Information Blocking Workgroup 1

Transcript March 6, 2019 Virtual Meeting

SPEAKERS

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

Operator

All lines are now bridged.

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

Okay, good afternoon, or good morning, for some. Welcome to the HITAC's Information Blocking Taskforce Group One meeting. Just as a reminder, the subgroup meetings for this particular taskforce will be public moving forward. So, with that, we will jump right in. We have a lot of material to cover today. I'll start with a brief roll call, then I'll hand it over to our chairs. So, Sheryl Turney? Do we have Sheryl on the line yet? John Kansky?

John Kansky – Indiana Health Information Exchange – Member

John is here.

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

Denni McColm – Citizens Memorial Healthcare – Member I'm present.

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

And Cynthia Fisher?

Cynthia A. Fisher – WaterRev LLC – Member

I am here, thank you. Yes, I'm here. Thank you.

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

Perfect. And Andy Truscott?

<u>Andrew Truscott – Accenture – Co-Chair</u> Present.

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

And Michael Adcock.

<u>Michael Adcock – Individual – Co-Chair</u> Present.

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

Great. All right. I'll turn it over to –

Andrew Truscott – Accenture – Co-Chair

It looks like Sheryl is just joining as well.

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

Oh, yes. I see her on the Adobe now. Thank you so much. Perfect. Andy and Mike, I'll turn it over to you.

Andrew Truscott – Accenture – Co-Chair

Okay. Thanks ever so much. It's Andy Truscott here. I'll be leading this workgroup, or at least chairing it. This is a dialogue between us all over the next couple of hours of our lives and going forward over the next few weeks. Thank you ever so much for taking the time and the diligence to go through this. These are very important foundational concepts we're dealing with in this workgroup around information blocking. So, thank you ever so much. I'm just gonna hand you over to Mark Knee, who's gonna take you through the structure of how we're gonna go through the next two hours, and then he'll hand it back to me, and we'll start working at it.

Mark Knee – Official of the National Coordinator – Staff Lead

Great. Thanks, Andy. And hello to everyone, and just want to say the same thing as Andy just did. Thank you so much for being a part of this group and for joining today. I think it's gonna be a great discussion today and moving forward. My name is Mark Knee. I work in the Office of Policy at ONC, and I've worked very closely on information blocking and other issues for the three-and-a-half years I've been here at ONC.

I'll just give you, I guess, maybe a brief overview of the document I sent around that we're gonna be working off of over the course of this workgroup. And we're gonna be able to pull it up, I believe, as a Google doc onto the screen, and you can work off of it on your own computer and make real-time updates, which I think will be quite helpful and a good way to collaborate on the document. It's really kind of a brief document, and I expect it to be quite long once we start incorporating the comments and recommendations. And you'll see that I just pulled the regulatory text into the various tables.

But I want to emphasize, as it was a discussion point that we had in the full task force meeting, that I included the page numbers for regulatory text and preamble, and it's really important that we read both the regulatory text and the preamble because that'll really create the best discussion. The regulatory text is a great place to start, and it really lays out the nitty-gritty of what we're looking at, but then the preamble is where you would look to find where the color is behind the regulatory text. It provides examples and explanations of how we got there and what our thinking was. So, I'd just encourage you, as we go through this exercise, to look at the regulatory text, but also to make sure to flip through the preamble pages I provided.

The other here on this document is a bit different than we have on the agenda today, which

is fine. We'll start with networks and exchanges, which is further down, and then we'll go to electronic health information discussion, which will include price information, which should be an interesting topic. So, I'm just scrolling through the document now. Then we have the definition of health information exchange and network. We have a request for comment regarding practices that may implicate the information blocking provision. And I know Andy, this is a topic that he's really interested in talking about, what specific situations would implicate the information blocking provision. And then we'll also talk about – this is one Michael, I believe, was interested in talking about – who is affected by the information blocking provision; subsequently, the exceptions that we're proposing.

So, that's the general framework of what we're gonna be doing. And like Andy said, I just look forward to a very open and honest dialogue, and to hear different perspectives on how we can improve on the regulatory text and preamble. So, with that – and my role, of course, if you have questions about anything in the regulation or how ONC got to the position we got to, feel free to ask. So, with that, I'll turn it back over to Andy.

Andrew Truscott – Accenture – Co-Chair

Thanks, Mark. Something I have noticed is that I more than anybody else has the square bracket indiscernible square bracket popping up in the closed captions. So, I will try and speak a little bit slower and enunciate a little bit clearer, because I anticipate that you guys are having a bit of a struggle understanding me as well. Okay. If we can scroll, please, to the health information network definitions of health information exchange and network, regulation text 682, preamble 339 to 344. It's midway through this document. Whoever is screen sharing captain? Mark, could you –

Mark Knee – Official of the National Coordinator – Staff Lead

Oh, oh yeah. I think now I share my screen. Give me one second.

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

Yeah, sometimes it's just a little bit of a delay.

Mark Knee – Official of the National Coordinator – Staff Lead

All right. So, it's currently sharing. Let me make sure I pull it up to the right screen. Give me one second.

Andrew Truscott – Accenture – Co-Chair

We can see your screen, Mark. So, if you'd just pop it up, that'd be good. Cynthia, Denni, John, Sheryl, have you guys got the Google document open on your desktops?

Cynthia A. Fisher – WaterRev LLC – Member

I'm just pulling it up.

Andrew Truscott – Accenture – Co-Chair

Okay. Because initially – oh, go on, sorry.

Mark Knee – Official of the National Coordinator – Staff Lead

I was gonna say, can you see my screen now?

Andrew Truscott – Accenture – Co-Chair

Sorry, what was that, John?

John Kansky – Indiana Health Information Exchange – Member

I said working on it.

Andrew Truscott – Accenture – Co-Chair

Oh yeah. Okay. So, if you'd just zoom in a bit, Mark, so we can see it clearly on the screen. But if everyone opens it up, then as you type and put in thoughts, it will go collaboratively all together, which seems a good approach to me.

Mark Knee – Official of the National Coordinator – Staff Lead

Are you able to see it now?

Andrew Truscott – Accenture – Co-Chair

No, because you just closed it.

Mark Knee – Official of the National Coordinator – Staff Lead

Oh. All right.

Andrew Truscott – Accenture – Co-Chair

We can see your desktop though.

Mark Knee – Official of the National Coordinator – Staff Lead

Yeah, actually, this is where I got married. It's in North Carolina, up in the mountains, so.

Andrew Truscott – Accenture – Co-Chair

Oh, lovely.

Mark Knee – Official of the National Coordinator – Staff Lead

Yeah, there you go. So, you can see it now? Is that good?

Andrew Truscott – Accenture – Co-Chair

Okay. Yeah, can see it now. You've got it open. Okay. Team, have we got it open?

John Kansky – Indiana Health Information Exchange – Member

Is the link connected to the invite, or where should I - I'm sorry to be a Neanderthal, but.

Andrew Truscott – Accenture – Co-Chair

That's okay. It came in an invitation from HITAC. It was HITAC something. It was an invite that had the Google doc **[inaudible] [00:08:12]** Google document.

John Kansky – Indiana Health Information Exchange – Member

Yeah, I got it, I printed it; but I'm trying to connect to it.

Cynthia A. Fisher – WaterRev LLC – Member

Yeah, I see it as an attachment, but I don't see where I can connect to it too.

Andrew Truscott – Accenture – Co-Chair

Okay. All right. So, it came in an email from HITAC Administrator by Google Docs on Monday at 4:01 Eastern Time.

Mark Knee – Official of the National Coordinator – Staff Lead

I can send it out real quick. I have it right here, the links if that would be helpful.

Andrew Truscott – Accenture – Co-Chair

[Inaudible] [00:08:42] might be 258.

John Kansky – Indiana Health Information Exchange – Member

Monday . . . Okay, found it.

Andrew Truscott – Accenture – Co-Chair

There we go. Katherine's posted a link – sorry, has posted a link to it in the presenter tag, people, so you can click on it now.

Mark Knee – Official of the National Coordinator – Staff Lead

Oh, great. Great.

John Kansky – Indiana Health Information Exchange – Member

Okay, I'm in.

<u>Andrew Truscott – Accenture – Co-Chair</u>

Cool. People are popping in. I love the way that everyone who logs in anonymously gets given an animal to go with them. And an anonymous pumpkin has appeared as well. Okay. So, guys, as we add to this, if you can just put your initials in square brackets, it just makes it easier to filter through who's done what.

So, this first one we're gonna look at is the definition of a health information exchange and the definition of a health information network, okay? So, we have these clear definitions here. If you look in the preamble, you'll see that the terms network and exchange are not defined in the information blocking provisions or in any other relevant statutory provisions.

And that's a bit of a theme in some of these conversations, that we're putting some of these definitions in a place where they haven't been clearly defined within statutory provisions before.

So, I'd like you guys to actually – just let's look at that first one there, the health information exchange, or HIE, means an individual entity that enables access, exchange, or use of electronic health information, primarily between or among a particular class of individuals or entities for **[inaudible] [00:11:06]** purposes. And . . .

Mark Knee – Official of the National Coordinator – Staff Lead

And Andy, can I jump in?

Andrew Truscott – Accenture – Co-Chair

Yeah, sure.

Mark Knee – Official of the National Coordinator – Staff Lead

I just wanted to just explain why this is really important, is that in the Cures Act, there are the regulated actors that you'll see throughout the document, we talk about regulated actors. And those include health IT developers, providers, and exchanges and networks. So, those are the folks that can be regulated under the information blocking provision. So, it's really important that we're clear about what an HIE and a HIN would entail. I just wanted to chime in there.

Michael Adcock – Individual – Co-Chair

So, Andy, do you want us to kind of just kick this around verbally before we start typing stuff in the document, or?

Andrew Truscott – Accenture – Co-Chair

Absolutely. Let's discuss it. Then we'll start making notes into it as well. Now yesterday, both Sasha and I were making notes based upon the discussion that was going on. I'd say Sheryl, because you can't access it, we'll make sure we capture that as well.

Cynthia A. Fisher – WaterRev LLC – Member

This is Cynthia. I just want to make sure I have the right thing. It was an email that was sent, and it just says Information Blocking Taskforce, Recommendations for Workgroup One. Is that what we're – on the slide? Does it start with 171-.102?

Andrew Truscott – Accenture – Co-Chair

Well, there should be a link that takes you to a Google document.

John Kansky – Indiana Health Information Exchange – Member

Mine came from HITAC Administrator, and in parenthesis, it says (via Google), blablabla.

<u>Andrew Truscott – Accenture – Co-Chair</u>

Yeah. [Crosstalk] [00:12:34] Cynthia.

Cynthia A. Fisher – WaterRev LLC – Member

Yeah. I went into Google Docs. I'm sorry?

Andrew Truscott – Accenture – Co-Chair

Okay, so as long as you've got it up in Google Docs, just try typing somewhere. Let's see.

Cynthia A. Fisher – WaterRev LLC – Member

Mm-hmm.

Andrew Truscott – Accenture – Co-Chair

Tell us where you're typing.

Cynthia A. Fisher – WaterRev LLC – Member

But I'm on my iPad. But you know what? I'm on my iPad, so I can just see these blue blocks with a request for comment, and then some comment underneath it that is already written. I just want to make sure I'm on . . .

Andrew Truscott – Accenture – Co-Chair

Yup. You're looking at the right – yeah.

Cynthia A. Fisher – WaterRev LLC – Member

Okay.

Andrew Truscott – Accenture – Co-Chair

If you can't add to it, just blaze it like Sheryl is, and we will capture those comments. And then you can see how specific **[inaudible] [00:13:17]**, right.

Cynthia A. Fisher – WaterRev LLC – Member

Okay. All right. I can also get my assistant on my laptop to dial her on, and then she can type for me on my laptop. But I'm traveling **[inaudible] [00:13:25]**. Okay, sorry. Thank you.

Andrew Truscott – Accenture – Co-Chair

Okay, no worries. Okay. I've got no problems with that. The first time, it's going to take us a little while to get used to this level of engagement. Okay, cool. So, Mark, you were commenting that this was very important.

Mark Knee – Official of the National Coordinator – Staff Lead

Yup. That was all I wanted to say. But it is very important. And so, as Andy said, the preamble discussion starts on page 339. And I can pull that over if we ever want to look at the preamble as well. Yeah.

John Kansky – Indiana Health Information Exchange – Member

Can I start by testing the "there are no dumb questions" and set the bar low?

Andrew Truscott – Accenture – Co-Chair

Yeah, for sure.

John Kansky – Indiana Health Information Exchange – Member

Okay, so on 339 – you guys can just clear this up for me. It says, and you just mentioned it, Mark, is that the terms "network" and "exchange" are not defined info blocking provisions, but we have information, health information exchange and network defined at 171.102. And are those definitions specifically applied whenever we're talking about actors and whenever we're talking about health information exchange or health information network as an actor, we are referencing these definitions at 171 .102, right?

Mark Knee – Official of the National Coordinator – Staff Lead

Yeah, no, that's a good point. So, in the preamble here – I'll pull that over – it says the terms "network" and "exchange" are not defined in the information blocking provision. So, what we're talking about there is in Cures, the information blocking provision, there's no definition. There is a definition of information blocking itself in Cures. So, because there is no statutory definition, we have come up with these definitions in the regulation.

John Kansky – Indiana Health Information Exchange – Member

Got it.

Mark Knee – Official of the National Coordinator – Staff Lead

And yes, to your question, yeah. Any time you see HIN or HIE, you would want to refer to this definition to see if it makes sense throughout the regulation.

John Kansky – Indiana Health Information Exchange – Member

And they look familiar. Do you know if these got borrowed from the draft TEF, or where have I seen these before? [Crosstalk] [00:15:27]

Mark Knee – Official of the National Coordinator – Staff Lead

Oh, sorry. Go ahead, Andy. What was that?

Andrew Truscott – Accenture – Co-Chair

They look very familiar to me as well too, John. And I was thinking they might come from TEFCA, or – because TEFCA had drawn other things from maybe even NIMH.

Mark Knee – Official of the National Coordinator – Staff Lead

Yeah. So, I joined the information blocking team kind of after these definitions had already been drafted a bit, so I can't speak specifically to where they came from, but I believe that we worked very closely with the TEFCA team and with other relevant definitions in coming up with these. I know that the HIN definition has been tweaked a bit over time to make it

more streamlined. But you're probably right. I would think you've seen this language before in some capacity.

John Kansky – Indiana Health Information Exchange – Member

But they weren't cut and pasted, so they have been edited and changed and Frankensteined enough that we should probably pay close – well, we definitely need to pay close attention.

Mark Knee – Official of the National Coordinator – Staff Lead

Oh yeah. You definitely should, because yeah, we worked them – we adjusted them so that they would apply in the information blocking context, as everything in 171 should. So, yes, you should look. And if you look at the definitions and you think, huh, this doesn't cover someone that should be covered, or this doesn't seem to make sense for information blocking, those are the types of things we want to hear.

John Kansky – Indiana Health Information Exchange – Member

Okay. Andy, should I just keep stirring the pot here?

Andrew Truscott – Accenture – Co-Chair

[Inaudible] [00:16:54] This is a discussion now.

John Kansky – Indiana Health Information Exchange – Member

Oh, go ahead. Cynthia?

Cynthia A. Fisher – WaterRev LLC – Member

Yeah, this is Cynthia. I just think that as we go toward the future of shared data across the healthcare system, in the 21st Century Cures Act, it spoke of networks and exchanges and providers that have patient data being held accountable for information blocking measures. And each one of those was in a small letter context. And I would just suggest that we keep it broad and keep it small letter context because as this unfolds, it's a network in a broad sense and exchange in a broad sense, and provider in a broad sense across the board that shares patient-specific data in healthcare. So, I think it's really important that we don't narrow that definition, and not hold players, actors, throughout the healthcare community accountable.

<u>Andrew Truscott – Accenture – Co-Chair</u>

So, your concern here, Cynthia, is that by defining HIN or HIE here, it limits the future?

Cynthia A. Fisher – WaterRev LLC – Member

My concern is that it limits the future, and it can be gamed to not hold a party accountable who has substantial healthcare information that they want to not share, potentially.

<u>Andrew Truscott – Accenture – Co-Chair</u>

Okay, so it could be gamed -

Cynthia A. Fisher – WaterRev LLC – Member

And we've seen that happen. And I think the broad exchange of patient information is a network of exchange of healthcare information, and that should be held accountable.

Andrew Truscott – Accenture – Co-Chair

So, I think the struggle we have is that the terms HIE and HIN are used throughout the rules. And it would mean almost defining, every time you would otherwise use the term, what you mean. Is that correct, that assumption I've made? [Crosstalk] [00:19:09]

Cynthia A. Fisher – WaterRev LLC – Member

Well, I think you could have those defined as they exist today, but that the definition of information blocking should apply to small N and small E in networks and exchanges as they unfold because there will be exchanges outside of the narrowed definition. And then you can have accountability across the board.

Andrew Truscott – Accenture – Co-Chair

Okay. Okay. So, you -

Cynthia A. Fisher – WaterRev LLC – Member

And there already are exchanges of health information that are related to the patient that are aggregated that are outside of the definitions as they are capitalized.

Andrew Truscott – Accenture – Co-Chair

Okay. So, I think what you're saying then is that just take care and say that the information blocking can occur through lowercase E exchanges and lowercase N networks, such as capital HIEs/HINs.

Cynthia A. Fisher – WaterRev LLC – Member

Beautiful, yeah. Yeah. Thank you. Yeah. That's very important. Thank you very much.

Andrew Truscott – Accenture – Co-Chair

Mm-hmm. Great. So, Mark, please make sure we cross-reference to the definition of information blocking.

Mark Knee – Official of the National Coordinator – Staff Lead

Sorry, say that one more - can we cross-reference to the definition -

Andrew Truscott – Accenture – Co-Chair

Well, we'll cross-check with the definition of information blocking, that information discusses lowercase exchanges and networks, such as HIEs in capitals and HINs in capitals, as per this definition. I'll put it in words.

Mark Knee – Official of the National Coordinator – Staff Lead

Here's information blocking in Cures, if you want to see it. And I think this is a good conversation. I guess I would just say one of the tough things about drafting regulations is

that you have to find that balance, right, between providing enough clarity so that people who read it understand if they're covered or not, but also, like Cynthia's saying, is to leave it broad enough that you make sure that the net captures everyone that should be covered in the definition. So, I think – yeah, go ahead.

John Kansky – Indiana Health Information Exchange – Member

This is John. I think I'm concerned about the side of the coin that Mark is referring to, is that with respect to Cynthia's point, which I think is valid, I'm concerned about organizations understanding the regulations and being able to follow them, and having the regulation written crisply. So, as somebody who's expecting to fit the definition of an HIE, I don't want there to be ambiguity around what that definition is, and then when you see that term in the regs, knowing what it is you're required to do.

Andrew Truscott – Accenture – Co-Chair

I think that's a good point too. And we are gonna need to **[inaudible] [00:21:55]** that today. I don't believe we can address everything **[inaudible] [00:21:59]** and say, yup, we got it **inaudible] [00:22:01]** advice to go forward. I think it's important we get it out. And John, I can see you're poised to type something in there, so let's capture those thoughts as well. Cynthia, I think you're gonna be very interested when we talk about the parties affected the information blocking provision and the definition of actors, and I think that might actually address an awful lot of your concerns here.

Cynthia A. Fisher – WaterRev LLC – Member

Yes. And there will be new actors, right? PBMs didn't exist years ago, and things evolve, and revolutions happen. So, I think we can reach that balance to define where we know definitions today, and they're practical, and just keep the broad sense, so that we have accountability. And you squeeze the balloon, and it doesn't go to one side because it doesn't fit the definition, but it's not providing access. So, yeah, I think this is all doable, and we can type something up there if you'd like. I'll have that done.

Andrew Truscott – Accenture – Co-Chair

Cool. Great.

Mark Knee – Official of the National Coordinator – Staff Lead

And I just wanted to be clear, though. I think that that's right, Cynthia, that the definition can expand a bit to cover different groups. But based on the Cures language, the four groups of actors that Cures lays out that can be covered are developers, providers, networks, and exchanges. So, for instance, you mentioned the PBM. If we wanted it to be covered – not we, but if it was covered under the information blocking provision, it would have to fall under one of those categories and based on the definitions we're laying out. So, that's kind of the task at hand, yeah.

Cynthia A. Fisher – WaterRev LLC – Member

Exactly. But I want to just warn that when you read Cures, that N is small, and the exchange is small. And it didn't narrow to what the industry has defined as the networks and

exchanges with capital N, capital E. So, I think we can still use the broad brush of the word and mention, as was mentioned earlier, about such as HIN, such as – I think you can accomplish both. Mm-hmm.

Andrew Truscott – Accenture – Co-Chair

Let's see. It's not a black and line we're gonna hit by the end of this two-hour session. It's gonna be for discussion, and I recognize this is gonna be a discussion point. And I want to see, Cynthia, if we can achieve your goals, which actually, the goals that you have around specificity, as well as huge proofing, I think we all share.

Cynthia A. Fisher – WaterRev LLC – Member

Okay, great. Thank you.

Andrew Truscott – Accenture – Co-Chair

Okay, so –

John Kansky – Indiana Health Information Exchange – Member

Oh, go ahead, Andy. **[Crosstalk] [00:24:50]** I was gonna throw the slider bar to the other extreme. When I think about these definitions, I think it might be useful for us to level set on making sure we're kind of generally talking about the same things. So, for example, is it okay to mention specific company names, like – as examples, I'll go with something safe, since it's my company, is when we talk about health information exchanges, an example, we mean like the Indiana Health Information Exchange. Can I offer examples in other categories to make sure I'm in the right ballpark?

Mark Knee – Official of the National Coordinator – Staff Lead

[Crosstalk] [00:25:28] I was just gonna say Lauren, if she has thoughts – I'm not sure. But I mean, if it's okay with you, Andy, I guess that's fine.

Andrew Truscott – Accenture – Co-Chair

Well, these are examples of organizations, and we're trying to ascertain whether they would fall inside or outside the criteria we're defining.

John Kansky – Indiana Health Information Exchange – Member

I'm not commenting on -

Andrew Truscott – Accenture – Co-Chair

But it depends on how we use it.

John Kansky – Indiana Health Information Exchange – Member

Yeah, just trying to confirm that -I mean, I think we need -it's really hard to think about writing and tweaking a precise definition if we're not able to at least start with being able to have test case examples to hold up against it.

Andrew Truscott – Accenture – Co-Chair

Contextualization. It's all about contextualization. So, you pick out Indiana as being an example of an HIE. Now, would something like Texas State –

John Kansky – Indiana Health Information Exchange – Member

Well, technically, Andy, Indiana is a state, but.

Andrew Truscott – Accenture – Co-Chair

Well, you know what I mean. The Indiana Health Exchange being an example of a health information exchange, whereas would Texas come under a health information network because that's actually a network of HIEs?

John Kansky – Indiana Health Information Exchange – Member

Do you mean HIE Texas?

Andrew Truscott – Accenture – Co-Chair

Yeah.

John Kansky – Indiana Health Information Exchange – Member

Okay, so this is exactly – yeah, this is exactly what I mean. So, an example of developers – I mean, the prototypical example of a developer is an EHR vendor. A prototypical of a provider is a hospital or a physician. A prototypical example of a health information exchange is the Indiana Health Information Exchange or Arizona Health Current, or CRISP, in Maryland, etc., etc. And the prototypical definition of a network was the one I wanted to be clear on. Are we talking about the eHealth Exchange? Are we talking about care equality? Are we talking about what is a health information network versus a health information exchange, is really something that would help me out to even be contributing to these definitions.

Andrew Truscott – Accenture – Co-Chair

So, we have the definitions there. And I think actually, the way that you just expressed it is kind of where my head was at with what I thought of as I read these.

Denni McColm – Citizens Memorial Healthcare – Member

So, this is Denni. I thought I noted in the preamble that it also – they had an example that was a provider who networked with their unaffiliated referring providers in the community.

Andrew Truscott – Accenture – Co-Chair

That was an example as well, yeah. So, the provider could come under either, actually.

John Kansky – Indiana Health Information Exchange – Member

So, in that case, they're what in my world we would call a private HIE. And so, adding that potentially to the definition of HIE.

Denni McColm – Citizens Memorial Healthcare – Member

So, if representing the provider, I'm with a hospital, if we did have an interface engine that had interfaces to three or four individual providers, would we suddenly be a private HIE?

John Kansky – Indiana Health Information Exchange – Member

I think that's a good question.

Andrew Truscott – Accenture – Co-Chair

So, if you had an interface engine that provided connectivity external to your organization. Is that what you mean, Sheryl? Sorry, Denni.

Denni McColm – Citizens Memorial Healthcare – Member

Right. I mean, lots and lots of hospitals have interfaces to facilitate exchange directly, with lab results, for instance, to unaffiliated providers.

John Kansky – Indiana Health Information Exchange – Member

Correct, yeah. And -

Denni McColm – Citizens Memorial Healthcare – Member

Documents, radiology reports.

John Kansky – Indiana Health Information Exchange – Member

So, this is John again. And this is the other point I was gonna – and we'll come right back to this, because I think it's a great question, in my opinion, is I'm obsessed with the ramifications of moving a comma in any of these definitions, because what seems to be important for this regulation to work properly is the intent of the regulation to cover that hospital system that has an interface engine – as you suggested, almost all of them do – that connects to outside entities; or is the HIE definition specifically intended to exclude them, and therefore, now we have some work to do to fix the definition?

<u>Andrew Truscott – Accenture – Co-Chair</u>

Well, my understanding was the reason or intent of 21st Century Cures was to cover all communications between organizations to enable the seamless flow of information at no cost to a patient. In which case, it seems to my mind to fit in with that spirit . . . Sorry, Denni, the example that she just brought up is relevant.

<u>Sheryl Turney – Anthem Blue Cross Blue Shield – Member</u>

So, this is Sheryl. I guess I'm confused because what we have here is not what they have in the rule. And are we saying we want to change what's in the rule to what we have on the screen? And I put in the chat box what's actually in the rule. And again, I know I'm struggling because I can't on my work computer get the rule, but I brought it up on my iPad, and I can on my work computer then look at what's actually printed in the federal register. What we have is not the same as what they put in there. And so, either we're gonna comment about what they put in there and change it to something, but I don't know why we're starting with a different definition.

Andrew Truscott – Accenture – Co-Chair

I'm confused, though, because – sorry, what you actually put in the chat box is what's in this top blue box.

Mark Knee – Official of the National Coordinator – Staff Lead

While we're looking, Sheryl, am I able to see the conversation? I'm sharing my screen, and I just see the Google doc. But I can't see what Sheryl posted. I want to make sure I'm understanding. [Crosstalk] [00:31:34]

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

That's correct, Mark.

<u>Andrew Truscott – Accenture – Co-Chair</u> [Crosstalk] [00:31:37] the network or HIN. Yeah.

Mark Knee – Official of the National Coordinator – Staff Lead

Okay.

Andrew Truscott – Accenture – Co-Chair

Sheryl, what you sent to Katie is exactly what's in the rule.

<u>Sheryl Turney – Anthem Blue Cross Blue Shield – Member</u>

All right, I guess I – yeah, okay. I'm not seeing exactly the same, so I don't know if I'm not seeing what you have, or whatever, but.

Andrew Truscott – Accenture – Co-Chair

Okay. So, we have the blue box that's labeled 171.102, Definitions of Health Information Exchange and Network. And that has the definition as precisely transcribed by yourself into there. And that's what we're discussing. The comments and recommendations we're capturing below as just, these are our discussion points as we're going through this. And right now, there are just discussion points that we captured. This is not a new definition or a redefinition. The discussion we have is whether this definition is what we want to have as it is, or whether we want to tweak it or change it in some way... or recommend that it gets to be changed in some way. Can you not see the box in front of it?

<u>Sheryl Turney – Anthem Blue Cross Blue Shield – Member</u>

The box now.

Andrew Truscott – Accenture – Co-Chair

If I just tried changing the color of it, can you see it now?

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

Yeah, no, I've got it up on my iPad now so I can read it. I couldn't read it before on your screen, but I have it up on the iPad, so now I can read it.

Andrew Truscott – Accenture – Co-Chair

Okay. Well, hey!

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

So, I'm all set now.

Andrew Truscott – Accenture – Co-Chair

Cool. Okay, cool. Great.

Mark Knee – Official of the National Coordinator – Staff Lead

And so, are we good now? Because I want to make sure I didn't make any mistakes. So, it looks like it lines up, Sheryl? There's no discrepancy? Okay. Sounds like we're good.

Andrew Truscott – Accenture – Co-Chair

Okay. So, I think Mark, we're gonna align your insight here. 21st Century Cures was designed to cope with all communication of health information outside the four walls of an organization, basically, I think. And is this definition, as John was saying, of HIE designed to cope with that, where you have a hospital communicating with a local lab, a local physician's lab, a local whatever?

Mark Knee – Official of the National Coordinator – Staff Lead

Was that for me, Andy, or you said for Lauren?

Andrew Truscott – Accenture – Co-Chair

It is for you, for you all.

Mark Knee – Official of the National Coordinator – Staff Lead

Okay. Well, I'll say I can't really speak to – I guess I can't speak outside of what we put in the regulation. So, I can only kind of say look at the definitions and look at the preamble, and if you think there are groups that should or should not fall within the definition of HIE or HIN, then those are the types of recommendations that we probably want to hear. But I guess I can only say in Cures or in our regulation, excuse me, we define electronic health information, so that is another topic we're gonna talk about for the scope of the actual information we're discussing. And then the discussion about health information exchange and the network is who are these actors that would be exchanging EHI? So, I can't really get into an analysis of who's in or out, necessarily.

Andrew Truscott – Accenture – Co-Chair

Okay. So, in the preamble, it actually says HIE is an individual or entity that enables access, exchange, or use of EHI between or among a particular case of individuals or entities, or for a limited set of purposes. And just that sentence, I would suggest, encapsulates exactly what

you were saying there, Sheryl, Denni, John. Yes.

John Kansky – Indiana Health Information Exchange – Member

Sorry?

Andrew Truscott – Accenture – Co-Chair

John's saying if yes, what are the ramifications? Well, the ramifications are . . .

John Kansky – Indiana Health Information Exchange – Member

Oh yes. Sorry, I was just kind of working independently here.

Andrew Truscott – Accenture – Co-Chair

No, this is the purpose. **[Inaudible] [00:35:56]** and work at the same time. So, yes. And the ramifications are that every organization is gonna need to comply.

<u>Sheryl Turney – Anthem Blue Cross Blue Shield – Member</u>

I guess from the hospital's point of view, are there different requirements to not do information blocking that apply to the different actors? So, I'm already a provider. I already have the requirement toward not information blocking as a provider. Do I have a new set now if my organization is also designated as a HIN?

Mark Knee – Official of the National Coordinator – Staff Lead

Yeah, so there's -

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

Go ahead.

Mark Knee – Official of the National Coordinator – Staff Lead

I was gonna say, there's two – oh, sorry. Sorry to interrupt.

Cynthia A. Fisher – WaterRev LLC – Member

This is Cynthia. Sorry. You know what is curious from a patient perspective and from looking at the global perspective is the provider, also we've seen a great consolidation not only of providers, but we've seen the oligopolies now be vertically integrated, so providers own insurers. They own their own GPOs, some of them. And then maybe even merged with pharmacies. Some of them have come together with pharmacies. So, the question that I think as we look at this, at least in business, you look for most favored nation language, which is, shouldn't all players and actors be treated the same? So, as the industry is consolidating and vertically integrating, we have information blocking penalties.

And my question is, as we look at this, and this is downstream, but as we look at the definition, if they're all sharing patient information and they all could block it under one of their entities, why not just treat the entities the same, so that as we look at this approach, if players and actors who share patient information are treated the same, maybe as we look at

this, it would be fair, right? So that one entity might not be able to use another form of itself to not get the penalty. Do you know what I'm saying? I'm trying to say, as we look at the definitions, as we look at this process, it'd be nice to have a more global perspective too. On accountability.

Mark Knee – Official of the National Coordinator – Staff Lead

I just wanted to clarify that the penalty structure is different for different actors. So, in Cures, it lays out that developers, exchanges, and networks are subject to civil monetary penalties up to a \$1,000,000.00 per infraction, but providers, it says that there will be disincentives, which we have a request for comment, and they haven't actually been identified. So, the distinction between the provider and the other actors is important there as far as penalties.

Cynthia A. Fisher – WaterRev LLC – Member

Okay, so that's to my point, is the hospital that's sharing information via these mechanisms that might accidentally, in my opinion, get defined as HINs, are sharing information freely. I mean, they're doing the right thing. And for us to subject them to additional penalties might discourage what's already working well.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

Or they may not be. In a lot of patient cases, they're not actually sharing information well. And so, if they're pushing it into a network –

Cynthia A. Fisher – WaterRev LLC – Member

If they're not sharing information well, they're not falling into this category.

John Kansky – Indiana Health Information Exchange – Member

The point of the regulation –

Cynthia A. Fisher – WaterRev LLC – Member

We're putting the people in this category who are trying to do the right thing.

John Kansky – Indiana Health Information Exchange – Member

Well, if I could offer that, I mean, we're talking about the confusion created if they fall into two definitions. There's no question that a hospital, with or without an interface engine, meets the definition of a provider and therefore will meet the regulations and be required to share information. And staff maybe need to help us understand the ramifications here. It doesn't seem helpful to me to write definitions without considering the intent that applies to more that one entity, and just now, everybody has to read the regs and ask themselves which role they're in when something happens. So, if there aren't negative implications of writing the definitions crisply and letting a hospital system know, oh, I read this definition. I can see that for my interface engine, that doesn't suddenly make me a health information exchange. If that doesn't negatively affect the intent of the regulation, then I think we should be crisp. **[Crosstalk] [00:41:10]**

Mark Knee – Official of the National Coordinator – Staff Lead

I was just gonna say that – sorry, go ahead.

Cynthia A. Fisher – WaterRev LLC – Member

Go ahead. I just think if we look at equity on information exchange, I don't understand why there's a carve-out for providers that are different than EHR vendors and the networks and exchanges on accountability. That little carve-out makes me concerned to say why – hospitals have a breadth of information, so we want them to share that information, and everybody would be better served for the practice of medicine, treatment and care. I guess, I think as we look at this, it's really important not to allow an escape hatch on accountability. And I think we should all play by the same rules, quite frankly. But it was written with a little bit of an open escape, so I just throw that out there as a heads up.

Andrew Truscott – Accenture – Co-Chair

Who do you think this is an escape hatch for?

Cynthia A. Fisher – WaterRev LLC – Member

The provider.

Andrew Truscott – Accenture – Co-Chair

Who is that escape hatch for? The provider. Because a provider would be locked up in the health information exchange, which talks about **[Inaudible] [00:42:21]**. It talks about state health information exchanges. And then it talks about other types of organizations, entities, or arrangements that enable EHI to be accessed, exchanged, or used between or among particular types of parties for particular purposes. For example, an HIE, that as a term, might facilitate or enable the access, exchange, or use of EHI exclusively within a regional area or for a limited scope of participants and purposes. And it actually says, such as a clinical data registry or an exchange established by a hospital physician organization to administer ADT.

So, that seems – I think **[inaudible] [00:42:56]** escape hatch in this. And I would suggest that the place to make sure that there is no escape path is in the very last section that we get to deal with in this workgroup when we look at the actors, and we actually say what actors are in the scope, and be clear about it rather than ambiguous. What would you think of that?

Cynthia A. Fisher – WaterRev LLC – Member

That may work. I think it's worth considering. Thank you.

<u>Andrew Truscott – Accenture – Co-Chair</u>

Well, we'll come back to this point though, because like I said, this isn't gonna be fixed today. Anybody else?

John Kansky – Indiana Health Information Exchange – Member

Go ahead.

Mark Knee – Official of the National Coordinator – Staff Lead

Just real quickly, I was gonna to – I'm not sure who was speaking, but the point about treating providers in the same way as we treat the other actors, I just wanted to note that that's from Congress. And I can pull it up on the screen right here. As far as the penalty structure – this is from Cures – that it lays out different penalties for developers, networks, exchanges versus providers. So, that's where that came from, from the Cures Act.

John Kansky – Indiana Health Information Exchange – Member

Hey, Mark. This is John. Other than penalties, can you cite any examples of where the regs are, if you're a provider, then this. If you're a developer, then this. If you're an HIE, then this. I mean, are there a million of those? Are there three of those? Are there none of those other than penalties?

Mark Knee – Official of the National Coordinator – Staff Lead

Do you mean within Cures or in our regulation?

John Kansky – Indiana Health Information Exchange – Member

In our regulation.

Mark Knee – Official of the National Coordinator – Staff Lead

Sorry, I'm not sure I totally understand. You're asking – can you restate it one more time, just so I understand?

John Kansky – Indiana Health Information Exchange – Member

Sure. So, the penalties differ depending on which actor definition you meet, and that was one of your points, right?

Mark Knee – Official of the National Coordinator – Staff Lead

Yes.

John Kansky – Indiana Health Information Exchange – Member

And I believe you're pointing out that that's encoded in Cures, question mark?

Mark Knee – Official of the National Coordinator – Staff Lead

Well, so what I'm saying is that in the Cures legislation, Congress said that the penalty structure should be different for providers than for the other actors.

John Kansky – Indiana Health Information Exchange – Member

Okay. So, now let's switch over to the proposed information blocking regulation. Are there a million places throughout the regulation where it's like, if you're this actor, then this is your set of circumstances, versus if you're that actor, it's a different set of circumstances? Or is that rare?

Mark Knee – Official of the National Coordinator – Staff Lead

No. So, I mean, the way we structured it is that we define the actors, so we provide

definitions for health IT developer of certified health IT. We reference the Public Health Service Act definition for the provider, and then we have these definitions of network and exchange. And then the application of whether you're an information blocker or not is the same; it's just a matter of whether you are identified as one of those actors, which is kind of a threshold question to ask if you're trying to figure out if you would be subject to penalties under the information blocking provision. So, you would ask, am I one of those four actors? And then you'd go through the analysis of whether you're dealing with electronic health information, whether it's required by law, whether there's an exception that would be applied. There are all these different questions that you would ask to go through that. Does that make sense?

John Kansky – Indiana Health Information Exchange – Member

But once you determine – yup, I fit this definition, therefore the regulatory applies to me. The requirements are essentially equivalent.

Mark Knee – Official of the National Coordinator – Staff Lead

Yes. And I think you guys are talking, but -

Andrew Truscott – Accenture – Co-Chair

Mark, isn't there some with a certification, etc.?

Mark Knee – Official of the National Coordinator – Staff Lead

Sorry, can you explain?

Andrew Truscott – Accenture – Co-Chair

Well, certification applies differently to different actors.

Mark Knee – Official of the National Coordinator – Staff Lead

Right. Okay. So, yeah. There are two different kinds of authority here with information blocking. There are the conditions of certification, which is another workgroup, which applies to entities under the ONC certification program with health IT developers. So, that's that authority. And that's for getting your product certified. But under – what Cures said is information blocking should be broader and would cover developers, providers, exchanges, and networks. And the Office of the Inspector General would be enforcing those penalties. And we're working with them to go through that. But they are the authority for the penalties and the analysis of information blocking.

John Kansky – Indiana Health Information Exchange – Member

Okay. But for information blocking, I'm trying to address or to determine if Cynthia's point is addressed, is that for info blocking, as long as you meet a definition, the information blocking rules are essentially consistent across the actors.

Mark Knee – Official of the National Coordinator – Staff Lead

Yes. There's the same definition for information blocking. There are the same exceptions.

And as we talk about for health information network, we talk about how it's a functional definition. I think you all were talking about this, that you could be defined as a provider, but you could also be defined as a health information network, and that distinction is important because providers have different penalties than health information networks. So, other than – go ahead.

Cynthia A. Fisher – WaterRev LLC – Member

And right now, to my understanding, is that the penalties are defined up to \$1,000,000.00 per occurrence by the Inspector General for everyone other than providers, and "providers" is to be determined. So, that has sort of the open end, which is open for comment. So, that's the only difference to my understanding of the rules. Correct me if I'm wrong. But that's my understanding as it's stated.

Mark Knee – Official of the National Coordinator – Staff Lead

That's right. There is a request for information about that. And that's gonna be discussed in the exceptions workgroup too. So, if you're interested in that, you can listen in. I think we're trying to limit the feedback in the group.

Andrew Truscott – Accenture – Co-Chair

And we will discuss it in full taskforce anyway.

Mark Knee – Official of the National Coordinator – Staff Lead

Yup, exactly. Yup.

Andrew Truscott – Accenture – Co-Chair

Okay.

John Kansky – Indiana Health Information Exchange – Member

Okay. So, if I could, that seems to – I don't want to oversimplify this, so I'm asking the group, this seems to dramatically simplify our task, because then, when you look at the definitions, you can focus on just characterizing – just writing definitions that take in everyone that should be subject to these regulations and not unintentionally bringing in anyone who shouldn't. And then we don't have to obsess about the ramifications of moving commas, which is what I was worried about earlier.

Andrew Truscott – Accenture – Co-Chair

What would happen if a provider is deemed by the inclusion of a definition to also be an HIE? What penalty would apply to them?

Mark Knee – Official of the National Coordinator – Staff Lead

Well, so we'd have to go through the analysis. And like I said, I'll pretty much just refer to the preamble because I think we discussed this pretty in-depth. But I think you just have to look at what category of actor they fall into based on the function that they are providing.

Andrew Truscott – Accenture – Co-Chair

I get that. But if we have a provider organization that also provides a local HIE, which they do – well, some do – they could fall into two different classes of actors and potentially have two different penalties ascribed to them. Would they automatically rise to the highest penalty, or what?

Mark Knee – Official of the National Coordinator – Staff Lead

So, on that one, I'd just defer to the preamble. I can't really get into that analysis. And also, that would be within the investigatory discretion that OIG would have as well. So, I'd just say I'd look at how we define these actors and what we say. If it's not clear, I guess, how that –

Andrew Truscott – Accenture – Co-Chair

It's not clear. The preamble doesn't count for that, as far as I can see. [Crosstalk] [00:51:24]

Cynthia A. Fisher – WaterRev LLC – Member

Let me give you an example where I think things get complicated. I'm hearing in medicine for the future that the providers want to have access to social determinants as it relates to the patient. So, what you can imagine is an entity is vertically integrated with a pharmacy insurance program and a provider, where they're all one big merged enterprise, that they can look at, okay, you're in the drugstore. You're buying Tums. You're standing in front of X, Y, Z. You add the social determinants into the patient record. Downstream, you could be part of the exchange or the network, and you could be a provider. But I think by carving out something different wherever patient information is exchanged, as we move into the future, it makes for very difficult compliance. So, I'd just throw this up, that I think it could be problematic, and that's why I think if we brought in the network and exchange definition, we capture everybody in the same net. And as it relates to single determinants with a patient, that everybody's under the same roof. It just makes everything much more – it creates a standard rather than a standard of carve-outs and exceptions.

Denni McColm – Citizens Memorial Healthcare – Member

So, the distinction there is that that one won't get caught in the health information network or health information exchange definition anyway, because they're all the same organizations. They're still gonna be only a provider. Who you penalize is the person who is trying to exchange outside the four walls. If you make every little hospital in America who has a couple of interfaces to providers or labs suddenly fall into this second category, that just seems like it discourages what we're trying to encourage.

Cynthia A. Fisher – WaterRev LLC – Member

Well, we're trying to encourage sharing to the patient. Ultimately, this is to deliver information to the patients and their caregivers.

Denni McColm – Citizens Memorial Healthcare – Member

Of course. Yes, we're widely known for that in our organization. But if you make me suddenly subject to a bunch of new penalties that I wouldn't otherwise be, then you are discouraging me from setting up this simple interface. **[Crosstalk] [00:53:46]**

Cynthia A. Fisher – WaterRev LLC – Member

But right now, you are subject to a penalty. You don't know if it's \$1,000,000.00 or bigger than \$1,000,000.00. It has not yet been determined by the Inspector General. So, you are under the lid of being subject to penalty. It's just not determined. It's up to the Office of the Inspector General.

Denni McColm – Citizens Memorial Healthcare – Member

But Congress intentionally said this penalty's gonna be different for providers. Right?

Andrew Truscott – Accenture – Co-Chair

Yeah. As it stands right now, yeah. But let's just – and that's a unique complication of that. Hang on a second. One point. I'll have my hand metaphorically raised. I'm not sure that I agree with by expanding the definition, you're gonna disincentivize a hospital with two interfaces because this is about information blocking, not about the type of sharing you do. So, you have to not block information sharing. So, I'm not quite sure why this would prevent that from taking place, because they have to do it.

John Kansky – Indiana Health Information Exchange – Member

So, Andy, that's where I was gonna go too, a version of that. So, listening to the discussion – let's just assume, okay, there's a penalty, and it may be better or it may be worse. We just don't know today. But let's assume that there's a penalty if you do something bad. What I think we need to ask ourselves is if we accidentally or on purpose include hospitals with an interface engine in the definition of an HIE, and then you try to – do we suddenly prevent them from doing something constructive for healthcare because of one of the rules of information blocking? In other words, oh, well, I'm just trying to efficiently deliver lab results here, so I have these interfaces that send lab results to my five top physician practices. And I didn't go on to numbers six through 10. Just for economic reasons, it didn't make business sense for me. And then somebody says, well, that's information blocking.

And I think it was Denni that was speaking – now Denni's organization has an unintended problem. That's what we have to avoid. Forget about the penalties. And this is just one example, which is what scares me – does pulling people, organizations accidentally into the definition end up creating unintended consequences? That's my question.

Andrew Truscott – Accenture – Co-Chair

But is that an unintended consequence or an intended consequence?

Cynthia A. Fisher – WaterRev LLC – Member

That's a good question. I would weigh in to say an intended consequence.

John Kansky – Indiana Health Information Exchange – Member

Well, it's just not as simple as everybody shares data with everybody, and nobody charges anybody anything any time, and everything's great. It's just not that simple. And I don't operate a hospital. I don't operate a large physician practice. But I'm thinking about what they do just to be an efficient operation. We don't want to unintentionally – and I'm not saying I can cite it. I don't know the regulatory yet well enough to say, oh, there it is on page 714. There's the problem that we're creating if we pull them into this definition. But I think we need to acknowledge that that could be there.

Andrew Truscott – Accenture – Co-Chair

Isn't one of the actual purposes of 21st Century Cures to say if you are going to provide healthcare and have information about patients, you must allow that information to be accessible wherever that patient seeks care and to that patient? I'm paraphrasing, but when Congress sat down and came up with this, wasn't that kind of the place which all of them sat behind this depiction of it?

John Kansky – Indiana Health Information Exchange – Member

Again, not saying that this is what the regulatory says, but are you saying – so, there's a critical access hospital who, for whatever business reason they have, builds a single interface to a local physician practice. Now they're required by the regulation to build an interface with anybody who raises their hand and accuses them of information blocking? You'll put them out of business.

Andrew Truscott – Accenture – Co-Chair

Sorry, you broke up in the middle of that sentence, so I missed out two words, which seem to be quite important. Can you just repeat it?

John Kansky – Indiana Health Information Exchange – Member

Okay. Sorry, I can probably do a better job the second time.

Andrew Truscott – Accenture – Co-Chair

Okay.

John Kansky – Indiana Health Information Exchange – Member

Not saying this is what the regulation says, but maybe people on the phone do know what the regulation says – if a critical access hospital builds a single interface to an external physician practice, who that for whatever business reason, that makes sense. But now they're an HIE under the information blocking rule. They were a provider before. Are they now going to be information blocking in any way? Could they be accused of information blocking by not having or being willing to build that interface for virtually anybody who might accuse them?

Cynthia A. Fisher – WaterRev LLC – Member

Well, I thought the purpose was gonna have open APIs and the ability for the interchange of longitudinal patient records that can be aggregated and utilized by providers and patients alike, and that the whole intent of Cures was to get the providers to share this information throughout the community, because we live in a transient world, on a mobile world. And just like any other industry, this information can be shared, and it's not a technological problem in today's world.

Denni McColm – Citizens Memorial Healthcare – Member

You would think it isn't a technological problem, but he's right. Every interface is gonna cost a bunch of money and a bunch of resources, and the **[inaudible] [00:59:48]** hospital couldn't possibly do that. So, that is –

Andrew Truscott – Accenture – Co-Chair

I think the outcome would be that an individual provider or a hospital center would integrate to health information exchange, health information network, so you don't have to go one to many. You can go one to HIN.

Mark Knee – Official of the National Coordinator – Staff Lead

This is Mark. I just wanted to point out that just at a very high level, I think what Cures and what our regulation is saying is that data should be shared unless there's a good reason not to. And so I think, John, what you're talking about is you'd have to go through the analysis and look at the seven proposed exceptions and see whether in that situation, whether it was a provider, or a HIN, or whatever the actor was, whether they qualified and met all the conditions of the exceptions. We have an exception about licensing interoperability elements on reasonable and nondiscriminatory terms. We have one about infeasibility. So, you'd have to see whether an exception applied.

John Kansky – Indiana Health Information Exchange – Member

Yeah, I think I just need to look at the exceptions again through that lens. And I'm trying to introduce a general concept, which is that – it's very simple. If you write a definition that pulls in unintended – and there may not be any – organizations, are there unintended ramifications? And if I read this in the context of thinking about a small hospital system, there may not be any – that may be an empty set, in which case we don't have to think about it.

Andrew Truscott – Accenture – Co-Chair

John, as I read and reread the preamble, I need to think of health information exchange in maybe a slightly different way than what you and I have traditionally. And I'm thinking of it more as a verb than a noun. And so, actually, okay, as I look at the preamble, health information exchange seems to be very focused upon the doings of sharing data, sharing information, as opposed to a health information network, which is much more of a verb – a noun describing a collection of organizations or entities. I know that's not exactly what the preamble is, but –

John Kansky – Indiana Health Information Exchange – Member

Yeah, I grasp what you're saying.

Andrew Truscott – Accenture – Co-Chair

Yeah. It's not exactly how . . .

John Kansky – Indiana Health Information Exchange – Member

We're defining two nouns here. And we've burned a good hour, so I'll let us move on on this

particular – can I do an abrupt change of subject and pose my question about the individual that I typed in there?

Andrew Truscott – Accenture – Co-Chair

Why don't we go to the very last section of this document, parties affected by the information blocking provision, and talk about the access? Because that seems to be where you're going.

John Kansky – Indiana Health Information Exchange – Member

I guess – yeah, I was reading. My question is that the definition as written acknowledges that an individual can be an HIE or a health information network, and I just couldn't think of any circumstances where they would, or we would want them to fit the definition. I'm just asking if anybody else has – does that make sense?

Andrew Truscott – Accenture – Co-Chair

Yes [inaudible] [01:03:30] by the specialty practice. So -

John Kansky – Indiana Health Information Exchange – Member

Well, then that practice is a legal entity. It's not an individual.

Andrew Truscott – Accenture – Co-Chair

Can you get an individual -

John Kansky – Indiana Health Information Exchange – Member

Can Bob be a health information network? [Crosstalk] [01:03:55]

<u>Sheryl Turney – Anthem Blue Cross Blue Shield – Member</u>

So, the thing of it is – this is Sheryl. We do have providers that are using, still, their individual identity and not a legal entity. So, I think for that purpose, that's probably why the individual comment is there.

John Kansky – Indiana Health Information Exchange – Member

Okay, so how would that individual – Dr. Bob, with no legal entity around him, under what set of circumstances could he possibly be a health information exchange?

Andrew Truscott – Accenture – Co-Chair

Well, Dr. Bob can be an exchanger of health information.

<u>Sheryl Turney – Anthem Blue Cross Blue Shield – Member</u>

That's right. So, that's the E with a small E and a small N that I was talking about earlier, is people – I know of a direct primary care provider that has his own beautiful software for his parents, and it works very well, and he practices as an individual.

John Kansky – Indiana Health Information Exchange – Member

Okay, yup. I do not dispute that Dr. Bob could be a small E exchanger of health information. Looking at our definition, Dr. Bob is an entity – he enables access, exchange, or use of health information, primarily between or among a particular class of individuals. I mean, just give me an example, when one of these rare physicians who's literally functioning without a legal entity is functioning as a health information exchange.

Andrew Truscott – Accenture – Co-Chair

Well, functioning as an exchange of health information, and in this definition, an HIE, yes. So, Dr. Bob receives a referral from a local hospital where he provides some specialty care services, and Dr. Bob receives Andy into his practice, where he provides treatment and notes, records around that treatment. Maybe creates prescriptions for Andy, which get transmitted to a local specialty pharmacy, let's say an Accredo or something like that. And then those records, records of that treatment, he also puts in a treatment note, which gets maintained in his local EMR that he's running and gets transmitted back to the hospital that referred Andy to him. So, yeah, I can definitely see a use case.

Denni McColm – Citizens Memorial Healthcare – Member

Well, that's every provider. [Crosstalk] [01:06:16]

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

Exactly. Exactly. That's the issue here, where it comes under the – and the provider's also a hospital. So, you could look at this blanket of networks and exchanges as anybody who shares patient health data across care.

Andrew Truscott – Accenture – Co-Chair

Well, we were talking about just **[inaudible] [01:06:39]**. That's why I said specialty. But yeah, I get your point there. It could be anybody. **[Crosstalk] [01:06:45]**

Cynthia A. Fisher – WaterRev LLC – Member

I think that was the intent of Congress. The intent of Congress was that we could be able to get access to our longitudinal health record, past, present, and future, if you look at the HIPAA definition from 1996.

Denni McColm – Citizens Memorial Healthcare – Member

But Congress did define differently providers from health information networks and developers.

Cynthia A. Fisher – WaterRev LLC – Member

Only in the penalties to be determined by the Inspector General. That was the only place that was separate in the amount of the penalty. It's not how they exchange or how they're responsible for the information. There was no carve-out on differentiating and how much information exchange because the big part of the problem is the providers. So, people want to keep you in their system, trust me. A community of three oligopolies, so it's very competitive. So, this is the intent, is to give it to the patient across the system, and

everybody's treated the same, except for penalties.

John Kansky – Indiana Health Information Exchange – Member

Yeah, no question. So, if you meet the definition of a provider, you're already required to share and not information block. Done. So, we've got the providers covered. So, when the writers of the proposed regulation reference a health information exchange and a health information network, their intent is not to – it's gonna be quite confusing if that definition takes in every health information exchange and every provider on the planet. So, I would offer that the intent of this definition is probably to make sure that health information exchanges and health information networks are not left outside the regulation. Is that a fair statement?

Andrew Truscott – Accenture – Co-Chair

I think that's a fair statement. But I'm looking at the preamble around health information exchange, and it does talk about a hospital physician singular organization to facilitate –

John Kansky – Indiana Health Information Exchange – Member

Where are you at, Andy?

Andrew Truscott – Accenture – Co-Chair

I'm on page 343, the final paragraph. Line one, two, three, four, five, six, seven, last words, such. As a clinical data registry or an exchange established by a hospital physician organization to facilitate ADT alerting.

John Kansky – Indiana Health Information Exchange – Member

Let me read that.

Mark Knee – Official of the National Coordinator – Staff Lead

I just pulled it up on the shared screen as well.

Andrew Truscott – Accenture – Co-Chair

And then if you look at the final paragraph that's on the top of page 344, it says we encourage commenters to consider whether this proposed definition is broad enough, or too broad – that's a helpful question – to cover the full range of individuals and entities that could be considered exchanges within the meaning of the information blocking provision. I can't help but see that this is designed to be a catchall.

Denni McColm – Citizens Memorial Healthcare – Member

Maybe ONC said that, but I don't think Congress said that. That's, I guess, my beef with it.

Cynthia A. Fisher – WaterRev LLC – Member

Where do you see anything different from the Cures Act? The ONC is consistent with the Cures Act on the intent of the law.

Denni McColm – Citizens Memorial Healthcare – Member

Not if exchanges include every provider, they're not consistent, because Congress did define providers as something separate from exchanges.

Cynthia A. Fisher – WaterRev LLC – Member

No, they did not. They did not -

Andrew Truscott – Accenture – Co-Chair

But I think they're talking about the penalty. They're talking about the penalty, right? And that was the only difference.

Cynthia A. Fisher – WaterRev LLC – Member

The only difference is in penalty. The only difference is in a penalty, because -

Denni McColm – Citizens Memorial Healthcare – Member

But definitely [crosstalk] [01:10:35] it as something different.

Cynthia A. Fisher – WaterRev LLC – Member

No, they defined the penalty as subject to the Inspector General. However, the intent of the law was to push the ability for information not to be blocked and to be provided by all players. And it was a small N and small E. It gets back to the beginning of the conversation, where wherever our health data is interchanged and exchanged, everybody's accountable in that bucket. Is it Andy? I'm trying to get everybody because I don't have spaces to see.

Andrew Truscott – Accenture – Co-Chair

I'm the English one.

Cynthia A. Fisher – WaterRev LLC – Member

You're the English one. Is Andy the English one?

Andrew Truscott – Accenture – Co-Chair

Yes, ma'am.

Cynthia A. Fisher – WaterRev LLC – Member

I thought, Andy, you said it well in the bucket of the catchall.

Denni McColm – Citizens Memorial Healthcare – Member

I don't think anyone, if you ask them to pass this law in Congress, meant for exchanges, for health information networks to include every provider. In the industry, those are different entities, different actors, and they intentionally separated them. [Crosstalk] [01:11:42]

Andrew Truscott – Accenture – Co-Chair

21st Century Cures actually says information blocking means a practice that is conducted by a health provider. Such a provider knows that such practice is unreasonable and is likely to

interview with, prevent, or materially discourage access, exchange, or use of electronic health information. This is pretty clear in the legislation.

John Kansky – Indiana Health Information Exchange – Member

So, what's the point of defining four actors, then?

Mark Knee – Official of the National Coordinator – Staff Lead

Well, so I just want to make one other distinction here, since Andy, you're talking about – the language from Cures is up on the screen. Along with penalties, there is a distinction in the knowledge that's requisite for the actor. So, if you look here at A, B is conducted by a health information technology developer, exchange, or network. Such developer, exchange, or network knows or should know, whereas if conducted by a provider, such provider knows. So, there's a different knowledge component for providers versus health information exchanges, networks, and developers. I just wanted to clarify.

John Kansky – Indiana Health Information Exchange – Member

So, at the highest level, what's the purpose of defining four actors?

Mark Knee – Official of the National Coordinator – Staff Lead

Okay, so the purpose of defining four actors – sorry.

Cynthia A. Fisher – WaterRev LLC – Member

Okay. I was just gonna suggest that there are many middle players also in the exchange of healthcare information that has significant control over patient information and results, and they aren't necessarily – so, there are middle players. And my understanding would be the actors would also incorporate other middle players.

John Kansky – Indiana Health Information Exchange – Member

If they meet a definition, they are impacted. If they do not meet a definition, then they're not, correct?

Andrew Truscott – Accenture – Co-Chair

Sorry, John, which definitions are we talking about now? This definition?

John Kansky – Indiana Health Information Exchange – Member

Okay. For the regulation to apply to an organization, that organization needs to fit the definition of a developer, a provider, an HIN, or an HIE. Those are the only four possibilities, correct?

Mark Knee – Official of the National Coordinator – Staff Lead

Yes, that's one component that you would look at. Correct, though. Those are the four actors that are identified by Congress in Cures.

Cynthia A. Fisher – WaterRev LLC – Member

And let me go back and say it's small N, small E, which also would include the other players in the healthcare supply chain that have patient information.

Andrew Truscott – Accenture – Co-Chair

Okay, so guys, we need to separate our conversation here. Actors is another piece of conversation we do absolutely have to have. And Cynthia, I hear exactly what you're saying **[inaudible] [01:14:37]** that in the last section of this document. But for right now, we're just talking about HIE and HIN. With the permission of the group, shall we move to go and talk about the parties affected by the information blocking provision at this point? Because I think we need to discuss that before we can come back and be clearer on HIE and HIN. What do you guys think?

John Kansky – Indiana Health Information Exchange – Member Sure.

Andrew Truscott – Accenture – Co-Chair Yeah. Okay.

<u>Sheryl Turney – Anthem Blue Cross Blue Shield – Member</u> I agree.

Andrew Truscott – Accenture – Co-Chair

Sheryl, Cynthia, Denni?

Cynthia A. Fisher – WaterRev LLC – Member Yes.

Denni McColm – Citizens Memorial Healthcare – Member

Yes, fine.

Andrew Truscott – Accenture – Co-Chair

Okay. So, let's scroll down to the bottom, Mark. We've got parties affected by the information blocking provision. Now, I've already made some notes in here anyway with some of my thinkings, which can be all open for discussion. My first one was, well, here we say access that's regulated by the information blocking provision include healthcare providers, health IT developers, health information exchanges, and health information networks. Okay. Do we have any suggestions on how to refine that? I ask one question, though. Does the term "actor" appear in 21st Century Cures? I'm not sure it actually does, but that's okay. But I am saying that we – and pursuant to the conversation we've just been having, the term "actors" – actors need a clear scope, okay?

And this is an ongoing concern I've had, that we're relying on definitions that have been – especially around providers – have been extant in legislation and regulation for some time, and that their healthcare delivery is changing in its very nature, and it's gonna continue to

evolve. And it's gonna be helpful for both industry and patients if we get some clarity here. And I was just throwing about in my mind the idea that what we consider provider for the purpose of the legislation should be sort of any party who processes electronic health information, or a party who creates software services. Or maybe not a provider, but the point is that we need to capture a changing ecosystem, where, for example, someone like a retail pharmacy **[inaudible] [01:17:02]** of health information. But they don't consider themselves to be a provider or governed or bound by any of this legislation. Discuss.

Mark Knee – Official of the National Coordinator – Staff Lead

While you guys are thinking that over, I just want to – I pulled up a relevant page in the preamble, page 331, where we talk about, Andy, your point about actors. That was a term of ours that we used right here. So, this might be a helpful paragraph to kind of explain to frame what we're talking about.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

Can you read it? I just have a black . . .

Mark Knee – Official of the National Coordinator – Staff Lead

Sure. It says Section 3022 A1 of the Public Health Service Act, in defining information blocking, refers to four classes of individuals and entities that may engage in information blocking, and which include healthcare providers, health IT developers of certified health IT networks and changes. We propose to adopt definitions of these terms to provide clarity regarding the types of individuals and entities to whom the information blocking provision applies. We note that for convenience and to avoid repetition in this preamble, we typically refer to these individuals and entities covered by the information blocking provision as actors unless it is relevant or useful to refer to the specific type of individual or entity. That is, when the term "actor" appears in this preamble, it means an individual or entity that is a healthcare provider, health IT developer, exchange, or network, for the same reasons we propose to define actor in our definition section.

Cynthia A. Fisher – WaterRev LLC – Member

So, let me give you an example of what I would consider from a patient perspective significantly is the payer as an actor in the interchange and the exchange, a significant actor. And I would think that's covered through the networks and exchanges, as well as the middle players we've discussed. But I mean, a critical component of that is the payer and the information the payer has, as well as the claims databases.

<u>Sheryl Turney – Anthem Blue Cross Blue Shield – Member</u>

Yeah, I agree with you, but I think they didn't list out all the actors. And I think there are dangers to listing out all the actors, because beyond payer, I can think that there are different services that combine social health and economic data, like LexisNexis, and lots of other things that could be listed here that we probably can't even get into. But no, I agree that they would be a payer. But I don't think the intent is to list them all out, but to describe the class of service, which I think is what we've been talking about for the last hour that they're trying to do.

Denni McColm – Citizens Memorial Healthcare – Member

Doesn't this preamble reference – the definition reference a specific definition of provider that's someplace else?

Andrew Truscott – Accenture – Co-Chair

Well, the proposed [inaudible] [01:20:11] privacy and security rules definition?

Denni McColm – Citizens Memorial Healthcare – Member

I thought it was not the privacy and security rules. It was -

Andrew Truscott – Accenture – Co-Chair

No, it says we are considering assisting the information blocking definition of a healthcare provider to cover all individuals and entities covered by the HIPAA healthcare provider definition.

Denni McColm – Citizens Memorial Healthcare – Member No.

Mark Knee – Official of the National Coordinator – Staff Lead

No. Where are you looking, Andy? Because we -

Andrew Truscott – Accenture – Co-Chair

332.

Mark Knee – Official of the National Coordinator – Staff Lead 334? Hold on.

Andrew Truscott – Accenture – Co-Chair

No, 332.

Mark Knee – Official of the National Coordinator – Staff Lead 332.

Cynthia A. Fisher – WaterRev LLC – Member Andy, I can't hear you very clearly.

Andrew Truscott – Accenture – Co-Chair

Sorry, I'll start speaking slower.

Cynthia A. Fisher – WaterRev LLC – Member That's better. [Crosstalk] [01:20:48]

Denni McColm – Citizens Memorial Healthcare – Member

The public health definition, and then it said, or we will comment on whether or not we should use the HIPAA definition.

Andrew Truscott – Accenture – Co-Chair

Correct.

Mark Knee – Official of the National Coordinator – Staff Lead

Yeah, exactly. So, right now we use the Public Health Service Act definition, but we opened it up for comment about whether we should switch to the HIPAA definition or any other definition.

Denni McColm – Citizens Memorial Healthcare – Member

So, the difference is that the Public Health definition does not include payers and clearinghouses, right? But the HIPAA definition does.

Mark Knee – Official of the National Coordinator – Staff Lead

So, I can't really speak to the differences. I think if you want to talk about it, you can pull up the definitions. And I think that's part of the goal of this group, is to decide whether the four categories of actors encompass all of the real-life actors that you think should be covered based on Cures and our rule.

Andrew Truscott – Accenture – Co-Chair

Okay. So, the HIPAA definition of the healthcare provider is a provider of services as defined in Section 1861 of the act. A provider of medical or health services, and any other person or organization who furnishes bills or is paid for healthcare in the normal course of business.

Cynthia A. Fisher – WaterRev LLC – Member

Yes, I think that's very important, because we have pricing on here. And if we look at the movement that's been made in insurance and coverage of pushing to the employed high deductible and higher copays and the high cost of insurance. So, if we're really gonna move to empower the consumer with access to their data, we're going to move to disruption through access to pricing, so that the patient can be in control of not only the management of their health, but the management of their wallet in their choices. So, I think we do want to make sure that we include anyone who transacts over a patient's misfortune. So, anyone who has a financial benefit or a financial transaction, just like we have in our bank accounts, we see it, every single transaction listed that affects debits and credits. So, I think it's really imperative as we look to the future. This is gonna play an ever more important role to the consumer having control of their financial health, which actually affects their physical health and mental health.

Andrew Truscott – Accenture – Co-Chair

So, I kind of made a suggestion, that we somehow suggest that we write this so that we just say any party who processes electronic health information. It's crisp and short and sweet.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

It would be pretty broad.

Andrew Truscott – Accenture – Co-Chair

It would.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

What's the matter with the definitions that are already in the various rules?

<u>Andrew Truscott – Accenture – Co-Chair</u>

Okay, because of the HIPAA one -

<u>Sheryl Turney – Anthem Blue Cross Blue Shield – Member</u>

I think the question is to use the Public Health definition or to use the HIPAA definition of a provider. And this is specifically the provider of the four actors, if I'm getting the question right.

Andrew Truscott – Accenture – Co-Chair

Well, the HIPAA one doesn't take into account any way where care is being provided either voluntarily or no cost. I don't think we'd want to inadvertently exclude that type of care.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

Doesn't it, though, include anybody who provides care, though? I thought it provided care or had payment.

Andrew Truscott – Accenture – Co-Chair

It's and any other person, actually. But we'd have to go into looking at the Act 42 USC, because I don't know that all by heart. And it seems like –

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

Could we get that from the -

Andrew Truscott – Accenture – Co-Chair

ONC can't provide that to us. From what Mark just said, they can't provide it outside of here.

Mark Knee – Official of the National Coordinator – Staff Lead

Yeah, I can look into – I mean, it might be okay to pull up those definitions on the screen. I can talk to Lauren. But I mean, it might be a good exercise –

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

That would be helpful. That would be helpful for us.

Mark Knee – Official of the National Coordinator – Staff Lead

I'll look into that. I mean, I might also just be able to email out those sections, and then

maybe it could be a discussion point for the next conversation we have.

Andrew Truscott – Accenture – Co-Chair

Yup, that's fine.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

I think that's a great idea.

Cynthia A. Fisher – WaterRev LLC – Member

And I think we need to look broadly because look at the future. I'm aware of employers and retirement funds that are gonna skip insurance, and they're gonna skip hospitals. They're gonna actually put in place their own care for employees and for customers to drive down costs because of the outrageousness of costs today. And so, I know this is coming, and I think we need to look outside of medicine as we know it today, because it will be disrupted. And this way, it kind of captures all, and I like your broader approach, Andy.

Andrew Truscott – Accenture – Co-Chair

But I can hear both sides of this. I agree with you. Self-insured companies is a good one. I must confess, guys, I do have a bit of a beam upon it right now about, firstly, conversions going on in the industry and nontraditional providers who are seeking to become healthcare providers. And we need to encompass them as well, otherwise, we're gonna – especially when they're targeting particular niches of patient groups, and we don't want those patient groups to not feel the benefits of this legislation, which I think we all agree that this is beneficial legislation. Do we agree?

John Kansky – Indiana Health Information Exchange – Member

In general, yes. I'm just exploring the other side of the – so, I'm trying to think of the most ridiculous potential – I mean, how familiar are you with local health departments? Most local health departments are two ladies in the basement of the county courthouse. But they're gonna exchange electronic health information in some way, somehow. And therefore, now they meet your definition and they're an actor. And is that okay? What do we now require of every local health department in the United States that we intended to or didn't intend to? I mean, I'm just asking myself the question.

Andrew Truscott – Accenture – Co-Chair

Do they have an exception? I'm musing on it now as well. You can imagine this is a virtual living room; we're kicking back thinking about this. Would they have an exception?

John Kansky – Indiana Health Information Exchange – Member

I don't know. [Crosstalk] [01:28:09]

Cynthia A. Fisher – WaterRev LLC – Member

I don't think they're included in either one of the definitions that are proposed by ONC.

Andrew Truscott – Accenture – Co-Chair

Well, what function are they performing, that local health department, John?

John Kansky – Indiana Health Information Exchange – Member

Immunization registries, delivering registries. In some cases, these cancer registries, disseminating information about H1N1, etc., etc., etc.

Andrew Truscott – Accenture – Co-Chair

So, I'm not sure disseminating information, because that's non-patient identifiable, etc. But then immunization records, registries, they are by definition individually identifiable. That will come under certainly the definition of EHI, which we'll discuss shortly, if not next time. And would they fall under – are they providing the immunizations?

John Kansky – Indiana Health Information Exchange – Member

In some cases. But let's just assume they don't.

Andrew Truscott – Accenture – Co-Chair

So, they'd come under reporting health information if they are the immunization registry for individuals, and they aren't able to provide access to that data, would that count as information blocking? It seems likely.

Denni McColm – Citizens Memorial Healthcare – Member

It seems like it's an example of why a broad statement of anybody who has any electronic health information would be subject to this isn't workable, because it includes so many people in the universe, so many entities.

Andrew Truscott – Accenture – Co-Chair

So, then we need to draw the line of how specific do we get, or do we not say anything about the actors at all, and just say if you do these things? So, if you exchange, use, store health information. Or do we suggest that actually, there are certain actors that should be excluded from this?

Mark Knee – Official of the National Coordinator – Staff Lead

This is Mark, just chiming in. Good conversation. Just want to note once again, though, that we are working off of the definition of information blocking within Cures. So, we're kind of limited in that regard. Just wanted to note that.

Andrew Truscott – Accenture – Co-Chair

I wouldn't describe the definition in Cures as limited.

Mark Knee – Official of the National Coordinator – Staff Lead

I'm saying that ONC and what we are defining. I think you all are more than welcome to -I think it's a good conversation. I just wanted, as the background of where we came up - what definition we're working off of and why we've identified those four actors, that's from Cures.

And I pulled it up on the screen.

Andrew Truscott – Accenture – Co-Chair

Okay. So, under **[inaudible] [01:31:36]** discussion there about, let's just say, immunization provided by the medical **[inaudible] [01:31:42]**. It seems pretty straightforward that they would actually classify as a provider. Do we all agree with that? Whether we agree with it or not, do we agree with the interpretation?

Denni McColm – Citizens Memorial Healthcare – Member

That who would classify?

Andrew Truscott – Accenture – Co-Chair

The local health department who's performing immunizations.

Denni McColm – Citizens Memorial Healthcare – Member

I just don't think that's the question before us. I think the question is do we accept the Public Health definition of a provider or the HIPAA definition of a provider? Maybe we could look at those two. And then if we disagree with that and we're saying we have a third definition of provider that we want to put forth, that's yet another question.

Andrew Truscott – Accenture – Co-Chair

Okay. Mark, could you, for the next time we meet, can you distill and pull down the HIPAA and the Public Health definitions of provider, please?

Mark Knee – Official of the National Coordinator – Staff Lead

Yeah. I'll touch base with Lauren to make sure that's okay, but I assume it is, so no problem there from my end.

Andrew Truscott – Accenture – Co-Chair

Okay. On that basis, guys, can we park this one until next time we meet?

Cynthia A. Fisher – WaterRev LLC – Member

Yes, thank you.

John Kansky – Indiana Health Information Exchange – Member Fine with me.

Denni McColm – Citizens Memorial Healthcare – Member Yes.

<u>Sheryl Turney – Anthem Blue Cross Blue Shield – Member</u> Yup.

Andrew Truscott – Accenture – Co-Chair

Okay. I'm in your hands at this point for the last 25 minutes. Do you want to go and look at the defendant of health information, or something around price information and looking for our comments on price information, or around additional practices that we think may implicate the information blocking provision? Each of those will take way more than 25 minutes, so has anyone got any burning stuff they'd like to discuss?

Cynthia A. Fisher – WaterRev LLC – Member

Andy, I'd like to come prepped for the price information and health information. I have a couple of questions. I want to look back at the HIPAA law. I think when Mark does the research for us, it might be helpful for him to go back, and when we get those two definitions from HIPAA and Public Health, it might be helpful to then deal with that definition at the same time as we're looking at actors and that. My suggestion is a real meat issue is the information blocking. And perhaps we start there. I was just gonna suggest that because that's the stake. And then we could go back to those other definitions. Just a suggestion.

Andrew Truscott – Accenture – Co-Chair

That works for me entirely. Can you just reiterate the additional things you want Mark to look into while we're in availance?

Cynthia A. Fisher – WaterRev LLC – Member

The health information definition at the top on HIPAA. You're gonna look at that.

Mark Knee – Official of the National Coordinator – Staff Lead

Well, we're talking about for healthcare provider, right, for the different Public Health Service?

Andrew Truscott – Accenture – Co-Chair

This is just and is also to look at the definition of health information as by HIPAA?

Cynthia A. Fisher – WaterRev LLC – Member

Yes, too. Yes, thank you.

Mark Knee – Official of the National Coordinator – Staff Lead

Well, so the definition of electronic health information is our definition. It's not from the Public Health Service Act or HIPAA.

<u>Andrew Truscott – Accenture – Co-Chair</u>

Yeah. I think the question was we're looking at how HIPAA does define it.

John Kansky – Indiana Health Information Exchange – Member

Is there an explanation as to why the HIPAA definition wasn't used in this reg?

Mark Knee – Official of the National Coordinator – Staff Lead

Yeah. Well, I'm not sure if we touch on that specifically. I can pull up the language. There's preamble discussion at length on how we came about defining electronic health information. So, I think that'd be a helpful . . .

Cynthia A. Fisher – WaterRev LLC – Member

Yeah, let's look at that. And then if you can give us also the HIPAA, that'd be helpful. And I think we'd just get our understanding, and then we can fine-tune it, if need be. But I think it's helpful to have that. Do you all agree or not?

Andrew Truscott – Accenture – Co-Chair

Yeah, I think it's useful to have that just to make sure they're at least lined up, or if there is a delta we think is a meaningful and appropriate delta, we recognize that.

Mark Knee – Official of the National Coordinator – Staff Lead

Okay. So, just to be clear, the request is the definition of care provider under Public Health Service Act and HIPAA, and then also the HIPAA definition of EHI. Is that right?

Andrew Truscott – Accenture – Co-Chair

Yes.

Mark Knee – Official of the National Coordinator – Staff Lead

Okay.

Cynthia A. Fisher – WaterRev LLC – Member

Yeah. And your preamble that you said that you had before the EHI or whatever. That's helpful, just for us to –

Mark Knee – Official of the National Coordinator – Staff Lead

Do you want me to pull that up? I can pull that up on the screen now, or if you want to take time to read through it and discuss next time, I can do that as well.

Cynthia A. Fisher – WaterRev LLC – Member

Can we do the latter? I can't pull it up, I'm sorry, because I'm -

Andrew Truscott – Accenture – Co-Chair

That's okay. We'll do it next time up.

Mark Knee – Official of the National Coordinator – Staff Lead

Okay, great.

Andrew Truscott – Accenture – Co-Chair

Let's move to – okay, so there is a request for comment regarding practices that may implicate the information blocking provision, okay? So, specifically, we request comment

regarding our proposed **[inaudible] [01:36:50]** practices that may implicate the information blocking provision. Specifically, we seek comment on the circumstances described and other circumstances that may present an especially high likelihood that a practice will interfere with access, exchange, or use of the EHI within the meaning of the information blocking provision. So, the comment is, is the definition . . . wait a second. Are the descriptions of practices of information blocking appropriate or not?

John Kansky – Indiana Health Information Exchange – Member

That sounds like fun to discuss. Where should I be looking for those practices? In the preamble?

Andrew Truscott – Accenture – Co-Chair

I'm just running down into it right now, because I made the mistake of searching for the term "information blocking" inside the PDF. And I found 540 separate places of it. Hang on a second. Mark, can you point us to the right page where the practices are described?

Mark Knee – Official of the National Coordinator – Staff Lead

Sure. Sorry, for the price information, or what specific language?

Andrew Truscott – Accenture – Co-Chair

Preamble, 353 to 379. Okay, so it's the last line of 353. And it's practice must be likely to interfere with the preventable materially discourage access, exchange, or use of EHI. And they discuss hypothetical practices that could implicate the provision. They do say these practices are illustrative, not exhaustive, which implies to my reading that these practices are examples of information blocking and aren't ones which could be reinterpreted as not being, I think.

Mark Knee – Official of the National Coordinator – Staff Lead

Well, let me jump in there, just to be very clear. No, you're not wrong. You're not wrong. And this is a very, very important point that we make. Well, we try to say it a bunch in the rule, is that to implicate the information blocking provision and definition is not necessarily to violate it. And we provide examples. So, in this section, we describe conduct that would most likely implicate the information blocking definition, meaning it would fall under the scope of the defendant in Cures. However, there are circumstances that we talk about, whether it would be required by law or covered by an exception, that would mean that even if it implicates the information blocking provision, it wouldn't necessarily violate the information blocking provision, it wouldn't necessarily violate the information is gonna be a very fact-specific analysis. So, it made sense to lay out situations that would be problematic, and then we get into the exceptions to say, you might have done this, but you had a really good reason that falls under the exceptions to do it.

John Kansky – Indiana Health Information Exchange – Member

I'm sorry if I'm being a Neanderthal. I'm trying to make sure I'm tracking with what we're trying to accomplish here. So, the issue is, in here, they're saying, hey, we've got these circumstances that – this list of practices that we think are examples of – I don't want to say

egregious, but prototypical information blocking. Do we have comments on whether they've got the right practices? Is that the question?

<u>Andrew Truscott – Accenture – Co-Chair</u> Yes.

John Kansky – Indiana Health Information Exchange – Member And where's that?

Andrew Truscott – Accenture – Co-Chair

Page 364. Examples of practices likely to interfere with access, exchange, or use of EHI.

John Kansky – Indiana Health Information Exchange – Member

Okay, navigating to 364.

Andrew Truscott – Accenture – Co-Chair

Yeah. I can hear you wheeling on your mouse.

John Kansky – Indiana Health Information Exchange – Member

I'll try and keep it down.

Andrew Truscott – Accenture – Co-Chair

Finally, when we actually get to the bottom of 265, we finally get to an example. The health system's internal policies or procedures require staff to obtain an individual's written consent before sharing any of the patient's EHI with unaffiliated providers for treatment purposes, even though obtaining an individual's consent is not required by state or federal law.

Mark Knee – Official of the National Coordinator – Staff Lead

And while people are thinking this over, just a heads up, I think we have about five minutes until the public comment period.

Andrew Truscott – Accenture – Co-Chair

Thank you.

Mark Knee – Official of the National Coordinator – Staff Lead Yup.

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Andrew Truscott – Accenture – Co-Chair

And the second one was an EHI developer's software license agreement prohibits customers from disclosing to its IT contractors certain technical interoperability information, without which the customer and its IT contractors cannot efficiently export and convert EHI for use in other applications. The third one is, an HIN's participation agreement prohibits entities that receive EHI through the HIN from transmitting that EHI to entities who are not participants of the HIN. And then lastly, an EHI developer sues to prevent a clinical data registry from providing interfaces to physicians who use the developer's EHI technology and wish to submit EHI to the registry. The EHI developer claims that the registry is infringing the developer's copyright, his database, because the interface incorporates data mapping that references the table headings and rows of the EHI database in which EHI is stored.

John Kansky – Indiana Health Information Exchange – Member

Honestly, Andy, I need to think about every one of these.

Andrew Truscott – Accenture – Co-Chair

I know. I think we probably all do. We've been asked to comment on those practices, and those are very, very specific practices. Mark, is the intention here at we would actually extend the list of example practices, potentially?

Mark Knee – Official of the National Coordinator – Staff Lead

Yes. So, just to clarify my position, so this wasn't initially one of the topics that I had on my list to discuss. But I guess I don't see it as requiring as much input as others, like the definition of EHI or exchange or network. And I know, Andy, you thought it was important and wanted to talk about it. And I'm fine with it. But as far as – I guess I didn't really have a goal. It was more that you felt that it was important and wanted to discuss.

Andrew Truscott – Accenture – Co-Chair

Yeah. I'd forgotten this was mine. Yeah. So yeah, John, I think, given the fact that you want to read it and think about it, it's important we discuss it.

Mark Knee – Official of the National Coordinator – Staff Lead

But just to add onto that, I do think we do have a request for comment that I put in there in the rule, so I think if you read these examples and kind of the categories of information blocking that we break it up into, and if there's conduct that you think maybe we aren't clear enough about or that it would be useful to add another example, or things like that, if we're missing something, or we got something wrong that goes throughout the rule, we want to hear about it. So, I think it is a good thing to read over and think about and digest, and I'm very open – of course, open to comments and suggestions on that.

Andrew Truscott – Accenture – Co-Chair

Cool. I'm also reminded by the comments that Denni and Sheryl have made as well around we've got to be cautious here about the unintended consequences of the rules, and that we don't inadvertently cause a restriction with blocking data information and care.

Mark Knee – Official of the National Coordinator – Staff Lead

Well, and not to be a broken record, but just – so, these are situations that, like we're saying, likely implicate the information blocking provision and are problematic based on the facts we provide. But it doesn't mean that it's a violation of the information blocking provision. So, it's not locking – people that do this, it's not saying you're locked into a penalty, because you would go through the analysis of whether it's required by law, whether an exception applies, and then you would see whether it actually violated the information blocking provision.

Andrew Truscott – Accenture – Co-Chair

My suggestion would be, at this juncture, I don't think we – I think all of probably need to go and have a think and consider a lot of the discussion today, and come armed and think about things for next time, and also, contribute to the actual document as we're drafting it. I'm happy to open up to public comment. Does the group agree?

John Kansky – Indiana Health Information Exchange – Member

Yes.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

Yeah, that works for me.

John Kansky – Indiana Health Information Exchange – Member

Perhaps they have solutions for all of our problems.

Andrew Truscott – Accenture – Co-Chair

That would be wonderful. I'm hoping they do.

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

And Operator, if you can open the public line, please.

Operator

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

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

Okay. And I don't think there are any public members on the participant list, so I think you guys are stuck with the hard part. But Operator, do we have any comments in the queue at this time?

Operator

We have none at this time.

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

Okay. So, we've got about 10 minutes or so. I know this was a pretty exhaustive conversation today. So, it's sounding like we're good for a break at this point, unless there's any last-minute burning items to discuss, and then we'll pick up again later.

Mark Knee – Official of the National Coordinator – Staff Lead

Hey, Lauren, this is Mark. Just a question. There was a request that I provide some different HIPAA and Public Health Service Act language as background. Is that something that, in my role – I mean, I'm fine doing it, but I just wanted to make sure that that is acceptable based on the HITAC –

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

Sure. As long as you're using any publicly used definition, that's fine.

Mark Knee – Official of the National Coordinator – Staff Lead

Okay.

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

Or publicly used material, sure. Mm-hmm.

Andrew Truscott – Accenture – Co-Chair

Great. Yeah, Mark, we just asked Mark to climb into the Public Health Service Act and HIPAA, jus to find out the definitions therein, so we can look at what we're being referred to.

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

Sure.

Andrew Truscott – Accenture – Co-Chair

Okay, great.

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

No problem.

Denni McColm – Citizens Memorial Healthcare – Member

So, this is Denni. I have a question about the Google doc. Do you want us to put comments in the Google doc between meetings, or is that just something we collaborate on during meetings, or how does that work?

Andrew Truscott – Accenture – Co-Chair

No. Stick comments in the Google documents at any time you feel it's appropriate. So, please do. I think we can only get through this task if we're putting in things as they come to us. I know that some of the comments I put in, I put in – I was on the move because it just came to me. So, please do.

Denni McColm – Citizens Memorial Healthcare – Member

All right, thank you.

<u>Andrew Truscott – Accenture – Co-Chair</u>

Guys, honestly, thank you, because this level of conversation surpasses my expectation. Thank you ever so much. Really, really do appreciate it.

<u>Sheryl Turney – Anthem Blue Cross Blue Shield – Member</u>

Andy, you're a great leader. Thank you.

<u>Andrew Truscott – Accenture – Co-Chair</u>

No, I wouldn't go that far, but we're a herd of cats, but okay. Thank you.

<u>John Kansky – Indiana Health Information Exchange – Member</u> Thank you.

<u>Mark Knee – Official of the National Coordinator – Staff Lead</u> All right, thanks, everyone.

Cynthia A. Fisher – WaterRev LLC – Member

Thanks, everyone.

Andrew Truscott – Accenture – Co-Chair

Have a good day. Thank you, guys.

Cynthia A. Fisher – WaterRev LLC – Member

Okay, you too. Bye.