Information Blocking (IB) Workgroup 2

Transcript
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Virtual Meeting

SPEAKERS

Name	Organization	Title
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Anil K. Jain	IBM Watson Health	Member
John Kansky	Indiana Health Information Exchange	Member
Steven Lane	Sutter Health	Member
Arien Malec	Change Healthcare	Member
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Sasha TerMaat	Epic	Member
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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	Staff Lead

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good afternoon everyone. This is Workgroup Two, looking at exceptions under information blocking. In the workgroup, we have Andy Truscott, Valerie Grey, Arien Malec. Steven Lane is absent, Anil Jain may be late, and Michael Adcock may not be able to join. So with that, why don't we go ahead and get started, and I'll turn it over to Andy to get us started.

Andrew Truscott - Accenture - Co-Chair
Thank you very much, Lauren. Good afternoon, everybody. Thank you for taking your time on this wonderful Friday afternoon. I appreciate it with all the people that are heading out for the weekend. In the meantime, between us and then, is a couple of hours to discuss the exceptions around information blocking. I'm going to turn the microphone now over to Mark Knee. So, Mark works for ONC and is going to guide us through just a half-hour information session around the thinking from ONC that went into the current drafting of the exceptions in the draft rules that we are making comments and recommendations upon. So, this is just a followup from the main task force meeting that we had earlier today, where we covered off a large amount of the thinking behind the other aspects of the information-blocking rule. And this is just to finish off that with the specific background information around the exceptions. I know he will be supported by a cast from ONC as well as he goes through that. Mark, over to you, sir.

Mark Knee - Office of the National Coordinator - Staff Lead
Yes. Thanks Andy. I don't want to take away too much of your time from this workgroup because I know there's a lot that we need to get done. But I appreciate that you all would like to have some more information provided about the intent of – I guess, what we have to present to today is just the exceptions for 204 and 206, which are recurring cost, reasonably incurred, and RAND licensing. And I'm happy to go through those. I do want to emphasize, of course, that it's really important to understand all of the exceptions. And we have great fact sheets available on heathit.gov/rm that has a lot of the same material that I'm going to be going over, generally speaking.

I guess you could do the next slide. It's the slide that starts with an overview of exceptions. And feel free to jump in if you have any questions as I go, or clarifications. We tried to make these slides pretty clear without overloading.

So, some of this is redundant for this group. I was expecting to be presenting for the larger task force, but as you all know, there are seven proposed exceptions, and each one has corresponding conditions that need to be met in order to get coverage under the exception. And those exceptions are proposed at 45 CFR 171.201-207. The second bullet here is important because it talks about the actions of a regulated actor. So, thinking of the scope of what we're talking about here, as we talked about earlier today, the actors that are regulated under Cures are the healthcare provider, health IT developer of certified health IT as we define it, health information network or exchange. They'd have to satisfy one or more exception, and if they did, the actions would not be treated as information blocking, and the actor would not be subject to the civil penalties if the actor was the developer, network, or exchange, or other disincentives as appropriate as Cures sets for providers.

Real briefly, where we are coming from with each of these groups of exceptions is with the first three 171.201 through 203, which is preventing harm, promoting privacy and security, we kind of thought that without these exceptions, actors would be reluctant to engage in reasonable and necessary activities that prevent harm or promote privacy or security. And in our opinion, this would erode the

trust in the health IT ecosystem and undermine efforts to provide access and facilitate the exchange and use of EHI in really important situations that they should be allowed to do so.

The next three exceptions, two of which we'll focus on over the next few minutes, have more to do with promoting competition and consumer welfare, and they emphasize that information blocking is critical for promoting innovation and supporting competition. Throughout these sections, there are some overarching themes. We talk about – we view patients as having an overwhelming interest in their EHI, and particularly observational health. And as such, thinking about it, I think I've said this before on this call or a different one, EHI should not be traded or sold to those actors who – or by those actors who are custodians of the EHI or control the access, exchange or use.

And the last exception, just 207 recognized kind of in its own category, it recognizes that it may be reasonable and necessary for actors to make Heath IT temporarily unavailable for the benefit of the overall performance of health IT. So, what we did here would be the seven exceptions. Big picture is that we took the definition of information blocking and Cures, they asked us to identify reasonable and necessary activities that would not constitute information blocking, and then we developed these categories of practices that could constitute information blocking, but if they were reasonable and necessary you could avoid being covered by the information blocking definition. All right. Next slide. Let's see where we're at, and does anyone have any questions or comments about that overview? No?

All right. So, for recovering costs reasonably incurred and RAND licensing, really, these came about because we heard from stakeholders throughout the process, like Mike laid out, that one of the main ways, among others that we heard, that entities were information blocking was through certain fees and costs, and licensing contracts, things like that. And so we wanted to address those bad actors and bad actions, but we also acknowledge that we want to promote innovation and competition, and that there are reasonable costs and licensing royalties and such that are appropriate. And without those, the ability to charge those costs and to make a reasonable profit, folks in the market wouldn't have an incentive to push the envelope and promote innovation and create new products.

So, we tried to create this balance with these exceptions that, like I said, promote innovation and foster competition. As you can see on this slide, we say that under the proposed exception it will not be information blocking for an actor to recover its reasonable costs of enabling access or exchange or use of EHI. The proposed exceptions did not prescribe the amount of fees that can be charged, but imposes conditions to ensure that an actor's method for recovering costs is reasonable and nondiscriminatory.

So, as you can see with the stacked diagram here, our approach, really, we look at the method for recovering costs. We don't prescribe the specific amounts of fees, or look at – we consider different approaches, but we landed on this one because we felt that it provided the most flexibility, and especially for an ever-changing health IT market. As far as our objective, I mean, this is a bit redundant, but I'll repeat it again, we want to enable actors to recover the costs reasonably incurred to develop technology and to provide services at an enhanced interoperability, while not protecting rent-seeking opportunistic fees and exclusionary practices that interfere with access, exchange, or use.

An important point, as you can see at the bottom of the objectives section, is that reasonable profits would be allowed under both recovering costs reasonably incurred, and also RAND licensing exception. And I just want to note that for both of these exceptions we worked very closely with the FCC to determine the right approach. And it's difficult because, as we talked about in our group about RAND

licensing, this is a new area of law and there is not always going to be a clean fit for other processes or standards. So, we tried our best to make – use existing approaches but also make it work for our specific purposes. Next slide. All right.

Arien Malec - Change Healthcare - Member
I apologize. Before you go on, so you use the term reasonable profit. I think we've already noted that that term is not included in the reg text, but is there a publicly-available interpretation of reasonable, or reasonability - reasonableness test that would be used or could be used in interpretation of that word?

Mark Knee - Office of the National Coordinator - Staff Lead
I think, Arien, this was brought up at the high tech meeting, and I think Elyse addressed it. What I'd say is, I would tell you to look at the preamble, and I am sure you have already looked at what we've said. You're right. We don't specifically say profits in the reg text, but we do explain our approach and our intent in preamble, and if that is not clear then we'd definitely take comments on that. As far as what is reasonable, that's the standard that we've used in a number of instances throughout this ruling. I think we provide examples in the preamble. I need to look specifically for what you're asking about, but I know we provide lots of examples of what could constitute reasonable. But as far as providing a definition, we don't have a set definition just as far as why. Reasonableness is a standard that's used in law, and also the wide scope and type of cases that we're going to see, sometimes it seems like if you try to put a definition on reasonable, it wouldn't really make sense. But that's to say we welcome comments, and if you have an idea of what you think reasonableness should mean in this context, we welcome those thoughts.

Arien Malec - Change Healthcare - Member
Okay, thank you.

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah, Sure. Okay, I'll try to get through these quickly because I know we have a lot to talk about. So, the next slide is just the method by which an actor recovers costs. So this is kind of a checklist of what the OIG would mostly look at in conjunction with us to determine whether a cost was reasonably incurred. The cost would need to be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests. So, I think Arien actually had asked a question about this perhaps at some point during a previous meeting, and we do kind of lay out – maybe it was in the context of what objective and verifiable meant, but we do try to clarify that uniformly applied for all substantially similar or similarly situated classes. That's a real tongue twister there.

Second, it must be reasonably related to the actor's costs of providing the type of access, exchange, or use. Two are at the request of the person to whom the fee is charged. The fees must be reasonably allocated among all customers to whom the technology is supplied or for whom the technology is supported. And this one you see a lot has to do with competition. It must not be based in any part on whether the requester or other person is a competitor, potential competitor, or will be using the data in a way that facilitates competition with the actor. So, throughout these provisions, we want to make sure that you couldn't treat someone in an unfair way because they were competition. So, we made that clear. And then it must not be based on the sales profit revenue or other value that the requester other persons may derive from access, exchange, or use, and this is important, that exceeds the actor's reasonable costs for providing access, exchange or use of EHI. All right. Next slide?

Okay. With that, what was that? Oh, actually there's one more, or should be one more. Oh, yeah, that one. Yup. Exactly. So, this one – so, our approach was at first we laid out the methodology that would need to be used to show that costs were reasonably incurred, but we also explicitly call out certain costs that are excluded and would not be recoverable. Those costs are listed here, are costs that are incurred due to the health IT being designed or implemented in a nonstandard way that unnecessarily increases the complexity, difficulty, or burden of accessing, exchanging or using EHI.

I think the question came up in this workgroup about nonstandard, and that language I believe is from Cures, so we took that from there, and we describe what we mean in preamble. The costs associated with intangible assets, opportunity costs except for the reasonable forward-looking costs of capital, the fee prohibited by 45 CFR 164.524 (c)(4), which is from the HIPPA privacy rule and has to do with providing copies of PHI under HIPAA. So, you couldn't have a fee that's prohibited by that, but it is an important distinction that we don't contradict HIPPA. Those fees allowable under that section are allowed. What we're saying is a patient should have free access to their electronic health information.

A fee-based in any part on the individual's electronic access to their EHI, so that's what I was just talking about. Six is what relates to the topic from the full task force meeting earlier, a fee to perform an export of EHI via the capability of health IT certified to the (b)(10) criteria for full data export or EHI export for the purposes of switching health IT, or to provide patients with their EHI. And then lastly, a fee to export or convert data from an EHR technology unless such fee was agreed to in writing at the time the technology was acquired.

We also – an important point to mention here is that we tried to be consistent and clear throughout our approach, and we felt that it made a lot of sense to describe the methodology that would need to be used to recover costs and then to exclude certain cost. But if others have ideas about ways to clarify our approach, we definitely welcome them. With that, maybe I'll stop since this is the end of this exception, to see if anybody has comments or questions.

Okay. Great. So, the next one we're going to talk about, next slide, is licensing of interoperability elements, unreasonable non-discriminatory terms. So, as we talked about in our workgroup, the difference here between 204 is that we're talking about licensing of interoperability elements which are essentially – it's a broad term and we've talked about how we define it broadly –

Arien Malec - Change Healthcare - Member
Sorry, hold on. I apologize, because I do actually have a question that I've just been puzzling over. So, I think I have already noted that my interpretation of recovering costs does not allow for profit. I think the preamble notes that the intent of ONC was to allow for a reasonable profit. Is there a defined term for recovering costs and relevant to, for example, gap accounting standards or other kinds of interpretive guidance where the term recovering costs that ONC was contemplating, if there's a reasonable definition of that anywhere? I used the word reasonable again.

Mark Knee - Office of the National Coordinator - Staff Lead
I don't know that I can speak to that. I will say that we looked at a gap and other approaches. And we felt that the approach we took was appropriate for the information-blocking context and provided the appropriate kind of flexibility that we were looking for. Again, if there is a specific concept or term within gap or other accounting approaches, we welcome those comments if you haven't thought on improvement.

Arien Malec - Change Healthcare - Member
No. I appreciate that. All I'm just looking for is there something I'm missing where there is a definition you may not have been following, that if only I understood that all the light bulbs would go off? It doesn't sound like there is.

Mark Knee - Office of the National Coordinator - Staff Lead
So, I mean, I think all I can really say is that our interpretation of the language you put in there is that reasonable profits would be included within the exceptions for costs reasonably incurred and RAND licensing.

Arien Malec - Change Healthcare - Member
Okay. Yes, got it. Thank you.

Mark Knee - Office of the National Coordinator - Staff Lead
Sure. Just a point though, Arien. It does sound like you are in agreement of what we're trying to get at. Maybe you just are saying that you want to suggest a clarification or perhaps a slightly different approach, but that's my interpretation of what you're saying.

Arien Malec - Change Healthcare - Member
Yeah, that's right. So I think in any case I'd be asking for potentially changes in the regulatory text to clarify these points. I think maybe some more wholesale revisions that we'll suggest, but I think with respect to cost recovery, I think we'll be making – at least I'll be making some comments and already have relative to clarifying the reg text. Thanks.

Mark Knee - Office of the National Coordinator - Staff Lead
Sure. Okay, let me…

Andrew Truscott - Accenture - Co-Chair
Mark, it's Andy. Yeah, I just want to echo Arien that I suspect that whilst we understand the intent, and we may or may not agree with the intent but we understand it, certainly, I think the way it's manifested right now is not as clear as you explain. Notwithstanding the fact that the use of the word reasonable here, I appreciate it's used elsewhere, but defining what's a reasonable cost is fairly subjective. So, I'm trying to look at how we could make some recommendations to aiding clarity both for those who are claiming these to be costs, and also those who are trying to gauge whether they are reasonable or not. So, yeah, I think there needs to be more thinking that's going in here.

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah, no, no, I think that's great. In fact, I keep saying it, but we welcome those comments. Our goal here with all the exceptions is to be clear about what the expectations are of the market and of actors, and we're not trying to trick anybody. So, we want to be real clear on that.

Andrew Truscott - Accenture - Co-Chair
No, that's right. No, I get that, and also frankly, I'm not sure the intent you had was to enable you to go on a voyage of discovery, and opening up books of commercial organizations to ascertain whether their costs are reasonable or not.

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah, I guess all I would say is I think…

Andrew Truscott - Accenture - Co-Chair
Or was that the intent? I don't know.

Mark Knee - Office of the National Coordinator - Staff Lead
What I'll say is I think our intent, as I pointed out, was to promote innovation and competition. And we provide I think a number of examples in both of these exception sections about what types of situations would or would not constitute reasonable in the context of the exceptions. But again, if you read the preamble and the reg text and it's still not clear or not aligned with what you think is the right approach, then we definitely would like to hear those comments.

Andrew Truscott - Accenture - Co-Chair
Yeah, you may disabuse me of this perception if I'm wrong or you think I'm wrong, the preamble considers the nature of the costs as opposed to the level of the costs. So, these are the types of things that you could expect to have thoughts on, but it doesn't say and this is what we think is a reasonable level that those costs could rise to. I think that may be the gap.

Mark Knee - Office of the National Coordinator - Staff Lead
Right. Perhaps. I wasn't sure if that was a question or a comment. But yes, I think we don't prescribe the amount that people can charge. And again, this was in conjunction with conversations we had with FCC and OIG about both what makes sense from a policy perspective, but also as far as enforcement goes, you need to be able to apply the proposals we put in the proposed rule and then eventually in the final rule. So, those were our considerations. But, yeah, we welcome thoughts on how to improve it.

Andrew Truscott - Accenture - Co-Chair
Okay, thanks.

Mark Knee - Office of the National Coordinator - Staff Lead
All right. Does anyone else have any comments? All right. So, as far as the RAND licensing goes, we talked about this the previous workgroup, and the key distinction here that we're talking about licensing of the interoperability elements, which is that broad term that we used about the means by which you can access the EHI you're trying to get. Some of the stuff that we were thinking about here with this one was, IT rights can be misused in ways that really undermine the promotion of competition and innovation, and there is a really high potential for abuse when the IP rights pertain to functional aspects of health IT that are needed to enable interoperability. And this was based off of stakeholder meetings, and research, and studies, and everything we've put into this work for the last four years or so, or even longer probably.

So under this one, it would not be information blocking for an actor to interfere with access, exchange or use by limiting access to an interoperability element so long as that element is available for use by those that need it on reasonable and nondiscriminatory terms. As we talked about, the terminology or the approach to use RAND is generally used in court cases for standards. We looked at it, and we thought that the approach made sense and fit well, and we adjusted it a bit, but generally speaking, we adapted it for our purposes. And so, if there was precedent to use it – not precedent to use it, but there was a standard that has been used and fit well.

As far as the process, here on this slide there's the timely response that's required, there's the offering of an appropriate license. And we talked about this one that you all might want to tweak, the

timeframe for that, and again, just to emphasize, it's not actually agreeing on a license, but it's just the first reasonable offer, RAND offer, being made. And there are some additional requirements I'll talk about, and there has to be compliance with the relevant conditions of certification. And again, just to emphasize to Arian's point, our intent is that reasonable profits would be allowed under this exception as well. Next slide.

Arien Malec - Change Healthcare - Member
Actually, before you go there…

Mark Knee - Office of the National Coordinator - Staff Lead
Sure.

Arien Malec - Change Healthcare - Member
The applicability – I think we got into some knotty details – but the applicability of the RAND licensing is to an actor. So, if there is a non-actor whose license, or grant, or IP is essential to interoperability, they would not right now fall under the reasonable, the RAND licensing terms. So, the example that I've given in the past – I'm stating this just for the purpose of clarification – so, the example I've given in the past is, let's say a medical society that comes up with procedural terminology that's endorsed or used by the nation's largest payer, but that actor is not an actor as defined by Cures, or by the Cures NPRM, I don't think. Maybe I got that wrong. And then that actor is not also an SDO relative to some of the sublicensing terms that occur in that section. So, again, I'm just stating this to make sure I understand it well. My understanding would be the fees that that actor, I shouldn't use the word actor. Fees that that entity might charge would not be – I guess they'd be costs reasonably incurred rather than IPR.

I'm thinking out loud, and I apologize. Let me also – so first of all, do I understand that right? And then secondly, does ONC or does the proposed rule have a perspective on licensing, IPR licensing, that is standards essential or essential for access, exchange, and use, where that licensing is not by an actor as defined under the rule? So, a two-part question, and apologies for thinking aloud as I was talking.

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah, and I think I'm understanding, but I'll frame it this way. And I think you were asking some similar questions or scenarios in the earlier sessions. I think they're great ways for us to think through some of these issues. The way that I look at any of these cases, and I'm going back to the element of information blocking checklist that was on the slide back previously, there are certain things that you can look at to see am I information blocking under the Cures act and under the regulation. Are you an actor regulated by the provision? So, we talk about how those developers, providers, networks, and exchanges laid out in Cures, and we have defined in our rule what those actors - who those actors are. So, if you fall under one of those categories as we define them, then you would be considered an actor who would be potentially on the hook.

Is there EHI involved as we define it? And again, you'd have to look at our definition to see if it falls under our definition. Is the practice likely to interfere with, prevent, or materially discourage access, exchange, or use. So, is the conduct you're doing going to interfere with the access, exchange, or use? There is the requisite knowledge of an actor, whether you're a provider or a developer, network, or exchange, and then we'd look at whether the blocking is required by law or it's covered by an exception. So, I can't really interpret or get into the details of the specific fact patterns, but that's the framework that we're working under to determine if it's information blocking.

Arien Malec - Change Healthcare - Member
Got it. Helpful. Thank you.

Mark Knee - Office of the National Coordinator - Staff Lead
Sure. And I'd refer you – I mean, I think we're going to post those slides pretty soon on our website. And I think that slide specifically will be helpful for folks just to frame the issues. I think there's a lot of, like Arien has talked about and others have talked about, these fringe issues that you're thinking about that you're not quite sure, and we want to hear if we miss the mark at all, or we haven't created the right balance. So, I think that would be helpful.

So, maybe just a quick example I'll provide about a scenario under the RAND licensing. This one would be implicated if an actor were to assert proprietary rights in medical vocabularies or code sets in a way that was likely to interfere with the access, exchange, or use. So, that would be a problematic situation that you could try to qualify for the exception, but that's a use case that, one of the many, many ones that we were thinking about as problematic. I won't get into the definition of interoperability elements because that was covered I think in the session earlier today, but it is quite broad. All right. Next slide. Oh yeah, I'm already on the next slide. Sorry. Previous slide. I was still on the last one.

Okay. Real quickly, we talked about this already, but there's a timely response requirement where after receiving the request to license or use the elements, the actor must respond to the request within 10 business days from receipt of the request. And the way we in the preamble describe this response, it's two-pronged. You have to negotiate with the requester in a RAND fashion to identify the elements that are needed and also offering RAND license – a license on RAND terms.

And then I won't get into this, because we've talked about this quite a bit and they're laid out here, but these are the components of a RAND license that we require and that we've talked about. A few points, though, I guess, for clarity as far as reasonable royalty. In preamble, we talk about how it would need to be nondiscriminatory based solely on the independent value of the actor's technology to the licensee's products, and consistent with the policies of the standards development organization through which it was licensed if that's applicable. So, I just wanted to make that point because I know reasonable royalty was a point of conversation. So, does anyone have any thoughts on this slide before I moved on to the last slide?

All right. Great. So, we're onto the next one, which I believe is the last one I'll be talking about. And here are some additional requirements that go along with previous slides. So, to qualify for this exception, the actor must not engage in any practices or a practice that has any of the following provisions or effects. And again, our intent here was to identify, you know, this is the conduct that we want to be on the lookout for and should not be allowed. So, impeding the efficient use of the interoperability elements to access, exchange, or use PHI for any purpose for which a person is authorized, permitted, or required to access, exchange, or use PHI under applicable law; impeding the efficient development, distribution, deployment, or use of an interoperability product or service for which there is an actual or potential demand. And then also making changes that break compatibility or otherwise degrade the performance.

So, overall these exceptions were intended like I've said to promote innovation and competition, and interoperability overall, and to make it easier to access, exchange, use information when there's a good reason to do so. Does anyone have any more questions?

Andrew Truscott - Accenture - Co-Chair
Yes. Does anybody have any questions?

Arien Malec - Change Healthcare - Member
I have lots of thinking out loud but probably no questions.

Mark Knee - Office of the National Coordinator - Staff Lead
Or thoughts. I'm not sure where you are.

Arien Malec - Change Healthcare - Member
Where I get a little stuck is it is one thing to impede access. So if I'm impeding access, then I am sort of standing athwart the record as it exists. It's harder for me to understand what materially impedes exchange or use, in particular, the way that use is defined it's basically interpreting, getting value out of, incorporating. There's a broad definition of the term use. And it occurs to me that there's a different – there might be a different standard that's required for access than for exchange or use in the sense that there's a whole lot more value-added services that are associated with exchange or use that I would believe that, I think sort of objectively are less problematic than the same. For example, fee structures applied to access, where you are truly impeding the underlying access to the data. So, that's kind of my thinking out loud is we may want to think about comment that tailors the requirements more narrowly to the classes of activities that are more or less problematic.

Mark Knee - Office of the National Coordinator - Staff Lead
And I am not sure if you're able – I'm trying to figure out how to make it bigger, but I pulled up the slide that we had in the previous deck from this morning where we talked about how we define access, exchange or use.

Arien Malec - Change Healthcare - Member
Trust me, I've been all over those definitions as well.

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah, and just to note, I know you know this, Arien, but for everyone on the line, is that those terms are taken straight from Cures. And again, we looked at what Cures was saying, and we came up with these definitions based on common understanding of the terms, but also within the context of information blocking.

Arien Malec - Change Healthcare - Member
Yup.

Andrew Truscott - Accenture - Co-Chair
If I try to think this through to an example, then where we've got let's say health information exchange who is routinely exchanging information, so they're providing access but they don't actually ever touch the semantic of the data itself. And so, they're allowing the exchange, they're enabling the exchange, but that it is borderline unusable by some of the recipients because of the semantics inside it. So, they can do exchange, they can enable access, but they're not enabling use. Would there then be provisions? Go on.

Mark Knee - Office of the National Coordinator - Staff Lead

So, Andy, not to throw it back at you but I believe throughout Cures it's an "or," so it's access, exchange, or use. So, it's not all three. It's just one of them.

Andrew Truscott - Accenture - Co-Chair
Yeah, I know, so you **[inaudible][00:37:57]**. That's fine. So, by that definition, then, they would certainly implicate the information blocking regulation, because they're not enabling the free use. Curious one, isn't it?

Arien Malec - Change Healthcare - Member
Yeah. The direction that I go in, Andy, in that with the same example is, so, in full disclosure I have run and operated results exchanges. And as part of the work that we've done, in operating results exchanges, we have interfaced with EHR vendors, many of which – and generally we would do a pass through relative to interface fees, but many of which do charge substantial interface fees for just opening an interface. And then on top of that, we do a whole set of activities including mapping coding terminology, making sure that when the lab says provider A that we map that to a known provider as and endpoint, etc. So, there's a whole set of mapping and remapping between one person's interpretation of an HL7 ORU and somebody else's interpretation of an HL7 ORU, so a whole set of activities there.

The thought process that I have is that there is one set of behaviors, and if I think about the EHR on the other end that has an inexpensive interface fee, it's hard for me to understand how much of that fee is associated with making the data available versus mapping or causing to be mapped proprietary data.

Andrew Truscott - Accenture - Co-Chair
Making it useable, yeah.

Arien Malec - Change Healthcare - Member
Making it useable. And then, likewise on my side to your point, I could just deliver the message as is, but it wouldn't be terribly useable for the recipient. So the work that I do to transform it, and recode it, and blah, blah, blah, that makes it useful for the recipient, seems to be a less problematic set of activities that I'm doing would affect information blocking then if I said this EHR can get it, but that HER can't, because that EHR completes with me. Or if I put in place provisions that were discriminatory in terms of who could or couldn't access it. So, those are the thought processes that I have in terms of how do we carve our way through this thicket and address the policy constraint without impeding activities that are non-problematic and helpful for the healthcare industry.

Mark Knee - Office of the National Coordinator - Staff Lead
Right. Yeah. I was going to say that I agree with that. I think that's exactly what we were trying to do, and to strike that right balance. So it's our aim to do that.

Arien Malec - Change Healthcare - Member
Okay.

Andrew Truscott - Accenture - Co-Chair
Yeah, we need to be thoughtful in that we don't inadvertently start preventing some activities, which – you know, they're good activities. Exchanging data is a good thing. Some organizations – not every organization is as enlightened as you are, but some organizations certainly have commercial models where they exchange information but they don't actually touch the data at all. They don't the semantic

at all. Now, would we inadvertently with this rule, or maybe intentionally with this rule, be determining that those organizations are not sufficiently creating utility. That would be a difficult statement to make, I think.

Arien Malec - Change Healthcare - Member
I'd agree with that, too.

Andrew Truscott - Accenture - Co-Chair
But the overall nature of some of these makes it particularly tricky.

Arien Malec - Change Healthcare - Member
Yeah, and let's say from a policy perspective, I think it's far more problematic to impede access, to charge a fee for access, than it is to charge a fee for exchange or use. And it is far more problematic to have IPR that impedes exchange or use. So, if I have to license IPR in order to meaningfully exchange or downstream use a piece of information, that's a far more problematic behavior or activity then if I purchase technology to remap or recode data that's a value add on top of the bare record. So, I try to get at these cases where if what we're doing is standing athwart the bare record and making the bare record less interpretable or less useful and not accessible, those seem like bad activities that we want to stop. To the extent that we're taking the bare record and plus-upping it, making it better, making it more valuable, adding more semantics to it in ways that are valuable to end users if they want to pay for, that seems to be less problematic. And I just think we need to find a policy framework that better tuned for that distinction.

Andrew Truscott - Accenture - Co-Chair
So, is there a difference, Arien, between an organization that elects not to utilize the semantic translation function as opposed to an organization that couldn't even if they wanted to because it's not available to them?

Arien Malec - Change Healthcare - Member
Right. So, one way to think about this is that if I'm a provider – let's say I run a lab. And some labs make available a set of services and technologies that get the lab result all the way into the EHR. Some labs might choose to stop at publishing an interface and saying hey, I've made it accessible, come at it. But it's not actually exchangeable in practice. So, maybe this is where you're going, which is what are the obligations of an actor with respect to making it accessible, exchangeable, and useable, and then what are the obligations of whatever service provider they do or don't use in terms of what fee structure they can or can't charge in order to do that.

Andrew Truscott - Accenture - Co-Chair
You're right. That's kind of where I am going. We use these three terms: exchangeable, accessible and usable, okay? All three. And there's an "and" in the middle. It's not exchangeable, accessible, or usable. It's and. So, the implication seems to be that to be determined not to be information blocking you have to satisfy all those three things. And if that's the case, then I could – you and I know of organizations right now that routinely exchange information, but they deliberately say we're not going to touch the content of that data because, for whatever reason. And it's up to the recipient organization to be able to translate and make use of it, and make that data understandable into truly understandable information. It certainly seems like that's the intent of this.

Mark Knee - Office of the National Coordinator - Staff Lead

I think it's important, Andy, just to remember that what we're looking at is from the standpoint of interference with access exchange or use. We're not looking at what they – we're are looking at if they are interfering with access, exchange, or use, whether it's a reasonable and necessary activity. But it sounds like what you're talking about has kind of flipped, maybe, but I'm not sure if I'm understanding that.

Andrew Truscott - Accenture - Co-Chair
Maybe I am.

Anil K. Jain – IBM Watson Health - Member
Hey, so this is –

Mark Knee - Office of the National Coordinator - Staff Lead
Go ahead, Anil.

Anil K. Jain - IBM Watson Health - Member
This is Anil. Yeah. I was just going to say that the example that I would probably give - maybe this at least helps me understand this better – but if the system had in there a set of blood pressures, and also had in there how those blood pressures were taken, was the patient lying down, were they sitting, were they standing, and they chose from that system only to transmit blood pressures without the context of whether they were standing, sitting, or lying down, to me, that is information blocking because the recipient of the blood pressures can't use it. They don't know whether the patient was sitting, standing, or lying down. Now, if that system didn't collect whether they were sitting standing or lying down then that's not information blocking because that information didn't exist in any electronic form. But I think the intent here should be that if you have information that helps somewhat understand how to use the information that's being accessed, exchanged, and you withhold it, then that's information blocking. Now if you didn't have it to begin with, then you're not really interfering, and therefore, it's not information blocking.

Arien Malec - Change Healthcare - Member
Yeah, so this is where we come down to these knotty issues of let's say to continue the example on blood pressure monitoring, I come up with an AI algorithm that correlates blood pressure changes over time with risk for events.

Anil K. Jain - IBM Watson Health - Member
[Inaudible] [00:48:23] sure.

Arien Malec - Change Healthcare - Member
And I'm more thinking ischemic events, but whatever. It doesn't matter what the algorithm is. So, I've got an algorithm that I've created that takes those raw facts and creates additional value on top of those raw facts. Is it information blocking for me to charge a price, charge a high price for that capability? Charge a price that's well above bare costs that I have that might have been some **[inaudible] [00:49:04]** time because it's a valuable service that nobody else can do? Or is it a required element of interpretation of the blood pressures, and it's essential for use, it is a use, and any fee that I charge that's not kind of a cost-plus fee is, ipso facto, information blocking.

Anil K. Jain - IBM Watson Health - Member

Well, I would probably say that if that model was used for patient decision-making and was part of the medical record, then I would consider it information blocking not to share that.

Arien Malec - Change Healthcare - Member
I'm with you there. If it's part of the designated record set, if it's part of the legal medical record, then if it's actually used by the clinician, absolutely would be there.

Anil K. Jain - IBM Watson Health - Member
All right. So now, let's assume that it's not part of the legal medical record. You get a series of blood pressures, and now you have a business of value-added services where you are now adding a risk score onto it because of ischemia, as you put it. Then I think you should be allowed to generate revenue from that. I think the part where you should not be allowed to do anything silly would be to take the original raw data and try to monetize that.

Arien Malec - Change Healthcare - Member
Amen. I'm so with you. Yeah. But I should be able to charge whatever price I want to as long as my counterparty pays for it, but I should not –

Anil K. Jain - IBM Watson Health - Member
And we'll figure that out.

Arien Malec - Change Healthcare - Member
That's right. But I should not further impede the use of the raw blood pressure values. So, I think we're all in agreement of the policy intent.

Andrew Truscott - Accenture - Co-Chair
Let's go back to Anil's example of the blood pressures case just for a moment. So, let's say that a transfer of care takes place and those blood pressure readings are wrapped up inside a CCD or something and are exchanged with the organization that's receiving the patient for continuity of care. However, the coding behind **[inaudible] [00:51:14]** is actually some localized form, okay? And the receiving organization doesn't understand those blood pressure readings, would that count as information blocking?

Arien Malec - Change Healthcare - Member
So Andy, if you remember this convoluted definition that I sent out to a number of people, I'm not going to share it more broadly, one of the things that I believed should be covered in the definition of information blocking and impeding access is any transformation that's associated with surfacing data in a certified standard. So, if I certify my health information technology – so let me give you my results example. Because this is a real example. There are – you know, EHR's have ORU you interfaces, and EHR's implement proprietary coding terminologies. But they are required to support the LRI's spec that has data available via LOINC. If a certified EHR technology is certified to use the LRI spec and certified to receive data via LOINC, and goes through ONC ACT testing of that, but then charges a fee for every interface for remapping LOINC to their own proprietary codes, that to me constitutes an unallowable fee under the nonstandard implementation. So, I would extend the obligation to provide the bare facts of the legal medical record. As Anil notes, in cases where value-added facts were used for decision-making, they're part of the bare facts of the legal medical record. And in cases where some level of transformation is required to adhere to a standard that I've certified to, that's on me as adhering to

that certified standard to be able to provide any of that mapping. So, again, a long drawn out thought process there.

Andrew Truscott - Accenture - Co-Chair
I think you're saying no.

Arien Malec - Change Healthcare - Member
Yeah. I'm saying no. I am saying no. That's not an allowed – it should be required of that actor to do the work to surface it in the proposed standard or in the certified standard.

Anil K. Jain - IBM Watson Health - Member
Yeah. I think the alternative is that anyone who wants to block data would simply create their own ontology and hide behind it. So, I think that the only answer can be that you're required where an appropriate standard exists to use that standard when you exchange.

Andrew Truscott - Accenture - Co-Chair
And the same goes for if there's an intermediary sitting in the middle, like a health information exchange, they are also obligated to do so.

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

Arien Malec - Change Healthcare - Member
No. Wait. Hold on.

Andrew Truscott – Accenture – Co-Chair
Yeah, it gets tricky.

Arien Malec – Change Healthcare – Member
Yeah, yeah, yeah. So, wait.

Andrew Truscott - Accenture - Co-Chair
I've received it, coded it in Arien's magic standard, and Andy wants to receive it in SNOMED CT, whose –

Anil K. Jain – IBM Watson Health – Member
No. Wait a minute. If the HIE is simply bringing data in from Arien, well the HIE and Arien, that would be where the transaction would occur. And the HIE could accuse Arien of information blocking, right? If you now lock that data from the HIE, whatever the HIE is exposing, whatever they have is the limits of what they could be accused of information blocking. They can't be accused of blocking information they really don't have.

Andrew Truscott - Accenture - Co-Chair
I agree with you. We need to be clear about that, then.

Anil K. Jain – IBM Watson Health – Member
Oh, okay.

Arien Malec - Change Healthcare - Member
Yeah. So, Andy, I would say in that sense if the HIE is certified to, for example, an IHE or fire-based information exchange standard, that I can't charge a cost for every – I can't charge an unreasonable cost for every XCPD or fire equivalent interface that I do. I can charge a reasonable cost to hook up to my HIE. Yeah.

Andrew Truscott - Accenture - Co-Chair
Now you're in the space of where the HIE is leveraging a product. So, the HIE organization is leveraging an HIE product which has been drawn up by a third party, and that product is well capable of doing it; however, the HIE's themselves as is the case in the US, some do, some don't, have elected to not do any transformation of data – translation of data, sorry.

Arien Malec - Change Healthcare - Member
Yeah. Let me give you an example of CommonWell. So, CommonWell is a service that I am the service provider for. CommonWell is a not-for-profit organization, and there are some activities that CommonWell does like patient matching and linking, like when we do record retrieval, we retrieve out to a whole number of endpoints and we consolidate the results back so that there's a single information feed, but we don't do anything to the content.

So, with respect to CommonWell, the interface to CommonWell is defined by the CommonWell standards, none of which are defined in terms of the resulting content. We're just as happy to ship you a PDF or consolidated CDA or an HL7 document. We don't get into that business, but if there's an unreasonable fee or if there's any competitive behavior then we do. Now, relative to who can join and who can't join, if we excluded arbitrarily, I don't know, EHR vendors from upper Midwest, then that would constitute information blocking. If we charged implementation fees that were egregiously above and beyond the cost of implementation or if we charge differential implementation fees that were unconnected to the complexity of hooking up to the network, those would be problematic behaviors. But choosing to say our interface is defined as XY and Z, but not Y, is not itself information blocking.

Andrew Truscott - Accenture - Co-Chair
It's a curious one given the use of the word utility. And because it's an "or" in the middle of all that.

Anil K. Jain - IBM Watson Health - Member
Andy, what do you mean by that? I'm not sure I understand.

Andrew Truscott - Accenture - Co-Chair
Okay, so I am just – I'm not giving an opinion, this is a discussion right now, so. But where we say we talk about exchange, access, or use, or and use, sorry, the implication I think is you need to be facilitating all three to be information sharing, and therefore if you're not facilitating all three, you're guilty of blocking, potentially, or you're implicated in blocking.

Anil K. Jain - IBM Watson Health - Member
I was going to say I don't think it means that you're facilitating all three. I think it means you're not blocking any one of them. That's different.

Arien Malec - Change Healthcare - Member

Yeah, and Andy, and if you look at the Cures – I think it's important to look at the context in cures that says discourage access, exchange, or use. So, we are talking about an "or," and we're talking about an interference of some sort. That's the context.

Andrew Truscott - Accenture - Co-Chair
No, I agree with you. I'm just working out how we'd give recommendations, which could make this very, very clear.

Arien Malec – Change Healthcare - Member
I look forward to that.

Andrew Truscott - Accenture - Co-Chair
Stop it. Okay, guys carry on.

Mark Knee - Office of the National Coordinator - Staff Lead
So, Andy, what you want to do? So, on the agenda, I think we're about an hour in here, and we still haven't talked about the additional proposals for – the requests for information if you have additional exceptions, complaint process, and the disincentives for requests for information. Do you want to try to get through those, or do you want to stick with…

Andrew Truscott - Accenture - Co-Chair
Let's go to the additional exceptions first. Let's see if we can bang through those quickly. Yeah, let's go there.

Mark Knee - Office of the National Coordinator - Staff Lead
Okay, do you want me to pull it up on my screen, or just we can talk…

Andrew Truscott - Accenture - Co-Chair
Yeah, you can pull it up. We're going to talk around it as we go through it. So, Val, Arien, Anil, do we actually think there are additional exceptions that we require? Actually, and while we're at it, we'll just quickly discuss whether the reasonable costs and the royalty exceptions, whether they actually we think maybe they should – should they stay as exceptions or should they be put into their own section or not?

Arien Malec - Change Healthcare - Member
Can you restate that question?

Andrew Truscott - Accenture - Co-Chair
Yeah, so should what are currently drafted as the exceptions around reasonable costs and royalties, whether they should actually be sitting in a separate section around appropriate financial transactions?

Arien Malec - Change Healthcare - Member
Yeah. I think it would be clearer if there was a single-fee exception.

Andrew Truscott - Accenture - Co-Chair
Okay. Or a single –

Arien Malec - Change Healthcare - Member

Because otherwise it gets – This is relative to my comment that we need to do a better job of helping people determine which fees are or are not subject to information blocking regulation, and what subparts of those fee are or are not allowable.

Andrew Truscott – Accenture – Co-Chair
Okay, I think that's probably – Val, what do you and Anil think?

Valerie Grey - New York eHealth Collaborative – Member
It seems like that might be a little bit clearer.

Anil K. Jain - IBM Watson Health – Member
Yeah. Agree.

Andrew Truscott - Accenture - Co-Chair
So, I think, Anil – I think, Arien, you're suggesting collapsing into a single exception around fees, and my reason of question was whether we should actually suggest it's separate from the rest of the exceptions. It covers reasonable fees that can be charged as opposed to – I'm not sure whether exceptions is the right language for the fees.

Arien Malec - Change Healthcare - Member
That's is just a cures thing, and I'm not sure that ONC's going to be able to get around it, but I do find it more helpful to think about allowable practices than exceptions to information blocking, you know, that's the same thing.

Andrew Truscott - Accenture - Co-Chair
Yeah, I do, too. I agree. Okay. So let's just take that as something for our drafting. The additional exceptions, does the team have any thoughts on that?

Arien Malec - Change Healthcare - Member
Well, I've already commented, probably duplicative, about better understanding BAA terms, in particular BAA data use terms, with respect to information blocking. My general statement is that I would prefer a policy framework that is permissive and allows data to flow. I recognize that HIPPA allows covered entities to – that BA's only have the rights that are granted to them by covered entities under BAA terms, and that those data use grants would restrict the BA's ability to comply with information blocking, and as a BA, I don't want to be in the middle. I want it to be clear.

Andrew Truscott - Accenture - Co-Chair
So on the BAA subject, elsewhere and in one of the other workgroups, we've been discussing where also a BAA is adjunct to a contract. And obligations for the rewriting – or the assessing and potential rewriting and re-agreement of contracts which may impinge upon information sharing, and obviously BAAs would fall under that. Is that germane to your point?

Arien Malec - Change Healthcare - Member
Could you say that again? You said a bunch of obviouslys, and I was having a hard time going down with the obviouslys.

Andrew Truscott - Accenture - Co-Chair
Okay. So, obviously it wasn't so obvious, so. Okay.

Arien Malec – Change Healthcare – Member
Yeah.

Andrew Truscott - Accenture - Co-Chair
BAAs are broadly considered – I'll make a statement, see if you agree with it. BAAs are broadly considered to be contractual between two entities, okay? And they're normally adjunct to a contract being agreed. There are obligations elsewhere inside the regulations around the way that contracts need to be assessed and re-agreed where they may impinge upon the ability to share information appropriately. And BAAs, then, would be part of those conversations as well.

Arien Malec - Change Healthcare - Member
Yeah. I don't follow that chain of logic. So, I have reviewed the preamble to the rule to look at every instance of the word contract, and my belief is that the problematic contractual terms that ONC has pointed out in the preamble are relating to, for example, gag clauses relative to safety issues or other kinds of problematic EHR contractual behavior. But I'm not of aware of anywhere in the preamble where this tension between HIPAA and data use rights granted to BAs, and information blocking, and the obligations of health information network are actually discussed or adjudicated. So, the statement that you're going down is a statement that presumes that the information blocking requirements trump the BAA terms, but, I'd prefer that to be explicitly stated.

Andrew Truscott - Accenture - Co-Chair
Oh, I agree with you. There's no presumption right here. It's a discussion point. So under line 17403, which is around communications, additional certification, etc., you touched upon the business practices developers were likely to exchange in electronic health information. And within that as well there's the whole maintenance of certification, which is currently drafted within one year of the final rule, any communication or contract provision will not be **[inaudible] [01:08:06]** developer, and then within two years that would have been amended. I'm not sure how you and your organization generally contract, and then me and mine we generally have the BAA as an appendices to a contract. So, by inclusion, it would be wrapped up. Maybe this is an area that we feel that should be deliberately carved out.

Arien Malec - Change Healthcare - Member
Yeah, my general comment would be it's an area that needs to be made clear.

Andrew Truscott - Accenture - Co-Chair
And what do we think our recommendation on that clarity would be?

Arien Malec - Change Healthcare - Member
My preference?

Andrew Truscott - Accenture - Co-Chair
Yeah, as a starter.

Arien Malec – Change Healthcare - Member
Just recognize that a provider who has negotiated BAA data use terms very deliberately may have a different preference. But my preference would be to, with respect to the bare facts of the record,

whether the designated recordset is the right term or not, my preference would be to, for permissible purposes, to share as broadly as possible. And, so my preference would be to override BAA terms. A provider organization -

Andrew Truscott - Accenture - Co-Chair
Arien, you broke up there. To me, you broke up. You went blank.

Arien Malec - Change Healthcare - Member
Okay. My preference would be to have a clear preemption. A provider organization who has negotiated very specific data use rights may feel otherwise. And all of this is subject to HIPPA minimization or minimization of use. So, there's a lot that needs to get adjudicated and a lot of perspectives that need to be collected with respect to that preference.

Andrew Truscott - Accenture - Co-Chair
Okay, so let's ask the man of the moment, Mark. What is the intent in the current drafted regulation around an artifact like the BAA? Is that BAA restrictive of information sharing?

Mark Knee - Office of the National Coordinator - Staff Lead
Yes so, I mean, Arien's right we don't explicitly talk about BAAs for the most part, except within the regulatory impact analysis. We have some language I can direct you to on page 365 through 366 where we talk about restrictions on access exchange or use. I'll read it, maybe it's helpful. One means by which actors may restrict access, exchange, or use of EHI is through formal restrictions. These may be expressed in contract or license terms, the EHI's sharing policies, organizational policies or procedures, or other instruments or documents that set forth requirements related to EHI or health IT. Additionally, in the absence of express contractual restriction, an actor may achieve the same result by exercising intellectual property or other rights and ways that restrict access, exchange, or use. So, we view these – all I'm saying is that we're pretty clear, I think, in preamble, that we view contractual obligations that restrict the access, exchange, or use of EHI outside of reasonable and necessary activities as problematic and cases that could be information blocking.

Arien Malec - Change Healthcare - Member
Got it. Very helpful.

Andrew Truscott - Accenture - Co-Chair
Do you see BAAs as being a matter of contract?

Mark Knee - Office of the National Coordinator - Staff Lead
Again, I can't speak to interpreting that. I can only say what we have in the preamble. Again. Yeah, sorry, go ahead. What did you say?

Andrew Truscott – Accenture – Co-Chair
You have or you have not?

Mark Knee – Office of the National Coordinator – Staff Lead
I have or I have not?

Andrew Truscott – Accenture – Co-Chair
See BAAs in the preamble as a matter of contract.

Mark Knee – Office of the National Coordinator – Staff Lead
Well, all I'll say is we don't specifically talk about BAAs, but we do talk about the problematic nature of contracts and policies, procedures, sharing policies, all that, license terms, all those different restrictions that we saw when we talk to stakeholders.

Arien Malec - Change Healthcare - Member
I think 365 is super informative. The commentary on page 365 is super helpful.

Andrew Truscott - Accenture - Co-Chair
You're making me scroll through it now, aren't you? Okay, it talks about other instruments, and it seems to imply BAA's.

Arien Malec - Change Healthcare - Member
I think you could certainly read it that way.

Andrew Truscott - Accenture - Co-Chair
Yeah. So, that's a reasonable point, you know. BAA's would not be a permissible exception.

Mark Knee - Office of the National Coordinator - Staff Lead
Well, and again just to be…

Andrew Truscott - Accenture - Co-Chair
No, I am not asking you for an interpretation.

Mark Knee - Office of the National Coordinator - Staff Lead
No. No, I know that, No, I was just going to stay there is not an exception. Just to be clear, that we have the seven exceptions, but there's not one for BAAs apparently.

Andrew Truscott - Accenture - Co-Chair
Certainly, and I'm trying to get to the bottom of that, whether we on the task force are suggesting that they should be or not.

Anil K. Jain - IBM Watson Health - Member
Well, this is Anil. I don't think there should be. I mean, I think that's one of the biggest criticisms in the market right now is that the BAA's are used to prevent information blocking. I think all the examples that Arien mentioned last time aside, I think that is one of the challenges in the market today. So, if anything, if we're going to comment on BAAs, is to maybe clarify the language a bit more, put them in context, maybe give them more time to be renegotiated. But I think the idea that we somehow threw in an exception because the BAA was written not to promote information sharing I think would be going in the wrong direction, in my opinion.

Andrew Truscott - Accenture - Co-Chair
And that's certainly the direction that's being considered in Workgroup Three around this, Anil. I'd actually just say, the contract re-discussion opening up, the recommendation is to go from two years to five years, just because of the level of discussions that might be required, and the fact that several organizations have very large numbers of these contracts in place, and it's going to take time. Okay. Arien –

Anil K. Jain - IBM Watson Health - Member
But to be clear, I also don't think that in the time that it takes to renegotiate those, that they should be allowed to engage in behavior that would be considered information is blocking. The clock starts right within that two-year period or whatever it is.

Andrew Truscott - Accenture - Co-Chair
The clock starts when the regulation starts.

Anil K. Jain - IBM Watson Health - Member
Right. But you have time to renegotiate, but it doesn't mean you can still behind it, even if you haven't renegotiated.

Andrew Truscott - Accenture - Co-Chair
Yeah. I'm just looking to see what the actual language was that they drafted. Actually, I think that's – you probably raised a point that needs to go back into that group because right now they've drafted up that within two years you would agree on an on a plan to amend the contract. Mark, I can't remember whether there was a **[inaudible] [01:16:45]** the obligations which are blocking in the meantime. I can't remember…

Mark Knee - Office of the National Coordinator - Staff Lead
I don't believe you guys specified that. I do believe that the current proposal from ONC's perspective, the two years, I need to look at it specifically, but I don't think it means that you could still have these bad contracts for two years regarding communications. I think it's similar to what Anil's saying. But I need to look –

Andrew Truscott - Accenture - Co-Chair
Oh no, no. I found it. It actually says in the meantime, a health IT developer must not establish or enforce any contractual agreement that contributes it. So, it's enforcing that.

Mark Knee - Office of the National Coordinator - Staff Lead
But, Andy, to your point, I think it's worth bringing up with that group just to make sure they're on the same page with that point that we proposed.

Andrew Truscott - Accenture - Co-Chair
Yeah, can you make a note to do that? We're nearly finished with that group.

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah, sure.

Andrew Truscott - Accenture - Co-Chair
Yeah. We've updated the paragraph to actually say a health IT developer must not establish, renew, or enforce any contractual agreement that **[inaudible] [01:18:03]** So the enforcement is definitely in their redrafting as well. So you should just mention that. Where would be the appropriate place to, at least in the preamble, mention the BAA? It sounds like probably over in communications on Section 17403. Is that the right place?

Arien Malec - Change Healthcare - Member

I think it needs to be more explicit in the rule. And then with respect to the preamble on the final rule, appropriate commentary. And also just to be clear, I believe that because of the definition of EHI, this is not a broad giveaway of unrestricted access to de-identified data, or data for sale, or data for secondary use. This is really with respect to access to data for permissible uses.

Andrew Truscott - Accenture - Co-Chair
All right. That's my understanding as well. I take that as mutual agreement.

Anil K. Jain - IBM Watson Health - Member
Yeah. This is Anil. I was just thinking. I just want to make sure I understand what you mean by secondary use. Because I think there is language in there that – you're talking about in the BAA's about secondary use. Are you speaking specifically about the BAAs, Arien?

Arien Malec – Change Healthcare – Member
Yeah, so among the –

Anil K. Jain – IBM Watson Health – Member
Okay. Yes, that's cool.

Arien Malec – Change Healthcare – Member
That's right.

Anil K. Jain – IBM Watson Health – Member
I just wanted to make sure we're not talking about one of the other exceptions where it strictly prevents someone from blocking data because of the secondary use that the recipient might get.

Arien Malec – Change Healthcare – Member
Yeah. That's right.

Anil K. Jain – IBM Watson Health – Member
Okay. All right.

Andrew Truscott - Accenture - Co-Chair
So, I think we're all in agreement that BAA's are not an exception. So, we're not going to propose them as one.

Anil K. Jain – IBM Watson Health – Member
Right.

Andrew Truscott - Accenture - Co-Chair
Whew, I thought for a moment in there you were saying they maybe should be.

Anil K. Jain - IBM Watson Health - Member
No. No, no, no, no, no. I think that's the biggest problem I've seen in the market right now, actually.

Andrew Truscott - Accenture - Co-Chair

Okay, are there any legitimate exceptions? I know that I mentioned, or we mentioned national security exceptions earlier. I don't know whether, Mark, you managed to get the divisions done around that, given that this has been a fairly busy week with other things.

Mark Knee - Office of the National Coordinator - Staff Lead
Sorry, the question was a national security exception?

Andrew Truscott - Accenture - Co-Chair
Yeah. Did you do the background to find out whether there are actually no special exceptions required, it's all covered, or is that still pending?

Mark Knee - Office of the National Coordinator - Staff Lead
Well, I think I kind of looked into it, but maybe I did not understand the question. So, it's not currently an exception. So, I guess maybe a fact pattern that you're thinking of could be helpful, but generally –

Andrew Truscott - Accenture - Co-Chair
We're only going to make recommendations for exceptions where there isn't an existing path to an exception.

Arien Malec - Change Healthcare - Member
Right. The national one, we're prohibited by law. If it's prohibited by law to exchange information deemed confidential, or whatever the appropriate classification is, then classified or whatever the appropriate classification is, then would that be covered under the required by law exception?

Andrew Truscott - Accenture - Co-Chair
Yeah, we just want to make sure that there isn't any unintended consequence of all these questions around law, whatever. We just want to make sure. Or do we need to include it as an exception?

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah, Just to clarify. So, the way that this is written is that is if there is interference by an actor with access, exchange, or use, like I said, you can go through that checklist. And then if you got down to whether there's an exception, you'd have to fit into one of those exceptions, or be required by law. When we talk about required by law, we're talking specifically to interferences with access, exchange, or use of EHI that are explicitly required by state or federal law. Looking at the preamble, we distinguish – well, we definitely do, I think it's within the privacy exception, we talk about – we distinguish between different interferences that are required by law and those that are pursuant to a privacy law which is not considered required by law. So, that's an example of what we were saying. You know, it has to be an explicit requirement that has to do with access, exchange, or use. And I can find the page number, but the discussion in the privacy exception might be helpful for understanding what we mean.

To basically, Andy, to your question, whatever the fact pattern is, we look to whether it's required by law to interfere, or whether it meets an exception. If doesn't fall under those categories as it's currently written, it could be considered information blocking and subject to penalties or disincentives.

Andrew Truscott – Accenture – Co-Chair
[Inaudible] [01:23:44] feels like a very legitimate reason to block –

Arien Malec - Change Healthcare - Member
You're underwater, Andy.

Andrew Truscott - Accenture - Co-Chair
In so many ways, in so many ways. What I'm trying to understand is, if we think there's a legitimate reason for information not to be shared, i.e., for a national security purpose, whether that is already taken care elsewhere in other legislation which we can obviously comply with, or whether actually it needs to be specifically called out in there. That's what I'm trying to understand.

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah. My thoughts, I mean like I said, we only have exceptions if there is a scenario that you can think of where there wouldn't be a requirement by law, and it wouldn't be covered by one of these exceptions like privacy, security, and feasibility, things like that, then you might want to recommend -

Andrew Truscott - Accenture - Co-Chair
Absolutely. A good example would be new large EMRs going in at both DOD and VA, and one of the key rationales for having the same EMR platform used in both would be to enable interoperability between the DOD and VA. So, it seems logical to presume that information around the care that's being tended to an individual when they're in service will also be on their record when they're being cared for by the VA.

And given that a large chunk of the care that the VA provides is actually paid for from the commercial world, or comes from the commercial world, so those records will be available in the commercial world. So, you theoretically have access to data that was out in the commercial world but was actually two hops removed, created when they were serving personnel. Now, it seems logical that there may be aspects of those service records which could be held to be especially sensitive, and that should not be routinely shared. But we wouldn't want that to inadvertently fall under the definition of information blocking when it's actually a national security issue. Is that a good example? Is that an understandable example? Let's not be too subjective on good yet.

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah, I think it's a good example, and I don't know that I can give the answer you want just because it really depends on those specific facts and circumstances. I think it could fall under security exceptions, I guess infeasibility could be in play. I mean, I don't really know unless I looked at what the specific EHR was, who the actors were –

Andrew Truscott - Accenture - Co-Chair
Okay. I'm going to say feasibility – take it from me, feasibility is not the issue. The issue is actually whether the VA and DOD would want to redact that information from the record at the point it won't be shared outside, and whether there is a security exception already in place to allow that or not. If there isn't, then should we have one? And if there is, then we're good to go.

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah, I can't really give you an answer, but it's a good point for the group to talk about whether those types of scenarios would be covered by our current exceptions.

Andrew Truscott - Accenture - Co-Chair
So, Arien, Anil, am I making sense, or is that stretching it too far?

Arien Malec - Change Healthcare - Member
I would tend to believe that this would be prohibited by law.

Anil K. Jain - IBM Watson Health - Member
Yeah, I'm with Arien.

Andrew Truscott - Accenture - Co-Chair
I agree with you, which goes back to my question of saying, is it prohibited by law or not?

Arien Malec - Change Healthcare - Member
If it's classified data, then sharing is prohibited law. I think. Hey, I've got a fun one that is a real one that I just came across in my inbox.

Andrew Truscott - Accenture - Co-Chair
Go ahead. I like the implication. Go ahead.

Arien Malec - Change Healthcare - Member
So, this is not a national security exception. But, so my understanding of the way that information blocking works, is that it's permissible to not share if the patient has expressed preferences for data not to be shared, even though it may be allowed under HIPAA, and I forget which exception that is. That might be exception No. 201 or 202.

Mark Knee - Office of the National Coordinator - Staff Lead
No. 202. It's under privacy.

Arien Malec - Change Healthcare - Member
No. 202. All right. And I'm dealing with an organization whose organizational policies require opt-in affirmation. So, I would believe that unless the state law requires affirmation in order for data to share, that in an information-blocking context, information should share unless the patient has actually expressed a desire for information not to share. Does that all make sense?

Anil K. Jain - IBM Watson Health - Member
I'm sorry? This is under 202?

Mark Knee – Office of the National Coordinator – Staff Lead
Can you say that one more time?

Arien Malec - Change Healthcare - Member
Welcome to the double negatives. Okay. So, under 202, there is an exception for where the patient has – what is the actual language? Anyway, so under 202 there is an exception where the patient has expressed a preference for data not to share. There is a very famous and rather annoying opt-in/opt-out distinction where some organizations or entities require affirmative consent to share information; that is, they presume that the patient has affirmed a desire not to share unless they have actually affirmed a desire to share. My reading of information blocking, of the information blocking rules as currently described, is that unless there was a state, and particular state law that said otherwise, the patient would have to affirm a desire not to share. Go ahead, Anil.

Anil K. Jain - IBM Watson Health - Member
I was going to say I thought 202 had organizational policy as well in there. And maybe I'm not completely understanding everything you're saying, but.

Andrew Truscott - Accenture - Co-Chair
It does. It does. **[Inaudible] [01:31:15]** organization policies and procedures that are in writing.

Anil K. Jain - IBM Watson Health - Member
And if the organizational policy is based on state law for that state, which it probably has to be, at least the basis of it, they wouldn't by nature 202 cover –

Arien Malec - Change Healthcare - Member
No. I'm agreeing that if they're complying with state law, they're okay. But if they define an organizational policy that requires an affirmation of a desire to share before any data's shared, is that permissible or not permissible? If the same law –

Andrew Truscott - Accenture - Co-Chair
Okay, it goes over and above what the state requires.

Arien Malec - Change Healthcare - Member
It goes over and above what state law requires and what HIPAA requires.

Anil K. Jain - IBM Watson Health - Member
Yeah. So, I mean, based on how 202 reads I think is what you're saying, Arien, is that it is a topic between that and other parts of the rules that you've read, that the organizational policy versus the state rules –

Andrew Truscott - Accenture - Co-Chair
[Inaudible] [01:32:15] organization that covers –

Arien Malec - Change Healthcare - Member
Hold on. Yeah. So, if the precondition requires on the provision of consent for authorization from an individual, the actor, subpart one, subpart I, did all things reasonably necessary within his control to provide the individual with a meaningful opportunity to provide the consent for authorization, did not improperly encourage or induce the individual to not produce or provide the consent for authorization... So, there is a two-part test with respect to provision of consent for authorization.

Mark Knee - Office of the National Coordinator - Staff Lead
And just a note for clarity there is also the sub exception for respecting an individual's request not to share information, which you're talking about the precondition not satisfied. Is that right?

Arien Malec - Change Healthcare - Member
Yeah, right.

Andrew Truscott – Accenture – Co-Chair
That's where we are.

Mark Knee - Office of the National Coordinator - Staff Lead

Okay.

Andrew Truscott - Accenture - Co-Chair
So, Arien, when you were talking about the over and above the requirements of the state, this actually happens reasonably often where you've got information that spans multiple states, and they have an organizational policy which is consistent with the most restrictive state.

Arien Malec - Change Healthcare - Member
Absolutely. Yup. Or they've got organizational policy based on a risk determination that says they've got to have a patient affirmatively consent, but they don't provide – it's not easy, they don't provide notice, patients don't know that they need to do that.

Andrew Truscott - Accenture - Co-Chair
Actually what happens is some cases is a policy issue. You get patient consent every single time you wish to share.

Arien Malec - Change Healthcare - Member
There's that too.

Anil K. Jain - IBM Watson Health - Member
Sorry. Arien, what's your – I understand that issue. What would the recommendation be? To create another exception? I'm not sure -

Arien Malec - Change Healthcare - Member
No. First of all, I'm just trying to understand what the actual language is.

Anil K. Jain - IBM Watson Health - Member
It sounds like to me there may be another issue, which is that organizational policies may need to be revisited in order to make sure there are no unintended consequences against the information blocking provisions. And that in addition to reviewing the contracts, the organizational policies may also need a two-year window to be revised, or whatever. Some language like that.

Andrew Truscott - Accenture - Co-Chair
As I said, this particular exception, which is 171.202, is one that we've reviewed, but we've had very little to say about it. **[Inaudible] [01:34:58]** documented and recorded, and the concept of meaningfulness. We asked whether that was expressed in HIPAA, and that was it. Arien, you talked about organizational practices **[inaudible] [01:35:17]** kind of what you were thinking about right now.

Arien Malec - Change Healthcare - Member
Yes, that's right.

Andrew Truscott - Accenture - Co-Chair
You actually made a statement here, "Organizational practices extra to HIPPA or other organizations should be clearly forbidden." I'm not quite sure that was the – this is particularly the context you meant it, but –

Arien Malec - Change Healthcare - Member

I think that's the national stance, and I think it's a reasonable stance to ask for. I believe in practice that organizational policy is used as an excuse not to share by many actors.

Andrew Truscott - Accenture - Co-Chair
So, let's say you have an organization that has a provider site in Delaware and one who's in Pennsylvania, all right?

Arien Malec – Change Healthcare – Member
Welcome to my world.

Andrew Truscott – Accenture – Co-Chair
Are we permitting the organization to have a single policy that covers both of them, or are we saying actually you need to have a different policy depending on the state?

Mark Knee - Office of the National Coordinator - Staff Lead
So, I direct you to page 406, where we talk about when there are conflicting state privacy laws. And it would probably be easiest just to read that. In fairness, it doesn't necessarily get at the organizational policy issue you're talking about, but does talk about –

Andrew Truscott - Accenture - Co-Chair
So, just to preface this may or may not answer that question.

Mark Knee - Office of the National Coordinator - Staff Lead
What? No, I think your question was about conflicting state laws, if one state has more restrictive privacy laws than others then another one does, and you do business in both states. I thought that's what you were getting at.

Andrew Truscott - Accenture - Co-Chair
Across state lines, yeah.

Arien Malec - Change Healthcare - Member
If an actor is required by law to obtain an individual's HIPPA authorization before providing access, then the individual's refusal to provide an authorization would justify the actor's refusal to provide access.

Andrew Truscott - Accenture - Co-Chair
Where are you reading, Arien?

Arien Malec - Change Healthcare - Member
This is 405.

Andrew Truscott – Accenture – Co-Chair
Oh, okay. Sorry, I was on 406.

Arien Malec – Change Healthcare – Member
If the actor is not required by law to obtain prior authorization...

Andrew Truscott - Accenture - Co-Chair

Sorry. Arien, go to the top of 406, where actually the preamble specifically talks about actors who operate across state lines. With organization-wide privacy practices – It's almost like you wrote this, Arien. I get what you're saying here. We're considering a sub exception that recognizes national observance of a legal precondition that is required to satisfy at least one state in which it operates.

Arien Malec - Change Healthcare - Member
I would say that as a platform that has done the hard work of trying to make this configurable, based on the differing of state law, I'd say if the result of this is to flow all restrictions down to the point of the most restrictive state, then I think that would tend to be a not good idea.

Andrew Truscott - Accenture - Co-Chair
We I kind of – just from a general patient benefit of view, because if we're looking at the market in general, we're not seeing an increase in consolidation, and cross-state boundary healthcare systems will become more than the norm than they are right now, and there are no notable ones right now. It seems that you could end up with a position eventually where the majority of the organizations you want to see care from would actually be multistate, and therefore it doesn't really matter what state you're receiving care in, it's always going to float up to the level of the most restrictive. I can't see why that would be good for patient care. I'm trying not to overly trivialize it, but just for the sake of having the hard work which, Arien, you've built already, to be configured appropriately in technology. And technology's supposed to cope with these differences in context.

Arien Malec - Change Healthcare - Member
Yup.

Andrew Truscott - Accenture - Co-Chair
Mark, thanks for directing us to this. You're obviously seeking comment on this? If you seek comment on whether there is a need, we'll give you comment.

Mark Knee - Office of the National Coordinator - Staff Lead
Well, great. Yeah, and I think that to tie in with the conversation about organizational policies fits as well for your comments if you wanted to make them.

Andrew Truscott - Accenture - Co-Chair
Well, I think organizational policy consideration is good, but I think I always minded are we as a group, obviously there's a greater wider task force for consideration, but are we as a group actually generally saying not only do we suggest that this isn't made an exception, but we explicitly say this should not happen.

Arien Malec - Change Healthcare - Member
I believe so.

Anil K. Jain - IBM Watson Health - Member
I think so, Andy. I mean, it's recommendations, right, in terms of how we should be approaching this. So, yes. Hey, guys, I've got to roll off of the call. I'm really sorry.

Andrew Truscott - Accenture - Co-Chair
That's all right. No worries. **[Inaudible] [01:41:37]** Thanks for joining.

Arien Malec - Change Healthcare - Member
Okay, hold on. Now, I'm getting it better. All right. So, the actual language in 202 is conditioned on if an actor is required by a state or federal privacy law to satisfy a condition prior to providing access, the actor may choose not to provide access if the condition has not been satisfied, provided that the practice conforms to the actor's organizational policies. And if the organizational policy requires – relies on a provision of consent or authorization, then there is also a two-part test, did all things reasonably necessary and did not improperly encourage or induce.

Andrew Truscott - Accenture - Co-Chair
Yup.

Arien Malec - Change Healthcare - Member
So, the way I read 202 is as I stated, which is that requiring affirmative consent prior to sharing is allowed only if required by a state or federal privacy law, and then only in cases where there is no – where there are all things reasonably necessary and no attempt to induce.

Andrew Truscott - Accenture - Co-Chair
So, I think that's what we were just talking about.

Arien Malec - Change Healthcare - Member
Yup, that's right. So, I think 202 states where the position that we think is appropriate, and I think we want to with respect to that comment or request for comment, I think we want to state that we actually think 202 is fine as is.

Andrew Truscott - Accenture - Co-Chair
It's fine as is but with consideration to be more explicit around organizational policies needing to conform to the state to which that consent is being sought, as opposed to "floating up" to the most restrictive.

Arien Malec - Change Healthcare - Member
That's right.

Andrew Truscott - Accenture - Co-Chair
Yup, okay. So, that was a good conversation that one. What about health providers that are not regulated by the HIPAA privacy rules.

Mark Knee - Office of the National Coordinator - Staff Lead
I mean, there's a sub exception for that as well.

Andrew Truscott - Accenture - Co-Chair
So, it's exactly the same. You're governed by your state rules and you shouldn't - let's say on – I'm trying to think of an example that would be multistate that wouldn't be governed by HIPPA. I think there are a couple. You're governed by the state laws. You should be putting in place an organizational policy which is conformant with the most restrictive. Got it.

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

Andrew Truscott - Accenture - Co-Chair
We just said the same thing. Okay. That was good. I'm actually going to suggest giving it to 3:18. Should we go to public comment?

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Why not. Let's do it. Operator, can you open the public line?

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

Andrew Truscott - Accenture - Co-Chair
Thank you very much. If you are in the public **[inaudible] [01:45:07]** on this, we really would like to have your comment. Operator, is there anybody entering the queue?

Operator
There are no comments at this time.

Andrew Truscott - Accenture - Co-Chair
I'm disappointed. Okay.

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

Andrew Truscott – Accenture – Co-Chair
Arien, where do you want to go –

Arien Malec - Change Healthcare - Member
There have to be some people who have been hanging on to our every word, and are just for whatever reason don't want to get into the act. But I just encourage all the thousands and thousands of people who are listening to these calls, to pick up the phone and make a comment because we really want to hear from you.

Andrew Truscott - Accenture - Co-Chair
Your cynicism is palpable, borderline. But actually, there are actually public comments, public observers on all the calls the now. We're noticing them more and more. So, it's really good to get public feedback to at least tell us whether we're on the straight and narrow or whether we need to go in another direction, or, you know. That would be good to receive.

Arien Malec - Change Healthcare - Member
Yeah. Maybe, Andy, we could talk about what's the process to getting – we've got a lot of comments now in the spreadsheet. We've had a number of discussion points that are captured through all the transcripts. In my past work as a task force chair, I have personally taken on the labor and effort of writing up the recommendations so that they're just so, and then gone through a review process with

task force members. I think we're supposed to deliver recommendations for next meeting, which is in three weeks from now, two and a half weeks from now? Is that right?

Andrew Truscott - Accenture - Co-Chair
Yup. Shall I gently chide you and tell you what I think the process should be?

Arien Malec - Change Healthcare - Member
Yes, please.

Andrew Truscott - Accenture - Co-Chair
And that was meant with all the love in the world. So, and that's on the public record now. The intended proposal – I'll just say that in Workgroup One we already have our first cut of drafting, and we're working through that and finessing as we go. Workgroup Three is pretty much in the same state. This workgroup, we haven't. So, my proposal is going to be that actually we divide and conquer on the drafting. I'm not sure – well, actually I think that's the policy committee was **[inaudible] [01:47:51]** But there's a lot of thinking in here. I think it's going to take quite a lot of time to actually come up with even just the first cut of our proposed regulation. I am proposing that we divide and conquer as a group, and Arien and Val left at completely the wrong times as to **[inaudible] [01:48:15]** some of this stuff. But we're going to have to, I think.

And the approach we've taken elsewhere, for rightly or wrongly, and this is in conversation with ONC and trying to make their jobs a bit easier going forward, is we created our recommendations in each area under three headings. Discussion, recommended regulatory text, and recommended preamble. The discussion is to capture the various different flavors and sentiments that we have discussed and the various different opinions and views which have been discussed into a short narrative for the understanding of context and where we're coming from on the recommendations.

The second part around the regulatory text is a complete rendition of the appropriate regulatory text with all our proposed amendments – amendments is probably the wrong flavor – recommendations to changes inside of it. And then the third with the preamble is either replace the preamble with this, or as is more often the case, we suggest that you put these paragraphs into the preamble as well. And that's kind of the approach that we've taken. It's worked pretty well in Workgroup One and three. I appreciate this Workgroup Two is a bit different. What is does give us is the ability and recommendation to say we suggest you change the entire regulatory text, or these big chunks of it, etc. And it makes it easier for ONC to say, okay, this is what they want all of the recommendations to do with this exception. Does that – is that clear?

Arien Malec - Change Healthcare - Member
Yeah. Do we have proposed definitions? So, and I think you've been following my logic, I believe that particularly the fee structure information blocking exception, there's a dependency between the definition of EHI, the definition of information blocking, the definition of health information network, and health IT, and developer certified health IT technology. And I wonder how we reconcile that plus the actual information blocking reg text. Because I could go, as you well know, I could go down a rabbit hole of tailoring all the definitional work to land out in the right point with the information blocking exceptions, but if we've already done that definitional work, then there's just a dependency back and forth.

Andrew Truscott - Accenture - Co-Chair

Yeah. So, up until about 36 hours ago I would have said, well just go and look at the Workgroup One document, and you've got it all in there, and it's pretty well laid out. **[Inaudible] [01:51:25]** there was a great deal of discussion around the scope, some of which was in alignment with your thinking. Some of it was clearly definitely not. This is a beast we're going to have to wrestle forward with. The fact that these things are going to line in and line out as we go, my suggestion is go and look at what the current definitions are and use those, whether or not you agree with them, use them. But make comment **[inaudible] [01:51:56]** in your agreement, and we will go back and take that on board in that workgroup. However, very, very short term, we're going to be moving into the full task force and considering all these together, so we actually get that relationship between them. And you're right. There is a directional dependency between them.

Arien Malec - Change Healthcare - Member
Yeah.

Andrew Truscott - Accenture - Co-Chair
Okay. If it helps, you could self-elect to take on specific exceptions to start drafting on that would not feel self-compromised.

Arien Malec - Change Healthcare - Member
I'm down with going for fees. If that is what you are asking.

Andrew Truscott - Accenture - Co-Chair
That's good. Yeah. As a matter of principle, I think we're kind of suggesting from your point earlier, we should collapse these into a single one.

Arien Malec - Change Healthcare - Member
Yup.

Andrew Truscott - Accenture - Co-Chair
Okay.

Arien Malec - Change Healthcare – Member
Pursuant to our comments, we should collapse the fees into a single one, we should make a distinction between where fees are problematic, and tailor the fee. This is where the definition of information blocking and the fee language are dependent. I don't know how to untie the knot, because I think we want to say some fees do not constitute information blocking and some fees could constitute information blocking, and here's the appropriate framework for those fees. Right?

Andrew Truscott - Accenture - Co-Chair
Arien, I'm just going to pick you up on a point note you made earlier which I think I agree with. You made the point earlier that maybe when we should be looking at fees in more of a permissive tone, under an exception tone. I am paraphrasing. And if we do that, then I've got no problems with the recommendation of the group being these two exceptions you've got, collapse them into one, and take them out of exceptions, and put them into a permissive section around fees that can be charged. And we can make that recommendation. Whether or not ONC can take it on is another matter, but that's for them to – It's our recommendation, and that can be our recommendation.

Arien Malec - Change Healthcare - Member

Yup. I'll take a crack at it.

Andrew Truscott - Accenture - Co-Chair
Okay, and on the Workgroup Two exceptions workbook, it will be the last box down at the bottom.

Arien Malec - Change Healthcare - Member
Okay.

Andrew Truscott - Accenture - Co-Chair
I think I have a chat with **[inaudible] [01:54:56]** over the last few days around where specifically we see the word royalty used, and I had a quick look at a bunch of contracts as well. We don't us it. We use the word charge.

Arien Malec - Change Healthcare - Member
That's a very different context.

Andrew Truscott - Accenture - Co-Chair
Yup. If it's a charge for the use of intellectual property, or a charge for a license to a component, or a charge for a particular service, we just use charge. The exception is if we've used the term – well, we won't use the term royalty, is where there's some kind of proportional payment that's due based upon revenues accrued. Is that helpful for you as you go through this?

Arien Malec - Change Healthcare - Member
Do you have comments in the document?

Andrew Truscott - Accenture - Co-Chair
Yeah, there are comments in the document.

Arien Malec - Change Healthcare - Member
Okay. Okay.

Andrew Truscott – Accenture – Co-Chair
Well, I was actually going to suggest that I'm happy to have a bit of a mini work session just for all of us to go through this if you feel that's appropriate as well.

Arien Malec - Change Healthcare - Member
Let me propose something, and then you guys can figure it out. It's honestly it's usually the easiest way to get this up is just for me to write something really terrible, and then throw it out to the group and have it nitpicked to death, and then we get something better.

Andrew Truscott - Accenture - Co-Chair
I'll take that as an appropriate knock back. That's fine. No problem at all. Okay. We're at the bottom of the hour. Have we got any calls coming through on the public line? I will take that as a no. Operator?

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Operator, were there any comments in the queue?

Operator
There are no comments in the queue at this time.

Andrew Truscott - Accenture - Co-Chair
Okay. So, then we can probably close down.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
All right. Thank you guys for another good call.

Male Speaker:
Thanks.

Arien Malec - Change Healthcare - Member
All right. Thanks, everyone.

Andrew Truscott - Accenture - Co-Chair
Goodbye guys. Have a good day. Take care. Goodbye.

[End of Audio]

Duration: 118 Minutes