Information Blocking (IB) Workgroup 3

Transcript
March 7, 2019
Virtual Meeting

SPEAKERS

Name	Organization	Title
Michael Adcock	Individual	Co-Chair
Andrew Truscott	Accenture	Co-Chair
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
Denise Webb	Individual	Member
Mark Knee	Office of the National Coordinator	Staff Lead
Penelope Hughes	Office of the National Coordinator	Back Up/ Support
Lauren Wu	Office of the National Coordinator	SME
Seth Pazinski	Office of the National Coordinator	Designated Federal Officer

Operator
Thank you. All lines are now bridged.

Seth Pazinski – Office of the Coordinator for Health Information Technology – Designated Federal Officer
Hey! Good morning! Welcome to the meeting of the Information Blocking Task Force Work Group Three. This is Seth Pazinski. I'll be serving as the Designated Federal Official for Lauren Richie for this call. I'd like to officially call the meeting to order. So, we'll start with a roll call and then turn it over to get our agenda started. So, just running through the roll call, if you can mention that you're here. Andrew Truscott?

Andrew Truscott – Accenture – Co-Chair
Present.

Seth Pazinski – Office of the Coordinator for Health Information Technology – Designated Federal Officer
Mike Adcock?

Michael Adcock - Individual - Co-Chair
Here.

Seth Pazinski – Office of the Coordinator for Health Information Technology – Designated Federal Officer
Denise Webb?

Denise Webb - Individual - Member
Present.

Seth Pazinski – Office of the Coordinator for Health Information Technology – Designated Federal Officer
Sasha TerMaat?

Sasha TerMaat - Epic - Member
Here.

Seth Pazinski – Office of the Coordinator for Health Information Technology – Designated Federal Officer
Lauren Thompson?

Lauren Thompson - DoD/VA Interagency Program Office - Member
I am here.

Seth Pazinski – Office of the Coordinator for Health Information Technology – Designated Federal Officer

Aaron Miri?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Good afternoon.

Seth Pazinski – Office of the Coordinator for Health Information Technology – Designated Federal Officer
And any additional folks that I've missed? Okay. All right. With that, I'll turn it over to Andy and Mike to lead us through our agenda.

Andrew Truscott – Accenture – Co-Chair
Thanks, Seth. So, hey guys, we're gonna start off by picking up where we stopped last session on the communications section, and then we're gonna go to the enforcement of all the conditions and maintenance of certification requirements which I think is buried in there somewhere. It's not actually a subject title that I could find so, we'll have to take some direction from the ONC goings on exactly what they mean by that on the agenda. Okay. So, let's go to the Google doc first. Guys keep me on the straight and narrow. I think we were getting caught up in the non-user facing aspects discussion.

Sasha TerMaat - Epic - Member
That sounds right to me.

Andrew Truscott – Accenture – Co-Chair
And hopefully, in the preamble there was actually a definition of non-user facing.

Sasha TerMaat - Epic - Member
There was. It said its things that are the opposite of user facing.

Andrew Truscott – Accenture – Co-Chair
I think that's what it said.

Sasha TerMaat - Epic - Member
On Page 193...

Andrew Truscott – Accenture – Co-Chair
Yeah.

Sasha TerMaat - Epic - Member
I can actually –

[Crosstalk]

Andrew Truscott – Accenture – Co-Chair
The interesting piece for me in that was that the definition of user facing says that it's manifest in how the health IT software works, which is actually your comments around accessing **[inaudible] [00:02:42]** etc. By that definition, that would go under user-facing, not non-user facing. I think.

Sasha TerMaat - Epic - Member

Well, I actually...I guess... I don't know if I'm clarifying or proposing a change, but one of the arguments that ONC put forward in this section for permitting restricted communication for non-user facing aspects of health IT is, I guess, two-fold. One is that when it's deployed in a wide-spread setting, not cloistered they call it, then it loses certain protections that might be there. And I think they lay out a case for that.

The second is that the user facing ones are the intent of the provisions in 21st Century Cures in terms of permitting free flowing communication for purposes like safety, security, and so forth. My proposal would be that administrative functionality, which is used by a much more limited set of users, right? Not millions of patients or thousands of clinicians, but a smaller set of administrative users doesn't necessarily need the same justifications for unrestricted communication. And I would therefore propose that administrative features should be considered non-user facing aspects. There certainly are administrative users. So, the definition might need adjusting in that sense. But I think that the arguments that ONC put forward for why non-user facing aspects should not be unrestricted would also apply to administrative features that have a much narrower user base.

Andrew Truscott – Accenture – Co-Chair
Okay. ONC will, I think...they were trying to be clear when they said, "Evident to anyone running using or observing the operation of health IT." So, that isn't kind of limiting it to clinical users. I see what you're saying, but ONC seems to be consciously saying something different.

Denise Webb - Individual - Member
I don't think we should just automatically assume that because when we say 'anyone running' I think they're intending for the clinical functions and purposes of the health IT. But again, they're not explicit about it. And so, I agree with the friendly amendment that Sasha has put forth as a recommendation because if you're running the health IT software, that could imply administrative function, but it's not clear if it does. And I think there's valid justification for why administrative users are not the class of users that this is concerned about in terms of unprotected, unrestricted communications.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
This is Aaron. I agree. I actually agree with you. That does make sense, Sasha. You're right.

Sasha TerMaat - Epic - Member
Oh, thank you. Andy. I can move my notes here. I was just...we're all looking at this part of the screen because that's where the definition is. I'll move it.

Andrew Truscott – Accenture – Co-Chair
Yup.

Denise Webb - Individual - Member
So, it looks like Aaron and Sasha and I are in agreement. What about Michael and Andy? What are your thoughts?

Andrew Truscott – Accenture – Co-Chair
I'm a humble Chair.

Denise Webb - Individual - Member
A humble Chair. Okay.

Andrew Truscott – Accenture – Co-Chair
I am the vessel that you manifest your thoughts within.

Denise Webb - Individual - Member
Okay.

Andrew Truscott – Accenture – Co-Chair
No one is capturing this call for some reason. Okay. I was looking forward to seeing that when pop up. Honestly, I don't have a problem with what Sasha is suggesting. I think it makes sense that the administration actually be a carved out. I have no issues on that. I'm intrigued as to why it was deliberately dropped like this and whether it was poor draftsmanship or whether there was a conscious desire to include these kinds of activities or not.

Sasha TerMaat - Epic - Member
It's an interesting question and maybe ONC can shed some light. Because they describe a very...one of the rationales for including user facing aspects as having large groups of users... I kind of suspect that they were not thinking about the fact that some features could have much more narrow sets of users like administrative features. Maybe an oversight in that sense.

Andrew Truscott – Accenture – Co-Chair
That's a pretty massive oversight. ONC, can you shed light on that? Mark?

Mark Knee - Office of the National Coordinator - Staff Lead
Penelope, do you have any thoughts on this one?

Penelope Hughes – Office of the Coordinator – Staff Lead
No. Not really. Just that in general I think that in the very beginning we talked about, for example, that we propose to broadly interpret the subject matters in the type of conduct so...but I don't have any particular familiarity with them...this section right here.

Andrew Truscott – Accenture – Co-Chair
Okay.

Mark Knee - Office of the National Coordinator - Staff Lead
Let me –

Denise Webb - Individual - Member
I was gonna say, it's probably valid to bring this forth to the full task force as a suggested recommendation and take it from there as a draft recommendation.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yeah. I think in general... this is Aaron... I think in general I appreciate such an approach of trying to pragmatically identify what...like not look at everything holistic as the same because it's not. If you look at it from a programmatic perspective, there's a distinct difference between administrative controls and clinical workflows and all sorts of things within an application or system or product. So, I think that's a very good hierarchy and structural...at everything that we look... every recommendation.

How do we specify appropriately because each of the control features that the developer may have built in will be different depending on the section and the users? So, it only makes sense.

Mark Knee - Office of the National Coordinator - Staff Lead
We'll note on the Google doc, we'll look into it and try to give some background on the next call.

Penelope Hughes – Office of the National Coordinator – Staff Lead
Okay. I'll put in a note. ONC question...

Mark Knee - Office of the National Coordinator - Staff Lead
Thanks very much.

Andrew Truscott – Accenture – Co-Chair
Thanks Sasha. Okay. I'm sure this will be a discussion which has no conversation at all. Intellectual property... Sasha finished typing.

Sasha TerMaat - Epic - Member
I think what I've been struggling with an intellectual property provision...I guess first off, I think it's an important recognition that HIC developers and others have important intellectual property investments in health IT. Right? Both the HIT developer and their investments in the research and development of the software, but then also other content providers.

For example, their intellectual property might also be part of health IT. And protecting all of that is important. It's kind of critical to the ongoing innovation and investment in the market. And so, I think that the tricky part I have with these provisions is they have to balance the proposed distribution of information for what our purposes that clearly have the public good in mind...safety, security, improved usability of products, and so forth with the risk that wide-spread disclosure of intellectual property. And I think this partly gives in to some of the questions about screenshots because I think design is something that developers invest heavily in could be used for nefarious purposes as well as the public good purposes. So, how do we balance the sort of public good purposes with the risk of a nefarious actor who really wants to copy the system and distribute it as their own work when it wasn't really theirs to start with. I think that the top balance to make, right?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yeah. You're right. Sasha, can I give you a real-world example as a CIO? Something I struggle with one of my vendors and then maybe we can use that as a dovetail into how we could find a middle ground. So, in one of my prior lives we were doing coordination around specialty care and being able to extend perhaps our EMR capabilities to partner with a sister hospital in China. We were trying to figure out could we extend care and/or do telemedicine, and also the medical records so that we could obviously get the clinical diagnoses all out within our medical record without a problem. In those discussions, the vendor we were working with said, "No. You're not allowed to share information particularly with any external parties of screenshots or whatnot." And so, we were sort of dead in the water because we could talk about...hey, it would be great to share HMPs. It would be great to share clinical diagnoses, maybe PAX images and whatnot as we're trying to see patients remotely, but because we were unable to share any kind of screenshots or visualization or even kind of do a WebEx with them, it really shot the whole thing down and the entire project fell apart. Thus, it's kind of limited the ability for us to deliver care with a sister hospital in China.

So, neither here nor there. That was several years ago. But I really think the question as to what is the middle ground? I appreciate your point. I completely agree that you do have to give protections to the developer community and making sure things that, like to your point, workflows and layout and UX are protected, but yet how do we not inhibit me as a hospital from partnering and extending care to, in this case, the country who was desperately asking for it because they have a massive issue of obesity and needing specialists. So, what's the middle ground there? How am I able to work through that being that we're in some cases really restricted today? What do you think?

Sasha TerMaat - Epic - Member
Yeah. Well, and I think in some cases we need to differentiate where sharing the data is important versus sharing the design of the health IT. Right?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
So, perhaps this suggestion could be that based on scenario...based on is it for treatment and care purposes versus generally sharing. Is that what you're asking?

Sasha TerMaat - Epic - Member
Well, that seems to me that in most cases when you're sharing for treatment and care purposes, what you're really interested in sharing is the health information contained within the health IT. Not the actual design of the health IT. Right?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yes, to a degree.

Andrew Truscott – Accenture – Co-Chair
Well, what do you mean –

Sasha TerMaat - Epic - Member
Cases under 21st century –

Andrew Truscott – Accenture – Co-Chair
When you say design –

Sasha TerMaat - Epic - Member
– are called out as different for sharing information about the design of the health IT are for other purposes not treatment, right?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Right.

Sasha TerMaat - Epic - Member
They are for purposes like usability analysis.

Andrew Truscott – Accenture – Co-Chair
Sasha, can you define what you mean by design, please.

Sasha TerMaat - Epic - Member

Sure. So, I guess a few were sharing information for treatment, what you want is the content of a note as an example, not the layout that one system might use for writing a note and the tools that might be available to users of that system. Does that make sense?

Andrew Truscott – Accenture – Co-Chair
I understand your point, but I know as well that very often I've seen notes which have been shared between physicians which are actually screenshots.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
And so, Sasha, I can appreciate your perspective. So, let me go back to my scenario for a second. In the case of what we were trying to do, it really was trying to get two systems to talk to each other and/or we would extend our EMR via Citrix or whatever else so folks could login and input the information as if they were sitting in our clinic. Again, the whole point is sort of a Telemedicine, Tele specialty. So, to the degree of it, it would have been difficult for us... and in this case, also with a language barrier, to work through just a basic structural note or whatever else without talking in some sense about here's how you would enter a note. Here's how you would enter something in. Do you know what I mean? It would take away from a lot of the discussion. So, I just kind of go back to is there a scenario base here that we could consider and work through to allow for the community to openly have these discussions in advanced care and advance the liberty of care across the country and across the world. I guess that's what I pull down question-wise.

Sasha TerMaat - Epic - Member
Sure. And I think one of the concerns is that when the help information...I think everyone is in agreement...that the health information needs to follow the patient for their treatment. I think the question of whether the design of the software, which in many cases represent a lot of research and development effort from health IT developers is necessary. It's one where we have to balance the risk of impeding treatment, which of course, is no one's goal, right? Everyone wants to facilitate that...with the risk of intellectual property protections are not afforded to health IT developers and their intellectual property is vulnerable to theft and copying by nefarious actors who don't respect U.S. property...intellectual property considerations, then that has a consequence on the whole industry because it discourages any further investment in the type of design and intellectual property that we're talking about.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Right.

Sasha TerMaat - Epic - Member
So, in that scenario, I guess, the question is how do we allow the types of projects that you're talking about to proceed while ensuring that doing that project doesn't inadvertently jeopardize and allow someone to copy the system as part of that access. Is there a way to protect that?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
And I completely agree with you and I completely appreciate, again, having built product in my most recent life before this one, I get it. I totally get it. I guess I go back to do we need to approach healthcare scenarios with, I'm gonna use your word here... the nefarious potential, or should we approach it where me and the hospital system...if you want to accept responsibility for this, and if your other party steals our design then you are culpable for that. I mean there may be a way to offer an ability because I was totally shut down by my vendor. They were like, "No. Absolutely not." And I

mean the condition was real. The situation was real. I had no reason to believe there was nefarious intent. I don't think hospitals enter into these discussions thinking the other party is a nefarious intent, but because of that, the whole thing collapsed. I just –

Sasha TerMaat - Epic - Member
Your proposal would be that the discloser of the intellectual property would then be liable for potential loss?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Accept the risk. As a potential scenario, yes. In that case, is that something that we want to propose? I'm just talking out loud here. That would be an acceptable compromise, right? Instead of the flat no, you're not allowed to do anything.

Denise Webb - Individual - Member
This is Denise. I just have a question for Aaron and Sasha. So, the scenario that Aaron described is one hospital speaking to another hospital. Neither were health IT vendors.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Correct.

Denise Webb - Individual - Member
And so, I guess...I mean, I could understand, Sasha, if you're gonna do a webinar and showed screenshots minus your EHI because that's for confidentiality reasons protecting the privacy, but that you would show screenshots as to how you would do something in particular. Let's say at your hospital and how you might leverage that in the sister hospital that doesn't currently use that software. I'm trying to understand what motive they would have for stealing the design of a screen design.

Sasha TerMaat - Epic - Member
Yeah. Well, and I don't know if –

Denise Webb - Individual - Member
If it was a vendor, I guess I could say –

Sasha TerMaat - Epic - Member
I think the tricky part – Sorry.

Denise Webb - Individual - Member
Go ahead... No. I was just gonna say when I think about having been a CIO if I'm gonna go out and look at different products and what might work best for just the, I would expect that fellow CIOs who are using these other products could share information about the product and actually let me see the product without the vendor being involved. My purpose is not to look at the product so I can steal the design of the screen...of the user interface.

Sasha TerMaat - Epic - Member
And I think that maybe the sense of purpose is important to what Oenzi is trying to put forward. There's like a whole spectrum of possible purposes, many of which are not even remotely nefarious, and others are more suspect, right?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Sure.

Sasha TerMaat - Epic - Member
So, to put something else on the spectrum we have folks who will come up to our booth at HIMSS and be like, "Hello, we'd like to record a demo of all your software because we're developers and we'd like to make something exactly like it." That is a different –

[Crosstalk]

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
That's just shady.

Sasha TerMaat - Epic - Member
And so, I guess the question is, how do we know the purpose for some sort of disclosure that includes intellectual property of the health IT developer? And then ensure that when the disclosure happens for a good reason, that there's not re-disclosure for a nefarious reason, right? So, if your re-disclosure is to another's CIO as in Denise's example, I agree. CIO's should be able to go around and look at other facilities and see how their HIT works and use that to inform purchasing decisions and other roles.

I think the tricky part is that if your disclosure is to like Twitter, then the possibility of the purpose of the initial discloser could be one of the ones in 21st Century Cures. This sort of secondary use of that though, could be one of the nefarious actors that's like, "Oh, I'm gonna use this to make a copy of that." And so, what I'm trying to figure out is how do you take that element of purpose, which it sounds like all of us are coming back to, and say, 'The purpose of this is important." And whether or not the discloser is restricted, seems to hinge on what the purpose of it is. And maybe also an element of redisclosure also hinging on the purpose of that, if that makes sense.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yeah. And so maybe we take the approach that ONC did with information blocking and state what the positives are versus all the negatives. So, we could give purpose to...and I just use the word purpose of disclosure in which case we assume good intent. And then anything outside of that is ill intent. So, in this case, one hospital talking to another hospital is good intent. One hospital talking to vendor A, B, C about vendor X, Y, Z, there could potentially be a question mark. Just an idea.

Sasha TerMaat - Epic - Member
Sure. I'm just trying to jot down some of what we're talking about, so we don't forget it later.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
I have to briefly step away. I'll be right back.

Andrew Truscott – Accenture – Co-Chair
So, I think as we are looking at this intellectual property clause, we ought to **[inaudible] [00:23:19]** refers you to B between so we ought to look at them in conjunction with each other. In going to the preamble, the preamble is pretty explicit. There's no intention here to infringe upon intellectual property concerns and those are...this condition of certification is not intended to operate as a defacto license for health IT users to act in any way that might infringe **[inaudible] [00:23:49]** property rights

for developers. Okay. So, we've got that. Do we think that this text...to channel my inner Aria Marrick, it's not in the reds. It's not in the reds. So, do we think that this regulation as it's currently drafted reflects that appropriately or not?

Sasha TerMaat - Epic - Member
Could you restate that question? Sorry...

Andrew Truscott – Accenture – Co-Chair
Okay. Do we think that the regulation as it is currently drafted...C and C.1 reflects the preamble as it's currently drafted? That, and I quote directly, "This condition of certification is not intended to operate as a defacto license the health writer uses and others to act in any way that might infringe the legitimate intellectual property rights of developers."

Sasha TerMaat - Epic - Member
I think the element of purpose that we've been discussing is not reflected in the regulatory text.

Andrew Truscott – Accenture – Co-Chair
Doesn't that come under fair use?

Denise Webb - Individual - Member
Are you speaking of C.1, Andy?

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

Denise Webb - Individual - Member
That that would cover what Sasha is concerned about or doesn't cover what would be –

Sasha TerMaat - Epic - Member
So, you're saying that if the purpose was for nefarious, it wouldn't be a fair use, and if the purpose was to show a fellow CIO how it works, that would be a fair use?

Andrew Truscott – Accenture – Co-Chair
Correct.

Sasha TerMaat - Epic - Member
Fair use is a legal term and I would have to brush up on exactly what that meant to weigh in on if that would sort of jive. Let me put a note.

Andrew Truscott – Accenture – Co-Chair
Okay. I'm sure I'm gonna see how all the lawyers advise on this. How about other people? Would you like to comment on this?

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah. This is another one I'm happy to look into as far as background goes. But I believe we did have legal folks looking.

Andrew Truscott – Accenture – Co-Chair
Okay. It will be... I can't see any examples of fair use particularly in the –

Denise Webb - Individual - Member
Yeah. I think we need more explanation of what the legal definition of fair use is and what are some examples. Because I know in the educational world there's the concept of fair use of copyright work that to deliver education it's not something you're disseminating to make a profit on or to compete.

Andrew Truscott – Accenture – Co-Chair
The standard definition is –

Denise Webb - Individual - Member
– the creator of copyrighted work.

Andrew Truscott – Accenture – Co-Chair
Yeah, but the standard definition is...you can use something for criticism, news, reporting, teaching, and research. That's the fair use doctrine in U.S. law anyway. I'm just brushing off my LLM days.

Denise Webb - Individual - Member
So, would it be helpful to communicate to the legal team that we're trying to capture the concept of purpose and kind of get their thoughts on that?

Andrew Truscott – Accenture – Co-Chair
Yeah. I think...Mark, did you pick that one up?

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah, but if... just so we're... yes. I think Sasha is noting it. And if you can note the fair use specifically. That would be great.

Andrew Truscott – Accenture – Co-Chair
Yeah, there's a curious lack of examples in the preamble compared to other sections which are exhausting in their examples. So, C.2...so, actually I propose we part this one until we've had some feedback from ONC over fair use and their intent.

Sasha TerMaat - Epic - Member
Yeah. And then I guess maybe that feeds into a question about D which is... I'm wondering if fair use would also have a volume component because...sort of like thinking of the scenario of doing a usability study with 12 screenshots is different than I'm going to take a thousand screenshots for the purpose of copying something. Hopefully that fair use definition might accommodate that concern of mine as well.

Andrew Truscott – Accenture – Co-Chair
Let's find out.

Sasha TerMaat - Epic - Member
Okay.

Andrew Truscott – Accenture – Co-Chair

I have an opinion, but I don't know if it's worth expressing at this point. Let's find out what they say. But the screenshots here... is it a deliberate carve out? So, if I just look at the wording: "A health IT developer may require persons to communicate screenshots." So, it seems to be embracing the fact that people communicate screenshots. Now in your –

Sasha TerMaat - Epic - Member
Well, that's in C.2, right?

Andrew Truscott – Accenture – Co-Chair
Yeah. That's in D.1.

Sasha TerMaat - Epic - Member
Well, C.2 says screenshots are allowed and then D.1 says you can restrict screen shot communication by saying you can't alter it. Right?

Andrew Truscott – Accenture – Co-Chair
Yeah. You can't alter it and you can't infringe on IP etc. Now do you...just in your day job, do you treat screenshots as IP? Because your comments around layout would make me think that you do.

Sasha TerMaat - Epic - Member
Yeah. Screen design is important to us.

Andrew Truscott – Accenture – Co-Chair
Okay. So, this seems to be clearly saying... not clearly or we wouldn't be discussing it. It seems to be saying that screenshots actually are not IP, or at least a screen shot isn't...at least on currently facing evidence.

Sasha TerMaat - Epic - Member
Yes. I think the argument is that use of screenshots for some of the purposes that are described, ONC says would be fair use and should not be restricted because it's important to the goals of 21st Century Cures of communication on those key topics. ONC makes the case that it should put minimal impact to intellectual property. I guess I worry that they are underestimating the value of knowing that type of design and the impact. That's the case as I understand it.

Andrew Truscott – Accenture – Co-Chair
When I look at D.3, I think you'll favor it. When I look at D.3, it says, "Without protecting the information if there is a consent." Okay. If there is a consent, what's the point of sharing the screen shot?

Sasha TerMaat - Epic - Member
Well, D.3 is about redacting PHI, not intellectual property.

Andrew Truscott – Accenture – Co-Chair
No, no, but D.3 is a subset of D. Okay? So, the health IT developer can require persons to communicate screenshots to protect health information unless consent is being provided. Okay, in which case, if there's no consent, does that mean that I can communicate the screen shot and disclose your layout? Is that not IP?

Sasha TerMaat - Epic - Member
Yes. I think that's what's proposed. They're proposing that you could require the PHI to be redacted like blurred or whatever, because you're not supposed to disclose PHI under HIPPA without authorization, but that the screen shot could still be disclosed is removing that opportunity to protect designs in that way.

Andrew Truscott – Accenture – Co-Chair
Yeah. So, it seems to me that ONC is saying a layout is not intellectual property.

Sasha TerMaat - Epic - Member
They seem to be saying that, yes.

Andrew Truscott – Accenture – Co-Chair
Okay. We're in agreement. At least on the understanding of what this seems to say. Mark, could we get clarification to confirm that because I think it's fairly obvious that layouts are seen by many organizations as being part of their intellectual property because they spend a lot of time, effort, research, and performing to correct design that they acquire. That could be considered IP.

Mark Knee - Office of the National Coordinator - Staff Lead
Sure. I don't want to speak out of turn, but I'm happy to look into it. So, if you can, again, Sasha if you can just note it, I'll add it to the list, and I'll report back.

Sasha TerMaat - Epic - Member
Sure.

Andrew Truscott – Accenture – Co-Chair
Sasha is on scribe mode today.

Sasha TerMaat - Epic - Member
I try to take good notes.

Mark Knee - Office of the National Coordinator - Staff Lead
I'm putting her to work. Thanks, Sasha.

Andrew Truscott – Accenture – Co-Chair
Mike, have you got any thoughts on this given you've been very quiet and giving your background working with multiple vendors?

Michael Adcock – Individual – Co-Chair
Yes. I have been very quiet. I've been enjoying the conversation. I think that the vendors that I've come in contact with have pretty much been along the same line that screenshots were seen as intellectual property. That screen design and the aspects of screen design were something that they spent a lot of time focusing on. I will say that as someone who has tried to connect with multiple different sites with multiple different areas and someone who has been involved with trying to create similar flow at other institutions who maybe just have acquired the same software or a different software, it poses challenges. But I certainly understand where the health IT companies are coming from from that standpoint. I think that there has to be some way to establish intent and what we're trying to accomplish in this communication is extremely important. I think as long as we're talking

about a healthcare entity to a healthcare entity, not some type of vendor or other type of actor, I think that we should give a lot of credence to that fact that if it's between two healthcare entities, the act is in all likelihood not nefarious and we need to be as open as we possibly can.

Andrew Truscott – Accenture – Co-Chair
Yeah.

[Crosstalk]

Andrew Truscott – Accenture – Co-Chair
After I'm thinking about it, it's almost like... you almost want to say something like... and Sasha, chip in... A screenshot communication is fine. If it contains PHI it has to be consented to buy the patient and is being shared from healthcare professional to healthcare professional for the purpose of providing care.

Sasha TerMaat - Epic - Member
I would certainly agree that it's fine in those cases. I guess with one caveat, that in many healthcare organizations people don't want to share PHI by taking screenshots because it circumvents the usual practices of having to record a disclosure. So, when you share information about a patient, you need to log a disclosure so that the patient can be provided an accounting of their disclosures under HIPPA and other mechanisms for sharing patient information like printing, faxing, sending information interoperably between systems would often automatically log a disclosure. If a provider circumvents that by just taking a screenshot, they would have to manually log that disclosure and it seems likely that they would forget to do that and end up in trouble with their HIPPA obligations.

Andrew Truscott – Accenture – Co-Chair
Actually, we've got clients who do, and they have specific systems to allow that, but you make a valid point. Some do and some don't

Sasha TerMaat - Epic - Member
Sure.

Andrew Truscott – Accenture – Co-Chair
Has Aaron returned to us yet?

Denise Webb - Individual - Member
Before we precede...this is Denise. As I'm listening to all of this and thinking about it, I know from my experience that most of these user interfaces tends to be configurable...or these screens depending on the workflow and the particular specialty, at least from some of the products I've seen, and I do know that there is this idea about healthcare provider to healthcare provider, particularly if you are a CIO and you are not supporting just one EHR, but you want to implement a particular workflow in a similar way with the two products that you have through configuration that that's not infringing on intellectual property rights. That's more tailoring the configurable features of a product if they are similar in workflow and steps.

So, I really do think this idea about between healthcare entities or trying to configure a product so that they are working similarly to support a workflow is different than copying somebody's work or design. So, that would just be my comment on this. And it may involve, particularly if you have a vendor

supporting the use of their health IT, that they may be involved in the communication. So, let's say you have EHRA and EHRB and there's a particular workflow for a lab to collect specimens and you want to have it similarly situated and configured in your two different EHRs. You have a health IT vendor of one EHR supporting you and telling you how you can do that in their particular configuration. Would that constitute copying or stealing intellectual property? I don't think so. But, Sasha can you comment on a scenario like that? How you would see that?

Sasha TerMaat - Epic - Member
I think that would pose very minimal risk to intellectual property. The only concern would be if it was communicated in a way where it would redisclose for another purpose. Like the healthcare provider users are not trying to copy the system, they're just trying to optimize their configuration. I think most health IT developers would encourage that.

Denise Webb - Individual - Member
Right. Now, if on the other hand –

Andrew Truscott – Accenture – Co-Chair
These rules touch everybody equally. Sorry ladies carry on.

Denise Webb - Individual - Member
I was just gonna say on the other hand then if the health IT vendor of the one product was to then go take what they saw and learned and then go change their software to mirror the other health IT vendor's product, then that would be infringing on intellectual property.

Sasha TerMaat - Epic - Member
Right. I think that provider users are a different case then the developer users. Of course, there's tricky scenarios where providers and developers are the same entities.

Denise Webb - Individual - Member
Yeah.

Andrew Truscott – Accenture – Co-Chair
Yeah. I was just gonna say if we're working on rules here, we need to touch everybody equally regardless of intent or motivation and creating rules that address the nefarious versus creating rules that affect the godly or vice versa is a dangerous place to be. So, I'm not sure that's a helpful comment or that these rules are tricky to work through because they touch everybody equally.

Sasha TerMaat - Epic - Member
I agree. And I think it's hard to draw lines around the behavior that seems to be intended by 21st Century Cures and behavior that I think we all agreed was not really what was intended. How do we make that distinction so that it would be...kind of draw that line that you mentioned?

Denise Webb - Individual - Member
And that may be our recommendation. That they need to make a clearer distinction in the regulation.

Andrew Truscott – Accenture – Co-Chair
Yeah. We made that comment in our purpose. I think that may be... that the purpose of the rules come into play. And depending on what they come back with in terms of the definition around 'fair

use', we might want to be a bit stricter and just say, "Hey, this feels like it might be a bit of a... a broad a brush stroke has been applied potentially." Let's look and see what they come back with.

Sasha TerMaat - Epic - Member
Okay. I tried to capture that.

Andrew Truscott – Accenture – Co-Chair
You did your job. You're better than the **[inaudible] [00:42:02]** at capturing my accent.

Sasha TerMaat - Epic - Member
I could try to put some British spelling in there. Maybe there's like some words that need extra 'u's?

Michael Adcock – Individual – Co-Chair
I think if you just put **[inaudible]** around most of what he says it will be fine.

Andrew Truscott – Accenture – Co-Chair
Just make sure everything's got an 'x' rather than a 'z', I'll be happy. Okay. I think we've probably exhausted D as far as we can for the time being. Would you guys agree?

Sasha TerMaat - Epic - Member
Though the one thing I would raise about D which is that a developer can restrict...like the scenario as I understand it under D.2.i that if a health IT product contained other IP...say an assessment scale or certain content, or images that were licensed for drawing on medical figures, that the developer could say, "Actually, you don't have the right to disclose that other content for this purpose." If all reasonable endeavors to secure a license and sublicense were pursued, it seems odd to me to put...I guess, thinking as a developer, the developer then has to basically either remove content that they can't pursue that license for or pay more for the content if the developer of the scale or the image or whatever it is, the content provider says, "Gosh, well, if my content is gonna be at higher risk to be exposed, I want more for it."

Andrew Truscott – Accenture – Co-Chair
I must confess, I've read 2.i and I thought it was saying provided you take all reasonable endeavors to secure a license, it's okay.

[Crosstalk]

Sasha TerMaat - Epic - Member
Okay. Is that a legal definition of 'all reasonable endeavors'?

Andrew Truscott – Accenture – Co-Chair
Well, it doesn't say best endeavors, does it?

Sasha TerMaat - Epic - Member
I'll just put in a comment so we can check on that.

Andrew Truscott – Accenture – Co-Chair
Yeah. I thought about it, but I thought they were saying that doesn't seem to pass the reasonableness test.

Sasha TerMaat - Epic - Member
Yeah. I think the other component of that is that D.2.iii seems to underestimate the complexity of doing this. When I think about trying to identify every aspect of a screen that might contain third-party content, especially when that's massively configurable and could include all sorts of code sets and so forth –

Andrew Truscott – Accenture – Co-Chair
Really? As a developer, you know what third-parties you're using within your platform.

Sasha TerMaat - Epic - Member
Sure. So, is the notice in D.2.iii if you incorporate these codes into the system at all then they might be on your screens and you shouldn't redisclose that without permission from the code set provider? Or is it on the screen you might see this code if the patient had that particular condition, or you might see this other code, or you might see an image if the patient had ever had an image and a past visit annotated, or you might see this content if you happen to have a reference incorporated into a note. Do you see what I'm saying?

Andrew Truscott – Accenture – Co-Chair
Yeah, but...I understand exactly what you're saying. So, my interpretation of this particular clause was that where you've got third-party software embedded inside your software, you would notify that third-party that if your software...a screenshot gets shared, it may include theirs. And that's it. But I didn't anticipate...I don't think code sets is a good discussion point given the way that they are licensed. But certain visuals –

Denise Webb - Individual - Member
But this is saying that the developer has to put all potential communicators of that screenshot on sufficient written notice.

Andrew Truscott – Accenture – Co-Chair
Oh! I'm sorry. I'm misreading it. Thank you for that.

Denise Webb - Individual - Member
Yeah. Not the third party. So, I think there is two versions of this. Is it just to put them on notice that here are the third-party code sets and things that we use that may appear in screenshots and you need to be aware of it if they're here in the screenshot? Not go by each screen. That would be an onerous burden. So, we should have this clarified that this is not per screen because it says, "sufficient written notice of each aspect of its screen display." Well, there could be thousands of screens with thousands of aspects.

Andrew Truscott – Accenture – Co-Chair
Sasha, I apologize for saying, "I don't think this is so bad." I understand. I misread the communicators on the top line of it. I agree with you. I'm not even sure technically how it's possible because you capture screenshots outside of the EMR. You can't just screenshot it using your desktop snipper. So, copy it into a local buffer and paste it wherever you're going to paste it. I'm not even sure if it's possible because every screen is going to have a different definition of potential third-party. And that's on every single screen. But then this actually says, "sufficient written notice of each aspect of a screen display that contains third-party content." That seems unnecessarily harsh.

Sasha TerMaat - Epic - Member
I'm glad that I... well, I wish I had been misreading it. But I'm glad I wasn't misunderstanding the consequence. I don't know how it would be possible realistically. I think you could potentially identify the types of third-party content that could be in an EHR or that are incorporated by the developer themselves. But that would be like a one-time identification to the healthcare system, not like a warning on every single screen that someone might look at because that would just clutter the screen in a way... well, 1) it would be too cluttering, and then, 2) I don't know with the configurability of systems that you would even know on a particular screen what the content was. It could depend on what someone had put in a previous note for that patient.

Denise Webb - Individual - Member
So, Sasha, I think the recommendation here is that they should be referring to a notice of the third-party products that are protected or could appear...where their information may appear in a screen. But enumerating per screen per aspect is, I think, unrealistic.

Andrew Truscott – Accenture – Co-Chair
I agree. It's heavy. Because normally the way that people would say there's going to be third-party content inside that product is on the smash screen on the front end which not many people read ever. And then –

Denise Webb - Individual - Member
And it says sufficient written notice. It doesn't tell you how you have to give that notice.

Andrew Truscott – Accenture – Co-Chair
No. But sufficient is a very strong term. Sufficient to whom? Sufficient to the...that you know that the reader has understood?

Denise Webb - Individual - Member
Yeah. How many people click through those...Yup, I read all the terms and conditions. Click.

Andrew Truscott – Accenture – Co-Chair
I'll tell you what. I'm assuming you have Outlook, okay? How many third-party products are inside Outlook? You have no idea, do you? None of us knows.

Sasha TerMaat - Epic - Member
I have Outlook.

Andrew Truscott – Accenture – Co-Chair
Yeah. But none of us... there's lots of third-party software inside Outlook and many commercial fellows out there. At most, everybody complains about the library. Okay. I'm kind of feeling I have difficulty with this.

Denise Webb - Individual - Member
Yeah, if you look at –

Sasha TerMaat - Epic - Member

With the proposal, or with the existing language? I tried to put the proposal that Denise suggested of a list of which content might appear.

Denise Webb - Individual - Member
Yeah. And then that way they can exercise...the communicators can communicate the screenshot after they've redacted the third-party content.

Sasha TerMaat - Epic - Member
Right.

Denise Webb - Individual - Member
So, if they're given a general list of...if these things up here in the screenshots, these are third-party. It doesn't go screenshot by aspect.

Andrew Truscott – Accenture – Co-Chair
Denise let's just think that through. If I'm a physician sitting there and I've got **[inaudible] [00:51:42]** I'm just gonna think the screenshot is of somebody, where am I gonna be told that there's third-party content on this screen?

Denise Webb - Individual - Member
That's a good point.

Sasha TerMaat - Epic - Member
Let's think about it and kind of play out that example. So, I guess the first question is how might third-party content be part of that screen? Right? If you think of a screen, there could be content that's incorporated by the developer and sort of part of the architecture of the chrome of the system, right? Which the developer would know about and know which screens it appears on. And then there could be third-party content that's available as reference material for a clinician. And the locations of that would presumably be known.

But then, I think more challenging from a sort of know-it's-there perspective would be third-party content that is incorporated into a patient's record. So, if there are specific images, or assessment scales, or tools of that nature that are in the patient's record that are licensed for the purpose of treatment, but not licensed for the purpose of redisclosure for these other reasons, how would you know that, "Oh, I can use this pain scale for treatment purposes, but I'm not allowed to disclose this pain scale and share it for purposes of comparative usability evaluation or whatever the other purpose would be, right? And I think the tricky part is that the developer would know some types of third-party content that would or could be in the software, but they won't necessarily know every screen that it appears on because of the variability of configuration at the healthcare system or of just the variability of a particular patient's chart.

Andrew Truscott – Accenture – Co-Chair
Yes. And many MRs are designed to have that level of flexibility, but the developer won't have any idea actually, especially when you get into some of the portal type technologies as well which by their very inherent nature work upon portlets which are highly configurable, and you can use third-party portlets as much as you like.

Sasha TerMaat - Epic - Member

Right.

Andrew Truscott – Accenture – Co-Chair
I must admit, I think one aspect you talked about there was third-party content. So, let's say you've got a screenshot that has something from medical literature that's actually partly there as well that's come from PubMed. Well, actually there's a license for PubMed, but that doesn't give you a distribution license, but there's actually a snippet on there from literature. The same goes if you're using Discover or something like that where you actually source medical knowledge and maybe mortality rates or something like that with a particular condition. That's third-party content. And then you've also got –

Denise Webb - Individual - Member
I was gonna say, yeah, like how about CPT codes. Aren't those licensed?

Sasha TerMaat - Epic - Member
Yes.

Andrew Truscott – Accenture – Co-Chair
Yeah, but they are licensed to everyone. Right?

Sasha TerMaat - Epic - Member
Yeah. For specific purposes, right?

Andrew Truscott – Accenture – Co-Chair
Yup.

Denise Webb - Individual - Member
Yeah. For specific purposes.

Andrew Truscott – Accenture – Co-Chair
Yeah. Something like snow maybe is covered by –

Denise Webb - Individual - Member
This is like opening a can of worms, I'll tell you.

Andrew Truscott – Accenture – Co-Chair
Well, I'll tell you, the other aspect I was thinking...let's say that there's multiple places to port this stuff, but also with something like SMART on file app, okay? They're designed to be render-able inside other EMRs. That's what SMART is there for. And say you've got the masterful vital signs out, which is used by lots and lots of people. And it's appearing as a SMART file inside your EMR as a little widget. And you don't know that's a widget. I'm just a physician trying to get on in the world. I think this is... I'm kind of talking around the same point of saying this is really difficult.

Denise Webb - Individual - Member
Yeah. I think we need to revisit this.

Mark Knee - Office of the National Coordinator - Staff Lead
Just for clarity...this is Mark... when you say this specific topic...

Andrew Truscott – Accenture – Co-Chair
D.2.3.

Denise Webb - Individual - Member
And even D.2.4 would be difficult if people don't know what they're looking at had third-party content like a physician.

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

Denise Webb - Individual - Member
It's just.... this is so wide and deep.

Andrew Truscott – Accenture – Co-Chair
It seems highly aspirational. Someone's gonna tell me I'm sure machine-learning can do this. I'll be like uh. Sasha, on your day job have you guys ever done anything to look into whether this is possible or not?

Sasha TerMaat - Epic - Member
To look into identifying third-party content in a system?

Andrew Truscott – Accenture – Co-Chair
Yep. Or whether there's any way of programming...well, there are ways of programmatically stopping your UI from being captured if there's a snippet going on. But, do you guys do that? Is that possible in how you built your UI?

Sasha TerMaat - Epic - Member
No. We don't disable Windows features for screen clipping.

Andrew Truscott – Accenture – Co-Chair
There are ways...this is putting a substantial burden on developers. I think is the point.

Sasha TerMaat - Epic - Member
Yes. I think my worry is that if this were enforced, the effective consequence would be to have to remove third-party content. And then the third-party content would all have to be incorporated by the healthcare provider which has its own sort of downstream burden. But realistically I think that's the way people would have to approach it.

Andrew Truscott – Accenture – Co-Chair
Yes. The law of unintended consequences.

Sasha TerMaat - Epic - Member
Right.

Andrew Truscott – Accenture – Co-Chair

Okay. Should we go to D.3?

Sasha TerMaat - Epic - Member
We kind of talked about D.3 earlier. I don't know that we had any comments. At least I didn't write any down.

Andrew Truscott – Accenture – Co-Chair
No.

Denise Webb - Individual - Member
I think it's fine.

Michael Adcock - Individual - Co-Chair
I agree.

Sasha TerMaat - Epic - Member
Okay. It makes sense. That's HIPPA, right?

Andrew Truscott – Accenture – Co-Chair
Right. "E" Pre-Market Testing and Development.

Sasha TerMaat - Epic - Member
So, this section...in the preamble, ONC talks about how they recognize that as part of the premarket development process. People might want to share designs, future ideas, strategic directions, potential software prototypes and so forth with their clients or with others who are advising them on the design and get feedback with a greater expectation of confidentiality then might be permitted by the earlier provisions once something is in widespread deployment. And they recognize, I think correctly, that if you couldn't do that it would impede the ability to get valuable user feedback during the design process which is, of course, an important feature of user-friendly design. So, this is allowing restrictions on communications that are about pre-release software.

Andrew Truscott – Accenture – Co-Chair
Yet, but isn't this clause saying that those extra restrictions would automatically be dropped once the software is actually being released?

Sasha TerMaat - Epic - Member
Yes. That's my understanding. So, if you are developing feature "X", I might share it with you, Andy, saying, "Hey, this is pre-release. Please keep it confidential." And then if feature "X" launched next month, at that point it would no longer be considered confidential.

Andrew Truscott – Accenture – Co-Chair
Yup. That's my understanding too. And you're more than welcome to share feature "X" with me.

Denise Webb - Individual - Member
Yeah. And then on page 200 near the bottom they are asking specific comment on should there be a time limit on how long something can be out in beta release or specific parameters for cover testing and I think getting into all of that is getting way too prescriptive. How many vendors leave something

in beta for an incredibly long time? And even if they did leave it in beta and it's only affecting one client or two clients, that's not a large population to warrant that unrestricted communication.

Andrew Truscott – Accenture – Co-Chair
Yeah. I agree with you. I don't think we should be getting into trying to be... I see they're trying to be helpful, but the fact is in this space it's hard to bring a product to market. It can take a very long time.

Denise Webb - Individual - Member
Yeah. And then sometimes it might not ever come to market because it just...things change in the landscape.

Andrew Truscott – Accenture – Co-Chair
Yeah. I don't think we're gonna try and say, "Okay, while some product is going quick and some is not. These are the type of ones that go quick..." it seems to be an unnecessary over reach.

Denise Webb - Individual - Member
Yep. And if there was something in beta and you're not gonna bring it to market, but you have a client that worked with you on it and still wants to use it, you might make some arrangement with them to allow them to have it but –

Andrew Truscott – Accenture – Co-Chair
In Beta?

Denise Webb - Individual - Member
– but I don't think they should get into setting time periods and all this because that's assuming that this...someone would really want to abuse this prohibition or restriction.

Andrew Truscott – Accenture – Co-Chair
So, 2.2.E... have you got that Sasha?

Denise Webb - Individual - Member
I think that that's the last communication piece, isn't it? Regulation text? Oh, and then there's maintenance and certification.

Andrew Truscott – Accenture – Co-Chair
Yep. That's the end of E. I think we're all kind of okay on E beyond the **[inaudible] [01:03:15]**, Denise.

Denise Webb - Individual - Member
Right. And then this last part of the regulatory text is around maintenance of the certification.

Andrew Truscott – Accenture – Co-Chair
It is. Yes.

Denise Webb - Individual - Member
Yeah. Which is kinda... what does Sasha think about the six months?

Sasha TerMaat - Epic - Member

Yeah. So, I think the effort that would go into this is dramatically underestimated by ONC. They estimate that the notice provision in 1, would take each developer 40 hours of work, which would be an office clerk paid $15.87 an hour. And then they estimate that in 2, they don't estimate any effort for that because they say that they think that amending contracts would be accomplished in the normal course of business. And so, to me the timeframes and the work here are certainly going to represent more than 40 hours of an office clerk. There's probably a fair amount of work from other roles like attorneys who draft contracts or amendments, not just office clerks. And then, also work from the recipients of these.

So, what do the third-party content providers think when they are sent this reasonable notice that their content might now be disclosed for more purposes? Will they want to talk about that? Will they want to try and negotiate changes to that provision? What will the customers think? This should theoretically be more permissive for customers so hopefully they would understand that, but in my experience, many of them might want to ask questions from that perspective. And so, I think that all of this section is very dramatically underestimated in terms of what it would actually mean for health IT developers especially as you play through the implications for notices to third-party content providers and if that content needs to be then removed from the system and all of those kinds of provisions.

Denise Webb - Individual - Member
So, would our recommendation be that they need to revise their estimates? Because I don't disagree with you, Sasha, because I was involved in a number of notices when I was in my former role and they shut down the IT company. We had to make a number of notifications to entities we had contracts with. It wasn't for this purpose, but to then say now your contract is being assigned to the health system. So, that did involve more than just the contract specialist. They weren't clerks, they were contract specialist that did those notices. I guess their salaries for their pay is probably around the rate that was estimated in here, but it did involve attorneys, it did involve people at the VP level, it involved the parties on the other side who had to receive the information and acknowledge it and accept it. So, I would say that they've underestimated the cost as well.

Lauren Thompson - DoD/VA Interagency Program Office - Member
What about the time frames? Do you have thoughts on what would be reasonable time frames? Or are you suggesting they shouldn't include timeframes at all?

Sasha TerMaat - Epic - Member
One of the questions I guess would be what is involved with these timeframes? Is this just about notice and contacting? Or is this about the earlier provision? So, for example if this timeframe includes the activity we talked about earlier as being potentially unfeasible, like determining screen by screen which elements might be under a different intellectual property license of a third party, or removing content from the system because it's unable to come to terms with the third party who holds that copyright license for redisclosure for these purposes. Some of those pieces would dramatically change my assessment of what timeframe is feasible.

Denise Webb - Individual - Member
Sasha, I think this is just referring to the notice that these communications that are allowed by these communicators...these protected communications, that if there's something in their contracts that says otherwise, they need to be noticed that these are now gonna be allowed even though your contract says it's not allowed. And until we do update your contract, they're not been enforced within

the contract related to this. And then Number Two is around actually updating the contracts within two years after the effective date of this rule.

Andrew Truscott – Accenture – Co-Chair
Well, isn't most of the effort incurred here under this notice the appraisal of your current contracts to identify provisions to which potentially contravene paragraph a, would and in much less effortful... If that's a word, approach be to notify all your clients that these are the rules and any clauses that contravene that, these are the rules? That would be legal drafting a common notice to everybody, so you don't have to go through and actually –

Sasha TerMaat - Epic - Member
I actually think the customer contracts are...well, I do think customers are likely to have questions. That's a more straightforward question than –

Andrew Truscott – Accenture – Co-Chair
Oh, they might have questions. That's fine.

Sasha TerMaat - Epic - Member
The third-party contracts...there are some types of contracts that a health IT developer will have with third parties that are not implicated by these provisions, right? So, if a health IT developer contracts with an auditor to look at their finances, they could presumably have whatever confidentiality language they want to with the auditor who was gonna look at their finances. That's not something that's restricted by these provisions. But if you have a third-party contract with an entity where their skill is going to be incorporated into your software, that might have to be revised per the intellectual property of someone else. Or if there's a third-party contract with another system to say, "Hey, we had an NDA to say we were gonna do some development work together and we agreed to keep each other's stuff confidential as part of that, "but now does that have to be revised because maybe we had a very broad term.

Andrew Truscott – Accenture – Co-Chair
But that's for the customer. Absolutely. That's for the customer developer to ascertain. I'm just thinking this whole B.1 is all about the health IT developer doing something. It's both a notice to their customers and to other parties they have agreements with what could be third parties, it could be whatever. And it just seems that the... because the back half of B.1 says, "Those who have agreements containing provisions that contravene paragraph A." Well, if you took out that contravention piece, then actually this becomes much more straightforward to comply with.

Sasha TerMaat - Epic - Member
No. I don't think so.

Andrew Truscott – Accenture – Co-Chair
Why not? Because you don't have to have somebody going to appraise the contracts. And you can have a standard notice at least for your customers that says, "This is what the rules say, and this is our position on those rules."

Sasha TerMaat - Epic - Member
I think 1 already permits the standard notice to customers. I think the tricky part is I don't think it's possible to do one standard notice to those with which it has agreements.

Andrew Truscott – Accenture – Co-Chair
Well, look, I'm in the same boat you are. Okay? And I'm thinking through how this would work and it's not like every contract is the same.

Sasha TerMaat - Epic - Member
Right.

Andrew Truscott – Accenture – Co-Chair
I think it could be done as a... I'm not gonna speak for a lawyer and will let legal people, but a blanket contractual amendment puts these...says, "We will comply with these terms as prescribed in law and where there is a conflict with anything in that contract, these terms will prevail" or something like that. I can see that working.

Sasha TerMaat - Epic - Member
I do think people will rely on standard language for many of these contracts, right? I think that would be common.

Denise Webb - Individual - Member
I think...really there's...most entities...I mean the company's I've dealt with have a standard T&C boilerplate that they build around for all their contracts. And then things are negotiated. So, I kind of agree with Andy that this could be handled in a much more streamlined way and it would meet the intent of the law.

Andrew Truscott – Accenture – Co-Chair
You do agree with me, or you don't agree with me?

Denise Webb - Individual - Member
No, I do agree with you. I think we might be reading way too much into what would have to occur here.

[Crosstalk]

Sasha TerMaat - Epic - Member
Perhaps we're conflating one and two. I think one there's a variety of approaches. I think ONC talks about potentially putting a notice on your website. Two, I think mandates the approach that individual goes back and has like a signed amendment to each –

Denise Webb - Individual - Member
Oh, yeah. You have to... you're gonna have to amend your contract.

Andrew Truscott – Accenture – Co-Chair
Hang on. I and II? Or one and two?

Sasha TerMaat - Epic - Member
One and two.

Andrew Truscott – Accenture – Co-Chair

Number one, number two. Okay.

Sasha TerMaat - Epic - Member
Correct. I think one could be accomplished in a variety of ways and some of them might be more work than others. And it seems to allow some amount of discretion as to how it would want to be approached by any individual developer. Two seems to require the more complicated approach of actually having an amendment signed in each case which is estimated as zero effort which I think is something that should be re-estimated.

Andrew Truscott – Accenture – Co-Chair
Well, you mean2.ii, right? Two i I think is fine. That's the perspective one. IT's 2.ii that says –

Sasha TerMaat - Epic - Member
Yeah. 2.ii is what I mean.

Andrew Truscott – Accenture – Co-Chair
And you've got two years. We all know that two years is reasonable because we have contracts that last five or 10 years.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Ten years. In this case ten years. This is Aaron. I agree with that.

Andrew Truscott – Accenture – Co-Chair
Hi, Aaron. Welcome back.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Thanks. I've been here for about 15 minutes listening.

Andrew Truscott – Accenture – Co-Chair
I'm glad I left this conversation.

Denise Webb - Individual - Member
I mean that gives them two years to amend every contract they have that has contravening language. That's not a lot of time. Contacting is a slow process.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
But I go back to my question I asked the other day, why two years? How do they come up with these durations of time? That I don't understand. There's gotta be a logic behind this. Why two years?

Denise Webb - Individual - Member
Because if you comply with Number 1 and you comply with 2.i, then why does it matter whether it's two years or three years as long as you're complying with the other provisions?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
I mean the way I would say it is "upon the next renewal contract date" or whatever that is because every contract eventually renews. So, whenever that duration is, fine. At that point you talk through it. But don't put it mandated two years.

Denise Webb - Individual - Member
Yeah. Let's recommend that, guys. Because I think that is...that doesn't make sense.

Lauren Wu - Office of the National Coordinator- SME
This is Lauren. I think you guys are welcome to comment whatever you want to recommend. For a little bit of context, that part of the reason why we might have recommended the two year time frame was more for from a compliance perspective to align with the two-year timeframe for the implementation of a few of the other proposals in the rule including the new API criterion as well as the new Electronic Health information export criterion which are also proposed on a two-year time frame.

Andrew Truscott – Accenture – Co-Chair
Okay. I have –

Denise Webb - Individual - Member
But I think those are animals of a different color. Because these contracts ae wholly different then implementation of development for APIs and so forth. I think by complying with one above and 2.i here, I think there can be some flexibility here in terms of upon the next renewal of a contract. I think that's a whole different category of thing compared to the other items that have a two-year time frame in the rules. But I appreciate your explanation as to why you believe ONC did it that way.

Andrew Truscott – Accenture – Co-Chair
Yeah, Denise, I think we should probably help ONC with a bit of a taking their calculations and just applying it to some of our specific situations. As a large-scale implementer of health IT systems, contracts typically take between two and six months to negotiate. Right? Let's just call it four in the middle because it makes them easier. And then let's say at any moment in time we probably have between 300 and 400 contracts. That's a lot of time to shoot all into two years.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
So... this is Aaron. Let me ask this question. I can appreciate what Lauren said. And I don't want to get away from the spirit of what ONC is attempting to do by almost co-terming all their provisions to be the same time. What if we come up with a middle ground? Like within two years the health IT vendor community will look at all of their customers and have a timeline to when each of these contracts will need to be amended so that you have a 2-year mark, but suddenly they have a water mark of these 10,000 customers...we know when their contracts are going to be due so we can provide that list upon demand of pay we need to include in this provision. So, at least within two years you're showing intent of goodwill to follow and adhere to the rule. That's kind of a middle ground here.

Andrew Truscott – Accenture – Co-Chair
Maybe if you updated 2.i to also say, "establish, enforce, or renew any contract or agreement."

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yep. Something like that. Something in the middle. Again, we can go back to the intent. Again, I do respect and really appreciate the good work that has gone into this even putting something out there to float. But I don't want to cause undue burden to the community. Sasha, what do you think?

Sasha TerMaat - Epic - Member
So, the proposal is to add or renew to 2.i and then remove the timeframe expectation in ii?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
That's right. Well, the timeframe would be within two years you have a list of all your customers, and you know when you're going to be renewing. So, when their contract expires in five years, or one year, or three years you could at least provide that and show evidence towards yeah, we're waiting for that renewal in three years and we're gonna add this provision as a part of it at that time.

Sasha TerMaat - Epic - Member
So, we would revise ii to say that instead?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yes. Language like that. Yes.

Andrew Truscott – Accenture – Co-Chair
Well, state a road map within two years with the date inside the roadmap for compliance not to be abusable or something like that.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
I'm not a lawyer so, I don't know the right legalese. But yes, something like that.

Sasha TerMaat - Epic - Member
I'm capturing this here. And then we're sort of proposing that kind of the capture it in the edits?

Andrew Truscott – Accenture – Co-Chair
Oh, don't capture it in the text of the **[inaudible] [01:20:39]** because –

Sasha TerMaat - Epic - Member
I'll put it down below.

Andrew Truscott – Accenture – Co-Chair
Yeah. I put it down below already.

Sasha TerMaat - Epic - Member
Oh, you did?

Andrew Truscott – Accenture – Co-Chair
Yeah.

Sasha TerMaat - Epic - Member
Thank you.

Andrew Truscott – Accenture – Co-Chair
I quite like this collaboration of folks. It's good.

Sasha TerMaat - Epic - Member
I did too. I think it's very engaging and much easier than –

Andrew Truscott – Accenture – Co-Chair

Everyone working in isolation.

Sasha TerMaat - Epic - Member
Exactly. Yes. Or when you start to send emails around and have 40 different slightly nuanced drafts proliferating...

Andrew Truscott – Accenture – Co-Chair
And when you're chairing a task force and have to compile it all into one document. Yeah, I agree completely. Okay, we staggered to the end of maintenance and certification. Are we all comfortable with where we're at right now?

Denise Webb - Individual - Member
Mm-hmm.

Andrew Truscott – Accenture – Co-Chair
We are gonna have to come back to communication because we asked ONC. And Mark, we'll look to the next meeting for you to do a readout on those in the first 20 minutes so we can look through this again.

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah.

Denise Webb - Individual - Member
So, Andy? This is Denise. And you wanted to know where enforcement was. It starts on page 304 of the preamble.

Andrew Truscott – Accenture – Co-Chair
Okay. I'm more looking inside the actual Regs document.

Denise Webb - Individual - Member
Oh.

Lauren Wu - Office of the National Coordinator- SME
It's 170.580.

Andrew Truscott – Accenture – Co-Chair
580 is it? Okay. Oh, okay. It's a different contract. ONCs review or certified Health IT or a Health ITs developer's actions. Got it. Thank you.

Sasha TerMaat - Epic - Member
Are you getting the questions that are in the google Doc? Because we've kind of addressed them earlier? Or did we want to talk about those? I think we mostly talked about them.

Andrew Truscott – Accenture – Co-Chair
Do you mean the requests for comment?

Sasha TerMaat - Epic - Member
Yes. Reading them over now, I think we did discuss most of them already.

Michael Adcock - Individual - Co-Chair
Oh, we have.

Andrew Truscott – Accenture – Co-Chair
Especially number five. Well, it just means the ONC preempted everything that we've actually discussed. I'm happy to move to sub-part E.

Lauren - Office of the National Coordinator
It's nice to know that we were thinking somewhat logically.

Andrew Truscott – Accenture – Co-Chair
No, no. We were just all thinking the same thing. It doesn't mean it was logical.

Lauren Thompson - DoD/VA Interagency Program Office - Member
Good job.

Andrew Truscott – Accenture – Co-Chair
Okay. 175.80. ONC Review of Certified Health IT or Health IT Developer's Actions.

Lauren Wu - Office of the National Coordinator- SME
Yeah, so if I can provide some commentary here, I think the reason why there's not regulation text the way that you would see for other sections is because what we're proposing to do is amending the section of the regulation text that already exists today for ONC direct review of certified health IT and using a process that we've already finalized previously in 2016. In the enhanced oversight and accountability final rule for ONC to directly review, certify health IT for certain concerns such as patient safety issues and use that same process with a few modifications to also enforce developer compliance with the conditions, and maintenance, and certification requirement which is basically I think what the text here just says. So, we can pull up the electronic code of Federal regulations so you can see what 175.80 looks like today, but it would not reflect what the regulation test would look like if we were to finalize the minor modifications to the process that are proposed for engaging with developers to work on compliance.

Andrew Truscott – Accenture – Co-Chair
Okay. Because in the preamble you've got Table Three which does seem to go a bit...go on...

Denise Webb - Individual - Member
Yeah, page 304 through 322. 323.

Sasha TerMaat - Epic - Member
I put Table Three into the Google doc for reference.

Andrew Truscott – Accenture – Co-Chair
Yeah. Please do. I just...it's a picture. That's why. I was like, "How the heck did she get that in?"

Sasha TerMaat - Epic - Member
I took a screen shot.

Andrew Truscott – Accenture – Co-Chair
I don't know anything about that....

[Laughter]

Andrew Truscott – Accenture – Co-Chair
I tried to paste a text and it all went pear-shaped. So, this is certainly... is ONC trying to discourage us from discussing this?

Lauren Wu - Office of the National Coordinator- SME
Sorry, could you repeat that, Andy?

Andrew Truscott – Accenture – Co-Chair
Are you trying to discourage us from discussing this?

Lauren Wu - Office of the National Coordinator- SME
I'm sorry. I missed that again.

Andrew Truscott – Accenture – Co-Chair
Okay. Are you trying to discourage us from discussing this?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
No. No. No. Anyway...

Lauren Wu - Office of the National Coordinator- SME
No. Not discourage you from discussing it. I'm happy to answer any questions for background.

Andrew Truscott – Accenture – Co-Chair
Well, it's just that this table actually seems pretty...this is an interesting one, this table. It depends on how ambivalent we feel about whether you want to give absolute rights of appeal or not.

Lauren Wu - Office of the National Coordinator- SME
I'll leave that up to you all, but I guess maybe to give you some more context, for the process that exists today, ONC's purview for directly reviewing health IT is only limited to the health IT. The certified health IT itself. And in today's world we can only suspend or terminate the certificate of the certified health IT itself. And if we were to do that in today's world, a developer could appeal that decision. The sort of nuance with the addition of the conditions and maintenance of certification requirements is that there are requirements that are both about the certified health IT itself.

And then, as you know well, a developer's behaviors, actions, and business practices. And so, a slight difference that we're proposing is that if we were to find a developer in non-compliance with a condition or maintenance of certification requirement, if there is a tie back to the certified health IT, we could take the option to terminate the certificate. But in all cases if there is a non-compliance with the condition of certification, we would ban the developer from the certification program as you see in the table here. And so, there could be one, two, or three possible outcomes. And depending on what that outcome is, a developer could appeal any of those decisions in our proposed approach.

Denise Webb - Individual - Member

Could I ask for clarification about the ban? Is that a broad ban where they are banned from getting any other products certified?

Lauren Wu - Office of the National Coordinator- SME
Correct.

Denise Webb - Individual - Member
Oh. Okay. Wow!

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yeah. Wow! That's...wow. Okay. I mean I get the point of the seriousness of this. I appreciate that. But as a CIO, there's some vendors out there with 100 products. One may not conform. Does that mean the entire kitchen sink is bad? I don't know.

Lauren Wu - Office of the National Coordinator- SME
Sure. So –

Andrew Truscott – Accenture – Co-Chair
Isn't that an extreme thought that you can ban...you can prevent modules from being released? But you don't have to ban the entire vendor.

Lauren Wu - Office of the National Coordinator- SME
So, yes. I'll give the answer to that question really quickly and then I'll shut up and let you all discuss. That is in an extreme case. As you see here, we would first, and we state this in the preamble, want to work with the developer through corrective action to remedy the non-compliance. So, that is our first and foremost priority. So, we're not trying to go to the last action as the first option. But in a few cases, if through working through the corrective action we find that the non-compliance cannot be remedied or the developer is not responsive, or there are a few other reasons, then that is sort of the stick if you will to encourage compliance.

And 21st Century Cure does say that ONC has the authority to encourage compliance with the conditions and maintenance of certification requirements in the way that it sees fit. And then two, the ban, a developer may work with ONC to request and see what we call remediation so that ONC may sort of reapprove a developer to re-enter the program after its proposed and completed some kind of remediatory action that ONC finds is satisfactory to fix the problem and make customers whole again. So, I'll just say those two things and then let you guys discuss.

Denise Webb - Individual - Member
So, just one thing I'd like to say concerning the ban. And Aaron's reaction and my reaction as well is if you have a very large health IT vendor that has several hundred products that a health system uses and the EHR around the interoperability. They have behavior that would result in a ban, that could have some serious implications for the health system for a product that really isn't even related to the particular issue. So, I just want to have you say again and clarify. You did say that the ban is for any certification of any products which they offer, not just the product that's the source of the –

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
I think she said that's like a final straw that if that one product doesn't conform, then they can go back and have a further stick to really say, "I mean it. We're gonna ban everything." And then they can.

Denise Webb - Individual - Member
Okay.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
That's what I heard Lauren saying.

Denise Webb - Individual - Member
And I assume, Lauren that that is not something...that is something that a lot of things would have to not happen for ONC to consider doing that.

Lauren Wu - Office of the National Coordinator- SME
Yeah. You're right.

Denise Webb - Individual - Member
That's a big stick.

Lauren - Office of the National Coordinator
It's a big stick and –

Andrew Truscott – Accenture – Co-Chair
It's not the first action. No.

Lauren Wu - Office of the National Coordinator- SME
Yeah. There's a whole flow of notices that we would send the developer in advance of any of that happening so there would be plenty of steps prior to any of that happening. And that would involve a lot of work between ONC and the developer.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yeah. The one thing I'm seeing, and Lauren, I appreciate that clarification. Thank you. The one thing I think as a customer of all these different vendors and some very large vendors is how do I become aware that a) I have a vendor that's being non-compliant. And then b) that there is a consideration for a larger enforcement because this vendor is not being forthright in helping to remediate? I guess I would say that at every stage it's escalated with a vendor that's behaving badly... we'll just use that terminology. I would wish that there was some sort of messaging to the community saying, "Hey, FYI, vendor X, Y and Z it has just completely run amok and we're having to continue..." Just some awareness because if I need to make a decision and change strategy of using a product, that's easily 12 to 24 months at a minimum to make that happen without impacting patients.

Lauren Wu - Office of the National Coordinator- SME
So, to your point, yes. We talk about this in the preamble of this rule and also refer back to our old rule. That's what we like to do. We like to make you go read our old rules. That we would intend to post any approved correction... corrected action plan between ONC and the developer publicly on the CHPL, our certified health IT product list as we do today. If we were to undertake direct review, we would put that Cap (Corrective Action Plan) on the CHPL. And we do that today. The ACB is the certification body that performs surveillance on our certified products post those corrective action plan summaries of them on the CHPL. So, that is one way.

We have a couple of sort of quick tabs on the CHPL on the homepage. One of them is for banned developers so you could quickly go and see who might be banned. You could also go and see which products and developers are currently under corrective action etc. So, that's one method which is kind of passive. I think in the Corrective Action Plan itself, one of the proposed elements of that Corrective Action Plan itself before ONC would approve it, is how the developer plans to notify all affected customers of the problem and what the proposed solution is as well as the timeframe for resolving the problem.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Ah. Got it. So, it would work almost like...okay. So, it works like a confidential integrity agreement that the OCR would give to a covered entity saying, "Hey, you've got two years to fix all these EPHI issues or HIPPA issues" and that's posted to the world. So, the same kind of process would follow here for a vendor?

Lauren Wu - Office of the National Coordinator- SME
Right.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Got it. Thank you.

Denise Webb - Individual - Member
So, when I read through 304 through 323, I thought it was fairly complete and a judicious and fair stepwise process that started out light and then gets firm at the end. So, I personally didn't have any suggested changes or comments now that the ban has been explained. That was my big question.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yeah. Now that I understand the process, that's fair. I think we need to have a fair process. I think absent the process, that stinks because then no one will do anything to **[inaudible] [01:35:51]** will discourage any kind of developer from being innovative. But a fair process ensures compliance. And I feel this is fair.

Denise Webb - Individual - Member
And the process is not unlike what the health IT vendors are presently accustomed to working within.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Right. The only thing I don't see on here, which is I don't even know if it is for us to debate this, is with some of the vendors that have acted really badly, a sort of remediation of some sort to their customers. In this case and thinking of one major vendor that paid back. Yes

Andrew Truscott – Accenture – Co-Chair
The next section which is certification ban, the section B of that is reinstatement.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Ah. There you go.

Andrew Truscott – Accenture – Co-Chair
We're gonna get to that in the fullness of time.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Let's do it.

Andrew Truscott – Accenture – Co-Chair
Okay. Just a question. Lauren, just as a broad brushstroke, how many vendors have experienced some kind of ONC sanction?

Lauren Wu - Office of the National Coordinator- SME
When you mean sanction do you mean by as initiating direct review?

Andrew Truscott – Accenture – Co-Chair
Yeah. Let's start with direct review and then let's work through the cone that it gets through and how many get banned at the very end? So, how many have had direct review?

Lauren Wu - Office of the National Coordinator- SME
So, on the CHPL we have never posted an approved corrective action plan between us and a developer. So, Andy, i.e. alluded to the certification bodies, right? They're the ones that actually issue the certificate because we have a third-party testing and certification program so we're more of the oversight body. And so, typically in non-compliance issues with a certified health IT, if the certification bodies that work with the developers through corrective action and remedying those issues. So, I don't have a number off the top of my head.

Andrew Truscott – Accenture – Co-Chair
Okay. I appreciate the certification bodies. I'm just looking to see under the auspices of the coded rules from 2016, how many have actually had direct...how many have been taken through the process. If you can find that out for the next time, I think that will help us with some of our considerations.

Lauren Wu - Office of the National Coordinator- SME
Right. So, none.

Andrew Truscott – Accenture – Co-Chair
None.

Lauren Wu - Office of the National Coordinator- SME
None.

Andrew Truscott – Accenture – Co-Chair
Okay.

Denise Webb - Individual - Member
So, and Andy, the big distinction here is... and probably why she's saying there's none is because ONC hasn't needed to get into a direct review situation because the certifying bodies have handled this. Because the current process looks at the health IT module, not the behavior. They don't have any authority around the behavior that the conditions of certification and maintenance now provide under the Cures Act which ONC has authority to act on. And in fact, in the preamble it goes into some detail about what the certifying bodies will continue to do related to the IT modules versus what ONC will do related to behaviors and business practices of the health IT vendors. That's where the big difference is.

Andrew Truscott – Accenture – Co-Chair
But specifically, the enhanced oversight and accountability rule...it changed the ONC as well and gave them the ability for direct review. I know they haven't used it, but they felt they needed it.

Denise Webb - Individual - Member
Under very limited circumstances. And the limited circumstances were mainly when it was reasonably believed that the certified health IT may be causing or contributing to serious risks to public health or safety or suspected nonconformity.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
So, can I ask an elementary type question here? And this is maybe my unawareness. How does this now cross the line with what the FTC does from a deceptive practice's perspective? Doesn't this begin to blur the lines a little bit on who holds whom accountable? Or is there clear enough delineation here?

Andrew Truscott – Accenture – Co-Chair
Lauren?

Mark Knee - Office of the National Coordinator - Staff Lead
Well, I guess I can chime in here. Can you hear me?

Andrew Truscott – Accenture – Co-Chair
That doesn't sound like Lauren at all.

Mark Knee - Office of the National Coordinator - Staff Lead
What I was gonna say is our authority specific...what we're talking about has to do with certified health IT products and a program...I mean we can't really speak to what FTC 's authority is or... I mean I think it's possible that they investigate a similar situation that we are, but we can only speak to our authority.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Okay. So, I mean...thank you. And I can appreciate that. So, in theory I just want to make sure everybody on this call is aware of that theoretically, if there is a situation with someone behaving badly, again hopefully that will never happen, but assume an extreme case. It is the realm of possibility that ONC could have its sanctions including a ban and FTC and/or other agencies could step in from their respective domain and do what they need to do.

Mark Knee - Office of the National Coordinator - Staff Lead
Yeah. I mean it's not mutually exclusive in any way. I mean Lauren, feel free to jump in, but I believe the FTC is free to investigate whatever they want to investigate, and we would look at the certified product for any conduct here. In this case the conduct, not the product.

[Crosstalk]

Lauren Wu - Office of the National Coordinator- SME
Yeah. Another example of somewhat overlapping authority which we talk about in the rule is in the specific case of information blocking. So, the HHS Office of the Inspector General was also given

authority in the 21st Century Cures Act to enforce information blocking that may be performed by health IT developers and then also providers and other actors, health information exchanges, etc. And so, from that perspective of the conditions and maintenance of certification, I want to clarify the ONC's authority here is just limited to health IT developers that have certified product under the health IT certification program for information blocking. That isn't to say that OIG may not also have authority over both the health IT developer as well as these other actors that may be found information blocking. So, that's another example of multiple agencies having maybe somewhat of an overlap of authority but maybe different investigatory approaches and possibly different outcomes of any investigation.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
That totally make sense. Thank you.

Mark Knee - Office of the National Coordinator - Staff Lead
Just one other clarification though as far as information blocking more broadly. We did have FCC review our proposal and, again not talking about the conditions of certification, but more broadly about information blocking, we were very clear with FCC and they wanted to be clear that they're anti- **[inaudible] [01:43:09]**. The laws that they're under are separate from what we're doing. And the standards for information blocking for instance for licensing and things like that would be different than standard antitrust laws. And our authority comes from Cures. Theirs is different. So, it's a different scope there.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yup. I just mean in the realm of all things extreme. Again, the far edge case. There could be circumstances of overlapping jurisdiction. I just wanted to make sure that I understood in my head correctly. So, I appreciate it. Thank you.

Andrew Truscott – Accenture – Co-Chair
Okay. After that spirited discussion, I'm just gonna take the opportunity now in the brief lull to open for public comment, Seth?

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

Seth Pazinski – Office of the Coordinator for Health Information Technology – Designated Federal Officer
Operator, do we have any comments in the queue at this time?

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

Seth Pazinski – Office of the Coordinator for Health Information Technology – Designated Federal Officer
Okay. All right. We can pick up where we left off.

Andrew Truscott – Accenture – Co-Chair

Okay, guys. Do we have any comments to make on this?

Lauren Wu - Office of the National Coordinator- SME
So, while people are thinking there are a couple of requests for comment I believe in this section. I'm not sure if they were pulled into the template.

Andrew Truscott – Accenture – Co-Chair
Yeah. I pulled one in that was a comment on the makes and types of non-conformancies. And we also solicited comment on whether the type of notice should affect the method of correspondence.

Sasha TerMaat - Epic - Member
So, I did note this proposal. ONC says in general they would communicate with HIT developers over an email. It seems to me that a specific correspondence of significance should, as it does in the other process for enforcement, be delivered by certified mail to avoid the incidence of it being overlooked.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yeah.

Andrew Truscott – Accenture – Co-Chair
Yeah.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Absolutely. I absolutely agree.

Mark Knee - Office of the National Coordinator - Staff Lead
Well, to that point I believe we talked about this more in the direct review rule, but email is the default I believe under the correspondence. And I believe we write in the preamble that we're able to have discretion based on the significance and type of situation. I can find that language, but I think there is discretion. But the default is email.

Sasha TerMaat - Epic - Member
Which...I mean I think the tricky part is that developers would want to rely on that discretion being exercised for a communication of significance.

Mark Knee - Office of the National Coordinator - Staff Lead
I'm gonna try and find that preamble language really quick, but go on...

Sasha TerMaat - Epic - Member
I think it's on 309.

Lauren Wu - Office of the National Coordinator- SME
Yeah. So, Sasha's right. We pointed to 17505 where Mark was right that by default a method of communication is email and that's what we're proposing for use in the direct review process. But we are soliciting comment on it. So, if that's the comment that you want to give back to ONC, again, that's up for you to decide.

Sasha TerMaat - Epic - Member

So, I guess my proposal for the group to consider would be that for notices of potential nonconformity, nonconformity, suspension, proposed termination, and termination, certified mail should be delivered.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Or both. Or just do both. I mean, email and certified mail. Just do both.

Sasha TerMaat - Epic - Member
Sure.

Denise Webb - Individual - Member
I agree.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yep. I mean you want to make sure that the developer had every opportunity to get wind and remediate and deal with. It's only fair, right? So, I think both. Send a three-eyed raven if you need to. Just do something.

Denise Webb - Individual - Member
So, let's recommend that.

Andrew Truscott – Accenture – Co-Chair
I must confess, it feels like the registered mail approach is in conjunction with electronic mail.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yes. Both.

Denise Webb - Individual - Member
That's what we're suggesting.

Andrew Truscott – Accenture – Co-Chair
Yeah, but it's not like every correspondence has to be through it. It needs to be correspondence of a certain level...to know that you've been put under the direct review by ONC, that notice, absolutely. But every piece of correspondence that goes back and forth seems a little bit over the top.

Sasha TerMaat - Epic - Member
I think that's fine. Do you think I worded it okay, Andy?

[Crosstalk]

Andrew Truscott – Accenture – Co-Chair
One at a time. Sorry.

Denise Webb - Individual - Member
I was just gonna say that. I think Sasha was referring to those major notices.

Sasha TerMaat - Epic - Member
I worded that in our proposal. I have it now under 580 still, unless we should move it somewhere else?

Andrew Truscott – Accenture – Co-Chair
Let's have a look. No, we said I think...yeah. It's more than **[inaudible] [01:48:59]** i's actually... what did they call it?

Sasha TerMaat - Epic - Member
Would that do it?

Andrew Truscott – Accenture – Co-Chair
Yeah.

Sasha TerMaat - Epic - Member
Okay.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yeah. This is good. I like that proposal.

Andrew Truscott – Accenture – Co-Chair
Yeah. And the notes and types of nonconformity... I imagine that what the intent is is that any nonconformity with any aspect of this proposed law could warrant ONC to intervene. Is that what everybody else is understanding?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
I believe so. Yes. I think ONC reserves a judgment depending on the severity, but yes, they can always intervene.

Andrew Truscott – Accenture – Co-Chair
I think this is quite important because as in some of the other calls that are going on at the moment...well, we need to lay down the guidance for OIG performance, etc. Well, actually, it's not just the OIG it's the ONC as well.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Right.

Lauren Wu - Office of the National Coordinator- SME
So, maybe a little bit of context here. I believe... was it Denise who was talking about this earlier that the sort of triggers for direct review today are different from what we're proposing under non-compliance with the conditions and maintenance of certification requirements. So, under direct review today one of the two major triggers is a severe threat to patient health or safety. Whereas as an example, if...so one of the conditions of certification that Congress mandated is that developers have to attest to ONC that they are meeting the conditions and maintenance of certification requirements. And I believe we are proposing that developers attest to ONC every six months of that.

So, using that as an example, if there are a number of developers who missed their every six months timeframe to attest to ONC, should ONC also send notices of nonconformity to them through certified mail? As opposed to if there is suspicion of an information blocking non-compliance with the conditions and certification. So, I think the point is is that there are more conditions and maintenance of certification requirements and they may vary in the perceived frequency severity of the type of

noncompliance. And so, the question is, should the perceived severity and frequency of the type of noncompliance affect how ONC communicates with a health IT developer.

Mark Knee - Office of the National Coordinator - Staff Lead
And just a little bit more background when we're thinking about it in the context of direct review, we're trying to weigh the expediting especially if it's on the issue of public health and safety making sure the notice gets out quickly. So, it can be addressed.

[Sound cuts out]

Mark Knee - Office of the National Coordinator - Staff Lead
...a paper copy.

Andrew Truscott – Accenture – Co-Chair
You're breaking up. Or is it just me?

Mark Knee - Office of the National Coordinator - Staff Lead
Oh, yeah. It's probably me. A paper copy might be better in some situations. So, it's just that balance is what I wanted to say. We've thought about it, but I think your feedback would be very helpful on that.

Andrew Truscott – Accenture – Co-Chair
I'm just thinking.... the conditions of certification which is section 406, off the top of my head, that is not in our scope for this group, is it?

Lauren Wu - Office of the National Coordinator- SME
Well, the conditions are in –

Sasha TerMaat - Epic - Member
Well, some of them are.

Lauren Wu - Office of the National Coordinator- SME
You have talked –

Andrew Truscott – Accenture – Co-Chair
Some are.

Lauren Wu - Office of the National Coordinator- SME
I think you talked about information blocking assurances in the communications which are the first three of the six. And one of the other task forces is talking about the other three that are the API, real world testing, and out of station condition.

Andrew Truscott – Accenture – Co-Chair
Yup.

Lauren Wu - Office of the National Coordinator- SME

So, I guess the idea is, I know you haven't talked about the latter three, but knowing that there are six conditions of certification each of which have their own specific conditional and maintenance requirements which may vary and that we're proposing to use one standardized direct review process for noncompliance with all of those. Does that affect sort of the way that ONC should communicate with health IT developers?

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yeah. This is Aaron. I still stand behind doing both modalities. That's just my vote for this group. Email and snail mail. Because that way you get the immediacy with email, but you get be assuredness that they definitely got the certified mail on the heels of it.

Mark Knee - Office of the National Coordinator - Staff Lead
Just a note... that from a legal standpoint it would be important to clarify potentially when notice occurs. If you send out both, clarifying if it's when the email comes or when the written notice comes or just maybe talking through that could be helpful for the recommendation.

Lauren Wu - Office of the National Coordinator- SME
What we say in 17505 is that when we send certified mail, the official date of when the clock starts is the date of the delivery confirmation to the address on record. So, that would be the date of delivery confirmation of the snail mail.... the certified mail method.

Denise Webb - Individual - Member
I think that's what should be used because the problem with email and the volume of email people get...I just think we're leaving a lot to chance by using that.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
I agree. And who knows what gets caught in a spam filter or whatever else. I'm curious, Sasha, what do you think?

Sasha TerMaat - Epic - Member
About when the clock should start when doing both methods?

Andrew Truscott – Accenture – Co-Chair
No. The most guaranteed communication.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
The modalities and the clock. I see both questions there.

Sasha TerMaat - Epic - Member
I think that when an important significant communication is being issued, we need a degree of liability that's greater than email to start the clock. So, I agree that in casual contact email is fine. I think I would be willing to try to draw lines around some amount of issuing reminders about not having submitted your stuff by a deadline over email. But I guess at the same time, if that reminder is starting a clock, that limits the process that eventually could go towards a ban. Maybe it does merit the more significant communication.

Denise Webb - Individual - Member

That might be the parameter to use then, Sasha. If it starts a clock, that kind of communication would have its date based on the mail. The snail mail delivery receipt.

Sasha TerMaat - Epic - Member
It avoids challenges of particular staff being on vacation or out on medical leave or buried in an inbox and missing something that could be very significant.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yep. The other thing I don't know is on the laundry list of all the HIT certified products, what e-mail address is captured? Is it the e-mail address of a generic inbox? Is it the e-mail address of...? I think of small developers might have Aaron@ABCcompany.com. If Aaron is in Africa on a safari for three weeks, well, gee...

Denise Webb - Individual - Member
Or Aaron no longer works there and nobody's getting the mail.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Right.

Andrew Truscott – Accenture – Co-Chair
Well, he definitely won't be if he doesn't answer his email. I think there's a conversation that's around timeliness and authoritiveness that we're kind of brushing around here. So, something that is sent to the registered address or the registered email, that's got the authoritiveness around it. The email has the timeliness because it's almost instant that you know you've dispatched it. But you don't know when anybody's read it. And depending on the level of urgency, I can actually see putting in a phone call in speaking to whoever you know is in charge of that company. Say, "This is happening guys." But the phone call will be followed up by an e-mail, which will be followed up by the certified mail. Those three have to happen or would happen together. Not have to. You see my point though? If it's really truly urgent, then you should treat it as truly urgent.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Yeah. Are we at time? I'm just curious.

Andrew Truscott – Accenture – Co-Chair
We are at time.

Aaron Miri - The University of Texas at Austin, Dell Medical School and UT Health Austin
Great discussion. Great discussion.

Andrew Truscott – Accenture – Co-Chair
The positive news is we're actually on target and on cadence which I'm given to believe slightly through the back channels that not all the task forces are.

Denise Webb - Individual - Member
Oh, now wait a minute. The task force I'm co-chairing...we're on target. You have a little competition here.

Andrew Truscott – Accenture – Co-Chair

Of course. Healthy is good. Okay. Good. Will congratulations that your task force is also on target and thank you for participating in this one as well.

Denise Webb - Individual - Member
You're welcome. Thank you to everybody.

Multiple Voices:
Goodbye. Thank you. Great discussion. Bye.

[End of Audio]

Duration: 120 minutes