# Information Blocking (IB) Workgroup 3

Transcript March 12, 2019 Virtual Meeting

# **SPEAKERS**

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

# Operator

All lines are now bridged.

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

Good afternoon or good morning for some. Welcome to the Work Group 3 of the Information Blocking Task Force under the HITAC. Just as a reminder, this work group is looking at conditions and maintenance and certification as it relates to information blocking. We'll start with a brief call to order, and then, we'll turn it over to our co-chairs. Andy Truscott, are you on the line yet? All right. He may be joining us later. Michael Adcock?

# Michael Adcock – Individual – Co-Chair

Here.

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

Denise Webb?

# Denise Webb – Individual - Member

Present.

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

Sasha TerMaat?

# Sasha TerMaat – Epic - Member

Here.

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

Lauren Thompson? I don't see her yet. And Aaron Miri? Okay. Hopefully, those guys will join us a little bit later. With that, I'll turn it over to Michael Adcock to get us started.

# Michael Adcock – Individual – Co-Chair

Well, where I'm at, it's morning. So, I'm going to say good morning, everyone. Welcome back to another call for the task force and Group 3. And we're going to go into communications. But first, we're going to turn it over to Mark Knee and Penelope and go through some of the outstanding issues because I think that will help us move forward in hopes of getting through the communication and all of our outstanding issues because we had quite a few when we left our task force last week. So, Mark?

# Mark Knee - Office of the National Coordinator - Staff Lead

Yeah. And I'm just trying to pull up the screen. I'm not sure why I keep having these issues but

give me one second. Any help from Accel? I just see the little bar at the bottom. And I'm sure you guys are just seeing my background screen. Where is the actual Adobe Connect screen? Where would I find that? Any help? I just did it now. Can you see that? I think the charge slide should be up on my screen?

# <u>Accel</u>

No, you'll need to reshare your screen.

## Mark Knee – Office of the National Coordinator – Staff Lead

Oh, shoot. That's the problem. All right. Great. Okay. Now, are you seeing my screen?

## <u>Accel</u>

We are, but we see your desktop.

## Mark Knee – Office of the National Coordinator – Staff Lead

Okay. I'm going to try to pull up. I feel very technologically challenged. But how do I get Adobe Connect up on the screen? It doesn't seem to –

# Accel

We can pull it over now if you'd like.

# Mark Knee – Office of the National Coordinator – Staff Lead

Okay. Great. So, you're pulling it over?

# <u>Accel</u>

Yes, you should see it now.

# Mark Knee – Office of the National Coordinator – Staff Lead

I don't see it. Do you see the -

# <u>Sasha TerMaat – Epic - Member</u>

Oh, I see it, Mark.

# Mark Knee – Office of the National Coordinator – Staff Lead

The Google Doc now I guess is what it pulls over. Okay. I got the Google Doc. That's all I need. Okay, great. Hey, everyone. Thanks for calling. I'm sorry to waste a minute or two there because we do have a lot to get through. So, we're going to pick up with the communications section, and I'm going to kick it over –

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

Mark, just one second. Can you zoom in on the doc? It's a little small.

# Mark Knee – Office of the National Coordinator – Staff Lead

Yeah, sorry. Good call. Is that good or bigger? I can go even bigger. There you go.

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

I can read it. That's perfect, thanks.

# Mark Knee – Office of the National Coordinator – Staff Lead

Okay. Thanks, Lauren. So, we're going to jump into communications. And I'll let Penelope start. And we're just going to go through some of those outstanding issues that you all had for us in the last call about communications with the caveat, of course, that we can only say as much as we put in the rule. And we can't provide further interpretation. So, I'm not sure. We'll see if the answers we provide are really – I think they'll be helpful. But I just wanted to put that disclaimer out there. And then, what I'm hoping to do today is to get through communications and then, run through the issues that we had in all of the topic areas since I think we've touched on them all so that then, in our next call, we can really work on revising and refining the recommendations so that we'll have some good draft recommendations for the HITAC meeting next week.

So, before I move on and let Penelope jump in, does anyone have any questions or comments about that plan? Okay. Great. So, I'm just scrolling through. And Penelope, you're on, right?

#### Penelope Hughes – Office of the National Coordinator – Back Up/ Support

I'm on. Can you hear me okay?

#### Mark Knee – Office of the National Coordinator – Staff Lead

Yeah, I can hear you.

#### Penelope Hughes – Office of the National Coordinator – Back Up/ Support

Okay. Great. Yeah. I should just start off with I think the first question was around some background on whether ONC had thoughts about administrative functions. And so, basically, as we mentioned in the preamble, we are drawing from Cures for this and the categories of communication that it's seeking to protect, which includes usability and the user's experience when using the health IT and the manner in which the user of the health IT has used the technology. So, it's very focused on user experience. And we also state that we intended to broadly interpret both the subject matter protected and the conduct that would violate the condition.

And we do note in the preamble that we consider administrative functions to be a user experience covered by the condition. And also a relevant user experience covered by the condition would include any aspect of the health IT that could positively or negatively impact the effectiveness or performance of the health IT. So, we envisioned it as being quite broad and encompassing a large variety of experiences. And I think on Page 178, there's a specific example to note here where we say that the user experiences that would be protected would include administrative functions performed using the health IT. So, hopefully, that helps clarify

that.

# Sasha TerMaat – Epic - Member

Which page did you say that was?

# Penelope Hughes – Office of the National Coordinator – Back Up/ Support

That's on Page 178, and it's in the section where they're talking about the categories of communications that we're seeking to protect. And it's talking about potential user experiences that would be protected.

# Denise Webb – Individual - Member

So, Sasha, it sounds like it does include administrative users. This is Denise.

# Mark Knee – Office of the National Coordinator – Staff Lead

And just a note for you all, again, thanks, Penelope, that was a great overview of the preamble. If what we're proposing and what Penelope described isn't clear or adequately clear for you all, we're definitely open for recommendations. But I think Penelope did a great job of explaining our position.

# <u>Sasha TerMaat – Epic - Member</u>

Yeah. I think that's helpful background context. Thanks, Penelope. It's, I guess, useful to understand what is proposed clearly. Some of the comments that we talked about related to administrative functions and the potential implications or intellectual property, the scope of features that are revealed, and then, also for potentially the security of how the software is configured, I guess, still could be relevant. So, it could still be pertinent for the committee to discuss if there's a way to carve out things that might be sensitive from that perspective in a recommendation.

# Mark Knee – Office of the National Coordinator – Staff Lead

Okay. Do you all want to talk about that now, or do you want to wait and have us go through all of the questions? I'm fine either way whatever you prefer.

# Michael Adcock – Individual – Co-Chair

Sasha, if you're good with it, I think we should go ahead and talk about it now.

# <u>Sasha TerMaat – Epic - Member</u>

Okay.

# Michael Adcock – Individual – Co-Chair

That way, we can go ahead and address them as we're going. Unless Penelope or somebody has to jump off the line, I think we should go ahead and work through them as we go.

# Denise Webb – Individual - Member

I'm in concurrence with Sasha. I think we should, in our recommendation, specify that there

may be some exceptions to this, particularly around the administrative users and functions and, in particular, related to security of the system.

## Michael Adcock – Individual – Co-Chair

So, hearing that security of the system, we would look at as a potential recommendation for an exception. What are some of the others? I'm not in the developer world. I'm looking to the group to discuss this out loud. Let's put down some of these on paper.

## Sasha TerMaat – Epic - Member

Sure. So, a few things to consider. I guess, one of them would be related to security and any vulnerabilities that would be shown by showing how something was configured. The other would be that one of ONC's arguments for why, for example, screen shots of software should be able to be used freely is that there is a very large user base. And it's not used as ONC puts it in a cloistered setting. But that would not be true of administrative functions, which have a much smaller scope of users and, therefore, wouldn't be sort of under that same argument. The other factor there would be that it's not as clear to me that the intent of 21<sup>st</sup> Century Cures was to show all of the configuration options that might be available in an administrative screen when 21<sup>st</sup> Century Cures was outlining important public good types of communication such as the usability and clinician experience of the software.

So, I would say the recommendation to exclude administrative activities would be based on the potential intellectual property that's revealed, the fact that it's not as strongly supported by ONC's own arguments about being widely used with many different user types. The linkage to the intent of 21<sup>st</sup> Century Cures is weaker. And then, also, revealing more of that configuration is more vulnerable from an intellectual property perspective and also, potentially, from a health system security perspective.

# Mark Knee – Office of the National Coordinator – Staff Lead

I was going to say, Sasha, you're on the Google Doc or someone is on the Google Doc. Perhaps we can capture some of this recommendation.

#### <u>Sasha TerMaat – Epic - Member</u>

I've been trying to, yeah.

#### Denise Webb – Individual - Member

I think Sasha gave a nice summary.

# Andrew Truscott – Accenture – Co-Chair

So, Sasha, I've been thinking about this one quite a lot since you were talking about it last week. It's Andy, hey. Sorry I'm late, guys. I'm subject to United's foibles this morning. And I actually agree with you. And I think there's a potential to disclose inadvertently intellectual property through an oversharing of the full configuration of information. That said, there are assets of configuration, which are particular and peculiar to patient desires, patient wishes, especially around the intricacies of consent and an increasingly granular level of consent. So, I'm kind of minded that when it comes to recommendations, the recommendations should

state that pretty clearly. Where such information is particular to how a patient may wish to express consent, then, that is not an exception.

But where it would disclose a truly unique configuration that is not specific or not pertaining to an individual patient that would be. Do you get where I'm coming from? Or am I being inarticulate?

## <u>Sasha TerMaat – Epic - Member</u>

I guess I would not necessarily think of a patient exercising their consent as an administrative feature. So, carving that out seems reasonable to me.

## Andrew Truscott – Accenture – Co-Chair

Okay, cool. And I'm actually kind of thinking something like audit as well. That usually, inside of provider organizations, is seen as a more administrative task. We wouldn't want to be providing that exception to prevent audit information being shared as appropriate, etc., as well. So, I'm always thinking that the recommendations should carve out particular things that we would say in scope and those which we would think of as being out of scope. Does that make sense?

# <u>Sasha TerMaat – Epic - Member</u>

And so, you would suggest as in scope patient consent and audit logs?

# Andrew Truscott – Accenture – Co-Chair

Yeah, just as two examples. You guys are in this stuff day in and day out as well. You can come up with some more but that kind of stuff. Something like formulary or **[inaudible] [00:14:01]** configuration and administrative type of function. It's not necessarily, depending on the organization, seen as clinical data. But it's for family definitely configuration data. Is it making sense?

#### <u>Sasha TerMaat – Epic - Member</u>

I think I understand your point and I agree. I am trying to think how we would craft a definition that met the sort of line that I think we're both sort of thinking about in our heads because the types of things I'm envisioning in my head as an administrative feature are not like the audit log. Though I agree with you that is often, for security reasons, the privacy officer might check the audit logs and not widely distribute that to others because – well, I think everyone understands why.

#### Andrew Truscott – Accenture – Co-Chair

Yeah, we get that.

# Sasha TerMaat – Epic - Member

So, I think that wasn't an example I had in my mind. And providing access to the audit log makes sense. I am trying to think about features like, especially ones that would reveal a lot of possible configuration options because I think those are competitively sensitive. If there's a screen that says, "Which of these 20 configurations would your organization prefer to use,"

that doesn't just tell someone who sees that screen the one configuration choice the health system has picked but all 20 options, which is competitively sensitive potentially for the developer.

#### Andrew Truscott – Accenture – Co-Chair

I'm with you entirely. And it's slightly scary that you and I are seeing eye to eye on it. But that must mean it's the right answer. I'm wondering whether rather than calling out specific examples, or maybe we do have specific examples, but the actual recommendation is recommendation is there's a clarification that by "administrative function" we mean, and then, we have more of a functional definition of it. So, configuration information relating to the form factor or the user interface or something like that. And then, no administrative information would be anything that pertains to a patient, their health, or the health of a patient population, or something with order just so we actually say the nature of the inclusion and exclusion.

#### <u>Sasha TerMaat – Epic - Member</u>

I'm wondering if it is going to come back to the quantity, the way in which access is provisioned to those features. I'm thinking it through.

# Andrew Truscott – Accenture – Co-Chair

What do others think?

## Denise Webb – Individual - Member

This is Denise. I think it's important to qualify or call out what we mean with some examples just so we can guide ONC in what our concern is.

# Andrew Truscott – Accenture – Co-Chair

I'll go with that. And I think this seems to be an area where we can probably draft some proposed wording for ONC to consider around the actual rule dropping. But we would also illustrate with examples and a sort of functional description of what it is we're trying to guard against whilst it is what we're trying to allow.

#### <u>Sasha TerMaat – Epic - Member</u>

Yeah.

# Andrew Truscott – Accenture – Co-Chair

That should make it into the preamble.

# <u>Sasha TerMaat – Epic - Member</u>

So, my notes are right below this, right. I'm just confused that my notes are not showing up in the – okay, they are.

# Mark Knee – Office of the National Coordinator – Staff Lead

Don't worry. I got you.

#### <u>Sasha TerMaat – Epic - Member</u>

I was just like wait, I'm so confused. Thank you. So, I'd love to ping a couple of co-workers about what some good examples would be maybe that, Andy, would be useful to this conversation. And I don't know if others would want to noodle on it also. Should we put a place holder here that we want to give a few examples as guidance and then, come back with some specifics later in the call or on a future call?

## Andrew Truscott – Accenture – Co-Chair

Yeah. I think that's sensible.

# Sasha TerMaat – Epic - Member

Okay.

## Andrew Truscott – Accenture – Co-Chair

And, frankly, I've had some gentle conversations with my colleagues and with some of my clients. And they just look at me with that slightly screwed up face saying, "We just can't get our heads around this one now." So, we need to give some examples because, otherwise, the wider and more masses that aren't reading this stuff as frequently as we are aren't going to get it.

## Sasha TerMaat – Epic - Member

Yeah.

# Mark Knee – Office of the National Coordinator – Staff Lead

I'm sorry. I refreshed it to get the most recent version, and it's being real slow. So, I'm trying to enlarge it and go back down there.

# Andrew Truscott – Accenture – Co-Chair

No worries. Is Mike on, by the way?

# Michael Adcock – Individual – Co-Chair

Yes.

#### Andrew Truscott – Accenture – Co-Chair

Oh, awesome. So, I'm not in the chair. I don't mind talking so much.

#### Michael Adcock – Individual – Co-Chair

There's no way for you not to talk so much. We appreciate the conversation. No, I'm here. I think examples would be great.

# Andrew Truscott – Accenture – Co-Chair

Cool.

# Mark Knee – Office of the National Coordinator – Staff Lead

Great. Okay. That sounds good. And from ONC's perspective, I think, with as much clarity to explain the issue and with examples would be very helpful.

## Andrew Truscott – Accenture – Co-Chair

If it helps, Sasha, I've actually tried to do some logic thinking through of this and actually particular scenarios and how it could impact, etc. And I'm happy to discuss those maybe next week when we're holding up in DC.

## <u>Sasha TerMaat – Epic - Member</u>

Sure. Yeah, that would be great.

## Andrew Truscott – Accenture – Co-Chair

If you want, we could have information blocking drinks ahead of the order of HITAC dinner.

<u>Michael Adcock – Individual – Co-Chair</u> That's a motion.

Sasha TerMaat – Epic - Member

All right.

Andrew Truscott – Accenture – Co-Chair

Passed, good.

# Mark Knee – Office of the National Coordinator – Staff Lead

And just a note, as I said, I think the next call we have this week, what I'm hoping to do is to refine these recommendations to come up with a good version that we can use for HITAC. So, I think it's okay. I think it's great to come back to this next call with examples and a better idea of the functional definition.

# Andrew Truscott – Accenture – Co-Chair

Okay, cool. Well, actually, guys, as we start thinking about this, let's just get it straight into the Google Doc because then, we're reviewing text and written down. This is the part that Mike and I wanted to take with the task force as well. Go through the discussion. We'll go through thinking. And then, we'll start noting it down. And then, we'll discuss some pressures at that.

# Mark Knee – Office of the National Coordinator – Staff Lead

Great. All right. Then, I guess we can move on. I think there were a few other issues that were raised that Penelope and I did some research on. So, Penelope, do you want to take it for the second one?

#### Penelope Hughes – Office of the National Coordinator – Back Up/ Support

Oh, sure. I think the second one was around fair use and what's meant by that and the legal

definition. So, on Page 196, we do have a cite. But we've pulled it, and I can just read it quickly if that's helpful. So, the fair use of a copyrighted work for purposes such as criticism, comment, news reporting, teaching, scholarship, or research is not an infringement of copyright. And in determining whether the use made of a work made in any particular case is a fair use, the factors to be considered shall include the purpose and character of the use, including whether such use is of a commercial nature or is for a nonprofit educational purpose, the nature of the copyrighted work, the amount insubstantiality of the portion used in relation to the copyrighted work as a whole, and the effect of the use upon the potential market for or value of the copyrighted work.

And then, also on Page 197 in the intellectual property discussion, we do say there that, under this condition, certification health IT developers are not permitted to prohibit or restrict or proport to prohibit or restrict communications that would be a fair use of any copyrighted work. And also, if it's helpful, the copyright office has a fair use index of cases providing examples. And I can provide you all with the link to that if that would be helpful.

## Andrew Truscott – Accenture – Co-Chair

That's a very helpful definition. Thank you. And is that the definition, which ONC is using as its baseline for the use of this language in the rule?

## Penelope Hughes – Office of the National Coordinator – Back Up/ Support

That's what we cite, too.

#### Mark Knee – Office of the National Coordinator – Staff Lead

And I added that citation. You might not have the document up, Andy, but it's 17USD107. And it's on Page 196 of the document. So, feel free to check that out.

# Andrew Truscott – Accenture – Co-Chair

I trust you implicitly on this. So, I must confess, and it's not often you'll find me going down this line, but I do have a bit of concern if I do a logic test on that because what that would imply is a scholarly article could be written in a peer review journal that compares the usability of different EMR systems. And they find that Truscott EMR is the most highly functional EMR on the planet, absolutely fantastic, all physicians love it. And everything else is just absolutely terrible. And that's the scholarly article where it falls under failures. There's a whole bunch of screenshots in there and a bunch of quite detailed information about why Truscott EMR is simply the best.

And then, that would, quite rapidly, get picked up by trade journals and the like and reported upon and probably reported fairly widely. And so, would that count as fair use? Would that begin as fair use and then, become unfair use? How would that play out?

#### Mark Knee – Office of the National Coordinator – Staff Lead

Well, I'm not sure. Again, we're not able to interpret the application necessarily of these terms beyond what we put in the rule. I will say that what we're doing with fair use is we're applying an understood IP term and idea. And we're not coming up with our own definitions. This is

already in –

#### Andrew Truscott – Accenture – Co-Chair

Mark, I wasn't looking for an ONC interpretation. I was talking to the members of the task force because I'm saying that, guys, how would we see that?

#### Mark Knee – Office of the National Coordinator – Staff Lead

Okay.

# Andrew Truscott – Accenture – Co-Chair

I'm sure Sasha has a view.

## <u>Sasha TerMaat – Epic - Member</u>

Well, I've been thinking about this one a fair amount, too, Andy. It sounds like both of us have been trying to puzzle it through. I do think that one of the challenges is that once something is sort of disclosed for one purpose, the ability to redisclose for other purposes seems harder to prevent in that sense. And I think that's part of the scenario you describe where the scholarly article might clearly fit the expectations of fair use. But if it then more widely distributes things for purposes that would not necessarily qualify as fair use, I guess that's another question. If the competitor of Truscott EMR – sorry, I was getting it backwards. So, then, Truscott EMR might want to use this scholarly article for marketing purposes, commercialization, to say look at this study showing that my product is great.

Well, that makes sense. But is that fair use? Because that has a totally different purpose than the scholarly article one would assume.

# Andrew Truscott – Accenture – Co-Chair

That's kind of where I'm coming from.

#### Denise Webb – Individual - Member

But aren't we in a capitalistic, free market society?

# Andrew Truscott – Accenture – Co-Chair

I don't know. I live in Texas, yes.

#### Denise Webb – Individual - Member

So, when somebody does a comparison of products based on usability and users' experiences, why isn't that fair?

# Andrew Truscott – Accenture – Co-Chair

Because that might inadvertently divulge IP within that scholarly article. And, certainly, some aspects of that scholarly research, which would be considered fair use of knowledge about the EMR products. And those scholars could have sat there with users and could have actually been looking at UI making notes about user interaction and all sorts of stuff, which the vendors

might have a legitimate claim that it is an infringement of their IP if that's actually released into the wider main. It would be fair use because it's a scholarly article. But then, if that gets taken forward and utilized by the lucky Truscott EMR vendor saying here's a great example that pushes it into is that non-fair use?

# <u>Sasha TerMaat – Epic - Member</u>

Well, I don't even know if it's using the article, which I think would be hard to restrict. But if there's a screenshot of unlucky EMR in this article, for the purpose of comparing the usability of a variety of products, and then, that screenshot is used by Truscott EMR in their marketing to say look how much better we are, they're not even using the whole article in that case. They're just taking advantage of the fact that they had access to screen design about one of their competitors because of the article and then, using the information for other purposes, in that case, marketing.

## Andrew Truscott – Accenture – Co-Chair

And let's go one step further – go on, Denise.

# Denise Webb – Individual - Member

I think that sounds illegal.

## <u>Sasha TerMaat – Epic - Member</u>

I guess that's what we're asking, right. If this information is available under this provision, how does that get negotiated?

# Denise Webb – Individual - Member

I know all of the vendors, you all publish glossies and handouts you give out at HIMS and so forth. Your competitor could take that and do something with it, too. There are laws to govern or protect your IP from unfair use or using it inappropriately, I would think. So, I guess I'm saying there are other avenues where competitors can get each other's material and the same issue comes to play.

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

But I think the difference here, Denise, is where this is a third party. You're absolutely right. There is a whole bunch of legislation that protects an organization from going and grabbing the intellectual property of another organization. But where you've got a third party who may potentially be granted a fair use exemption taking and using that information in a legitimate way, which the product of that research could then be utilized in a way that infringes, is that something that we just need to stay well away from, guard against, or what? I'm trying to think through the adverse consequences of some of this, especially with that definition of fair use.

#### Denise Webb – Individual - Member

I think this starts to get into very legal issues and that's beyond my scope of expertise.

# Andrew Truscott – Accenture – Co-Chair

Yeah. And maybe that's in the recommendation to ONC that the unintended consequences of this definition of fair use and the use of fair use here should be explored fuller by ONC as they pull this all together. Maybe that's our recommendation.

#### Denise Webb – Individual - Member

Yeah. Because, clearly, it sounds like there are concerns about risks to vendors' intellectual property, which is a fair concern.

#### Andrew Truscott – Accenture – Co-Chair

Yeah, because we don't want to impinge upon innovation.

<u>Sasha TerMaat – Epic - Member</u> Do we mean infringe?

<u>Andrew Truscott – Accenture – Co-Chair</u> Well, I meant impinge, but infringe would work just as well.

<u>Sasha TerMaat – Epic - Member</u> All right. That must be a Texas word.

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

I was going to say British and let you all off the hook.

#### Mark Knee – Office of the National Coordinator – Staff Lead

That definitely sounds British.

#### <u>Sasha TerMaat – Epic - Member</u>

I'm Googling it. All right. I got it. That seems like a reasonable recommendation. I think we've certainly identified that there's a consensus about the concern. I don't know that any of us have a great sense of what the solution is to recommend a solution. So, maybe articulating the concern is a good path.

#### Andrew Truscott – Accenture – Co-Chair

Yeah. I think the bottom line is we're trying to achieve a particular goal with this exception. And we need to make sure that in achieving that goal, which is a perfectly legitimate one, we don't inadvertently permit some other kind of exploitation for other means, inadvertently or not.

# Michael Adcock – Individual – Co-Chair

Given that, Mark, can we move on to the next item?

#### Mark Knee – Office of the National Coordinator – Staff Lead

Yeah, sure. Okay. I think the next one was screen shots. And we did a little more research on

this one as well. So, Penelope, do you want to take it?

## Penelope Hughes – Office of the National Coordinator – Back Up/ Support

Oh, sure. So, on that one, the way that's addressed in the preamble is that it does state that the reproduction of screen shots in connection with communication about one of the protected topic areas would ordinarily represent a fair use. And then, further, with respect to IP, health IT developers are not permitted to restrict communications that would a fair use of copyrighted work. So, that's what we say about that.

## <u>Sasha TerMaat – Epic - Member</u>

It sounds very related to the conversation we were just having.

## Penelope Hughes – Office of the National Coordinator – Back Up/ Support

Very much, yes.

## Andrew Truscott – Accenture – Co-Chair

Aaron is being very quiet. Is Aaron on the call?

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

Aaron said he was going to be late, so I don't think he is on.

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

That's why it's quiet. That's fine. We have to start this way. The screen shots are just one example of IP, but it has the added friction that a screen shot might actually be the means of communication of patient information.

# <u>Sasha TerMaat – Epic - Member</u>

Sorry, I missed that. Say it again.

# Andrew Truscott – Accenture – Co-Chair

I'm in a windy place. It has the added dimensions, the screen shot might be, in a worst case scenario, the means of communicating the patient information through the capturing and distribution of the screen shot. So, it's a bit of a hoary one.

#### <u>Sasha TerMaat – Epic - Member</u>

It seems to me that the recommendation above would encompass our concerns and discussion here also plus the possible proposal that we had had previously.

# Andrew Truscott – Accenture – Co-Chair

Yeah. But I think we should note that one is about scholarly research with fair use. The other is around the actual communication and the actual meeting of the information blocking requirement could inadvertently fall into this line. It's a bit different. Screen shots are **[inaudible] [00:35:55]**.

# Michael Adcock – Individual – Co-Chair

Is that all of the discussion around screen shots? Hello?

# Andrew Truscott – Accenture – Co-Chair

It's gone silent.

## Michael Adcock – Individual – Co-Chair

I'm guessing that's all of the discussion around screen shots. Mark, is there another one?

# Mark Knee – Office of the National Coordinator – Staff Lead

Yes. So, the other one was just, and I can take this one quickly because I think we resolved it based on Lauren Woo's input last time, but there was a question about why two years was proposed as a timeframe for compliance. And we looked back, and I think the preamble – I think what Lauren said was accurate. And also, just as far as timing goes, a lot of times, when we're drafting proposed rules, you want to come out with a reasonable proposal. But, of course, it's open to discussion and changing based on feedback we get from you all and from public comment. So, that's all to say. I think we covered it in the last meeting. And I think you do have an amended recommendation that you guys wanted to bring forward. And I just wanted to say that one more time.

We're trying to do our best to come up with a reasonable timeframe, but we're open to suggestions.

# Michael Adcock – Individual – Co-Chair

I thought the proposed recommendation was very solid. So, I don't know if anybody else has had since we've had time to think about, had any different thoughts. But I thought it made great additions to the two years.

# Mark Knee – Office of the National Coordinator – Staff Lead

I guess, one thing I would say just going back through our proposal, the proposal to restate it, and I think Sasha is hovering over it, is can we add a contract renewal in here and state a road map within two years with compliance not to be unreasonable. We do say in the rule regarding the renewal issue that we understand that some of these contracts will extend out way beyond two years. I think we provide five years as an example. So, that's one of the issues that we are trying to address is a reasonable timeframe that would make the changes relatively quickly with the understanding that it does take time to do these things.

#### Andrew Truscott – Accenture – Co-Chair

So, I actually went and did a bit of math around this about what the impact would be to us. And I talked to my legal team as well about the level of effort. We think we'd have to take on four full time lawyers to handle this.

#### Michael Adcock – Individual – Co-Chair

To handle it within the two years?

## Andrew Truscott – Accenture – Co-Chair

Yeah. Which I don't believe is the intended consequence.

## Denise Webb – Individual - Member

Yeah, I think that was one of our concerns is that the level of effort and the cost estimates were way underestimated. And, clearly, they were based on Andy's information that he just shared.

# Andrew Truscott – Accenture – Co-Chair

And it's a sheer numbers exercise. The more contracts you have, the more effort it's going to be. And also, different clients work at different cadences. Sometimes, we might not actually be able to have this happen within about two years no matter how many people are on top of it. So, I like the idea of actually laying out a road map of compliance within a two year period. That, I think, is perfectly doable.

## Denise Webb – Individual - Member

Well, at least the road map is evidence that a vendor has assessed all of the contracts that are going to be impacted and need to be updated. So, they didn't just blow it off.

#### Andrew Truscott – Accenture – Co-Chair

I concur. Sasha?

#### <u>Sasha TerMaat – Epic - Member</u>

I agree.

# Michael Adcock – Individual – Co-Chair

Yeah, I think we're all in agreement on this one.

# Andrew Truscott – Accenture – Co-Chair

Getting through contracts is a great celebration when you think because reopening them is a bad thing.

#### Sasha TerMaat – Epic - Member

We're speaking with the previous proposals here with the additional justification that Andy brought up.

# Andrew Truscott – Accenture – Co-Chair

Yes.

<u>Sasha TerMaat – Epic - Member</u> Okay.

# Michael Adcock – Individual – Co-Chair

So, Mark, was that the last outstanding issue?

# Mark Knee – Office of the National Coordinator – Staff Lead

I believe so unless you all remember another one. But those are the four that Penelope and I did additional research on. And if there aren't any additional issues, we can just go through all of the outstanding issues we had on all of the topic areas and try to work through them over the next hour and 15 minutes.

# Andrew Truscott – Accenture – Co-Chair

Sure.

# <u>Sasha TerMaat – Epic - Member</u>

Wait, so we have other outstanding issues?

# Mark Knee – Office of the National Coordinator – Staff Lead

No, I don't. I was just saying if there were any, beyond what Penelope and I have addressed, we're open to those questions. But those were the four that we saw in the Google Doc.

# Sasha TerMaat – Epic - Member

I did have a question about communication if folks were willing to discuss that slightly further. But I don't want to interrupt from the agenda if we have to move on to a different topic.

# Michael Adcock – Individual – Co-Chair

No, I think that's perfectly appropriate. Go ahead.

# <u>Sasha TerMaat – Epic - Member</u>

Well, as Andy mentioned earlier, a lot of us have been thinking further about this communication provision and how to balance the goals of 21<sup>st</sup> Century Cures and what ONC has proposed, some of the possible unintended consequences. One of the possibilities I was thinking about was carving out a bucket of never protected communications. So, ONC puts together a bucket that says these communications like sending safety issues to a PSO are always protected. But it seems like there could be a bucket of never protected communication, which would involve potentially false communications, communications protected by attorney/client privilege, other things that are sort of under a legal hold, for example.

And I don't think the intention of 21<sup>st</sup> Century Cures is to protect false communications, for example. The goal isn't to let liable be protected. But it's not actually called out that that restriction is there. And I think that might be useful to the framing context and to avoid unintended consequences.

# Michael Adcock – Individual – Co-Chair

Andy, Denise, thoughts?

# Andrew Truscott – Accenture – Co-Chair

Sasha, can you say that again? I'm just reparsing that sentence.

## <u>Sasha TerMaat – Epic - Member</u>

So, in the framework of communications, ONC has this sort of bucket of always protected communication. And then, they have the general topic areas where some restrictions could be permitted under limited circumstances if they qualify. I would propose another bucket for the framework of I guess what I would inelegantly call never protected communications but to clarify that false communications, for example, are not eligible for the protections that otherwise ONC is describing.

## Andrew Truscott – Accenture – Co-Chair

Unprotected communication.

## <u>Sasha TerMaat – Epic - Member</u>

Right. So, that you're not inadvertently saying that someone liabling a product is protected under these provisions if the content of their communications is false. And I think there are other categories of communication that might make sense to put into that bucket. Things protected by attorney/client privilege, for example.

## Andrew Truscott – Accenture – Co-Chair

I think you'll hear a common theme starting to emerge from me, which I picked up as I've gone through many of these rules and that having a functional component and an illustrative component when we go through some of this definition type stuff. So, it's what it is we're trying to achieve and the nature of what would be unprotected and then, give some examples such as attorney/client privilege.

#### <u>Sasha TerMaat – Epic - Member</u>

Yeah. And I guess just for whoever is on the screen, I'm putting the notes on what I just proposed in the request for comment section a little bit below, which is maybe not the best spot for it but I can move it. But if you scroll down, you'll see it.

# Mark Knee – Office of the National Coordinator – Staff Lead

Great. Thank you for letting me know. I was lost.

#### Denise Webb – Individual - Member

This is Denise. I'm not opposed to that. I think it makes sense. It creates a balance in the equation.

#### Michael Adcock – Individual – Co-Chair

This is Michael. I'm in agreement as well. So, as Sasha finishes that, was there any other areas under communication that we need to discuss, any other outstanding issues? I know that we all talked about going back and looking at examples of certain pieces that we've talked about

today before we come back with our recommendations. But are there any other items that we need to go back that we discussed sometime last week? Andy, I missed the first work group call. So, I'm asking you as well are there other issues that we needed to discuss or other issues that came up maybe on the first call that I missed that we need to go back through?

#### Andrew Truscott – Accenture – Co-Chair

No. I think we need to crank through the remainder of the areas we haven't really touched upon. So, there's 403 and 581, the certification ban. We need to actually crank these out so we actually have some initial thoughts scribed down because we haven't gotten to those at all. And I think self-developers is also an area that we need to have some conferences on. I think it's quite useful that none of us on this call are actually self-developers per se. And I think it will be good that we start rounding around that as well because that's certainly an area of space.

## Denise Webb – Individual - Member

Andy, I would just clarify though that the organization I was most recently with was very heavily into self-development.

## Andrew Truscott – Accenture – Co-Chair

Indeed, but you're not there now.

## Denise Webb – Individual - Member

No. I left in June. So, I have some familiarity with the issues possibly.

# Andrew Truscott – Accenture – Co-Chair

You do, cool.

# Michael Adcock – Individual – Co-Chair

So, Mark, can we move to that area in the Google Doc?

#### Mark Knee – Office of the National Coordinator – Staff Lead

Yes, sorry, which area was it that we wanted to move to?

#### Michael Adcock – Individual – Co-Chair

The areas that we haven't covered yet, the self-development -

#### <u>Sasha TerMaat – Epic - Member</u>

Are we going to the certification ban or the self-development piece? I'm confused, too, sorry.

# Andrew Truscott – Accenture – Co-Chair

I'm just saying move on, and I was commenting that I really want to get to self-development but not necessarily there first.

# <u>Sasha TerMaat – Epic - Member</u>

Okay.

# Andrew Truscott – Accenture – Co-Chair

Chair, the floor is yours.

# Michael Adcock – Individual – Co-Chair

So, we'll start with the certification ban.

# Mark Knee – Office of the National Coordinator – Staff Lead

All right. Great. And just to frame it, this does tie into the enforcement piece that we discussed the last call.

# <u>Sasha TerMaat – Epic - Member</u>

Yes. I was going to say I think that the comments and discussion that we recorded in the box above, particularly some of the concern about the ban being quite dramatic and its consequences would really actually be more applicable perhaps in this box.

# Mark Knee – Office of the National Coordinator – Staff Lead

Agreed. I can move those down right now.

# <u>Sasha TerMaat – Epic - Member</u>

Let's just leave it there but I'm just going to put a comment to also see above.

# Mark Knee – Office of the National Coordinator – Staff Lead

Great. And it's all intertwined just as long as we're clear about specifically what you're talking about.

# <u>Sasha TerMaat – Epic - Member</u>

So, I'm putting the notes into the box below with a cross reference going back up if we want to. I misspelled ban. Is there more feedback from the work group, or did we really kind of already cover the ban in the earlier conversation?

# Andrew Truscott – Accenture – Co-Chair

We covered this one that actually we don't really have much in the way of comments that we think it's remarkably well thought out and we quite like it.

# Mark Knee – Office of the National Coordinator – Staff Lead

I think we should direct quote that.

# <u>Sasha TerMaat – Epic - Member</u>

I'm not sure I'd put it that way.

# Andrew Truscott – Accenture – Co-Chair

The only proposal we have is around using email as certified mail.

#### Michael Adcock – Individual – Co-Chair

That's the only one that's written down and the only one I recall.

#### Denise Webb – Individual - Member

Yeah, I think that was principally our discussion about some of these have pretty dire consequences and should be communicated by other means than just email.

## Michael Adcock – Individual – Co-Chair

Was there any other discussion to be had on that, or are we ready to move on to the selfdevelopment?

## <u>Sasha TerMaat – Epic - Member</u>

I think the next piece is actually the public listing of certification bans. But I don't know if we have any comments on that.

## Mark Knee – Office of the National Coordinator – Staff Lead

And I've pulled that proposal and request for comment onto the screen. It's a short paragraph if folks want to just give it a read. And if there aren't, I'll wait for you all to finish, if you want to think about this one and come back to it as far as if you have suggestions about time periods or anything else, we can definitely do that.

# Michael Adcock – Individual – Co-Chair

Thoughts from the group?

#### Denise Webb – Individual - Member

So, just for our group because maybe ONC can't comment on this but if a developer has sought and received reinstatement under the program and is no longer under the certification ban, I guess it seems like continued punishment to leave them listed on the ONC website. And that doesn't seem appropriate. But maybe if you take it from a customer's point of view, they might want to know that they have been banned before.

# Andrew Truscott – Accenture – Co-Chair

I think it's entirely appropriate.

# Denise Webb – Individual - Member

I'm trying to look at both sides of this, from the developer's side and from the customer's side. I think customers want to know these things. And so, if they have a choice between Vendor A and Vendor B, and they're very close in the running on what they're going to choose, and Vendor A had had problems with maintaining their certification, and Vendor B didn't, I guess that would be important to know.

#### Andrew Truscott – Accenture – Co-Chair

And the vendors are not going to volunteer that information.

#### Denise Webb – Individual - Member

No, they're not.

# Andrew Truscott – Accenture – Co-Chair

It's an authoritative record. And ONC is the authoritative record.

# Denise Webb – Individual - Member

Yeah.

# Michael Adcock – Individual – Co-Chair

So, Andy, your thought is this should be included indefinitely?

# Andrew Truscott – Accenture – Co-Chair

I, personally, have absolutely no involvement with that because it's a matter of fact. It's not a matter of conjecture. And also, the bans are so far down the road.

## Denise Webb – Individual - Member

Sasha, what do you think?

#### Michael Adcock – Individual – Co-Chair

Right. There are many steps before it gets to that point. I understand.

# Andrew Truscott – Accenture – Co-Chair

Yeah. To get a ban is you have to be basically ignoring every single email and, basically, sticking your fingers up at ONC. I've got no problems with that.

#### Denise Webb – Individual - Member

Yeah. I guess a customer should know that. And it doesn't matter when it occurred.

# Michael Adcock – Individual – Co-Chair

Sasha, what are your thoughts?

# <u>Sasha TerMaat – Epic - Member</u>

It's hard to say. Certainly, I value the integrity of the **[inaudible] [00:56:14]**. But I do worry that the certification ban is already an extremely significant consequence. I can see both sides, I think, as Denise said.

# Denise Webb – Individual - Member

I don't know. Let's take a scenario where the vendor was the bad actor, and then, they were acquired. I would think that that would erase that for the new company that acquired that

they shouldn't have to carry the sins of the past organization that they acquired. I don't know how that would play out.

# Andrew Truscott – Accenture – Co-Chair

My point of view is when something is a matter of fact and there is a public statement made, then, it's a matter of public record. The fact that you've remediated is true, and it's great, and you're back in compliance. And it's just a matter of a fact. Otherwise, the opportunity for misrepresentation and hiding of that fact is too great or too tempting. And also, the likelihood of it being a big impact is pretty small because we never had a ban yet. Although, I feel that we may be heading down the line to having one with these rules.

# Lauren Wu – Office of the National Coordinator - SME

So, this is Lauren. Just to kind of make a technical clarification. In today's world, one of the actions that can result in a certification ban is under ONC direct review. However, there are some other circumstances where a developer may be subject to a certification ban. And this is, I think, a little bit outside of the context of the ONC direct review when we're talking about enforcing compliance as a condition for certification. But I did want to just for the record state there is actually one developer currently that is banned. And it is listed on the chapel. We do have a specific page for banned developers. But the reason for that ban is separate and apart from ONC direct review.

# Andrew Truscott – Accenture – Co-Chair

That doesn't change my point of view but thank you for the expansion. Sasha, you are quiet on this one. I can almost feel your conflict.

# Denise Webb – Individual - Member

So, are we going to just suggest – they're asking should they no longer be listed? Are we in concurrence that they should be listed once they achieve recertification?

# Andrew Truscott – Accenture – Co-Chair

Well, you don't have a time if they're banned from this state to this state.

# Denise Webb – Individual - Member

I'm fine with that from the perspective, Andy, that you did say that is a fact and it did occur. It's a matter of record.

#### Andrew Truscott – Accenture – Co-Chair

You, obviously, need to have an end date when the ban was lifted.

# Denise Webb – Individual - Member

Right.

# Michael Adcock – Individual – Co-Chair

If they're listed on this site, I haven't looked at it, is there an area for active and then, an area

for ones that have been lifted or ones that have been reinstated but still had a ban? Is there a way to tell the difference between an active ban and one that's been reinstated? Because I agree they should be on there. It is a matter of fact. And they should be on there indefinitely. If I was looking at the list, these are under the active ban. Here are bans that have been – these were banned, they've been reinstated. It's more for information purposes.

## Sasha TerMaat – Epic - Member

I don't know that it is today. But I guess isn't this kind of a proposal about what the design might be in the future?

# Denise Webb – Individual - Member

Yeah, I think.

# <u>Sasha TerMaat – Epic - Member</u>

Because today, if you go to the chapel and you look at banned developers, there's not a timeframe beside a date, which I assume was the start of the ban.

# Michael Adcock – Individual – Co-Chair

Maybe someone from ONC could help us with that. Because there's only one on there now, was it planned that there be an active date and then, reinstated? How was that expected to look? Because we can't discuss how it can look in the future but I guess we could but if we don't know how it's intended to look now.

# Lauren Wu – Office of the National Coordinator - SME

This is Lauren. I can definitely research that for you and get back to you. Right now, the banned page, the developers under the certification ban list three items, the developer, the date that they were subject to the certification ban, and then, who the ONC ACB is. But I can follow up and just double check to make sure what additional information might be on the specific page for that health IT developer's actual products on the chapel.

# Michael Adcock – Individual – Co-Chair

Okay. I think that's helpful. I don't know how anybody else feels. If I was going to look at the ban page, I'd want to know who was banned versus if a developer is telling me if I asked the question if they had ever been banned, and they answered it honestly that they had been but that it's been lifted. I think it would be pertinent to have a way to double check that. If ONC is going to be the place where that is listed, as an operator, I would want a way to be able to double check that information. But I welcome any thoughts from others.

#### <u>Sasha TerMaat – Epic - Member</u>

I tried to capture that proposal in the Google Doc, but it's on the next page. Does that seem appropriate?

#### Michael Adcock – Individual – Co-Chair

Yes. I think that summarizes at least what I was thinking. I just think there needs to be a way

to discern between the two. An active ban is one thing. If a vendor actually did finally do the right thing and they're one of the ones I'm looking at, I'd like to know that they actually did do whatever was necessary to have the ban lifted.

#### Denise Webb – Individual - Member

So, if it wasn't already intended in the existing posting to show a ban end date, we are suggesting that that be included. So, the start date of the ban and the end date, there would be an end date if the ban was lifted. Otherwise, there would be no end date. That means it's active. Is that what we're suggesting?

## Michael Adcock – Individual – Co-Chair

This is Michael. Yeah, that's what I think. I don't know. If the rest of the group is okay with it, I think it's great.

## Andrew Truscott – Accenture – Co-Chair

Yeah.

<u>Sasha TerMaat – Epic - Member</u>

I'm good with it.

## Michael Adcock – Individual – Co-Chair

Okay. Any other comment on this area? If not, Mark, let's move along.

# Mark Knee – Office of the National Coordinator – Staff Lead

All right, great. Self-developers now? Fine?

# Michael Adcock – Individual – Co-Chair

Andy, you said you had some thoughts on this that you wanted to get into a discussion on this.

# Andrew Truscott – Accenture – Co-Chair

Yeah. Frankly, my personal view is self-development should be impacted exactly the same way as any other health IT developer. The problem would be if a self-developer gets a ban, does that, therefore, ultimately trigger any of the other punitive actions on the basis that they must, therefore, be guilty of information blocking in their operations, in their actual care operations. Discuss.

#### Denise Webb – Individual - Member

Well, I have a question to pose to the group to see what your thoughts are. So, what if the selfdeveloper had their own self developed EHR, they had it certified let's say for the 2014 edition, and now the 2014 edition goes away, and they don't upgrade their software to the current edition? What interview would they be subject to in all of this as a self-developer? Because there is some language in the rule about if you've ever had your product certified, and then, you don't continue certification I was reading in the information blocking portion that you would still be subject to the information blocking requirements of the Cures Act. So, take a health system that developed and maintained their own electronic health record system but then, they have decided not to update their software to meet the current requirements.

#### Andrew Truscott – Accenture – Co-Chair

Honestly, I think that needs to be less the case for a health system because the vast **[inaudible] [01:07:10]** have moved over to more commercial type battles. And there are a couple of exceptions. We can talk about the VA if you wish, but they are going through a process right now. But I think it's more for people like the retail pharmacy type organizations where they have extensive patient records around prescription dispensing type activity, which falls under the EHR definition clearly. But invariably, they have their own home grown pharmacy master systems, which also include the patient medical aspects as well. Some of the things like physical therapy companies, which are very, very specific needs.

## <u>Sasha TerMaat – Epic - Member</u>

You're saying, Andy, that those groups would have self-developed software?

# Andrew Truscott – Accenture – Co-Chair

Absolutely. If you choose the four largest retail pharmacies in this country, every single one of them has got a home grown pharmacy management system sitting in the middle of their organizations that handle millions of patients and records data.

## Sasha TerMaat – Epic - Member

And they certify those?

# Andrew Truscott – Accenture – Co-Chair

No. But that's why we're having this discussion.

#### Denise Webb – Individual - Member

Yeah, but they wouldn't be subject to the information blocking if they'd never had certified software from what I read in the preamble.

# Andrew Truscott – Accenture – Co-Chair

Yeah. They wouldn't be subject to the certification requirements. But they absolutely have selfdeveloped software that they're using. And they should be subject to information blocking.

# Mark Knee – Office of the National Coordinator – Staff Lead

This is Mark. I think that's a really important clarification just to jump in. What we're talking about here is a specific request for comment that's specific to the conditions and maintenance certification, which is for certified developers. Information blocking, as I explained, is broader than the conditions of maintenance and certification. So, that's an important clarification.

#### Andrew Truscott – Accenture – Co-Chair

Yeah. With a self-developed organization, they don't need to go through certification because they develop for their own purposes. They have no need to go through certification.

# <u>Sasha TerMaat – Epic - Member</u>

That's not true, Andy, because if they want to be eligible for federal programs that require certified software, and they self-develop their software, then they do need to go through certification.

#### Andrew Truscott – Accenture – Co-Chair

But they don't want to be eligible for certain programs.

#### <u>Sasha TerMaat – Epic - Member</u>

Well, some of them do.

#### Denise Webb – Individual - Member

But, Andy, I just came from a health system that has self-developed software. And it is certified, but it's certified to the 2014 edition.

#### Andrew Truscott – Accenture – Co-Chair

That's what I said in my opening **[inaudible] [01:09:51]**. I'm not going to comment about health providers in the same way. I think there is a gap where it's not a health provider organization such as where you were, Denise, but more some of these **[inaudible] [01:10:04]** organizations that I just think there's a gap. And whether we want to try and address that gap or not I don't know.

#### Denise Webb – Individual - Member

But ONC can clarify. But I believe this provision here applies to all self-developers. And it includes health systems that do their own self development and have certified software.

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

I know it applies to them, Denise. But, in general, if I look across the market, the number of health systems that are self-developers in terms of EMRs is diminishing rapidly.

#### Denise Webb – Individual - Member

So, I wouldn't disagree with that.

#### Andrew Truscott – Accenture – Co-Chair

Really?

#### Denise Webb – Individual - Member

No, I said I wouldn't disagree with you on that.

#### <u>Sasha TerMaat – Epic - Member</u>

I don't know, does it matter how many there are though? I guess this question is about that group.

# Denise Webb – Individual - Member

lt is.

# Andrew Truscott – Accenture – Co-Chair

If that's the way that we want this to be because I must confess, I am trying to address a problem, which I believe is out there in the market right now where there are volumes of patient records, which are kind of on the fringes of any kind of regulation, basically, because the organizations don't believe they are required to comply. If the purpose of this is to focus upon systems who are self-developers, then, that's fine by me, too. We can just –

# <u>Sasha TerMaat – Epic - Member</u>

Well, Andy, I don't disagree with either of your points but I think they're separate. So, I guess one question is for self-developers who have historically pursued certification, which components of this new proposal should be relevant to them. And someone has a lot of background noise. I don't know if they can mute.

# Andrew Truscott – Accenture – Co-Chair

lt's me, it's me.

# <u>Sasha TerMaat – Epic - Member</u>

Oh, sorry. So, I guess part of it is some groups, and Denise has given us some examples, have pursued self-development and certified their self-developed solutions. Some of the things that are proposed in these conditions of certification should probably be relevant to those self-developed systems and some of them maybe not. And we need to discuss which ones. There's a separate question that Andy raises, which may or may not be in our task forces scope, which is are there some types of health information technology, and Andy gives an example of systems used in pharmacy networks that ought to be subject to certain provisions under the 21<sup>st</sup> Century Cures proposal either through certification or through information blocking or otherwise and aren't currently covered.

But I don't think that's what this particular section on Page 323 is asking about.

# Andrew Truscott – Accenture – Co-Chair

Okay. I'm okay.

# Denise Webb – Individual - Member

And I'd agree with Sasha. And, actually, as I'm thinking about this, let's just take a health system, and they have their own self developed certified software, but they don't sell it to anyone, they only use it themselves, why should they be subject to the conditions of maintenance and certification for communications?

# <u>Sasha TerMaat – Epic - Member</u>

Well, Denise, are you saying that that screen shots of that system would not be eligible to be

used in a usability study comparing the self-developed usability and a commercial system?

# Denise Webb – Individual - Member

No, I'm not saying that. That's why I wanted to throw that question out because I wanted to see can you help me see this from what perspective communications would apply. And I just thought of one, actually, where it would apply. So, the user experience, if you have providers using the self-developed system, and they want to talk about their experience that should be a protected communication. So, I guess, then the self-developer would be subject to the communication. So, I'm talking myself through this. I'm trying to think this through.

## Mark Knee – Office of the National Coordinator – Staff Lead

And just to chime in just in context, we do talk about self-developers in the info blocking context on Page 338. And I think throughout there's a decent conversation about it in the health IT developer definition, health IT developer certified health IT. And we reference a previous definition of self-developer that we used in prior rule making. And there's a citation to that around Page 338.

## Denise Webb – Individual - Member

I'm seeing if I have that page. Oh, okay, yeah.

# Lauren Wu – Office of the National Coordinator - SME

So, as a matter of process, I think this question was made, maybe Mark and Lauren Richie. The question was whether this group needs to address that request for comment. I would suggest since it is within the scope of this task force to respond to ONC's proposals about the information blocking assurances and communications conditions of certification that they do consider this request for comment for those three conditions. And then, that the other task force, which is addressing the other conditions of certification, if they can fit that into their schedule, if it's not already planned, address this request for comment further specific conditions of certification.

# Denise Webb – Individual - Member

That's a good idea. So, I'm on that other task force, and we didn't address this.

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

Yeah, I was just going to say, this is the other Lauren, that's fine with me. I just wanted to make sure we check with the other task force. And we can do that offline. But I don't have a problem with it as long as –

# Andrew Truscott – Accenture – Co-Chair

It's Denise's task force.

# Denise Webb – Individual - Member

Mine and Raj's, yeah. We certainly could bring that up, Lauren, to look at the conditions and

certification for self-developers for the ones that we're covering.

## Lauren Wu – Office of the National Coordinator - SME

Sure. Thank you for considering that. I think like it was mentioned, it may be a small group, but I do think it presents a unique situation, which is why we are soliciting comment. And so, it would be helpful for us to have some of your expert thinking on thinking through the use cases of self-developers for each of the conditions and their proposed requirements.

# <u>Sasha TerMaat – Epic - Member</u>

Are we going to go through each of the proposed requirements then?

# Denise Webb – Individual - Member

It's probably the way we need to do it.

## <u>Sasha TerMaat – Epic - Member</u>

Just logistically, do we want to list them out here and put our notes into this section? I think that would be best. But I need someone to remind me what the first one at the top of the document is.

## Denise Webb – Individual - Member

It was information blocking, conditions of certification and maintenance.

# Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. So, we're dealing with information blocking assurances and communications.

# <u>Sasha TerMaat – Epic - Member</u>

Okay. And then, the second one is communications.

# Mark Knee – Office of the National Coordinator – Staff Lead

Oh, no, assurances are separate from information blocking.

#### Denise Webb – Individual - Member

Assurances is separate.

# Mark Knee – Office of the National Coordinator – Staff Lead

Exactly.

#### Sasha TerMaat – Epic - Member

Okay. And then, was there a fourth one or communications was the one right before this?

# Mark Knee – Office of the National Coordinator – Staff Lead

No, that's it for this group.

## Denise Webb – Individual - Member

No, those were the three.

## Sasha TerMaat – Epic - Member

Okay, thank you. All right. Information blocking first.

# Denise Webb – Individual - Member

Well, I don't think it matters whether your system is self-developed or whether it was a commercially developed system. I think they equally are subject to the information blocking, in my opinion.

## <u>Sasha TerMaat – Epic - Member</u>

I would agree. The second one is assurances. It seems like self-developed products could still make the same assurances.

Denise Webb – Individual - Member

And should.

# Michael Adcock – Individual – Co-Chair

Yes, agree.

# Sasha TerMaat – Epic - Member

And then, we briefly touched on communications.

# Denise Webb – Individual - Member

Yeah, we sort of have to break that one down, don't we?

# <u>Sasha TerMaat – Epic - Member</u>

Sure.

# Denise Webb – Individual - Member

So, let's see. I'm trying to recall the subtopics in communications. I don't have that in front of me. What was the first one?

#### <u>Sasha TerMaat – Epic - Member</u>

I'm scrolling. They cover subjects of communications, types of communications, the meaning of prohibitor restrict, communications with unqualified protections, and then, permitted prohibitions and restrictions.

# Mark Knee – Office of the National Coordinator – Staff Lead

It's on the screen now if you have access to that.

#### Denise Webb – Individual - Member

Yeah. Obviously, the unqualified protection of certain communications that's a given.

# <u>Sasha TerMaat – Epic - Member</u>

The permitted prohibitions and restrictions seem like it would be the same also.

<u>Denise Webb – Individual - Member</u> Yeah. So, could we scroll up to the protected communications?

<u>Sasha TerMaat – Epic - Member</u> I think you went past it. It's the yellow part there.

<u>Denise Webb – Individual - Member</u> Oh, no, those are unqualified. Those are by law.

## <u>Sasha TerMaat – Epic - Member</u>

You said the protected ones, right?

## Denise Webb – Individual - Member

Right. Or is it just the general? I'm trying to remember if it's just the general definition unless it's one of these permitted prohibitions, it must be communicated. Is that the definition?

#### Sasha TerMaat – Epic - Member

Correct. It can't be restricted unless it is one of the permitted prohibitions. But never, in any case, could unqualified protected communications be restricted.

# Denise Webb – Individual - Member

Okay. Well, I guess I don't see –

#### <u>Sasha TerMaat – Epic - Member</u>

So, one thing that's going to be weird about this, and I don't know how to address it, but thinking through the communications component, one of the exceptions, the permitted prohibitions, it's A right there, is the developers, employees, and contractors. And I think that's an important restriction in the sense that employees receive all sorts of access to confidential information. It shouldn't be expected that they can just put it online. But in the case of a self-developer, if the self-developer is the health system, the employees of a health system is a different user group than the typical employees of health IT developer. And you wouldn't necessarily want to restrict the communication of a user of the health IT at that self-developed system with this provision, right?

#### Denise Webb – Individual - Member

That's an important point. So, a healthy IT developer may prohibit or restrict the communications of the developers' employees.

# Sasha TerMaat – Epic - Member

Right.

## Denise Webb – Individual - Member

Or contractors. So, if the developer is the health system, there probably needs to be some qualification here in that in the case of the self-developer, they cannot prohibit or restrict communications by their users of their health IT. That's different than being the developer of their health IT. So, we probably ought to suggest, in our comments or recommendations that this is the one place where they're going to need to differentiate the fact that a self-developer may be a health system that has users of the health IT. So, that has to be called out as an exception to this A. Does that make sense?

#### <u>Sasha TerMaat – Epic - Member</u>

Yeah, it does to me. Is this A2iiA?

Denise Webb – Individual - Member

A2iiA, yes.

# <u>Sasha TerMaat – Epic - Member</u>

I'm writing down the proposal.

## Denise Webb – Individual - Member

All right. And then, let's just kind of look at these to make sure there's no other nuance like that. What was B? Can you scroll up, Mark?

# Mark Knee – Office of the National Coordinator – Staff Lead

Yeah, sorry, it's frozen for a second. Here we go. Let's see. There we go.

# Denise Webb – Individual - Member

Communicating information on the prohibition. I was trying to look at the second prohibition.

# Mark Knee – Office of the National Coordinator – Staff Lead

Yeah, sorry. I'm just going to give it a second. It's not moving. There we go slowly. Okay.

# <u>Sasha TerMaat – Epic - Member</u>

I thought we wanted to look at B.

# Denise Webb – Individual - Member

B, next page, top of the next page. Okay.

# <u>Sasha TerMaat – Epic - Member</u>

B seems the same to me.

#### Denise Webb – Individual - Member

Yeah, that one is okay. And the intellectual property that one is okay.

#### <u>Sasha TerMaat – Epic - Member</u>

Yeah. Screen shots, it seems like it would be the same.

## Denise Webb – Individual - Member

Yeah. So, our comments that we made for these areas would apply whether it's commercial or self-develop.

# Sasha TerMaat – Epic - Member

Correct.

Denise Webb – Individual - Member Okay.

## <u>Sasha TerMaat – Epic - Member</u>

Would there be anything different about E?

## Denise Webb – Individual - Member

I don't think so because where I came from, we were actually trying to develop a new version that would be 2015 edition. And we protected that because it wasn't released.

# Sasha TerMaat – Epic - Member

And that makes sense to me. The only thing that would be weird under E is if a self-developed system was deployed in beta and then, it said this is being used but in beta and then, never moved out of there because there were no other users. I don't know. It seems like it would be a very unlikely scenario.

#### Denise Webb – Individual - Member

But you can't get something certified that's in beta. If you substantially change your software, I think you have to go have it revisited, right, through certification?

# <u>Sasha TerMaat – Epic - Member</u>

Yes, if there were significant changes to the certified capabilities.

# Denise Webb – Individual - Member

Yeah. I guess there would be more of a likelihood that a health system that's self-developed and had a certified product and then, made some changes to it but not substantial enough to get it recertified and then, left it in beta. They'd be probably more likely to do something like that than a commercial vendor. I don't know.

#### Sasha TerMaat – Epic - Member

I don't think it's worth trying to get it -

## Denise Webb – Individual - Member

Yeah. I just think that it's so insignificant that the juice isn't worth the squeeze.

#### Michael Adcock – Individual – Co-Chair

Agreed.

## Denise Webb – Individual - Member

All right. What about maintenance of certification on the contracting? So, obviously, they're not going to have necessary contracts, unless they let others use their software. Maybe they don't sell it. I know, in my former role, there was some of our software that we provisioned use to other entities. There was no cost. So, I think this would apply to self-developers as well because they do have NDAs and things like that that might prevent communication.

## <u>Sasha TerMaat – Epic - Member</u>

I suppose if they didn't then, there would be nothing to update.

## Denise Webb – Individual - Member

Correct. That wasn't as hard as I thought it was going to be.

# Andrew Truscott – Accenture – Co-Chair

That's good. So, what's next?

# Michael Adcock – Individual – Co-Chair

The Google Doc stuff again.

# Mark Knee – Office of the National Coordinator – Staff Lead

Sorry. So, do you want me to scroll down?

# <u>Sasha TerMaat – Epic - Member</u>

That's the end of the Google Doc.

# Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. So, it looks like we have about 20 minutes until public comment. Are there specific issues that you guys want to come back to or we could just start from the top and see where we get to?

#### Andrew Truscott – Accenture – Co-Chair

It would be good if we could actually go from the chair submission. Go from the top and just say for each of these sections, are we going to pull out some specific proposals and actually start working through what we think those proposals could be, especially for the intellectual property one. Mr. Chair?

## Michael Adcock – Individual – Co-Chair

Oh, I thought we were co-chairs. I thought you were making that recommendation.

## Andrew Truscott – Accenture – Co-Chair

We're co-chairs of a task force. You're chair in this work group.

## <u>Sasha TerMaat – Epic - Member</u>

So, our conversation in the first one, 401 information blocking, seems to indicate we didn't have any proposals.

## Andrew Truscott – Accenture – Co-Chair

It works for me.

Mark Knee – Office of the National Coordinator – Staff Lead All right.

## Denise Webb – Individual - Member

I think that was fairly straight forward.

## <u>Sasha TerMaat – Epic - Member</u>

And then, under assurances, we have -

## Andrew Truscott – Accenture – Co-Chair

Oh, Sasha, we've gone backwards and forwards. Come on.

<u>Sasha TerMaat – Epic - Member</u>

We did. We went back and forth here.

## Andrew Truscott – Accenture – Co-Chair

Oh, yeah, because I started channeling my inner Arien Malec and said it's not in the rule but it's in the preamble. I must confess, I get squirrely because preamble almost sounds forced out of preamble. They're going to raise it and say it's just the preamble. It's not the regulation. If it was that important, it would be in the regulation.

#### Mark Knee – Office of the National Coordinator – Staff Lead

That's not our position. The preamble is very important, from our perspective.

## Andrew Truscott – Accenture – Co-Chair

I'm sure that's not your position. But I would much prefer this to be unambiguous and not something that could be litigated through the courts.

## Mark Knee – Office of the National Coordinator – Staff Lead

Yeah, we agree there. Again, I think just to clarify ONC's position, as far as preamble goes, the preamble is an extension of the reg text. It's an explanation. It providers color and justification for why we put what we did in the reg text. There should not be new requirements in the preamble that are not in reg text. So, that's something to flag if we do that. And, additionally, if you think that reg text requires more clarity, we're open to that. It's just, again, as someone who worked on this, you're trying to find the balance between a succinct regulatory text that's not confusing but providing enough explanation so it's clear enough to stand on its own but also works with a preamble to really holistically address the issues.

## Andrew Truscott – Accenture – Co-Chair

We're in agreement.

## Michael Adcock – Individual – Co-Chair

So, what's our proposal?

## <u>Sasha TerMaat – Epic - Member</u>

I think from the notes, we were in discrepancy about if we wanted to make a proposal about records retention. I had proposed that if a developer withdrew their products from the program, with an example of it being common to do that if there are no longer any users of an older version of a product that a shorter record retention period was appropriate. And then, Andy proposed an indefinite retention period, which I thought was quite problematic given the scope of the potential records.

#### Andrew Truscott – Accenture – Co-Chair

I think then, there was a clarification that we're not talking about absolutely everything. We're just talking about the record about what's been certified over what period. We're not actually talking about all of the records to get to that certification.

#### Sasha TerMaat – Epic - Member

Was that clarified?

#### Andrew Truscott – Accenture – Co-Chair

I believe the conversation went there. Whether or not that's captured in the notes is unclear. Certainly, that was my understanding.

## Mark Knee – Office of the National Coordinator – Staff Lead

Just to restate it, the question is whether we're talking about the scope of records retention specific to assurances or whether we're talking about broader record retention.

## Andrew Truscott – Accenture – Co-Chair

Yeah. Because in B1I, we're saying that the developer will retain all of the records. Okay? And then, I was saying the fact that that product was certified or otherwise, at some point in time, should be, I believe, infinite retention. Aaron and I had that conversation because, obviously, the 10 year and the 3 year, those are moderately arbitrary but also, they're not keyed into any

of the records retention obligations upon providers for patient records. And the fact that I point out was certified or not, at a point in time, should be something that that's not volumeless data or difficult to curate.

#### <u>Sasha TerMaat – Epic - Member</u>

I don't disagree. Andy, I think it's reasonable to retain a record that a product was certified and over what timeframe. If we wanted to amend B1 to say that there is an indefinite time period for recording a table, for example, of what products were certified over what timeframes, I don't think anyone would have a challenge with doing that. But to retain the records specified currently in B1 for an indefinite timeframe is not reasonable.

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

And I think we're in broad agreement with that. I think the nuance we need to work through still is that middle ground between the three different vectors we have here. There's, obviously, your position, there's my position, but then, there's also the point that Aaron was making, I wish he was here to defend it, around what if you've actually got patient records, which still extants, the system that they were extant within no longer is certified, but it was at the time that they were created. And the provider is relying upon those records to prove that they appropriately handled that information. Now, we've been through this in the UK with the national program just as an aside around where you had records that were recently created in systems, which were innovated a long time ago.

But providers are saying look, I made these decisions for patient care based upon what I thought to be the right decision at that point in time from the system I had in front of me, from the electronic records that I could work upon. And I made my best judgment call. And we got to the extent in the UK that we were going to actually have a graveyard of retired platforms so that you could, theoretically, go and actually view records within the context of that system. Now, I'm not promoting that for one moment here. But what I'm actually suggesting is that I think there is something a bit more than what we have here to enable us to protect providers. Now, I know that's not the purpose here, but there's got to be something in the middle there though. Can you see where I'm coming from?

#### <u>Sasha TerMaat – Epic - Member</u>

Yeah. I'm trying to jot that down in the notes here.

#### Andrew Truscott – Accenture – Co-Chair

Oh, okay. Cool. Why don't I do it because it's my words?

#### Sasha TerMaat – Epic - Member

Sure.

#### Denise Webb – Individual - Member

While you're typing that, Andy, aren't those records different from the records we're talking about here? The records we're talking about here are the records related to compliance with the certification program.

## <u>Sasha TerMaat – Epic - Member</u>

Yeah. I think Andy means patient records, which we should clarify.

## Denise Webb – Individual - Member

The records we're talking about here in a Legacy system, patient records and how long those are held, actually, we just dealt with that in the health system I just came from when we moved off of one product to another. And we needed to retain the patient records that were in that other product, which was being sunset. And we actually took them and archived them into an archive retrieval system.

## Andrew Truscott – Accenture – Co-Chair

That's not what I'm talking about, Denise. What I'm talking about is where we got – 15 years ago, Dr. Truscott provided care to a patient. And that care, for whatever reason, fell short of the standard of care that we would want. And that patient, over time, had some reason to litigate against that provider. And that provider says, "Look, this was certified health IT that I was utilizing. I acted upon the best information that I had at that point in time." And that was certified health IT. Lots of people sat down and went through the clinical physician's report of the facility that was in there that I depended upon. Now, with what it says right here in the current drafting, I wouldn't have that available to me to help defend myself in that prosecution.

## Denise Webb – Individual - Member

So, in your country, they can go back 15 years to prosecute?

## Andrew Truscott – Accenture – Co-Chair

This is my country. Yes. Yeah, because in certain cases you can in the US, too.

## Denise Webb – Individual - Member

No, I mean in Great Britain.

## Andrew Truscott – Accenture – Co-Chair

In Great Britain, in certain cases, especially when you've got a patient who has reached the age of maturity, yeah, you can. And it would be good to get some clarification of whether you can here because, obviously, this is not the UK, this is the US. And I'm a bit concerned about what we can and can't do here.

#### Denise Webb – Individual - Member

It's really an important aspect of records based on what the records might need to be used for in a legal case. But I would have thought that ONC would have looked at, from the legal standpoint, what the –

## Andrew Truscott – Accenture – Co-Chair

Well, let's ask them.

## Denise Webb – Individual - Member

I'm trying to think of the words.

## Andrew Truscott – Accenture – Co-Chair

Let's ask them. Mark, did you guys consider this when you -

## Denise Webb – Individual - Member

How far back a patient could go in terms of taking legal action against a provider.

## Mark Knee – Office of the National Coordinator – Staff Lead

Sorry, can you just restate it so I'm clear what the question is?

## Andrew Truscott – Accenture – Co-Chair

Well, what's the maximum time that could have expired between the provider doing something and the patient being able to take action against that provider?

## Denise Webb – Individual - Member

From a legal standpoint.

## Mark Knee – Office of the National Coordinator – Staff Lead

Are you talking about in this specific time -

## Andrew Truscott – Accenture – Co-Chair

Ignore this completely. But what we'd like to understand is what the maximum time period that could have elapsed, including all of those rare situations where they could theoretically have come back on a provider, beyond which that patient can go back to that provider with some kind of action.

#### Mark Knee – Office of the National Coordinator – Staff Lead

Sorry. I think this is not only outside the scope of this conversation but probably outside of the scope of ONC because you're asking about not even related to certified products. You're talking about just legally.

#### Andrew Truscott – Accenture – Co-Chair

No, we're using that as a boundary.

## Denise Webb – Individual - Member

But there is a connection because what Andy is saying is if a patient can go back 15 years and say this doctor harmed me, and the doctor's defense is I was using certified health IT, the physician support that was provided to me and used my best judgment on what was provided to me, and they wanted to go back and look at how that certified health IT worked, there would need to be some records on that. So, I guess what we're trying to say is there is a connection.

## Mark Knee – Office of the National Coordinator – Staff Lead

We do have a records retention section in regulation that I could refer you to. I think that's probably the extent to which – I can follow up on this. But as far as ONC's requirements, the record retention for the program is the extent of really what I can comment, I believe, on that. I can't speak to general records retention and legal lawsuit practices and the statute of limitations kinds of things.

#### Andrew Truscott – Accenture – Co-Chair

Okay.

## Denise Webb – Individual - Member

Yeah, that's the word I was trying to think of, statutes of limitations. But, Andy, if there is a record retention period, and I do know this from having been in government a long time, there's different record retention periods. They don't necessarily all align with each other. If the record has been disposed of per the record retention period, in a lawsuit, if it's not producible, it's not producible because they complied with the record retention law that was specified for those types of records.

## Andrew Truscott – Accenture – Co-Chair

Don't get me wrong here. All I'm seeking to do is ensure that these retention periods are aligned to the requirements that might be made of them. That's it.

#### Denise Webb – Individual - Member

All right. So, the statute of limitations concerning records retention for the ONC program. Mark, are you saying they do align?

## Andrew Truscott – Accenture – Co-Chair

Yeah, keep it aligned up. And I've just called up all of the state based ones, and they're short. The maximum is five years. That's cool. And that's a Maryland thing, three or five. Everywhere else is like two or one, four in Minnesota, three in South Carolina, which is fine. And maybe 10 years is too long in places. I just don't want these to be misaligned. That's all.

## <u>Sasha TerMaat – Epic - Member</u>

Is someone going to do research to find that and bring the numbers back to our next meeting then?

## Mark Knee – Office of the National Coordinator – Staff Lead

I assume you mean ONC's side probably?

## <u>Sasha TerMaat – Epic - Member</u>

Well, if Andy has a table of all of the numbers, maybe he could stick that in the Google Doc.

## Andrew Truscott – Accenture – Co-Chair

Yeah. I wouldn't take it as being authoritative but sure.

## Mark Knee – Office of the National Coordinator – Staff Lead

I'm happy to look at it from our side as well just to look into it.

## Denise Webb – Individual - Member

Yeah. Because ONC is going to comply with what their statutes are. And a state can be more restrictive but not less restrictive than the federal government.

## Andrew Truscott – Accenture – Co-Chair

Whichever way is more, whichever way is less.

## Denise Webb – Individual - Member

Yeah. So, like on privacy.

## Mark Knee – Office of the National Coordinator – Staff Lead

Just a note just to scope this. This is specific to the assurances. I understand that there's a broader conversation you all are having. But within the maintenance of certification for assurances, we say a health IT developer must retain all records and information necessary to demonstrate initial and ongoing compliance with the requirements of the program. So, this is specific to this condition as far as the scope goes.

#### Denise Webb – Individual - Member

So, it sounds like we need to resolve your concern, Andy.

## Andrew Truscott – Accenture – Co-Chair

No, I think my concern is largely resolved. I'm surprised we have wording which is longer retention than is required. That's all. I just like things neat and tidy and lined up. You can't have everything you want in life.

## Sasha TerMaat – Epic - Member

Before we go to public comment, are we saying we're not making any recommendations in this category?

#### Denise Webb – Individual - Member

Actually, I agreed with your recommendation, Sasha.

## <u>Sasha TerMaat – Epic - Member</u>

Okay. I didn't know if we had lost that.

#### Denise Webb – Individual - Member

No, I think we need to make that recommendation if the others agree.

## Andrew Truscott – Accenture – Co-Chair

Didn't we have an agreement that we'd have unlimited for the basic if something was certified between these dates or not?

#### <u>Sasha TerMaat – Epic - Member</u>

Just like a table of what is or is not certified. What if ONC just retains that on the chapel indefinitely, and then, it doesn't have to be maintained by the developer?

## Andrew Truscott – Accenture – Co-Chair

That's fine, too.

## <u>Sasha TerMaat – Epic - Member</u>

Okay. So, we have two proposals, the one that I made and the ONC retains basic records on the chapel. And I know we have to go to public comment, so I'm going to try to note those and people can do the wording.

## Michael Adcock – Individual – Co-Chair

That will be good. It is time for us to go to public comment.

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

Sure. And Katie, do we have the slide up? Sorry, my Adobe crashed on me. Awesome. Operator, can we please open the public line?

## **Operator**

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

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

Okay. And I don't think we had a lot of public attendants. But, Operator, do we have any comments in the cue at this time?

## **Operator**

We have none at this time.

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

Okay. Mark and team, 10 minutes back. I think we may want to put the final touches on those last points of recommendations, and then, we can adjourn.

## <u>Sasha TerMaat – Epic - Member</u>

If you scroll down a little bit, I tried to capture the two points below the line where we're

## supposed to put our final - did I capture the wording there appropriately?

<u>Denise Webb – Individual - Member</u> I think that's the intent of what we were saying.

<u>Sasha TerMaat – Epic - Member</u> Thanks.

<u>Michael Adcock – Individual – Co-Chair</u> Andy, are you good with both of those?

## Andrew Truscott – Accenture – Co-Chair

Yeah. I just made a bit of an update. It was essentially to pull the records for three years I think is what we agreed.

## <u>Sasha TerMaat – Epic - Member</u>

For the scope of what's under B1.

## Andrew Truscott – Accenture – Co-Chair

Oh, actually, no. Hang on a second. We were saying that ONC should retain the records.

#### Sasha TerMaat – Epic - Member

Yeah.

## Andrew Truscott – Accenture – Co-Chair

The first one is fine if we have the second one. If we don't have the second one, then, we just need to put all the records on the first one. I'm good with that. Guys, one of the reasons I'm staying a bit more silent about this than I did other things is I've seen too many situations where it's been a problem and unintended consequences as while we think of these more things.

#### Mark Knee – Office of the National Coordinator – Staff Lead

And while there's a bit of a break, I just wanted to note that regarding the 10 year period, I think we talked about this previously, but there is preamble language that we say we believe that the 10 years is an appropriate period of time given that many users of certified health IT participate in various CMS programs as well as other programs that require similar periods of records retention. So, that's the logic there.

## Andrew Truscott – Accenture – Co-Chair

Well, they did in doctor records, right?

#### Denise Webb – Individual - Member

Right. And those other programs reference the certification program or required certified

health IT, so I can see -

#### Andrew Truscott – Accenture – Co-Chair

This sounds like a vicious circle. Each one depends upon the other.

Denise Webb – Individual - Member Well, yeah, it's a circle.

<u>Mark Knee – Office of the National Coordinator – Staff Lead</u> So, they should be the same, right?

## Denise Webb – Individual - Member

Well, the maximums of whichever one has the maximum. So, one of them must be -

[Crosstalk]

## Mark Knee – Office of the National Coordinator – Staff Lead

Are you all proposing a change to the 10 years? I'm not seeing that in the proposals or is that down further?

## Andrew Truscott – Accenture – Co-Chair

Yeah, I think I've lost that part.

## Sasha TerMaat – Epic - Member

I don't think we are.

## Mark Knee – Office of the National Coordinator – Staff Lead

Okay. So, all of that stuff with the state laws is just for this knowledge?

#### Andrew Truscott – Accenture – Co-Chair

I'll just take that out. There's a difference between state retention periods for records and state boundaries on malpractice, the statute of limitations on malpractice suits. Retention laws are around providing the best possible care you can to the patient or having clinical histories. Malpractice suits are a completely different matter.

#### <u>Sasha TerMaat – Epic - Member</u>

I think the discussion of state retention laws was somewhat mitigated when we saw the actual timeframes in what Andy pasted, which was helpful. And we're not, as far as I understand, making a recommendation there.

## Mark Knee – Office of the National Coordinator – Staff Lead

Okay. I just wanted clarification but that's really helpful.

#### Denise Webb – Individual - Member

And I would suspect, Mark, that since what you read in the preamble about the reliance on this program by other HHS programs and so forth, CMS, that the interdependency is sort of what drove setting the timeframe. I just assume that one of them must have had an on the outside limit 10 years. Otherwise, you wouldn't have picked 10 years.

## Mark Knee – Office of the National Coordinator – Staff Lead

I think that's probably fair. I wasn't necessarily involved in that deliberation but I think that's fair, especially based on what we say in the preamble.

## Denise Webb – Individual - Member

Right. Because if all of them were seven years or less then, you all would have picked seven years.

<u>Michael Adcock – Individual – Co-Chair</u> Okay. So, we have our proposals.

<u>Sasha TerMaat – Epic - Member</u> Are we going to keep going to TEFCA or are we going to adjourn for today?

## Michael Adcock – Individual – Co-Chair

I think we only have five minutes left.

#### Denise Webb – Individual - Member

I thought on TEFCA, we refrained from making any recommendations.

## Andrew Truscott – Accenture – Co-Chair

Let's keep going.

## <u>Sasha TerMaat – Epic - Member</u>

Yeah, I don't think we had any.

## Andrew Truscott – Accenture – Co-Chair

Well, do we have an update as to when the next live with of TEFCA is going to be available?

#### Mark Knee – Office of the National Coordinator – Staff Lead

Yeah. So, that's what I wanted to provide. I really can't say much. I can just say soon.

## Andrew Truscott – Accenture – Co-Chair

Okay. Thank you. So, guys, why don't we make the recommendation that this task force actually stay – our recommendation is not to make a rule change or anything like that. It's actually to stay engaged so that when TEFCA is available, we will actually make recommendations for this based upon TEFCA. That's just a suggestion.

## Denise Webb – Individual - Member

Yeah. And also, I don't know if the previous trusted exchange framework task force gets reengaged once the TEFCA is out. I don't know how that would matter, Mark, if we had a task force if the task force starts meeting again.

## Mark Knee – Office of the National Coordinator – Staff Lead

You're talking specifically about the TEFCA task force from last year?

## Denise Webb – Individual - Member

Yeah.

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

Denise, this is Lauren. We're still working on that. That's yet to be determined but certainly a possibility.

## Denise Webb – Individual - Member

Okay.

## <u>Sasha TerMaat – Epic - Member</u>

Do we want to call that out as an option in the recommendation? If you scroll down a little bit, you can see my –

## Andrew Truscott – Accenture – Co-Chair

Yeah.

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

That sounds good.

## <u>Andrew Truscott – Accenture – Co-Chair</u> I can't remember who is on the task force. Are you on the TEFCA task force, Sasha?

<u>Sasha TerMaat – Epic - Member</u> Yes.

Andrew Truscott – Accenture – Co-Chair Was I?

<u>Sasha TerMaat – Epic - Member</u> I think so.

Denise Webb – Individual - Member

Yeah, I think you were. Maybe not. And, actually, it was just a task because the common agreement didn't exist yet.

#### <u>Sasha TerMaat – Epic - Member</u>

We have to have a modified version.

Andrew Truscott – Accenture – Co-Chair

Okay, cool.

Michael Adcock – Individual – Co-Chair

So, moving down.

<u>Andrew Truscott – Accenture – Co-Chair</u> I actually started making some proposals in this, by the way, at the bottom end.

<u>Sasha TerMaat – Epic - Member</u> Okay. At the bottom, you're saying?

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

Yeah. Below this line our proposed recommendations to the work group, we can change that to be recommendations if people agree.

<u>Sasha TerMaat – Epic - Member</u>

I'm scrolling still.

#### Andrew Truscott – Accenture – Co-Chair

It's a long way. There are lots of short ones.

#### <u>Sasha TerMaat – Epic - Member</u>

I think we had this one, too.

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

Yeah, we did. I did the non-pretentious ones.

#### Sasha TerMaat – Epic - Member

Okay. So, you got the timeline one. I'm trying to make sure. Here, we had this view as possible –

Michael Adcock – Individual – Co-Chair

So, there's lots of scrolling going on. Which area are we looking at?

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

We're looking at 2I and 2iiB and C.

## Michael Adcock – Individual – Co-Chair

Okay. Very good.

## Andrew Truscott – Accenture – Co-Chair

Sasha, could you actually take the first stab at the modification or drafting in here?

## <u>Sasha TerMaat – Epic - Member</u>

I'm sorry. I was just copying another one down into this section. What are we going to modify here?

## Andrew Truscott – Accenture – Co-Chair

I was just saying we need to probably take – if you look below to 2BI and B2ii and one edition of B2Iii, I've actually made some drafting proposals. Are you the best person to do the first cut on drafting proposals for the IP ones?

# Sasha TerMaat – Epic - Member

Around the earlier things that are pink?

# Andrew Truscott – Accenture – Co-Chair

Yeah.

# <u>Sasha TerMaat – Epic - Member</u>

Sure. I'm just putting a comment.

## Andrew Truscott – Accenture – Co-Chair

And that side is the easy one.

## Michael Adcock – Individual – Co-Chair

I'm sorry. I've been talking this whole time. Yes. So, it is time for the call to end. I was curious is this where we will pick up, I'm assuming when we meet again to finalize the recommendations? So, everyone take a look at the Google Doc. Whoever is taking stabs at language, if there's anything you want to add, change, or whatever, let's do that. And then, we'll be able to finalize this on our next call.

## Denise Webb – Individual - Member

That sounds like a plan.

## Mark Knee – Office of the National Coordinator – Staff Lead

And to Andy's point and I think what you just said, Michael, people can take a look and add their thoughts between now and the next meeting, I think we'll have a really productive meeting just getting through all of the recommendations.

## Michael Adcock – Individual – Co-Chair

Yeah. I think we've made a tremendous amount of progress. I don't think we have the time left to finish our recommendations. So, if everybody could look at it between now and then, we can finalize it at our next meeting. That being said, we're one minute past time to be over so I want to be punctual and thank everybody for their time.