Information Blocking Workgroup 1

Transcript
March 14, 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
Cassandra Hadley	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Mark Knee	Office of the National Coordinator	Staff Lead
Penelope Hughes	Office of the National Coordinator	Back Up/ Support

Transcript

Operator:
Thank you. All lines are now bridged.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good afternoon everyone, and welcome to the Information Blocking Workgroup No. 1 meeting on relevant statutory terms and provisions. Thank you for joining us. I will officially call the meeting to order, starting with the roll call. Andrew Truscott. Is not here. Michael Adcock?

Michael Adcock – Individual – Co-Chair
Here.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sheryl Turney. John Kansky?

John Kansky – Indiana Health Information Exchange – Member
Here.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denni McColm.

Cynthia A. Fisher – WaterRev LLC – Member
Sorry.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Was that Denni? Okay, Cynthia Fischer?

Cynthia A. Fisher – WaterRev LLC – Member
Present.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Great. Thanks, everybody. And so now, I'll turn it over to your chair, Michael Adcock.

Michael Adcock – Individual – Co-Chair
Good afternoon, everyone. Thank you for all being here. I know Andy sent me a message earlier saying he was going to be a little bit late, so – but obviously, that doesn't slow us down. We've got lots to talk about. The goal for today, we are going to start with practices that may implicate the information blocking provision then move on to parties affected by it, and then the primary focus – hopefully we'll get through a lot of this today – is to narrow and revise the draft recommendations. Mark has a lot of those recommendations to put together and put into a slide deck by tomorrow

evening – late tomorrow evening, so that we can have them out by Saturday. As you all know, we're quickly approaching our deadline and quickly approaching the in-person meeting, so we'll go ahead and get started. Unless someone has something they want to bring up from last meeting.

We'll go ahead and start with practices and then hopefully have some discussion on that, and then parties, and then move on to the draft recommendations. All right, Mark, if you – I see you've pulled your screen over. We'll go ahead and get that pulled up. I know John said he had some comments prepared for practices, so we'll go ahead and open that part up for discussion.

John Kansky – Indiana Health Information Exchange – Member
Thank you. This is John. So, what I did – and tell me if this is, hopefully, consistent with the intent of what we're trying to discuss today. We're back to the preamble pages 364 through – I don't know, about 370 – where the examples are listed. We talked about some others on previous calls and I had the chance to go through those in more detail. And, comments in general, I think they're reasonable in their intent, and I have some specific examples I want to focus on that were offered in the preamble. I think they're all fair in their intent. I wanted to make the general comment that I think the subjectivity that's implied in a lot of these examples in the terminology in the preamble is going to create a lot of need for adjudication and possible mitigation that to me, in my view, is undesirable for regulation. To the extent that, whether it be definitions we discussed on previous calls, or clarifying examples, I think subjectivity is going to be bad for those who are trying to comply with the regulation and those who are going to try to enforce the regulation. So, let me stop to take a breath there.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, this is Mark. I think that's great, and I look forward to hearing about your thoughts on the examples. For the group, I'm sure when you read it you understood this. I just want to be very clear once again that the intent of these examples was to provide not an exhaustive list, but just relevant examples of when the information blocking provision would be implicated. We say a number of times that to implicate the information blocking provision does not naturally equate to violating the information blocking provision. Meaning, something could be required by law or covered by an exception. So, I just wanted to add that disclaimer as we jump into this conversation.

Michael Adcock – Individual – Co-Chair
No, and I think that's – this is Michael. I think that's understood. John, did you have some specific concerns, or things that we might want to address, whether some definitions or other areas that we might want to put forward as recommendations or thoughts? John?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
I wonder if he cut out or is on mute.

Michael Adcock – Individual – Co-Chair
I was glad it wasn't me. I thought maybe I had cut out.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
No, I'm still here. I hear you. John, are you there?

Cynthia A. Fisher – WaterRev LLC – Member
It looks like he got disconnected.

Michael Adcock – Individual – Co-Chair
Okay. Cynthia, did you have any thoughts on this area? Maybe everyone got disconnected but us.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Maybe. It could be a short call. Do you want to hold here, Michael, for a minute and just let him jump back on?

Michael Adcock – Individual – Co-Chair
Yeah, let's – and maybe Cynthia as well, I'm not sure.

Cynthia A. Fisher – WaterRev LLC – Member
No, I'm here.

Michael Adcock – Individual – Co-Chair
Okay, good, good. I thought maybe we'd lost you with John.

Cynthia A. Fisher – WaterRev LLC – Member
I'm sorry, did you ask a question?

Michael Adcock – Individual – Co-Chair
Yeah, I was just curious if you had any thoughts. I know that John brought up some concerns about subjectivity of the examples. I didn't know if you had any thoughts on this area, other than I know you put some down in the document. I can see those.

Cynthia A. Fisher – WaterRev LLC – Member
Yeah –

John Kansky – Indiana Health Information Exchange – Member
I'm sorry, this is John. I'm sorry. I got dropped, John Kansky's back.

Michael Adcock – Individual – Co-Chair
Okay, go ahead, Cynthia.

Cynthia A. Fisher – WaterRev LLC – Member
I'm sorry, I didn't hear the last person.

Michael Adcock – Individual – Co-Chair
That was John, he just –

John Kansky – Indiana Health Information Exchange – Member
I'm sorry.

Michael Adcock – Individual – Co-Chair
Cynthia, you can go ahead with your comments.

Cynthia A. Fisher – WaterRev LLC – Member
Yeah, I – you know, I have my comments in the recommendations that were highlighted. So, unless… can people see them? I don't know if they're – can people see them? Yeah, there we go. Yeah. So, that pretty much does it with what my comments are. Thank you.

Michael Adcock – Individual – Co-Chair
Yeah, I appreciate that. I appreciate you taking the time to put them in. John, I don't know if you were able to hear my question or not, but I was wondering **[Inaudible] [00:07:11]** things that need to change or look at in other workgroups **[Inaudible].**

John Kansky – Indiana Health Information Exchange – Member
Sure. So, in terms of my initial comment just about the subjective – and Mark, thank you for your comments earlier, I dropped off right after I heard. Absolutely though, the preamble was extremely helpful, the examples were helpful, and the words "could constitute information blocking" was prominently displayed. In adjudicating whether those will or will not be information blocking – like on page 366, there's a couple of examples that included the words like, "implausible reasons," and a couple other things that were obviously going to be in the eye of the beholder. Insert a period. Going on to some specific examples, if it's helpful, specific examples of examples, on page 365 there were four examples that were given. We spent a little bit of time on a previous call, and went back and I read those, and I think one, two, and three are all absolutely reasonable.

Even the one I focused on about HINs, I think the word "transmitting" in that example maybe possibly should be "retransmitting," to be a little clearer. On example four, on 365, what I wrote is that if there's a way that doesn't require disclosing proprietary information, for example an API, but the registry in the example doesn't have API capability, does that constitute information blocking? So, the example that they give is that an API wants – I'm sorry, a registry – wants to connect in a specific way. And, I believe it was a certified technician **[Inaudible] [00:09:31]** in that way, well, what if they're proposing a different way that doesn't require them to disclose what they feel as proprietary, and wouldn't that be reasonable? As an example.

Michael Adcock – Individual – Co-Chair
And Mark, correct me if I'm wrong, didn't we cover some of that yesterday under being able to look for alternatives? In another workgroup, I know it wasn't in this workgroup, but in another workgroup, we talked about alternative means of that communication.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, so – and you cut out for a minute, so I'm not sure I caught the full scope of the example. What page was that, that you were looking at?

John Kansky – Indiana Health Information Exchange – Member
There were four bulleted examples that began on, I believe, page 365.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Okay.

John Kansky – Indiana Health Information Exchange – Member

And it's the fourth one that I'm referring to, where it gives us an example of a registry.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Okay. Yeah. Maybe I'll – just for clarity, I'll read it – I have it out right here. I'll read it out, and then I'll kind of say my piece. I think the one you're talking about is: "An EHR developer sues to prevent a clinical registry from providing interfaces to physicians who use the developer's EHR technology and wish to submit EHI to the registry. The EHR developer claims that the registry is infringing the developer's copyright in its database, because the interface incorporates data mapping that references the table headings and rows of the EHR database in which the EHI is stored." Right?

John Kansky – Indiana Health Information Exchange – Member
Right, that's the one. So, the point I'm trying to make is, if the registry is saying – if the EHR vendor, or the technology vendor is saying, "Wait a minute. You're forcing us to expose proprietary information, or IP that we want to protect, but we are happy to do this via a different method, like API or whatever that doesn't require us to disclose that information." But the registry's saying, "Yeah, but we want to do it this way." That doesn't quite seem fair.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, and… No, I hear you on that. I guess what I would say is, it's definitely open if you have suggestions on ways to make the example clearer. Please, whenever you have a chance, put them into the Google Doc. With this one, and with every one, you know, it's kind of tricky, right? With information blocking? Because everything is going to be very fact-specific and based on the specific circumstances in a case. So, we tried to provide a general framework of examples that kind of shows the direction we are going in, and the types of situations that we find are problematic.

With this one, I think if we followed it through – you know, say the situation actually happened, and we followed it through to the exception analysis, I think one of the exceptions that might be looked at was whether a reasonable or nondiscriminatory license was offered to use the technology for the interface or something like that. Or whether it was infeasible, the request that was being made. So, there are some exceptions that might apply. I'm not trying to analyze the specific fact pattern but I guess that's kind of what we were thinking. But again, if the example isn't clear, definitely feel free to provide edits.

John Kansky – Indiana Health Information Exchange – Member
If I could add, I think the examples are extremely helpful. They certainly helped me, and I think that's why I opened with the comment that I did. I think what it points to is – you know, what you are saying is each case is going to need to be sort of adjudicated on its set of circumstances. I just – and it may be covered elsewhere in the preamble. But I'm just trying to extrapolate the – who will do that, and what's the – how many? It just seems to invite a tremendous workload and burden on both sides of the equation of adjudicating all these – is it or is it not info blocking?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, so I guess it's a little bit outside the scope of this work group. I'm happy to give background to you all really quickly on that process. So, basically, the 21st Century Cures Act gives enforcement authority to the HHS Office to the Inspector General. So, we're working very closely with the OIG down the road. Right now, we're still receiving complaints of information blocking on an ongoing basis and working to implement our processes, but I can't speak to the staff that is going to be required or –

you know, it will depend on the types of, and the scope of, and number of complaints we get. But I agree it is going to be a lot of work, and it is going to be very detailed and complex a lot of times, which is why OIG and ONC are going to work hand in hand to make sure that the subject matter expertise is available for these types of complex cases.

John Kansky – Indiana Health Information Exchange – Member
And then, I had a couple more comments related to other examples, but I want to give others a chance to have some airtime.

Michael Adcock – Individual – Co-Chair
No, I think that is fine, John. Go ahead. Because Cynthia put her comments into the Google doc, so she has listed several **[Inaudible] [00:15:16]**.

John Kansky – Indiana Health Information Exchange – Member
Okay. I think these are pretty quick. Page 366, there's a brief paragraph, and what I'm considering the fifth bullet after the prior four. I just wanted to make a comment about – there's clearly federal laws giving companies the right to protect their intellectual property. I'm not a lawyer, but my comment on that particular bullet was that we need to allow companies to protect their IP without information blocking, if that makes sense.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
No, that makes perfect sense. That is what we had in mind when we drafted the – there's an exception for licensing on reasonable and nondiscriminatory terms. So basically, it's saying that if you have an interoperability element, meaning some means of sharing that's necessary for the sharing of electronic health information, you have to offer that interoperability element to license or use on reasonable, nondiscriminatory terms, and we go through the interaction that would be necessary. And we have innovation and IP rights in mind, but your concerns are definitely legitimate, and I'd encourage you maybe to take a look at that exception, to make sure we covered everything as far as IP goes, if you have concerns.

John Kansky – Indiana Health Information Exchange – Member
Thanks. And then – almost done – two bullets later, which I'm considering seven and eight, those are the second and third bullets on page 367. They both sounded like nasty anti-innovation things that a company might do, but I was just posing the question: are they information blocking? If you want to – both of those examples sound like, "Oh, yeah. That's kind of crappy. I hope companies would refrain from doing that," but I'm asking the group, is it information blocking?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, and I'm going to pull – for those looking at my screen, I'll pull over those examples that you're talking about for clarity.

Michael Adcock – Individual – Co-Chair
That's exactly what about what I was to ask. Thank you.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
There you go. I think it's these two that John is talking about, right here.

John Kansky – Indiana Health Information Exchange – Member
It begins with, "An EHR developer ostensibly…," and then the other one, "A provider notifies the EHR developer..." I'm not saying they're not information blocking, I'm saying those examples lead to a broader place than I was before I read them.

Michael Adcock – Individual – Co-Chair
Maybe I'm just – maybe I'm a little too broad on my thoughts of information blocking, but they certainly seem like information blocking to me.

Cynthia A. Fisher – WaterRev LLC – Member
Yes, I agree. This is Cynthia. I think when you look at language about, "the developer will provide only the EHI in PDF format," I mean, we all know that the technology industry is best served to have everything in a machine-readable format in the patient records themselves. I think Andy said it well the other day, that they need to be in human and machine-readable format to deliver timely ability for interoperability and exchange, otherwise you're really looking at clever blocking mechanisms.

John Kansky – Indiana Health Information Exchange – Member
And then, I see your point and respect the opinion. I guess what I was keying on in that last example of the EHR developers switching systems is that it seems very indirect to the intent of the info blocking legislation. Meaning, we're trying to make sure its data can be exchanged between actors and patients, and this seemed to be a business transaction between a technology vendor and a provider. But I see your point.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
And just as a little bit of – I'm sorry. Go ahead, Cynthia. Sorry.

Cynthia A. Fisher – WaterRev LLC – Member
If patients are best served, we're going have the world of open APIs, and the ability for that interchange to work as seamlessly as banking does in a transactionary way today. So, I think we just need to support optimization the way we live in the rest of the world in our mobile society. In the benefit of the patient and physicians that can't get access in trying to provide and diagnose care.

Michael Adcock – Individual – Co-Chair
And John, I agree –

John Kansky – Indiana Health Information Exchange – Member
Go ahead.

Michael Adcock – Individual – Co-Chair
This is Michael again. The only thing I would add is, if the last sentence in there wasn't that it could and does produce the data in a commercially reasonable format, if it couldn't and didn't, then we might be talking about something different, but if they're already doing it, it just seems like a way to keep the provider from being able to have information that they need to assist patients.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
To me, that's –

John Kansky – Indiana Health Information Exchange – Member
I'll get off with this one. The last thing I would add is that in Cynthia's point, which is valid, I would say if the current EHR vendor and the future EHR vendor are both implementing APIs, then I think there's a version of what Cynthia's suggesting would be achieved. I get your point. I'll get off of it.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
I just wanted to jump in with a point of background. A lot of these examples are based off of stakeholder feedback we've heard for years, and this is a prime example of holding up data because a developer doesn't want a provider to export it and move it. Just to emphasize what Michael said, that last clause is really important, that they have the capability of doing this, and they're already doing it. If they didn't, then they would probably look into an exception – maybe feasibility, or something like that – to determine whether they're covered or not.

John Kansky – Indiana Health Information Exchange – Member
Got it, thank you.

Michael Adcock – Individual – Co-Chair
Okay, are there any other comments? Has anybody joined that wasn't on before? Are there any other comments on the practices portion of this?

Cynthia A. Fisher – WaterRev LLC – Member
It's Cynthia. I just think also, as we look at open APIs, and we look at how we manage the rest of our lives, we are in a moment in time to deliver on real price transparency across the system. So, to that end, it's really to have the broadness as we approach this. I think as we look as a team at the entire proposal on information blocking, as a consumer, as a patient, as a caregiver, and as physicians trying to get access to be better doctors, we see that the patient's both physical health and financial health are impacted by care decisions. So, it's the whole spectrum. Medical debt and financial duress also circles back and impacts health, right? I think it's ever more important too, that as we look at these definitions, we keep that in mind about letting us be able to allow for the open API architectures to allow for the Uberization of healthcare.

That, wherever we are, and wherever we go as we manage the rest of our lives – that push and pull for the consumer – that our definitions and who is accountable in the exchanges and the networks includes everybody who is transacting and financially benefiting from the care provided to that patient. And who has those contract-negotiated terms throughout that system, so that care decisions – such as insulin regimen, when new drugs cost five times the amount of an old regimen, and can desperately put a patient in duress financially, which causes blood sugar to go up, right? We don't know the relationship there. I mean, if you look at the impact, I think we behoove ourselves to make sure the net is cast wide enough and our terms are broad enough that we can allow technology to deliver the best quality of care at the lowest possible price, and choices, and fairness in the system.

Michael Adcock – Individual – Co-Chair
I hear what you're saying, for sure, Cynthia. Did we have – I noticed that all these are, as appropriate, comments above the line. Were there any other solid recommendations besides comments that we wanted to make in this section?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
You don't need to have them now. Like I was talking to some of you before the call, if you come up with ideas for recommendations, I'd ask that you maybe input them into the Google Doc between now and COB tomorrow. That would be helpful.

Michael Adcock – Individual – Co-Chair
Okay. We can certainly do that. And if there's – I'll say this, to the comments above, and I'm sure Andy will do this as well, if there's things above the line that you want to be below the line, certainly feel free. Just copy those and put them below. If there's no more discussion on practices, we will move on to parties. Any more on practices? Hearing none, if you'll scroll a little bit, Mark.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yep. I'm on it. There we go.

Michael Adcock – Individual – Co-Chair
Yes, I know that there were a lot of comments on this one as well, and I would like to open the floor up to anyone that would like to discuss the term 'actors.' I know there's been discussion about 'actors' being broad. There was a discussion about 'actors' not including payors, how we want to include them, make sure that we're not being restrictive… and then we had a recommendation at the very bottom. I don't know if that was a recommendation that we had worked through as a group, it may have been on the call that I missed, but I open the floor up for discussion.

John Kansky – Indiana Health Information Exchange – Member
This is John. I may have missed the previous discussion or comments on payors being actors or not being actors. Given the definition that has cast of HIE and – okay, so let me start that sentence all over again. We talked about, on an earlier call, that as written, the definition of HIE and HIN seems so broad as all providers would also be health information exchanges, for example. Has anyone checked the hypothesis that a payor would also be a health information exchange or health information network?

Cynthia A. Fisher – WaterRev LLC – Member
So, I'm sorry. This is Cynthia, is that question about whether payors would be actors?

John Kansky – Indiana Health Information Exchange – Member
Essentially.

Michael Adcock – Individual – Co-Chair
Go ahead, I'm sorry.

Cynthia A. Fisher – WaterRev LLC – Member
John, did I hear you agree that they should be encouraged, that they should be considered as actors?

John Kansky – Indiana Health Information Exchange – Member
I don't know why we wouldn't want to include them as actors.

Cynthia A. Fisher – WaterRev LLC – Member

I 100 percent agree with you, John. I'm just editing now into my comments that we need to include payors as actors and keep a very broad definition of the actors to include anyone who has contract-negotiated terms, or financially benefits from the healthcare transaction with the patient, to be inclusive. So, that would be providers, payors, it would be all the middle players as well. That would be your pharmacy benefit managers, your GPOs, your brokers, all along the food chain, or the supply chain of healthcare. All the middle players engaged in delivery of care that benefit financially from the patient's transaction.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead

And just to – I think that's a great conversation, I just want to steer it in the right direction. So, as far as actors go, that's what Cures said: providers, developers, exchanges, and networks. As far as payors and other groups, I think it's helpful for the conversation, if you think they are a group that should be included, instead of saying that they would be an actor, trying to decide how they would fit into the already identified definitions of actors. Whether it is an exchange, a network, whatever. Because we have to work within the four actors that Cures laid out. Does that make sense?

Cynthia A. Fisher – WaterRev LLC – Member

Yes, is that Mark's voice?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead

Yes. That's Mark.

Cynthia A. Fisher – WaterRev LLC – Member

Okay. Mark? This is Cynthia. So, along that line, that sort of brings up the conversation we had yesterday, which is when the Cures Act wrote about networks and exchanges, it was those players that engaged in networking and the exchanging of health information. So, that does include the broad list of players and actors in the supply chain. I believe if we stick with the broad definition of networks and exchanges, it includes everyone in the supply chain of the delivery of healthcare as players and actors. Then we can get to this new world of empowering consumer during care.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead

Sure, and I think that those are great points. I think that all I was trying to say, really, I think I don't make a lot of sense, but if that's the position the group takes, it might be better to house those recommendations under network and exchange as opposed to where we are now, which is the broad discussion about actors. Because I think they would be more specific. I think what you're saying, if I'm understanding, is that you think networks and exchanges should very broad and inclusive of groups like plans and payors. So, I think that would be recommendations to be included for that specific category.

Cynthia A. Fisher – WaterRev LLC – Member

Yes, although perhaps we should give examples of the participants in the supply chain that financially transact, and name them, and list them. It includes but not exclusive of, that it is a broad definition of network and exchange of those participating, but it's inclusive of payors and providers in the middle players of the supply chain. You get at the whole thing, but you can list them out, and say "inclusive of, but not limited to."

John Kansky – Indiana Health Information Exchange – Member

This is John, reacting to Cynthia's suggestion. Mark, just like those examples that we just went through of practices that might not lead to information blocking, are there examples elsewhere in the preamble of, "So, here is an organization that might be the definition of fill-in-the-blank," and if not, is there an opportunity to introduce that in future guidance documents?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead

Yeah, so there is definitely not as substantive of a list of examples. I'd have to look at the preamble and go back to that to remember if we put examples, but I will say specifically with regards to networks and exchanges, we tried to focus on providing a functional definition. So, you would look at the actual words in our definition and start from there, I think would be a good way to look at it and say, "Is the definition provided by ONC – if I read it, if I'm a normal person reading it, does it cover these specific groups that you're talking about?" As far as putting examples in, that's definitely something we can do in preamble, but generally you don't put examples in reg text, because reg text is supposed to be pretty much exhaustive language, so you're not supposed to put in there "includes but not limited to" example types of situations.

John Kansky – Indiana Health Information Exchange – Member

Yeah, I'm not suggesting anything to the reg text. I guess I'm just suggesting it in the preamble or in future guideline documents, but the only thing I want to observe is that I don't think – we sort of debated this a little bit on an earlier call – I don't think there is general agreement on whether the definition of actors should be very broad and fuzzy or made more precise. As you point out, we are given the actors that we have, we can't create new actors. The only thing I would point out is that taking the functional approach of the definition is going to, in my opinion, cause fuzziness that's going to create unhelpful confusion to the organizations figuring out if they're actors or not. If there were the opportunity to say, "Here are a dozen examples of organizations that meet the definition of this type of actor or that one, and here's five examples of organizations that are no kind of an actor," I think that I, personally, would find that very helpful.

Cynthia A. Fisher – WaterRev LLC – Member

I agree with that. If we can do – there's nothing to restrict us from identifying what it can include, what we know today, and not limit it, too. I think, if you link the actors to having a financial vested interest in the healthcare transaction of the supply chain because they are sharing that information about the patient to the supply chain because they are accounting for their own financial portion of that provision of care, they are actors.

John Kansky – Indiana Health Information Exchange – Member

So given there is dead air, I'm just going to point out – and I think that it is slightly off-topic, but we can come right back – given this broad approach that we're taking with the definition of actor, when you look at the definition of access, which requires connection to all source systems overlaying that with the broad definition of EPHI, that implies a tremendous number of organizations are going to have a very costly, complex, and burdensome time connecting all kinds of sorts of things in all kinds of ways to meet this regulation. While we want the open flow of health information, I'm just pointing out practicality of implementing and enforcing the regulations.

Cynthia A. Fisher – WaterRev LLC – Member
John, that was you, right?

John Kansky – Indiana Health Information Exchange – Member
It was, in fact, John.

Cynthia A. Fisher – WaterRev LLC – Member
Okay, thanks. John, just help me if you can. I'm just kind of thinking this through. Your point is valid. Don't you think electronically and digitally, for decades and throughout their act and course of doing business, that if they already have the invested systems that electronically and data-ly keep track of – I just made up a new word, data-ly! – that digitally keep track of their cost of doing business and they already have it built into the system, and that they are indeed players in the system, and it is already electronically baked in, and is a matter just being bodily part of this system?

John Kansky – Indiana Health Information Exchange – Member
Let me offer what I believe is actually a fairly simplistic example. There's a physician practice, who is clearly an actor, and they have financial data in one system for billing and accounting, and clinical data in another system for patient care. The definition of access and EPHI combine that they have to provide data from both systems, included in a cohesive way in response to inquiries, and they have to be able to do that via API. So, somehow they've got a provider of their **[inaudible] [00:39:03]** that has written an API, they've got a provider of their accounting system that's presumably written a completely different API, and they somehow need to unify a data response from those two different systems, with two different vendors, from two different APIs, and they are a physician practice that has no I.T. department.

Cynthia A. Fisher – WaterRev LLC – Member
They can still provide to the patient the information. Though it is both digitally available, and we are moving to the place where they can provide it to the patient, the information. Even if they need to print it, they can still provide it in a printed form **[inaudible] [00:40:03].**

John Kansky – Indiana Health Information Exchange – Member
If they can't do what I said, if they can't do what I just described, it seems to me anyone can accuse them of information blocking.

Cynthia A. Fisher – WaterRev LLC – Member
If they can provide, I just can see that the systems would be encouraged to be able to provide. You could provide on both sides of that equation.

Michael Adcock – Individual – Co-Chair
Mark, would any of the exceptions kick in here? Would we be looking at a reasonable, non-discriminatory – wouldn't there be something to kick in? Because I hear what John's saying, and I do, especially being in rural Mississippi, and dealing people who have very rudimentary digital health electronic health information systems, EHRs, EMRs. Some really don't have much of anything, they certainly don't have an I.T. department there in the practice by themselves. What mechanism is there to protect those providers, who – they're trying to deliver care to their patients, trying to make sure they have what they need, but certainly don't have the ability or resources to deliver APIs in all these different pieces we are discussing.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Sure, yeah. So, the scenario, just so I am clear, is the situation where an entity would like to act in the right way but doesn't have the money, resources, or capacity to do so, is that generally the scenario we're talking about?

Michael Adcock – Individual – Co-Chair
John, tell me if I'm hearing that – certainly **[inaudible] [00:42:05].**

John Kansky – Indiana Health Information Exchange – Member
I think that's right. It's money, it's sophistication, it's all of the above that are going to be barriers to complying with this reg if we overreach.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah. So, I have got to be careful because I can't really provide analysis, but I will say that I think someone in that situation might look to the infeasibility exception, which talks about relative burden to the person or the entity requesting the information versus the entity that would be providing the information, and we provide a list of factors to determine the relative burden on those actors. It also talks about if an actor is unable, or it's such a financial burden, or they just don't have the capacity to do so, we say that's okay if you show that based on all the conditions and the exceptions, but you would also need to work with the person or entity requesting the information to provide a reasonable alternative means of accessing the relevant information.

Cynthia A. Fisher – WaterRev LLC – Member
Yes, and Mark, to your point on that, so you have this exception basis; however, the reasonable alternative can be in print copy in timely and real-time request to the patient to the best of their abilities on those small practice types of exceptions. We also see so much today in so many systems that care providers actually can provide their, whether it's their primary or their pediatrician – I'm just looking at a system right now in front of me, that's my assistant's pediatric practice, which is non-hospital affiliated. It has health, it has visits, it has messaging, it has billing, it has the entire profile. So, I think there are provisions, and I think we need to move into this new age, and I think these rules are really trying to get us there.

Michael Adcock – Individual – Co-Chair
This is Michael. I don't think anybody's against moving into the future for sure, into where most people are right now. But there is a large portion of the country that doesn't have the resources. So, as long as there are exceptions there to meet them, I don't think any of those practices are information blocking or trying to keep their patients from having what they need. I know a lot of these practices personally, and they'll certainly print things out and everything. I just wanted to make sure there is some exception there, and that we don't overreach.

The second part that I was curious about is – I'm thinking this was one of the workgroups I had to miss, but we have a proposed recommendation in this section concerning actors, is that something we're still wanting to move forward with, or are we wanting to change that, and define all these people under a different group now? I don't know if everybody can see the Google doc, but we do have proposed wording for a proposed recommendation from this workgroup concerning parties.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, I think that might have been – I think Andy might have started working on that, so he might want to weigh in once he joins. If others have thoughts, feel free.

Michael Adcock – Individual – Co-Chair
John, is that something you have access to, or do you want us to read it?

John Kansky – Indiana Health Information Exchange – Member
I don't have access to it at the moment.

Michael Adcock – Individual – Co-Chair
Alright. Mark, do you want to read, or do you want me to?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Sure, I can read it. So basically, and I'm not sure, I can't speak to Andy whether he still feels this way, but it says the workgroup recommends that the definition of actors be augmented to include a functional component followed by illustration of common names for those actors. Proposed wording: "Actors regulated by the information blocking provision include all those organizations and individuals who create, store, curate, or otherwise process electronic health information about a patient, as an individual or an aggregate. Such organizations and individuals may include healthcare providers, healthcare insurers, Health IT developers, health information exchanges, and health information networks."

John Kansky – Indiana Health Information Exchange – Member
I find nothing unreasonable about that statement.

Cynthia A. Fisher – WaterRev LLC – Member
Mark, I added in the comment above, that we could also include the middle players that would engage in – you know, I kind of outlined that it's not limited to, but the players that benefit financially from that patient's transaction, that would include the pharmacy benefit managers, and pharmacy script purchasing organizations, technology companies, IT developers, laboratories, medical device suppliers, brokers and other similar middle-market players that have financial interest in the healthcare supply chain.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
I see that comment, I think that's great. I would kind of try to drill down a little bit more, because – I guess I probably sound like a broken record. Within Cures, Congress said that developers, providers, networks, and exchanges are the groups that are going to be regulated. I think that in our rule we developed the term actors to refer to those four categories of people or entities. So, if the recommendation, like Cynthia put here, is to keep very broad actors, I would just – again, these are your recommendations - I would maybe nudge you in the direction of addressing each of those four actors, namely: exchanges, networks, providers, and developers, and say how you suggest we change those definitions, because that's the construct that we're working under. Just saying that actors should be broader, I am not sure how we would reasonably make those changes, based on Congress's construct.

Michael Adcock – Individual – Co-Chair
So, if I hear you right, Mark, ONC is recommending we broaden the definition, but we broaden them under the four defined actors that are already defined for us. That we go ahead and broaden that under each one of those individually. We try to fit people and others we're talking about into those definitions, or make sure that they fit into those definitions clearly.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Essentially yes. But just since this is being recorded, ONC is not recommending any action by this group, nor am I – I just want to be clear. All I'm saying is that I think everything you all are saying is reasonable and well thought out. I would just direct you to add those comments to the definitions and preamble discussion of networks, exchanges, providers, and developers as necessary in your opinion. This category of actors – I think this was something Andy wanted to add – but, the scope of what we call actors really isn't in question, because like I said, that is from Cures. They're the four actors that Congress laid out. It's more that we are trying to ensure that our definitions of those actors fit – struck the right balance of entities that would be covered. Does that make sense?

Michael Adcock – Individual – Co-Chair
Yes. It does, to me. So, unless somebody else has something to add to this, I think that we can wait for Andy to come and speak to his point about actors, if that was all written from home. I assumed, since it didn't have an "AT" by it that was something that was discussed in the group. So, I guess we need to work on our recommendations under these definitions, then.

Cynthia A. Fisher – WaterRev LLC – Member
Yes, I hear the same. Thank you. Mark, could you just flag that, that we do that in the subsequent meetings, then?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Sure. Yes, I can do that. So, would you all just like to start from the top? Michael, what were you thinking?

Michael Adcock – Individual – Co-Chair
Yes.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Okay.

Michael Adcock – Individual – Co-Chair
That's what I was – go ahead, that's the bottom of the good one. Let's work back from the top down and work through our recommendations, so that we can start the discussions on revisions of, so we can get as far as we can before we run out of time today.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
So, I guess the first one is electronic health information, but it sounds to me that maybe you want to go to health information, network, and exchange definition? That sounds like what you are honing in with the payor and plan discussion. Is that right?

Michael Adcock – Individual – Co-Chair
I think we went through – did we have a recommendation on – didn't we come up with a recommendation yesterday on EHI? They're all running together, so whenever we had the last workgroup meeting.

Cynthia A. Fisher – WaterRev LLC – Member
Yeah, and I added a comment under…

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, Cynthia. I just pulled it up on the screen now.

Cynthia A. Fisher – WaterRev LLC – Member
Ok, great. Thanks.

Michael Adcock – Individual – Co-Chair
So. Mark, it might help if you – I know John is in transit, do you mind reading through that?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Sure. So, just for clarity. Right now, John, below the line items we have regarding the definition of electronic health information – I'm not sure if this right here that I'm highlighting, I'm not sure who pulled that down, that just might be repeating the text. I might just delete that. That just looks like it's number two in the definition.

Cynthia A. Fisher – WaterRev LLC – Member
It might be IT pulled the definition, and was just putting the definition above it, so we can look at it at the same time, close by. I think that's the reason why it was there.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Oh, okay. I'll just put…

Cynthia A. Fisher – WaterRev LLC – Member
So you could see the comments and the definition on the same page.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Oh yeah. No, that's helpful. I'm just going to put "current text" there for clarity. We have one proposed recommendation and we talked quite a bit about this yesterday, is to add text and preamble that clarifies that information is inclusive of human or machine-readable forms. I believe everyone was on board with that, correct?

Michael Adcock – Individual – Co-Chair
Yes.

Cynthia A. Fisher – WaterRev LLC – Member
Yes.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Okay, great. The next one is an addition that Cynthia added to the definition of EHI. So, right now, I will explain the changes she made. It says, "Suggest we update the definition of EHI to" – the first change is – so there's one and two in the definition – that the electronic protected health information and any other information, but Cynthia has added a three to be any other information that relates to the past, present, or future payment for the provision of healthcare to an individual. So, it looks like, Cynthia, correct me if I'm wrong – you pulled out the last clause in two, and moved it to three. I guess, so that that's clearer? Is that right?

Cynthia A. Fisher – WaterRev LLC – Member
We just made it clearer that if any other information – well, that it's still part of it, it's just any other information that relates to it. So, Andy's concern was machine-readable and human form, and it's any other information that – it was just sort of reiterating that. That it's both.

John Kansky – Indiana Health Information Exchange – Member
This is John. I am not sure I am engaged enough to follow… On the very first call, we debated the inclusion of pricing information in the definition of EPHI. Is this group recommending absolutely yes? Because if so, I would like to add the asterisk that the implications of including that data in the national cost of complying is going to be significant.

Cynthia A. Fisher – WaterRev LLC – Member
I had trouble hearing, could you clarify those?

John Kansky – Indiana Health Information Exchange – Member
I could probably say it better – I'm sorry, are you talking to me or to Mark?

Michael Adcock – Individual – Co-Chair
I think it's to you, John. She just wants you to restate what you said.

John Kansky – Indiana Health Information Exchange – Member
Yeah, so on the first call, we were asked to debate whether pricing information should be included in the definition of electronic health information. It sounds like there is a comment the document, I guess I'm asking, that says, "Yes, absolutely it is," which I'm a little nervous about. I'm just – so if that's where we're coming back, I would just like to add the observation that including that information in the definition of what has to be made accessible in all circumstances to avoid information blocking, that there's a recognition that the national cost and complexity of complying with the regulation is driven up by that inclusion.

Cynthia A. Fisher – WaterRev LLC – Member
I think you really have to look at this – as Mark pointed out to us, that this has been promulgated as a rule since 2000 and law since '96 is part of the health information definition.

John Kansky – Indiana Health Information Exchange – Member
That was an entirely different regulation, which was designed to define a category of information that should only ever be shared under certain circumstances. Now we have a regulation that is defining the times where only rarely should the information not be shared so I think employing the same definition for both regulations is unquestionably going to have unintended consequences.

Cynthia A. Fisher – WaterRev LLC – Member

I think the consequences ultimately will be that patients that are getting surprise billings for surgery from a physician fee of $101,000 that appear to be within their network, and they check that it's within their network, and it's advertised as in their network, and they get more than three times the average income of the American worker for a two-hour surgery, that would, in-network, be a $2500 fee to the surgeon. When surgeons and medical practitioners are charging whatever they want and the patient has no negotiating leverage, the opportunity we have at hand is to honor what HIPAA, through the Portability Act, defined as health information. And that is a law, and it will ultimately allow consumers and patients not to have surprise egregious price-gouging and overcharge that is bringing them to financial ruin. And –

John Kansky – Indiana Health Information Exchange – Member

Cynthia, while I acknowledge that – I'm sorry, finish your point.

Cynthia A. Fisher – WaterRev LLC – Member

I understand that selling prices in any of the market, whether it be grocery, or retail, or all other functional markets – we are at a moment in time where we can honor the HIPAA definition, and we can deliver, to patients and employers, visibility to see the clear and real prices of healthcare, and be able to shop. Without us doing our job and putting up roadblocks, I am sorry. I believe by not honoring the HIPAA definition, that we are, in fact, information blocking. We are, in fact, **[Inaudible] [01:00:29]** the consumer to know the price.

John Kansky – Indiana Health Information Exchange – Member

Can I get in a point? Can I jump in here? So, I absolutely acknowledge the situation that you described sometimes happens. I have personally experienced this. What I'm suggesting is that if we write a regulation that increases .5 percent, 1 percent, 1.5 percent, the total cost of healthcare nationally, we'll just bankrupt the country faster, with certainty.

Cynthia A. Fisher – WaterRev LLC – Member

Well, I disagree with you, John. I disagree with you because we see competitive market forces work in other industries that – I know that it can be fair and equitable in pricing. So, why should an oligopoly hospital system be able to charge someone 11 times the Medicare rate, by not allowing the patient to see price, when they could have gone to another clinic across the street and gotten the same lab test for **[inaudible] [01:01:42].**

John Kansky – Indiana Health Information Exchange – Member

I completely agree with you, that is the desired future state. And maybe if the regulation ultimately has a compliance timeline in the stepwise process that is reasonable, then we can both be comfortable. When I don't hear any discussion of, or very little discussion of, at the workgroup level or the task force level is extrapolating the complexity and cost of implementing this regulation nationwide. And therefore, I feel a responsibility to keep bringing that up.

Cynthia A. Fisher – WaterRev LLC – Member

John, I feel a responsibility, because look – I speak as a business owner, I speak as someone who has self-insured plans for thousands of employees. I speak as someone who has worn a hat in various businesses. Guess what? Showing your prices is the cost of doing business.

John Kansky – Indiana Health Information Exchange – Member
Sure.

Michael Adcock – Individual – Co-Chair
So, we obviously have – I wouldn't say differing viewpoints, but differing viewpoints. We have things that we need to note on both of those. We did discuss on the last call, and discussed on the task force, about payment being included in the definition of EHI and what is EHI. I think we had come to an agreement on that last time. We also had a pretty long discussion about the fact that there would have to be a lot of regulations put in place, there'd have to be – and Mark, you can correct me on this. We discussed last time about a regulation having to be written around this. There would have to be a lot of details, that it wasn't going to all be covered under this particular piece of regulation.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, so I think that is all great conversation. I think that's right. We do have the request for information – price information – kind of split out, and I think that is probably the next conversation have potentially, but just so I get some clarity from Cynthia on the suggested change to electronic health information, it seems like in the – I guess I'm just confused. Is it just pulling out, Cynthia? Because in the current text, in the definition we say, "or the past, present, or future payment for the provision of healthcare to an individual." So, I think you just kind of pulled that out, and made it a number three just so it's more central? Is that right? I'm just trying to understand the change.

Cynthia A. Fisher – WaterRev LLC – Member
Yeah, I think I can stand to add, but it's like any information that relates to that payment. Maybe it is just a reiteration of it. We just want to make sure it is broad enough that the pricing still stands. We want to leave it in there that it is – and if the patient requests, or not even if the patient requests it, and they should be provided the past, present, and future payment of the provision of healthcare.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Got it.

Cynthia A. Fisher – WaterRev LLC – Member
I think it's there – and any other information that relates to it. But you know what? I think stands strong at is. It's part of HIPAA, it's part of '96. It's in law.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Okay, yeah. I was just going to see if that's a recommendation, if others are on board with it, which would be great. Michael, how do you want to proceed with that one? Do you want to – or Cynthia?

Michael Adcock – Individual – Co-Chair
Mark, I'm sorry. There's a touch of a delay, so I don't mean to interrupt. No, I just don't understand how if it's already stated in the definition that the payment's in there, and it speaks pretty clearly. If we have the proposed recommendation that was in the preamble about what information is, aren't we already covered in the definition in the current text? Do we need to add this, or is it just…? I don't know, it seems – it's already there.

Cynthia A. Fisher – WaterRev LLC – Member
I think we can keep it. I just think that… Let me collect my thoughts for one second.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
And while you do, Cynthia, I might just suggest that if – and I'm not trying to push you one way or the other – if you feel like the current definition is good, you could also make a recommendation to add preamble language to explain the things you are saying, potentially, without changing the definition.

Cynthia A. Fisher – WaterRev LLC – Member
Okay, I think, Mark, in the preamble, I think another concern would be – and I think we can leave the definition as is – but I think the other concern is just getting at pricing. Where any information that goes into the electronic health record identifying the individual with respect to where the individual has reasonable basis to believe the information could be used to identify the individual, that long phraseology. If you look at the broader definition in HIPAA, there are two levels of HIPAA where all of the nuance of that individual is more on the protectionism side, and then the broader definition is to provide the individual with their health information as a provision of care to the individual. Broad enough that the concern is, obviously, when the individual looks at pricing, that they can actually get access to that, and have that be applied system-wide and through the open API abilities.

Michael Adcock – Individual – Co-Chair
Okay, so we have proposed recommendations. We're going to leave the definition the way it is, we're going to add text in the preamble that we've already discussed earlier about information is inclusive of human and machine-readable forms. And then Cynthia, it might be best if under this recommendation, if you've got some time to write down your thoughts so that Mark doesn't try to have to interpret your words. If you could put those under a proposed recommendation to go into the preamble, as well, I think that makes a lot of sense. I certainly hear the points that you're trying to cover. I do agree that needs to be somewhere, I think that in the preamble may be the best place for it. I think the definition is clear.

Cynthia A. Fisher – WaterRev LLC – Member
Thank you. I will do so.

Michael Adcock – Individual – Co-Chair
Perfect. Thank you so much. Mark, if we can scroll and start looking at the rest of the recommendations or any recommendations we want.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, absolutely. Just give me one second. Just adding a note for…

Michael Adcock – Individual – Co-Chair
Yep, absolutely.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Alright. There's a weird delay on this Google doc. I think that's great. Cynthia, please just go in there on your time, and let us know what the proposed recommendation would be there. I think the big ones we have left, then, moving on our – to circle back on the conversation you are having with pricing information, and to circle back on the definition of health information network and exchange, which we were talking about earlier. So, of the two doors, what are you picking? Where do you want to go first?

Michael Adcock – Individual – Co-Chair

I honestly – this is Michael – I think that for the pricing discussion, we can certainly have some of that discussion now. I think as we talk tomorrow in the large task force thing, I think that's another one of those "big rocks," as Andy likes to say, that we need to pick up again and discuss later just to let the group know where we're going – the task force – but certainly welcome to any more discussion there. From what I understand of the points yes, we have this opportunity to address pricing and pricing transparency, we also need to make sure that we understand fully the consequences, both intended and unintended. I think some of the ones that Cynthia mentioned, the patient being able to have better information to make decisions and not be surprised, I think honestly that would be an intended consequence.

I think an unintended consequence is that it's going to cost a lot of money and take a lot of time and effort to be able to get to this point. I'm not saying it should or shouldn't, but that it will. I think that we've have heard all those points. I don't know that anybody has any different points to add. I think that we've – I won't say that we've exhausted that discussion, but I think that we've had a lot of intelligent discussion around that matter and have covered points from all different sides. But we're certainly welcome to open that up for a little bit. I do think that we could spend some time on electronic health exchanges and networks, and I think that if we could work there, it might actually lead to recommendations.

Cynthia A. Fisher – WaterRev LLC – Member

Yeah, I just agree to disagree on some of these points. Like, these systems – pricing and payment systems are very well sophisticated and built and opening up the kimono to be able to just have price discovery, real price discovery, is very doable and is done in every other industry as a norm of the cost of doing business. If you look at the actors in the system, and you look at the profitability, just look over the past 10 years versus the burden to the patient, you can see the inverse relationship. I think it's already baked in, and it's doable, and it's the cost of doing business. It's almost insulting; in any other sector, prices are known, and posted, and digitally available, in the Amazon world, the Google world, the Uber world in which we live. So, this is – I disagree with you, and I believe that's the role of the enterprise to disclose. Thank you.

Michael Adcock – Individual – Co-Chair

Okay, so Mark, what areas of this that you have identified there? Is this about the pricing information?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead

Yeah, so what I have right now – so it sounds like maybe we'll hold on the pricing conversation and try to move on to get more clarity on health information network and exchange. To Cynthia's point, and to others, so what I have right now, I just made a note when we spoke last that I think everyone seemed to agree the proposed definition of EHI should be read to include price information. But I would ask, is that accurate to everyone on the phone right now? That the definition of EHI should be read to include price information?

John Kansky – Indiana Health Information Exchange – Member

I think I'm the minority on that one, but I'm not going to make a fuss. I'm not saying it shouldn't, I'm saying we seem to be silent on the implications.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, so actually, John, that's a really good point. There is the issue of whether the definition should be read to include it, which there is the payment part of the definition, but also what I was getting at is we have this request for information where we want more detail about the scope and parameters of price information that would be included and the implication of such information in the definition. That's what we're really looking at and getting more information from you all and the general public about. So, John, your thoughts on that, if you want to put them on paper or whatever, I think that would be really helpful – and Cynthia, as well, to get both sides on that one.

Michael Adcock – Individual – Co-Chair
I think one of the things Andy mentioned yesterday was one of the recommendations could very well be to create a task force to look at this. We're tasked with looking at multiple different definitions as a part of one work group of a larger task force, does this need to be discussed? Because there is a lot of detail to discuss under the pricing language.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Just making a note really quick about John's point. Sorry, I want to make sure I am conveying it right. John, basically what you're saying is you're concerned about the unintended consequences and the scope of what price information could be included, if it's included in the definition of EHI, is that accurate?

John Kansky – Indiana Health Information Exchange – Member
Yeah, that we need to look at the implications. It's not a question of including it in the definition or not, it's a question of also considering the cost of compliance – the complexity.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Okay, I'm writing it down, but feel free to go in there and delete what I wrote or update it however you want. I just said that you're concerned about the unintended consequences, and complexity, and cost of complying. Okay. Great. Michael, do you want to try to move to the health information network and exchange definition now?

Michael Adcock – Individual – Co-Chair
Yes, please. So, we have the definition there, but didn't we make some recommendations below, or did we not?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, I'll scroll down. Here's all the conversation. Since John is on the phone, I can recap what we have right now. So right now, we have a proposed recommendation that the definitions for HIE and HIN are currently unclear. For example, an RHIO may well fall under the definition of an HIN within this meeting, yet they are specifically drawn out as an HIE. Just reading that, my comment is: I'm not sure what we mean by drawn out, but again, they're not mutually exclusive. So, you could be an HIN and an HIE, so I'm not sure I totally understand that recommendation.

John Kansky – Indiana Health Information Exchange – Member
I didn't write that and I'm not trying to interpret it for you. The definition as written seems so broad and inclusive as to almost lose their meaning. As we discussed on an earlier call, if every provider also meets the definition of a health information exchange, I get that that's the intent. As we discussed

earlier, there's not a desire to leave out key organizations that represent a key part of the health of the supply chain. That may not be a problem, but I find it very – the definitions are very broad, and if every provider is also a health information exchange, I'm not sure what the purpose of the definitions – what purpose they serve.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Do others have thoughts on that? I'm looking at the proposed recommendations and it looks like there's just a lot of original text copied in there. I don't see many recommendations, actually.

John Kansky – Indiana Health Information Exchange – Member
If I were to offer a recommendation, it would be what we discussed earlier, and that would be to offer examples of organizations that fit each definition and examples of organizations that do not fit any definition.

Cynthia A. Fisher – WaterRev LLC – Member
This is Cynthia. I think what we said earlier was to broadly cover the platform for today and the network and exchange on the financial food chain or the supply chain of transactions of actors that exchange patient electronic health information over through exchange and over networks. John, I don't know, maybe Mark can clarify, but maybe a provider that's held separately outside of the network and exchange definition is that small rural Mississippi physician practice that has the exception, and they are under a provider definition, and so they are looked at to provide real-time in the best way they can for their patients.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Just a point of clarity. I guess, the way the definitions work, I would ask John, if you think the definition of HIE or HIN encompasses all providers? Because that's not the way I am reading it, but I would ask you provide more detail about the issue there. But I would say that the definition of HIN and HIE is, like I said before, is functional. So, there could very well – we have an example in the preamble where we explain that the provider could be considered an HIN or an HIE if they act in that capacity under those definitions. That is just my point of clarity right there.

Cynthia A. Fisher – WaterRev LLC – Member
Yeah. Mark, I also see it that – why wouldn't a provider who has electronic health records – that they are transferring that information – that they are defined as a network or an exchange. So, it does include those providers and it is all-inclusive of the payor and the provider and all those actors that share that patient information in the supply chain. I think we want to broaden it because the providers are part of that. I think what would be more helpful is to also say where is a carveout where the provider is thought of as separately. To me, I thought the only change for a provider was the penalties for violation under the Inspector General. Whereas, there's up to $1 million per occurrence for all other players. I would look at this committee, even though we're not doing it right here, but as we address it, we can look at fairness and say, "Why wouldn't you have most favored nations like you do, and just allow the same penalties to apply to all actors, and all players, because it's defined, and it's clear." Unless there's a carveout for the individual – mental health, social worker, therapist, or a small, rural provider carveout is defined in that first provider bucket, the rest of the world is under the provider and payors. Actors would come under the network and exchange.

John Kansky – Indiana Health Information Exchange – Member
Mark, when you have a chance to circle back, I wanted to ask about one of your comments.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Okay, sure.

John Kansky – Indiana Health Information Exchange – Member
I just didn't want to stomp on Cindy's point. I'm trying to figure this out because it will help me tremendously if you could help me understand this. The way you read the definition of HIE would exclude providers, and I assumed when I read this the first time that was ONC's intent.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Let me stop you there. I'm not saying we'd exclude providers, because like I said a provider could act in that – what we're trying to do, just to break it down, is to just provide the function of an HIN or an HIE, and not say explicitly who the entities are that would follow that function.

John Kansky – Indiana Health Information Exchange – Member
Okay, let me play this out. So, a physician practice, by definition, is going to have to enable the exchange of electronic health information with its patients, or it's information blocking, right?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
I mean, I can't say yes or no because it all depends on the facts or circumstances and whether an exception applies, and things like that. But generally, yeah.

John Kansky – Indiana Health Information Exchange – Member
So basically, every provider is going to have to enable the exchange of health information between or among a class of individuals or entities, i.e. their patients, i.e. their trading partners. I don't want to open up a whole can of worms, but the way we've defined health information exchange in other contexts is that that's their primary business. Meaning if you said an individual or entity that's primary purpose is to enable the access, exchange, or use of **[inaudible] [01:25:51].** I mean, that to me is a better definition of the health information exchange. Now if that has unintended consequences – frankly, as a health information exchange, selfishly, I think if almost everybody in the healthcare system is subject to the same regulations as an HIE, meaning almost every provider? Fine. That doesn't bother me at all. But when I consider writing a narrower definition, that is, in my view, one way to try and fix it, if that is desirable.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Sure.

Cynthia A. Fisher – WaterRev LLC – Member
John, I totally disagree with you on this, because I don't think we want to have a narrower definition. I think the impact of Cures act was to allow for patients to get access and players to be held accountable. If you narrow the definition, you are narrowing accountability. Frankly.

John Kansky – Indiana Health Information Exchange – Member
Can you offer an example of who that would be about?

Cynthia A. Fisher – WaterRev LLC – Member

Well, to the example of the providers are functionally, as HHS has defined it so far, we interpret it that providers are under the functional definition, and they should be treated as such. As are plans. If they are functionally acting, they are functionally providing network and exchange. And, in the broader sense of the term, they are functionally providing it, and should be treated as such.

John Kansky – Indiana Health Information Exchange – Member

I would say to ONC – I have no problem with what you just said. My issue is it that it's in no one's interest to write a regulation that is confusing for players in the industry to understand which definition they meet and how to comply. We should write a regulation that achieves the desired end with as much precision as possible, that isn't vague, fuzzy, and therefore costing the government and the industry more money to comply with it. So that's where I'm coming from.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead

And from my side, I agree with everything you said there and that was our goal and intent. If we miss the mark, this is the forum to let us know. I'm not sure, Michael, how you want to try – it seems like I'm hearing it right, John, you take a narrower view on HINs and HIEs, and Cynthia believes they should be broader, and with a lowercase 'n' and 'e'.

Cynthia A. Fisher – WaterRev LLC – Member

Well, I just think the intent is a functional intent. Mark, I'm not – I thought our role was to look at the actors that play in this interchange, and I thought that was where we were going from the earlier discussion today. I didn't think HHS was weighing in with an opinion, yet. I just thought we were looking for comment.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead

Oh yeah. I'm sorry, I apologize. My intent is not to weigh in. I will be quiet and let you all move forward.

Michael Adcock – Individual – Co-Chair

I certainly think that your intent was to direct the conversation. I think we're just trying to get to the point of recommendations. I guess my confusion is around if we are trying to define these four actors, if providers are acting as providers, then they fall under the provider definition. If the providers are acting in an exchange role, then would they not fall under a health information exchange? Is that fair?

Cynthia A. Fisher – WaterRev LLC – Member

I just want to be clear because earlier, John, you had mentioned about it being a primary role, and I don't see that anywhere in the regs. I think it's whether they are functionally acting in that capacity, do we have agreement on that?

John Kansky – Indiana Health Information Exchange – Member

I'm not suggesting it is incorrect, I'm just trying to provide the function of the task force in getting feedback to ONC to write a good and precise regulation. I have no problem with broad definitions, if broad definitions are what is required. What I have an issue with is writing a regulation that the industry is going to have trouble interpreting and figuring out how to comply with. So, at the end of sentence one, let me offer this: is it possible to offer a recommendation that the regulation be written such that if you meet more than one definition, then pick the one that is most obviously you. If you

are a physician practice and you meet the definition of a health information exchange, you're a provider. If you're a health information exchange and you meet definition of something else, just be a health information exchange. You only have to be covered by the regulation once. Having to consider the implications of meeting more than one definition, I'm not sure is constructive.

Cynthia A. Fisher – WaterRev LLC – Member
Determination of where you fit is based upon the penalties, right? So, that's where the definition matters on accountability and penalty.

Michael Adcock – Individual – Co-Chair
Do we even know the difference yet, or do we just know there's going to be a difference? Could be more, could be less, could be – we don't know. Right. If there is accountability and we make sure we have the groups defined, not that we are going to be inclusive of everyone, but if we have a provider group defined, and we have an HIE defined, and an HIN defined, and a health information technology defined, can we put something in the preamble that covers all the different examples of who might fit into what? Instead of trying to – because there is a difference between – although, after reading this definition multiple times here in the conversation, I'm confused as to what the difference is now, but there is a difference between an HIE and an HIN. But if you fit into one of them, or you fit into both of them, you're still going to be held accountable regardless.

I guess I'm kind of repeating John's point, but if you are a provider and you are exchanging information, which certainly happens every day, as long as people are being held accountable, I guess that's lightyears ahead of where we are right now. I'm not trying to be funny, but it is. I just think that if we try to include everybody into every definition, we're going to have a bunch of definitions that are – basically only need one. I mean, at that point, you get rid of all the actors, and anybody that provides any type of health information from, to, around, by, near a patient, you fall under this rule. I think it was very clear that we need to have these four different categories of actors. I'm not exactly sure how to do the examples, unless we put them in the preamble. But I do think there are differences between HIEs, HINs, providers, and health information technology companies.

Cynthia A. Fisher – WaterRev LLC – Member
Was that Mark speaking?

Michael Adcock – Individual – Co-Chair
No, that was Michael. I'm sorry.

Cynthia A. Fisher – WaterRev LLC – Member
Michael, good point. I think, just to share with you all, yesterday's call with Andy, we all got confused and entangled in our own underwear trying to figure out the definitions, quite frankly, and we moved it to today, because… I think it begs on HIE and HIN for preamble clarity as we look at the actors, like we just did in our former conversation, is to at least give examples of and clarity to as we look at this project's mission. And then, I think the other role is to look at accountability. We know they'll all be accountable, it's just that there is a difference for three of them versus one, and we do not know what that is, but that doesn't mean we can't comment on it.

John Kansky – Indiana Health Information Exchange – Member
I think, and I may be stating the obvious, the desired future state on these definitions of actors is that the definitions are not written so narrowly that an organization like a payor can sneak through a loophole of the definition and not be covered by the regulation, but that there isn't any point in having an organization be covered multiple times and be confused, for example, about what penalties under what circumstances. That's all we're trying to achieve, is that everybody who should fit the definition fits it, but nobody's unclear on what definition they fit.

Cynthia A. Fisher – WaterRev LLC – Member
I think it's really also that the net is cast wide enough that anybody who is on that supply food chain – supply chain financially transacting and benefiting from the patient's care is accountable, right? So that they're all under those buckets of **[Inaudible] [01:36:31]**.

Michael Adcock – Individual – Co-Chair
Right. No, I think we're all in agreement that it needs to be broad enough to capture everybody but narrow enough that it makes sense to have more than just one definition. Mark, there was some proposed language around, and to me, they were pretty simple changes to HIE. Can you scroll down to those? We had discussed those yesterday on the call, and I think it might help John just to hear what we changed, because it wasn't a huge change, but it was a change.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, I'm not sure where it is…

Michael Adcock – Individual – Co-Chair
Yeah, because we ended, instead of…

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
I'm reading it. Did we have processing handling, or –? Yeah. So, John, just for your benefit, because I don't think you got to hear the definition yesterday, one of the things we talked about under – I'll read the potential health information exchange language and then go over what was deleted and added. But the proposed language that we put in there was health information exchange, or HIE, means an individual or entity that enables, facilitates, or performs the access, exchange processing, handling, or other use of electronic health information. We added the word "facilitates" and added the words, "processing" and "handling". What we took out was the last sentence that talked to primarily between or among a particular class of individuals or entities for limited set of purposes, because nowhere could any of us come up with what that primarily, particular, and limited set of purposes meant.

We narrowed the definition a little bit, but also broadened it to the point where it's not just for those folks that enable it, but also the ones that facilitate that enablement, or process and handle, so that you could be looking at pharmacy benefit managers and other groups that could potentially fall into this.

John Kansky – Indiana Health Information Exchange – Member
I think that the suggested change represents improvement of clarity. Thank you.

Cynthia A. Fisher – WaterRev LLC – Member
Yes, I do, too. And Michael, I think that was really well said. Thank you.

Michael Adcock – Individual – Co-Chair
I think what we should do in that is, in the preamble, talk about some groups that would potentially fall into HIE. I know that I certainly – I don't want to use Cynthia's term, but "got caught up in my underwear." I certainly did. Because every time I would read it, I would get confused between an HIE the way it's written, and an HIN the way it's written. I think if we could potentially recommend or propose recommendation under that is to add something to the preamble that gives examples. Like Cynthia said earlier, that includes but it's not a complete list. That we could give examples of, and that could include the pharmacy benefit manager that was doing X, Y, or Z. And potential cases could include providers that would be acting in this way primarily, not in the definition that would meet providers. Thoughts on that?

Can we spend some time, not right now, but this evening, maybe tomorrow looking at potential examples or some language to go into the preamble? I don't want to spend too much time doing that now. I'd really like us to focus on – maybe we can get through HIN. If people could, over tonight and tomorrow, put something in there that we think might belong in the preamble, just to make sure we're including or giving examples of groups that might fall in that might otherwise think they don't.

John Kansky – Indiana Health Information Exchange – Member
Yes, I agree. That would help.

Michael Adcock – Individual – Co-Chair
Now Mark, I don't remember exactly where we got to yesterday on HIN. Did we have any proposals on that? Or did we not get to the HIN piece?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Let's see… I don't really think we got into it. It looks like we just have the original there. Nothing proposed.

Michael Adcock – Individual – Co-Chair
John, I'm sure you are aware of, but have you seen the original definition and how it's written now? I don't remember any discussion around HIN, other than it talked about – was that the one that talked about affiliated? Being the primary difference? Mark, I can't see it right now.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Oh, sorry. Yeah, that's unaffiliated. Let me pull up the definition.

John Kansky – Indiana Health Information Exchange – Member
Mark, I literally have it in front of me right now.

Michael Adcock – Individual – Co-Chair
Beautiful. So, if you could provide some thoughts to that, maybe we can button up that definition or our recommendation as well.

John Kansky – Indiana Health Information Exchange – Member

My feedback is that I have pictures a dozen highly intelligent ONC people in a conference room for three hours working on this definition, to come up with all these words, and I'm afraid to move a comma. With that said, it seems like a really hard way to describe – I'm not sure. Let me start that over again. Look when I think health information network, I'm assuming that we're trying to define some of the primary things that exist in this country that people think of as health information networks. The Exchange, Commonwealth, perhaps EPIC's Care Everywhere capabilities, REX, etc., etc. This seems a lot of words to get at that if that's the intent.

Michael Adcock – Individual – Co-Chair

It is a little wordy. This is Michael again. Do you have some recommendations on what you think could be changed to meet what people think of as a health information network now, but also that would still contain broad enough language that if someone was acting in that way, that we would be able to identify them without all the words.

John Kansky – Indiana Health Information Exchange – Member

I don't suppose it's fair to ask Mark, when the definition was being crafted, if there were examples of organizations outside those that I mentioned that are supposed to meet this definition? Is that – yes or no is the answer to the question, Mark.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead

What I would say is that we definitely thought through the implications of these definitions and tried to strike the right balance. I would really just refer you to the preamble. We're running short on time, so I would say maybe before the next call where we discuss this, for everyone to read over the preamble and just kind of get an idea of where we were coming from. As always, recommendations are welcome.

John Kansky – Indiana Health Information Exchange – Member

That's fair. I'm just latching onto things like "influences policies," or "agreements and influences technology or service." That seems crazy broad, but I will revisit the preamble. Thanks.

Cynthia A. Fisher – WaterRev LLC – Member

Is that counting the number of lobbyists? Sorry, that was a joke.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

I'm sorry to interrupt, can we break in for public comment really quick, and then you guys can jump back in?

Michael Adcock – Individual – Co-Chair

Yeah, I knew we still had about a minute. That's one of the things I was going to ask before we break into public comment, if John and Cynthia, and I'll certainly take a look at it, as well. If we could make some recommendations on the definition of HIN, that would be very helpful, just before the next call. And then we'll break, because it's time for public comment.

Cynthia A. Fisher – WaterRev LLC – Member

Okay.

John Kansky – Indiana Health Information Exchange – Member
Is the preamble page reference for HIN handy?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, it's in the – that whole conversation is around 339 to 344.

Michael Adcock – Individual – Co-Chair
Mark, if you could, put that in the comments there so we can –.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, it's in the document right here. Right there – page numbers.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Operator, can you open the line for public comment, please?

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

Cassandra Hadley – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Do we have any calls on the public comment line?

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

Cassandra Hadley – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay, thank you. Michael, we can jump back in.

Michael Adcock – Individual – Co-Chair
Certainly. Mark, could you pull the –? There, you're ahead of me every step of the way. So, that's our homework, is to look at the HIN for actual recommendations for the definition there, but also to look at what language we think should be added to the preamble for HIE. What do we have below that, since we know what our homework is there?

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead
I think the big ones are other comments on EHI. The price information is still definitely out there, and like you said, refining the HIN issue. There's also the actors and practices, but it sounds like maybe we covered those.

Michael Adcock – Individual – Co-Chair
Yeah, I think that we covered the practices for sure. I think the actors, since Cures has defined what the four actors are, we just need to make sure – I'm assuming in the preamble – one, that the Reg text

covers the groups in broad enough terms that we are able to cover those groups. But in the preamble, that we write out which area those groups would fall into, or what we think that those groups would fall into. Whether – back to Cynthia's term - around pharmacy benefit managers and the others that work along the healthcare continuum, either delivering care, delivering information, delivering product, whatever it might be. That we make sure that we fit those folks in those categories, so that we have a clear – well, we won't put it all in the Reg text, we have clear examples in the preamble so that no one slips through the cracks of fitting into one of the categories. Is that pretty much what the group thinks?

John Kansky – Indiana Health Information Exchange – Member
Yes.

Cynthia A. Fisher – WaterRev LLC – Member
Yes, I think your request is the right way to go.

Michael Adcock – Individual – Co-Chair
Alright. Well, perfect. Well, that was good. I think we all have work to go do. I don't know that we can cover anything else during the meeting that's going to be able to clarify any of this other than while we're not writing or while we're not working on other things this afternoon, to go in. And not only give thought to it, but also put those thoughts down in writing in the Google Doc, so that we can look at those, so that we can be ready for the bigger task force meeting tomorrow, and so that we can have some recommendations for Mark as we move closer and closer to the in-person meeting and us being able to report out on this. I know that there's been lots of discussion today. I certainly appreciate it, I've learned a lot. I appreciate the respect that we all give each other when we have different viewpoints.

I think that's very important, that we all are able to voice our viewpoints, and also respect those of others, so I personally thank each and every one of you. I know this has taken a lot of time. I know that I may have been a little confused on some of these, because we have multiple taskforces every day, and I can't remember which one is which and who's in which one. So, I appreciate everybody's patience as we 're working through this, and certainly everyone's hard work. Unless anybody has anything they want to add for this specific call, I'm not opposed to ending a few minutes early, so that we can give that time back and spend the time potentially **[Inaudible] [01:49:50]**.

John Kansky – Indiana Health Information Exchange – Member
Nope. Much appreciated, and it's a privilege to be part of this process.

Cynthia A. Fisher – WaterRev LLC – Member
Thank you, Michael, for leading the call today so well. Thank you.

Michael Adcock – Individual – Co-Chair
Thank y'all. And Mark, I guess that'll be the end of the call, unless there's a public comment that's popped up since we last asked.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
No. We're good to go, everybody.

Michael Adcock – Individual – Co-Chair
Well thank you. Talk to you tomorrow for the task force call.

John Kansky – Indiana Health Information Exchange – Member
Thank you.

Cynthia A. Fisher – WaterRev LLC – Member
Sounds good, thank you. Bye.

[End of Audio]

Duration: 111 minutes