HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

GROUP 1: INFORMATION BLOCKING

May 9, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Steven Lane	**Health Gorilla**	**Co-Chair**
Steven Eichner	**Texas Department of State Health Services**	**Co-Chair**
Hans Buitendijk	Oracle Health	Member
Hannah Galvin	Cambridge Health Alliance	Member
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Member
Deven McGraw	Invitae Corporation	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
Wendy Noboa	Office of the National Coordinator for Health Information Technology	Acting Designated Federal Officer
Daniel Healy	Office of the National Coordinator for Health Information Technology	ONC Program Lead
Cassie Weaver	Office of the National Coordinator for Health Information Technology	Presenter
Rachel Nelson	Office of the National Coordinator for Health Information Technology	Discussant
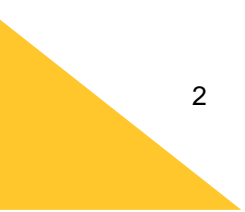
Call to Order/Roll Call (00:00:00)

Wendy Noboa
Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task Force. I am Wendy Noboa with ONC, and I would like to thank you for joining us today. All Task Force meetings are open to the public, and your feedback is welcome, which can be typed into the Zoom chat feature throughout the meeting. You can also make verbal comments during our public comment period that is scheduled towards the end of the meeting this morning. I will now begin to do a rollcall of our Task Force members. When you hear your name, please indicate that you are present. Let's start with our cochairs. Steven Lane?

Steven Lane
Good morning.

Wendy Noboa
Steve Eichner?

Steven Eichner
Good morning.

Wendy Noboa
Hans Buitendijk?

Hans Buitendijk
Good morning.

Wendy Noboa
Hannah Galvin?

Hannah Galvin
Good morning.

Wendy Noboa
Adi Gundlapalli?

Adi V. Gundlapalli
Good morning.

Wendy Noboa
Deven McGraw?

Deven McGraw
Good morning, everyone.

Wendy Noboa
Eliel Oliveira? Fil Southerland?

Fillipe Southerland
Good morning.

Wendy Noboa
Sheryl Turney? Okay, thank you, and please join me in welcoming Steven Lane and Steve Eichner for our opening remarks.

HTI-1 Proposed Rule Task Force Charge & IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities (00:01:17)

Steven Lane
Thank you very much, Wendy, for getting us started, and thank you, everyone, for attending what I think is the third meeting of HTI-1 Group 1. We have a full agenda today. We will review our charges once again, refocus ourselves on the manner exception and the new TEFCA manner proposal, dig into some new TEFCA reasonable and necessary activities, and then we will talk toward the end about our planning for the HITAC meeting, where we are going to meet next week and provide a brief update on the work of our Task Force. We will have public comment at 10 minutes before the hour, and we really want to encourage members of the public who are joining us today to feel free to utilize the public comment time. I see we have a few people. Some of you have been attending every meeting. I am very impressed by your commitment and perseverance to all of this, and I really want to invite members of the public to participate in the chat during the course of the meeting, the written chat, as well as provide verbal public comment at the end. Ike, do you want to add to that?

Steven Eichner
It is hard to follow that wonderful performance, but I would like to say my gratitude and appreciation for everybody participating today, and I do encourage the public to take advantage of the opportunity for public comment as we get to the end. I am excited by the material that we have to look at today, and hopefully we can provide some wonderful feedback to our federal partners.

Steven Lane
Once again, as we go along, I will be leading the verbal discussion, Ike will be watching for questions and trying to capture any core comments or ideas in our spreadsheet as we go along, and then we will be using that material to put together our formal recommendations to the HITAC. Thinking ahead to the 11:40 time when we are preparing for next week's HITAC meeting, I really want to encourage Task Force members to be thinking about any key items, topics, or perspectives that we want to include in our presentation to the HITAC from the work of this particular workgroup, or really, any of the workgroups, if they come to mind.

Typically, in these intermediate updates, we just review the fact that we have been meeting, and what we have been discussion, who has been participating, and what subject matter experts, but if there are any key points that you all think the HITAC should be thinking about prior to our final recommendations, please think about those during the course of our meeting and raise those at the 11:40 slot. With that, why don't we go ahead? We will review the Task Force charge that has been before us here, and here, I will just say that we are not going to read through this every time, but this is a review of what we have been asked to do as a Task Force. Next slide.

We are going on through our charge, and then, here are the topics that have been specifically assigned to this workgroup, the Tuesday Group 1. We have already talked about the information blocking defined terms and the exclusions regarding offering health IT. We are now diving into Bullets 3 and 4, and we will continue on down this list as we go along. Next slide. So, with that, I think Cassie and Dan are going to take us through this next topic.

IB Manner Exception – TEFCA Manner Proposal (00:05:21)

Daniel Healy

Great. Thanks so much, Steven, and thanks to you all. Great to be with you today. I know we have a lot to jump into, so let's get started. I will be going through the first portion of the presentation today with some background context and overview on the policies and proposals that we are discussing today, and then I will be turning it over to my colleague Cassie Weaver for the second part of the presentation, where we can dive into some more specifics. Next slide, please.

So, as a brief disclaimer before we jump in, the materials contained in this document are based on the proposals in the Health Data Technology and Interoperability Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule, also known as HTI-1. While every effort has been made to ensure the accuracy of this restatement of those proposals, this document that you see today is not a legal document, and the official proposals are contained in the proposed rule. Please note that other federal, state, or local laws may also apply. In addition, we note that ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the proposed rule as it is contained in the proposed rule. ONC cannot interpret that information, clarify, or provide further guidance, and this information is produced and disseminated at U.S. taxpayer expense. Next slide, please.

So, here is our agenda today. As I mentioned, I will give some comments on the policy overview, context, and background of the proposals, and then turn it over to Cassie, and in the last two bullets, you can see, as Steven mentioned, what we are set to discuss today. Next slide, please. So, what we have here on the slide is a summary of the proposal and the RFI that we are discussing today. First, ONC proposes to add a TEFCA manner condition to the proposed revised and renamed manner exception to be codified in 45 CFR 171.301C. We are also calling this the TEFCA manner proposal for short. In parallel to the manner exception proposal, we propose to define in Paragraph D of 45 CFR 171.301 the terms used in the TEFCA manner condition. Thirdly, the RFI, the HTI-1 proposed rule also includes a request for information on possible additional TEFCA reasonable and necessary activities. Next slide, please.

So, before I jump into some background on the TEFCA manner proposal, I will just say a very brief word on TEFCA. It is not on the slide here, but TEFCA stands for the Trusted Exchange Framework and Common Agreement. The overall goal for TEFCA is to establish a universal floor for interoperability across the country. The common agreement will establish the infrastructure model and governing approach for users in different networks to securely share information with each other, all under commonly-agreed-to expectations and rules. The trusted exchange framework describes a common set of nonbinding foundational principles for trust policies and practices that can help facilitate exchange among health information networks, and more information can be found on our website about that.

So, to jump into the background on this TEFCA manner proposal here, we note that in the CURES Act proposed rule, we requested comments on whether we should propose in a future rulemaking a narrow exception to the information blocking definition for practices that are necessary to comply with the requirements of the common agreement. We stated that such an exception may support adoption of the common agreement, and it may encourage other entities to participate in trusted exchange through health information networks that enter into the common agreement. We also discussed that it would do so by providing protection if there are practices that are expressly required by the common agreement or that are necessary to implement common agreement requirements that might implicate the information blocking definition and would not qualify for another exception.

We also noted that such an exception would be consistent with the complementary roles of the information blocking provision and other provisions of the CURES Act that support interoperability and enhance the trusted exchange of EHI, including the interoperable network exchange provisions, the definition of interoperability, and the conditions and certification, to which we have citations here on the slide. We further noted that such a proposal would be narrowly framed such that contract terms, policies, or other practices that are not strictly necessary to comply with the common agreement would not qualify for the exception. Similarly, we expect that any future proposal would provide that an actor could benefit from this exception only if the practice or practices the actor pursued were no broader than necessary under the circumstances. We also commented that these limitations would ensure that the exception would be narrowly tailored to practices that are most likely to promote trusted exchange without unnecessarily impeding access, exchange, or use of electronic health information. Next slide, please.

So, to continue on with some background on the proposal, a majority of commenters asserted that there should be some form of "safe harbor" for TEFCA participants, while other commenters contended that such an approach was unwarranted and that all actors should be subject to the same information-blocking practices and requirements. Overall, the comments received in response to the CURES rule RFI that were in favor of an exception outnumbered those that were not in favor. Some commenters advocating for an exception covering or incentivizing TEFCA participation noted that such an exception would provide certainty and reduce the compliance burden for the market.

The HITAC's recommendation regarding the CURES rule RFI urged ONC to "consider carefully the enduring demand of the CURES Act to promote information sharing and prohibit information blocking amongst all actors" and expressed a view that a careful balance needed to be struck between encouraging compliance with the information-blocking regulations, potentially through the adoption of TEFCA, and the need to investigate information-blocking practices and not inadvertently allow bad actors to circumvent compliance with the information-blocking regulations.

So, during the development of TEFCA and since the publication of the common agreement on January 19th, 2022, ONC has continued to receive requests for clarification regarding the potential information-blocking implications or interpretations of practices, practices defined under the information-blocking regulations as acts or omissions, that the common agreement requires of QHINs, qualified health information networks, and of participants or sub-participants through the common agreement's required flowdown provisions in either participant QHIN or participant sub-participant agreements. Those agreements are also referred to as framework agreements. Interested parties have continued to request

that ONC provide certainty that such practices would be considered reasonable and necessary activities that do not constitute information blocking. Next slide, please.

So, with that background, I will give some additional context about the TEFCA manner proposal that we are set to discuss today. So, we noted that each QHIN participant or sub-participant has chosen to become part of the TEFCA ecosystem and that, where there are mechanisms consistent with TEFCA's technical framework and other requirements relevant to particular types of EHI and purposes of exchange, can support EHI access, exchange, or use for any purpose permitted under the common agreement and the applicable framework agreements, we believe it is reasonable and necessary for actors who have chosen to become part of the TEFCA ecosystem to prioritize use of those mechanisms rather than other mechanisms that are potentially less interoperable, less secure, or less scalable for sharing EHI with requesters who have also chosen to become part of the TEFCA ecosystem.

This proposal aligns with a foundational policy construct that underpins the manner exception, it facilitates an actor reaching agreeable terms with a requester, and acknowledges that certain agreements have been reached for the access, exchange, and use of EHI. The proposal also incorporates multiple aspects responsive to public comments and feedback received on the ONC CURES Act proposed rule, which we discussed a little bit previously in the background slides. Next slide, please.

So, to illustrate the proposed TEFCA manner condition, if a responding actor fulfills a request to access, exchange, or use EHI from a QHIN participant or sub-participant through TEFCA means, then that would be sufficient for meeting this proposed new condition, and in this scenario, the responding actor would not be required to conform any fees or any license agreements to the fees or licensing exceptions respectively. The TEFCA manner condition could be satisfied regardless of whether the requesting QHIN, participant, or sub-participant initially requested access, exchange, or use through TEFCA means or through another manner.

Another important feature of the proposed TEFCA condition is it can be satisfied by the responding QHIN, participant, or sub-participant either fulfilling or offering to fulfill the requesting QHIN's, participant's, or sub-participant's request for EHI using TEFCA means. So, to illustrate that feature of the proposal, if a QHIN, participant, or sub-participant actor offers to fulfill a request to access, exchange, or use EHI from a QHIN participant or a sub-participant through TEFCA means that are available to both the requester and the responding actor, then that would be sufficient for meeting this proposed new TEFCA manner condition, even if the requesting QHIN, participant, or sub-participant initially requested access, exchange, or use in some other manner or refused to accept the responding actor's offer to fulfill the requested EHI access, exchange, or use through TEFCA access. Next slide, please.

So, some additional context and notes here on the proposal as well. The TEFCA manner condition would be an additional option under the revised and renamed manner exception. The manner requested and alternative manner conditions would also remain available to QHINs, participants, or sub-participants responding to any requesters. I would also note the establishment of the TEFCA condition would not preclude a QHIN, participant, or sub-participant information-blocking actor from making a different choice with respect to supporting non-TEFCA means in complement to TEFCA means of information sharing with others who also choose to become QHINs, participants, and sub-participants. I believe that is the conclusion of our slides on this portion of the presentation. On the next portion, I will pass the mic to my

colleague Cassie Weaver to talk about the proposed revisions more specifically, but I see Deven's hand is up, so maybe I will pause there before passing to Cassie for questions if you have any questions.

Deven McGraw
I have so many questions, but I will start with one because it is pertinent to something that you just covered. So, I want to understand a little bit, and if you could go back a slide, how a couple of things fit together. So, this last bullet allows people who are signatories in some way, shape, or form to participating in TEFCA to choose a non-TEFCA pathway to exchange information, and yet, on the prior slide, it looked like it was actually sufficient for at least one of those parties to say, "I am offering you TEFCA," and therefore, that seems to be… As long as one party wants TEFCA, TEFCA is the manner that has been offered, and that is the pathway that I assume the entities are supposed to go down. So, it seems like this last bullet on this slide would apply only if both parties to the EHI exchange transaction wanted to go outside of the TEFCA bubble. Is that a safe assumption? Am I reading those two things right?

Daniel Healy
Cassie and Rachel, feel free to jump in as well, but the word I focus on there, I think, is "supporting," supporting non-TEFCA means in complement with TEFCA means of information sharing. So, really, I think what I would say there we are saying the establishment of this TEFCA condition of the TEFCA manner or proposal… As we mentioned in one of the previous bullets, if there are two entities who are both participating in TEFCA, that would be one of the conditions that would have to be in place for an entity to use this, but that being in place does not preclude one of those entities from also supporting non-TEFCA means in complement to the TEFCA means of information sharing, if that answers the question.

Deven McGraw
Sort of. So, it sounds like if I am a QHIN, I can have a TEFCA line of business and a non-TEFCA line of business for exchanging information, but where my requester is in the TEFCA ecosystem, I can say, "You have to use TEFCA," even though I also support non-TEFCA. Is that a proper way to crystallize that?

Daniel Healy
I think that sounds reasonable to me, yes.

Deven McGraw
Okay, thank you.

Cassie Weaver
I would just add, too, that if both are participants, it could also satisfy the manner exception generally to provide it in a different means if both agree to it. So, we are saying that just because we have this TEFCA condition, if two participants have decided to exchange otherwise, that is not going to be de facto information blocking just because they could have satisfied, but did not satisfy, this TEFCA condition, obviously subject to whatever constraints might be in the relevant SOPs and things like that.

Deven McGraw
Right, but both of them would have to agree, correct? As opposed to one party going, "You are going to go down my TEFCA swim lane."

Cassie Weaver
Right.

Deven McGraw
Okay, thank you.

Cassie Weaver
We have a couple more questions, and before you ask them, Steve and Steven, I just wanted to let you know I am going to walk through the actual proposed language in a bit more detail, so if your questions might be answered by that, you might want to hold them and see if I address them, but if you do not think so, then we can go ahead and take them now.

Steven Eichner
This is Steve Eichner. I am not sure mine would be answered subsequently. Looking at TEFCA participants and sub-participants, how are you addressing exchanges within a single QHIN where it is not necessarily going across or between QHINs? Are you considering those as TEFCA exchanges or not?

Daniel Healy
For exchanges within a QHIN, meaning exchanges within members of a QHIN or within a QHIN itself, internally to the QHIN?

Rachel Nelson
I am going to hop in here and suggest we put a pin in that question and come back to it if you still have it after Cassie steps through what the proposal says.

Steven Eichner
Lovely.

Cassie Weaver
Thank you. And then, Steven, I think you put your hand down, so can we go to the next slide? So, here are the proposed revisions. Next slide, please. In plain language, the way this would work is if you recall the current content and manner exception, it says that if an actor provides the EHI in any manner requested, then the actor and requester can agree to any terms they would like for that exchange, obviously subject to any restrictions like patient requests and the right-of-access rule. Also, if the actor is providing the EHI in any manner requested, the actor does not need to satisfy any of the requirements of the fees and licensing exceptions, which puts certain restrictions on the negotiation and terms of that agreement.

Again, this is the current regulatory language that I am speaking to. But, if the actor is unable to provide the EHI in any manner requested or if that actor and requester are unable to come to agreement on the terms of the exchange, then, currently, the actor would move to the alternative manner condition, which is a series of alternative means of providing the EHI, which are open source and based on interoperable standards, and then, as a sort of last resort, an actor could provide the EHI in a machine-readable format, all the other exceptions still being available.

So, where does this proposed TEFCA manner fit in? It actually can slot in at any point, but the idea is that it identifies as reasonable and necessary an information-blocking actor's practice of prioritizing using the appropriate TEFCA means, even if the actor could feasibly provide the EHI in other manners, including manners that the requester may have asked for, if certain conditions are met. So, this would cover any and all EHI for which access, exchange, or use can be supported by TEFCA means for both the actor and the requester, and only so long as the requester is a QHIN, participant, or sub-participant, and the purpose of the exchange or use is permitted under the TEFCA governing agreements. It is available regardless of whether the request is initially made through TEFCA means or otherwise, and regardless of whether all of the particular data classes or exchange purposes requested are yet required by TEFCA's governing agreements to be returned in response to a TEFCA request.

So, if you can satisfy the entire request through TEFCA means, even if all of those data classes are not yet covered by, for example, a TEFCA SOP or any of the other governing agreements, then you can still satisfy this exception. It is not unavailable because you are sharing all of the EHI, even if that EHI is beyond what TEFCA would require. And then, we also have an RFI with this that is considering whether we should require an actor to check the directory of all the QHINs, participants, and sub-participants under the TEFCA governing agreements in order to see if that requester is listed. This would not necessarily be dispositive as to whether or not the actor has satisfied this exception, but it would obviously inform an assessment of the actor's intent in using it and would improve overall efficiency of these exchanges, so we are asking for feedback on that. Next slide, please.

So, here is the proposed new test for the new manner agreement, which you will recall that we are proposing to rename, since the content half of this exception has timed out and all EHI is now covered by the definition of information blocking. So, this is very small type, but you can see here that the first manner, A, "Manner requested," is the one I discussed, which is when the actor provides in any manner requested, the actor and requester come to any terms they want, subject to other applicable laws and regulations, and then, B is that alternative manner where an actor who cannot reach agreement or cannot provide the EHI in the manner requested would try to provide that access, exchange, and use under an alternative manner that the requester has agreed to, like using health IT certified to the ONC health IT certification program content and transport standards specified by the requester and published by the federal government or another standards developing organization.

Finally, and again, only if the actor agrees, an actor could provide the EHI in a machine-readable format including the means to interpret that EHI. When the actor provides this in the alternative manner, then the actor is subject to all the limitations found in the fees and licensing exceptions in 171.302 and 171.303. So, this is relatively close to current day. Again, it is the renamed one and the content part has been removed, but otherwise, there is not much new on this part. Next slide, please.

So, this is where ONC is proposing to slot in this new TEFCA manner as C, and this is the exact regulatory text. So, if an actor who is a QHIN, participant, or sub-participant offers to fulfill a request for EHI access, exchange, or use for any purpose permitted under the common agreement and framework agreements from any other QHIN, participant, or sub-participant using connectivity services, QHIN services, or the specified technical services in the applicable framework agreement that is available to both parties, then the actor is not required to offer the EHI in an alternative manner, and any fees charged and any license of interoperability do not need to satisfy the exceptions in 171.302 and 303.

So, you can see how this condition sort of parallels the manner requested condition, and so far as the licensing and fees exceptions go, they do not apply, but another difference you can see here, which Deven pointed out, is that the requester does not have to agree in the way that the other conditions require, but in this case, the class of requesters is limited because, as I think Dan touched on, we want to make sure we are using this exception for requesters who are able to receive the EHI in the manner that it is being provided. We do not want to just say, "Sure, offer it in a TEFCA manner," so we do want to make sure that the EHI is still being exchanged, and the manner itself is also restricted in that the actor has to provide it using what we sort of have internally shorthanded as TEFCA means, which are those connectivity services, QHIN services, or the specified technical services. Next slide, please.

So, obviously, we have introduced a bunch of new terms in that C TEFCA means condition, so we went ahead and proposed to add this new section D, and you can see here we are proposing to define QHIN, participant, sub-participant, connectivity services, and framework agreement, and also QHIN services. These proposed definitions are all informed by the relevant TEFCA agreements, and we worked internally with our TEFCA experts to make sure these made sense. So, I am not going to read through them, but I actually just caught a typo as well. I hope that is not in the actual reg text. Anyway, those are the proposed definitions that cover all of the new terms in C, the TEFCA manner condition. Next slide, please.

Here is the RFI for this portion of today's conversation, which is possible additional TEFCA reasonable and necessary activities, and there are sort of three different parts to it. We are looking for comment on whether there are other practices that are not otherwise required by law, but are required of a QHIN, participant, or sub-participant that pose some sort of concern or uncertainty regarding whether such practices could constitute information blocking. And then, we are also requesting comment on if any particular practices required of QHINs, participants, or sub-participants may pose such concerns or uncertainty, and what is the specific source of the requirement, obligation, or commitment. Is it in the common agreement, the flowdown requirements, the QHIN technical framework, the SOPs? Let us know where the source is that you might see some sort of conflict.

And then, finally, we are also requesting that commenters identify the practices that they believe are not covered by existing IV exceptions, and if commenters would advocate reassessment for potential identification as reasonable and necessary activities that do not constitute information blocking, knowing that not all individuals who have a right or are allowed under applicable law to access, exchange, or use EHI may be in a position to become a QHIN, participant, or sub-participant. We want to know whether and how any identification of additional, reasonable, and necessary activities might pose concerns about unintended consequences for those individuals or entities who are not QHINs, participants, or sub-participants. Next slide, please. At this point, I will hand it back over to our cochairs to lead the discussion.

Steven Lane

Thank you so much. Great presentation. A couple of questions are stacking up in the chat, mostly from me, but maybe I will go ahead and put one out, and then Hans has one as well. Mine was an observation, but I will phrase it as a question, just to be sure that I have it right, and that is to say that you are using the terminology here that requires the ability to default to TEFCA exchange for any purpose of exchange that is permitted under TEFCA, as opposed to limiting it to those purposes for which a response is required. So, this would seem to create an avenue to really push people to start to use TEFCA for some of the new

purposes that are not yet required, some of which are not even yet defined in SOPs, and I am just curious what the limitations of that extension are. Are we assuming that all of the permitted purposes will be defined by the time this rule goes into place, or might there be a period of time where there could be confusion around that?

Cassie Weaver

That is a good question that might be something to raise in a comment, but as far as using "permitted" instead of "required," I would just maybe observe that a reasonable and necessary activity could also be seen as sort of an incentive to participate in TEFCA, so an exception can serve dual purposes here.

Steven Lane

Okay. So, as you say, maybe a comment would be in order. Ike, you had your hand up just before Hans.

Steven Eichner

Just to glom onto that added component and look at what is currently permitted under TEFCA, some things may not be able to be implemented under TEFCA for a variety of reasons, not necessarily with every actor. For example, looking at prior registration for providers with public health systems, they are necessary to access the data. That is another level of the cake that TEFCA has not really fully contemplated. There are not SOPs or processes in place and laid out today, and it may be quite some time before they are. Even though public health purposes are currently listed as a valid exchange purpose, there is no underlying documentation or actual processes laid out to actually do it at this time, so how is that gap addressed?

Cassie Weaver

Well, I would say that the text of this proposal does say that using the services specified in the framework agreement available to both parties, so it has to be doable, but I also would like to recognize, obviously, that you are all hitting on a common point that is something that we are trying to both capture and struggle with here, which is that all of this is happening at the same time. We are working on all of these TEFCA SOPs at the same time that we are drafting and proposing these rules that will not go and be finalized for a few years now, so, in some ways, the rule almost has to get out ahead of the SOPs in hopes that we are capturing it correctly because by the time it is finalized, ideally, we will be further along in this TEFCA process, so I appreciate all these questions and do encourage everyone to submit them as comments, but there will be things that, obviously, I cannot answer today or in general because TEFCA is catching up in some ways to this proposed exception.

Steven Lane

Hans?

Hans Buitendijk

Thank you, Steven. I think my comment is going to be in the same category, that it is probably not something you can answer today, but I want to bring up for HITAC how we shape the questions or the recommendations. Another aspect of that is that as a participant, sub-participant, or QHIN, easier for a QHIN, but more specifically for a participant and sub-participant, they may not participate in all the purposes of the use yet, so is there intent in the way it was written that one must support all the exchange purposes before one can even consider that, or is it that as long as it is for the purpose of use at hand where the QTF

is in play, and therefore the format is in play, that is where you can do it, even though you do not support everything?

I think it is on that scale of what is the entry point that you can start to claim that and what is it that we are actually looking at. Is it the SOP? Is it the QTF? What element clarifies that if that is in place for this instance, then at that point in time, you claim that you are part of TEFCA and can hone in on that? I think it is part of the way we need to shape the recommendation because there is a continuum there of when you start to be eligible and what you actually need to point at to be eligible.

Cassie Weaver
Rachel, do you want to jump in with a clarification? I might have misstated something.

Rachel Nelson
No, I do not thing you misstated anything, Cassie. I just wanted to point out that I think where that comment started was asking about intent, which we cannot clarify beyond what we said in the preamble at this point in time, but I would just point out that the current text, which I think you already noticed based on where you landed with that comment, does not say that the responding actor would have to be able to support any and everything in order to fill the wording of the exception.

The wording of this condition of the exception is if an actor who is a QHIN, participant, or sub-participant offers to fulfill a request for EHI exchange, access, or use for any purpose permitted under the common agreement and framework agreement from any other QHIN, participant, or sub-participant using connectivity services, QHIN services, or the specified technical services in the applicable framework agreement available to both parties. We do say a little more in the preamble, but I did want to make sure we were aware that the idea of a restriction to say you had to support everything in order to be able to satisfy the conditions as this exception is not placed in here as a requirement of this condition.

Hans Buitendijk
Thank you.

Cassie Weaver
As we are taking questions, it might actually be helpful to drop back to Slide 22, just because that has the actual proposed text on it, so we can refer to it as we are answering. There, perfect. I see Deven has her hand up.

Deven McGraw
I do. I am going to ask the application of licensing and fee exception aspects that have been raised in the chat because that was another question that was spinning through my mind as well, so if you do, in fact, have both a requester and a data holder who are participating in TEFCA and there is the offer on the table to exchange through TEFCA, then, as I read this, the limitations that are set up in the fee exception and the licensing exception would not apply, so does that mean that if there is a fee associated with that transaction, as long as it satisfies whatever are the TEFCA requirements, if there are any around fees, they are not bound by any of the potential limitations of the existing fee and licensing exceptions?

And then, in the context of individual access, does that mean that the limitation that currently applies that there can be no fee for individual access when done through electronic means that do not require any manual labor would be off the table then, and that, essentially, anyone who is seeking to do individual access through TEFCA might actually get charged fees and should not expect to be protected by that fee exception that currently would preclude those fees in the context of individual access? Am I reading that right?

Cassie Weaver
You are reading it right in the first sense, that those restrictions in the fees and licensing would not apply, but as far as individual access, the request does have to come from one of the specified parties here, QHIN, participant, or sub-participant, and an individual would not be one of those.

Deven McGraw
Right, but an individual could be using, for example, an app that decided they would like to take advantage of being able to tap into the TEFCA so that their users could get their information from multiple sources through a single query versus having to maintain API connections at every juncture and say, "We are not in facilitative FHIR, we are in a different landscape around how individual access occurs through the QHIN." Then, that fee exception would not apply in that context. But, tell me if I am wrong about that because that is one of the concerns that I have had around the fee exceptions not applying when TEFCA is used. What is the impact on TEFCA for individual access? We either want an individual seeking information just as a patient launching a query, whether they have hired an app to do that on their behalf, where the app becomes a sub-participant as a mechanism of being able to get queries into the TEFCA.

Cassie Weaver
Rachel, can you speak to this?

Rachel Nelson
I think we do not want to go beyond what is in the rule, and for procedural purposes, we cannot. I do think that, as we say in the preamble, this condition of this exception… Remember, the manner exception would continue to function, as explained in the preamble, as a pick list, and like all information-blocking exceptions, it is voluntary, so if an app wants to set themselves up as an individual access service provider under TEFCA, then there would be certain features to how the responding QHINs, participants, and sub-participants could interact with that TEFCA IAS provider that might not apply if that particular app chose to go down a different path, but it was their choice. We noted that this condition of the exception, this new way to meet the manner exception, would recognize that folks who are a QHIN, participant, or sub-participant have decided to become a part of TEFCA and that certain agreements have already been reached among the people who have chosen to become a part of TEFCA, and that is really as much as I know off the top of my head that we can say today within the bounds of protecting the rulemaking process.

Deven McGraw
Yes, and I am simultaneously looking at Zoe's response in the chat. I am just going to say I think for purposes of our subgroup, this is worth some further consideration because I do think that we need to think more about whether this creates a disincentive for anyone to become an IAS participant under TEFCA if, in fact, that might translate into higher fees. So, just put that in the parking lot. Thank you.

Steven Lane

I think that the fees question goes both ways. Would this new manner proposal potentially lead to higher fees, or would it, in any way, prevent the charging of fees that might otherwise be charged? That was my original question. I think Deven put my mind to rest there. So, the key here is that people are getting out, potentially, of the limitations on fees. Is that right, Cassie and Dan?

Cassie Weaver

Yes, in the same way as the "satisfying the manner requested" condition. That language is the same.

Steven Lane

All right. Does anyone else have any questions? Did anyone put anything into the chat that they want to raise? Hannah, you have a comment here in the chat.

Hannah Galvin

I just threw a couple comments in the chat, but I think they have been mostly reflected in the comments that others have made already. At a high level, my understanding is that the purpose behind this is to encourage the industry to participate in TEFCA, to become QHINs, participants, and sub-participants, and to offer this as a manner to exchange data, and yet, at the same time, we are very early in this process, and we only have specific SOPs we have not quite tested out. We do not know who is going to become sub-participants, nor exactly how that is going to work.

I have questions about that implementation and what that is going to look like, and if we say this would be for all permitted uses, and then an actor wants to say, "Well, I can exchange data in this way because you, requester, are a participant or sub-participant in TEFCA" and they want to exchange data in a manner outside one of the current SOPs that has not been adequately defined or tested, do we know that that information is being achieved successfully, or are we just trusting that that is happening, or do we want to have some limitations within the current SOPs and how that has been defined? I think that is one of my questions, how this would work in the real world, but I think that is sort of a chicken-and-egg discussion, and with some of that, we would have to wait and see how it worked and whether there needs to be further definition after it, but I think that is where both of my comments went to. Do we have enough information yet to give this broad-based manner exception around it, or does it need to be a little bit narrower?

Steven Lane

Were you looking for an answer, Hannah?

Hannah Galvin

Or for us to consider. I do not know if Cassie or Rachel has an answer to that. My thought there would be are we willing to consider what this would look like in the real world in the implementation considerations and some of those edge cases? I do not know if we need a little virtual article, but, Cassie, do you have a reply?

Cassie Weaver

I do not have anything specific to that. As Rachel put in the chat, it is true that at some point, we do need to step back and let you all decide what to do as far as recommendations, but just personally speaking for myself, I do appreciate hearing all of this and all the points being raised.

Steven Lane
Hans?

Hans Buitendijk
I have a reaction to a couple of the thoughts that that would particularly **[inaudible] [00:55:26]**. I think it is a good question to ask and contemplate, for which I am not sure what the answer is and that we have a clear recommendation, but there is this balancing of, on the one hand, encouragement of participants, sub-participants, and everybody participating in TEFCA to use TEFCA capabilities that are out there is good, and in that sense, that is rebuilding and continuing to build from the investments that everybody is making, and whether that results in the way this is phrased, where somebody is asking to do it differently than what TEFCA does, I am not convinced that that would necessarily make it more expensive or otherwise, but I think it is a fair topic to contemplate.

Does this have the desired effect by encouraging a use of the shared capabilities that are put in place? And if that means that, from the use cases and the scenarios to that being raised, to say that what is available does not quite fit, and we have this other variant there that seems to also be an encouragement for TEFCA at that point in time to find a way that there is an agreed-to method that all can participate in consistently that would address that. So, generally, with how I have seen some of these networks operate, it happens to coalesce and allow you to coalesce around common solutions rather than one-offs for individual scenarios. So, that is why I am trying to look at if it can help reinforce TEFCA to align on common use cases and appropriate variants where that needs to be.

Steven Lane
Ike?

Steven Eichner
Again, going back to my earlier question from a participant or sub-participant perspective, is it the intention that the same set of exceptions apply to exchanges between participants and/or sub-participants within a single QHIN, or is the trigger in this case for the TEFCA requirements solely looking at exchanges between QHINs?

Cassie Weaver
I cannot speak to intent beyond what we have said in the preamble and also the definitions here, which does address the definitions of QHIN, participant, or sub-participant for purposes of this exception. I am not sure if Rachel can offer any other insight on that, but insofar as what the intent is, I cannot say, beyond what is there. I know that is not satisfying.

Steven Eichner
I guess there would be an opportunity to provide some feedback, depending upon how the other Task Force members feel. I am not saying it is right or wrong in that context, it is just understanding, looking for clarification about which is the universe to which this applies. If I am the only one who does not understand it, it may not require a comment. If there are other folks who do not have a clear understanding, that is a different subject.

Steven Lane

Ike, I did capture your question in our Task Force discussion in the spreadsheet. I do think that the language is pretty clear. If two participants or sub-participants are in the same QHIN, this would not seem to differentiate if they are in the same or different QHINs. This would seem to apply, then, also to exchange between QHIN participants in the same QHIN if, in fact, they were requesting data from one another, but just asking ONC to clarify that point in their final rule would make a lot of sense. I got a plus-one out of Deven, so, hey! All right, we should probably go on so that we can stay on task here.

I really appreciate Rachel's comments in the chat, which is that we have all been asking questions for clarification, we need to decide what of this is going to turn into recommendations to the ONC or to HITAC to then give to the ONC, and here, again, I think it is important that if we are not clear, that suggests that perhaps there is an opportunity for greater clarification, so that would be our recommendation, or maybe that we just did not read carefully enough. All right, this is discussion on this whole topic, correct? So, one thing we have not touched on is the question of the RFI, as to whether an actor would be required to check the QHIN directories, and I am curious what people think of that. Maybe we can go back to the slide that includes the language in terms of what you are asking. Can we pop up a couple of slides?

Cassie Weaver

I think it is just one back.

Steven Lane

Okay, here we go. Perfect. Does anyone have any thought as to whether our Task Force would want to provide comment on these points? Cassie, I think you were presenting at this point. Do you want to walk us through the highlights of this one more time, just so that people are not trying to read it on their own?

Cassie Weaver

Sure. So, really, we are looking for folks to catch anything we might have missed, which is a broad statement, but are there any particular practices that are not required by law, but would be required by virtue of an actor's status as a QHIN, participant, or sub-participant? Are there practices, basically, that are required by some kind of agreement in TEFCA that could constitute information blocking, and if so, what practices are those, and where is the source that requires them? Is it in the common agreement or flowdown requirement and the framework agreements? And then, if there are practices that they believe are not covered by the current exceptions and that you would advocate we do assess for potential identification as an exception, as a reasonable and necessary activity, to let us know, and also let us know if any of these activities might pose concerns about unintended consequences. I think some of these have already been raised here today, especially about the unintended consequences for EHI access by individuals or entities who are not QHINs, participants, or sub-participants.

Steven Lane

Okay. Deven, you have your hand up.

Deven McGraw

So, we do have the benefit of having you here, Steven, as a QHIN, and others on the group who have tried to keep up with where the common agreement and other sorts of policies are playing out with respect to TEFCA participation. So, some of us may be more aware of what some of those requirements are and be

a little bit more attuned to where there might be some unanswered questions, some obstacles, or some further things that would need to be addressed.

But, to the extent that there are probably other things that other potential participants in TEFCA and/or the Sequoia Project, which is the recognized coordinating entity, are thinking about, it does not make sense to have them come and talk to us about what they see and their thoughts on this, or do we just decide that they are going to be the ones to comment specifically on that? It does occur to me that, depending on the time we have allotted for us to handle all the issues in our purview, that would be very interesting to get a sense from the Sequoia Project about what they think about this and where some additional avenues of questions or comments might come up. I have raised the ones that have occurred to me initially. I am going to do some more thinking by going back through the common agreement and different policies and procedures to further refine my thoughts, but it does occur to me that if we wanted to bring in experts around this topic, we could, or we could count on them to raise those issues through their own comments.

Steven Lane
I think it is a good point, Deven, and Zoe, you are still here with us. I think if you want to either put something responsive in the chat or consider coming on the mic here when we move to public comment shortly, that would be helpful. Hans?

Hans Buitendijk
Yes, thank you. I have been trying to figure out in our discussions what would fit under this, and there still might be some thoughts coming up, but at this point in time, with the clarifications on the manner, the opportunity, and the ability to focus on capabilities that TEFCA is establishing, and thereby have already acquired a reach. I am hard pressed at this point in time to find any other activities that are being contemplated or already defined under TEF that should be raised here. That is not to say that something might not come up, but I am not convinced at this time, as part of this round, how much that will be. I think it might be more likely to occur once TEF takes off more, there is an actual production environment, and we see what is happening that something may come up that says actually, there is something else that is happening that is reasonable and necessary that does not quite jive with the information blocking and the exceptions that needs to be addressed, but at this point in time, I cannot bring up anything.

Steven Lane
Okay, good. Thanks, Zoe. We have Hannah's hand up.

Hannah Galvin
I am just going to say briefly that I agree with Hans, and I think that was a little bit of my point earlier, that I think we are not going to know some of the issues that are going to come up until we see this in action. I am interested to understand, though I know ONC cannot publicly comment on this today, what the next steps in policy development may be once we see TEFCA in action, but I agree with Hans, and others on this call know far more about TEFCA and the common agreement than I do, but I am very interested to see what happens in the next 24 months as we really put this thing in process, and I think there will be more to really understand around how the data exchange is happening and maybe more opportunities to clarify or have future policy after that time.

Steven Lane

Okay, any other thoughts? I would not be averse to cutting to public comment early to give Zoe plenty of time to come online and join the discussion. Would that be acceptable to our ONC colleagues?

Wendy Noboa
That works for us.

Cassie Weaver
Yes.

Steven Lane
Great. Why don't we do that, and then, if we have some time left over, as it seems we might, we can transition to the discussion of preparations for next week. ONC, do you want to do the public comment honors here?

Public Comment (01:09:59)

Wendy Noboa
Sure, thank you. So, we would like to open the meeting to 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, please press *9 to raise your hand, and once called upon, press *6 to mute or unmute your line. Okay, I see Zoe Barber. Do you have a question?

Steven Lane
Can we unmute Zoe?

Zoe Barber
Can you hear me?

Steven Lane
Now we can.

Wendy Noboa
Yes, now we can. You have three minutes. Go ahead.

Zoe Barber
Okay, I will try to make this brief. The first comment is also reinforcing some of the discussion here about getting too far ahead of the common agreement and the various SOPs, understanding that this rule will be finalized in a couple of years, potentially, but I just wanted to underline that it is not the SOPs, but the whole scope of the common agreement is being revised to support the facilitated FHIR and brokered FHIR, so the current definitions of things like connectivity services, which have a primary place in the codified text in this condition, may not even mean what it currently means today, so I just want to make sure that is understood.

And then, I have a couple of other clarifications. So, as I read the preamble text and the codified text, I believe that I understand that both parties have to be subject to a framework agreement for this condition. However, it is unclear, based on the phrasing of the proposed text, if the exchange is actually intended to

be happening pursuant to one of those framework agreements. Is the exchange actually happening under the legal structure of one of those framework agreements? My assumption, based on the preamble language, is that the answer to that is yes. However, the codified text seems to refer only to or talks about the connectivity services, QHIN services, which is a new term, and specified technical services in the applicable framework agreement available to both parties, but it does not say if the exchange is supposed to be happening pursuant to one of those framework agreements, or could it be using the specified technical services within a QHIN pursuant to their intra-network QHIN agreement that is totally separate from the framework agreement?

I have a clarification there also in that the term "framework agreement," which encompasses the common agreement, as you know, the QHIN/participant agreement, participant/sub-participant agreement, and any other flowdown agreements, is limited to the QHIN-to-QHIN-based exchange. So, different QHINs may set up their framework agreements differently, and they may combine their TEFCA exchange, which is QHIN-to-QHIN, with their intra-network exchange, and maybe that is all in one document, or those could be two separate documents. So, I just wanted to clarify that distinction between the technical structure and the legal governance structure.

Wendy Noboa
Great, thank you, Zoe, for your comment. I do not know if anyone would like to respond to that. Okay, if not, Zoe, I am sure that was all noted. Thank you again. I am going to pass it right back to you, Steven and Steve, if you would like to close us out.

Steven Lane
Well, we are not ready to close out just yet.

Wendy Noboa
You have more comments?

Planning for May 17th HITAC Meeting Task Force Update (01:14:38)

Steven Lane
Yes. Let's go back to our slides here. I think we want to be on Slide 23, which is the next one. Yes, there we go. Sorry, 26. I am looking at the numbers wrong. My bad. So, this is what we just covered, and I have tried to capture a bit in the Task Force discussion. Here, again, we really want to invite people to come back to the spreadsheet and start to submit any recommendations that you would like us to consider bringing forward to the HITAC. On the next slide, we do want to plan for our presentation on the 17th, so, just as a reminder, next week, this group will be meeting on the 16th, and Workgroup 2, which normally meets on the 17th, will not meet next week because we will be giving an update to the HITAC.

What I wanted to ask all of you, and I asked you at the beginning to think about this, is if there are any topics that we have discussed specifically in this workgroup that you feel warrant giving the HITAC a heads up, anything that we might be particularly controversial or just warrant them thinking ahead. Let's quickly slide back up to Slide 8, which is the topics that our Group 1 has been working on, and the first one was information blocking defined terms. This is just as a reminder. The second was an RFI around additional exclusions to offer health IT, and I know we had a lot of thinking about that. Then, there were the two we just covered, and of course, we cannot anticipate our discussions next week in our presentation the

following day, so we will leave it at that, but is there anything that comes to mind for anybody from our discussions thus far that you think we should be calling out in our HITAC presentation next week? Hans?

Hans Buitendijk
Perhaps the one discussion around clarifications around the offeror and outsourcing the use of consultants, that we have some more clarifications and questions. That is the only one that jumps to mind so far. I do not want to jump to infeasibility, but there will be something coming up there, but we have not talked about it yet.

Steven Lane
Right, and it is hard to anticipate that. Deven?

Deven McGraw
I do not really know that anything that we have talked about so far is so controversial that we need to give folks a heads up that something big is coming. I think a lot of what we have raised are some really important clarification questions and a few concerns, but we also have not really fully discussed them yet, we have just started to amass a spreadsheet, so, in my view, it feels a little bit premature, but I do think it is not horrible to say, "Some of the issues that come up include…but we are not finished with discussing them yet." Obviously, there is no harm in doing that. These are public meetings, anybody could have sat through them to give a little bit more color to the conversation, but we have not landed the plane on anything, in my view, from a recommendation standpoint.

Steven Lane
I agree, Deven, and again, I am not suggesting that we necessarily prime the pump with things, I just wanted to open that up as an option if anybody had anything they were particularly concerned about. So, maybe what we should do at this point, given that we have 10 minutes left, is to return to the spreadsheet itself, which, of course, is Slide 28, but we can pop over there. Also, I will just point out to members of the public that we are continuing to watch for any raised hands, and if somebody has something they decide they want to bring forward, anyone who sees a hand pop up, we can certainly go over to that. In terms of the spreadsheet, let's look… It is funny, people keep putting a B in Cell 1A on our tab, and I am not sure why. Dan and Wendy are both in this cell, and I went in and deleted that B, and it came back again. I do not know if this is just a…

Steven Eichner
[Inaudible] [01:20:02]

Steven Lane
Are you seeing that? Yes, we are all seeing that, I see. I am not sure why. I am going to try once again to delete that B and see if it goes away. Okay, good. All right, good. So, we are on our Group 1 tab, and we have had some recommendations come in on 5.2, the first topic, information blocking defined terms and proposals, and perhaps this would be a chance for us to discuss whether any of these can start to turn into Task Force recommendations or whether they, at the very least, warrant any discussion or inclusion in our report back to HITAC. I will point out here that I actually went in and monkeyed with some of your recommendations. Hannah and Ike, I hope you do not take too much exception to that. I was really just trying to add some clarification to the language you had provided, but I highlighted my edits in red. Hannah,

do you want to say anything about your recommendation here and whether you think this is something that we will want to bring forward as a Task Force recommendation?

Hannah Galvin
Yes, thanks, Steven. I liked the language that you added there. I do not feel very strongly that this should be a Task Force recommendation. I think this is something that I presume is happening in the back halls anyway, but it is something I wanted to point out, though I do not think it is our top need to bring forward as a recommendation. I would bring it forward on a spreadsheet and see what our other recommendations are, and I do assume that the groups are working together, and that OIG, in their auditing, understands this, so I do not think this is a formal recommendation that is needed at this time, unless others disagree. Deven, I am interested in your thoughts.

Steven Lane
Go ahead, Deven.

Deven McGraw
I was raising something totally different, Hannah. Sorry.

Steven Lane
Why don't you go ahead, then, Deven?

Deven McGraw
Sorry about that. I am going all the way down to the comment from Ike and you, Steven, around clarification that exclusions around public health access and activities are not necessarily offering health IT, and I want to dive back into that proposed language a little bit more, but data registries offered by other entities… A rare disease nonprofit is not a provider, so they are not going to be subject to the information-blocking rules, period. If you are not an actor, you are out of the mix. But I think we need to be a little bit careful that a disease registry offered by an actor does not mean they are offering health IT, but they might be covered as a provider per our prior discussion. So, I will just say that I am not so sure about that comment. We want to be very careful not to step too broadly in terms of defining that exclusion, and again, a rare disease NPO is not an actor nor a provider, and anyway, offering health IT is really something that is relevant to the certified health information technology vendor definition of an actor.

Steven Lane
So, given that, Ike, do you feel that there is a comment here that we might want to be bringing forward to the HITAC?

Steven Eichner
I think it falls in the category of "it depends." I really appreciate Deven's point, but again, looking at the actor component, it is still not entirely clear looking at the definition of actors and their role to different activities as to what constitutes enough of being a medical provider to trigger whether things relate or not. The same kind of thing applies to public health. In some cases, public health is a healthcare provider, and in some situations, it is not, so what becomes enough of a crack-the-door-open, if you will, for it to count?

Deven McGraw

I would not say that it is not worth further exploration around a comment that we might make, but it feels very premature to raise this with the HITAC.

Steven Lane
Oh yes, and again, I am taking this opportunity, Deven, to just do some of our work here, and Hans, I will look to you. Here, again, is what you mentioned as potentially…

Deven McGraw
He had to drop off.

Steven Lane
Too bad. I see that. Well, we are nearing the end of our time. Any other thoughts from either workgroup members or members of the public that you want to raise here in the last few minutes? Ike, you had one other comment in here, to provide clarification at meeting one or more exclusions in one role offering may not create another role. I do not know the context there.

Steven Eichner
I think it is looking at basically how being excluded in one category does not mean you are necessarily excluded from another role. In other words, I am just clarifying that if you are not included because of a role you are playing in one space, it does not preclude you being included in a different role you may be performing somewhere else.

Steven Lane
Deven?

Deven McGraw
This relevant to the discussion that we just had, Ike, unless I am getting it totally wrong, which is that exclusion may mean you are not offering health IT, but it does not mean you are not a provider, who would be subject to the rules that apply to providers. Do you see what I am saying? Just meeting an exclusion in one area does not exclude you from the rule entirely. **[Inaudible – crosstalk] [01:27:10]**

Steven Eichner
Exactly.

Deven McGraw
…if it feels unclear. The exclusion is not your get-out-of-jail-free card, necessarily.

Steven Eichner
Or a single exclusion.

Deven McGraw
Right, right.

Steven Lane

All right. Again, I am just trying to capture some of that. All right, well, that brings us to time. I really want to thank everyone for your participation. We have one more slide, Slide 30, which, again, outlines where we are heading. We will meet again next week to talk about information blocking infeasibility exception proposals, revise the existing condition around uncontrollable events, and a new condition about third parties seeking modification use, which I am fascinated by, and then, as I said, we have the HITAC update on the 17th. You are all welcome to attend that, and then we will meet again later in the month. Any final words? Ike?

Steven Eichner
Nothing, except, again, thank you all for participating, thanks for being here, and thank you for continuing to contribute great information to provide feedback to ONC.

Steven Lane
Great. All right, thank you all, and we will see you next week.

Adjourn (01:28:37)