and TEFCA. We have had a very robust and healthy conversation about the beginnings of this task force, and I look forward to reading and updating the recommendations coming from the committee and the general public. Thank you for making time to attend today. That is back to you.

Peter Karras
Thank you. Goodbye, everyone.

Adjourn (01:11:46)

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT
Katrina Miller Parrish: Go Team(s)!

Eliel Oliveira: Sorry, I am here but with audio issues

Bryant thomas Karras: I'm Bryant thomas Karras   joining when i can

Michael Lipinski: A good example where the "day" paradigm would apply is the response requirement under the Infeasibility Exception.

Rochelle Prosser: Thank - you Rachel for your overview of the definitions.

Hans Buitendijk: There is a wide range of sensitive information that based on applicable privacy rules and patient consent directives may or may not be able to be shared. We do not have an agreed to set of standards, computable rules, and the necessary infrastructure to manage that well, thus having a risk of sharing too much or too little. The latter could drift into information blocking concerns that we have to be aware of and understand whether it is truly blocking, or rather conservatively protecting patient data in the absence of the full means to share as authorized.

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 - July 25, 2024, Meeting Webpage

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