Information Blocking (IB) Workgroup 2

Transcript
March 15, 2019
Virtual Meeting

SPEAKERS

Name	Organization	Title
Michael Adcock	Individual	Co-Chair
Andrew Truscott	Accenture	Co-Chair
Cynthia A. Fisher	WaterRev LLC	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil K. Jain	IBM Watson Health	Member
John Kansky	Indiana Health Information Exchange	Member
Steven Lane	Sutter Health	Member
Arien Malec	Change Healthcare	Member
Denni McColm	Citizens Memorial Healthcare	Member
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin	Member
Sasha TerMaat	Epic	Member
Lauren Thompson	DoD/VA Interagency Program Office	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member
Mark Knee	Office of the National Coordinator	Staff Lead
Penelope Hughes	Office of the National Coordinator	Back Up/ Support

Operator
All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Welcome, everyone to Work Group 2 looking at exceptions under the information blocking task force. We'll do a quick roll call and then, we'll jump right in. Andy Truscott?

Andrew Truscott – Accenture – Co-chair
Present

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Michael Adcock? I believe he's on. Valerie Grey? Anil Jain?

Anil Jain – IBM Watson Health - Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Arien Malec?

Arien Malec – Change Healthcare - Member
Good morning still, at least my time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Steven Lane?

Steven Lane – Sutter Health - Member
I'm in the same time zone as Arien. Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning, guys. All right. I will turn it over to our co-chairs. Mark, did you have anything that you wanted to start with first with the revisiting any outstanding issues?

Mark Knee – Office of the National Coordinator – Staff Lead
No. I think just to focus, I believe we left off last time with the 206 licensing on RAND terms. And I think we need to get through that our initial review. And then, I'll leave it up to Andy to go back through and revisit the big topics.

Andrew Truscott – Accenture – Co-chair

Thanks.

Mark Knee – Office of the National Coordinator – Staff Lead
Actually, the request for information, too, also, right?

Andrew Truscott – Accenture – Co-chair
There were. Do you want to get those out now before we get into it?

Mark Knee – Office of the National Coordinator – Staff Lead
Yeah, sure. Do you want to finish up RAND licensing –

Andrew Truscott – Accenture – Co-chair
No, you get the requests out. Just get them done so I don't have to remember to come back to them later.

Mark Knee – Office of the National Coordinator – Staff Lead
Okay. Sounds good. Can you all see my screen?

Andrew Truscott – Accenture – Co-chair
Yes.

Mark Knee – Office of the National Coordinator – Staff Lead
All right. Great. The first one is, Arien raised this one this morning, we have a request for information on potential additions of an exception for complying with the common agreement for trusted exchange. So, as background we thought long and hard about having this exception but because the timing wasn't right with TEFCA, the request for information is what we ended up putting in the proposed rule.

Arien Malec – Change Healthcare - Member
And I think you heard a perspective this morning that having an affirmative set of obligations that provide at least the effect of a safe harbor, unless there's other nefarious behavior going on, would make it substantially easier to comply with the Cures NPRM and information blocking penalties.

Mark Knee – Office of the National Coordinator – Staff Lead
Yeah. So, I guess just to push back a little bit, are you talking specifically about TEFCA or just more broadly laying out examples of practices that are okay?

Andrew Truscott – Accenture – Co-chair
That's a different thing.

Arien Malec – Change Healthcare - Member
I had a perspective that at some point, ONC would line up the TEFCA and the information

blocking exceptions such that doing the right thing was the easiest way to comply with information blocking provisions.

Mark Knee – Office of the National Coordinator – Staff Lead
Gotcha.

Arien Malec – Change Healthcare - Member
So, I think the general notion of an affirmative set of activities that a provider or health IT developer or health information exchange or health information network could comply with that at least are presumed to be good acting is necessary. And then, in particular, I had an assumption that the TEFCA would outline such a set of activities.

[Crosstalk]

Mark Knee – Office of the National Coordinator – Staff Lead
Yeah, that's fair.

Andrew Truscott – Accenture – Co-chair
I must confess, Arien, I was labored under the same presumption as well that if you comply with TEFCA, you will be held not to be information blocking to sum it up.

Steven Lane – Sutter Health - Member
Well, I just want to chime in because it seems to me that that's not a guarantee that some of the behaviors that we're all trying to prevent and avoid and call out if they occur, it just doesn't seem immediately obvious to me, again, not knowing what TEFCA is going to look like that one would preclude the other. So, I've always paused on this whole safe harbor notion. And I guess I just want to understand it better. What makes you think that somebody in compliance with TEFCA wouldn't have some sort of minor behavior that we wouldn't want to watch for and potentially be able to call out? I can't come up with an immediate example in my mind but it just doesn't seem to me intuitive that just being a good actor on TEFCA means that you wouldn't also have some behavior that's information blocking.

Arien Malec – Change Healthcare - Member
And the way that I phrased it was deliberate when I was trying to make the words appear out of think air. But I said compliance with TEFCA in the absence of other significant indicators of information blocking would be presumed. So, I agree with you that I think there are some cases where there may be some other behavior that itself is problematic. But at least it gives people an affirmative set of things to shoot for that create at least – I've also used the word presumption of. Presumption doesn't mean the behavior isn't going on. It just means that if I'm making data freely available via APIs to patients and to other requesters in accordance with permissible purposes that I'm doing something right.

Andrew Truscott – Accenture – Co-chair
I'll go a little bit further. In the absence of having TEFCA defined is a bit difficult to say that yes, it's appropriate or no, it's not at this point. I think all we have is, as Arien said, it would

make sense if you complied with TEFCA there at least was a presumption that you were not information blocking and maybe there would be a shift in onus as to how these regulations would apply if you were to comply with TEFCA. I don't know because we haven't finished TEFCA yet. We are still in the request for information from Mark. Have you got anything else, Mark, to raise to us?

Mark Knee – Office of the National Coordinator – Staff Lead

Specifically?

[Crosstalk]

Andrew Truscott – Accenture – Co-chair

Across the **[inaudible] [00:07:03].**

Mark Knee – Office of the National Coordinator – Staff Lead

So, there's another request for information that's just a more general one about, in addition to possibly TEFCA down the road, to other new exceptions that you feel might be appropriate to add as reasonable and necessary activities.

Arien Malec – Change Healthcare - Member

So, one thing that I raised in my incredibly long Twitter thread that I want to raise here, and this may be deliberate or it may not be deliberate, is the notion of complying with contracts and BAA terms as constituting or not constituting information blocking. So, I come at this at least at one level from the perspective of working through the issues involved in supplying information to patients as a clearinghouse and as something we'd very much like to do. But in areas where we have BAA terms that are restrictive or do not give us data use permission to do certain activities, the general rule is that we follow the BAA rather than follow – a clearinghouse is a defined covered entity under HIPAA.

But even though patient access is part of the responsibilities of a covered entity, when the BAA prohibits it, our stance right now as a legal matter is that we're prohibited. Complying with BAA terms and other contractual requirements is not a defined exception category. And so, we would have to make a choice. And patient access is slightly different because I think you could argue that Cures overrode BAA requirements for clearinghouses for patient access. But even in the case of let's say supplying claims data for the purposes of risk adjudication or clinical quality measurement. I think you could make the case that we would be deemed information blocking if we held by the BAA terms that we have with our counterparties.

Steven Lane – Sutter Health - Member

So, Arien, aren't you really suggesting that the BAA terms may need to be adjusted to account for the information blocking regs?

Arien Malec – Change Healthcare - Member

I want to make sure, No. 1, that ONC was deliberate about the not including BAA terms as an exception.

Steven Lane – Sutter Health - Member

Anyone can write anything they want into a BAA, right? That shouldn't be an excuse to information block.

Arien Malec – Change Healthcare - Member

As a business associate, business associates have only the data uses that are granted to it by the covered entity. And so, that's a matter under HIPAA. And, typically, HIPAA has a minimum necessary standard. So, it could be. I am posing this as a question for ONC. And I don't know if it was covered in the commentary or covered anywhere. It could be that it was a deliberately not included exception such that it is intended that the Cures obligations apply regardless of BAA terms. And Steven, to your point, we have to update our BAA terms or BAA terms would be null and void because they'd be superseded. Typically, contracts have language that if it's superseded by law that section is struck.

So, we'd either have to update our BAA terms or in the case of being sued by one of our counterparties, we could claim that the intent of Congress and the implementation of Cures overrode those BAA terms. Right now, it is neither fish nor fowl, I guess. It's not explicitly stated that Cures obligations override BAA terms. And it's clearly not listed as an exception.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. So, I guess that's directed at me. And I'll say this, you're right. There's not an exception for that. That's accurate. And we also do have some preamble language that you may have seen that addresses just broadly that we don't think that contractual obligations should be an excuse for information blocking. But we're open to suggestions about clarifying the issue.

Arien Malec – Change Healthcare - Member

Yeah. It's interesting because we've got HIPAA as a regulatory framework, on the one hand, I think, that says that BAAs have only the data use rights that are provided for under BAA.

Andrew Truscott – Accenture – Co-chair

That is correct, yes.

Arien Malec – Change Healthcare - Member

And then, on the other hand, we have Cures saying that in addition to those rights is a general purpose right to enable information exchange and provide data for any permissible purpose.

Steven Lane – Sutter Health - Member

Arien, educate me a little more. My understanding of BAA terms is that they are pretty flexible. That in our organization, we have a kind of standard BAA language that we start with. But then, we make adjustments to suit the needs. Are you suggesting that there is sufficient specificity of what needs to be in a BAA that's defined by HIPAA that that could be relied upon here?

Arien Malec – Change Healthcare - Member

I am not a lawyer but I play one on FACAs. So, at some point, we may need additional clarification here. But my understanding of the way that HIPAA and BAAs work, and I've spent nearly as much time reading HIPAA as I have read the information blocking exceptions, is that it works this way. Covered entities have a certain set of data use rights that are enumerated. So, rights to PHI are enumerated in a broad set of rights under TPO that are permitted purposes under HIPAA. There's a subset of those rights that are enabled for information exchange. And then, BAAs have only the right granted to them that are granted to them or effectively delegated to them though – sorry. BAA business associates have only the data use rights that are delegated to them through the BAA.

So, as an example, as a clearinghouse, if a payer or a provider, if Sutter Health CPMC has a contract for a clearinghouse, and they say, "Dear clearinghouse, you can use our data only for the purposes of transmitting, editing, and providing other necessary services sufficient to get it to the payers accurately," then, we have as a BA only those rights.

Steven Lane – Sutter Health - Member

As a business associate.

Arien Malec – Change Healthcare - Member

As a business associate, yeah. And there's been a sense of ambiguity for clearinghouses but this is actually a much more general matter because it applies to any BA that falls under the definition network or health information exchange or certified health information technology. There's been a level of ambiguity specific to clearinghouses that clearinghouses are covered entities but also generally subject to BAs. But if we take a health information exchange, I talked to a friend of mine who runs a health information exchange whose contracts with providers an payers are restricted in the sense of how data may be used. They may be used for treatment purposes but they may not be used for pricing negotiation. Pretty typical HIE terms where you've got payers and providers in the mix. There is a limitation. Go ahead.

Anil Jain – IBM Watson Health - Member

This is Anil. Are you saying then that you would like some recommendation from this group that they clearly spell out those BAAs and what must happen to those within 24 months in order so that there's nothing in there that would be considered information blocking? Is that what you're saying?

Arien Malec – Change Healthcare - Member

I would like either a clear statement of preemption or a clear statement that BAA terms for data use are an exception. I would prefer, honestly, preemption because, as a clearinghouse, as an order and results in information exchange, as a provider of information exchange services broadly, there's a whole set of things we could do, for example, to provide patients transparency that we can't do right now. But we can't do them right now because they're in violation of our BAAs. So, I think it would be useful.

Steven Lane – Sutter Health - Member

So, you're saying that either the Cures needs to preempt the BAA terms or complying with your BAA terms needs to be a safe harbor under Cures, basically?

Arien Malec – Change Healthcare - Member

That's exactly right. And right now, it is ambiguous and I think it could be argued either way. And anything that can be argued either way is going to generate lawsuits.

Steven Lane – Sutter Health - Member

Well, I would just argue as a civilian that Cures should preempt the BAA terms because Cures is newer and it's more progressive, I think that HIPAA, which is the foundation of the BAA terms.

Andrew Truscott – Accenture – Co-chair

Actually, my understanding as Cures was being drawn was that it was intended to preempt.

Arien Malec – Change Healthcare - Member

Relative to patient access. So, there's very clear language in Cures that implies preemption with respect to patient access but not with respect to other permissible purposes. And, Mark, I'd welcome your comment here.

Mark Knee – Office of the National Coordinator – Staff Lead

Sorry. I was just jotting some notes. Can you say that one more time?

Arien Malec – Change Healthcare - Member

So, there's an argument that's being made, which is a reasonable argument that Cures is more modern and more progressive and is sort of the newer rule and preemption should be clear. There's a statement that says, I think it was Andy who said he understood that Cures already did preempt. And my understanding of Cures –

Andrew Truscott – Accenture – Co-chair

No, no, no. That's not what I said.

Arien Malec – Change Healthcare - Member

Okay, sorry.

Andrew Truscott – Accenture – Co-chair

My understanding was the intention was that Cures would preempt.

Arien Malec – Change Healthcare - Member

Okay. So, my understanding of Cures as a piece of legislation is that there's specific language relative to patient access that could be construed as preemption but that, as I said, at this point, it's neither fish nor fowl. And I think it would be useful to clarify it.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. So, I can't really speak to that. Cures are legislation. What we're trying to do is draft a regulation based on Congress's mandating Cures to lay out these reasonable and necessary activities that would not constitute information blocking. So, I can't really speak to whether or not Cures preempts other contracts or laws or anything like that.

Arien Malec – Change Healthcare - Member

So, you understand the difficulty this places people in, which is that on one hand, it's not an exception on either hand. There are contractual terms. And so, at some point it's going to have to come and be adjudicated likely in a legal setting. And that's probably not a great place for policy to be.

Mark Knee – Office of the National Coordinator – Staff Lead

Sure. So, I definitely understand your point. I think it's a clear point. I'd say that's why we have the request for comment and information if you have a suggestion about one way or the other. I understand the two options you laid out so I think it's a good one for the group to consider.

Steven Lane – Sutter Health - Member

Also, can we agree as a group that we believe that preemption is the way to go and that it should be spelled out?

Andrew Truscott – Accenture – Co-chair

I'm not sure we all agree to that. Arien, would you agree with that?

Arien Malec – Change Healthcare - Member

I already stated that I think we would prefer clear statement of preemption because I think there are some activities that we'd like to do that would provide more patient access and more access for quality measurement, risk analysis, that kind of thing. I'm not sure all of our customers would because they put those BAA terms in for a reason.

Mark Knee – Office of the National Coordinator – Staff Lead

One thing I would point out is just when you're thinking about which option to go with, take a look at the preamble again. We do in a number of instances talk about the problematic nature of contracts and how they tie into information blocking. So, as far as understanding ONC's intent on the issue, I'd refer you to preamble there.

Arien Malec – Change Healthcare - Member

Cool. Is there specific language –

[Crosstalk]

Andrew Truscott – Accenture – Co-chair

My understanding was an awful lot of what got put in place in Cures was because there was an intricate web of BAAs of many different flavors that have been woven, which were in part perceived to be restricting information flow. And, therefore, with Cures, the attempt was to actually move beyond them and actually put them to one side. This is what we want to have happened.

Anil Jain – IBM Watson Health - Member

This is Anil. Andy, I don't think I would say that was the intent to put BAAs aside. I think it's very useful –

Andrew Truscott – Accenture – Co-chair

I overstepped my language there. But it was preempted is probably a better word.

Anil Jain – IBM Watson Health - Member

What I would say is I think you'd get different opinions if you talked to the covered entities versus those who would want greater flexibility under the BAAs. I think the other language that I've seen throughout our discussions have been giving an amount of time to either revise or renegotiate those agreements. And I think this would fall under there where the entities would have 24 months to re-examine their BAAs and ensure that there is no information blocking practices that are in there. I think you need to give people time to renegotiate. I think Arien's point about there are things that he would like to do can still be supported because in that 24 months of redoing that BAA, an argument can be made.

But I don't think we should get rid of the agreements that a covered entity makes with a business associate just by simply waving Cures and saying all of the agreements that are there, we can just get rid of them because the intent of Cures is to make information free flow. Yes, but there still needs to be some discussion between the covered entity and the business associate. And that 24 months, I think, is what I've seen in other places.

Arien Malec – Change Healthcare - Member

I still think it places some organizations in a poorly defined middle ground.

Anil Jain – IBM Watson Health - Member

Yes.

Arien Malec – Change Healthcare - Member

So, if a payer comes to you and says we need this data to adjudicate to do risk management for this patient population. It's a legitimate purpose under Cures. And for whatever reason in the 24 months, the covered entities that you are a BA to have not included BAA language that is in compliance with the general provisions of Cures, you are then stuck between breaking a contract or being subject to penalty under Cures potentially under either potentially OIG or False Claims Act enforcement.

Anil Jain – IBM Watson Health - Member

I get it and I'm not a lawyer either but it would seem to me that if there is any kind of federal

statute that would always trump the BAA regardless. I think what you're saying is that the HIPAA privacy and security provisions that make a BAA important, at least the way you're seeing it that that's in conflict with the Cures Act. I get that. Otherwise, I think you're going to have too many folks who will make presumptions about what they're allowed to do with the preemption. And on the flipside, if we don't allow for that renegotiating during that time period then, I think you might end up having some unintended consequences of covered entities being accused of something that they're not really doing. And so, I don't know if there needs to be some language about time.

And then, what you're describing is inadvertent – you're breaking your BAA trying to comply with Cures or comply with the interoperability rules versus the other way around. This happens all of the time where BAAs have been written and then, they need to be rewritten in order to compensate for new mandates. Aren't we saying that in other parts of this particular rule, too, that they have 24 months to renegotiate agreements and contracts?

Steven Lane – Sutter Health - Member

That's my understanding.

Arien Malec – Change Healthcare - Member

It's parallel with the language of contracts in the commentary, almost all of the language of contracts is relating to prohibitions that a health IT developer makes on a provider organization that are restrictive covenants and the like.

Anil Jain – IBM Watson Health - Member

Right. And so, what I'm saying is let's extend that to covered entities and BAAs who have gone into an agreement with something that now needs to be reviewed based on these rules.

Mark Knee – Office of the National Coordinator – Staff Lead

Anil, I think you might be talking about the communications condition of certification. So, you might want to take a look at that section possibly. I think there might be language to the effect of what you're talking about.

Andrew Truscott – Accenture – Co-chair

To bring this one just to a close for now, I'm sure we're going to discuss this again, I do think there's an opportunity here for ONC to give some guidance on the relationship between Cures, BAAs under HIPAA, etc., outside of the regulations themselves in more kind of user friendly terms. Is that reasonable as a recommendation?

Arien Malec – Change Healthcare - Member

Yes.

Andrew Truscott – Accenture – Co-chair

Mark, you've given us more work that's not even in this regulation now. Thanks a bunch. Mark?

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah, sorry. I was on mute. Are you updating the document or are you not near a computer?

Andrew Truscott – Accenture – Co-chair

Oh, I can do. I can insert it in, that's fine.

Mark Knee – Office of the National Coordinator – Staff Lead

I was just typing some stuff but I want to make sure you all capture your –

Arien Malec – Change Healthcare - Member

Again, Mark, I'm reading through this language and every reference I have to contracts is with respect to, for example, contracts to prevent users from sharing or discussion technological impediments to information exchange or prohibiting a restricted communication. Those are the context in which contracts are discussed. And I don't see anyplace where contracts or BAA terms and data use rights are discussed in the context of contracts.

Mark Knee – Office of the National Coordinator – Staff Lead

Again, I'll just say within the preamble and take a look, but I think you're right that, generally speaking, we refer to contracts in a broad sense. And I don't know that there is specific discussion of BAAs in that context. We do talk about BAAs some in the regulatory impact analysis, I know that.

Andrew Truscott – Accenture – Co-chair

[Inaudible] [00:30:44] around some guidance. I also put in while I was thinking through this in terms of whether it would be a national security exception.

Arien Malec – Change Healthcare - Member

Interesting.

Andrew Truscott – Accenture – Co-chair

Partly because of the work that I've been doing with BA and DOD.

Arien Malec – Change Healthcare - Member

Yeah, absolutely. DOD data I have a lot of experience with this because we maintain data for the DOD, PHIs for the DOD. And DOD data on DOD personnel are classified as readiness data, which is held at not quite the highest level of classification but certain pertinent information security and SRG perspective is classified at the highest level of risk. So, it's associated with Fed RAND high not Fed RAND moderate. And I think it's either the highest or second highest level of SRG compliance relative to DOD ATO. So, again, it's probably gobbledygook to a lot of people. I'm sure Andy and I are on the same wavelength. But somebody could come and ask me to share information about DOD members that could be a permissible purpose but this may be sharing effectively readiness data that is sensitive.

Andrew Truscott – Accenture – Co-chair

And let's take it a bit further. DOD personnel who have served, been discharged, and are now receiving care through the VA and certain aspects in their clinical notes still have elements, which will be considered necessary to be secure.

Arien Malec – Change Healthcare - Member

Yes, that's right.

Andrew Truscott – Accenture – Co-chair

And they receive –

Steven Lane – Sutter Health - Member

Andy, can you give me a for instance on that because when I read your note, initially, I wasn't quite getting the idea of the former personnel.

Andrew Truscott – Accenture – Co-chair

Okay. Without having any national security issues in my example, where an individual who has received treatment for wounds which were received in particular areas of the world. Where an individual has received care from a military provider in various different geographical locations. Where they've received treatment for particular wounds received whilst undertaking specific activities. So, all of these are things, which would appear and do appear inside narrative clinical notes routinely.

Arien Malec – Change Healthcare - Member

And my readiness example would be an example of the geographic area that's been affected by, for example, flu, in areas that would lead an adversary to conclude that –

Andrew Truscott – Accenture – Co-chair

Operations that were commencing in that area.

Arien Malec – Change Healthcare - Member

That or the particular area is weak or amenable to attack by that adversary.

Steven Lane – Sutter Health - Member

I see. So, the fact that there are these textual notes in people's clinical records that make reference to sites of warfare or operations, etc., and that those – but then, how does the VA share anything? Because most of the veterans, they're all veterans.

Arien Malec – Change Healthcare - Member

The VA doesn't share anything. That's a different question.

Andrew Truscott – Accenture – Co-chair

Was that not your next statement?

Steven Lane – Sutter Health - Member

I get stuff from the VA. How would we apply this as an exception?

Andrew Truscott – Accenture – Co-chair

The VA says there is manipulation of records so that certain information is redacted. First of all, to what extent does 21st Century Cures even apply to DOD and VA? Mark, can you give us that?

Mark Knee – Office of the National Coordinator – Staff Lead

Are you talking about specifically in the information blocking context?

Andrew Truscott – Accenture – Co-chair

Yeah, are they covered or are they given some great rewarding services anyway?

Mark Knee – Office of the National Coordinator – Staff Lead

No, I would just say you'd have to go through the analysis of who is covered under the information blocking provision. Do they fit into the definition of at least one of the four actors that are identified? Are they dealing with EHI? Do they have the requisite knowledge component? Is there an exception? Is it required by law? That's generally the framework we're looking at.

Arien Malec – Change Healthcare - Member

Required by law is probably the blanket out though for relative national security.

Andrew Truscott – Accenture – Co-chair

Now, when I was thinking about this, I was actually like okay, do we just want to acknowledge the fact that with a better integrated care system, and let's be straight, both DOD and VA provide care to their covered people and their dependents via the paid care commercial – as Steven just said, he gets stuff from the VA all of the time. So, it's not like a linear process. You go from DOD, they provide you care. If you then get to decide to go to the VA, they provide you care and then, you go somewhere else. It's much more of an interconnected and inconsistent. And we are certainly beginning to share more information and to message EHR programs, which are underway inside of those organizations right now is going to mean even more information sharing.

It will be good if there is meant to be some exception for that that we embrace it here, I think. So, is it **[inaudible] [00:37:11]** stated and we know how to handle it if there's supposed to be one?

Anil Jain – IBM Watson Health - Member

This is Anil. This is probably not a good question but don't the current exceptions already include provisions for that? Both the privacy and security ones say that if it's not legal to do it

and you don't share them, you can't be accused of information blocking. So, wouldn't that be covered if your policies don't allow for that?

Arien Malec – Change Healthcare - Member

I would think there's a general blanket of prohibited by law that would actually be more the blanket that would address that.

Andrew Truscott – Accenture – Co-chair

Yeah.

Anil Jain – IBM Watson Health - Member

Okay.

Andrew Truscott – Accenture – Co-chair

It sounds like that's more of a definition of when we get into the definition of information blocking, which actually Mark and I had had a little conversation offline about that because we're not actually looking at the definition of information blocking in any of the work groups because that's taken verbatim from Cures. And does that definition, Mark, actually have lawful inside of it?

Mark Knee – Office of the National Coordinator – Staff Lead

It has required by law. It says these are bad act exceptions required by law or covered under the reasonable necessary activities that ONC is going to lay out.

Andrew Truscott – Accenture – Co-chair

Maybe we should talk to Lauren about this given that she's the VA DOD person on HITAC. Actually, she's not said anything. And it would be useful to know whether it's an exception that they have just assumed they have or whether it's something they would wish us to include. Would that make sense, Arien?

Arien Malec – Change Healthcare - Member

Yes, I agree.

Andrew Truscott – Accenture – Co-chair

Okay. That's the first hour. And now, is the group okay if we move on to the actual main content of the day?

Arien Malec – Change Healthcare - Member

Yay!

Andrew Truscott – Accenture – Co-chair

Reasonable and nondiscriminatory terms, 171.206. Where did we get inside of this?

Arien Malec – Change Healthcare - Member
Not very far.

Andrew Truscott – Accenture – Co-chair
I feel that we got through A and we were –

Arien Malec – Change Healthcare - Member
We did get through A.

Andrew Truscott – Accenture – Co-chair
We got through B1, scope of rights. But then, I think we stopped at the end of that.

Mark Knee – Office of the National Coordinator – Staff Lead
Sorry to interrupt. There was another request for comment, the complaint process.

Andrew Truscott – Accenture – Co-chair
I was going to come back at the end. Mark, we have to get through RAND today, I'm afraid.

Mark Knee – Office of the National Coordinator – Staff Lead
Okay, sure.

Andrew Truscott – Accenture – Co-chair
So, 171.206 B2, reasonable royalty.

Arien Malec – Change Healthcare - Member
I'm just reading again.

Andrew Truscott – Accenture – Co-chair
Yeah. It's probably nondiscriminatory. I assume, Steven, this is you highlighting key things like independent value, standards essential.

Steven Lane – Sutter Health - Member
Yeah, I'm the red. It's just things I thought we needed to think about.

Andrew Truscott – Accenture – Co-chair
I think that's fair.

Arien Malec – Change Healthcare - Member
One confusion I have, and I think it was a confusion that is sort of inherent in this, is the notion of royalties as opposed to fees. So, the fees for cost recovery all speak in terms of fees. This section speaks in terms of royalties but royalties are typically used in the term of licensing of IP whereas the definition of an interoperability element is much broader than an IP consideration. So, the use of the word royalty confuses me.

Steven Lane – Sutter Health - Member

Can the ONC provide us any insight there, Mark?

Mark Knee – Office of the National Coordinator – Staff Lead

Sorry. Can you repeat that one more time?

Steven Lane – Sutter Health - Member

The word royalty, why did you choose that word and what are you getting at?

Mark Knee – Office of the National Coordinator – Staff Lead

All I can really say is we're looking at royalty in a basic sense of the word. I'll look in the preamble to see if get into the specifics. But I think our position is that it's a term the meaning should be pretty self-explanatory, I guess.

Andrew Truscott – Accenture – Co-chair

Well, we're obviously the first patent holders, right? Royalty is a sum of money paid to a patent holder for use of a patent.

Arien Malec – Change Healthcare - Member

The reason there's royal in there is that, originally, it was a king's right that was granted.

Andrew Truscott – Accenture – Co-chair

Obviously, it's **[inaudible] [00:42:58]**. But there you go.

Mark Knee – Office of the National Coordinator – Staff Lead

Right. We're talking about someone who owns the license here though so I think it's the same concept.

Arien Malec – Change Healthcare - Member

If I offer a service, again, this is the language that I think is somewhat confusing, I'm running, managing, and operating a service that meets the definition of an interoperability element but I'm not licensing any IP. I'm merely running a service and charging you for the service.

Mark Knee – Office of the National Coordinator – Staff Lead

Okay. Is this going back to royalty or is this a different issue?

Arien Malec – Change Healthcare - Member

No, it's going back to the term royalty where, typically, I wouldn't think of the fee associated with the service that I'm running as being royalty. I would think of it as a fee, a license fee, a service fee.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. All I'll say is I can look into our thought process on that. But we have the section in the preamble. And, generally speaking, I think we thought that it was a term that fit the purpose within this exception that we were trying to explain.

Andrew Truscott – Accenture – Co-chair

Mark, can you look into that and whether it really does fit? Because royalty is used generally, obviously, in the patent/patentee approach or where you actually share a percentage of revenue in lieu of asset use or something like that. So, you'd say I'll give you a 20 percent royalty because I'm going to be using your asset. That doesn't seem right what you were getting at earlier. I think Arien said it. It seems like much more that it's a reasonable fee.

Mark Knee – Office of the National Coordinator – Staff Lead

Okay. Yeah, I'll look into it. I think the difficulty with fees is, if you use a term like that, it would blend in even more to what Arien was saying about the differentiating between costs reasonably incurred and this licensing exception. But that's just a consideration. But yeah, I'll look into it.

Andrew Truscott – Accenture – Co-chair

If it's a licensing, so just say reasonable license charge or reasonable charge. Okay. Have a look into it. Royalty does seem to have a bunch of connotations, which are distinctly unintended.

Anil Jain – IBM Watson Health - Member

This is Anil. I'm not sure I agree, guys. I think royalty is an appropriate word here. We're talking about getting paid for giving someone or extending the rights to your IP whether it's a book or whether it's a patent or whatever.

Arien Malec – Change Healthcare - Member

No, we're not. Absolutely not.

Anil Jain – IBM Watson Health - Member

I thought that's what we were doing here.

Arien Malec – Change Healthcare - Member

No, we're not. That's the issue. Let me give you an example. I'll give you the purest example that I know how. So, let's say I take an open source component, and I host it in AWS or some other cloud provider. And there is zero IP that I'm licensing. Maybe I even make the code that I used for that hosting also available under an open source license. Nonetheless, there is still some value that I'm offering by actually doing the hosting and actually working with AWS and taking on some of that activity. It meets the definition of an interoperability element. It meets at least two definitions of the interoperability element, I think Definitions 1 and 5 but it is not a piece of IP that I am licensing.

Anil Jain – IBM Watson Health - Member

Okay. I'll read it more carefully. But I thought the concept of licensing was embedded in here but maybe I'm mixing up –

Mark Knee – Office of the National Coordinator – Staff Lead

So, I'm not sure I'm following, Arien. Can you explain that again? Because to Anil's point, this exception is about licensing of the interoperability element. So, your point is that maybe our definition of interoperability elements –

Arien Malec – Change Healthcare - Member

It's a royalty for the use of interoperable elements. And as we discussed last time, the term interoperable element is really any doohickey.

Mark Knee – Office of the National Coordinator – Staff Lead

Right. But I think the way we're using interoperability element is it's a means of getting that data. And you're talking about services. Can you explain why services?

Arien Malec – Change Healthcare - Member

This is related to my general confusion between 204 and 206. Most of my experience is not licensing software or IP. It is running a service. It is a fast service and it's sort of irrelevant as to whether I've written a code or stood up open source code and hosted it on a machine that I own or whether I use AWS. I'm running and operating a service. There's some value for that service. I am somewhat uncertain. I was reassured and then, maybe now not reassured and somewhat uncertain as to whether the fees that I charge for running that service are adjudicated under costs reasonably incurred or adjudicated under RAND license.

Mark Knee – Office of the National Coordinator – Staff Lead

Yes, the way you're describing it, again, I'm not trying to interpret, but 204 has to do with the costs that you incur for things like providing the access exchange and use of the EHI. So, it seems to me what you're describing would fall under 204. And 206 it's in the title of licensing of interoperability elements.

Arien Malec – Change Healthcare - Member

Yeah, but an interoperability element is a functional element of health information technology where I'm interpreting health information technology under 42USC300JJ. So, that's whether hardware or software, they could be used to access, exchange, or use. And I don't believe functional element is a defined term. And then, any other means by which electronic health information may be accessed, exchanged, or used. So, this is the source of my perennial confusion between 204 and 206 in the context of running a service.

Mark Knee – Office of the National Coordinator – Staff Lead

Right. I think this is, again, just a hypothetical situation. But I think what you're saying is there's a service. I think the service itself would fall under 204. If while you're doing the service, you use an element like we're talking about and there's a license of that element then, it could go to 206. I'm not trying to break down this example but 206, in the title we're very clear it's licensing. That's the issue there.

Andrew Truscott – Accenture – Co-chair

But, Mark, are you saying then that the 206 is designed to be me licensing my IP?

Mark Knee – Office of the National Coordinator – Staff Lead

All I'll say about 206, I guess, we explained the intent of 206 in the preamble. I don't want to try to ad lib that.

Andrew Truscott – Accenture – Co-chair

Well, yes or no would be fine. But 2iii is talking about where I have actually used property there but I have actually licensed from SGO.

Mark Knee – Office of the National Coordinator – Staff Lead

Right. I'm sorry. I didn't hear the last part.

Andrew Truscott – Accenture – Co-chair

Sorry. So, 2iii is talking clearly about where I as the actor have licensed an interoperability element from an SGO. And so, it's not my IP at all. So, this whole conversation comes from whether royalty is the right word. It's definitely not –

Arien Malec – Change Healthcare - Member

Well, there's even more of it but I'm just trying to figure out 204 versus 206 and I'm now a little more worried than I used to be.

Andrew Truscott – Accenture – Co-chair

Well, we'll come back to 204. Don't worry.

Arien Malec – Change Healthcare - Member

Yeah, okay.

[Crosstalk]

Arien Malec – Change Healthcare - Member

I also struggle with Definition 5 and Definition 1 of interoperability element where Definition 5 is any other means. And I have a hard time distinguishing any other means from, again, my issue with 204 versus 206. But what I'm offering in my hypothetical service is a means.

Andrew Truscott – Accenture – Co-chair

Arien, I don't think you should be worried about 204 versus 206 because 204 is about recovering reasonable costs. And 206 is about licensing and making reasonable profit.

Arien Malec – Change Healthcare - Member

This is why understanding these two are really essential. But I'm just trying to ask a basic

question, which is is the service that I'm running a means by which health information exchange may be accessed, exchanged or used or is it a functional element of health information technology that could be used to access, exchange, or use health information for any purpose?

Andrew Truscott – Accenture – Co-chair

Well, it says interoperability is to refer to any means by which EHI can be accessed, exchanged, or used.

Arien Malec – Change Healthcare - Member

So, I think my service is an interoperability element.

Mark Knee – Office of the National Coordinator – Staff Lead

So, would you be licensing your service though?

Arien Malec – Change Healthcare - Member

That's not what is in the definition of interoperability element.

Mark Knee – Office of the National Coordinator – Staff Lead

Right. I'm just saying you're asking whether it would fall under 204 or 206. And a key aspect of 206 is the licensing aspect. So, even if you're making the argument that a service could fall under the definition of interoperability element, there's still the absence of a license.

Arien Malec – Change Healthcare - Member

I see. So, your perspective is the term royalties deliver it or a license fee may be a broader term that might be better than royalty and that 206 is really only intended to address use of license fees. I guess what I'm going to have to do is I'm going to have to form a whole set of subsidiary organizations that drive license fees to the part of the business that operates the service so that I can claim the license fees that I'm using to operate the service as a reasonable cost for my cost basis.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. I can't speak to that. All I'll say is that the intent of 204 is that an actor can recover cost reasonably incurred for providing access, exchange, or use. And the intent of 206 is that an actor can make a reasonable amount of money for licensing of interoperability elements that allow for the access, exchange, or use of information.

Andrew Truscott – Accenture – Co-chair

We got that. That's my understanding of them, too.

Mark Knee – Office of the National Coordinator – Staff Lead

To me, I guess I'm still not understanding where there's a gray area there. But, again, I'm very open to recommendations.

Arien Malec – Change Healthcare - Member

So, I was following logic that said that the service is a means by which health information exchange may be accessed, exchanged, or used assuming that I could charge fees under 206 and then, getting tripped up under the term royalty. I think what you're saying is the use of the word license under 206 implies that we're talking about only cases where there are capabilities that are truly offered under license.

Mark Knee – Office of the National Coordinator – Staff Lead

Yes. Also, just take a look at 206. I have it on the screen. A good way to look at it is we say to qualify for this exception, each practice by an actor must meet the following conditions. And I know you guys think you might add all of the following conditions at all relevant times. I understand the point there. But the first one is just responding to requests for a license. So, that's one of the conditions.

Arien Malec – Change Healthcare - Member

Request to license or use. It does say license or use.

Mark Knee – Office of the National Coordinator – Staff Lead

Right.

Arien Malec – Change Healthcare - Member

I use a service, I license IP or content.

Mark Knee – Office of the National Coordinator – Staff Lead

Okay. Then, let's go down to – I see your point. And I guess if there isn't clarity about that, I can say our intent is that this has to do with licensing of interoperability elements. And I don't think we used service as an example but I understand your point about the breadth of our definition.

Arien Malec – Change Healthcare - Member

Yes.

Andrew Truscott – Accenture – Co-chair

Okay. Arien, are you straightened out a bit now on your understanding of 206 versus 204 or intent anyway?

Arien Malec – Change Healthcare - Member

Intent, absolutely.

Andrew Truscott – Accenture – Co-chair

Okay. So, let's go back to the language of No. 2. My personal view is the term royalty is unhelpful. I think Arien agrees. I think Anil disagrees and says he thinks royalty is fine and right. Steven has been mute.

Steven Lane – Sutter Health - Member
I don't have an opinion one way or the other. I'm just trying to understand it.

Arien Malec – Change Healthcare - Member
I'm a doctor not a lawyer.

Andrew Truscott – Accenture – Co-chair
Since when has a doctor not had an opinion? Okay. I'll take another run at this mainly to see if I can get Anil to see where I'm coming from. I struggle with royalty because it has a connotation that either it's my own IP as opposed to potentially that of a third party or there's some kind of linking of the royalty to the use that my client is going to make of it.

Anil Jain – IBM Watson Health - Member
Yeah. Andy, I get where you guys are coming from. But when I look at this provision, let's assume that you had a bunch of interoperability elements. And I as a customer wanted to use them to do interoperability. I'm not going to get smarter people than me to figure out whether royalty is the right word or whether licensing is the right word. But I've always used the word royalty in our conversations when you expose to me a set of capabilities in technology where I'm using it now, not you, to go do something related interoperability and I'm paying you based on that ability for me to use your technology. And so, think about, for example, the AMA will license a CPT. We pay royalties for it.

If I now create something that uses CPT codes for another client that client might also pay me royalties. And then, I would have to pay derivative royalties or royalties back to the AMA. So, the third party thing doesn't bother me. That happens all of the time.

Andrew Truscott – Accenture – Co-chair
And they actually call it a royalty?

Anil Jain – IBM Watson Health - Member
They do. They absolutely call it a royalty.

[Crosstalk]

Andrew Truscott – Accenture – Co-chair
Because **[inaudible] [00:59:36]** that don't.

Anil Jain – IBM Watson Health - Member
I'm not the expert on this but I know that when we license technical content and capabilities, we will pay a royalty fee as IBM to a group that makes that intellectual property available to us. And if we now create something new, we will expect that the client pays us a licensing fee. And likely, it's going to be a royalty so that when they call it a royalty, it means something different for the way that they look at that particular fee as well. Again, we've got to get smarter people but that word, I believe, was chosen on purpose because of the way

it's treated.

Mark Knee – Office of the National Coordinator – Staff Lead

And there's probably not one definition that can be decided on. But I just quickly did a little search and in a business dictionary, it says compensation, consideration, or fee paid for a license or privilege to use an intellectual property or natural resource and some other stuff. So, that seems to be what we're getting at.

Arien Malec – Change Healthcare - Member

Yeah. I believe relative to all of the rest of the discussion that the term interoperability element would be much clearer if it was actually defined as intellectual property because I do agree that royalty is a reasonable term to use with respect to all forms of IP and IP licensing. It wasn't obvious to me, and maybe this is just the source of the meta confusion, that that was the intent of this section. But if I understand that the intent of this section is really about licensing IP then, it's probably a reasonable use term to use.

Andrew Truscott – Accenture – Co-chair

It is if that's what it's about. But that's why I got –

[Crosstalk]

Arien Malec – Change Healthcare - Member

That's why I got confused, too.

Andrew Truscott – Accenture – Co-chair

And when you've got 2iii, it's something else's IP.

Mark Knee – Office of the National Coordinator – Staff Lead

Right.

Arien Malec – Change Healthcare - Member

Right, but that happens all of the time.

[Crosstalk]

Andrew Truscott – Accenture – Co-chair

Then, it's not royalty then, is it? The definition of royalty is –

Anil Jain – IBM Watson Health - Member

It is. What you're basically doing is you're collecting somebody else's royalty for them but you're passing it back to them. So, if you have a solution that happens to use the AMA CPT codes, it's a perfect example of care solution. You're going to collect it but then, you're also going to give it back to the AMA. So, that happens all of the time.

Steven Lane – Sutter Health - Member
That's a great example.

Andrew Truscott – Accenture – Co-chair
I'd like to make some margins.

Anil Jain – IBM Watson Health - Member
Well, you may not be able to if you're using someone else's IP. But hopefully, that was a joke.

Andrew Truscott – Accenture – Co-chair
Well, that's the point of that. No, no, I'm kind of serious. If there's something that I need to somehow carve out where I'm using third party IP in any of my solutions and pass back that royalty and I can't actually make a margin on the section of the solution that is theirs, I don't want this to inadvertently discourage innovation and discourage third-party solutions.

Anil Jain – IBM Watson Health - Member
I don't read it that way. I'm not saying that you can't make money off of it. I think what they're basically saying is you have to apply it in a nondiscriminatory way and you have to be on a level playing field. You can't pick and choose who you want to do business with because you may think that someone might compete with you down the road. I think it's a general theme that we see in this, right? I think if you have a program where you're licensing interoperability elements through a [audio skip] and fair with your competitors alike then, I don't see where the issue is. You can still have –

Andrew Truscott – Accenture – Co-chair
Okay. So, when I looked at the preamble, what I thought this paragraph was trying to do was say that in glancing the license, you're not going to charge somebody on the charge to use it. That's what I thought the intent was but it sounds like that might not be the intent.

Arien Malec – Change Healthcare - Member
You're going to put the AMA out of business.

Andrew Truscott – Accenture – Co-chair
Let's not have that conversation here. But I thought the intent was not to be charging egregious pricing. I thought that was what we were trying –

Mark Knee – Office of the National Coordinator – Staff Lead
I'm confused though. What are you looking at that makes it seem like that is not the intent?

Andrew Truscott – Accenture – Co-chair
I'm looking at the way that 2i, 2ii, and 2iii –

Arien Malec – Change Healthcare - Member

What was reasonable. How it's reasonable not to find in terms of value –

Andrew Truscott – Accenture – Co-chair

Yeah.

Mark Knee – Office of the National Coordinator – Staff Lead

Again, if it's not clear, we want to hear from you all. Just in the title of the exception, licensing of interoperability elements on RAND terms, RAND is a commonly used term. And the meaning has to do with reasonable and nondiscriminatory and not gauging people. So, I guess I'm confused.

Andrew Truscott – Accenture – Co-chair

The reason I brought this up is because if I change the word royalty per charge in that entire paragraph, it makes complete sense to me.

Arien Malec – Change Healthcare - Member

I suggest we keep going on to the other sections and just bracket this as an issue.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. Again, this is why we have you guys to make recommendations. I think if the group agrees that's definitely something you can recommend.

Andrew Truscott – Accenture – Co-chair

And we can have part of the group said this and part of the group said that. Okay. Are we going to park all of No. 2 at this point?

Arien Malec – Change Healthcare - Member

Well, there's no reasonable test. Is that okay?

Andrew Truscott – Accenture – Co-chair

No. The word reasonable was used across the entire rule set.

Steven Lane – Sutter Health - Member

What is the test of reasonable?

Arien Malec – Change Healthcare - Member

In the context of IPR associated with standards RAND or FRAND as it's sometimes also called is used in the context of standards-essential IP where a standards body wants to license something like a standard but there is some patent holder. And the intent is to make sure that the patent holder feels comfortable including their patent rights in the standard and that standards users feel comfortable incorporating and using the standard. It's typically reasonable and has the implication of being low and not impeding use of a standard. I'm not

sure that's the intended use here. I'm not sure what is reasonable.

Andrew Truscott – Accenture – Co-chair

My interpretation was that whatever you're going to charge for the accessing interoperability element is a sensible and not gauging charge.

Arien Malec – Change Healthcare - Member

But say there was a medical society that created content for encoding, I don't know, procedures that required a major payer. Under what terms would that medical society's fees associated with that procedural terminology be considered reasonable or not reasonable? Everybody would pay this hypothetical fee but not because it's the best terminology ever but because it's required by the largest payer in this hypothetical country.

Andrew Truscott – Accenture – Co-chair

So, I would imagine that what's reasonable is what the market is willing to tolerate without actually going back to the payer and saying no way, we're not going to pay this anymore.

Anil Jain – IBM Watson Health - Member

This is Anil. I think we should flag this as an area where we need either a test of reasonableness or we need a more specific definition of what is reasonable because I don't think we're going to be able to solve this on this call.

Steven Lane – Sutter Health - Member

I think that's very reasonable.

Andrew Truscott – Accenture – Co-chair

Reasonable comes up 289 times inside the rule.

Anil Jain – IBM Watson Health - Member

Also, I think it depends on whether there's an alternative. For certain things, there is no alternative. And, therefore, the word reasonable has no meaning. For other things, there are alternatives and reasonable could simply be something to do with what is tolerable in the market.

Arien Malec – Change Healthcare - Member

Now, you're going at my proposed way of better addressing this entire confusing section on fees, which really gets at that question, which is in cases where there is a potential for rent-seeking behavior, I think there's a rationale for tighter regulation of prices. In cases where there is no potential for rent-seeking behavior, it seems to be nonproblematic to let prices be determined based on value to actors.

Anil Jain – IBM Watson Health - Member

As long as it's consistent and nondiscriminatory. I think that would make sense.

Arien Malec – Change Healthcare - Member

As long as it's consistent and nondiscriminatory, absolutely yes.

Anil Jain – IBM Watson Health - Member

We do not want to stifle what we think is an amazing marketplace for innovation and capitalistic behavior that guides innovation. So, I would agree with that.

Arien Malec – Change Healthcare - Member

Okay. Can we continue through the section and then, circle back?

Andrew Truscott – Accenture – Co-chair

Yeah. So, 2i, I don't think we're going to have any concerns over. It's got to be nondiscriminatory whatever it is. And 2ii, independent values. Steven has highlighted it. I had a **[inaudible] [01:11:02]** reaction. Both of those words, independent and value, are heavily overloaded words. What does it say in the preamble around that?

Arien Malec – Change Healthcare - Member

It's basically trying to avoid against rent-seeking situations. Let's give another example that's totally hypothetical. Let's say that to open up an API to an EHR, that EHR charges a subsidiary fee for licensing some doohickey. And the price for that is based on discouraging access to that API or has the effect of discouraging access to the API. I think that's what's intended. You can't make me license something just because that's the only way to access data. You have to license me something because I actually want the thing that you license.

Andrew Truscott – Accenture – Co-chair

Okay. So, what the actual preamble says, "The reasonableness of any royalties will rest solely on the basis of the independent value of the access to technology to license this product, not on any strategic value stemming from the actor's control over essential means of accessing, exchanging, or using health information. For instance, the reasonableness of royalties could not be assessed based on the strategic values stemming from the adoption of the technology by customers or users, switching costs associated with technology, or what the circumstances are of technology or independence." This is a curious preamble.

Anil Jain – IBM Watson Health - Member

I think what they're saying is that if you're going to make money, make money on the parts of whatever you do that is not specifically related to access, exchange, and use of health information related to those interoperability elements. So, Arien, you mentioned this last time. Whatever value add you do that's fair game. But those elements that are specifically for information sharing, they have to have independent value.

Andrew Truscott – Accenture – Co-chair

No, I understand exactly what it says. And I agree with your interpretation. That's what the intent is.

Anil Jain – IBM Watson Health - Member

So, I think that makes sense, right?

Andrew Truscott – Accenture – Co-chair

Well, I understand what it's saying. I'm trying to work out whether there's an inadvertent – maybe it's deliberate. It seems to be pushing the market in a particular direction. Incidentally, this paragraph does describe the royalty base and rate as well, which does seem to indicate a very clear use of the term royalty in this paragraph, which we probably need to look at. Okay. It does seem very market directed. Is that the intention, do we think?

Anil Jain – IBM Watson Health - Member

This is Anil. I would think yeah, they want us to innovate on everything around the use of information not the actual exchange of it, which should be relatively commoditized and straight forward. And so, if we all want to innovate around it, we can but not in that specific activity.

Andrew Truscott – Accenture – Co-chair

Yeah.

Anil Jain – IBM Watson Health - Member

And then, as Arien put it, if there are a bunch of us doing this sort of work then, the market will go to whoever does it well and does it better. But no one should be monetizing interoperability in a way that would build businesses out of just that act itself.

Andrew Truscott – Accenture – Co-chair

Beyond recovering reasonable costs.

Anil Jain – IBM Watson Health - Member

Yeah. Of course, right.

Andrew Truscott – Accenture – Co-chair

But it means that when you have an organization – let's say I've got a health information exchange, which its only reason for living is to exchange that information. Would this exception feasibly kind of make them borderline untenable? At least they can't be a profit making entity.

Arien Malec – Change Healthcare - Member

This is the discussion that I think we need to go back to cost recovery.

Mark Knee – Office of the National Coordinator – Staff Lead

I'll just chime in here just as far as intent. We say this in the rule but just generally speaking, we take the position that health information is not a commodity that should be bought and sold in the same way that other commodities would be. So, just in the scope of all of this conversation, that's kind of where we're coming from.

Andrew Truscott – Accenture – Co-chair

But you go further than that. Access of exchange or use of health information is not a commodity that can be bought and sold.

Mark Knee – Office of the National Coordinator – Staff Lead

Right. But we tried to strike a balance between promoting innovation and competition and allowing reasonable profits but also saying that you can't really gauge or take advantage of the circumstances or your position.

Andrew Truscott – Accenture – Co-chair

But there's a long gap between recovering costs and gauging. There is a big space between those two poles.

Arien Malec – Change Healthcare - Member

Part of the issue here is that the commentary contemplates profit and cost recovery whereas the reg text I read as contemplating only cost recovery. But then, I also – anyway, I think there is a different way of getting at the policy goal that I think is really well articulated. So, I'll be proposing some alternatives here.

Andrew Truscott – Accenture – Co-chair

Yeah. Okay. Independent value of the access technology to the licensee's products.

Arien Malec – Change Healthcare - Member

It seems clear enough. Why don't we move over this – I think we've got some questions relating to this question. Maybe I'd suggest we go to No. 3.

Andrew Truscott – Accenture – Co-chair

Yeah. Because No. 3 is so straight forward.

Arien Malec – Change Healthcare - Member

Yeah, No. 3 is super straight forward. At least we'll have novel sources of confusion.

Andrew Truscott – Accenture – Co-chair

Okay. If the actor has licensed the interoperability element through an SGO in accordance with the SGO's policies regarding licensing of standards-essential technologies on reasonable and **[inaudible] [01:19:09]**. Standards-essential technologies. When an SGO's license interoperability elements broader than standards-essential technology, right?

Arien Malec – Change Healthcare - Member

SGOs may in some cases require membership to access IP.

Andrew Truscott – Accenture – Co-chair

Yeah.

Arien Malec – Change Healthcare - Member

Which is not a standards-essential technology but is at least a cost that needs to get passed on. And maybe that would be done – there are organizations, again, let's take the hypothetical example of a medical society that licenses procedural terminology that's used by the largest payer in a hypothetical country. Licensing terms may actually require not only that the licenser but also the license that the data requester and the requestee both have access to that license. And this is, again, not standards essential. Maybe that would go under a fee basis. It's super confusing.

Andrew Truscott – Accenture – Co-chair

Yeah. I find this one – I am tripped up on standards-essential technologies because what you've just described isn't actually a technology. What you described is an information asset.

Steven Lane – Sutter Health - Member

Right. So, what is an example of a standards-essential technology?

Arien Malec – Change Healthcare - Member

Typically, the definition of a standards-essential technology is an IPR, intellectual property right, that is reasonably required or formally required in order to use the standard. So, in the example of electronics, there may be a patent for some sub technology used for Wi-Fi that some organizations developed for use of video codex and audio codex. There are specific compression algorithms that have been done under patent.

Andrew Truscott – Accenture – Co-chair

But, Arien, this is in the context of an SGO.

Arien Malec – Change Healthcare - Member

Yeah.

Andrew Truscott – Accenture – Co-chair

So, let's just list out the SGOs. It's SnoMed. It's HL7.

Arien Malec – Change Healthcare - Member

Well, I'm trying to give the general definition of standards-essential.

Andrew Truscott – Accenture – Co-chair

Yeah. But I'm talking about within the context, I'm trying to think of what SGOs actually have standards-essential technologies.

Arien Malec – Change Healthcare - Member

So, I think your point is it's much more likely that IPR is licensed through copyright than through standards-essential technology.

Andrew Truscott – Accenture – Co-chair

Okay. Mark, I'm reaching out to you with an olive branch asking for help here. The preamble talks about Microsoft Corporation versus Motorola in a ratio of IP ventures and real text semiconductor. Help? The SGOs in this particular sphere, I just named two of them, that's the largest chunk of –

Mark Knee – Office of the National Coordinator – Staff Lead

What page are you on?

Andrew Truscott – Accenture – Co-chair

I'm in the preamble.

Mark Knee – Office of the National Coordinator – Staff Lead

Is it 472?

Andrew Truscott – Accenture – Co-chair

It's 479.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah, so what's the question?

Andrew Truscott – Accenture – Co-chair

Where it says tasks pursuant to a commitment to an SGO to license standards-essential technologies. The actor SGOs we're talking about in the healthcare space are HL7 and SnoMed, right? **[Mumbling]**. And what are the examples of standards-essential technologies that are going to be licensed by HL7 or SnoMed?

Steven Lane – Sutter Health - Member

So, Regan Street and LOINC would be another, right?

Andrew Truscott – Accenture – Co-chair

Regan Street is not an SGO.

Mark Knee – Office of the National Coordinator – Staff Lead

So, I guess was your question about the case law that we cited to or not?

Arien Malec – Change Healthcare - Member

I think Andy's point here is that the case law is really important in the consideration of standards that are associated with technology and that there is a good body of that but that not much of that is actually that applicable to health information exchange. And with the practices that are involved here are much more about copyright than they are about royalty stacking.

Mark Knee – Office of the National Coordinator – Staff Lead

So, just as background, we did a lot of research and looked at case law. And because this is a new area of law, what we did was we looked at what we thought was a standard that could be applied. And in reading this case law, we thought that the idea of RAND terms. And as you noted, it is generally used in the SGO context. We felt like there was a symmetry there that we could use and that it would be applicable and make sense. I guess that's all I can really say. But if you disagree, of course –

Andrew Truscott – Accenture – Co-chair

No, no, that's helpful. I'm just struggling a bit because in the health SGO space, I can't come up with a single example of a standards-essential technology. I just don't know a standards-essential technology.

Arien Malec – Change Healthcare - Member

I apologize but I need to drop at this point because I've got a conflicting –

Andrew Truscott – Accenture – Co-chair

No worries. This was all too riveting for you, was it?

Arien Malec – Change Healthcare - Member

Oh, it is riveting. I got thoughts but I'll write them up over the weekend.

Andrew Truscott – Accenture – Co-chair

Thank you, sir. Take care.

Arien Malec – Change Healthcare - Member

Thank you.

Mark Knee – Office of the National Coordinator – Staff Lead

Have a good weekend.

Andrew Truscott – Accenture – Co-chair

Look, we'll park this one.

Anil Jain – IBM Watson Health - Member

Andy, when you say there's no technology, what do you mean?

Andrew Truscott – Accenture – Co-chair

A standards-essential technology I get as a term. I'm trying to come up with an example that an SGO would be able to license a standards-essential technology.

Anil Jain – IBM Watson Health - Member

The crosswalk table. Wouldn't a crosswalk table be standards-essential technology?

Andrew Truscott – Accenture – Co-chair
No, not technology.

Anil Jain – IBM Watson Health - Member
Why not?

Andrew Truscott – Accenture – Co-chair
Why is that technology?

Anil Jain – IBM Watson Health - Member
Are we saying that health information content is not in the broader HIT? I guess we're talking about the definition of technology now. I don't know. I would think it would be.

Andrew Truscott – Accenture – Co-chair
Well, it does **[inaudible] [01:27:19]** definition of technology and also standards-essential patents. I have to do some joined-up thinking myself. I think I'm going to have to take this one off to think about. And I appreciate the fact that Mark specifically called out there the language. Mark, in this, do you mean standard-essential technologies or standards-essential technologies?

Mark Knee – Office of the National Coordinator – Staff Lead
I can look into that. I think if we put standards in there, I think that's what we mean.

Steven Lane – Sutter Health - Member
That's a good point though because, in the preamble where you're citing the case law, you say standard-essential technology.

Andrew Truscott – Accenture – Co-chair
Yeah.

Mark Knee – Office of the National Coordinator – Staff Lead
Okay. That's a good point and that is an inconsistency. And I'll look into that. But is there a key difference in the meaning that you are pointing at?

Andrew Truscott – Accenture – Co-chair
Absolutely because in this paragraph right now, you're talking about a standards development organization. An organization that's developing standards. Okay? Later in the paragraph, you use the term standards again. If actually, you don't mean that, you mean standard essential – actually, maybe you don't.

Mark Knee – Office of the National Coordinator – Staff Lead

I think we need –

Andrew Truscott – Accenture – Co-chair

I think you mean the same thing. Yeah. I think the standard is a FRAND.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. Your point is well taken but I agree. I think as the meaning –

Andrew Truscott – Accenture – Co-chair

No, no, no. The meaning is the same thing it's just a discrepancy. Okay. I'm going to take this off to think about. I'm happy to move on. This whole paragraph has been fun. It's obvious from the preamble that you guys thought about this for weeks.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. Weeks is an understatement. There was a lot of research done on this. And we did work closely with FTC and OIG on a lot of these concepts and the terminology and all of that. Without weighing in one way or the other, I will just say it is a very complicated thing as you're seeing. And finding the right balance and the right terms is tough. So, any help you can give us to improve the language would be appreciated.

Andrew Truscott – Accenture – Co-chair

Yeah. And I'm trying to work out actually whether this paragraph might potentially disincentivize an SGO from declaring something standard essential because it intrinsically becomes less valuable because of this.

Steven Lane – Sutter Health - Member

It becomes less valuable.

Andrew Truscott – Accenture – Co-chair

It does.

Steven Lane – Sutter Health - Member

They can't charge as much for it.

Andrew Truscott – Accenture – Co-chair

Correct. And then, does it actually matter given the two SGOs that I've been citing on this call, which are the only ones in the space. One of them doesn't charge because it's IP and the other one has a national license, which is made by **[inaudible] [01:30:59]**. But does it even matter? Well, it might not matter now but it might matter in the future. And the last thing I think we want is the SGOs to say we actually don't want to make stuff standard essential. Okay. I'm going to have to have a think about this.

Mark Knee – Office of the National Coordinator – Staff Lead

And I understand the terminology is loaded so it's key to get it right. But the purpose here is

just the actor may charge a royalty that's consistent with those policies. That's the key point. I understand the first part is very important that we get it right but just a note there.

Andrew Truscott – Accenture – Co-chair

Yeah. Just in the spirit of full transparency so you guys are aware, I'm on the board of HL7 as well, which is one of these SGOs. So, just so everyone is completely clear. And what I can see, maybe not in our SGO but in another SGO, would be it actually reflects our policies to take this into account. So, that's not helpful either.

Mark Knee – Office of the National Coordinator – Staff Lead

Right. So, it seems in closing this one, you agree with the intent of what we're getting out. You just might have some tweaks in the language potentially. Is that right?

Andrew Truscott – Accenture – Co-chair

Unintended consequences notwithstanding the fact that I don't like the term royalty but yeah.

Mark Knee – Office of the National Coordinator – Staff Lead

Okay.

Andrew Truscott – Accenture – Co-chair

Okay. Nondiscriminatory terms. I'm quite okay with this one actually apart from, as Steven has outlined, objective and verifiable. It's a bit like reasonable.

Steven Lane – Sutter Health - Member

Yeah. And, again, so many of these things seem to me that they will be applied in the context of a complaint. Some of them will bring a complaint of information blocking and what will be asked is for the entity that's the object of the complaint to be able to present objectives and verifiable evidence, right?

Mark Knee – Office of the National Coordinator – Staff Lead

You're exactly right, Steven. One of the key things to remember is that every situation is going to be very fact specific and based on specific circumstances. And in thinking through all of this, this terminology about reasonable and objective and all of that, if you think about the landscape of health IT, it's really hard to come up with terms that would be applicable that are narrower, in my opinion. So, the reasonableness standard and other kinds of those types of standards that are legal standards often would be applied by OIG who would be enforcing this.

Andrew Truscott – Accenture – Co-chair

Yeah. I think that's the important thing that this is being mindful of the fact that there is a high level of contextualization to what is reasonable, what is objective, and what is verifiable, which will change over time and situation.

Anil Jain – IBM Watson Health - Member

This is Anil. And I think you need that in order to make sure that we don't end up getting ourselves into an unintended consequence situation since healthcare is changing as long as that group that is making those decisions is stacked with peers who understand what is a standard practice so they can identify those that are not standard practices. If it's not then, I think this is not the right way to go. But I wasn't sure last time because, Mark, you said it was.

Mark Knee – Office of the National Coordinator – Staff Lead

Well, I don't control the budget but we are going to do everything in our power to staff with the right people, yeah.

Andrew Truscott – Accenture – Co-chair

Guys, I'll be straight with you. This seems to be one of the prime benefits that having a group like HITAC is that it can provide you with that objective verifiable and broad assessment within a particular context. Anil, would you agree?

Anil Jain – IBM Watson Health - Member

Yeah. I would agree but I don't think we want to be in the business or we as a FACA team or committee be in the enforcement or verifying or review.

Andrew Truscott – Accenture – Co-chair

Oh, no, we're not.

Anil Jain – IBM Watson Health - Member

We can make suggestions on that review board but I think one of the things that I would say, and I don't know the rules well enough to know whether this is in there, we also have to make sure that the burden of filing a complaint and then, having it reviewed doesn't get to the point where those that have very deep pockets see this as a cost of just doing business. I don't remember the language in there but I think this particular one where we talk about licensing components, you don't want to be in a situation where there's simply the cost of supporting this kind of regulatory mandate gets folded into the cost that they're going to charge back to their users.

Mark Knee – Office of the National Coordinator – Staff Lead

I'll just note that I don't think it will because, under Cures, you can be fined up to $1 million per violation if you're a developer, network, or exchange so it's pretty significant.

Anil Jain – IBM Watson Health - Member

Well, perhaps but for some vendors with a single client, in the history of their client, might be bringing in a half a billion dollars, my point is if you start to think about it as a business and amortize, those fines that might be leveled against you and then, try to fold that into the cost of running your business, I think that should be discouraged, if you will, within the rules.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. That's a good point. I get it.

Andrew Truscott – Accenture – Co-chair

Okay. That's the end of No. 2 for now. Actually, no, sorry, we're on No. 3. I was okay with 3ii. It's just the standard nondiscriminatory pieces. Steven, Anil?

Anil Jain – IBM Watson Health - Member

Yeah, I think it's fine. There are still questions. I think I wrote a note below a while back about how do you verify. But I think it's the same usual concern that I've been having.

Andrew Truscott – Accenture – Co-chair

Yeah. I think proactively or retroactively, the answer is probably both.

Anil Jain – IBM Watson Health - Member

Well, I don't know how you would do it proactively. It's not going to be –

Andrew Truscott – Accenture – Co-chair

Well, there will be some guidelines, I think. I think I can see that there will be some published guidelines about what those terms should be. I foresee that. One can hope. No. 4, collateral terms. Okay. As an exclusion, the actor must not require the licenser or his agents to do or – okay. The actor must not require, not compete. The actor must not require to not compete. Is that right?

Anil Jain – IBM Watson Health - Member

Yeah, that makes sense.

Andrew Truscott – Accenture – Co-chair

The actor must require the –

Anil Jain – IBM Watson Health - Member

Right. So, if I license my components to you, I can't tell you, Andy –

[Crosstalk]

Andrew Truscott – Accenture – Co-chair

I understand the principle. They are now competition. Got that.

Anil Jain – IBM Watson Health - Member

Yeah. That makes sense.

Andrew Truscott – Accenture – Co-chair

Yeah, okay. And it must not require **[mumbling reading]**. Okay. That's an interesting one. I'm

not even sure that's part of that collateral term. Except reasonable royalties unless it's a reasonable cost. Okay.

Anil Jain – IBM Watson Health - Member

Actually, I have an issue with No. 4iv, license, grant, assign, or transfer to the actor any intellectual property of the licensee. That seems like it prohibits any kind of bartering arrangement, which is quite common in our industry. Am I reading that right?

Andrew Truscott – Accenture – Co-chair

It's saying it's trying to prevent an actor requiring the licensee –

Anil Jain – IBM Watson Health - Member

Oh, require. Yeah, okay. They could do it but they can't require it. Yeah. They can do it, they can barter but they can't require it to be –

Andrew Truscott – Accenture – Co-chair

Yeah.

Anil Jain – IBM Watson Health - Member

Sorry. Okay.

Andrew Truscott – Accenture – Co-chair

It can happen but they must not mandate it.

Anil Jain – IBM Watson Health - Member

Yeah. Okay.

Andrew Truscott – Accenture – Co-chair

So, I had to read that three times.

Anil Jain – IBM Watson Health - Member

[Audio skip] and not law school, I'll tell you that.

Andrew Truscott – Accenture – Co-chair

Can you imagine how well we'd get on at law school? We say too much. So, 4B, I think I'm twitching at 4B because I'm channeling my inner Arien probably. But it's saying the only fees can be a royalty or to meet reasonable costs. Am I reading it correctly, Mark?

Anil Jain – IBM Watson Health - Member

Yeah, and I think that makes sense.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. It's basically saying that there are these two different categories of allowable costs that

we're talking about, reasonable royalty and cost reasonably incurred in 204.

Andrew Truscott – Accenture – Co-chair
What does that cost? What is the charge?

Mark Knee – Office of the National Coordinator – Staff Lead
Sorry, you're right, terminology charges. So, reasonable royalty and costs reasonably incurred, we've laid those out. So, those are the exceptions to this. But, otherwise, you can't require to pay a fee of any kind whatsoever beyond those two.

Andrew Truscott – Accenture – Co-chair
Can only be a royalty or cost recovery.

Anil Jain – IBM Watson Health - Member
For this element, for this stuff. We could do business together –

Andrew Truscott – Accenture – Co-chair
No, for any interoperability element.

Anil Jain – IBM Watson Health - Member
Yeah.

Andrew Truscott – Accenture – Co-chair
So, just to use an example, does that mean then that a health information exchange, anybody who is connected to it, it can only recover its reasonable costs under 204 or a royalty where there's some kind of licensing going on for any of the APIs? That's the only charges it can make.

Mark Knee – Office of the National Coordinator – Staff Lead
And just a note that we do say in preamble, Arien has pointed out it's not in reg text, but we consider reasonable profits to be included as costs reasonably incurred.

Andrew Truscott – Accenture – Co-chair
That's interesting – I'm glad you pointed that out to me. That's an interesting read into the term cost. I'm not really that comfortable with cost.

Mark Knee – Office of the National Coordinator – Staff Lead
You're talking about for 206, not for 204, right?

Andrew Truscott – Accenture – Co-chair
No, this is for 204.

Mark Knee – Office of the National Coordinator – Staff Lead

No, we're saying that you can make a reasonable profit under 204 or 206. The idea is that we want people to be able to innovate and bring new products to the market but it would still have to be reasonable, the terms. I think that still fits in the construct of costs reasonably incurred and RAND licensing. We're still talking about reasonable profits.

Anil Jain – IBM Watson Health - Member
Okay.

Andrew Truscott – Accenture – Co-chair
Policing profits of commercial entities is a really interesting decision.

Anil Jain – IBM Watson Health - Member
It happens in **[audio skip]**, right?

Andrew Truscott – Accenture – Co-chair
Okay. I think we're –

Mark Knee – Office of the National Coordinator – Staff Lead
But as always, if that point isn't clear or you need more clarity on any of that –

Andrew Truscott – Accenture – Co-chair
Oh, no, you've made it crystal clear.

Mark Knee – Office of the National Coordinator – Staff Lead
Well, no, I mean as far as your recommendations go. We're trying to improve on everything so if you have recommendations.

Andrew Truscott – Accenture – Co-chair
No. What I'm trying to do is work through the healthy balance because I see what you're trying to do with this to not stand in the way of innovation. But we also don't want to disincentivize innovation. There's not a health profit that can be made by someone who is innovative. Why would you bother?

Mark Knee – Office of the National Coordinator – Staff Lead
Exactly. And I know we have to take public comments but that's the point is if you don't allow any profits, what is the incentive for people to push the limits and make new products and innovate.

Andrew Truscott – Accenture – Co-chair
Let's open to public comment.

Mark Knee – Office of the National Coordinator – Staff Lead
Makes sense.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Operator, can you please open the lines.

Operator

If you'd like to make a public comment, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in the cue. You may press star 2 if you'd like to remove your comment from the cue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Thank you. We put the phone number up just to give folks time to dial in. But do we have anyone in the cue at this time?

Operator

None in the cue at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Okay. So, Mark and Andy, I think we should probably just wrap up on this last recommendation or at least on this last section before we conclude. But anything else before we end the public comment period?

Mark Knee – Office of the National Coordinator – Staff Lead

I don't have anything. Andy, do you have anything?

Andrew Truscott – Accenture – Co-chair

On what, sorry?

Mark Knee – Office of the National Coordinator – Staff Lead

Just any other issues regarding – I guess we're trying to close up this conversation. Do you want any other recommendations?

Andrew Truscott – Accenture – Co-chair

Was there a deliberate use of the word trade secret instead of intellectual property under No. 5?

Mark Knee – Office of the National Coordinator – Staff Lead

Under No. 5, let me take a look.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

And Mark, while you're taking a look, Operator, have we had anyone dial in?

Operator
There are no comments at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Thank you.

Mark Knee – Office of the National Coordinator – Staff Lead
Yeah, that definitely is a deliberate term. I'm not sure of the question beyond that.

Andrew Truscott – Accenture – Co-chair
Only because elsewhere, we've been talking through intellectual property in other rules but not trade secret.

Anil Jain – IBM Watson Health - Member
Andy, this is Anil. What do you mean? What's the issue with it? I just want to make sure I understand what you're saying.

Andrew Truscott – Accenture – Co-chair
It's a very deliberate use of a term and I'm trying to work out whether we mean the same thing.

Anil Jain – IBM Watson Health - Member
If I license someone intellectual property, I have to disclose to them what it is that I've licensed them. But if it's a trade secure, by the nature of it, I don't have to disclose that to them. So, I could have a nondisclosure agreement. And then, if I do happen to share it with them because of the business I'm doing with them, I could make sure they don't share it with anyone else because it's a trade secret. So, I think that's an important distinction.

Andrew Truscott – Accenture – Co-chair
I agree and I think that's the intent. I just wanted to make sure that **[inaudible] [01:48:50]**.

Anil Jain – IBM Watson Health - Member
Okay. Yeah.

Andrew Truscott – Accenture – Co-chair
Actually, don't we have the USTA that covers this anyway? Okay.

Mark Knee – Office of the National Coordinator – Staff Lead
It just goes to, again, we're not trying to say you have to be so loosie goosy as to not be able to have a nondisclosure agreement but it has to be a reasonable one that you're requiring.

Andrew Truscott – Accenture – Co-chair

That's fine. It was just the way we used the language inside of it. I'm fine. Anil was helpful. Okay. Actually, C, I'm okay with it because that seems pretty clear and straight forward. Anil, Steven, was I ahead on that one?

Anil Jain – IBM Watson Health - Member

Yeah, I think it's fine.

Steven Lane – Sutter Health - Member

Agree.

Andrew Truscott – Accenture – Co-chair

And D was pretty self-explanatory. So, I think the understanding is Paragraph 2 and then, details of objective verifiable and then, Nos. 4 and 5 as well. Guys, it's really obvious the amount of heavy lifting that's going into drafting this. So, I'm not trying to make recommendations which are unhelpful or ungrounded.

Steven Lane – Sutter Health - Member

I'll second that. We spent so many months waiting for this rule to come out. and I don't think anybody had a good sense of how much work was going on behind the scenes to put this together. The deeper I dig into this, the more impressed I am with the work that you guys did to draft it.

Mark Knee – Office of the National Coordinator – Staff Lead

Thank you very much. That's great to hear. Thank you. And I do want to say I think these conversations are really helpful for me. And they're really helpful for us moving forward. So, thank you, guys.

Andrew Truscott – Accenture – Co-chair

You're welcome. Okay. That one is to start another conversation in the last five minutes. I'm happy to five people five minutes off before you go to the weekend. Has anyone got anything else you want to raise?

Anil Jain – IBM Watson Health - Member

No. I look forward to seeing everyone next week. Thanks for your leadership, Andy and Michael.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Thanks for your time today.

Anil Jain – IBM Watson Health - Member

Thank you, everyone. Have a good weekend.

Andrew Truscott – Accenture – Co-chair

Take care, team. Bye.

[Event Concluded]