Information Blocking (IB) Workgroup 2

Transcript
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Virtual Meeting

SPEAKERS

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

Operator
Thank you. All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good afternoon, everyone. Welcome to Work Group 2 of the Information Blocking Task Force. As a reminder, this group is looking at exceptions as it relates to information blocking. We'll do a quick roll call and then, we'll jump right into it. Andy Truscott?

Andy Truscott – Accenture – Co-Chair
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
I believe we have Michael Adcock on Adobe. We'll see if we can get him on the phone. Valerie Grey, I don't see yet. Anil Jain?

Anil Jane – IBM Watson Health - Member
I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Great. Arien Malec? And Steven Lane?

Steven Lane – Sutter Health - Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Awesome. All right. I'm going to turn it over to you, Andy, until we can get Michael on the phone to kick us off.

Andy Truscott – Accenture – Co-Chair
Thanks so much. Hi, everybody. Welcome back. Thanks ever so much. I'm thinking of running a sweepstake to try to ascertain if anyone could identify the music that's on hold when we start off these calls. I think I've got it this time. I'm not quite sure. Okay. So, we've got a number of discrete topics to go through today. The first one –

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Andy, sorry to interrupt. I think we're getting a little bit of echo.

Andy Truscott – Accenture – Co-Chair

Okay. One second. Yeah, we are. Okay. How is that? Is that better?

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

Much better, thank you.

Andy Truscott – Accenture – Co-Chair

I had the speaker on the laptop, but I had my headphones on with the call. And I couldn't actually tell that the speaker was on the laptop. Anyway, okay, we're into promoting the security of EHI. And let's go from the beginning. Anil, did you have any comments that you made in this? I'm scrolling to it.

Anil Jane – IBM Watson Health - Member

I think just some general comments. Nothing above and beyond what we touched very briefly the other day when we moved from privacy. But no, nothing specific.

Andy Truscott – Accenture – Co-Chair

Okay. In general, I think we've probably agreed with it fundamentally as it's drafted. Is that fair?

Steven Lane – Sutter Health - Member

Yeah, that's how I feel. I didn't see any real challenges with it.

Andy Truscott – Accenture – Co-Chair

Okay. Well, this will be one of the quickest sections on record that we've actually got.

Steven Lane – Sutter Health - Member

I guess, one question that I did have, when I was reading it under A, the practice must be directly related to confidentiality, integrity, and availability. Confidentiality, in my lexicon, tends to map more to privacy than security. And we have a whole other section on privacy. I don't mind seeing it here. But it just struck me when I got there as to why is that under 3 as opposed to under 2. But, again, it doesn't bother me.

Anil Jane – IBM Watson Health - Member

This is Anil. I think, perhaps, it's because security may have more to do with the unintentional release of the information. That could break confidentiality as opposed to a practice that might cause issues with privacy.

Steven Lane – Sutter Health - Member

That makes sense.

Andy Truscott – Accenture – Co-Chair

Just so you guys are aware, in a previous life **[inaudible] [00:03:32]** security business. And, in general, we tended to use the term privacy where it was more patient and initiation drove

and confidentiality when it was more from the provider and technology side of things. But I'm happy as it is. Steven, you've raised it. So, I feel good. We've done a bad thing if we just skip over this one. So, do you want us to do something with it or not?

Steven Lane – Sutter Health - Member

No. Again, I'm comfortable with it. It just struck me. It was like the only thing that struck me about this so I'm happy with the outcome of our conversation. And also, aren't you supposed to say privacy instead of privacy?

Andy Truscott – Accenture – Co-Chair

I'm translating for you guys.

Steven Lane – Sutter Health - Member

Oh, we appreciate it.

Michael Adcock – Individual – Co-Chair

Don't worry. He'll use some British words in just a few moments.

Andy Truscott – Accenture – Co-Chair

Thank you, Mr. Adcock, for joining. You can take over now. And second, I am quite enjoying the fact that the captioning has said, "Also, are you supposed to say privacy instead of privacy?" Okay. Mike, you can lead on then. Hang on a second, guys. Arien is just joining. Before we move on from this one, shall we just let Arien join?

Anil Jane – IBM Watson Health - Member

Sure. Just one quick comment. I think whatever we said for privacy around documenting the reasons. If you look at the sections, they're very similar. We should have the same consistency around 203 in terms of documenting. If there is going to be a practice that doesn't have a security policy, the same kind of documentation that we required in privacy exception should be under this one as well. It should be consistent, basically.

Andy Truscott – Accenture – Co-Chair

Okay.

Anil Jane – IBM Watson Health - Member

Yeah. If I, as a provider, decide I don't want to share or make the information available to a third party because of security concerns, I need to somehow disclose that and document that the same way that if I decide not to share for privacy reasons that I would do that, too. It's under E in this particular exception.

Andy Truscott – Accenture – Co-Chair

Yeah. Actually, something does come to mind a little bit on this is it's quite a softened word for the exception because B says the practice must pertain to the specific security risk being addressed.

Anil Jane – IBM Watson Health - Member

Okay.

Andy Truscott – Accenture – Co-Chair

It doesn't really say what security risks are acceptable and what isn't, does it? Or what could be called a security risk and what couldn't?

Anil Jane – IBM Watson Health - Member

Yeah. I think that's kind of what I was getting too down below in my initial comments. This is Anil, again, around how does one decide whether the security policies are going to require some level of an audit and some way of knowing that they passed an audit, some sort of certification like an SOC2? Or is it enough to know that that particular app doesn't use dual authentication or whatever the requirement may be spelled out and, therefore, I decide not to share? So, I think it's soft, you're right. But if this is going to require some level playing field where it's consistent then, it should be spelled out what are the minimum requirements that someone would need to have. And I think it's obvious if you will.

Steven Lane – Sutter Health - Member

See, I was reassured by D3 where it says align with one or more applicable consensus-based standards or best practice guidance. That seems to me someone has to be able to come up with, and maybe this warrants being flushed out more, but the defender of the practice needs to be able to point to a consensus-based standard or best practice guidance that supports their behavior. I'll let you use Point E.

Anil Jane – IBM Watson Health - Member

Yeah. The issue of practice though is we've seen this with VA, for example, in the past is that VA implements consensus-based standards that are FISMA or aligned with FISMA, aligned with DOD SRG requirements, aligned with FED RAM. And the net of aligning to those consensus-based standards is that there's actually not a whole lot of sharing that goes on.

Andy Truscott – Accenture – Co-Chair

It's going to come down to who is the group, whose consensus is defining our standard.

Anil Jane – IBM Watson Health - Member

Right.

Andy Truscott – Accenture – Co-Chair

I think it's in the interest of the group not to share. The standard is probably going to be not to share. As I poke and probe on this a little bit more, it comes down to the nature of trust because I could under this appear perfectly legitimate because I am unaware of the security policies which are prevalent in the organization requesting the information. I'm not going to share because I don't know whether they're going to appropriately protect it when they bring it to their organization.

Arien Malec – Change Healthcare – Co-Chair

Yeah. This is also historically a really good point is that trying to drive security posture to the highest common denominator does have the effect of inhibiting sharing and practice. This is a tough issue because this is one of those areas where technology is not a good substitute for aligning policy or for driving clarity on risk. So, if I send information to you, you've got a legitimate reason for that information. It's a permissible purpose. There needs to be some boundary transition where it's no longer my problem, it's your problem. And I think the failure to define that boundary and define risk and define who ultimately bears penalty contributes to some of this issue.

Anil Jane – IBM Watson Health - Member

Perhaps we could just add some comments about if the actor has minimum compliance with the security as spelled out in this rule plus HIPAA that would not be a good enough reason to prevent someone from having that information. Just because my organization's security policy may have higher standards that should not be an easy out for sharing as you guys put it. I don't see those words in here. We talk about security in this proposed rule. We have it in HIPAA. Why not say that if it meets those requirements that can't be an out.

Andy Truscott – Accenture – Co-Chair

But it does meet those requirements. It says something like legitimacy check that if the organization requesting the information is a, we need to wordsmith it, a registered act so within the meanings of these rules then, you're an unawareness of their security disposition is no reason to deny the sharing of information. We need to do wordsmithing.

Arien Malec – Change Healthcare – Co-Chair

I recently requested a letter or statement of coverage, in this case, statement of withdrawn coverage or terminated coverage, and was told that despite my preference to receive it by email, I could only receive via means X, Y, and Z because of the organization's stated security policies. So, we also need to ensure that security policies can't override HIPAA access.

Andy Truscott – Accenture – Co-Chair

So, how do you capture that?

Arien Malec – Change Healthcare – Co-Chair

Well, I think there needs to be an exception for HIPAA access where the patient has explicitly made a request for information in the form and format that's readily producible through a means that the patient is accepted may have lower security requirements than the actor stated security policy.

Andy Truscott – Accenture – Co-Chair

I'm going to take a militant line in this test case with you. Is what you're saying potentially that where the requester is the data subject, there is no exception for security purposes to not share the information with them?

Arien Malec – Change Healthcare – Co-Chair
Yeah. That's a little strong.

Andy Truscott – Accenture – Co-Chair
Well, soften me up.

Arien Malec – Change Healthcare – Co-Chair
No, the reason it's a little strong is that there are cases that are legitimate to deny access. Cases where you have reasonable suspicion that the person is not the person who he or she claims to be. But outside of those basic identity restrictions, the patient under patient access has the right to the form and format that's readily producible. And if that's via unsecured email, it's via unsecured email.

Andy Truscott – Accenture – Co-Chair
And to the example that yeah, it's basically mask of an aide. Well, that means I wouldn't be the data subject, therefore, that's a legitimate reason for denying it.

Arien Malec – Change Healthcare – Co-Chair
Yes.

Andy Truscott – Accenture – Co-Chair
And to think we were going to move on from this one. Do you want to capture that? I must admit, I thought I heard typing and I thought someone is typing away and I looked back at my screen. Is someone typing this up?

Arien Malec – Change Healthcare – Co-Chair
Yeah. That was me, sorry. I was just putting Anil's documentation concern.

Andy Truscott – Accenture – Co-Chair
Okay. We need to capture that one that we've just been discussing. Does that make sense, guys? It's kind of what we were talking about.

Arien Malec – Change Healthcare – Co-Chair
Wait, is this still the same point? Is it still too strong? Security is no reason to prevent sharing?

Andy Truscott – Accenture – Co-Chair
Yeah. Where the requester is the subject.

Steven Lane – Sutter Health - Member
If the patient is asking for access to their own data, don't say, "Oh, no, I can't give it to you because of security reasons."

Andy Truscott – Accenture – Co-Chair
Yeah.

Anil Jane – IBM Watson Health - Member
So, we're saying if a patient says send this to me via clear email, unsecure email, the patient –

Arien Malec – Change Healthcare – Co-Chair
That's their choice, yeah.

Anil Jane – IBM Watson Health - Member
Right. And is the provider then indemnified from any consequences of that?

Arien Malec – Change Healthcare – Co-Chair
Yes. It's actually established under OCR guidance. The provider may tell the patient this is insecure and make sure that the patient understands that. But it's the patient's choice for access.

Anil Jane – IBM Watson Health - Member
And so, the doc just documents that this is what the patient asked for. So, when there's any kind of audit, they're covered, right?

Arien Malec – Change Healthcare – Co-Chair
Yeah.

Anil Jane – IBM Watson Health - Member
Okay.

Andy Truscott – Accenture – Co-Chair
So, quite militant. Arien, are you happy with that?

Arien Malec – Change Healthcare – Co-Chair
Yes.

Andy Truscott – Accenture – Co-Chair
You've been thinking about those.

Arien Malec – Change Healthcare – Co-Chair
Yeah.

Andy Truscott – Accenture – Co-Chair
Okay.

Arien Malec – Change Healthcare – Co-Chair

And I had that same consideration for the documented privacy compliance. It's a little easier because, basically, for the privacy work, there should be very clear reasons to not share. And they should be very rare. This is one where I suspect that there are more reasons to not share that are "security".

Anil Jane – IBM Watson Health - Member

Right.

Andy Truscott – Accenture – Co-Chair

I don't think that it's our ambition to try and enumerate all of those here. I think what we've discussed here both in terms of aligning with policy exception and documentation but also the ignorance point and the patient request point, I think those seem to be two fairly broad exceptions, which could be utilized. And I think plugging them makes sense. Does the group agree?

Arien Malec – Change Healthcare – Co-Chair

Yeah.

Andy Truscott – Accenture – Co-Chair

Okay. Mike, lead us on. Is Mike Adcock on or not?

Arien Malec – Change Healthcare – Co-Chair

Are we at infeasible?

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

Did you say, Mike or Mark?

Andy Truscott – Accenture – Co-Chair

Mike Adcock. I can't see because I've not got presenter's view on Adobe.

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

Yeah. He says he's on the call.

Andy Truscott – Accenture – Co-Chair

Oh, there you are. I've now been given it. It says he's there. Mike, are you on the line?

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

Katie, can you tell if he's muted by chance or not on the VIP line?

Andy Truscott – Accenture – Co-Chair
I bet you can't talk, Mike.

Arien Malec – Change Healthcare – Co-Chair
His phone isn't working, he says. But I think we're down to infeasibility exception 171 205. I think that was next on the agenda. So, that's on the screen right now.

Andy Truscott – Accenture – Co-Chair
Okay. Infeasibility. The door is open. Anil, do you want to start or Steven? You had something to say about it.

Anil Jane – IBM Watson Health - Member
This is Anil. I'll give it a shot. I think there's a lot of vagueness to some of the languages in here. Substantial burden, what does that mean? And I think you can go from the spectrum of small practices that don't have the resources to respond as could this be infeasible for them to respond to a single one if they don't have the resources and staff. Or to bigger practices if there's a risk of a request for a community affiliate practice that's requesting bulk for lots and lots of patients. I just think this is a little bit of vague language in here that I think perhaps could be quantifiable to quantify it better.

Arien Malec – Change Healthcare – Co-Chair
Just to be clear, I don't think I have the staff is at all a reason to qualify for infeasible.

Anil Jane – IBM Watson Health - Member
It says resources somewhere in here. Maybe I'm mixing up stuff.

Andy Truscott – Accenture – Co-Chair
Well, when I read this, this one uses the word burden quite a lot. And burden seems to be something that's more to do with cost, which was addressed earlier. I thought this one was supposed to be around it's impossible.

Arien Malec – Change Healthcare – Co-Chair
It's impossible, correct.

Andy Truscott – Accenture – Co-Chair
Yeah.

Arien Malec – Change Healthcare – Co-Chair xyz
If you ask me for records on **[inaudible] [00:22:18]** form, that's not a reasonable request.

Andy Truscott – Accenture – Co-Chair
Yeah. But if you ask me for my records, but you don't have my records. That's infeasible.

Anil Jane – IBM Watson Health - Member

As we go through it, it might make me think differently. But I thought when I read it that not having the resources to be responsive was a reason. And once they had the resources, they could then do it, from a compliance point of view.

Steven Lane – Sutter Health - Member

Well, it does say the cost, the cost to the actor. So, that could be interpreted as resources.

Andy Truscott – Accenture – Co-Chair

Yeah. It says you've got to demonstrate, taking all of this into account, it's not possible for you to deliver.

Steven Lane – Sutter Health - Member

Yeah. And there, again, and in A1(3), the financial, technical, and other resources available to the actor. We want to make sure that we're supporting new entrants and folks who may not have all of the resources in the world. What made me feel a lot better was at the end under D where they say if you can't do what they asked you to do, you must work with the requester in a timely manner to identify provider reasonable alternative. So, somebody says you've got to send it to me in Fyre, and you see I haven't developed it in Fyre, I'm sorry. It's like I can't do that but I can get it to you in X, Y, and Z. Or you've got to send it to me in GCA, and I only developed it in Fyre. That's probably more realistic.

Andy Truscott – Accenture – Co-Chair

The way this is drafted, it seems to be saying if somebody else has got the same data about you, I can direct you to them. That's in it. And I thought okay. So, if I as a patient go and ask Memorial Herman in Houston or go and ask the Greater Houston Health Exchange for information about myself for the last two years of my treatment, for example, and Memorial Herman says you can get it from the Health Information Exchange, I don't need to give it to you, that doesn't strike me as infeasible. That strikes me as passing the buck.

Anil Jane – IBM Watson Health - Member

I agree with that.

Steven Lane – Sutter Health - Member

Well, it is passing the buck. But the point here is to make sure that the requester gets what they want. And I think, again, this is now under A1(7). If someone is going to charge you with information blocking because you don't give the requester what they want, but you can prove that they could get the same data from another source, and you're happy to help them do that in a timely manner, the accused should not be considered to be information blocking because they're focusing on the true goal, which is getting the requester what they want.

Arien Malec – Change Healthcare – Co-Chair

I would interpret that as if I requested in Kenaya form, and I don't have the ability to produce it in Kenaya form, but I can point them over here who actually does have a consolidated CDA and a Kenaya form translator. That's a reasonable alternative. But if they ask for it from me

for the data in Fyre, and I can produce Fyre but I don't want to because somebody over there can readily produce Fyre also, that's not a reasonable basis for refusing the request.

Andy Truscott – Accenture – Co-Chair

It sounds like there's almost another exception around where there is a better route to get access to the same data. So, as long as **[inaudible] [00:26:32]** and say, actually, I can give it to you, but I'm just not in the right place to get it to you, you should go over there. And that's not infeasibility, it's just doing what's most appropriate.

Anil Jane – IBM Watson Health - Member

This is Anil. I'm still having a little bit of trouble with that one. If someone came to my clinic let's say and said, "I want my information," but I know that I exchange with a local HIE and say go over there and get your data from them. But I'm the original place where the data was generated. I'm their place of care.

Andy Truscott – Accenture – Co-Chair

The system of record, yeah.

Anil Jane – IBM Watson Health - Member

I don't think it's appropriate. Yeah. I don't think it's appropriate for me to tell that patient to go elsewhere. If I'm using certified technology, and I'm managing patients then, I should be able to provide this person with that. They can choose to go wherever they want. But I should be able to give them what's in my system because it may not be identical to whatever downstream systems they may end up going to. I like the comment made earlier where I think what they're saying here is simply that I might give them an equally substitutable way of representing the data if their original request was something a little different.

But as you guys put it, I don't think this is a good way to have an exception to this to allow another person to be able to give that data because there's no assurance that it's the same data that the patient was looking for.

Andy Truscott – Accenture – Co-Chair

So, it seems to be sketching around about that it came back to the title of this one. It should be around something that is truly impossible to do as opposed to difficult, it requires doing something a bit differently, or I think there's a better place to get it. That's not impossible.

Arien Malec – Change Healthcare – Co-Chair

Putting my entrepreneur for a moment, a small startup, three or four people maybe, they're working on some stuff. And someone says, "I need a copy of this." If they can, in the time that they're under-resourced, if they can show that it's not an intentional data blocking, it's just they don't have the ability yet to be able to respond to all of the queries that may come their way, I'd like to think that's what they were thinking when they put it here. Otherwise, they would have said impossible, not infeasible.

Andy Truscott – Accenture – Co-Chair

If you look at B, you have the actor must timely respond to all requests. There isn't well, I can respond to the ones I can get to and then, say it's infeasible to the others.

Arien Malec – Change Healthcare – Co-Chair

No, just to be really clear, I do interpret the intent of information blocking is that the small start up must respond to all requests for permissible use. And this exception would only be triggered in the case where, and I keep going back to Kenaya form, but this exception would only be triggered in cases where the request is for a form and format that I cannot produce or for a means of transmittal that I cannot adhere to. And then, I have an obligation to provide a substitute way of meeting that same request. So, let's tie this back to maybe a more real-world example of I'm CPMC. And I want to provide an API for providing access into data in my EHR for purposes of clinical quality measurement and risk measurement.

And my EHR vendor says, "No, that's not feasible because the data aren't structured that way," and that's the end of the story, I think what this is saying is that's information blocking. If the EHR vendor says let me give you a different way of doing it that accomplishes the same end then, that really is responsive to the request. So, it's really about alternative ways for the same actor to respond to the need for the request. Again, that's my interpretation here. It would be useful, if Mike is on or if we have other ONC staff representation, to maybe help us interpret through the means of the commentary or otherwise whether we're sniffing around the right thing.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. This is Mark. I think the conversation you guys are having is pretty spot on. Like you talked about, we didn't make it an impossibility exception. It is infeasible. So, really, we'd be looking at whether the actor is unable to comply with the request to provide or facilitate access, exchange, or use or whether the actor could only comply with a request by incurring costs or other burdens that are clearly unreasonable. So, it wouldn't have to be impossible, but it would have to be difficult. And you guys are honing in on a really key part of the exception, which is the provision of a reasonable alternative. So, what we are getting at is that we understand that based on your resources or your staff or all of these different capabilities, all of these things, and we talk about that in preamble, it might be very difficult for a small startup or others to provide the same information in the same manner as a bigger company.

So, we're just saying that if you show that it's really a huge burden on you to provide the information, you'd have to provide a reasonable alternative of providing the same access exchange or use to the electronic health information. And we have a discussion of what factors we would consider for substantial burden, which I think might be helpful to take a look at in preamble.

Arien Malec – Change Healthcare – Co-Chair

Just to be super clear, if I'm a small practice, single doc practice, skeleton staff, and a payer comes to me and says I'm doing risk adjustment and I need all of your data, under what conditions in the rule as currently constituted would it be permissible for me to say I can't do that? Or are there none where it would be feasible or permissible for me to say I just can't do

that where, basically, there's no reasonable alternative because any cost that I bear is over my ability to operate as a practice?

Mark Knee – Office of the National Coordinator – Staff Lead

So, you're asking in that hypothetical what evidence you would have to provide to meet the exception? Sorry, I'm not sure if I follow this.

Arien Malec – Change Healthcare – Co-Chair

Yeah. So, one of these issues that were posed earlier. I'm a single doc practice. I've got one MA and one front office staff person, and a payer comes to me and says, "I'm doing HEDIS and risk adjustment for your patients. Here's the list of patients that are covered based on the claims data. And I need any and all clinical data associated with these patients in order to do risk adjustment and HITUS measurement." So, both of those are payment based permissible purposes under HIPAA. I've got an obligation as a provider to return that data, but I just don't have the staff to do it. Do I have an obligation to present a reasonable alternative? Or can I just stand back and say, "Sorry, I just don't have the staff to do it?"

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. Under D, the actor must work with the requester in a timely manner to identify and provide a reasonable alternative. So, that's the whole point, I forget who was saying it, is that we understand that there are circumstances beyond your control that might limit your ability to provide access for exchange or use. But if that's the case, and you provide a good reason, you'd have to give your best effort to help the requester get that information in an alternative way.

Arien Malec – Change Healthcare – Co-Chair

Okay. So, there is an absolute obligation to provide a reasonable alternative. Failure to provide a reasonable alternative in itself constitutes or could be considered to be constituted information blocking.

Steven Lane – Sutter Health - Member

And it will cost you $1 million.

Arien Malec – Change Healthcare – Co-Chair

Only if you're a health IT vendor or HIN or HIE. If you're a provider, it's something we don't know yet. It could be larger because there could be false claims if you're an HIT provider who has got a certified application, certified technology.

Andy Truscott – Accenture – Co-Chair

So, it seems like we need to somehow clarify the feasibility test, which has to be quite strong about something, which is truly unfeasible as opposed to inconvenient.

Steven Lane – Sutter Health - Member

How do you propose we tackle that?

Andy Truscott – Accenture – Co-Chair

Well, I just come up with the ideas. I'm just the monkey, not the organ grinder. I'd love to see that being captioned.

Anil Jane – IBM Watson Health - Member

This is Anil. I'm going to read the preamble one more time just to make sure that I can – are you hearing music? Okay. I'm going to read the preamble one more time before I make a final assessment on this one. But I think with Provision D, with Point D, around a reasonable alternative, I think it's going to be very interesting to see in real life why people would use this exception if they also have to identify a reasonable alternative and document why it was a hardship for them. So, this may be a narrow set of use cases where people would use this exception. I've just got to think about it a little bit more in terms of the context of the examples I was thinking of. This is helpful in getting that clarified for me.

Steven Lane – Sutter Health - Member

So, a couple of other things jump out here. One is the repeated use of the word timely and a question of whether or not that requires any definition. Clearly, there are other places in the proposed rule where things are stated very specifically within 10 working days. That's what it's saying. I don't know whether that would be helpful here or not. I don't know where you came up with 10 working days, but it seems timely for a lot of things. But when we get down to the whole purpose of access, clearly, if you're talking about a clinical situation, someone is in the ICU, 10 working days doesn't do much good where in other situations it might be quite reasonable.

Andy Truscott – Accenture – Co-Chair

It's curious that we use timely so much here given that we are subject to timelines in other –

Mark Knee – Office of the National Coordinator – Staff Lead

Sorry. All I was going to say was I think that's a good point. And just as background, we try to be as clear as possible with timing as much as we could. I guess there were situations when, based on the variation in the types of use cases, perhaps it seemed to us that saying timely was a better approach than maybe narrowing it to a certain amount of days. But based on your experiences, we're very open to suggestions about how to be clearer.

Arien Malec – Change Healthcare – Co-Chair

Yeah. It occurs to me this is similar to HIPAA patient access where patient access does provide an outside window. But then, the actor should have an obligation. This is honored more in the breach than in the rule. They should have an obligation to respond in as quick a timeframe as is possible or is reasonable given the nature of the request. So, if somebody requests information electronically that's readily producible then, I don't feel like pushing the button is not a feasible response. But if the information is available on an offsite DR backup or records retention, and I've got to go pull it and photocopy the data and provide it electronically then, that would argue for a different timeframe.

So, maybe there should be some language here in terms of timely assumes or provides an obligation on the requestee to produce the data as fast is as reasonably possible, business reasonable. You'll often see this in contractual terms in terms of business reasonable, commercially feasible.

Andy Truscott – Accenture – Co-Chair

How are we going to police or how is ONC or OIG going to police reasonable timeliness?

Mark Knee – Office of the National Coordinator – Staff Lead

Is that a question for me?

Andy Truscott – Accenture – Co-Chair

Yeah, if you've got an answer, go ahead.

Mark Knee – Office of the National Coordinator – Staff Lead

I don't know if I have one that will do. But I will say first, as a disclaimer, I can't speak for OIG's enforcement. I think much of the enforcement is going to be based on a reasonableness standard looking at the specific facts and circumstances of the case. As you all know, health IT situations can vary quite a bit. So, it would be really looking at the specific facts and circumstances on a case by case basis and seeing what's reasonable and what's not.

Arien Malec – Change Healthcare – Co-Chair

Yeah. With regard to HIPAA enforcement, what tends to happen is much more of letters requesting corrective action than legal enforcement in that legal enforcement a penalty is typically sought for egregious and repeated behavior.

Andy Truscott – Accenture – Co-Chair

Also, I'm not so concerned about the **[audio glitch]**. If we have a term which has a different meaning depending on who the actor is like timely, whether it's a big, large, hairy company like an Accenture or Change versus a small startup then, the definition of timely could be different. Who is going to arbitrate and assess whether that timeliness is the right interpretation or not? It seems like we might be creating inadvertently by trying not to be too descriptive a burden for the administration of the rule.

Mark Knee – Office of the National Coordinator – Staff Lead

And to that point, we welcome if you all can narrow it or put an appropriate time or different terminology. We definitely welcome those suggestions.

Steven Lane – Sutter Health - Member

Again, I think the challenge here depends on the purpose. As I said, if you've got a patient who is in front of you, and you need data right away, timely has a very different meaning than if you're a payer, and you're contracting for 100,000 lives, and you want to make a request to feed your database. Does it make sense?

Mark Knee – Office of the National Coordinator – Staff Lead

And just for clarity, if you go to Page 466 of the preamble, we say we clarify that the duty to timely respond and provide reasonable cooperation would necessarily be assessed from the standpoint of whether it's objectively reasonable for an individual or entity in the actor's position. And we provide some examples. So, that's where we're coming from.

Steven Lane – Sutter Health - Member

Got it. I see that now.

Arien Malec – Change Healthcare – Co-Chair

I'm sorry, what subsection is that?

Steven Lane – Sutter Health - Member

Page 466, the preamble.

Arien Malec – Change Healthcare – Co-Chair

Oh, in the preamble.

Mark Knee – Office of the National Coordinator – Staff Lead

Yes, it's our good friend, preamble.

Arien Malec – Change Healthcare – Co-Chair

Is that language that's appropriate to put into the regulatory text? I know you can't answer that.

Steven Lane – Sutter Health - Member

It's interesting. In the preamble, you were sort of focusing on who was the actor, small practice versus a big hospital. I guess I'm coming at it more from the perspective of what is the need. Again, when a patient's life depends on access to data, you'd want a small practice to even go out of their way to make that available.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. And Arien, to your point, this conversation came up in an earlier workgroup today. The whole preamble and reg text situation, how to decide what to put in what. And, basically, what I was saying was that if you read the regulatory text and you feel like it's not clear and there's something in the preamble that can be added that would make it clearer, you might want to add it. But if what's in the preamble is serving as good to understand the reg text then, it's appropriate there.

Andy Truscott – Accenture – Co-Chair

[Audio glitch] just looking at the regulatory text and looking at the preamble part, if you've got a moment.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah, do you want me to pull over the preamble?

Andy Truscott – Accenture – Co-Chair

Well, no. Just trust me when I read it out to you. About halfway down 466 at the end of that paragraph, it says the actor's failure to meet any of these conditions would disqualify the actor from the exception and could also be evidence that the actor knew it was engaged in a practice of **[inaudible] [00:46:27]** the information blocking. So, the bit that's key here is the actor's failure to meet any of these conditions would disqualify the actor from the exception. If I look at the actual exception, one says on the actor that is unreasonable under the circumstances taking into consideration. And that seems to be a slight difference in tenor. Whereas the preamble is you've got to do all of these things. And the regulatory text is saying you've got to look at these things and some of them aren't really important.

And that seems to be a difference in tone certainly. Is that intentional or inadvertent?

Mark Knee – Office of the National Coordinator – Staff Lead

I guess I don't totally agree or maybe I'm not understanding. With every one of the exceptions, we say that the actor must meet all relevant conditions at all relevant times. So, when I'm looking at the regulatory text, the first condition is that the actor must demonstrate that the request is infeasible. And then, we go through the different factors and then, the burden and all of that. And then, we go through the other conditions, which are responding to the request, the written explanation, and the provision of a reasonable alternative. So, in my mind, those are the conditions. And if you don't meet any of those conditions, you would not qualify for the exception.

Andy Truscott – Accenture – Co-Chair

But the reg text was saying if you don't meet all of them.

Mark Knee – Office of the National Coordinator – Staff Lead

Right.

Arien Malec – Change Healthcare – Co-Chair

That's the interpretation. And we might have some meta-commentary that says in cases where all of the conditions must be met. It probably should say to qualify for this exception, each practice by an actor must meet all of the following conditions at all times. And that's, in this case, A through D.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. It sounds like we're on the same page. I think it's just a matter of whether CES is being clear enough about that. So, yes, definitely, if you think that would – I'm not sure if you're suggesting an addition to reg text or preamble, but that seems reasonable.

Arien Malec – Change Healthcare – Co-Chair

Yeah. I would think it would be helpful clarity in these cases where we're talking about exceptions. In some cases, we're talking about all of, and in some cases, we're talking some

of, in some cases, we're talking one of. And I think that language is a useful clarity in the actual reg text. So, I read D as saying the actor must work with the requester to identify and provide a reasonable alternative. So, I interpret that as saying that the, in this case, there's an actor and requester and that if the actor says this is infeasible and refuses to provide a reasonable alternative in a timely manner that that then constitutes information blocking. You can't say there is no reasonable alternative.

Andy Truscott – Accenture – Co-Chair

I like that.

Arien Malec – Change Healthcare – Co-Chair

And then, relative to Steven's point, I think we should put in some guidance around timely that notes that what's reasonable for the timely exception should take into account the nature of the request, the nature, and urgency of the request.

Andy Truscott – Accenture – Co-Chair

That kind of seems to be compounding unclear with unclear. Why don't we say something like it's timely and in no event longer than X words as those? That's where you get into the HIPAA issue where many people take the HIPAA I think it's 45 days as the requirement to be bound to the requirement. I heard Steven say that if it's an emergent case, we expect the actor to, if feasible, to respond emergently.

Steven Lane – Sutter Health - Member

Yes, exactly. I've been in a number of conversations about this recently where people say the same day is really the expectation for clinical. The patient is getting admitted, or the patient is in the ICU, or the patient, etc. We really do seek same-day access.

Mark Knee – Office of the National Coordinator – Staff Lead

And I don't want to shift. I think the timeliness question is a good one. But I did want to make the point that for each exception, I have the language on the screen, we do say in the first line of the reg text, to qualify for this exception, each practice by an actor must meet the following conditions at all relevant times. So, it seems to me to be what you're asking for unless I'm missing something. And there are some that you don't need to meet every one of them. For 202 the privacy exception, we say to qualify for this exception, each practice by an actor must satisfy at least one of the sub exceptions in Paragraphs B through E.

Anil Jane – IBM Watson Health - Member

This is Anil. I think maybe adding the words must meet all of the following conditions at all relevant times might satisfy the discussion here because I think it's just a matter of a few words. But I think the way it's written here is probably okay, too. It sounds like it says that you have to meet the following conditions. And they list out four of those conditions. That's perhaps to sort of make it easier and not open to interpretation. It's just all of the following conditions.

Mark Knee – Office of the National Coordinator – Staff Lead

Okay. That seems fine.

Anil Jane – IBM Watson Health - Member

And going back to the comment about timely and urgency and emergency, my only concern is that I don't know how one is going to determine and convey the urgency or emergent nature of a situation in this scenario where you're trying to create an exception for why the information should be given. I think we would all agree that once a patient gets admitted and in the Emergency Room, they need scans, they need whatever the information is that needs to get there in order to make the best decisions should happen. But how are we going to not overburden the process by now introducing some other concepts? How are we going to transmit the urgency of a situation or the emergent nature of it? I get the intent. It makes sense clinically.

But how do we do it programmatically? And I think it's probably, and I'm not sure I should be saying this, but I think it's probably okay to have a little bit of vagueness around the timing because I don't know whether we know what the unintended consequences might be if we're too firm on specific timing. But I worry a little about how do we actually convey some of those nuances about the clinical status of a patient who might be critical? And how does a system make itself aware of that in order to respond to it? And what are the downstream ramifications for our system? I don't know if that makes sense but it just seems like too many vague issues.

Steven Lane – Sutter Health - Member

I think you make a good point. It's hard to legislate these things, right?

Anil Jane – IBM Watson Health - Member

Right. But I think we have to have –

Steven Lane – Sutter Health - Member

But we need some language that makes it clear that the standard changes with the situation and the mood.

Anil Jane – IBM Watson Health - Member

Yeah. I think one way we could do it, just to prevent some of the bad actors from hiding behind certain things, would be somehow adding the lines of consistency in terms of a reasonable alternative and consistency in terms of timeliness. Therefore, as a potential bad actor, I couldn't say to Steve, "Here's an alternative, but I'll provide it to you in 10 days," and then, tell Arien, "I'll give it to you in 5 days," and tell somebody else I'll take 20 days. So, if I'm going to be timely, I need to be consistent. And I can't choose based on who is asking how I'm going to respond when I have an infeasible –

Steven Lane – Sutter Health - Member

Can't discriminate.

Anil Jane – IBM Watson Health - Member

Can't discriminate, thank you. Because that, I think, eliminates some of the squishiness of the timeliness aspect. There could be a legitimate reason why someone might not be able to respond to any request that seems infeasible for 20 days. But then, that way, they're not able to go back and forth and discriminate.

Arien Malec – Change Healthcare – Co-Chair

Yeah. So, I hear all of that. I'm more focused on the infeasible as an excuse to fall back on some alternative means that don't actually address the clinical need. So, it gets me off the hook from installing the buying the thing from the EHR vendor that allows me to respond in a timely way. It gets me off the hook of, in my previous example, relative to patient matching, if I can just rely on I can't identify the patient, but I have no obligation to invest in patient matching. Those are the areas where I worry about reasonable costs that I can just say are infeasible for me because I can't afford it.

Anil Jane – IBM Watson Health - Member

Yeah. I think those are really good points. If I decide to not implement the technology in the way that I should and, therefore, create something that would have been a one button issue into an infeasible issue, I 100 percent agree with you that somehow that language needs to be – what you just described needs to be spelled out here. Maybe it has to do with the implementation of certified technology to support the request for information cannot somehow be crippled or unimplemented or something to that effect. But wouldn't that be caught by some of the other requirements, the 2015 edition changes where if I'm going to use technology that I have to have that export capability and all of that and the HL7 Fyre APIs? Would that be covered?

Mark Knee – Office of the National Coordinator – Staff Lead

I was just going to make the distinction. The distinction with those like the B10, like the export criteria and that, that's specific to the certification program. So, it only applies to health IT developers. Information blocking is broader.

Anil Jane – IBM Watson Health - Member

Yeah, okay. That's a good point.

Andy Truscott – Accenture – Co-Chair

My only advice is certified health IT.

Arien Malec – Change Healthcare – Co-Chair

And it's the point that is in the preamble that whether something is infeasible should be adjudicated based on whether similarly situated actors or similar sides and similar capabilities have or have not been able to implement the required feature. So, I think if you adjudicate whether data exchange via Kenaya form is reasonable, you'd say nobody produces data exchange via Kenaya form. But if you adjudicate whether Fyre based access is infeasible, and the doc down the street has that same capability, it's going to be really hard for you to make the claim that for you it's infeasible.

Anil Jane – IBM Watson Health - Member

I think that's a really good point.

Arien Malec – Change Healthcare – Co-Chair

So, I think that's similarly situated needs to be in the regulatory text.

Anil Jane – IBM Watson Health - Member

Yeah. It's like what we do in clinical medicine where we practice the standard of care. You want your peers to. I think it's a similar concept here. And in the review process, when someone complains about this, is it, folks who would review the case within ONC and OIG, are they folks that would have that understanding of what the typical person in that scenario would have done? Or are we disconnecting that process? Meaning, what would the practice down the street do? But then, when it comes time for reviewing the complaints, is that being considered? Is it a group of peers that would be evaluating that issue?

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. What I'd say is I think that's the goal is to make sure both OIG – OIG is staffed up with investigators and other folks who have the appropriate background. And also, from our ONC side, we're going to be helping them with our subject matter expertise, including with clinicians and lawyers and everybody to help with the analysis.

Anil Jane – IBM Watson Health - Member

Okay. Thanks.

Andy Truscott – Accenture – Co-Chair

Okay. Any more thoughts on this?

Arien Malec – Change Healthcare – Co-Chair

Are you exhausted now?

Anil Jane – IBM Watson Health - Member

I'm sorry. Did you guys capture Arien's comment about moving some of that language from the preamble into the text so that it helps clarify?

Andy Truscott – Accenture – Co-Chair

No, I haven't. Arien, you commented on these. Are you going to paste these in later when you're able to access the document?

Arien Malec – Change Healthcare – Co-Chair

Yeah, I guess I will.

Andy Truscott – Accenture – Co-Chair

Well, that's probably better than me trying to channel you. That's kind of impossible.

Arien Malec – Change Healthcare – Co-Chair
Yeah.

Michael Adcock – Individual – Co-Chair
More infeasible, but yeah. My phone is working now.

Andy Truscott – Accenture – Co-Chair
Okay. What's the next one we're going to look at? I can't remember the agenda.

Arien Malec – Change Healthcare – Co-Chair
Oh, boy, did we get RAND?

Mark Knee – Office of the National Coordinator – Staff Lead
Yeah, I think we're on to RAND.

Steven Lane – Sutter Health - Member
Just a heads up, I'm going to have to leave at the half hour.

Arien Malec – Change Healthcare – Co-Chair
My general statements apply that I need to actually write down when I can do this from home and can access Google Docs that it is unclear to me. So, first of all, I would advocate for finer discrimination of cases where RAND seeking behavior is likely to be an issue and fine-tune the pricing regulations to those areas of RAND seeking behavior. And I actually think I've got a model for it that I'll probably tweet out later today for the Twitterati comment. But we'll also add it into here. And I am taking Steve Posnack up on the offer to submit a one-line comment to ONC to the effect of this Twitter thread and all linked sub-threads are herein incorporated by reference. But I can't figure out reading the reg text or the commentary when I use the cost recovery mechanism and when I use the RAND interoperability element licensing.

I think it's probably worthwhile starting this exception discussion with the definition of an interoperability element because I think it would be clarifying for the group. And I don't think an interoperability element is what you would think of as an interoperability element. An interoperability element really kind of amounts to any thingamajig that you use for interoperability. So, and there are actually in the reg text some commentary that alludes to cost recovery and interoperability element licensing being able to be both applied at the same time. So, just from the perspective of addressing the RAND seeking behavior, if I can license an interoperability element and I can do cost recovery, it's not clear to me what pricing restrictions actually are in effect. Nor is it clear to me when I can use one versus the other. So, I've just got these basic meta-issues about these two areas.

Andy Truscott – Accenture – Co-Chair
Arien, just a quick question. Is there a difference between an interoperability element and an

essential interoperability element?

Arien Malec – Change Healthcare – Co-Chair

There is and that's probably also something we should get to. But I think we should start with the definition of what is an interoperability element and then, get to the definition of what an essential interoperability element is and then, start to decipher some of this language.

Andy Truscott – Accenture – Co-Chair

Okay. Well, Page 353 in the preamble defined interoperability element, doesn't it?

Arien Malec – Change Healthcare – Co-Chair

I was going with 171 102, Page 683 interoperability element means.

Andy Truscott – Accenture – Co-Chair

Well, that means we're going to have and interesting conversation because I want a paragraph that says in this proposed rule, we use the term interoperability element to refer to.

Mark Knee – Office of the National Coordinator – Staff Lead

Right. So, I think you're looking at preamble and Arien is looking at the reg text.

Andy Truscott – Accenture – Co-Chair

Okay. That's okay then. I'm looking at preamble on 353.

Arien Malec – Change Healthcare – Co-Chair

So, I think the relevant definition and, Mark, correct me if I'm wrong, but I think the relevant definition for interoperability element is on Page 683 under 171 102 where it says interoperability element means dash, that's an endash, I believe. And it's any functional element of health information technology. By the way, we're going to have a whole subconversation on what does compatible technology mean because compatible technology is used three times in the definition of interoperability element but is not itself a defined term. So, Mark, I would love your commentary on compatible technology. But I'm going to start from the bottom. Interoperability Subpart 5, any other means by which electronic health information may be accessed, exchanged, or used.

That's the catchall term. Subpart 1 is any functional element of health information technology where the hardware or software that could be used to access, exchange, or use for any purpose, including information transmitted or maintained **[inaudible] [01:06:57]** of information systems, health information exchanges, or health information networks. So, an interoperability element is a functional element or any other means by which health information can be accessed, exchanged, or used. And then, there are three subparts that deal with compatible technology, two that explicitly address compatible technology, which is 3 and 4 and then, 2. So, 2 is any technical information that describes the functional elements of technology and a person of ordinary skill in the art may require to use the functional elements of the technology, including for the purposes of developing compatible

technologies that incorporate or use the functional elements.

And then, 3 and 4 are technology or service required to enable the use of compatible technology or license, right, or privilege that may require to commercially offer and distribute compatible technologies. So, I interpret 4 as being generally IPR. So, a patent that might need to be licensed. I interpret 2 as technical specifications that may need to be licensed in order to use the technology. So, the classic examples of this are there's a schema of the database that describes the elements of the database that are reasonably required in order to get data out of the database, but the schema itself is IPR that may need to be licensed. When I was reading these definitions, I think I understood maybe what was required by compatible technology.

But I didn't have a clear notion of what was and wasn't compatible technology. So, Mark, I'll try this out and see if you can say whether this does or doesn't capture the intent. I believe when the language on compatible technology was being written, it was really about, for example, an API, an app that implements an API where the app might be the compatible technology. It's compatible with the API or a module or application or submodule that may need to be applied to an EHR or a larger system where the interoperability element is required to make that thing work. But it's a big definition, a big, sprawling definition, I guess, is the punchline to what does Section 406 apply to. It's a kind of big, sprawling class of stuff.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. So, maybe I'll take a stab at kind of explaining where we're coming from broadly about the concept of interoperability element. As you said, since we didn't really define compatible technology, I think I'm somewhat limited in what I can say about that. But definitely, if you think it's a term that should be defined, I think that's a reasonable recommendation. So, broadly speaking, we used interoperability elements in a way to analyze the likelihood of interference under the information blocking provision and as a way in RAND to structure some of the exceptions. There is a catchall in No. 5, which is maybe a clearer way to understand the broad scope of it. Any other means by which electronic health information may be accessed, exchanged, or used.

I missed, as you can see in the other 1 through 4, it would include things like functional elements, technical information, technology, services, licenses, rights, privileges so really broad. I guess, we emphasize that an actor who controls the interoperability element that could be used to access, exchange, or use EHI is at risk of violating the information blocking provision if they refuse to allow others to license or use that element. And you can't get do it based on competition, which is a key concept we have here. As far as your question about how to differentiate between 206 and –

Arien Malec – Change Healthcare – Co-Chair

Yeah, 204 and 206, sorry.

Mark Knee – Office of the National Coordinator – Staff Lead

So, 204 or 206, I think, if I was going to give guidance, I can't really give guidance, but what I would say is it would really depend on the facts and circumstances. The way I see cost

reasonably incurred, we're looking at the methodology used to recover costs. So, is it reasonable? Whereas in the RAND licensing, we're looking at the actual licensing of the product and how you went about doing that. Granted, there is some overlap there. And like I said last time, you only have to meet one of the exceptions to be covered. So, it's not a situation where you would be punished if you met the RAND exception but you were not able to meet the costs recently incurred.

Arien Malec – Change Healthcare – Co-Chair

Which, again, to me just raises, given the breadth of the term interoperability element, what would drive somebody to prefer the cost recovery mechanism to the RAND licensing mechanism. I guess the only reasons to prefer the cost recovery mechanism is with respect to things like non-disclosures or non competes that are forbidden in 206 but permitted by **[inaudible] [01:12:54]** assumption in 204.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. And, again, I can't get into it now. But I think with costs reasonably incurred, we're talking about it could be about the actual interoperability element cost. But it could also be about the data itself versus with the RAND licensing, we're talking about the means for accessing the data essentially.

Arien Malec – Change Healthcare – Co-Chair

I see. Interesting. That's a spin on the cost discussion that I had not considered or contemplated. As many times as I've read these two sections, there is a perspective that one could argue or one could offer, particularly suggested by one who may or may not have looked at and/or written some of this language that would apply cost recovery to data and other fee structures to licensing of interoperability elements. Fascinating.

Mark Knee – Office of the National Coordinator – Staff Lead

And, again, just a disclaimer that it really just comes down to the facts, circumstances, and looking at the conditions in each exception and seeing if it's applicable. That's how I would say it.

Arien Malec – Change Healthcare – Co-Chair

Got it. Andy, where do you want to take us now?

Michael Adcock – Individual – Co-Chair

Is that the end of the discussion around RAND?

Arien Malec – Change Healthcare – Co-Chair

It's not the end of the discussion. It's the end of the preamble to the discussion.

Michael Adcock – Individual – Co-Chair

Can we get back to the other document?

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah, sorry. There we go.

Arien Malec – Change Healthcare – Co-Chair

Sorry, just to cover the ground, I think what we learned from that discussion is A) what an interoperability is or intended to be, and B) maybe some clues about what cost recovery was intended for and what interoperable element licensing might be intended for, which could help inform some of the commentary that we do.

Michael Adcock – Individual – Co-Chair

Right.

Arien Malec – Change Healthcare – Co-Chair

And then, again, I think if I'm reading 206 correctly, an actor must meet the following conditions at all relevant times means all of A, B, C, this is a big one, D and E, which are responding to requests, reasonable and nondiscriminatory. Two pages down, additional requirements and compliance with conditions and certification.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah, that's right. And I'm sure you've looked at these, Arien, but it just kind of made me think again. We do have these fact sheets online that are good cheat sheets on these requirements. Not right now, necessarily, but on our website, healthit.gov under the NPRM. You might find them useful.

Arien Malec – Change Healthcare – Co-Chair

Obviously, I've read this language so many times and I still learn something the more times I read through it. It might be worthwhile, Andy, just to break it down into those sections looking at each of A, B, C, and D.

Andy Truscott – Accenture – Co-Chair

No, I'm comfortable to do that. I'm still lead.

Arien Malec – Change Healthcare – Co-Chair

B is super sprawling. But A is the 10 business days that obligates the actor to respond in a reasonable and nondiscriminatory fashion and offering appropriate licensing. And I interpret the intent here as saying that an actor can't use nonresponding as a way of getting around these requirements. I know for my own purposes that there is an implied compliance requirement that what does a request mean. So, if somebody asks me at a conference what would it cost to do X, and does that start the time clock ticking? Does an email? So, let me give you some real-world examples where somebody sends an email to somebody that they know at the organization that isn't him or herself in sales or marketing. Somebody sends a request in or discusses somebody in a support line, does that start the time clock ticking?

What constitutes a request to license or use in ways that drive compliance? And I have

absolutely seen even an RFP and code to response. I've seen RFP processes where the RFP gets to the RFP team and the business team like a day before the RFP is due because it got someplace else inside of the organization. So, I just raise the question as to what starts the time clock ticking.

Anil Jane – IBM Watson Health - Member

This is Anil. I think the fact that there has to be public information about the programs, there has to be notification to a named individual or group that's spelled out in the public disclosure of how to get access. So, the clock would start when the request is made of the right person.

Arien Malec – Change Healthcare – Co-Chair

Where do you see that? I'm sorry.

Anil Jane – IBM Watson Health - Member

I thought there was some language. Is there something where you have to describe some of your documentation and all of that? Or am I mixing up stuff again?

Arien Malec – Change Healthcare – Co-Chair

You may be mixing up an API restriction with the more broader language.

Anil Jane – IBM Watson Health - Member

Right. So, what I was thinking is this would be very similar documentation. There's no other way to be able to do this. One would have to know that this capability exists in order to reach out to someone that would be able to give them access. And in your question, the clock should start whenever a formal request is made of the right people. The right people would be described and should be described publicly. Otherwise, I don't know how you would do this.

Arien Malec – Change Healthcare – Co-Chair

So, that seems like it should be some commentary is that there's an obligation on the requester to find the correct channel. And there's an obligation on the actor to publish the correct channel.

Anil Jane – IBM Watson Health - Member

Exactly. Otherwise, I don't even know how you would enforce anything like this.

Arien Malec – Change Healthcare – Co-Chair

Well, you would enforce it through a compliance department and somebody would, as I said real world stuff, somebody sends an email to a buddy of his or hers who lives in some other part of the organization. It takes meandering ways to go find the right person. And by the time they find the right person, the clock is over and then, you get sued.

Anil Jane – IBM Watson Health - Member

Yeah, exactly. That's what I'm getting at is without having a formal recognition of who, it becomes a risk.

Arien Malec – Change Healthcare – Co-Chair

Andy, do you want me to drive, do you want to drive in terms of just walking us through this section?

Andy Truscott – Accenture – Co-Chair

Yeah. I must confess, I'm still reading through **[inaudible] [01:21:54]**.

Arien Malec – Change Healthcare – Co-Chair

Okay.

Andy Truscott – Accenture – Co-Chair

Add it. I'm pondering. I'm trying to be more of a participant than a chair.

Arien Malec – Change Healthcare – Co-Chair

So, any more commentary on Subpart A?

Andy Truscott – Accenture – Co-Chair

I think when you say receipt of the request, I think that allows for some vagueness. Receipt by somebody who actually understands it or receipt of request by the organization in the mail room or what?

Arien Malec – Change Healthcare – Co-Chair

Exactly. That was the nature of my commentary as well. And I think that maybe we just formalize. So, I think we want to say that it's a receipt of a request by an appropriate party and that we want to comment that there's an obligation on the licenser to publish appropriate contact information and an obligation on the requester to use appropriately published contact information. So, in my mind, for example, if I put marketing collateral on a web page, and I put contact sales@changehealthcare.com, emails into sales@changehealthcare.com would start the 10-day clock. But emails to Joe in the mailroom would not.

Andy Truscott – Accenture – Co-Chair

Yeah. I'm pondering about this one because, like you, I realize how communications can get lost in the **[inaudible] [01:23:48]** of our mail room organization. It's just a matter of fact. However, to treat all parties equitably, it does feel like this should be 10 days from receipt of the request by the entity itself. And that's it. It's more for real if it gets lost inside your organization or paradigm.

Arien Malec – Change Healthcare – Co-Chair

So, I guess what I'm saying is, Andy, you and I probably live in similar words. You're probably more similar than I am because you deal with government entities. But the notion of

complying with information requests or other activities that may have significant compliance activities associated with them, the more that they're locked down and nailed down, the better off you are. And as I said, I think as the licenser, you have an obligation to have a channel that requests go into.

Andy Truscott – Accenture – Co-Chair

I think so. I think we're actually serving the same piece of **[inaudible] [01:24:58]** at the moment.

Arien Malec – Change Healthcare – Co-Chair

Yeah. And I think we're saying that the requester has an obligation to discover and use the appropriate channel.

Andy Truscott – Accenture – Co-Chair

Absolutely right, yes.

Arien Malec – Change Healthcare – Co-Chair

Yeah.

Andy Truscott – Accenture – Co-Chair

So, I think we can say from receipt of request by the entity.

Arien Malec – Change Healthcare – Co-Chair

And then, respond – Mark, maybe help me here. Respond does not mean quote. Does respond mean request to quote?

Mark Knee – Office of the National Coordinator – Staff Lead

So, respond in this context is two-part. We're defining respond as negotiating with the requester in a RAND fashion and offering an appropriate license. And we do have some commentary in there about how it's not a matter of you have to actually agree to terms because it's possible that you could offer an appropriate license and the requester is being unreasonable. So, it's not that you have to reach an agreement in the 10 days. It's that you have to negotiate, and you have to offer an appropriate license.

Andy Truscott – Accenture – Co-Chair

Okay. That's quite strong.

Anil Jane – IBM Watson Health - Member

This is Anil. I think just getting something like that done in 10 days, even with a boilerplate agreement and offering terms depends a lot on the requester. And if you have a large organization where you have a compliance process, you've got to look back at all of the other business you might do with them, etc. I don't know how you can do even a boilerplate offer in 10 days.

Arien Malec – Change Healthcare – Co-Chair

It also implies that the request is for something that you have on your price sheet that doesn't have complex bundling requirements. So, my perspective would be it is reasonable to enter into a sales negotiation, etc., process. But I could read this language as saying, if I send in an RFP request and you don't respond within 10 days then, you're out of compliance. And most RFP processes are egregiously short but not quite that short.

Mark Knee – Office of the National Coordinator – Staff Lead

And just as background, we did work with other agencies like FTC to try to nail down a reasonable timeframe. But as we talked about with our discussion of timely, ironically, we're taking different positions here that we felt like we needed to identify a time period. Ten days seemed reasonable to us. But, again, we're open to suggestions.

Arien Malec – Change Healthcare – Co-Chair

I would suspect it would take you more than 10 days to list something on contracts.gov.

Andy Truscott – Accenture – Co-Chair

The 10 days seems to be you've entered into dialogue. So, no, we're not being ignored. But sometimes, heck, I don't know what agencies you necessarily talked to but I could send a request to a government agency and could then begin nine months of discussion.

Arien Malec – Change Healthcare – Co-Chair

Yeah.

Andy Truscott – Accenture – Co-Chair

Quite easily.

Anil Jane – IBM Watson Health - Member

I think there are three different activities here. One is an acknowledgment of receipt of the request, and we need to put a timeline for that. And I think I don't have a favorite number but within 72 hours of the request that you've acknowledged that you've seen it. And then, the next activity is actually negotiating to make sure you understand what the client needs. And then, you should be able to start within 10 days like it's written here. But then, actually offering an appropriate license that clock needs to start after negotiations are sort of underway. And maybe there is no specific time. An offer at the cease of negotiations within 30 days, within whatever it might be. But 10 days, I don't even think it's credible for any of the work that I've seen done whether it's with us or with others.

Andy Truscott – Accenture – Co-Chair

I can see situations where 10 days could be completely reasonable where there's an existing contractual relationship. It's **[audio glitch]** to existing services, which are being done. Yeah, it's very, very straight forward and it's just a service request. But if it's a completely new relationship between two unknown entities, the adverse consequences of moving at a pace because of this obligation could be extreme. I get the premise. We don't want people to hold back. I got that. But we need to be thoughtful.

Mark Knee – Office of the National Coordinator – Staff Lead

And just one other consideration just to think about is there could be circumstances where getting access to this interoperability element could mean being able to access really urgent information. So, that's just a consideration.

Anil Jane – IBM Watson Health - Member

Yeah. I think that this is, again, just from a – if there's an urgent patient situation, negotiating a contract in order to get that information so you can deal with an urgent patient situation seems like the wrong way to go. I think you would want to hit the print button and have a family member or have a transmission of that information be sent to the ER or to the hospital. I just don't know whether we could hide behind an urgent or critical patient situation behind this one. I think this is a business practice one. And just doing a security review or a policy review might take a while. And you don't want someone making a request of an organization and that organization now has to put an offer out in 10 days. Maybe we put some sort of contingency around that offer because there are things that have to happen before –

Andy Truscott – Accenture – Co-Chair

Yeah, this is about licensing. This isn't about urgent access and very different concepts.

Anil Jane – IBM Watson Health - Member

Exactly.

Mark Knee – Office of the National Coordinator – Staff Lead

No, I understand that. I was just saying that we're dealing with the licensing. I understand your point. I think it's a good one. And I think it's worth a conversation to talk about what is a reasonable time period. All I was saying that we're talking, still in the broad scope, about licensing of interoperability elements that would allow access to important health records or things such as.

Anil Jane – IBM Watson Health - Member

Therefore, it definitely should be timely. I'm sorry, go ahead.

Arien Malec – Change Healthcare – Co-Chair

I think we've hit this one pretty hard. I would suggest we move on. I don't know who is consolidating notes but I would suggest we move on to the great big monster, which is B.

Andy Truscott – Accenture – Co-Chair

We're trying to avoid moving on to the great big monster that is B at the moment. But yeah, guys, where I think we want to go, I think we're all going to have some homework to do on this **[audio glitch]**. And I'm saying this to all of the work groups. We need to start coming and drafting our recommendations. My proposal is that actually, I think for a lot of the ones that we are discussing, we're actually going to recommend some verbiage changes to the text itself of the regs and potentially some additions or other massaging to the preamble text.

And I'd like us to actually start drafting those in the bottom of these sections. I don't think we're going to have much of a massive narrative. Frankly, I'll leave that to Arien and your Twitter feed to get that in.

But I think this group should actually be saying, okay, the group thinks that the regs should say this and tweak and tune.

Arien Malec – Change Healthcare – Co-Chair

So, what I've heard is a general agreement that it's reasonable. First of all, what I've heard is general agreement that we need to be clear about obligations on both parties, 1) of the licenser to publish a contact inbound, and 2) is on the requester to use the published contact inbound as starting the time clock. For No. 2, I think we've heard general acceptance of reasonableness in terms of quote to engage – sorry request to engage. But, generally, very strong perspective that request to quote is highly context sensitive and depends on the nature of the request, how cut and dry the licensing is, whether there's an existing contract, and getting from request to quote in 10 days is, in many cases, completely outside the realm of reasonable expectation.

Andy Truscott – Accenture – Co-Chair

Yeah, agree with that.

Anil Jane – IBM Watson Health - Member

Agreed.

Michael Adcock – Individual – Co-Chair

Agreed.

Arien Malec – Change Healthcare – Co-Chair

Easy. That was six lines out of five pages, four pages.

Andy Truscott – Accenture – Co-Chair

We are being very diligent. I think that's a good thing actually. Okay. Reasonable and nondiscriminatory terms.

Arien Malec – Change Healthcare – Co-Chair

Right. So, this is one where there are one, two, three, four subparts, five subparts.

Andy Truscott – Accenture – Co-Chair

And they're all ands, aren't they? There are no ors. I can't even see the word. I think they are.

Arien Malec – Change Healthcare – Co-Chair

Yeah.

Andy Truscott – Accenture – Co-Chair

That's my inner **[inaudible] [01:35:30]** that I'm going there.

Arien Malec – Change Healthcare – Co-Chair

Right. So, the first one basically amounts to, and there are little subparts of it, but the first one amounts to the license is a license is a license. And there's some detail about what that means. And 2) is that it's reasonable and nondiscriminatory – or reasonable. And there's a whole bunch of tests for reasonableness. And 3) is that it's nondiscriminatory. And there are a whole bunch of tests for nondiscriminatory. 4) Addresses restrictions on the ability to add on collateral terms, in particular noncompetes, exclusives, or sneaky ways of getting around the licensing requirements. 5) Are restrictions on nondisclosures.

Andy Truscott – Accenture – Co-Chair

I'm not forewarned with the double negative – actually, the triple negative because we're inside of an exemption.

Arien Malec – Change Healthcare – Co-Chair

Yeah. It's an exception –

Andy Truscott – Accenture – Co-Chair

That does not require the licensing –

Arien Malec – Change Healthcare – Co-Chair

Can't require a noncompete, that's right. Should we go back up and just deal with each of the –

Andy Truscott – Accenture – Co-Chair

Yes. Let's go back to the scope of rights.

Arien Malec – Change Healthcare – Co-Chair

Yeah. If you license something, you've got to develop a license that's sufficient to develop products or services that are interoperable. I haven't read this one in as much detail as I probably should have. Or any third party who currently uses the actor's interoperability elements to interoperate with the actor's health IT or health IT under the – so, this one deals with health IT. I guess it's okay. And this is health IT, Mark. Every time I hear the word health IT, I go back to the definition of USC 42 300JJ. Is that what I do?

Mark Knee – Office of the National Coordinator – Staff Lead

Let me follow up on that. No, I mean, health IT is not a defined term in the regulation.

Arien Malec – Change Healthcare – Co-Chair

It's not a defined term in the regulation. So, my interpretation is that if it's not a defined term in the scope of this section, I go back to the bounding context, which is 42, yeah.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah, PHSA, yes. I think that's right. And we use the term health IT as a broad term to refer to the broad scope of health IT that could be covered. I guess we think it's reasonably clear. But if you do not –

Andy Truscott – Accenture – Co-Chair

Just because he's clear, my only question would be around or any third party who currently uses the access interoperability elements. That could be curious. It's I'm leveraging the Explorys platform from IBM. Well, what does that, therefore, obligate IBM or me to if IBM only utilizes Explorys in other directions? So, I'm just trying to work out –

Anil Jane – IBM Watson Health - Member

This is Anil. So, what they're saying is that if I offer an interoperability program with Explorys interoperability elements and I license it to you, if one of our customers, a third party, is out there using an Explorys platform and I've licensed those interoperability elements to you, you should be able to then go market your product or services to that third party who is using this platform.

Andy Truscott – Accenture – Co-Chair

So, what this license shouldn't do is give me the right to access something that's going to involve another third party who is using your elements.

Anil Jane – IBM Watson Health - Member

Right.

Andy Truscott – Accenture – Co-Chair

That's what it says right now. And I'm not sure that that's right.

Arien Malec – Change Healthcare – Co-Chair

Yeah. Is this a right to sublicense? Is the intent the right to sublicense? So, let me give you an example of what I think is an interoperability element in my world. And I'm trying to decipher what third party you currently use would imply in this context. Maybe it would be useful for Mark to outline what was intended.

Mark Knee – Office of the National Coordinator – Staff Lead

Sorry, I thought you were going to go on. Are you saying you want me to –

Arien Malec – Change Healthcare – Co-Chair

Yeah. I stopped in midstride. Rather than make it up, it might be better where there might be some clear intent that's clarified in the commentary.

Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. I think we talk about this in the preamble. In broad strokes, I'm just going to repeat what we have in the regulatory text, but the idea is you should provide all rights necessary to

access and use the interoperability elements for all of those parties that should be able to use those interoperability elements. And I think what we're getting at is, in this case, a third party should have that same – the scope of rights should be covered. But I can pull up the preamble.

Arien Malec – Change Healthcare – Co-Chair

That's not quite what it says though. So, let's say I have a Fyre server, and I license the Fyre server or the Fyre mapping technology and I give it to you or give a license to you. But there's another third party who also uses that same technology. This language says that through that license, I should also be able to interoperate with a third party.

Andy Truscott – Accenture – Co-Chair

Well, that's easy. This language says I should also have a license to use any of that third party's other technology like they also have an X12 server that they license from somebody else. That's what it's kind of saying.

Anil Jane – IBM Watson Health - Member

I don't think it's saying that.

Mark Knee – Office of the National Coordinator – Staff Lead

Go ahead, Anil.

Anil Jane – IBM Watson Health - Member

No, I was just going to say I don't think what they're saying is that if a third party has licensed other technology that by extension now you can use that technology. I think it's basically saying that if two different entities licensed your stuff, Arien, those two different entities are third parties to each other. They can create products that just operate with each other's products. It doesn't have to be only your product. I think that's what they're saying, which is the true purpose of interoperability, I think.

Andy Truscott – Accenture – Co-Chair

Yeah.

Arien Malec – Change Healthcare – Co-Chair

Let me give you a concrete example. So, I develop a service for results and orders orchestration. So, think of it as a pipe. Into one end of the pipe goes a lab. The other end of the pope splits. And at the other end of the pipe are multiple providers using EHRs. And they use those pipes to send and receive orders and results. If I license to Practice A, and I license to Practice B, both Practice A and Practice B clearly should be able to use those interoperable elements to send and receive orders to appropriate labs. But it's not reasonable for Practice A to use those interoperable elements to interoperate with Practice B to send – Practice B may also have an onsite lab and may also want to send and receive orders.

But it's a service that I've offered, and I haven't licensed the service to Practice B to be a lab. I've licensed it to Practice B to be an EHR.

Andy Truscott – Accenture – Co-Chair

Okay. So, I think the fact is we want to constrain the license to be for only those interoperability elements that you've been licensed to use.

Anil Jane – IBM Watson Health - Member

I think that's already there.

Andy Truscott – Accenture – Co-Chair

Is it? That's the third party.

Mark Knee – Office of the National Coordinator – Staff Lead

I was going to say the way Anil has described it was accurate from our perspective what we were going for.

Anil Jane – IBM Watson Health - Member

And there are tangible examples of why that has been a problem in the industry and why it's important to have that so that you can start to –

Arien Malec – Change Healthcare – Co-Chair

Yeah, can you give me an example of where this language would be needed?

Anil Jane – IBM Watson Health - Member

Sure. So, let's just take your example, Arien, but let's assume that these two practices want to innovate the way that lab results are shown and are displayed. And I'm just making this example up. I'm not saying there's a huge market for that. But if they wanted to do that, they could use the technology that you have provided Practice A. Practice A has licensed it from you. Practice B has also licensed it from you. So, Practice A and B could theoretically work together on a new product that takes your capabilities that they both have licensed from you so you're getting paid for that but to create a brand new, innovative product. Now, obviously, Practice A should not be able to leverage a component from Practice B that they themselves haven't licensed.

I don't think this is what this is saying. But if they both have licensed the same stuff, but they should be able to interoperate and create new products and services or hire IBM or Accenture to do the same to create something new where I've also licensed it from you. I've also licensed it so I'm already paying you, too, for those same services. But now, I'm also able to create something new. Does that make sense?

Arien Malec – Change Healthcare – Co-Chair

I suspect this is a software SDK world not a services world.

Andy Truscott – Accenture – Co-Chair

Guys? We have to pause right now just while we open the line to public comment. Hold that

thought. Please open the lines now, operator.

Operator

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

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

Do we have any comments in the cue at this time?

Operator

There are no comments in the cue at this time.

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

Sorry, Andy. I know you were hoping for more public input.

Andy Truscott – Accenture – Co-Chair

That's okay. I have thrown myself in front of the train.

Arien Malec – Change Healthcare – Co-Chair

Can we please stop discussion and get some public comments?

Andy Truscott – Accenture – Co-Chair

Exactly. Arien, go on, carry on. Where were you?

Arien Malec – Change Healthcare – Co-Chair

So, that seems to me to imply software that I own as opposed to services that I license. And the world of software is moving much more towards service licensing as opposed to general purpose software licensing.

Andy Truscott – Accenture – Co-Chair

Yeah. I must admit I hadn't read this in just a product tenor. I've read it in an order of no matter where the software was. I wasn't planning that connotation. I must confess, I'm still tripping myself up on the or any third party who currently uses the access interoperability elements because it seems to be that on one case, it's got functional aspects. On the other case, it's got a scope aspect. And it's developing products or services that are interoperable. Function got that. And that is using interoperability elements or those which have been licensed. Got that. But then, it says any third party who uses the access interoperability elements. And maybe it's the grammar in there because if you read it, any third party who currently uses the access interoperability elements or interoperability access health IT or health IT under the access control.

I think what we're trying to say is I can use the license to interoperate with the third party using those interoperability elements. I think that's what it's trying to say. I don't think the last part of that sentence quite says that right now. It's almost like there should be a comma before the to interoperate. Just to bind that very tightly so we're only meaning using the licensed interoperability elements because that license to the interoperability elements, which I got from the access does not mean that I have a license or anything else from the third party. Or am I misreading this?

Arien Malec – Change Healthcare – Co-Chair
I fundamentally can't wrap my head around this clause.

Andy Truscott – Accenture – Co-Chair
Okay. So, we need to rewrite this, don't we?

Arien Malec – Change Healthcare – Co-Chair
Yeah.

Andy Truscott – Accenture – Co-Chair
If you and I don't get it then, there's a fairly good chance it's torturous.

Anil Jane – IBM Watson Health - Member
Let me just ask, do we all agree on the intent of what this is trying to say in terms of taking the –

Arien Malec – Change Healthcare – Co-Chair
Yeah. Can you restate the intent? If you're stating that the intent is to allow call it derivative products, which would be the typical IT language, the intent is to not constrain third parties from derivative or add on works that are built on top of the interoperable elements then, I think that's something that really should be on the rider clauses or the collateral terms section and not in the core license section.

Andy Truscott – Accenture – Co-Chair
Actually, I'm utterly **[inaudible] [01:50:57]**. I kind of think that 1I should literally say developing products or services that are interoperable using those interoperability elements and that's it.

Arien Malec – Change Healthcare – Co-Chair
Yes, I think that's right. I think it's right. I think simpler is better. Next, let's skip to 2 or II. So, do I interpret B1II as requiring me to make all licenses redistributable?

Anil Jane – IBM Watson Health - Member
Where are you getting that?

Arien Malec – Change Healthcare – Co-Chair

Marketing, offering, and distributing the interoperable products and/or services to customers and users. I see, okay, sorry. So, 1I says that the interoperable license has to be sufficiently developed products or services that are interoperable. And 1II says that I can't license in ways that prohibit you from – Anil, this is the add on or the resale or innovation. I can't prevent you from creating derivative works.

Anil Jane – IBM Watson Health - Member

Well, I think there are two parts to this. One part is the license must allow me – if I'm the app maker, let's say, and I've licensed your elements and I'm creating an off product, I should be allowed to go market it and offer to any customer. But I think what's missing here is there also should be something in here that says that you cannot preferentially somehow diminish my ability to sell. That's not written here. All it says is the license should allow me to do that but I don't see this as saying – an example might be that you might invite your favorite vendor to your conference to your user group but not another one. If that's in the nondiscriminatory area then, that's fine.

Arien Malec – Change Healthcare – Co-Chair

Yeah, that's nondiscriminatory. So, I'm still trying to wrap my head around this one. So, I think this is in the context of an app maker who has used let's imagine a proprietary API set non Fyre based. So, I published a proprietary API set. And somebody licenses my API. The grantable license must be sufficient for them to build an interoperable product and to sell that interoperable product to a third party. Am I redistributing the license that I bought to that third party? Or is that third party obligated to purchase the interoperable element?

Anil Jane – IBM Watson Health - Member

That's a good point, Arien. I think what would have to happen is if I'm going to go sell to a customer that customer – that's a good point. It's not clear at least the way I'm reading it as well. I would think that they would have to have either a license with you or the license I have with you ought to allow me to only use those in the product. But there are no further rights beyond that for my end customer.

Arien Malec – Change Healthcare – Co-Chair

Does 1II forbid GPL licensing? So, if I release something, if I build an open source component and license it under GPL, I've got a license that anybody can get by using it. But that license restricts the licensee's rights or obligates the licensee to do certain things, including republishing as open source under the GPL.

Andy Truscott – Accenture – Co-Chair

Yeah. I'm the same. I think I'll have to look into this. The same goes I think with creative commons, which unfortunately what Fyre is under.

Arien Malec – Change Healthcare – Co-Chair

That's right. And then, in many cases, a creative commons license has notices that are required or obligations and notices that are required. So, there's to open marketing and

offering. There's often marketing offering and distributing with collateral terms.

Andy Truscott – Accenture – Co-Chair
Okay, guys, we're on time. Arien, we're going to have to go and dig into this one a little bit.

Arien Malec – Change Healthcare – Co-Chair
Boy, this is just one of those things where no matter how many times you've read something, you can read it again and go wow.

Andy Truscott – Accenture – Co-Chair
Did we read it? How did I miss that the first time?

Arien Malec – Change Healthcare – Co-Chair
Yeah.

Mark Knee – Office of the National Coordinator – Staff Lead
So, one thing just to kind of level set before we end the call, we are trying to put together some draft recommendations and pull it together by the end of our next call so we can have those for next week. So, all I'm saying is if you guys are able to update the document and think about these things and work on the recommendations between now and then, hopefully, we can kind of nail some of those down next meeting that would be helpful.

Arien Malec – Change Healthcare – Co-Chair
I've got a lot of writing to do. That's what I heard.

Andy Truscott – Accenture – Co-Chair
If it's not there already, just copy and paste it in the main red text, Arien. And then, we'll start editing it. I've started on this one already.

Arien Malec – Change Healthcare – Co-Chair
I'll just do refer to my tweet storm by reference.

Andy Truscott – Accenture – Co-Chair
No, do not do that. Posnack might have allowed you to do that but I will not permit that on this task force. Can you actually, Mark, just before we sign off, given where Arien and I are going on this, did the team consider both GPO and creative commons as it was drawing together these licensing terms?

Mark Knee – Office of the National Coordinator – Staff Lead
Sorry, I didn't quite hear it. You were cutting out a little bit. Can you repeat that?

Andy Truscott – Accenture – Co-Chair
Did the team consider GPO and creative commons whilst it was pulling together these

licensing terms?

Mark Knee – Office of the National Coordinator – Staff Lead
You're talking about in the scope of writing the section or in general?

Andy Truscott – Accenture – Co-Chair
In this specific section.

Mark Knee – Office of the National Coordinator – Staff Lead
I don't think I can speak to that. We didn't put too much discussion into the preamble. But I refer you to the preamble. And I can look into that but I don't have any comments on that right now.

Andy Truscott – Accenture – Co-Chair
If you could, that would be cool.

Mark Knee – Office of the National Coordinator – Staff Lead
Just so I can jot it down, you said GPO and what was the other?

Andy Truscott – Accenture – Co-Chair
Creative commons.

Mark Knee – Office of the National Coordinator – Staff Lead
Creative commons, okay.

Andy Truscott – Accenture – Co-Chair
Yeah. Creative commons is how FHIR is licensed.

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

Andy Truscott – Accenture – Co-Chair
For the caption of creative commons.

Mark Knee – Office of the National Coordinator – Staff Lead
Okay. I will say that I'm not too familiar with that but I'll look into it.

Andy Truscott – Accenture – Co-Chair
As you're a lawyer and we're not.

Arien Malec – Change Healthcare – Co-Chair
We only play one on TV. We play one in FACAs.

Andy Truscott – Accenture – Co-Chair

Thank you ever so much for the diligence today. We have made good progress so, obviously, the hard stuff is about to happen with the actual recommendations that we also haven't pulled together. But this is good.

Mark Knee – Office of the National Coordinator – Staff Lead

Thanks, everyone.

[Event concluded]