

Transcript
April 4, 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	Back-up/Support
Morris Landau	Office of the National Coordinator	Back-up/Support
Lauren Wu	Office of the National Coordinator	SME

Operator

All lines are now bridged.

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

Good morning, everyone. Welcome to the information blocking task force meeting. A quick roll call and then, we will get started with an **[inaudible] [00:00:13]** from our two workgroups, one and three. Andy Truscott?

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

Present.

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

I believe Michael will be late. Steven Lane?

Steven Lane - Sutter Health - Member

Good morning.

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

Sheryl Turney? Denise Webb?

<u>Denise Webb – Individual - Member</u>

Present.

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

I believe Sasha is going to be absent. Aaron Miri? Arien Malec may join us late. Valerie Grey?

Valerie Grey – New York eHealth Collaborative - Member

Here.

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

Anil Jain?

Anil Jain – IBM Watson Health - Member

Good morning.

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

Good morning. Cynthia Fisher?

Cynthia Fisher - WaterRev LLC - Member

Yes, present.

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

John Kansky? All right. Lauren Thompson and Denni McColm? Okay. Andy, I'll turn over to you to get us started.

Andrew Truscott - Accenture - Co-Chair

Thank you so much, Lauren. Hi. Good morning, everybody. Thanks for joining. This is the first of the come togethers of the task for with the outputs from the various workgroups. As we start walking through these together, we do actually have a revised **[inaudible] [00:01:21]** working, too. So, Mark, could you quickly just keep us all up to speed on that?

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Do you mean just share my screen or did you want me to talk about the document?

Andrew Truscott - Accenture - Co-Chair

Well, you could do both.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> <u>Lead</u>

Yeah. I'll share the screen. Just generally speaking, Andy has taken much of the recommendations that are cleaner from the Google docs we've been working off of and made a separate document that we're going to kind of go through this morning. I appreciate everyone joining so early, especially the folks central and west coast. So, I think the goal here is we're going to start with Workgroup 3 and try to get through those recommendations. And it seems like those are pretty well settled but we definitely want the entire group or whoever is able to join today to weigh in. Then, hopefully, we'll have some time to start jumping into where Workgroup 1 is at with their work.

There are still some outstanding issues. We're talking about price transparency later today and we're not going to discuss that on this call I don't believe. But we've made good headway in all three groups. And as far as Workgroup 2 goes, we're saving that because the workgroup members are working through their different recommendations and putting pen to paper right now. But we'll have more in the coming meetings.

Andrew Truscott - Accenture - Co-Chair

Thanks for that. That wasn't guite what I wanted.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Okay, what did you want?

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

The revised timeline that we're working to.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Oh, the revised timeline, okay. Let me try to pull the screen back up and stop sharing because it's my misunderstanding.

Andrew Truscott – Accenture – Co-Chair

But thank you for the introduction to [audio skip]. It was good.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Well, now, I'm having issues. Lauren, do you have the timeline? I'm trying to figure out to stop sharing.

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

It's up now.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Okay, it is? I can't find the screen. Let me try to do that. I've had some issues once I started sharing where the – can you run through the changes?

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

Okay.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

I've got it up. Bear with me, folks. Oh, shoot.

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

I've got it, Mark, if you can't see it. So, the plan is to hopefully present final or near final draft recommendations next week on the 10th. I would say as many as possible. If we're able to present those for a vote for the full committee, we'll do so. But otherwise, we will do that at our next full HITAC meeting on the 25th, which is virtual. I think we'll see how it goes with today's call with getting through any outstanding issues for those recommendations that are near final. And then, I think we'll just have to regroup with the co-chairs offline to see what, if any, will be ready to present for a final vote next week on the 10th.

Andrew Truscott - Accenture - Co-Chair

Thank you, Lauren. This is the timeline we're marching to, guys. Let's crack on with it, basically. Any questions from the task force membership? I will take that as tacit agreement and we'll carry on. Okay. Mark, can you now put up the document we're going to start working through?

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Yeah. I just had to exit out of Adobe and I'm going to try to get back in now because I was having some issues. So, give me one second.

Andrew Truscott - Accenture - Co-Chair

So, what we've done, team, is we've produced a single document. We've taken out a lot of the discussion notes and everything we've made. We've, obviously, retained those for posterity but we've taken out a lot of the notes we were working through. And we just simply have the original regulation draft. And we have our proposed regulation draft. And we also have alongside that, so you can see all three together, a marked up version that has the proposed text with all of the mark ups in and deltas from the original text. So, we can completely see the changes that we are making and see them in context. We've also preserved in that document the discussion points and any preamble recommendations that were made as well.

It's our intent that this is the content, which will form the backbone of the letter of transmittal that goes to the Office of the National Coordinator. And we take it that way. So, I hope that's pretty clear. And we're going to start with Workgroup 3, which is scrolling on the screen.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Can you all see that, Andy?

Andrew Truscott - Accenture - Co-Chair

Yes, we can in markup mode.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Mark up mode.

Andrew Truscott - Accenture - Co-Chair

You're not logged in appropriately, are you? So, you can't see the actual comparison mark up and deltas.

Mark Knee - Officer of the National Coordinator for Health Information Technology- Staff

Lead

Sorry, how do I have to log in for this? My apologies. Do I need to exit out? I just clicked on the link and this is what it took me to.

Andrew Truscott – Accenture – Co-Chair

Yeah, it's not logged you in.

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

Try the top right where it says sign in.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Thank you. I appreciate that. Let me take this off of the screen so not everyone sees that.

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

Hey, Andy, real quickly, it's Aaron Miri. I joined.

Andrew Truscott - Accenture - Co-Chair

Hey, man, how are you doing?

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

Good.

Andrew Truscott - Accenture - Co-Chair

We're just getting up with the technology.

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

That's the whole point of this task force.

Andrew Truscott - Accenture - Co-Chair

Well, we're discussing health IT. This is just more general.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

All right. Let's see if this is better. I'm signed in and it's still not showing it.

Andrew Truscott – Accenture – Co-Chair

If you scroll to the bottom of the first page of Workgroup 3, you should be able to see something there.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

All right.

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

Go to the first tab left. We're all watching you now. You're not logged in appropriately.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

I just gave my Google log in.

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

That's okay. I'll do it.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Let me get out of here and then, share. How about that? No, that's not right. I'm in.

Andrew Truscott – Accenture – Co-Chair

Okay. You should be able to see my screen now. Can you see my screen?

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

We can see it.

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

Can you guys see my screen now?

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

Yes, I can see it.

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

Okay, fine great. Okay.

Steven Lane - Sutter Health - Member

But you'll need to blow it up bigger. You'll need to go to like 150 or 200 percent.

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

Is that better?

Steven Lane - Sutter Health - Member

That's perfect, thank you.

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

Okay. So, this is Workgroup 3. I was going to suggest that actually, someone from Workgroup 3 might want to take us through these and walk us through. Is that achievable? If not, I'm happy to but you're going to get really board of me talking for two hours.

Denise Webb – Individual - Member

Andy, this is Denise. I'm willing to help but I'm going to have to read through each of these.

Andrew Truscott – Accenture – Co-Chair

No, that's fine because we need to be up to speed anyway.

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

I'm happy to help as well, I just don't have the computer open in front of me.

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

Okay, no worries. Well, you can do color commentary about our discussions. I'll kick off and, Denise, when I get tired, you can kick in. How about that?

Denise Webb - Individual - Member

Okay.

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

So, the first regulation we looked at was purely the same in that round, thou shalt not do information blocking. And the workgroup endorses the rule with no recommendations to it leaving as written a health IT developer must not take any action, which constitutes information blocking as defined in [inaudible] [00:10:55], etc. And we were quite happy with that and had no recommendations to make.

Denise Webb – Individual - Member

Right. And this is a condition of maintenance and certification. The first one of several.

Andrew Truscott - Accenture - Co-Chair

Yes.

<u>Denise Webb – Individual - Member</u>

And this task force or workgroup just looked at information blocking assurances and communications.

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

Yes.

Denise Webb - Individual - Member

I'm just hoping that whoever else is listening to know that we only looked at three in this task force.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

And just to chime in, we also looked at the enforcement overall issues with that.

<u>Denise Webb – Individual - Member</u>

Right.

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

Okay. So, the second was 402, Assurances. And Denise, do you want to walk through this?

Denise Webb - Individual - Member

Okay. So, assurances that had to do with making assurances that you were not taking any action that constitutes information blocking that could inhibit the appropriate exchange, access, and use of electronic health information and also ensure that the health IT certified under the ONC program works as advertised and meets the requirements. I'm trying to recall here, Andy, what we changed in our proposal. Here we go. Down in No. 3, the health IT developer must not take any action that could interfere with the user's ability to access or use the certified capabilities for any of the purposes within the scope of that technology certification. And we are proposing to add and the health IT developer shall provide honest communication and expert advice as required by a user.

And otherwise, we left this intact. I believe this is the only change we proposed in the first part.

Cynthia Fisher – WaterRev LLC - Member

So, does the red line meaning that you're eliminating it? It reads as –

Andrew Truscott – Accenture – Co-Chair

No, no, no. The red line is additions. If it's a strike through then, it's a recommendation to eliminate. And you'll see that on other ones where we're proposed taking out some language. This is purely a [inaudible] [00:13:36].

Cynthia Fisher - WaterRev LLC - Member

Okay. It matches the recommendation, I see. Okay. Thank you.

Denise Webb - Individual - Member

Right. So, that's A3 is where we made a change. And then, on maintenance of certification, 1i and 2 are the same. And we're proposing to add Roman numeral III here. If for a shorter period of time, a period of three years from the date of withdrawal by the health IT

developer of a certified health IT product and certification. So, this has to do with the documentation as far as showing that you have compliance.

Andrew Truscott – Accenture – Co-Chair

Yeah, it's about [audio skip] records the fact -

[Crosstalk]

Denise Webb - Individual - Member

This is about retaining the records. So, the ONC's proposed rule, if you scroll back up so I can — was 10 years from the time you're certified or for a shorter period of time for three years from the effective date that a health IT developer removes — excuse me, that certification criteria are removed from the Code of Federal Regulations.

Andrew Truscott - Accenture - Co-Chair

Basically, we just said you're going to have to have it for three years at least. Now, there should be nothing contentious there. That just seemed like a slight loop hole that was there. This is in Section 2, Denise, was where we were looking at the timeline.

Denise Webb - Individual - Member

And this concerns when they must comply with the requirements as far as providing the customers with certified health IT. And it was 24 months of the final rule's effective date. No change there. And we struck within and whichever is longer for the second part for 12 months of certification of the health IT developer but never previously certified. And then, we added No. 3 that ONC will preserve on the CHPL or in another format a list of the start and end dates of each previously certified health IT product. We want that to be retained in perpetuity on the site. So, any discussions on these proposed changes?

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

So, I'd like to watermark proposed rules against a real world scenario for a second here and just make sure it stays muster. So, let me give you a story. I'll redact names but let's just see if our proposals pass muster in terms of the vendor's information blocking behavior. So, large, ginormous certified health It EHR vendor, there's not one that sits on the HITAC, refuses to allow for hospital provider to have a test environment to build against ATIs, forces any downstream vendors trying to connect to them as exchange data to go and be a partner with them through a development program so they can take a portion of profits and/or charge for the interfaces and for any hospital charge or bill against the development partner thing. They want a portion of any proceeds or additional dollars to compensate for information sharing.

So, when I look at that situation, which, obviously, completely dissatisfies everybody, including any startup from wanting to exchange data and try to do things better with the EHR data, which is the whole point of it because they want more money or they want to forbid this practice. Do our proposed rules help stifle that kind of behavior to allow more freely

exchange of information?

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

Would this be the right regulation to address that within?

Denise Webb – Individual - Member

This is conditions of certification and maintenance so what conditions they have to meet under the certification program and what they must maintain under the certification program. This particular part of the regulation does not address — what I think you're describing is information blocking and where that would fall. They're violating a condition of certification and maintenance.

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

Right. That's what I'm saying.

[Crosstalk]

Denise Webb - Individual - Member

Right, right.

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

I think they're violating multiple things, including the certification of **[audio interference]** and making sure the won't do that. Go ahead.

Denise Webb - Individual - Member

Right. So, then in the scenario, the way I read it, the scenario you described, they would be actually not meeting the condition of certification and maintenance for the assurances piece of this as well as for the information blocking. And then, the enforcement actions would then come into play. So, I don't think there's anything we're proposing or need to propose in these conditions that would preclude that all happening. These conditions would create those protections, I believe.

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

Yeah. No, I agree. That's why I wanted to run it against an actual real world scenario that's less than one day old of me yelling at people. So, good. I'm good.

<u>Denise Webb – Individual - Member</u>

Oh, boy.

Andrew Truscott - Accenture - Co-Chair

I do want you to hold onto that anger and concern because I think there is something we'll

discuss in Workgroup 1 with definitions where I think that might come more into play again. So, hold onto that.

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

Roger that.

<u>Lauren Wu – Office of the National Coordinator for Health Information Technology - SME</u> Hi, this is Lauren Wu from ONC.

Andrew Truscott – Accenture – Co-Chair

Hello, Lauren.

Lauren Wu - Office of the National Coordinator for Health Information Technology - SME

Hi, there. So, I think I recall the initial discussion around the addition of this recommended language for No. 3. And maybe someone could add some commentary here. And, of course, you are all welcome to provide whatever recommendations you feel are appropriate. But as I read it right now, I believe the CHPL already does this.

Andrew Truscott – Accenture – Co-Chair

Does what, Lauren?

Denise Webb - Individual - Member

Are they required to do it? No. 3 here on the screen, Andy.

Lauren Wu - Office of the National Coordinator for Health Information Technology - SME

Yes. Well, we do because that's the way that the certification ID is created when a provider or other end user goes in to create the unique ID for purposes such as attesting to CMS payment programs. There's a necessary tie in to the dates when that product was certified.

Andrew Truscott - Accenture - Co-Chair

As I said, Lauren, this is a question that the workgroup asked ONC and the input we got was that was not a public list that was available in perpetuity. Are you telling us that it is?

Lauren Wu - Office of the National Coordinator for Health Information Technology - SME

I can double check on this but your question or the recommendation here is that, if I understand it, you would like the start and end dates to be publicly available for every single listing whether or not it currently is certified or not, correct?

Andrew Truscott – Accenture – Co-Chair

Yes.

Lauren Wu – Office of the National Coordinator for Health Information Technology - SME

Okay.

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

That was the intent of the workgroup. And we're now talking about this as a full task force. I'll just put words in the task force's mouth, but I don't think anyone would argue with that. And if that is the case, it's what you do right now then, great.

Lauren Wu - Office of the National Coordinator for Health Information Technology - SME

Okay. I feel 85 percent certain on that but I will just go triple check and I can get back to you.

Andrew Truscott – Accenture – Co-Chair

That's [inaudible] [00:22:15] certainty, cool. Let's move on to the next one.

Denise Webb – Individual - Member

Andy, before we move on, this is Denise, I just have one question. So, if ONC is already doing that, is there something that requires them to already do that? Because they could decide we're going to implement some other system to track. I just want to make sure is that just a practice or are they required to do that? If Lauren can get back to us on that, too.

<u>Lauren Wu – Office of the National Coordinator for Health Information Technology - SME</u> Okay. Got it. Will do, Denise.

Andrew Truscott - Accenture - Co-Chair

Okay, next one. So, we were asked for additional information on participation in the TEF. And I know across the task force, we've discussed this in the different workgroups. We've said we're going to revisit this when things are published out and park that until then. And I know we've got another similar comment from elsewhere as well. Okay. No comments. Let's move to communications. Denise, I'll hand it over to you for the meaty ones.

<u>Denise Webb – Individual - Member</u>

Okay. So, I wish I had this on paper so I could read down the whole thing to see what we're proposing here. So, this is – all right.

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

I forgot everyone is looking at my screen. I'm sorry, guys.

<u>Denise Webb – Individual - Member</u>

Oh, I am looking at your screen but it's hard to launch a discussion until I see the whole context of what we changed. And had I known I was going to be speaking on this, I would have printed these off. I didn't have your documents. If you can scroll all the way down to where we made our change.

Andrew Truscott - Accenture - Co-Chair

There you go, the first one.

Denise Webb - Individual - Member

So, this portion discusses the communication about the health IT developer's products and what's protected and what's not. And those protected communications that are to be permitted, if the health IT developer blocks these in any way, that's going to be considered information blocking under the conditions of the certification and maintenance requirements. So, we're proposing – actually, that looks –

Andrew Truscott - Accenture - Co-Chair

This is protecting people who blow the whistle.

Denise Webb - Individual - Member

Right. We added that to E. Any person who makes communication covered by 2i to an appropriate entity must not be subject to retaliatory action.

Steven Lane - Sutter Health - Member

And it kind of goes without saying that this includes employees of the health IT developer.

Andrew Truscott - Accenture - Co-Chair

Yes, that's what it says. Any person.

Denise Webb - Individual - Member

Actually, I believe that we are adding some text in another part here relating to self-developers and that they are not permitted to restrict their users within their company. So, if a health system develops their own certified IT then, the users — because there is an exception where health IT developers can put a gag on their own employees, except in the case of self-developers, the users of their product would not be able to do that. And I don't remember which section of the regulation that was in.

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

We'll get to it shortly.

Denise Webb - Individual - Member

So, we did address that. All right. This is a pretty straight forward –

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

This is straight forward and basically saying that there are these five reasons that you have to do. And any person who alerts, if you're not doing that, you can't retaliate against them. We know full well that, obviously, there is whistle blowing legislation in place. However, having asked the question back to the ONC, that's primarily focused at federal employees, etc. So, we wanted to make a more general statement that you can't take retaliatory action against someone who blows the whistle when you're failing.

Denise Webb - Individual - Member

Right. Good. Let's see. Where's that next change, Andy?

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

There we go. This is where we get into fair use.

Denise Webb – Individual - Member

Right. And this is why it would be good to have Sasha on but she's not. But I know Aaron is on. So, let's see. I'm not sure why fair use is in red there because it's the same –

Andrew Truscott - Accenture - Co-Chair

We added it.

Denise Webb - Individual - Member

All right. So, 1 and 2, we added the words fair use, communication of screen shots of the developer's health IT. And subject to the limited restrictions, which are in Paragraph A2iiD, which I don't know what that paragraph says, I apologize. And then, we're adding and with the understanding that any actor disclosing the screen shots are responsible for ensuring that each use is being put to fair use.

Andrew Truscott - Accenture - Co-Chair

The basic point around this was – go on, Denise.

Denise Webb - Individual - Member

I was just going to say there was a concern by some of the members in the workgroup that once screen shots are disclosed for fair use, there were some concerns, I believe, about redisclosure, if I'm recalling that conversation on this. And the original actor who had disclosed the screen shots needs to be responsible for what happens to those screen shots.

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

That's right. Let me speak to the example that I gave. It has good coloring here. So, the example was in a prior life, I was trying to work with another hospital to exchange information. We were trying to figure out how to show specialists and whatnot. It was across country borders. And in order to do that, again, this is all for treatment purposes, it was like let's look at the EMR and see if we can gather the right data on your population so that we can be able to do telemedicine, tele consult, etc. And I was told by the vendor that I was using that I'm not permitted to share any screen shots because of fear of IP leakage and whatnot.

And in working it through, Sasha brought up a good point about how do you control and keep people from stealing your UX design and layout and whatnot because that could be IT in proprietary nature of how things are laid out, which is a fair comment. But in this case, it was hospital to hospital. I'm not talking about a developer. We're trying to help take care of patients. And to that end, it should be my responsibility to make sure nobody is doing anything nefarious with it. Again, assume innocent intent and fair intent. And that's how this

came up to be.

<u>Denise Webb – Individual - Member</u>

Right. I remember that, Aaron. That was a really good example. So, we just definitely didn't want to preclude that kind of activity from being permissible for sharing work flows or trying to work out a situation with a particular patient but then, to alleviate some of the concerns about that sharing to make it clear that there is responsibility on both parties' parts. So, the two health systems that are sharing the screens to make sure that fair use is applied throughout.

Andrew Truscott – Accenture – Co-Chair

If you look at the original drafting over here on the left hand side, this entire clause is around enabling developers to protect their intellectual property. In Clause 1 in the original drafting, it does utilize fair use of the copyrighted work. So, with our proposed drafting, we just added fair use to screen shot usage as well. And there is actually an additional section we're about to get to that discusses screen shots ad nauseum. Mark, you're about to jump in.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> <u>Lead</u>

Yeah. I just wanted to note that we do discuss fair use in the context of screen shots in the preamble. I understand you all might be making the recommendation because you want the reg text to be clear. But I'll just read out the sentence we have in the preamble just for everyone's clarification. We say we consider that the reproduction of screen shots in connection with the making of communication protected by this condition of certification would ordinarily represent a fair use of any copyright subsisting in the screen display and developers should not impose prohibition to restrictions that would limit that fair use. So, I just wanted to make the point that we do talk about it in the preamble.

Denise Webb – Individual - Member

I think we were concerned and we wanted it clear that the health IT developer does not prohibit the fair use communication of screen shots.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

No, and I get that. I think it might be helpful. I understand this is a proposed recommendation for reg text. It might be helpful, Andy, when you're putting together the final transmittal of recommendations to kind of explain where you're differentiating. Give more background on what the recommendation is because I guess what we're saying is what would – exactly. Yeah. That's fresh content. I haven't read everything yet. But I just wanted to make it so we could understand where you think that line is drawn with regard to screen shots and fair use.

Andrew Truscott – Accenture – Co-Chair

Yeah. We have some fairly exhaustive conversation there and we try to capture it all. And I appreciate this is new material for everybody. It's Meeting 1 of the full task force. That's okay

that not everyone is completely up to date on it.

<u>Denise Webb – Individual - Member</u>

Right. And that's why as we're going through this, it's hard to just look at the regulatory text and not be able to see the contextual notes as well. So, that's why I'm struggling a little bit with explaining some of this.

Andrew Truscott - Accenture - Co-Chair

That's okay. So, the next section we have, which is more exhaustive around screen shots, in general. We've left much of that intact until we get to this third section. And the premise being here you don't infringe any third party intellectual property provided that and then, we cut to whatever is done. And we focus in on this a point around the potential re-users of the communicators of that IP, Denise.

Denise Webb – Individual - Member

So, on this one, Andy, I can give some context to the whole task force. So, If you think about a certified health IT product that there are thousands of different screens in the user interface. And what was being proposed in the rule is that each aspect of that screen display, there must be written notice that each aspect of every screen display that contains third party content. And we collectively thought that was extremely complex and onerous when you think about thousands and thousands of screens that could have different third party content. So, we thought it would be more feasible and appropriate to suggest a change in the regulation to instead require that a notice of the list of types of content, who the third parties are, and what kind of content would appear in the screens instead of an enumeration by each screen. So, that's what this change is proposing here. Excuse me.

Andrew Truscott – Accenture – Co-Chair

Is that clear to everybody? I'll take that as a yes, Denise.

<u>Denise Webb – Individual - Member</u>

Yes. And, obviously, we know that this is going to require the person who is releasing those screens to just like there would be PHI in the screen, they have to be sensitive to that already under HIPAA regulations. So, they're just going to have to be cognizant of what other types of content might be in those screens.

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

Yeah. And then, move on to unprotected communications. You'll like this one.

<u>Denise Webb – Individual - Member</u>

Right. So, our workgroup had quite a bit of discussion about communications that should not receive protection and are actually proposing here as a recommendation to ONC that they add in the regulatory text some language around unprotected communications. So, we're actually – this is an entire addition of a new category. Specific communications that are not extended the protection or restrictions in protection where those communications are considered unprotected in that. They are either protected by other legislation or regulation

or are false or unlawful. Andy, weren't we also going to suggest, too, here that ONC add some examples in the preamble?

Andrew Truscott – Accenture – Co-Chair

We somehow managed to distill about seven hours of conversation into thirty words. And this is the preamble recommendation that goes alongside that.

Denise Webb - Individual - Member

Thank you for pulling that up. So, things like communications that are protected by attorney/client privilege is an example. We had quite a bit of discussion about where this belonged because, originally, I think there was a proposal to have it in the regulatory text. But that is usually not what's done in regulation. I have all of these examples.

Andrew Truscott - Accenture - Co-Chair

Yeah. So, that point makes it clearer for the task force as well about where I think it was, too. So, where there is existing legislation, which would have an impact, we've defined some things there. But where something is clearly unlawful or false, we think we found pretty much every example in there. Mark, have you got any comments on this? Because I know you were pretty much in the weeds in this conversation.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

No. I think what Denise said about generally regulatory text should not include the types of things as examples. So, I think that's right to put it in your recommendation for the preamble. And it's a recommendation that you all made. So, I don't have any comments on that.

Andrew Truscott - Accenture - Co-Chair

Okay, cool. I love this. Doing alternate ones with Denise means I get all of the short ones. There was a request for comment around communications. We read through these. We discussed them. And we actually believe we used many of these comments to inform the recommendations we're making on the **[inaudible] [00:39:52]** set of regulations, which has worked. So, we decided that we wouldn't actually have additional commentary to make. That said, as a task force we might. So, we're going to give everybody access to these complied drafts once we've worked out exactly how to do that with Mark. And then, at that juncture, I'd like it actually if you have suggestions and additional comments to make, we should get these in because then, we can discuss them in the upcoming task force meetings and get them churned out in our recommendations. Okay?

Cynthia Fisher - WaterRev LLC - Member

Andy, can we print this out just because I didn't catch that last paragraph. I'm just wondering if there's a way that we can get access to that and print it.

Andrew Truscott - Accenture - Co-Chair

Sure. Absolutely. This is a Google doc just the same as everything else that we've been working with. So, you can have access to it. Lauren, can you circulate the URL to this please

around the entire task force?

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

I can do that.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Andy, I think since you created this Google doc, you would need to provide access rights to everybody. So, it might be easier –

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

It's already done.

[Crosstalk]

Steven Lane - Sutter Health - Member

If we have access, can you send us the URL?

Cynthia Fisher – WaterRev LLC - Member

Yeah. We need the URL because we can't get access otherwise, Andy.

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

That's why I asked Lauren to send the URL. Also, we will be moving this into an ONC doc. This is just one I created because they were unable to import the markup. But we are going to be addressing that when we find out how to. So, please don't make changes to this one right now. Please just view it. Is that okay?

Steven Lane - Sutter Health - Member

Sure.

Andrew Truscott - Accenture - Co-Chair

Thanks. Okay. Moving on.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Andy, just a note. In telling me about the Google doc, I think it says anyone with a link can view but you would need to either change it to anyone with a link can edit or you need to invite people to edit. I think that was the issue with my version. It wasn't showing —

Andrew Truscott - Accenture - Co-Chair

No worries. I've just told everyone that they can only view it anyway until we sort out of the final one.

Denise Webb - Individual - Member

Okay. What I think Mark is saying is for the task force to see the red lines, you have to send it to –

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

Oh, okay.

Denise Webb - Individual - Member

Yeah, because if you just send it for view, I don't think the task force can see the red lines. It's just going to be black and white.

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

There you go. Now, you can. Mark, go back into it. Can you see the red lines?

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Keep moving on and I'll check.

Andrew Truscott - Accenture - Co-Chair

Okay. So, this is the review of certified health IT or health IT developers' actions. So, the original ONC proposal was to utilize the existing processes that have the direct review, which we all know and love have been in place around maintenance and certification for a number of years now. We actually did suggest a slight addition to this in how notices are communicated and to say whilst the majority of communication is done by email, where there is a notice that initiates direct review, potential nonconformity, nonconformity, suspension, proposed termination, termination, ban, or anything around appeals is simultaneously issued by both certified mail and email because these are notable events inside the certification process. And there has been concerned raised in the past where email hasn't necessarily gone to the right place or been viewed in a timely fashion.

And we want these to be timely. These are important notifications and will become increasingly important as we go through the needs around information blocking. So, the group felt that it was important that these were provided simultaneously in certified mail as well as email. So, there's a guarantee of delivery and has no guarantee of being read but there's more of a guarantee that it's being received.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> <u>Lead</u>

And, Andy, as far as the group's intent with this, I just want to make sure. Are you saying that you want both means of sending out a notice for all of the steps that would be included for the conditions of certification or are you saying for also the previously established direct review that's tied specifically to certified health IT? And I ask because, in our proposals for the condition of certification, we're not including suspension or proposed termination. So, those probably wouldn't be relevant if you're talking only about the conditions and

maintenance of certification.

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

That's a good point. I don't believe the group has discussed that at that level of detail. Does anybody else on the workgroup have a view?

Denise Webb - Individual - Member

Well, this is Denise. I have a comment on that. If that was not done in the past and it was only done by email under the program to give notification of proposed termination, I would suggest that we don't want this just to be specific to the conditions and maintenance of certification requirements.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

So, I'll talk and then, if Lauren Wu, I know she knows this issue very well but in Section 505, we talk about communications. I believe the way it's written now is that for direct review, for certified health IT, the default is email but there is the possibility that it's discretionary that ONC could use other means like certified mail if necessary. And I believe that's the way it's currently written.

<u>Denise Webb – Individual - Member</u>

Right. And that's what we didn't agree with. We think these are significant actions. And for ONC to use the discretion and default to email that we know things get lost in people's junk folders or it goes to the wrong party and no action is taken. These are pretty serious matters to propose termination. And we just didn't – we are proposing that the regulatory text is changed.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

I guess I'm also – oh, sorry. Go ahead.

<u>Denise Webb – Individual - Member</u>

So that it is isn't discretionary whether it just defaults to email for just these big ticket items.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

And your point is well taken. I guess I just want to be cautious to the fact that the scope of what this task force is looking at is really dealing with the new proposals for condition and certification and information blocking, including suspension and proposed termination ties back to already kind of established and litigated proposals that have been finalized. I guess I don't want to blur the lines there, if possible.

Andrew Truscott - Accenture - Co-Chair

Well, it sounds like we're saying two things. One is we think for information blocking, it's

important that these communications go through both channels. And I think we might be saying okay, this might implicate how ONC is working, in general, if some of these communications are not going through registered mail and they're only being done through email. And are you suggesting, Mark, actually, we're overstepping our boundary here?

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Well, no. What I would suggest, and you can make whatever recommendations you want, but I would suggest that you keep your recommended edits to this regulatory text specific to the conditions. And you could also make a general recommendation outside of that that ONC should revisit our approach to communications for certification of health IT or with issues concerning this specific health IT that's addressed in direct review in the EOA final rule just because – sorry, go ahead.

Denise Webb - Individual - Member

Mark, I was going to say we generally have handled it that way. I know in our other task force, we had some general recommendations that were not specific to what our charge was. But in this case, ONC is proposing to use the same process that's already in existence for conditions and maintenance of certification requirements. So, if you're going to overlap a process and apply it to these new conditions, it's not totally new. It's using existing regulation with a few nuances. So, I think that's why we were suggesting this. I certainly appreciate what you're saying. We can stick to conditions and maintenance of certification in that we, as an overhead recommendation, say that these matters concerning CMC should have a certified mailing. But it's using the same process and the same portion of the regulation for CMC as it is for the overall program.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

And I think -

Lauren Wu - Office of the National Coordinator for Health Information Technology - SME

Mark, I can weigh in here a little bit. So, I hear Denise's point. And I think that the way that you recommended it, Mark, is actually fine. I think going back to the EOA final rule, what we say in the final rule preamble is that we do, for EOA direct review, intend to send those notices via certified mail. And we state that in the preamble. However, as you can see, the regulatory text for Section 175.05 remains as it is today where we generally say the preferred method of correspondence is email. And then, if you scroll up a little bit, I think it says unless there is a specified reason to use certified mail. So, I think maybe the point here is that, to Denise's point, since we're proposing to reuse the same sort of process and approach that we could really look at that and see if the entire reg text needs to be updated to reflect that history of our intent.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Yeah. And I think the placement of the changes, Denise, makes sense broadly. I guess maybe I got us through a rabbit hole or whatever. All I'm saying is that in the recommendations that

you all please be clear that if you want it to apply both for direct review concerning the certified products and conditions, maybe in the text that describes your proposed recommendations just make that clear. That's all I would say.

Denise Webb - Individual - Member

Well, maybe what we could do in our preamble recommendations is say that we acknowledge that the final rules relating to this process before, just as Lauren described it, had it in their preamble for these big ticket items to actually use certified mail, even though the regulatory text left discretion and preference to email. I think the same applies here for CMC. But now that we're at a point where we do have the opportunity to modify the regulatory text because of the Cures Act in this proposed rule, we could make our overall recommendation to be that that intent of the preamble gets incorporated into the regulatory text.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

And just thinking through, as Lauren said, the background, it might make the most sense to take a similar approach, in the end, I'm just kind of thinking through, that we took in the direct review because the communications section that's up here is a very broad application. And we're talking about specific, really serious cases. So, I think you should make the recommendation however you all think it would be best. But the approach we took for direct review could be applicable.

Andrew Truscott – Accenture – Co-Chair

There was a fair amount discussed on this in the workgroup. Much of that discussion was fueled by very direct experience and observation of the process and also, a belief that there is a fair chance that the direct review process will get greater than we have exercised in the enforcement of information blocking regulations. And we wanted to make sure that a stifle in communication was not actually preventing the benefits and the reason why these regulations existed in the first place. And that the very real administrivia of an organization around vacations, out of offices, human resource turnover, etc., that stops that communication if you're depending upon email. So, we just wanted to make it clear.

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

I would agree. This is Aaron. I'm going to add a little commentary. Again, this is what I do. I add real world experience here and examples. So, a real world example is even when communicating with say a very large vendor that is doing some unsavory practices, if it is over email, nine times out of ten if it's not something that they want to talk about or listen to or change a practice on, they're going to ignore you. And so, to the degree that we were worried about enforcement action and then, simply saying we never got it and tough bananas, which is exactly the attitude a lot of vendors take today and to the degree of a certified mail or another modality is a way to make sure that that is heard loud and clear to stop it, stop misbehaving. So, that just kind of gives some real world perspective.

Mark Knee - Officer of the National Coordinator for Health Information Technology- Staff

Lead

I think that's a really helpful background, by the way.

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

No worries. We're a helpful group. Okay, shall we move on? The certification ban, we felt that actually, we've made updates in our previous comments that were perfecting of this RFC so we didn't actually need to go anymore. But there was a question on the public use and recertification bans and terminations. Denise, do you want to walk us through these two recommendations you made?

Denise Webb - Individual - Member

So, our first recommendation is around providing some indefinite communication in the past records. And we do believe that that's appropriate and would like to see the start and end date. So, if there's a ban on a health IT developer from the program entirely and then, the health IT developer actually remediates and takes action to then be allowed to enter back into the program, there was discussion about how long should they be subject to the ban and should there be information provided to potential customers of that developer's product about whether they had a ban or not after it's listed. And we are proposing there should be indefinite communication at least in the form of who the developer is and when the ban started and when it ended. We think that's appropriate. And then, we don't recommend a minimum period of time over which a ban must last.

The rule asked us to consider that and make a recommendation on whether we thought there should be a minimum time period, even if the health IT vendor has multiple offenses.

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

Yeah. We felt that there was very much contextualization to which it would need to be done through the enforcement process. And there could be, while it's not legitimate, understandable reasons. And we didn't want to try and second guess what they could be through regulation. Any comments?

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

This is Aaron and I agree. That was the representation of the conversation.

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

You agree, of course, you're in the workgroup. Anybody else because I know there are other people on the call who –

<u>Steven Lane – Sutter Health - Member</u>

I also agree. This is Steven.

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

I'll move on to the next one then.

Denise Webb - Individual - Member

The next area concerns self-developers. So, the proposed rule requested comment on whether the conditions of maintenance of certification requirements should apply to self-developers. And our workgroup just looked at the three conditions and maintenance and certification around information blocking assurances and communications. And we concluded that all of these should apply to self-developers. But then, the one difference for self-developers related to the communications conditions and maintenance of certification and those areas where the health IT developer had an exemption on A here related to developer employees and contractors. And I mentioned this earlier in our call this morning. We are proposing that those healthcare organizations that develop their own certified systems cannot block or restrict communications on their employees using the products.

Andrew Truscott - Accenture - Co-Chair

This is directly the one we referenced earlier when we were talking about [inaudible] [00:59:53].

Denise Webb - Individual - Member

Otherwise, everything would apply to a self-developer for these three conditions and maintenance of certification. And just for the task force's benefit, the CMC task force actually looked at the other conditions and maintenance and certification as it relates to self-developers. So, we split that up.

Andrew Truscott - Accenture - Co-Chair

Hey, Denise, maybe the ONC guys can help us here, what's the plan for feathering these together? Is it that's going to happen when we meet as a full committee and not before?

Denise Webb - Individual - Member

As a full committee is my understanding. But Lauren can weigh in or Mark.

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

So, all of the IB recommendations, do you mean?

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

Only where we have a feathering in like here where there is a recommendation coming out of the information blocking task force. Actually, it lives alongside the regulations of another task force. And whilst I know that we have enough meetings on our calendar, I'm pretty sure that I've got probably a little bit of space one day in the next two weeks where maybe just the co-chairs get together and just make sure that they tick and tie it together.

<u>Denise Webb – Individual - Member</u>

Well, on these, Andy, on the application of the -

Andrew Truscott – Accenture – Co-Chair

And you could do it on both.

<u>Denise Webb – Individual - Member</u>

Well, no, I was just going to say on these conditions and maintenance of certification requirements as they apply to self-developers, each of these is distinct. So, our task force information blocking has charge for three of the conditions and the other task force has charge for the other conditions. And I can tell you since I'm on both for these, there really is no overlap that I can see. The place where there was the overlap between at least our two task forces was related to the definition of electronic health information or EHI and the EHI export recommendation we made. Those had the feather. But I'm not seeing that on this particular area.

Andrew Truscott - Accenture - Co-Chair

That's cool. Mine was more of a general statement just because we came across this one but okay, that's fine.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Andy, I agree with what Denise said that this seems to be specific to what we're talking about with information blocking. But if you do think of issues that are overlapping that we need to reach out to the other workgroups about, I'm happy to help coordinate that and make sure that they are aware and the ONC staff leads are aware as well.

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

That's cool. Okay, guys, we're at the end of Workgroup 3, I think. Yeah, we are. Has anyone got anymore questions about work of Workgroup 3, recommendations and conditions [inaudible] [01:03:32]?

Lauren Wu - Office of the National Coordinator for Health Information Technology - SME

This is Lauren Wu, again. I can circle back to the issue on the public listing of the start and end dates of a certificate. That was around the assurances condition. So, it is a programmatic choice of ours, nothing in the HITAC Act or our regulations requires us as ONC to post that information online. I will say that we've had the CHPL website up for many years for the duration of the program and have continued to make enhancements to it and make the data as open and available as possible. And I recall the discussion we had earlier. And I apologize if I might have misconstrued or misunderstood the topic that day.

When I mentioned that not all of the records are publicly available and some are really on the back end between ONC and the certification bodies for the administration of the program, I was referring to the very detailed records of testing and certification. But information that we consider pretty necessary to have transparent to the providers and other end users and potential purchases would include information such as the start and end dates of the certificate. So, I might have misunderstood the discussion at the time. I think we were talking about the records retention policy. And it was just my point that not all of the

records that are being proposed to be retained would include everything that's publicly available. There are a lot of records related to certification that are kind of kept for administrative reasons that are more on the back end.

Denise Webb – Individual - Member

But I think the reason we were concerned here is that there is a record retention period and where the information that you retain has a retention period. And we didn't want the fact that there was a health IT product that had a start and end date and was no longer in the program for that information to go away because your retention period expired and you don't have to keep it any longer.

<u>Lauren Wu – Office of the National Coordinator for Health Information Technology - SME</u> I understand what you're saying.

Denise Webb – Individual - Member

And maybe one thing I might suggest to our group is that rather than being prescriptive and suggesting in the regulatory text that ONC preserved the information on the CHPL, I think we should be more because it's the CHPL today, it could be something else tomorrow. I think what we're trying to get at is we want the transparency for these specific elements of information to be public facing in an electronic format or an online format where it's readily available to the public. So, just to my group, I suggest we might not be so prescriptive in this regulatory text in terms of referring to CHPL.

Andrew Truscott – Accenture – Co-Chair

Yeah. We'll go back and look at this, I think. We do say or in another format. We give the option. I made a comment, we'll come back to it. Is there anything else on Workgroup 3? In which case, we'll move to Workgroup 1. Okay. So, who is on —

Steven Lane - Sutter Health - Member

Just a comment that that was great work and, Denise, thanks for walking us through it. That was great.

<u>Denise Webb – Individual - Member</u>

Thank you.

Andrew Truscott - Accenture - Co-Chair

And Workgroup 1 -

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff Lead</u>

Andy, I just wanted to clarify for the group that unless Andy and Michael hear otherwise, I think these are generally the recommendations that we're going to move forward with for Workgroup 3 with the tweaks and changes that we've discussed today. So, I just wanted to be clear about that. So, last call if anyone has any additional updates, sent them to Andy and

Michael.

Andrew Truscott – Accenture – Co-Chair

Yeah. I want to be respectful of certain people are looking at these potentially for the first time. Get feedback back to us. We've got some time before we meet again in full committee. And even when we meet in full committee, these aren't the final because I'm sure other committee members also have feedback. But if you can get your feedback in to Mike and myself ASAP and I would prefer it if people would actually send me an affirmation to say, yeah, we're good with it, move on rather than me to have to assume tacit acceptance.

Denise Webb – Individual - Member

This is Denise. Just to be clear with the entire task force, there are two levels of final. There's final vote for the task force that we agree with the recommendations that are going to be advanced to the co-chairs of the HITAC that Carolyn and Robert for deliberation and vote by the entire committee. And then, there's that level of final when the entire committee votes on our recommendations. So, what ONC is trying to get us to do is for our task force to provide final recommendations of our task force that we all agree on. So, it would be helpful to hear from the rest of the task force today very soon or possibly before our meeting tomorrow whether we can vote on Workgroup 3's recommendations as a task force to advance them as our final recommendations.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Very well said.

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

In the absence of any commentary coming through, we'll move to Workgroup 1. Who is on the line from Workgroup 1? Nobody?

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

I think we have Sheryl and Cynthia.

Andrew Truscott – Accenture – Co-Chair

I thought we had Sheryl and Cynthia on the line.

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

I don't think we have John.

Andrew Truscott - Accenture - Co-Chair

No, John said he wouldn't be able to make this call.

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

This is Sheryl, I'm on the line.

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

Hey, Sheryl. And Cynthia? Cynthia is not there? Okay.

Denise Webb - Individual - Member

I thought I heard her earlier.

Andrew Truscott - Accenture - Co-Chair

I thought I heard her but maybe I'm wrong. Mike, are you there? Otherwise, it might be you and me, Sheryl. Okay. Let's move on. So, Workgroup 1 was concerned with a lot of the definitions, which are new in both of the acts and the regulations and just making clear much the scope of what we're talking about with regard to information blocking. I actually helped with the first one, which is around the definition of electronic health information. Now, considering we've added four words and a bit of punctuation that is not representative of the length of time that the group has spent discussing this in many, many, many shapes and forms. The basic genesis is we are predominantly comfortable with the definition as it stands.

We were seeking to have some clarity around when we say electronic protected health information, which was the original drafting over here on the left from ONC, we wanted, just to be clear, and I know it throws it out in the preamble, but just to be clear in the regulations that this is as defined in HIPAA. So, Section 2 in this definition is additive to the HIPAA definition. The group just wanted to make that clear. And then, we have this much broader definition, which is just saying EHI includes any other information, which could identify the individual. Or there's a reasonable basis to believe that you could identify the individual. And that it's either transmitted or maintained inside your electronic media.

And this can relate to the past, present, or future health or condition of an individual such as focused around the individual but has that broad temporal basis but can also include anything around the provision of care but also the past, present, or future of payments, and we pluralized that, around that care. So, it's a very broad definition of electronic health information that's encompassed inside of this rule. Sheryl, I don't know if you want to add some comments to that point or anybody else from the task force in looking at this definition and what people feel.

Sheryl Turney - Anthem Blue Cross Blue Shield - Member

Andy, I think you said it very well. In the task force, we spent quite a bit of time talking about this definition and changing it and then, changing it back to what we came up with here. I think the focus of the group was to try to provide clarity in terms of what is included in electronic health information but also, strike the right balance. Because at one point, we even talked about including information that didn't identify the individual. But then, it becomes the world and how do you manage that. So, I think where we ended up is a good place.

<u>Steven Lane – Sutter Health - Member</u>

And I agree. I think that, obviously, there are minor changes in quantity but they all do make sense.

Denise Webb – Individual - Member

This is Denise. So, when I think about this very, very broad definition and how it applies to the rest of the proposed rule, when you think about who is subject to the information blocking requirements and thinking about it from a large, integrated delivery healthcare perspective, which has providers and has the health plan to the extent that they have and are using certified technology, they would be subject to providing all data, every piece of data, that falls under this definition if requested by the patient or requested for other lawful reasons if there was a request for that electronic information in electronic format. So, then if you carry that over to the health IT developer in the certification program, there's a requirement now instead of data export to do EHI export.

And that would include all systems or products provided by a vendor, even those that are not certified products if they meet the definition of a certified health IT developer. So, I'm just bringing this up because that's the downstream impact of that definition. And I know the CMC task force is recommending a narrower scope than all of what's included in EHI here for the EHI data export.

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

That is helpful context, Denise. Thanks for that. And this is possibly an opportune moment just to have a slight tangent discussion around the health IT developer. And we have discussed this at length because much of the remainder of our deliberations have been around the definition of access. And the listed mandate that's actually been given in 21st Century Cures is particular around the developers of certified health IT, not all health IT. And Workgroup 1 is coming to the task force asking for input here because we are struggling slightly with the evolving nature of health IT in this country since just in the last three years since 21st Century Cures was even enacted. And there is a shift towards two different groups of developers, which are quite different groups as well. I think we're all familiar with the act developers.

The developers who are both large organizations but also very small organizations down to single person outfits that build and construct health IT apps who are not developing certified health IT are unlikely to ever pursue certification. However, they do maintain and transmit identifiable care information about the past, present, or future care or condition or individual and potentially both their provision of care and payments around that. The second class or group of pejorative, the second group of developers are those large companies who are seeking to construct large health IT information systems, which they have no intention of ever selling. And they wish to offer them as a free good and maintain information within them around patients, both direct care and also secondary use. And they would never dream of getting certification because it's not in there but it's more of what to do.

And we were wondering whether there was an unintended consequence of the definition, which was recently put around certified health IT and developer and the constraint to certified health IT developer, which was there for all good reasons. But that might

inadvertently be creating a business model for noncertified health IT developers. And so, I'll pause there and just offer that one out to the board or task force for discussion because it's – go ahead.

Steven Lane - Sutter Health - Member

Andy, this is Steven. I'll say since our meeting yesterday, I had a chance to discuss this briefly with the VP of a large health IT vendor who is represented on the task force. And the same concern was raised that this creates an uneven playing field. That there are health IT developers out there who are creating niche products that don't end up getting certified or needing to be certified. And that there is a disadvantage or, as I said, an inequity across the industry created by this differentiation based on certification status. And that doesn't really seem — I appreciate the question that does cures give the ONC the legislative authority to determine the requirements on noncertified products. But as we were discussing in our call yester, our workgroup call, it seems that this is worth asking. And it seems like just intuitively, we might as well ask for or look for an even playing field for all health IT developers regardless of whether they seek certification.

Denise Webb - Individual - Member

This is Denise. And I appreciate those comments that Steven made because if you think about it, a number of these developers who would not be subject to these regulations actually cannot be successful with their products without having access to data that is derived from certified technology. So, they are often times accessing and using data within their products that come from certified technology, is collected by certified technology. So, I draw a linkage between those app developers and their products to this program through that actual connection, the data connection. And I totally agree with Steven that the way things are laid out right now, it's not a level playing field. And so, there are certain developers that have huge onerous requirements placed on them and others that have none that impact the healthcare ecosystem.

Cynthia Fisher - WaterRev LLC - Member

This is Cynthia. One of the comments just to make is to think about how we got here. Is the government provided the certified developers' via the whole system to require electronic health records through \$26 billion of taxpayer money? And so, a lot of where we are today is because of the federal government funding the electronic health record health IT developer chain, which is really a few players in the oligopoly. So, those outside noncertified entities that are providing and catapulting development systems didn't have the benefit of that \$26 billion of taxpayer dollars. So, let's also look at the playing field from that perspective. And we are where we are because —

Steven Lane - Sutter Health - Member

Well, didn't they, Cynthia?

Cynthia Fisher - WaterRev LLC - Member

We are where we are because patients don't have access. And the proposed rulemaking was because we're trying to deliver access that patients can go anywhere in the system and have access to their data and their mobile device and their physicians and they can get the best

quality of care and at the lowest price. And, God willing, they can get the actual payment information electronically as our children do through their mobile apps on banking and us through banking or Venmo. All of this is doable with the technology that exists today. But I just want to say we're here to deliver patients their data and their health records comprehensively. And I understand the concerns but I also think that the whole story needs to be considered.

Steven Lane - Sutter Health - Member

Cynthia, I'm sorry, I didn't mean to interrupt you earlier. This is Steven. I guess I feel like the whole industry of health IT has been bolstered and really birthed by the incentive program. Whether or not an IT developer needs to certify or chooses to have their product certified doesn't change the fact that their products are being purchased by folks who got gazillions of dollars of money to build up their health IT infrastructure and get it up and running. And they now are the customer base. So, I guess I don't see that differentiation. The tax dollars were spent on A but not on B. We are where we are today because of the tax dollar infusion and that creates the market for products whether they're certified or not. And, again, why continue or create an unequal playing field for developers.

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

Any other commentary from any other members on the call?

Anil Jain - IBM Watson Health - Member

Yeah, this is Anil. I think being at a place where we have parts of our portfolio that are certified health IT and significant parts of the portfolio that are not, I really appreciate the comments about having a level playing field. We don't want to disincentivize an organization for not having any certified products so that they can assert the requirements among the entire portfolio. And also, we need to be sensitive to a very large organization that may have certain products that are certified but now beholden to some of these rules in other parts of the portfolio that were never envisioned to be in the space that they might find themselves in because of another part of their business having a certified product.

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

Anil, just hold it there just so everyone completely understands what you're saying. In the way the rules are drafted right now, if you have one product, which is certified health IT, you are considered a developer of certified health IT and, therefore, in scope in the current drafting of the rules, even for those products, which are not certified health IT. That's just what you were saying there, right, Anil?

<u>Anil Jain – IBM Watson Health - Member</u>

Yes. At least that's the way that not just myself but others are understanding it, too. And I'm not saying that we –

Andrew Truscott – Accenture – Co-Chair

That's the way we're all understanding it, yeah.

Anil Jain - IBM Watson Health - Member

And I'm not suggesting that we not have a higher burden for certified products. Clearly, that's why they're being certified. But we don't want to be in a position of creating a cottage industry of subsidiaries that don't have any certified products just so that organizations can somehow not have to have anything in their portfolio that's certified. That would seem to be not the intent of what we're trying to do here.

Andrew Truscott - Accenture - Co-Chair

That's yet another unintended consequence.

Anil Jain – IBM Watson Health - Member

That's right.

Andrew Truscott – Accenture – Co-Chair

Any other members? No? Okay. So, with this in mind, I was reading back thinking this through and my screen might have gone back. Hang on a second. Okay. So, much of the rest of the work that this group has undertaken has been focused around considering the definitions of actors. Now, as you all are aware, there are four predominant groups of actors who are referred to in 21st Century Cures known as providers, health IT developers of certified health IT, health information exchanges, and health information networks. And the next piece of regulation that we looked at in some degree of detail was around the definition of a health information exchange and a health information network. And just to refresh everyone's memory, you can see the original text from ONC on the left.

Our recommended proposing of what we're recommending could be changed to regulation and then, the comparison markup version of it shows you the strike throughs and the added text.

Denise Webb - Individual - Member

Andy, I'm not seeing your screen any longer.

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

Are you not?

<u>Denise Webb – Individual - Member</u>

Is that just me or is it everybody?

<u>Aaron Miri – University of Texas at Austin, Dell Medical School, and UT Health Austin - Member</u>

I'm seeing it.

Andrew Truscott - Accenture - Co-Chair

It could just be you, Denise.

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

Yeah, it went blank for a second but then, it came back.

Denise Webb – Individual - Member

Oh, okay, I've got it now. It came back.

Andrew Truscott - Accenture - Co-Chair

You're at the edge of a very [inaudible] [01:30:37] piece of string.

<u>Denise Webb – Individual - Member</u>

Yeah.

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

Okay. So, when we were talking about through health information exchange, we went back to the drafting of 21st Century Cures and something we realized as we went through is that, actually, and ONC do not need to comment on this because this is a view for the group, there are different uses of the group. There are different uses of the phrase health information exchange in the actual drafting the legislation to our mind in our interpretation. And I think those of us that work in the industry on a day to day basis across organizations, we see the term health information exchange viewed in many, many different ways. And, frankly, we see health information network also used in some slightly different ways, too. But certainly, health information exchange is used very differently. And in our recommendation, we're seeking to bring a little bit of clarity to that.

The reason why these definitions of "actors", the term actors is an ONC use, it's not actually in the legislation itself, is because the different types of actors have different sanctioning processes against them both in terms of fine levels but also in process. And so, it's important. And as we've been considering this through, we've been trying to think through the function that these actors perform. So, a provider, that's pretty self-explanatory, developer is pretty explanatory. But what's the difference in the function of the health information exchange versus the health information network performs. And we struggled with this. And we talked about this at least as much as we talked about the definition of electronic health information. And so, we've come up with this proposed mark up and a closed recommendation to go to HITAC for consideration to maybe go to ONC.

But looking just to bring a bit more clarity over what these definitions mean and where you as an organization would sit fully recognizing that some organizations will sit as both a provider and a health information network, for example. So, yeah, here's the drafting. And I'm sure you guys are pretty sick of my voice. And I've been reading this through as well. As you can see, what we're suggesting here for your consideration is kind of tying down the health information exchange term a little bit to be focused more upon the act of accessing, transmitting, processing, handling, or similar use of electronic health information capitalized because that's now a defined term because we just defined it in the previous regulation. And then, just there are a couple of circumstances where an organization might just be doing

those acts. So, it could be the organization conducting that act. However, in general, HIE would be the act, the verb.

And then, health information network itself would actually have this definition that we've got down that is conducting health information exchange.

Cynthia Fisher - WaterRev LLC - Member

Andy, I see a problem with these changes. If I go back to the ONC's definition of health information exchange if you go to the top there without all of the strike outs because if you look at how they defined it, it means an individually or entity that enables access exchange or use of electronic health information. If I read that, the exchange would include a provider, correct, as part of that health information exchange? And so, different types of providers or entities would be included in that because of that sharing. Whereas —

Andrew Truscott - Accenture - Co-Chair

As would in the revised text as well potentially. But there would also be providers, which are another actor.

Cynthia Fisher - WaterRev LLC - Member

I'm just pointing out the meaning. The meaning there would include a broader number of players as an exchange whereas the health information network seems to play a different role the definition is written because the network appears to be overseeing, administering, and setting policies and agreement on the hand off of the operational technical. So, I'm reading this —

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

Cynthia, it's both if you look at the second definition of health information network. It's not just the policies. It's also actually doing the technology or service. And we've been through this one in the workgroup. And we discussed that the actual proposed –

[Crosstalk]

Andrew Truscott - Accenture - Co-Chair

Did nothing to narrow.

Cynthia Fisher - WaterRev LLC - Member

Yeah. It just has more strike outs. And as it's been typed in this way, I'm just pointing it out that it reads a little bit differently as to who would be included under that umbrella, does it not?

Andrew Truscott - Accenture - Co-Chair

Well, I appreciate the sentiment. And we did discuss this and actually went through it how it doesn't change the scope. It just makes it clearer, we felt. And that was the big genesis that we were seeking to bring clarity as opposed to change the scope.

Denise Webb - Individual - Member

This is Denise. I think when you read this in total when you take the definition of EHR and the definition of HIE, you've incorporated the definition of HIE in HIN. I don't think you've lost anybody in the scope.

Andrew Truscott - Accenture - Co-Chair

Absolutely not.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Andy, I just wanted to make the point from ONC's perspective to what Cynthia said that a provider could act as a HIN or HIE. But as we describe in the preamble, they are separate definitions from the provider definition. So, I just want to be clear about that. We're looking at the function of the HIN or HIE in our definitions. As I said, it's possible that there could be overlap but the definitions are distinct and separate.

Andrew Truscott - Accenture - Co-Chair

And as we discussed at length, you are seeking to channel the absolute wording that was put into 21st Century Cures. Broader task force, there is verbose discussion underneath this section that shows you all the different usage of the term health information exchange inside 21st Century Cures. And you can see the different usages. And this is an opportune moment to correct this without changing the scope and without alleviating any of the intent.

Cynthia Fisher - WaterRev LLC - Member

Okay. I can't see the bottom, the second point under health information network. But where is as ONC defined health information exchange included in the health information network?

Andrew Truscott - Accenture - Co-Chair

Clearly, it says health information exchange and health information exchange just there.

Cynthia Fisher - WaterRev LLC - Member

As ONC had determined the individual and the entity role up above, where is that included in the HIN definition?

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

Because -

<u>Cynthia Fisher – WaterRev LLC - Member</u>

So, what you're saying is no one is held accountable — I think the challenge for ONC is Congress gave four buckets of accountability but there is no player accountable if you define the health information exchange as just an act, right?

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

We have actually said –

[Crosstalk]

Cynthia Fisher - WaterRev LLC - Member

The players are accountable by -

Andrew Truscott - Accenture - Co-Chair

Cynthia, as you said, as it says here, or the organizational entity conducting that act because we wanted to make it clear in the regulation versus the concept of a particular class of individuals or entities or a limited set of purposes. We wanted to make this rather than focus the definition upon what you're doing versus your intent because a limited set of purpose, well, what's the purpose. Let's just make it accessing, transmitting, processing, handling. It's much clearer, much more succinct and has that level of inclusiveness that you're looking for.

Denise Webb - Individual - Member

And it still does include or the organization or entity conducting that act.

Andrew Truscott - Accenture - Co-Chair

Yeah.

Denise Webb - Individual - Member

So, I don't think we lost anything in the definition. We've tightened it up is what we've done.

Michael Adcock - Individual - Co-Chair

Right. It's still broad enough to capture every one that needs to be captured. I don't think we lost anything with this. I think that it looks – it covers what we need to cover and still allows for two separate definitions.

Andrew Truscott - Accenture - Co-Chair

Yes.

Cynthia Fisher - WaterRev LLC - Member

Why did you strike then, primarily between among a particular class of individuals or entity? Or for even a limited set of purposes, why did you strike those?

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

As we discussed, we all had difficulties with the term primarily because then, what's the exclusion criteria for that, and particular because what's the exclusion criteria for that, and limited, what's the exclusion criteria for that. If anything, in our definition we've just said, no, it's not about whether it's primarily. It's if you're exchanging information. It's not about whether it's a particular group of individuals. It's if you're exchanging information. And it's not a limited set of purposes. It's if you're accessing, transmitting, processing, or handling. It's the act. It actually makes it, we think or we felt in the group, much more precise and —

actually, precise is the wrong word, clear.

Michael Adcock - Individual - Co-Chair

Right. It cleared up the definition. It took away words that are very vague.

Denise Webb – Individual - Member

Yeah. I would say ONC's proposed definition here has lots of vagueness and room for varying interpretation.

Cynthia Fisher - WaterRev LLC - Member

Aren't there entities that would consider themselves health information exchanges in the use of the word?

Andrew Truscott - Accenture - Co-Chair

I'm sorry?

Cynthia Fisher - WaterRev LLC - Member

In today's world, are there not organizations that actually consider themselves health information exchanges?

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

In terms of proper nouns, there is a use that says yeah, we are a health information exchange. They are more in the definition of a health information network. And I'm going to try and paraphrase John and puts words in his mouth but that was kind of one of his sentiments he articulated that, fundamentally, the Indiana Health Information Exchange is a health information network. But he didn't have an issue with that. There are also – go on, Sheryl.

Denise Webb – Individual - Member

No, this is Denise. I was just going to say I can give another example in Wisconsin because I was part of creating legislation. We have the Wisconsin Health Information Network, WSHIN, Statewide Health Information Network, that's what their name is WSHIN. And we used HIE and HIN interchangeably. When you talk to WSHIN, they provide services for health information exchange to facilitate that. But they call themselves an HIE. But they also say we're an HIE noun, we're an HIN in our name, noun, and we conduct HIE, verb. So, I really like what you're proposing here because it really does clarify the word that's used in various fashions. So, I know in Wisconsin, they serve as a statewide network. And they conduct HIE functions.

Andrew Truscott – Accenture – Co-Chair

Thanks, Denise. That's helpful context. At the end of the day, there are vendors out there who sell health information exchange products. So, yeah, it's used in many, many different ways. And if you quickly scroll down, in 21st Century Cures, there are different uses of the term both uppercase and lowercase. And, actually, we found three different contexts around

how it was used and you can read that at your leisure. So, it's useful feedback from the board or group.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Andy, can I ask you a question or a point of clarification, I know we need to get to public comments in a minute. But are you all intending to differentiate between the noun and the verb by capitalizing the noun and not capitalizing the verb? I'm just trying to figure it out because right now, in Cures, Congress specifically said access, exchange, or use of electronic health information would constitute information blocking if you interfere with the access, exchange, or use. And we define those terms. So, just for clarity, I'm trying to understand if there would be a distinction made in what you're doing between the noun and the verb.

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

I personally haven't considered that. I'm not sure if anybody else in the group is thinking about that. I was much more if it's capitalized, it's a defined term. If it's not capitalized, it's not. Given that we have a definition of health information and then, our health information exchange. That would be why that was capitalized in the health information network definition. But you're telling us that that actually – if you and Mr. Lipinski come back and tell us that you don't want to do it like that, then, that's fine, too. Just tell us.

Steven Lane - Sutter Health - Member

And it's interesting. I've also been in the habit of capitalizing defined terms. But I really like the idea here of saying the term is defined. In the definition, we should clarify that the term can be used as a noun or a verb. And then, perhaps capitalize it when we're using it as a proper noun and then, lowercase it when we're using it as a verb. It seems weird to have a capital verb. But I think that if we go back to the definitions and we just say this is the term as it's being used. It can be used as a noun or a verb and then, go on from there.

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

Yeah. I must say part of me would almost like to not have all of the organizational entity conducting that act. So, the HIE is the act. HIN is the organization. But I fully take on board the way that Cures is drafted, it has HIE as a noun as well as a verb. And also, to Cynthia's well made point, we want to make sure we don't inadvertently lose somebody by tidying up this a little too much. So, that's why we've got that in there.

Denise Webb – Individual - Member

And there are other words in the dictionary that can be both a noun and a verb. And it describes it in the definition. So, I think we've done that. Your workgroup has proposed that HIE is a verb, an action, or it's the organization doing that action, a noun. And then, so I think we've captured both the verb and the noun in that definition. And then, when you use it down in the HIN definition, you're going to refer back to the HIE definition to see what that means.

MA

Hey, Andy, I don't mean to [audio interference], we need to go to public comment.

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

We do. Okay. Operator, can we do the public comment, please?

Operator

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

Andrew Truscott – Accenture – Co-Chair

Thank you very much. We'll pause for a couple of moments. I'll just carry on until we see that the comments are cued up. So, that's the drafting in there. There was actually another key sort of delta that we did in here. It's around the use of the term unaffiliated and affiliated. So, if you look in the original ONC drafting, there was a term around unaffiliated. And there's a good level of description inside the preamble on their intent there. And it all makes sense. But then, as we were considering this through in process of drafts, instead of having two either/or on the definition of HIN, we had four to counter affiliated and unaffiliated. And then, yesterday we just removed the term unaffiliated completely because we don't believe that in the definition of health information network, we should be talking about only unaffiliated individuals and entities because it can also include affiliated individuals and entities.

So, we shouldn't really have that distinction in there. And that was another key delta. Have we got any comments on public lines?

Operator

No comments at this time.

Andrew Truscott - Accenture - Co-Chair

Thanks. So, unaffiliated versus affiliated, does anyone have any sentiment on that nuance that's in there?

<u>Denise Webb – Individual - Member</u>

I got the sense that ONC was trying to capture the idea that there may be, for instance, a health system that has several entities connected up but they own or control those entities in some legal fashion. So, they would be considered affiliated. And I got the sense that they were trying to not apply some of this to the internal operations of the health system when it came to their interoperability within their own legal framework.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> <u>Lead</u>

So, from our perspective, like Andy has said and I don't want to sound like a broken record, but in Cures, there are these four distinct actors, developers, providers, networks, and

exchanges. And the way I'm reading it, we tried to make definitions that made clear the distinction. And we tried our best. And, of course, you have a recommendation about the distinction between those four actors. And making that distinction is really important particularly because, as Andy mentioned, Congress described that there would be a different knowledge component for providers versus developers, networks, and exchanges and also different penalty structure for developers, networks, and exchanges versus providers. And I'm not going to get into the interpretation of our proposed definition for HIN.

But my read is that if you take out unaffiliated, the definition could potentially swallow all actors, including providers. If you read it, it would probably – I think most providers could fall into that definition potentially.

Andrew Truscott - Accenture - Co-Chair

So, we can have a long conversation about that. I'd like to think that's true because many, many providers don't determine, oversee, or administer or provide, manage, or control health information exchange. They participate in it but they don't fall into the HIN definition. But there are, as Cynthia pointed out, some providers who do. We have large provider groups that cover many, many geographically disbursed sites that do participate in health information exchange and, therefore, would fall under the definition of a health information network. And I believe the sentiment coming out from the workgroup, which is [inaudible] [01:53:28] I think we've heard since HITAC was created was that we want to promote information sharing across all of those entities, between all of those entities. And we want to address information blocking, which does occur inside of those organizations right now.

I can give you a list of a dozen large, multisite provider organizations who do not exchange information between their sites, which would be beneficial for a patient if they were to so do. So, this is now a personal comment and not as your chair, I personally do not have an issue with a provider being also an HIN. My position would be I don't think we should. Obviously, we have to build a consensus. But I don't struggle with that.

Steven Lane - Sutter Health - Member

I think that by that notion that a lot of large providers are HINs and do have trouble sharing data, even within the bounds of their organization.

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

Yes. Someone else was trying to say something there as well.

Cynthia Fisher – WaterRev LLC - Member

Yeah. I was agreeing with both of those points where the point is to get access to the information and that a provider that needs to share that information for that patient to get the best of care, if they're acting and exchanging that data and they're acting as an HIN or they're acting in the exchange then, they would fall under that definition to have equitable types of penalty under that definition. So, they may be able to be a provider but even if you're a provider and you're acting as an HIE or HIN, one would argue well, why wouldn't you be penalized equitably to any other HIE or HIN for information blocking to the patients.

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> Lead

Right. And just a quick point, I think it was to Steven's point, and we talked about it in the preamble is that HIN specifically is a functional definition. So, as I said before, the way I'm reading it is and what we say in the preamble is providers could potentially be a HIN based on their function. The point I was trying to make is that we were cautious. And I just would say that you all in making your recommendation should do the same that Congress made these four buckets of actors and you don't want to have a definition that would always swallow the other actors in another group. And that's what we were cautious of.

Andrew Truscott – Accenture – Co-Chair

And, Mark, we recognize that and we recognize the boundaries you're working through. What we also recognize, similar to the conversation that we had earlier about health IT developers, the health IT ecosystem is a fast moving beast and changing substantially. And it is beholden upon this group and HITAC going forward that we're supposed to bring those changes to Congress's attention so that they can react accordingly. So, personally, if we all agree, I don't have a problem representing that.

Steven Lane - Sutter Health - Member

Also, just to that notion of swallowing entirely, a solo chiropractor or optometrist's office is very different than a large organization with a health IT shop that's developing internal APIs to share data across their network. And so, I don't think that saying that some providers are health information networks means that all providers are.

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

Oh, that's absolutely true. I think it was more the HIE/HIN distinction. Although by your definition there, the single man podiatrist is a provider. The 1,500 physician hospital group is a provider. They are by default the same thing in terms of how this is has addressed them. So, you can't have it both ways.

Cynthia Fisher – WaterRev LLC - Member

But isn't the 1,000 group that's sharing also an HIE or HIN?

<u>Denise Webb – Individual - Member</u>

It may be if it creates the infrastructure.

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

But maybe not.

Cynthia Fisher - WaterRev LLC - Member

But wait a minute, that goes back to the verb.

Steven Lane - Sutter Health - Member

That depends.

<u>Cynthia Fisher – WaterRev LLC - Member</u>

If you're saying exchange, you don't need to say I am by default a capital letter HIE. I am actually providing exchange and, therefore, I should be int eh bucket of an exchange or an HIN.

Denise Webb - Individual - Member

But, Cynthia, they may be using their native capabilities of their EHR to share information but yet, they have not created a network infrastructure and policies and control and governance around exchange between all of their entities within their health system that they are all on the same integrated platform and that's how they exchange within and without outside. So, I get it that provider could encompass an entire health system with 1,200 providers. You almost have to look at that as it's the corporate structure that's providing the infrastructure for those 1,200 providers to conduct their business. And they would be an HIN, in that case, if they created all of these health information exchange capabilities. But they're just not native to the product that they're using.

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

And let's scale it down a bit -

Cynthia Fisher - WaterRev LLC - Member

I would like ONC to weigh in on this because as I first read, their original definition of HIE that that provider would be, under the way it's written now before all of these changes were made, that that provider would be accountable as an HIE also.

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

Cynthia, they are. We're not discussing that point. The point we're discussing right now is that –

[Crosstalk]

<u>Mark Knee – Officer of the National Coordinator for Health Information Technology– Staff</u> <u>Lead</u>

Well, no, that's not accurate. I just want to clarify. By our definition, a provider, based on the function they're providing or I shouldn't say providing, based on their function could be an HIN or an HIE. But a read of our definition I don't think says that all providers acting as a provider would constitute an exchange or network. You have to look at our definition. So, I just want to be very clear about that. And just, Andy, I'll let you go, I know we're over, all I'm saying is to look at the implications of removing unaffiliated in your recommendations and see if you all want to move forward with that.

Andrew Truscott – Accenture – Co-Chair

And that is a good point and that is something we are doing. We're meeting again as Workgroup 1 later today predominantly on price transparency to also touch upon this.

Cynthia, the point we were trying to discuss there was that when you've got a very small provider that might only be a single person shop and you've got someone who is a bit larger that is maybe just a single hospital site, they fall under the same definition of provider right now. But because they're not involved in setting up infrastructure to exchange information, they wouldn't fall under either the HIE or HIN definition in either the original ONC's drafting or our redraft. And that is something we need to be aware of. And if we need to address that then, I welcome your input on that.

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

No thanks, Andy.

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

Okay, no worries. Guys, thank you very, very much for bearing with us for two hours this morning. We're going to meet again and again and I think maybe again. And also, coming out after the next HITAC meeting, we have an early morning session the morning after to meet again as a task force. And I'll be looking to bring in the input we should have received from the board of HITAC there and then. Thank you very much for your time.