# Information Blocking (IB) Task Force

Transcript
March 22, 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 |
| Lauren Richie | Office of the National Coordinator | Designated Federal Officer |
| Cassandra Hadley | Office of the National Coordinator | HITAC Back-up/Support |
| Mike Lipinski | Office of the National Coordinator | Staff Lead |
| Mark Knee | Office of the National Coordinator | Staff Lead |
| Penelope Hughes | Office of the National Coordinator | Staff Lead |
| Morris Landau | Office of the National Coordinator | Back-up/Support |
| Lauren Wu | Office of the National Coordinator | SME |

**Operator**
All lines are now bridged.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Good morning, everyone. Welcome to the full Information Blocking Taskforce meeting. We have a very **[inaudible] [00:00:11]** agenda today. So, I'm going to start with the roll call and then we will turn it over to Andy first for discussion on electronic health information export. Andy Truscott?

**Andrew Truscott - Accenture - Co-Chair**
Present.

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

**Michael Adcock - Individual - Co-Chair**
Present.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Steven Lane? Sheryl Turney? Denise Webb?

**Denise Webb - Individual - Member**
Present.

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

**Sasha TerMaat - Epic - Member**
Present.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Aaron Miri? Valerie Grey?

**Valerie Grey - New York eHealth Collaborative - Member**
Here. Present.

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

Anil Jain?

**Anil K. Jain - IBM Watson Health - Member**
Present.

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

**Cynthia A. Fischer - WaterRev LLC - Member**
Present.

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

**John Kansky - Indiana Health Information Exchange - Member**
Here.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Lauren Thompson? And Denni McColm? Okay. Thank you. I'll turn it over to you now, Andy.

**Sheryl Turney - Anthem Blue Cross Blue Shield - Member**
Hi, this is Sheryl Turney.

**Arien Malec - Change Healthcare - Member**
This is Arien.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Hi, Arien. Thank you. Okay. The floor is yours now, Andy.

**Andrew Truscott - Accenture - Co-Chair**
Thank you so much. Hey, guys. Thanks for joining. We've got about an hour and a half together today and there are two principle topics I'd like to touch upon. This call is coming out of this week and I'm sure the last thing you need on a Friday is to spend more time on information blocking. So, we're going to spend more time on information blocking.

I would like to touch upon the EHI export and the uncertainty that's been discussed in another taskforce. I'm also going to have a walkthrough of the ONC thinking that led to the drafting of the regulations as they come **[inaudible] [00:02:08]** around information blocking. The purpose of these two sections is to be primarily in listening mode.

Although, when it comes to the EHI export, I think **[inaudible]** I would say about 15 minutes just to understand that. We need to understand the touchpoints with the work that we're doing over the information blocking taskforce as well.

Then for the second session, it's going to be led by Michael Lipinski from the ONC team, which is for us just to understand the work that ONC has done and the thinking that they have pulled together and the balances and tradeoffs that they've made against regulation and legislation that has gone before as they formed their positions which are inside the regulations. That's not really for us to litigate through that and to overly discuss, but it's for us to seek to understand their thinking and their reasoning to get there. Does that make sense, guys?

**Michael Adcock - Individual - Co-Chair**
Yeah.

**Denise Webb - Individual - Member**
Yes.

**Andrew Truscott - Accenture - Co-Chair**
Cool. Okay. Magic. So, without further ado, I'm going to hand over to whoever it is – because I don't know who it is – who's going to be presenting on EHI export.

**Denise Webb - Individual - Member**
I think that's our topic, right?

**Andrew Truscott - Accenture - Co-Chair**
I hope so. It's definitely not me.

**Denise Webb - Individual - Member**
Okay. This is Denise. I have not gotten the Adobe up, but in the recommendations that we provided from the Conditions of Certification and Maintenance Taskforce, one of the recommendations that we're putting forth related to the EHI export recommendation No. 23 that we provided at the HITAC meeting, it says, "ONC should provide clarity around the scope of the EHI export."

Our taskforce was recommending it be limited to EHI collected and retained by the certified EHR technology and apply only to the EHI that is part of the legal medical record. Narrowing to the legal medical record was important in particular for the scenario where research data may be stored in EHR.

So, I know Sasha is on and she can also add some commentary on this, but we wanted to bring this up with the information blocking taskforce because as we look at the definition of EHI – and that's been a topic of discussion for, I believe, the work group one, of our

information blocking taskforce, the definition of EHI as proposed in the rule is quite broad. In fact, it includes information that is stored in health IT that is not necessarily certified or required to be certified.

So, we struggled with this and had quite a bit of discussion around the requirement to create an export function that exports information from other than certified technology. That's what we were grappling with. We think that while the information blocking rule and requirements will require data providers, health systems and so forth, to provide information to a patient or for an HIT developer to assist an organization that wishes to move to a different platform, to assist them with getting all of their data out, even if the data is in part of the system that is not a certified EHR module. It was restrictive to say that this had to all be handled by this EHI export function.

So, I hope I'm being clear. On one hand, under information blocking, all the data must be provided, but the EHI export is specifying that this is how it will be provided. We think it should only apply to certified technology and the narrow definition around the legal medical record. So, that's what we wanted to bring forth to this group since this group is deliberating on recommendations around the definition of EHI.

**Arien Malec - Change Healthcare - Member**

Hey, this is Arien. Do you have a proposed definition of the term "legal medical record?" So, I'm aware of a definition under HIPAA called the designated record set. What's the operational definition of legal medical record?

**Denise Webb - Individual - Member**

I'm going to let Sasha comment or any of our other taskforce members that are on. But that would have been my interpretation of what we were speaking about is the designated record set under HIPAA.

**Sasha TerMaat - Epic - Member**

Yeah. Arien, in our conversation, the idea was that when a patient would request their record under HIPAA, the data set that they would get would be the legal medical record. That was sort of the nature and tone of our conversation as we talked about it. If the language needs refinement, I don't know that our conversation was set on that tone. The concept was the information that the patient is already entitled to receive under HIPAA should, of course, be provided.

But there was concern about other types of information that might not be considered by some of the providers in our workgroup part of the legal medical record. Some of the examples that came up included a half-written note – if you have a half-written note and a patient says, "Export my electronic health information," providers were concerned that the half-written note isn't complete yet.

That's not legally part of the record yet in their determination and they didn't think that was appropriate to export until it was completed. Similarly, there were concerns about research

data, which would typically not be considered part of the legal medical record if it's part of a clinical trial, but that that might be electronic health information and could certainly, of course, invalidate the study, if exported.

**Arien Malec - Change Healthcare - Member**

Yeah. For me, I think some of these – we're struggling in information blocking with defining the applicability of the information blocking exceptions. In particular, the pricing exceptions to make distinctions between access to data and additional services that might be supplied up and above access to data. When you trace it back, getting the definition of EHI correct is pretty critical.

I guess where I struggle is we're introducing a new term called the legal medical record. There's an existing term, which is the designated record set. Then there's the proposed definition of EHI. If you look at the definition of the designated record set, it includes payment and billing information.

So, it's really everything about the patient that's used for decision making. I think that definition would exclude half-written notes that aren't used for decision making. But I'm just trying to figure out when we introduce the term called the legal medical record, is it co-extensive with the designated record set, where does it differ from the proposed definition of EHI? How do we provide guidance back to ONC that they can operationalize? I struggle with that.

**Andrew Truscott - Accenture - Co-Chair**

Yeah. Arien, just so you're aware, within workgroup one, there is considerable discourse on similar lines around the EHI definition and what the final recommended definition of that should be. It's very similar sets of discussions to what we're having now based on the applicability of EHI export.

**Arien Malec - Change Healthcare - Member**

If you look at the definition of designated record set, it includes other records that are used in whole or in part by the covered entity to make decisions about individuals. I think that definition would exclude the half-written note issue.

**Denise Webb - Individual - Member**

What about data related to research?

**Arien Malec - Change Healthcare - Member**

I don't know that it would exclude data related to research. This is one of those areas – that might be a where prohibited by law, but there's an alignment between information blocking and the common rule that I think is a really important comment to the – so, the information blocking, there's not really an exception, but information blocking says that information must flow except where prohibited by law. I think that's the definition. These are grey areas.

Does the research common rule and the study protocol, is that sufficient grounds to prohibit

information flow even if it's not a defined exception? It might be better to handle research as a defined exception than to exclude it from the record set.

**Andrew Truscott - Accenture - Co-Chair**

Yeah. Arien, a comment that's been made as well is when you're looking at using HIPAA-type definitions, they were definitions created to place restrictions on data sharing as opposed to definitions created to enable information sharing.

**Arien Malec - Change Healthcare - Member**

I don't think that's correct. So, the designated record set is the defined term that is the boundary for patient access. It was intended to be fairly broad as saying basically, the patient has the right to access of anything that's used to make a decision about the patient.

**Andrew Truscott - Accenture - Co-Chair**

Okay. Hang on a second, Arien. John Kansky has raised his hand.

**John Kansky - Indiana Health Information Exchange - Member**

Yeah. I think I just really wanted – first of all, I understand and support where Denise and Sasha are trying to go. I'm glad they've worked on that and I think their suggestion is completely rational. I think I'm agreeing with Arien. I just wanted to underscore that if it meets the purpose of what they're trying to achieve, I think the designated record set defined in HIPAA would be a convenient existing industry definition to use if it meets their purpose.

**Andrew Truscott - Accenture - Co-Chair**

Okay. Thanks, John. Denise Webb?

**Denise Webb - Individual - Member**

Yeah. So, this issue around the definition of legal medical record is important. The other half of our recommendation is around the idea that it's only data that is collected, received, retained in certified technology that would be subject to the EHI export function. We're not saying the other data collected in non-certified systems shouldn't be made available. What we're saying is that it can be made available by other means.

But right now, we believe that ONC's rule is proposing that the EHI export cover all data as defined for EHI be made available for this export function, whether the technology is certified or not. That's what we really were having an issue with and why we came up with our recommendation.

**Andrew Truscott - Accenture - Co-Chair**

What was the intent of the drafting? Does someone from ONC want to comment on that?

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

So, remember, the developer who gets certified – this is Mike Lipinski, ONC – it's the data that they electronically manage or store. So, there has to be that piece to the puzzle as well to hold them accountable, the certified developer. It's not just every piece of information that's stored in by that healthcare provider. It's got to be the information. The reason why that is, as we say on the rule, is they would know the format that it was stored in because they're responsible for it. Therefore, they can provide the data dictionary to export that information.

**Denise Webb - Individual - Member**

So, I just raised my hand. Hopefully it's okay that I speak. This is Denise. Let's take a scenario here – if a health IT developer such as one of the EHR vendors provides as part of their integrated suite the revenue cycle management portions of that. Is that considered part of the certified EHR technology? Let's just speak in today's world. Is that part of the certified EHR technology and would be subject to the previous data export or this new EHI export?

We were struggling with that because while demographic data and admissions might come from the registration system that is not certified and then that data is available in the EHR, that certainly would be subject to export. What about other data such as billing data and such that it's sitting in a non-certified technology? While it's managed by the developer that is a certified technology developer, that piece of their software is not a certified module.

**Andrew Truscott - Accenture - Co-Chair**

Arien's got his hand up.

**Arien Malec - Change Healthcare - Member**

This is an interesting issue because it does mean the record set does include eligibility, billing, payment, information that's used to make decisions about the patient. So, provider organizations are already obligated to supply all of that information to the patient. So, there's a provider obligation to make the data available.

I think the issue that you raised is, is it reasonable for a particular certified health IT module that is being – the intent here by Congress was a concern that some EHR vendors were making it intentionally difficult to transition technology. I think the intent here from Congress was to make it easy to transition EHR technology.

So, I guess maybe two things to keep in mind that may be contradictory – No. 1 is the patient already has the right to all of that data and it's a provider obligation to provide that data. No. 2 is I do think it's reasonable with respect to a certified health IT module to be responsible for the portion of migration that is relevant for the data that's being held by that certified health IT module.

**Sasha TerMaat - Epic - Member**

Arien, do you think – so, if there were a company that produced revenue cycle products but no products they would ever present for certification, then they wouldn't ever be subject to this export provision even though the providers using that revenue cycle product would have

to still comply with providing patients the designated record set, correct?

**Arien Malec - Change Healthcare - Member**

Yeah. So, the hooks in information blocking are to providers, which I think everyone is aware that the definition of provider is extremely expansive. There's a patient download obligation that's incumbent upon providers that's actually well-aligned with the HIPAA-designated record set. Then you're raising the issue about what's the responsibility of any particular certified health IT technology. They're responsible for a piece of it.

So, we're really delegating responsibility to the provider. I think under this proposal, we're delegating responsibility for the provider to be the one to pull it all together, but it's already a provider obligation under the designated record set capability or definition. That's a slightly different timeframe relative to 45 days and could be paper copies. These are the alignment issues that I think we're struggling with.

**Sasha TerMaat - Epic - Member**

I'm struggling with – it seems like we have an expectation for all health IT, any revenue cycle system, for example, but it's only being imposed on health IT that happens to be developed by someone who also produces certified health IT.

I think there's a fundamental challenge there because some of the expectations will go unmet if the developer happens to not also produce any certified health IT and it presents a competitive inequity for developers of certified health IT for their products that are not actually part of the certification program because the program is sort of inequitably applied across health IT modules that don't have any relevant certification criteria.

**Denise Webb - Individual - Member**

And if I can add to that, I'm aware of – I know we shouldn't use vendors' names, so, I'm not going to use it – so, there's a vendor that provides a totally integrated EHR, which also includes the revenue cycle management. But then they also, through acquisitions, acquired a revenue cycle management system, which the data exists in a totally separate database. Health systems can acquire the integrate EHR and choose to use the vendors revenue cycle management product outside of the EHR.

So, you have a certified EHR and then you have your revenue cycle management. They both have separate databases. If I understand what ONC's proposing on the EHI export, it would only be the EHR that is certified that would be subject to the EHI export requirements, the data that is –

**Arien Malec - Change Healthcare - Member**

No. No, that's not right. I think Sasha's got this exactly right, which is that the information blocking provisions –

**Denise Webb - Individual - Member**

Oh, I wasn't –

**Arien Malec - Change Healthcare - Member**

By developers of certified health IT technology, which I think Sasha is right, would cover all of the products produced by just one – eating one taste is enough to get you hooked.

**Denise Webb - Individual - Member**

Okay. So, you're just saying if one vendor has several products and they're not all certified, but they're used together to provide service to treat the patients and all of that data whether they're in separate databases would be subject to EHI export. So, the export would have to work with both systems.

**Arien Malec - Change Healthcare - Member**

My understanding is that the way that the information blocking rule works is that it applies to developers of certified health IT technology that your developer of certified health IT technology, if you have at least one technology certified, but that the applicability of that definition is to the entity and not to the technology. So, Sasha's point is that any of the products of that certified health IT technology are covered under the export.

**Andrew Truscott - Accenture - Co-Chair**

Okay, guys? I'm going to have to stop the conversation here. This is exactly the dialogue I wanted to make both taskforces aware that the sentiment exists. Sasha and Arien, we're going to have to look very hard about whether we want that definition. I think you're correct in what the current data is and we are being asked to HITAC about whether we recommend any changes to that definition or not. We need to work through that.

I'm going to hand it back to Mike Lipinski because I know he had a couple comments to make upon this and then I'd like to move forward into understanding – I'm sure Mike will touch back upon this part about understanding the presentation, but also just to walk through the ONC thinking that has brought us to where we are. Denise, thank you so much for bringing this to the fore from your taskforce. Is that okay?

**Denise Webb - Individual - Member**

Yes, thank you, Andy.

**Andrew Truscott - Accenture - Co-Chair**

Sorry to cut this through. We have time not on our side, but I think people understand the scope and the scale of the issue here and that we actually need to put some serious thought into these definitions. Mike, can we hand over to you?

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

Yeah. I just want to say – folks maybe overlooked it or didn't catch it, but I misspoke when I used the word store. I meant to say produces and electronically manages. So, therefore, they're producing the data in whatever format, proprietary format in some instances. So, that is the rationale behind why they should be able to export it. I'll just leave it at that. Did

you want to turn to the presentation on the terms at this point related to info blocking or did you want to talk more about it?

**Andrew Truscott - Accenture - Co-Chair**

No, I'd like to move forward because I'm conscious that we've got not a huge amount of time today.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

True.

**Andrew Truscott - Accenture - Co-Chair**

But actually, we've set this up so that Mike is prepared. He's not just going to present nonstop for an hour and we pepper him with questions at the end. Raise your hands and I will interject and we will get questions going as we go through this. It's important that we all understand across the taskforce the thinking that Mike and the team had as they brought this together. So, please raise your hands and let us interrupt that way. Thanks.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

Thank you, Andy. So, we'll be getting assistance here so we can go to the next slide. We're going to try to give you a presentation. So, the disclaimer – I think it does apply to anyone and everyone. So, we can tell you what is consistent with what we said in the preamble of the rule. We can't do any interpretation on that.

If you feel something is unclear, ambiguous or even just not the right policy, we obviously encourage comment on that. This is part of the process. So, I'm going to talk briefly about what we went through to get to this proposed rule, but then this is also part of that process before we get to a final rule, which is taking the public feedback here on the policies we're proposing.

So, let's move on. Let's get into it. This is what we're going to try to get to – a little bit of background, try to focus on the terms. If we can, we'll get to these two particular exceptions. We've heard there have been some questions about clarity regarding them. All right. Move to the next slide.

So, where did it all start? I can't say for sure this is where it all started, but in ONC Department's Fiscal 2015 Appropriations Act, Congress asked us to do a few things. One was to issue a report about how pervasive information blocking was, what a strategy would be to address it. It focused on vendors eligible, hospitals, providers. So, they were talking in terms of, at the time, the EHR incentive program.

That was kind of what that first bullet point was about. They wanted us to try to take some action that we could at that point. You can see how they talk about how info blocking frustrates congressional intent and devalues tax, payer investment in particular, I think over

$28 billion in the EHR incentive program. That was like late 2014. Within that short period of time they gave us – move to the next slide – we issued a report to Congress.

So, if you haven't read that yet, it's probably a really good thing to go back to and just take a quick look at. Unlike our rulemaking, It's about one-eighth the size. It depends on how you look at one-tenth if you doubled the pages and so forth. But it's only about 30-some late pages, single-space, though.

So, one thing I wanted to draw out from it here on the screen, just so you can get a sense and do a comparison to what's actually in the Cures Act – this is the definition we put forth in our report to Congress. It talks about a lot of things you probably will see or have seen already in the Cures Act talking about interference with the access exchange in use, about a knowledge standard for those parties who are engaged in info blocking, and then about the unreasonableness of it and talking about the need to balance certain public policy interests. You can see there we listed out some of them and this is almost four years ago from today about privacy, safety, security, and then obviously there's a legitimate economic interest related to innovation.

So, I just wanted to give you that little bit of background about it, where at least from our perspective, we got started with this process. So, in the time after that, we continued to engage stakeholders. We also did what agencies are sometimes asked to do, which is provide technical assistance to Congress on various drafts of bills they're putting together.

So, we did all that. Then on the next slide, this happened – the 21st Century Cures Act passed. That was December of 2016. In it included a comprehensive approach to addressing information blocking. So, it has a definition. It talks about activities that could be reasonable that you could partake in that wouldn't be info blocking and asks the secretary to identify those.

It gave power for enforcement, primary to the Office of the Inspector General to investigate claims. In certain instances – it will be on the next slide – give out civil money penalties. We jumped a little soon. I'm sorry. You heard the word next slide. We can move to that now because we'll talk all about this complaint process too.

Let's go to the next slide, definitely. So, I thought this could be helpful to lay it out big picture. You have the definition there and things to identify are who are the actors, the likely interference – it not saying they have to. It's a likely interference, which I think is important in how we interpreted the statute and provide our proposals. Then what you see there are all the elements of information blocking. All this has to happen here, these steps, before you, whoever you are, actor, obviously, are an info blocker.

So, first, you have to be a covered actor based on how that's defined. It's got to be EHI based on how we define EHI. It's got to be a practice that interferes or discourages that access exchange or use of EHI. It's got to have the right knowledge standards, which differs between certain actors. Congress put in the definition itself if the law said don't share the information, then you can't be an info blocker.

Lastly, to be an info blocker, all that other stuff has to happen, then what you're doing, your practice isn't covered by one of the exceptions either we propose and I should say finalize as well because that's what the comment period is for. So, let's get into those elements now. So, we can move to the next slide.

Sorry. I'll tell you a little more about those consequences. I think these are going to be important when we talk about how we interpreted the statute and put forth our proposals. So, penalties – as I was alluding to earlier, civil money penalties for developers, health information networks, health information exchanges, and developers, certified health IT. That is specifically from the statute, that wording you see there in terms of certified health IT. They have to be developers of that and they have to be health information networks and health information exchanges.

Then from healthcare providers, it leaves it to the Secretary of HHS to, through rulemaking, provide appropriate disincentives for those healthcare providers found to have information block by the Office of the Inspector General. So, it's still the Office of the Inspector General that investigates that claim of information blocking and makes a determination of whether or not that healthcare provider did indeed information block.

So, what have we done? In our role, we, under the authority of ONC Health IT Certification Program, are proposing a ban against developers who are found to information block. There's a condition of certification that allows them to – or doesn't allow them, asks them to attest that they don't info block. Then also, we would publicly list that ban and any determination of certified health IT related to that information blocking claim.

CMS, in their interoperability and patient access proposal that was released simultaneously with our rulemaking, they proposed a public report on clinicians and hospitals who don't attest that they don't info block. Double negative there, but that's their proposal at this point.

Again, also in this rulemaking, we won't talk about it today – our rulemaking, to be clear – we have requests for comment on what would be appropriate disincentives related to information blocking, including whether their current approaches are sufficient in programs or whether there would be new disincentives needed to address information blocking. So, I just want you to be aware of that. It's a request for information and comment on behalf of the entire department, not just ONC.

Moving on now, next slide – let's talk about that first element, the actors. Four of them are specified in the Cures Act. We provide a definition for each of them. Let's jump right in. Next slide.

Healthcare providers – here it is kind of in a bulleted form. I want to make you aware that – and maybe we can just quickly do this for folks – it doesn't necessarily have to do it, actually – at the end of this deck is an appendix. It provides the – I think it starts on slide 31. It provides a definition of healthcare provider as found in the Public Health Service Act. It

includes a bunch of cross-references to other parts of the act and other acts, in some cases, about how you should interpret those terms.

So, we included – I think it's slide 32 through 39 – a table that kind of helps provide more specificity to some of these terms you see on the screen – so, for example, what is a covered entity. So, we lay that out for you in those slides, what entities are covered, same with practitioner. So, practitioner is like a clinical nurse specialist, a clinical social worker, a psychologist. I think also what's important under that covered entity, it gets into states and municipality run hospitals that are covered as well.

The hospital definition is also quite broad. I just want to make people aware about that. We're also requesting some comment about whether we she would focus more on the HIPAA definition, which gets into more the furnishing of services or billing for medical services in terms of how it covers healthcare providers.

So, I'm going to take a breath and tell you why that definition of healthcare providers. So, what the Cures Act did is it amended the Public Health Service Act. So, we looked at the Public Health Service Act. Does it have a definition of healthcare providers? It does. Where did that definition come from? That definition came from the HITAC Act. So, the HITAC Act amended the Public Health Service Act almost in the same way the Cures Act did for the same section, the health information technology, the title, I should say.

So, that definition that we're using was provided through the HITAC Act and then was further amended via the Cures Act. You'll see that same issue come up with health information when we start talking about EHI. Health information, which originally started for purposes of HIPAA through the Social Security Act, that was brought in through the HITAC Act as well and by that same section. So, when we get to that, we'll talk about that. That's how we got to this definition. We are obviously taking comment on it.

We'd be happy if what we provided so far doesn't provide enough clarity to these various terms to provide that via comment and finalization, but we wanted to make sure there was – in the actual rule itself, it just talks to the cross reference, the healthcare provider definition in the Public Health Service Act. Hopefully, this gives you a better sense of why HITAC is what amended the Public Health Service Act to put it in and further amended by the Cures Act.

So, I want to just stop for a second. I feel like I've been talking a lot and I appreciate that. Are there any questions about this as far as some of the background or on this particular definition? Everybody can hear me, rigth?

**Andrew Truscott - Accenture - Co-Chair**

I think so.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

I see them transcribing it. So, I think I'm okay. Great. Thank you.

**Arien Malec - Change Healthcare - Member**

I do have one question. I saw that Congress noted that the penalty is to the developer of certified health IT. Maybe you'll get into this, but the way that the definition of applicability of information blocking goes is it's applicable to the entity that is the developer of certified health IT. I'm having a hard time looking at the intent to Congress and the proposed language. Maybe when you get to that section, you can comment on that.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

Yeah. We don't talk extensively about principles of any type of statutory interpretation in the rule. So, I have to be careful about that. There are a lot out there that are common. Looking at the whole act, avoiding surplusage, which means that you're giving each word or phrase meaning and you want to avoid interpretation that would make any other words or phrases either redundant or meaningless.

So, that comes into play too. Processes such as knowing what it means from a dissociation, how it's been used throughout the act or section of that act in particular, things like that we were looking to – specialized meanings of words as well versus an ordinary meaning – these are all things to look at when you interpret a statute in which we apply in this case.

One thing about legislative intent in history – I'll just speak for myself. You usually don't look at legislative intent unless it's there. It's usually only there in committee efforts, which there weren't. Sometimes you can rely on past versions of the bill to understand that. There are committee hearings. We do cite some of them when it comes to the communications provision and the gag clauses. But unfortunately in this case, there wasn't much legislative history to look at. So, I should just note that when you're talking about legislative intent. But usually, there are approaches of how you interpret statutes outside of that.

Okay. I think we can go to the next term. We'll open up one for debate based on comments I've heard. So, this is our definition of health IT developer or certified health IT. So, I think as Arien mentioned, the provision as the definition goes of information blocking doesn't say health IT developer of certified health IT. It just says health IT developer. But back to some of the things that I mentioned earlier in terms of how we interpret the statute, we actually are pretty specific about this in the preamble. We look at the other provisions.

So, most importantly, a provision that we looked at is – and this is in the same section, Section 4004 – is how to enforce it. So, how would this be enforced? So, the enforcement says that for – that's the Office of the Inspector General – can only investigate a claim that a health information technology developer of certified health information technology or other entity offering certified health information technology either submits a false attestation under the conditions of certification or engages in information blocking.

It also says it can only investigate if a healthcare provider engaged in info blocking or specifically, again, a health information exchange or network engaged in information blocking.

There's also actually another provision that talks about the reliance on health information technology or developers and their certified health IT and not holding a healthcare provider or penalizing them, holding them liable, so to speak, if that developer or entity didn't meet the requirements of certification.

So, contextually looking at it, our approach was to interpret health information technology developer consistent with that provision as a – whether we're going to talk **[inaudible] [00:43:44]** – we didn't do it that way – there would be no enforcement against any developer that didn't certify. Nobody could investigate them for information blocking if you had a broader definition under the statute, at least.

We did all make clear and I think I heard in the discussions earlier that folks understand that, that it isn't limited to just their certified health IT and we talk about why we reach that conclusion – for example, how providers are treated in the section, how HIMSS are treated, that they're not limited. In fact, the examples provided in the Cures Act aren't specific to only certified health IT in terms of giving examples of information blocking.

So, bottom line is if a developer certified a product, they would be subject to the information blocking provision for any actions, not just actions with their certified health IT, but any actions that would constitute information blocking under our proposals.

We do talk, though, about a temporal nexus. I think that's important. So, did the action occur while they were a developer of certified health IT? So, for example, we say like if you would have came in, got a product certified, maybe don't sell your product, you decide this is me anymore, I want out of the program, and so, five years later, somebody tries to allege you're an info blocker.

We don't think that was what was intended by the statute of provision. So, we didn't interpret in that way. However, the one instance that we were concerned about is if I'm a developer of certified health IT. Maybe I get wind of an allegation against me. So, I withdraw or my products get terminated. They should still be held accountable. So, if it's allegation while they were one, it's important.

But also, we posit that what if they dropped out of the program, but then wouldn't release the information? So, for example, the export situation – we talk about comments and information from stakeholders received about concerns about that holding the data hostage. So, we wanted to make sure those types of situations wouldn't occur. There are two different options we've kind of thrown out there. It's not the only options.

We're definitely looking for comment on this, but how we can hold developers still accountable in those situations, so, whether we should require for a period of time you're still accountable of the information or if you continue to store or control the EHI, you should still be accountable. So, I wanted to mention that. We feel like we've laid that out quite clearly in the rule, all different interpretations related to this definition. **[Audio Skipping]**… if there are any questions as to that.

**Arien Malec - Change Healthcare - Member**
Is there a definition of the term "entity?"

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
There is not a definition. That arguably could be plain meaning. We do define an offer what health IT is. So, that is actually in the preamble section, what would constitute still offering the health IT. So, for example, if a third-party is offering certified health IT or you sold it or something of that nature, you're a developer, you get it certified, but then you sell or license the ability to offer the information – excuse me, the health IT. So, you invest that from a coverage perspective in the preamble.

**Andrew Truscott - Accenture - Co-Chair**
Mike? We do refer to organization or individual or entity and individual in various places.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
Right. So, the individual entity is straight from the statute. That's used throughout the statute. So, we kept it individual entity in that regard.

**Andrew Truscott - Accenture - Co-Chair**
So, is it fair to interpret that –

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
You mean that we call them all developers – like, from our perspective, they're still a developer of certified health IT. So, we've created that term that encompasses them, including the offer as well.

**Andrew Truscott - Accenture - Co-Chair**
Cool. Arien, have you got an additional question?

**Arien Malec - Change Healthcare - Member**
No. Sorry. That was my question.

**Andrew Truscott - Accenture - Co-Chair**
Oh, Denise?

**Denise Webb - Individual - Member**
Is there a distinction between developer and self-developer?

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff**

**Lead**

There's a part of the **[inaudible] [00:48:40]** who that's been assigned to which work group, but we ask questions about that. It should be treated differently. I think we've laid that out pretty clearly. I don't actually have that in front of me. I could pull it up. I'll do my best for my top-of-my-head recollection on that, but we were definitely concerned about who were they acting as at the time. Are they acting as a developer?

Really, to offer it or sell it to someone else, normally, you should be – and I think we proposed – treated as a healthcare provider. However, the uniqueness of that is they're still coming through the certification program. So, then the conditions of certification apply to them. So, we've asked how best to reconcile that or if there's really any need for reconciliation regarding that in terms of the application. For example, do you think that certain conditions should not apply to them?

**Denise Webb - Individual - Member**

Right. I know you probably can't respond to this, but it may be something for the taskforce members to think about – so, if a self-developer decides to withdraw from the program and the healthcare provider, they're users that are using the system trying to figure out how there could be – there could be a claim of information blocking of their own providers.

**Andrew Truscott - Accenture - Co-Chair**

Yeah, Denise. This is an area that when we come back out of the workgroups into the full taskforce we'll be directly considering. It touches on workgroup one and workgroup three actually both having touched upon this, but yeah, understanding the context by which ONC has used the actor definitions to structure the regulations. I think we are going to have **[inaudible] [00:50:39]** on that. Michael, back to you.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

If we are going to treat them – we propose to treat them as a healthcare provider, but I think you're raising the issue if they would draw – so, let me think about that some more and see if there's something further we can clarify for you on that one. I'll talk with some of the other folks who are supporting that.

**Andrew Truscott - Accenture - Co-Chair**

You've got 27 minutes.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

Okay. We'll see. Next slide. We have health information networks –

**Aaron Miri - The University of Texas at Austin - Member**

I'm sorry. It's Aaron. I had my hand raised. I do want to ask a quick question on the previous slide. I'm going to ask one more question around the developer question inside there as related a provider organization. To the degree that a provider organization wants to

commercialize a product and it's still part of the provider, in my case as a university, it's not a commercialized product, but it's still under the university, still under the academic medical center side, but it is commercialized. So, potentially, it's a JV or whatever else. Where does responsibility help there? We do this today, by the way. How is that enforced?

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

So, you definitely could be considered a health IT developer of certified health IT if you're offering commercialized – I assume what you mean by commercialized, you're selling it or licensing it. So, it would depend on what the allegation was, right? You're a healthcare provider with the allegation related to use of that health IT, that health IT itself, how you'll be treated. So, as we said throughout the rule, it's very specific and it's that Congressional report, we even said the same thing.

I think the most important point and we'll talk about that a little bit here – you change a couple things when it comes to the **[inaudible]** case. Your knowledge standard changes. Also, you're subject to civil money penalties if you end up being treated as a health IT developer, certified health IT. So, that's what we most wanted to get across in terms of awareness for somebody such as you situated and if you have comments related to that, but the allegation would go to what you were acting as at the time.

Were you a health IT developer at the time of the allegation or were you acting as a healthcare provider? That's the same thing with the HIMM. We give that example. Were you acting as a HIMM in the role when the allegation of information blocking came across or were you acting as a hack provider and providing the information to another healthcare provider.

**Aaron Miri - The University of Texas at Austin - Member**

Got it. Got it. Thank you.

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

Sheryl Turney has got her hand raised as well. Sheryl?

**Sheryl Turney - Anthem Blue Cross Blue Shield - Member**

Thank you, Andy. So, where do you see payers that have tools that they make available that are bought by employer groups and others? They have consumer transparency tools and we have other tools that we utilize, some communicate directly with the member and others communicate directly with our providers. Where do you see that falling in this?

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

So, I think you said payer, right?

**Sheryl Turney - Anthem Blue Cross Blue Shield - Member**

Yeah.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
Then you said payer to commercialized health IT tools is what you probably meant?

**Sheryl Turney - Anthem Blue Cross Blue Shield - Member**
Right.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
So, I can answer only in terms of the definitions, which are did you get that product certified? Are you a developer of certified health IT now? Are you functioning as a health information exchange or a health information network? So, if you want to ask for further clarity about a specific exit situation and whether this entity is functioning as a health information network, I would recommend you make that as a comment on the rule. That's probably not exactly what you wanted. I'm sure you're looking for an explanation one way or another.

**Andrew Truscott - Accenture - Co-Chair**
Michael, we appreciate the regulatory process and the fact that you can't give that kind of interpretation. So, let's move on. Thanks, Sheryl. That's a good point and we are going to discuss that in workgroup and taskforce.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
All right. So, next slide – health information networks – so, as I was saying, we looked at it in terms of how they function. Again, networks, we interpret, I think it's important to say, as health information networks. We took that from the context in which that term was used. Again, as I said, we look at the Inspector General authority and ability to enforce and they use the term health information exchange or network.

The term health information network is used before in two other sections, coordinated sections, I'll call them – trusted exchange and common agreement. Health information network is used throughout and also in reference to the Health Information Technology Advisory Committee. It talks about a role related to health information networks.

So, that's how we landed on health information network instead of just network. The definition is consistent with the functionalities that we're familiar with related to health information networks. I think a key point called out here is it has to be between two or more unaffiliated individuals or entities and it **[Audio Skipping]**. Obviously, that's open to comment.

So, this goes back to what I said earlier on about giving meanings to every term. So, we had to make sure we interpret this in a way that it didn't subsume all the other terms and then those terms would be meaningless. If it was overly broad, you pull in all the other – like a

normal healthcare provider exchanging with another healthcare provider.

So, hence you're facilitating exchange between two or more unaffiliated. So, it isn't just you **[Audio Skipping]** because that could be – that's healthcare to whoever exchange, one-to-one exchange all the time. So, you're providing either the technical infrastructure or you're controlling through policies how that exchange occurs over the network, a third-party network.

We talk about that example in the rule, where a large healthcare provider can create an entity in an area, use a developer's health IT to provide the functionality of the exchange, but if they're the one who is substantially influencing how that exchange occurs under what policies it occurs, then they can be considered health information network. Again, as I was talking to you earlier, the importance of that is it changes the knowledge standard for them and what they're subject to from a penalty perspective.

That is our proposal related to that. Are there any questions about that? Not whether you agree or disagree with it – that's the comment period, but –

**Andrew Truscott - Accenture - Co-Chair**
Arien has got a question.

**Arien Malec - Change Healthcare - Member**
Yeah. So, when I chase these definitions down between EHI and health information network, I conclude that organizations like banks are health information networks under the rule, at least to the extent that they supply or some portions of their businesses that remit payments back to providers that are where the payments are associated with a claim or remittance that has an identifier that's tied back to a patient.

The logical thought process – let me just pause at this – the logical thought process I use is that a health information network is sending or controlling the sending through policies and procedures. The electronic health information, which is defined as information relating to past, present, future condition, provision of service or payment, and that the data has to be identifiable or could be identifiable.

When I spider out those definitions, I at least mentally, the conclusion is that there is a broad range of activities that fall under the health information network definition. I wonder with respect to the way the definition is laid out or with respect to preamble if there is any clarification of organizations that are very clearly not health information networks and organizations where the intent is to make them health information networks. When I mention this, I think people get confused to why I would think that and I get confused to why people would confused why I would think that.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
I think **[Audio Skipping]** one of them confused. Can you explain more how they are either

provider network **[Audio Skipping]** between let's say the patient or provider or how they're influencing the exchange between the patient and the provider. If they're just the stopping point, like information goes from point A to point B and then point B gives the information to point C, that is not, at least in our definition, controlling the sharing between C and A, like providing technology for C and A to exchange.

**Arien Malec - Change Healthcare - Member**

This is an interesting distinction. If I'm a bank and I remit payment from a payer to a provider and I manage the information which is the payment identifier, the change of money, but also, the identifying information associated with that payment, and I am, I would think, providing a service that facilities that exchange of EHI between two or more unaffiliated individuals and entities – that's where I get the definition.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

Be careful how far –

**Andrew Truscott - Accenture - Co-Chair**

**[Inaudible] [01:02:30]** here –

**Arien Malec - Change Healthcare - Member**

I hear you. I'm just trying to understand the definition and where the boundary points of the definition are so that I can understand whether I'm dancing angels on heads of pins or whether there's a breadth of the definition that may be unintended.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

Okay. I don't know if I have any more of an answer for you at this point.

**Arien Malec - Change Healthcare - Member**

I hear you.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

Other than what I said – it's those two – you're affecting the exchange between those two unaffiliated. I wish we had – I have good examples that we did not put in the rule. So, I think you're just – you should comment on that.

**Elise Sweeney Anthony – Office of the National Coordinator for Health Information Technology - Executive Director of Policy**

Arien, this is Elise Anthony. I agree with Mike. Our goal in definitely having you review these are to tell us whether we struck the right balance, right? Are they appropriately inclusive, overly inclusive, or not inclusive enough? So, I think what I'm hearing from you is you may have some concerns about the appropriate inclusivity and whether the definition we have

here works. So, that would be a great place for you to comment. When that comes in, we can consider that.

**Andrew Truscott - Accenture - Co-Chair**
We can do that. Arien, we can do that through the workgroup as well. You can open a Google doc and you can do it as part of the taskforce.

**Arien Malec - Change Healthcare - Member**
Thank you.

**Andrew Truscott - Accenture - Co-Chair**
Mr. Kansky, you had your hands raised in eager anticipation.

**John Kansky - Indiana Health Information Exchange - Member**
Yes. How did you know? So, a rhetorical question and an actual question on that conversation – the rhetorical question is how would a – I think you're going to say, "Yeah, that's what we just said, John, so, you should comment." How would a reader of this rule as written with the definitions as written not come to the same conclusion that Arien would is my rhetorical question.

My actual question is I want to make sure I understood that particular point because it seemed really, really important to my understanding of the rule – if a bank is moving information that's defined as EHI between a payer and a provider and a health information exchange is moving information between a provider and a provider. Why is a health information exchange not a bank – not a bank, but why would we not overlay that same interpretation on the health information exchange?

**Andrew Truscott - Accenture - Co-Chair**
That's a good question and one which we will take forward.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
Yeah. I don't know if this will help, but it's who – you need an allegation of information blocking, right? So, who have you info blocked? Let's say in this case you're saying the bank, but who did I request the information from? Did I request the information from a healthcare provider or did I request the information from the bank? They're controlling the policies of exchange between us two or more unaffiliated providers.

So, if I'm requesting it from the hospital and somehow it has to run through the bank to get to me and that bank determined how that exchange happens, then I see more what you're saying, but I'm not quite sure how I'm following otherwise or the bank provider the tech and said how the tech had to be used for that exchange. It was an exchange between two unaffiliated entities.

You're controlling how they access the information. It isn't like – I'm a pediatrician and I request the information from an urgent care hospital where my **[Audio Skipping]**. Similarly, then, I go see **[Audio Skipping]**. Now, it goes from my pediatrician to the orthopedist and the orthopedist requests the information from the hospital. They request it from the hospital. It's still a one-to-one request for information.

So, that hospital is a healthcare provider. Do they not give him that information and potentially are an info blocker and for whatever reasons they don't give it to the orthopedist? Same approach with the pediatrician and then the orthopedist requests the information from the pediatrician because they want more information. They want their notes too over the network that the healthcare provider provides.

So, now, if they're not affiliated with either one of those, the hospital, they are now facilitating the exchange technically. Maybe they're even doing it through policies between two unaffiliated providers and therefore, they can be seen as a HIN if someone them alleged they blocked the sharing between those two.

But see where the request is going to? It's a one-to-one request and then it's a request between two unaffiliated either through policies established by that third-party, which is a HIN, or across their own network, that healthcare provider/hospital's network exchange.

**John Kansky - Indiana Health Information Exchange - Member**

Should I be able to understand that from reading the preamble? That makes sense.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

So, the example we give is about a large healthcare provider in there, but it's more focused on them substantially influencing the exchange through their policies and therefore, they're going to be treated as a HIN. It's still two unaffiliated parties exchanging through an entity. It's similar. The example in the rule is they develop in an area, a third-party, like they decided to establish this HIN or this entity.

What we were trying to instill there is about the fact about the part about substantially influencing. They establish a third-party and then this third-party, which most folks would call a HIN, it permits the exchange between those two unaffiliated parties in the area. So, we focus more on the healthcare provider substantially influencing how that entity controlled that exchange and therefore they can still be considered the HIN, even though there's this other third-party.

It wasn't actually the healthcare provider who was doing technically setting the policies. They were influencing the policies. It's the same thing in terms of the unaffiliated – we talk about there didn't need to be a certain amount of notes for it to be a network.

It just had to be between two at minimum, two affiliated parties that they were supporting the exchanging, how they either administered it, the policies and agreements, or how they

did with the tack itself. I would welcome comment. I think that's what we were back at. If this is not clear enough or if it's not the right policy even, that's what we **[Audio Skipping]** about this. So, I really just encourage comment on that point.

**Andrew Truscott - Accenture - Co-Chair**
Thanks, Mike.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
Next slide, I think, is health information exchanges – so, again, going to that point about giving each term meaning so that they're not redundant or given another term making it meaningless, we look to define health information exchanges different than how we defined an HIN. I think we relied on both context, our common understanding of this very specialized term based on overseeing a grant program related to HIE and so forth and then we give examples of how we interpret this, both the definition and then how we interpret it.

So, we talk about how it can be a RHIO, a state health information exchange – there again, you see states being identified as potential info blockers as well as I told you the example with the hospital. Then we even talk about how it can be a clinical data registry or so forth because if it's scoped on a particular class of participants or a purpose. So, I don't have much more to say on this one.

**Andrew Truscott - Accenture - Co-Chair**
We've got six minutes before we go to public comment. Mike?

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
Pardon me, I didn't catch that. Did you want to go to the EHI, you said?

**Andrew Truscott - Accenture - Co-Chair**
You have six minutes before we go to public comment.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
Okay. If there are no questions here, I can move to the next one.

**Andrew Truscott - Accenture - Co-Chair**
Move along, please.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
EHI – again, from what I initially said, health information, that definition is part of the section of the Public Health Service Act both amended by the HITAC Act and the Cures Act. So, we started there. The definition talks about – it's pretty broad, whether it's **[Audio Skipping]** any

form or medium, but it talks about who did it and received it, whether it's the healthcare provider plan, public health authority, employer, life, insurer, school, university, healthcare clearinghouse.

Then the second part talks about how it relates to the past, present, which you still see in our definition. Future physical or mental health of condition of an individual, provision of healthcare to the individual or the past, present, or future payment for the provision of healthcare to an individual.

So, what we did here is we focused on the information itself and how it relates to the individual, not on who created or received it. At this point, it only mattered whether one of the actors covered by info blocking had the information or not. So, with that in mind, one clarification we made was that it could include – we propose that it could include information from an individual, but similarly, it could include information from a device, from a school, from any other entity if it's in the possession of one of the covered actors of information blocking.

The other thing we did was – we can move to the next slide – we're clear that we do include PHI. So, just so you're clear what PHI is, it really is individually identified health information. In our workgroup discussion yesterday, one of my colleagues, Morris, was trying – I think it got lost what he was trying to say if he used that definition, protected health information specific to individually identifiable health information is the fact that the individually identified health information definition focuses on who created or received it.

So, then it would be limiting to only information that was created or received by a healthcare provider, a health plan, an employer, or healthcare clearinghouse. The rest is similar in terms of it identifies the individual that is related to those past, present, future pieces, but it would be more limiting because it would be focused on who actually created or received the information.

So, we do include that protected health information as part of our definition, to be clear, but we are broader, as I think it's quite clear to everyone right now. The last two pieces are that we excluded, de-identified, consistent with the HIPAA provision there, 164.514, which talks about what is the definite data and how you would go about de-identifying the data.

Then last, we made it clear that payment information, that would include price information as well. So, that was our approach to defining EHI. The statute, either as amended by the Cures or HITAC, has a definition for "electronic health information." But it does have a definition of health information – also, the same definition that's in the Social Security Act for purposes of HIPAA.

All right. So, I don't think I have much more to say on EHI. I can talk about the price transparency piece, but I don't know if you want me to stop here first.

**Andrew Truscott - Accenture - Co-Chair**

No, keep going.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

All right. Next slide. I forgot this slide. This gives you a better example of some stuff that we think is EHI. You'll see that about additional information that could be considered EHI. Again, I talked about the price information piece, but all the other information that we believe could be EHI, we do have a section of the preamble talking about, for lack of a better term, focus on observational health information – so, this is the clinical information used for the care of the patient.

When I say focused, we tried to emphasize that information blocking concerns would be pronounced when conduct involved. Typically, **[Audio Skipping]** in that article, the preamble, when it involves price information too. So, nothing is precluded, so to speak, but noting here a strong concern about observational health information.

All right. Next slide.

**Andrew Truscott - Accenture - Co-Chair**

Actually, this is a probably a good point to go to public comment, please.

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

Operator, can you please open the public line?

**Operator**

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

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

Thank you. We have a number of public members joining us today. So, we'll give them a minute to dial in. Have we been joined by Steven Lane or Denni? Okay.

**Andrew Truscott - Accenture - Co-Chair**

I believe Steven is actually on vacation. He was leaving on a plane earlier this morning.

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

Okay. Thanks, Andy.

**Andrew Truscott - Accenture - Co-Chair**
No worries.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Operator, do we have anyone dialing into the public comment?

**Operator**
Not at this time.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Okay. Mike, how many more slides do you have?

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
You're talking to me? A lot of it is appendix, but there are a couple of slides – obviously, we have the exceptions slide, but as far as I go, we have the price information one in terms of definitions and the interoperability element. After that, it's really more back to the other elements of info blocking, such as what do we mean interfere with acts or exchange of use, some examples of what practice could implement.

**Andrew Truscott - Accenture - Co-Chair**
Whilst we're waiting for public comments, can you go and talk through the price information, please?

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
Sure. I think I can probably offer some clarity there for folks.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Sorry. One more quick check from the operator. Any public comments?

**Operator**
We have none at this time.

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

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

Okay. Next slide, then. So, price information – so, we have a section, like I alluded to a few times, our interpretation of payment and future for payment. That includes price information. We have an extensive discussion in there about why we find it to be problematic, not knowing the price information, how we think it would improve both competition and lower the cost of care in the market.

On behalf of the Secretary and the Department, we have extensive questions for the public about how we should capture that information, what information we should capture, can it be technically captured, and what the department can do to make that information more transparent. We also talk about how it relates to information blocking too.

So, I want to make sure of the clarity and distinction between that because we talk about how we have a unique role in setting the stage for such future actions by establishing the framework to prevent the blocking of price information. So, we've asked about what are the parameters related to price information in terms of its scope as part of EHI. So, I just wanted to touch on that quickly. If there are no questions, we can go to another slide, I think.

**Andrew Truscott - Accenture - Co-Chair**

Sure. No questions, carry on.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**

Interoperability element – so, as you can see, I think this slide is pretty much self-explanatory. It's almost everything we say in the preamble about this. So, we were looking at trying to make sure we capture anything that would lead to the ability to access the EHI. That's important particularly when it involves intellectual property rights or other rights that may need to be licensed to get to the information. That comes into play particularly with the exception we provided.

So, on RAND terms – reasonable and non-discriminatory terms – the licensing, Mark could talk about that in the appropriate work group. I know we don't have time today. But generally speaking, Congress didn't provide any type of exception to sharing of information based on IP, intellectual property rights. They didn't say, "You don't have to share it if you have intellectual property rights." But we know that's important regarding information and the development of new products.

So, while we still want to make sure there's access to information, the balance here is that we would ask that whatever needs to be licensed to the intellectual property rights are done on RAND terms. RAND terms take into account things such as the novelty of the product that has the IP in it or the technology in terms of deciding what is appropriate price for a license, so to speak, or royalty. So, I won't say much more about that, but the purpose of that we've tried to make pretty clear why we think the definition of interoperability element and how that relates to some of the exceptions.

Next slide – I think I can at least get through this. So, access, exchange, and use – we tried to define those terms. Again, we looked at HIPAA here. Not that it's positive, but we tried to be

aligned with that. There's how we define it, but actually, we say rewrite and modify when it comes to use. I don't really have much more to say about this one. We can move to the next slide.

So, these are just some of the practices that we thought could implicate the provision. It's important to note there that it doesn't necessarily violate it. Let me just go to the next slide so I can talk about why that's true. There are certain things that have to also be met going back to that prime **[inaudible] [01:24:42]**, whether or not you actually violated the information blocking provisions. So, you have to have knowledge – if you're a healthcare provider, you have to know that what you did was likely to interfere and that it was unreasonable.

So, that goes back, if you remember, the congressional report in some respects, we talked about it being unreasonable. I think that's also the reason you have those necessary and reasonable activities congress asked for us to identify. Comparatively, if you're a developer of certified health IT, a health information network, or a health information exchange, this also was noted in the congressional report to Congress, it could be simply you should have known that the practice was likely to interfere.

You don't actually have to know. This is like mens rea in legal terms and criminology. So, it's more of a gross negligence type of approach. You should have known, just as a comparative analogy. So, I just wanted to identify that difference as part of one of the elements. We can go to the next slide.

So, required by law – Congress, specifically in the definition talks about how if it's required by law not to share the information, then you're not an information blocker. We give an example in the rule to that. There's certain privacy under the privacy rule that permits the not sharing of information that essentially is required by law. I want to make clear – I'm sure this has been talked about before – it's different than normal privacy, the HIPAA, which is really disclosures are, for lack of a better term, dismissive.

Certain conditions have to be met before the information can be exchanged. For example, most of the time, it's consent and authorization. So, from an info blocking perspective, we don't see it that way. Information should be exchanged and you should have policies in place to meet those conditions, not the lack of a condition being, "I didn't share it." That's why we say you should be having organizational policies when we talk about the privacy exception and how you're going to fulfill any conditions, whether it's through the privacy rule or through a state law that requires certain things to be in place before that information can be shared.

I think that pretty much takes us to the exceptions, at that point. The next slide would be exceptions. That's the last –

**Andrew Truscott - Accenture - Co-Chair**

Mike, it actually completely takes us to time as well.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
Great.

**Andrew Truscott - Accenture - Co-Chair**
Well, not great.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
I'm still comfortable getting rid of that.

**Andrew Truscott - Accenture - Co-Chair**
What I would like, Mike, if you can, could you possibly join us at 2:30 on the workgroup two call and actually work through these at the beginning of the call?

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
Okay. I was actually going to let Mark talk about these exceptions, but I can check my schedule and see if I can join.

**Andrew Truscott - Accenture - Co-Chair**
If you're happy to let Mark loose on it, that's fine too. You guys sort it amongst yourselves.

**Mike Lipinski – Office of the National Coordinator for Health Information Technology - Staff Lead**
Okay.

**Andrew Truscott - Accenture - Co-Chair**
Are there any final questions from the taskforce as we go into sunset of this call? No. Great. Okay. Thanks ever so much for joining us. Members of the public, thank you very much for joining us as well. Lauren, I think we're good to adjourn.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Yes, we are. Thanks, everyone.