



## Information Blocking (IB) Workgroup 2

Transcript  
April 3, 2019  
Virtual Meeting

### SPEAKERS

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



**Operator**

All lines are now bridged.

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

Good afternoon. Welcome to Workgroup-2, looking at exceptions under Info Blocking. We'll get started, quick roll call: Andy Truscott?

**Andy Truscott – Accenture – Co-Chair**

Present.

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

Michael Adcock?

**Michael Adcock – Individual – Co-Chair**

Here.

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

I believe I heard Valerie Grey on the line?

**Valerie Grey – New York eHealth Collaborative – Member**

Yep, I'm here.

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

Anil Jain? Not yet? Arien Malec? And Steven Lane?

**Steven Lane – Sutter Health – Member**

Here.

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

Okay. We're all set, I turn it over to our co-chairs. Michael or Andy, are we kicking off?

**Andy Truscott – Accenture – Co-Chair**

Thank you very much indeed. Hello. Hey Steve; hey Val; hey, Mike. Welcome back. Right, we need to start putting our thinking caps on around getting the drafting done around the recommendations we want to make. Has either of you been working on them? Arien's worked extensively on the fees-associated ones and has done a lot of drafting around that. I am not proposing to review that right now; I'm proposing for us to go and work on some of the other ones together. Now, I'll either be guided by you guys – the way that I'm seeking to do this is for an individual to take on the responsibility of drafting one of the regulation texts, or we can draft them together. I am ambivalent as



to which way, but if anyone has one that they particularly would like to work on in the privacy of your own laptop and bring it back, I'm happy to support that as well. So, it's your call on this.

**Michael Adcock – Individual – Co-Chair**

Well, so Andy, I already sent out some homework that divvied them up, so I'm not sure if folks have already gotten started on those assignments or not.

**Steven Lane – Sutter Health – Member**

Yeah, this is Steven Lane. You assigned me privacy and security, and the furthest I've gotten is just to sort of go back over them and kind of deepen my familiarity with the comments that people have made and add a couple of comments of my own. But I have certainly not started drafting any feedback.

**Andy Truscott – Accenture – Co-Chair**

Okay.

**Valerie Grey – New York eHealth Collaborative – Member**

This is Val. I was assigned infeasibility, and maintenance and improvements, as well as the complaint process. For infeasibility and maintenance, I did something similar in terms of re-reading everything. And I was interested – there were a number of areas where task force members had comments, and I wanted to re-review those if possible. And then, if we had time for that kind of conversation, I would expect in the next day or so I can draft.

**Andy Truscott – Accenture – Co-Chair**

Okay, so look, given it is you, Steven, and myself on the call, I am happy for you to say let's go back through those comments and get that level of application you're looking for, and then we can adjourn whilst you go – and you can use the rest of the time—we've got two hours set now—you can use the rest of this time to be working on that.

**Valerie Grey – New York eHealth Collaborative – Member**

Okay. I mean, that works for me. What do you want to tackle first?

**Andy Truscott – Accenture – Co-Chair**

Well, hang on; so, Steve, does that work for you?

**Steven Lane – Sutter Health – Member**

That's fine. Yeah, I'm actually at an all-day regional HIE meeting at Stanford that I am co-sponsoring. So, it's going to be tough for me to work on it right now. I mean, once we free-up I'll probably go back to the meeting I just stepped out of, but I'll have to work on it probably this weekend.

**Andy Truscott – Accenture – Co-Chair**

Okay, as long as you can because we do need to get this [inaudible] [00:03:59]. I'm sorry to –

**Steven Lane – Sutter Health – Member**

Let me look at my week. Yeah, I've got time to tomorrow afternoon I can dedicate to this.

**Andy Truscott – Accenture – Co-Chair**

Thank you. And frankly, if you want us to keep you away from your meeting, we can stay on the call just –



**Steven Lane – Sutter Health – Member**

No, no frankly, I'd love to go back to my meeting. I really am missing it. So, no, that's fine.

**Andy Truscott – Accenture – Co-Chair**

Okay, so –

**Steven Lane – Sutter Health – Member**

Yeah, let's discuss the process and the approach, and then I will make writing time tomorrow for sure.

**Andy Truscott – Accenture – Co-Chair**

Okie dokie. So, we've got – Steve, we'll go through yours first and then, Val, we come to yours, does that work?

**Valerie Grey – New York eHealth Collaborative – Member**

Sure.

**Andy Truscott – Accenture – Co-Chair**

Okay. So, Steve, the first one that I think you commented on was around the 202 exceptions and promotion of privacy and mandatory health information.

**Steven Lane – Sutter Health – Member**

Yeah, yeah. So, I looked at the privacy one, and I'm going to keep badgering you on that.

**Andy Truscott – Accenture – Co-Chair**

[Laughs] That's okay.

**Steven Lane – Sutter Health – Member**

And why don't we go down to the comments? I don't think...yeah, slide down a little further there. I just wanted to make sure—I think kind of like Val—I want to make sure that I understand what people's comments were. So, "What are overhead requirements for organizations to address the policies it would need to be developed to manage the exception?" that same comment was proffered on privacy and security. And I just wanted to sort of understand better what were the concerns; what generated that comment? So that I can be clear where we're going with that.

**Andy Truscott – Accenture – Co-Chair**

Okay, so if memory serves me correctly, we discussed how where we have multi-state organizations—so let's say integrated care delivery network that's focused across several states—rather than implementing discrete policies and procedures state-by-state, there is a general habit of imprinting organizational "why policies" which put in a common bar at the most restrictive state requirements.

**Steven Lane – Sutter Health – Member**

Aha, okay. Right, I recall that discussion, that's right. And I think what we're saying is we do not want the most restrictive state to drive the policy and procedure, we'd rather it go the other way. That we set a floor which is the least restrictive, and that if there are restrictions necessitated by local regulation that they be applied only locally and not across the board.

**Andy Truscott – Accenture – Co-Chair**



Yeah, yeah, I think where we got to as a group was certainly the second part of that statement. I think we said rather than making everything the least restricted, it was purely restrictions and policies should be entirely aligned with the state in which you are within.

**Steven Lane – Sutter Health – Member**

Right.

**Andy Truscott – Accenture – Co-Chair**

As opposed to the highest bar across all the states you operate within.

**Steven Lane – Sutter Health – Member**

Right, aligning to the state that would have jurisdiction over the given transaction, right.

**Andy Truscott – Accenture – Co-Chair**

Yes, that's right, yeah, yeah.

**Steven Lane – Sutter Health – Member**

Yes, okay. I think we're saying the same thing using different words.

**Andy Truscott – Accenture – Co-Chair**

We are; your words are better.

**Steven Lane – Sutter Health – Member**

Okay. Was there anything else in terms of the overhead that was discussed that we want to capture?

**Andy Truscott – Accenture – Co-Chair**

I think that was the only real concern that we had...yeah.

**Steven Lane – Sutter Health – Member**

Okay, and the second one, Andy –

**Andy Truscott – Accenture – Co-Chair**

I'm sorry, and your first call is – I'm curious what you're thinking here, "I have a hard time [inaudible] [00:08:04] new costs associated [inaudible] pharmacy protections." Yes and no, because given our point around consistency and that you work with the policies in play where the jurisdiction to transaction is governed by, rather than governing all transactions the same way across the most restrictive policy your organization is required to abide by, that could potentially increase policy definition and enforcement overhead for an organization that runs across multiple states.

**Steven Lane – Sutter Health – Member**

Yes, that's fair.

**Andy Truscott – Accenture – Co-Chair**

That's where I was going on that first statement based upon where we got to with the last statement.

**Steven Lane – Sutter Health – Member**



Right, okay. Yeah, there's definitely going to be a cost. And also, just having a process that analyzes a given transaction in relation to the applicable laws, as opposed to against a standard policy for an organization.

**Andy Truscott – Accenture – Co-Chair**

Yes.

**Steven Lane – Sutter Health – Member**

Got it, okay. Super.

**Andy Truscott – Accenture – Co-Chair**

And then there were some comments around the expression of consent or dissent should be recorded, and that's part of the record.

**Steven Lane – Sutter Health – Member**

Right.

**Andy Truscott – Accenture – Co-Chair**

That's part of the HI.

**Steven Lane – Sutter Health – Member**

Okay.

**Andy Truscott – Accenture – Co-Chair**

And then C-3 there was, yeah, "meaningful disclosure," and the term "meaningfully" was a bit ambiguous.

**Arien Malec – Change Healthcare – Member**

Hey, by the way, it's Arien. I am finally on and actually connected.

**Steven Lane – Sutter Health – Member**

Excellent.

**Andy Truscott – Accenture – Co-Chair**

Welcome.

**Steven Lane – Sutter Health – Member**

So, "meaningful disclosure," say more about what you're thinking.

**Arien Malec – Change Healthcare – Member**

Well, I think that was the question; we're not quite sure what was being thought.

**Steven Lane – Sutter Health – Member**

Okay. So, what does that mean?

**Andy Truscott – Accenture – Co-Chair**

Arien, we're on 202-C3, and what we're doing is we're just touching base upon the questions that Steve –



**Steven Lane – Sutter Health – Member**

The comments.

**Andy Truscott – Accenture – Co-Chair**

– yeah, that Steve and Val have because they’re going to go off and do their drafting, and we’re not going to take the full two hours now. Although, we might need to, to go through your comments.

**Arien Malec – Change Healthcare – Member**

You’re probably well just to read my comments.

**Steven Lane – Sutter Health – Member**

Indeed.

**Andy Truscott – Accenture – Co-Chair**

Okay, so essentially, you had, “Previously been meaningfully disclosed to the persons and entities that use the actor’s product or service.” All right, so the term –

**Arien Malec – Change Healthcare – Member**

“Previously been meaningfully disclosed.”

**Andy Truscott – Accenture – Co-Chair**

Yeah.

**Arien Malec – Change Healthcare – Member**

So, this is a non-HIPAA actor...so I think it – yeah, the term “meaningfully disclosed,” I think...is an awkward way of saying, “prior notification, clear and prior notification.” It’s got to be documented, right? It’s got to be documented, and it has to be documented in advance.

**Andy Truscott – Accenture – Co-Chair**

I would just use – remove the term “meaningfully.”

**Arien Malec – Change Healthcare – Member**

Yeah, I think the intent here is that – I believe the intent here of this language is that if I’m a non-HIPAA, Certified Health IT actor, and I’m implementing a privacy policy that promotes the privacy interest of an individual, I can choose not to share if I meet all tests, one, two, three, four and five. Four and five are pretty clear. Two says it’s got to be described in our organizational privacy policy; one says it’s got to comply with applicable state and federal laws. And I think what three’s saying is: I have to have told – I have to have documented it in ways that the persons and entities that use my service know and understand. And so, I think “meaningful” is a little bit of a red herring here; it’s commercial reasonable prior notification.

**Andy Truscott – Accenture – Co-Chair**

Let’s just say “disclosed.”

**Arien Malec – Change Healthcare – Member**

Disclosed, yep.



**Steven Lane – Sutter Health – Member**

Right, well, he's basically saying that the word "meaningful" adds ambiguity as opposed to clarity.

**Andy Truscott – Accenture – Co-Chair**

It's not meaningful.

**Steven Lane – Sutter Health – Member**

Right.

**Andy Truscott – Accenture – Co-Chair**

It's amazing how the word "meaningful" ceases to mean a lot, isn't it?

**Steven Lane – Sutter Health – Member**

Any comments from the author?

**Arien Malec – Change Healthcare – Member**

I can't say whether I'm the author or not. But I think it's definitely probably getting at what we were trying to – we were trying to say that you can't just, say, disclose it and then it's off in some obscure place. It has to actually be accessible, and I guess meaningfully disclosed. But that's about all I can –

**Andy Truscott – Accenture – Co-Chair**

Okay, so could you actually –

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

So, Mark. Can I just add two cents to that?

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

Oh, yeah, yeah. Sure, Morris.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

Sorry about that. I'll just add two cents just to – [inaudible] [00:13:40]. "Meaningful" means plain language; it's twofold: one is it's in plain language. And secondly, exactly what Mark says, it has to be in a prominent place, similar to the notice – in HIPAA's the Notice of Privacy Practices, it's sort of that concept.

**Andy Truscott – Accenture – Co-Chair**

Okay.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

So, we're obviously open to any suggestions to make it clearer. So, that's what we were trying to articulate, or that was part of the intent behind it.

**Steven Lane – Sutter Health – Member**

Okay, that's helpful. Yeah, I think if that's the intent, we can just suggest that that be stated somewhere in the documentation.



**Andy Truscott – Accenture – Co-Chair**

Yeah.

**Arien Malec – Change Healthcare – Member**

“Clear and prior” seems to be the test then?

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

I’m sorry, you said? I didn’t hear you, say that again?

**Arien Malec – Change Healthcare – Member**

I said, “clear and prior” is the test that we –

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

Yeah, clear and prior, plain language, easy access to those sites so a reasonable consumer could understand...yeah, that’s –

**Steven Lane – Sutter Health – Member**

And would we think that that would belong in the preamble, that kind of explanatory language?

**Arien Malec – Change Healthcare – Member**

I think if we mean clear and prior, we should say “clear and prior,” rather than “meaningful.”

**Andy Truscott – Accenture – Co-Chair**

Actually, Morris just gave us – I thought gave us the word we needed, he gave us the reasonable word. Why don’t we just change “meaningfully” to “reasonably disclosed”?

**Steven Lane – Sutter Health – Member**

Well, I’m not sure that “reasonable” clarifies “meaningful.”

**Andy Truscott – Accenture – Co-Chair**

Well, okay. Well, I actually preferred “notified” and replace both words, but that’s probably a step too far.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

So, I was suggesting “clear and prior notification.”

**Steven Lane – Sutter Health – Member**

Yeah, I like that.

**Andy Truscott – Accenture – Co-Chair**

So, instead of saying, “has previously been,” we just say, “had clear and prior notification to the persons and institutes”?



**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

Okay.

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

Just a point – I mean, when you say “notification,” you might—if that’s the recommendation you’re making—there might be questions about how that notification would work; “disclosing” is more of a passive word. But “notification” is more of a proactive kind of term, just something to think about.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

That’s a really good point, Mark, and I was just gonna say in **HIPAA** you have to have an acknowledgment of that notification. So, this is something that’s –

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

Okay.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

– just wanted to point that out.

**Steven Lane – Sutter Health – Member**

So, are we more interested in “disclosure,” which is the more passive? Or “notification,” which is the more active? I mean, “clear and prior disclosure”...yeah, I –

**Andy Truscott – Accenture – Co-Chair**

But let’s look at what we’re trying to achieve.

**Steven Lane – Sutter Health – Member**

Okay.

**Andy Truscott – Accenture – Co-Chair**

We’re trying to say an actor can choose not to provide access exchange, or use the HI, provided that that practice—so, their decision—has previously been meaningfully disclosed to the persons and institutes that use the actor’s products or service. I think that’s quite a big deal, actually.

**Steven Lane – Sutter Health – Member**

Yeah. Yeah, we can do whatever we want, so long as we warned you about it ahead of time.

**Andy Truscott – Accenture – Co-Chair**

Yeah, that –

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

This is a non-**HIPAA** actor; it’s a non-**HIPAA** actor, it’s got to comply with state and federal law. So, part of the reason for having this is –

**Andy Truscott – Accenture – Co-Chair**



It's a non-HIPAA actor of Certified Health IT.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

Right, so part of the reason for having this is that HIPAA doesn't have any teeth here.

**Andy Truscott – Accenture – Co-Chair**

Yep.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

And I think –

**Steven Lane – Sutter Health – Member**

So, HIPAA can't compel it.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

HIPAA can't compel it, but all we're saying here is that there's no legal authority to compel certain kinds of behavior, as long as they're not in conflict with state and federal policy, but you have to tell people prior. And I'm just looking at the notes for privacy practices languages, and it says, "Right to adequate notice," so we could also use "adequate notice" or "adequate notification."

**Andy Truscott – Accenture – Co-Chair**

But do we want to give these teeth? Because it's basically I think trying to take the place of – because HIPAA's not pertinent to actually –

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

Yeah, it's just a...it's a legislative authority issue.

**Andy Truscott – Accenture – Co-Chair**

Yeah.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

We might want to give it teeth, but there are no teeth to give it.

**Steven Lane – Sutter Health – Member**

There are no teeth to give it, right. We have no teeth to give it teeth, okay.

**Andy Truscott – Accenture – Co-Chair**

Well, actually, hold on, that's not true. We do have teeth to give it because this is an exception for a Certified Health IT developer not covered by HIPAA. So, it's actually because we're effectively saying, "Unless you do this, you don't have an exception."

**Steven Lane – Sutter Health – Member** So, we do that for –



**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

I think we're wandering off our straight-and-narrow lane.

**Andy Truscott – Accenture – Co-Chair**

No, that's Steven Lane. Actually, I mean, I'm not sure we are. I'm just re-reading this exception again. This exception –

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

We could say – yeah, we could say in our comment that we believe the information blocking regulation gives ONC right to enforcement for privacy policies for...Certified Health IT developers that are not covered by HIPAA. It clearly would then fall to OIG and other folks to tell ONC whether we're right or wrong. But I assume that ONC's already explored that.

**Andy Truscott – Accenture – Co-Chair**

Mark, thoughts?

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

Sorry, I didn't realize there was a question there.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

Yeah, so the question is – so I think Andy is asserting that because –

**Andy Truscott – Accenture – Co-Chair**

No, actually, he's questioning, he's not asserting anything.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

He's questioning, that's right. Andy is raising a topic which is: since Cure has provided legislative authority for regulating information blocking, and since voluntary certification of Health IT for non-HIPAA covered entities provides some framework to hook these things on...can we go beyond prior notification and actually require HIPAA-like privacy protections?

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

Yeah, I mean, I think you can make that recommendation. I mean, I think we considered different levels of language and requirements here, and we felt like we struck the right balance. But I don't see why you couldn't make that recommendation.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

Yeah. So, I think we No. 1 want to clarify that we're really talking about whether it's prior notice or adequate prior notice—to use the notice of privacy policy practices language. Whatever language we want to use other than “meaningful” that would be easier to follow, that's one recommendation that we have. And the other recommendation that we have is suggesting that ONC may want to go farther and suggest that ONC may actually have the legislative authority to go farther given the hook of certification and the hook of information blocking.



**Andy Truscott – Accenture – Co-Chair**

Okay, Steve –

**Steven Lane – Sutter Health – Member**

And the “going father” would be essentially to say – to remove this opportunity for them to block.

**Morris Landau – Office of the National Coordinator for Health Information Technology – Back Up/Support**

Basically saying effectively the same rights as under HIPAA, particularly for patients.

**Andy Truscott – Accenture – Co-Chair**

Yeah, so basically he’s making it a higher bar that they would have to pass through for them to say, “We have an exemption here.” So, rather than just saying, “Yeah, we’re sure we told you.”

**Steven Lane – Sutter Health – Member**

Essentially removing C3 is what we’re saying?

**Andy Truscott – Accenture – Co-Chair**

I don’t think we’re saying remove it; I was just saying that we’ve made it clear and prior.

**Steven Lane – Sutter Health – Member**

No, no, but if we were setting a higher bar, is what I’m saying. We would basically be saying you don’t have that opportunity to simply block because you told them you were going to block, right? Obviously, they need to comply with federal law, right? It needs to be tailored, so one, four, five. But I guess we could say that if we removed two and three, that would be setting the higher bar, right? We wouldn’t say, “It’s – ”

**Andy Truscott – Accenture – Co-Chair**

Well –

**Steven Lane – Sutter Health – Member**

“– it’s simply up to you have a policy.”

**Andy Truscott – Accenture – Co-Chair**

I don’t think I would agree because you’ve highlighted the word here which is “and” it’s one and two and three and four and five.

**Steven Lane – Sutter Health – Member**

Right.

**Andy Truscott – Accenture – Co-Chair**

So, those –

**Steven Lane – Sutter Health – Member**

But I mean – but if we were going to say that there would be a higher bar, that if we wanted to encourage ONC to set a higher bar, wouldn’t that be done essentially by eliminating C2 and C3? And simply saying that –



**Andy Truscott – Accenture – Co-Chair**

No, because that's removing some of the –

**Steven Lane – Sutter Health – Member**

No?

**Andy Truscott – Accenture – Co-Chair**

– that's removing two of the bars. What I think we're suggesting is we update the language in C3 to say, "It's not sufficient to do a meaningful disclosure"—whatever that means—"you have to have done a clear and prior"—and whatever language Arien suggests.

**Steven Lane – Sutter Health – Member**

Adequate, right.

**Andy Truscott – Accenture – Co-Chair**

Adequate, yeah. Which actually raises the bar and makes this harder. Whereas –

**Steven Lane – Sutter Health – Member**

Well, it raises the bar a little bit, but it doesn't raise the bar in the way that I think Arien was discussing, which is to say that we would hold these non-HIPAA-covered Certified HIT actors to essentially a similar standard as HIPAA-covered Certified HIT, yeah.

**Andy Truscott – Accenture – Co-Chair**

We're only going to do that –

**Arien Malec – Change Healthcare – Member**

I don't think we're saying we should do that; I think we're saying that ONC should explore whether they have the legislative authority to do that.

**Steven Lane – Sutter Health – Member**

Okay.

**Andy Truscott – Accenture – Co-Chair**

Oh, as an additional recommendation?

**Arien Malec – Change Healthcare – Member**

Yeah, they have to –

**Steven Lane – Sutter Health – Member**

Yeah, that's what I was trying to get it.

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

Yeah, and just a point about your recommendations: we're limited in what we can really discuss about what our thought process was on some of this stuff. But you can definitely make a recommendation that you think there should be a higher bar and address that there might be limitations on ONC, but still make the recommendation, if that's your analysis for the recommendation.



**Arien Malec – Change Healthcare – Member**

Yep.

**Andy Truscott – Accenture – Co-Chair**

Yep, okay, that's cool.

**Steven Lane – Sutter Health – Member**

All right, I think I got that.

**Andy Truscott – Accenture – Co-Chair**

Steve, have you captured enough to work on this one?

**Steven Lane – Sutter Health – Member**

Yep, yep. Okay.

**Andy Truscott – Accenture – Co-Chair**

Magic! Valerie?

**Valerie Grey – New York eHealth Collaborative – Member**

Andy! All right, so I apologize—I had sent a note earlier—I only can stay on until about 5:00.

**Andy Truscott – Accenture – Co-Chair**

Okay.

**Valerie Grey – New York eHealth Collaborative – Member**

I sent everybody a document where I tried to organize the comments that the workgroup members had and some of my reaction and questions. We can maybe try to see if we can get through this quickly, but maybe we can start with maintenance and improvement for Health IT performance exceptions. One of the workgroup comments was that the exception should include negotiated SLAs. And I wanted to check because my reading of the preamble indicates ONC intends to include negotiated SLAs in the exception and that basically they're just seeking to ensure that when EHI is unavailable because the supplier takes the system down for these reasons, that there's some sort of agreement to that effect. So, I just wanted to check.

**Arien Malec – Change Healthcare – Member**

Yeah, this was me, and my comment here was that – first of all, I think it should be clear that it includes negotiated SLAs. And secondly, I was trying to raise...no, I could read, "For a period of time no longer necessary to achieve the maintenance or improvements," and "Agreed to by the individual," as really covering scheduled downtime only, and not covering unscheduled downtime, emergency downtime—system failure, those kinds of things that are outside of maintenance windows. And I just want to make it clear that negotiated SLAs, failure to achieve negotiated – or limited negotiated SLA is just part of the prior written agreement. And the second set of comments that I have is that if there aren't any negotiated maintenance windows or negotiated SLAs, I think you need to fall back on usual practice and not make having a maintenance window or SLA an information blocking issue.

And the third comment is that if I'm outside of SLAs, but I'm making commercially reasonable efforts to address the issue, then again, I don't think the enforcement here should be OIG or FTC enforcement of FTC, that's perfectly adequately handled through contract law. They're really aware where there's



problematic behavior—I think there’s a famous example of an EHR vendor that went out of business and didn’t make the EHR data available. We’re really trying to prevent against those issues where there is so much downtime or so much negligent behavior, that effectively we’re treading into information blocking.

**Valerie Grey – New York eHealth Collaborative – Member**

Okay. Well, again, I apologize because I’m very new to this whole area. But it seems kind of clear to me that negotiated SLAs were included when I read the language in the preamble—I think it’s Page 7551 of the official document. So, I guess, I’m just trying to maybe go back to that other issue of if it’s clear in the preamble ONC says it’s covered, does it have to be in regulatory language? And then with the unplanned downtime, when I read the preamble language it does seem to include unplanned. And it even goes so far as to say if there’s something that happens that is outside of a traditional arrangement that you can have an oral agreement or you could do something by email. And when I looked at the concept of “as long as you’re trying to remediate,” I was just trying to figure out, and I was a little bit concerned because it sounds like as long as somebody’s trying, you could be down as long as you want to despite agreements. And again, if I’m missing something major here, that’s why I’m trying to revisit it.

**Arien Malec – Change Healthcare – Member**

Well, so first of all, I tend to take the perspective that if it’s not clear in the text, the preamble can help provide interpretive guidance. But preamble isn’t a substitute for the actual reg text itself. And the second concern is: at what point do we pass from contract law to information blocking regulation? So, if I’ve got a remedy and contract for SLA failure...we’re not saying it’s appropriate or okay for an actor to have downtime outside of SLA, just saying that the remedy for that typically is a contract remedy or a contract law remedy. At what point is the appropriate remedy OIG enforcement or FTC enforcement?

**Valerie Grey – New York eHealth Collaborative – Member**

But my sense was that they weren’t going to necessarily enforce unless it was down for longer than what it needed to be, that you’re doing it in a discriminatory way based on competition and things like that. But maybe, again, if ONC can help me better understand the intent, that would be helpful.

**Arien Malec – Change Healthcare – Member**

Well, I get nervous when you read one thing in the preamble and I read something in the reg text, and you think is really clear in the preamble and I don’t think it’s clear in the reg text. I’d rather have the reg text be clear, and then provide examples, and glosses, and those kinds of things in the preamble.

**Andy Truscott – Accenture – Co-Chair**

Yeah, I think it’s reasonable for us to maybe just tweak the reg text, so it refers back to the preamble for amplification, but the reg text actually covers the maintenance window issue and that kind of stuff. That doesn’t feel like that’s a big job to do, does it?

**Arien Malec – Change Healthcare – Member**

That’s right.

**Valerie Grey – New York eHealth Collaborative – Member**



Yeah, I guess I'm struggling, though. There are hundreds of pages of the preamble that go around setting the stage for the regulatory text, and why are we adding certain things into the regulatory text and not the rest of it?

**Arien Malec – Change Healthcare – Member**

Yeah, we're trying to make for the reg text to stand alone – yeah, we're trying to make the reg stand alone, and understanding that the preamble is there to provide examples, discussion, justification –

**Andy Truscott – Accenture – Co-Chair**

Color.

**Arien Malec – Change Healthcare – Member**

– that color to the reg text, but the reg text – I should be able to read the reg text and understand it and understand how it applies.

**Andy Truscott – Accenture – Co-Chair**

And the name “preamble” implies that you read it first; no one ever reads the preamble first.

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

Well, I don't think that the—I'm not the one who came up with the name—but I think that just probably “preamble” means that it comes before the regulatory text in order. I don't know that it means you're supposed to read it before it.

**Arien Malec – Change Healthcare – Member**

Yeah, that's right.

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

And I would say you are not supposed to. What I would say—just to chime in—I think, Valerie, I think your interpretation especially based on what you're saying sounds accurate as to what we were trying to do here. I guess I'm just not clear—and you all can make the recommendations—what is missing from the regulatory text to make it clearer to convey the message that you've been talking about?

**Arien Malec – Change Healthcare – Member**

So...I can come up with some language, that's probably the best way to handle this. But to me...the missing bits are reasonable and not addressed through – where downtime is not addressed through other remedies. I don't think it's appropriate for OIG enforcement or FTC enforcement for things that fall kind of within contractual dispute. It's obviously appropriate for areas where downtime is impeding access to data, and I think there have been some examples of that. So, I'm trying to make sure that we're narrowing the exception to the areas that raise the level of information blocking and are appropriate for that remedy, as opposed to a contractual dispute resolution process remedy.

**Valerie Grey – New York eHealth Collaborative – Member**

But even –

**Andy Truscott – Accenture – Co-Chair**

Okay, yeah that's – oh, sorry, go ahead, Val.

**Valerie Grey – New York eHealth Collaborative – Member**



No, I was just going to say, but even to that point then, it's not so much if downtime exceeds the SLA, we're talking about it exceeding for some extended period of time. But even then I thought one of the criteria is that it can't be down for longer than needed, so. But I totally – this helps me understand where this one was coming from.

**Arien Malec – Change Healthcare – Member**

Well, that could be – the easiest addressing of this is just to remove/strike bullet three, and say that “maintenance is for a period of time no longer than necessary and implemented in a consistent and nondiscriminatory manner,” and maybe “consistent in accordance with – ” the language that we've used another place – that the reg text has used in places: “if in accordance with organizational policies then documented; if not, then with clear written notice.”

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

Yeah, and just as a background – or not background, but just clarification on three: we've talked about it in the context of other exceptions, but we talk about how contracts and other agreements like that have been a real source of information blocking in the past from what we've seen, so. Three is an attempt to address potential inappropriate – or making sure that the individual or entity to whom the Certified Health IT is being supplied is on notice and agrees to it. So, that's why that's in there.

**Arien Malec – Change Healthcare – Member**

Yeah, but yeah, so here's my real-world issue, which is that I have oversight for a gazillion services. Sometimes they go down. I try to do RCA; I try to do remediation; I try to make sure I've got appropriate monitoring. We had an incident where VMware failed in a spectacular fashion, and it took us a substantial amount of time to bring it back up. We were working as hard as we possibly could for service restoration. That stuff happens in the real world. So, the question is: at what point does the behavior of the actor go to information blocking where the appropriate remedy is OIG or FTC? That's really what I'm trying to get at: is in the real world stuff goes down; in the real world SLAs are negotiated imperfectly, and sometimes people fall back on commercially reasonable, sometimes the appropriate approach is: I have a Twitter Fail Whale, and Twitter provides appropriate channels for letting me know that Twitter is down and...stuff happens in the real world. What point is the behavior sufficient to trigger information blocking?

And I could imagine reading this text and complaining to OIG that my vendor was down for an hour longer than SLA. And I negotiated this SLA; the vendor's down for longer than the SLA; so, therefore, that's information blocking. The appropriate remedy there is contract law, but it's a lot harder to go to a contract law remedy because I have to go lawyer-up and go to courts, and do all that fun stuff. Whereas I can just defer to OIG and kind of harass people at the OIG, that's really what I'm trying to get at. Anyway, I'm happy to propose something. It sounds like maybe there are some differences of opinion in the task force, and we can work it through.

**Valerie Grey – New York eHealth Collaborative – Member**

Yeah, I mean, and I hear you, and I'll try to do the same. I guess it's really just striking a balance because, from my perspective, we run a hub that's in the middle of a federated HIE system, so I totally understand, I've missed SLAs before. But I think it's sort of a question of: at what point are people not able to access EHI and people's health and welfare are at stake here? An exception that just says “as long as somebody is trying, it's okay,” or “if it's something out of my control, it's okay.” That seems like



**Arien Malec – Change Healthcare – Member**

I wasn't going to "trying," I was going to "commercially reasonable efforts." And I think in this area "commercially reasonable efforts" are SWAT teams that are descending on the data center and making sure that we got service restoration.

**Valerie Grey – New York eHealth Collaborative – Member**

Yeah, yeah. No, I hear you, I hear you. I guess the one other question I had on the force of nature and other unusual events: when I thought about that a little bit, I wondered if those instances are already covered by the infeasibility exception and the security exception? Those were the two main things I thought of when things were really crazy-wacky, and I guess I wanted some help in understanding what other situations were you thinking of here that might not be included in those other exceptions?

**Arien Malec – Change Healthcare – Member**

Yeah, so if a hurricane takes out my datacenter, or if an airplane falls on my data center, and my service is down for an extended period of time and I've got to go to business continuity and disaster recovery policies and procedures, I may have a service that's down for a week. And again, in the real world, that kind of stuff happens. I have to provide written notice, tell people what's going on, go through by BCDR approach, and try as fast as possible to get service restoration.

**Valerie Grey – New York eHealth Collaborative – Member**

I think that that falls under the infeasibility exception where there's actually specific references to natural disasters, and hurricanes, and things like that.

**Arien Malec – Change Healthcare – Member**

In the reg text itself or...?

**Valerie Grey – New York eHealth Collaborative – Member**

Oh, no, in the preamble.

**Arien Malec – Change Healthcare – Member**

Mm-hmm, okay.

**Valerie Grey – New York eHealth Collaborative – Member**

Yeah...I'm trying to find the exact – oh, here it is! On page 7543 of the Official Federal Register document, where it talks about for example, "an actor could seek coverage under this exception if it's unable to provide access of change or use of EHI due to a natural disaster like hurricanes, tornadoes, earthquakes, wars," and these are just a couple of the examples and not an exhaustive list.

**Arien Malec – Change Healthcare – Member**

Hmm.

**Valerie Grey – New York eHealth Collaborative – Member**

So, that's why I wondered whether it's really something that is in this exception or maybe those instances are covered in another exception? So, I don't know if maybe take a –

**Arien Malec – Change Healthcare – Member**

I had never read 205, just based on reading the reg text as covering force majeure and natural disasters. Fascinating.



**Valerie Grey – New York eHealth Collaborative – Member**

Yeah, I mean, maybe I got it wrong. I mean, ONC folks if you're on the line because again, give me a state reg and I can totally get it; federal stuff is a little bit different for me.

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

No, I mean, I think you called-out the applicable examples we provided in the preamble. I think all of these situations are going to be fact-specific and based on the circumstances. But what we're saying is that that would – those types of natural disasters would potentially qualify you as infeasibility because you really wouldn't be able to provide the data. I guess there is the requirement in infeasibility about another means of providing it, so that's something to consider.

**Arien Malec – Change Healthcare – Member**

Okay.

**Valerie Grey – New York eHealth Collaborative – Member**

Okay, so those are the areas I had hoped to get this good, robust conversation on, to go back and think about what we might want to recommend of—I have about 10 or 15 more minutes—I did have some other questions, issues, input that I was hoping to get the –

**Andy Truscott – Accenture – Co-Chair**

Please, please ask.

**Valerie Grey – New York eHealth Collaborative – Member**

So, on the infeasibility exception...so there were a few – maybe start with the easier ones, although none of these are exactly easy. The observation that the use of the word “timely” is unclear; I definitely agree that there's no definition of “timely” that I found in the rule. But to ONC's earlier point, as I read this infeasibility exception, to me, I was just struck by the emphasis on the variability of circumstances, and the restating of fact-based approach. And it felt to me like ONC was purposely trying to build in a little bit of flexibility by using the word “timely,” so that “timely” for an actual disaster might mean weeks; “timely” for something else could be something much shorter. And so, I've thought about like we could recommend a particular number of business days, and there are some precedents like in-state freedom of information laws, and HIPAA, and things like that. But then, I sort of felt like we'd have to try to do days with each kind of infeasibility circumstance, and then that would get wacky, and could we can ever really get it quite right? So, I guess I was going to – I was looking to ask the group again if we're seeking to try to define timely, or are folks now more comfortable with the use of that word?

**Andy Truscott – Accenture – Co-Chair**

In general, I feel words like “timeliness” or “meaningful” are a legal little too subjective, and I'd like to update the regulations, so we actually say what we mean. I don't think that's – I mean, that's tweaking and tuning, and that's part of the insight I think the ONC appreciates from us, we can read it without those lenses on.

**Valerie Grey – New York eHealth Collaborative – Member**

So then—you guys are definitely more experienced than I am—so, what's the range of “timely” that we think is appropriate for the best-case and the worst-case?



**Andy Truscott – Accenture – Co-Chair**

Well, I wouldn't give a best-case; I would say, "no longer than X."

**Valerie Grey – New York eHealth Collaborative – Member**

But then that means for the places where someone could respond much more timely, you could just drag it out. Not that – most everybody is a good actor, but there are a few – you could delay responses that could otherwise be much more timely if we have everybody moved to the latest.

**Andy Truscott – Accenture – Co-Chair**

Yeah, but you make that the "no longer than" number not a high number, so five business days or something like that.

**Valerie Grey – New York eHealth Collaborative – Member**

Okay. All right, let me play around with that.

**Anil K. Jain – IBM Watson Health – Member**

Yeah, this is Anil.

**Andy Truscott – Accenture – Co-Chair**

Go, Anil.

**Anil K. Jain – IBM Watson Health – Member**

No, I was just gonna say, I think in a prior conversation we all had, we discussed this idea of "timely," and I think I can see it in both ways. I think having specific timing could be less confusing, but times change. I mean, what might be timely today may not be what's timely a year from now, or five years from now. And so, one of the concepts I thought we all discussed as a group was that it was going to be a little bit like what the standard of care might be in medicine, right? So, over time that changes. But if more of your peers were to think that this is timely, than it probably is. But if your peers—people that are similar to you, in similar industries or similar businesses—don't think what you did was timely, then it's not timely. But I think having a specific timing for some of these things, kind of makes the rule obsolete before it even launches.

Because I think that there was the intent of keeping some of these words vague and letting the community decide what could be considered to be timely or what could be considered to be adequate, for example, or things of that sort. That was something I thought we had discussed as a group, but maybe I'm confusing things.

**Andy Truscott – Accenture – Co-Chair**

Okay, so it's like leaving it a bit more open because there's going to be a need for interpretation in different situations?

**Anil K. Jain – IBM Watson Health – Member**

As long as it's our peers, our industry peers with whatever stakeholders we are, who are going to be making a decision about: what would the average person do in this situation; was it timely enough in the average more-often-than-not? Otherwise, I think it gets to be problematic for some of the same reasons that Arien spoke of earlier, that you miss it by a day on the SLA, well, that may be okay, but I think that the rule with a very specific number could be problematic for lots of reasons.



**Andy Truscott – Accenture – Co-Chair**

Okay.

**Valerie Grey – New York eHealth Collaborative – Member**

And then, on the requirement for identifying a reasonable alternative—I had a little bit of maybe a silly question—but when you read the preamble, and you look at the one-pager infographic thing, it says that “the actor must work with the requester to identify and provide a reasonable alternative means of accessing and changing or using EHI-comma-as applicable,” but the reg doesn’t have “as applicable.” And I wondered first, if there was any significance to that? And then secondly, I wondered if: are there instances where the recipient of a request for EHI wouldn’t actually know where a reasonable alternative would be? Or is it a fair assumption that as long as you’re holding EHI, that it’s really just – the whole thing is about which format and how it gets transmitted? I don’t know if I’m asking that in a very articulate way, but I guess first: is there any reason why “as applicable” shows up in some places and not others? And as it at all related to the question of maybe sometimes you just don’t know where an alternative – a reasonable alternative is?

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

Is that directed for ONC or the group?

**Andy Truscott – Accenture – Co-Chair**

Anybody who’ll answer.

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

I guess all I’d say is I think you’re right as far as – the reasoning behind when it is used is that there might be situations where it just isn’t applicable to have a reasonable alternative or to provide one. To your point about language and that clause being in the preamble and not in reg text, I mean I think that’s something that the group could recommend reconciling. There’s no reason it can’t be in reg text.

**Valerie Grey – New York eHealth Collaborative – Member**

And if it were in the reg text, it would be clearer that there are sometimes maybe instances where the recipient of the request would not know and could not actually identify and provide a reasonable alternative means. Am I reading more into it than I should?

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

Well, I mean, that’s probably more for the group; I can’t speak to whether it would be clear or not. But I think if you all think that it’s not clear that intention or that understanding of the clause and the preamble makes that clear, and you like the way it’s written there, I think that’s a fair recommendation.

**Valerie Grey – New York eHealth Collaborative – Member**

Okay, okay. And then, one last thing and then I have to hop off. But there was an observation and concern—which I generally agree with—that we want to make sure that startups with limited resources are not somehow given a pass from information sharing. And I was hoping just to – I mean, when I went through the documents, it seemed like multipronged test on substantial burden as well as a requirement for a response, identifying alternative means, having solid evidence. So, do we think that that will be enough to ensure that startups are – just because they’re startups and they’re new, they don’t get held to this very different standard? Or do we want to start to think about breaking up the Health IT developer/actor category between well-developed, and late-stage versus early-stage?



Which I thought might be kind of problematic given the way the rest of the reg is written. So, I was hoping –

**Andy Truscott – Accenture – Co-Chair**

Yeah, that feels being a little bit overly subjective and open to interpretation, and therefore confusion.

**Valerie Grey – New York eHealth Collaborative – Member**

Yes, yes. Agreed. So, I wasn't sure what we wanted to think about doing here? I mean, I think in a way, the way it's been set up it does reach the startups. The limited resources to me is just one of eight – I think eight different tests that they have to go through. So maybe it's okay. But I just wanted to raise it again and get some input.

**Andy Truscott – Accenture – Co-Chair**

Yeah, I think the concern is well-founded, and I think we should state it that we've discussed this, and we'd like ONC to consider how they would address it in enforcement. Because it feels like this is actually an interpretive enforcement issue, and it's not necessarily something that we can reasonably capture in regulation.

**Valerie Grey – New York eHealth Collaborative – Member**

Okay.

**Andy Truscott – Accenture – Co-Chair**

Because it's going to come down to how – and that's just my inclination.

**Valerie Grey – New York eHealth Collaborative – Member**

I think that –

**Andy Truscott – Accenture – Co-Chair**

Arien, Anil, what do you think?

**Anil K. Jain – IBM Watson Health – Member**

Yeah, I mean, I think that—this is Anil—I think one of the things that I've been thinking a lot about recently is—and I do a little bit of judging of innovation competitions in different communities— how do we actually promote interoperability as a competitive advantage for startups? So, the idea that we don't single them out and somehow give them a pass I think is important. And providing them the variety of different exceptions I think in the same way that a large company would be expected I think is fine, as long as we go back to the community standard. Whoever is going to review the complaints needs to look at it through the lens of that particular lens. But we should not be creating a mechanism by someone's definition of a startup is allowed to circumvent what I think is an incredibly important point, which is: we're trying to create interoperability within all the different players within the ecosystem. And startups should be –

**Arien Malec – Change Healthcare – Member**

Yeah, and I think the – yeah, sorry, I apologize.

**Anil K. Jain – IBM Watson Health – Member**

No, go ahead.



**Arien Malec – Change Healthcare – Member**

No, and I think when we get to the comments that I have on pricing, it's really I think supportive of that, which is trying to get at the problematic behavior that in fact impedes startups—I can remember being a startup and trying to interoperate with the HRs, and finding that my business model really, really was hard because certain actors wouldn't want to ball—but still provide the opportunity for organizations who want to add innovation to be able to do so and make money doing so. So, I do think there's a perspective that there are certain behaviors that are problematic no matter who you are—like being nondiscriminatory, for example, is a problematic behavior, or being competitively discriminatory is a problematic behavior.

**Andy Truscott – Accenture – Co-Chair**

Now, guys, I just want to mention –

**Arien Malec – Change Healthcare – Member**

I don't think we should create a safe lane for startups. I think we should make the rule more amenable to a wide range of ecosystem actors that provide innovation.

**Andy Truscott – Accenture – Co-Chair**

Which would be –

**Arien Malec – Change Healthcare – Member**

Because even IBM can do innovation.

**Anil K. Jain – IBM Watson Health – Member**

That's right, and I think the other quick comment I would say is that one recommendation we could have as a group would be to also say that if ONC or HHS is going to do a demonstration project or fund a demonstration project and they do work with startups, is that that interoperability ought to be a key criteria for funding. Because otherwise, I think we'll – we do need to push everyone towards this goal, not just those who can afford to go in that goal.

**Andy Truscott – Accenture – Co-Chair**

That's right, so guys, we have talked about this once before. Is our general consensus then that we leave this drafting alone, recognizing that—and we probably need a say—that we think this is going to come down to an enforcement issue, versus something which needs to be somehow tailored regulation for different types of organization?

**Arien Malec – Change Healthcare – Member**

I would generally want to reduce the burden and create clarity for the infeasibility exception. And my hope, in general, is that the other comments that we have on providing a safe harbor or a safe lane are another way of addressing some of this issue of infeasibility.

**Andy Truscott – Accenture – Co-Chair**

Okay. And that's – yeah, and that's been touched upon as well. Guys, I just want to put into your ear while we're at this juncture because I think it's pertinent—and it's come up in conversation in workgroup-one, so it's going to be all up in conversation with the entire task force—is around the scope of the regulations and the actors which are covered. And obviously, there are four discrete actor types which are mentioned by name inside the 21<sup>st</sup> Century Cures: so you've got health information



exchanges, health information networks. The Health IT providers of Certified Health IT and – sorry, Health IT developers and Certified Health IT, and providers.

And something we have been discussing in workgroup-one—and we’re going to talk about in **[inaudible] [01:01:29]**—is about whether – where we talk about Certified Health IT developer, we are inadvertently leaving a place for those developers who don’t want to get certified, have no need to get certified. And one of the use cases that’s been discussed is around app developers where you’re developing smaller mobile apps, and they don’t get certified. You could potentially fall outside many of these other regulations because you’re not a developer or Certified Health IT.

**Arien Malec – Change Healthcare – Member**

Is that an ONC problem, or is that a congress problem?

**Andy Truscott – Accenture – Co-Chair**

Aren’t they one and the same?

**Arien Malec – Change Healthcare – Member**

Nope. ONC only has the authority that Congress provided it and –

**Andy Truscott – Accenture – Co-Chair**

Yeah, you’re right there. Yeah, the actual...yes, you’re right, the legislation I think says “Certified Health IT.” And we’re trying to wrap our heads around: well, when the legislation was written that was the game in town, and Health IT developers have moved on profoundly since that point in time. And actually, we have a different vendor ecosystem to look at potentially than what there was then. And yes, ONC can’t do anything outside of what the legislative powers it gets given. But whether there’s a question that ONC can ask Congress about, “Actually, do you want to broaden this out?” Potentially. And that’s one to think about. Because we do have the – if you are the developer of a single certified application, then all new applications and the scope for information blocking, so there is the implication that we want to be broader than we can, so if we were to recommend ONC could go and look at this with congress then that might be helpful.

**Arien Malec – Change Healthcare – Member**

Yes. Agree. And it does create a net disincentive to have certified products, which is a little odd.

**Andy Truscott – Accenture – Co-Chair**

Oh, it absolutely does. And that whole thing about you can have one product and therefore all yours are covered, that’s just a strange-ism. I get why, but it’s just – yeah, and you’re right, it adds disincentives. And also, there are some pretty big platforms coming down the pipe—which they’re not going to be certified— which then contain significant volumes of EHI.

**Arien Malec – Change Healthcare – Member**

Mm-hmm.

**Andy Truscott – Accenture – Co-Chair**

Okay, I’ve digressed slightly. Valerie has dropped, I believe. But when we’re talking full task force, we’re going to be touching upon that scope and issue, or we’re going to need to. I think those are the areas that people want to go to. Arien, have you – I’ll ask you – I’m sorry **[inaudible] [01:05:04]**, Anil



with the drafting that you're doing, have you got any questions around the regulations you're looking at that you want to just share with the group?

**Anil K. Jain – IBM Watson Health – Member**

I've been heads-down in two conferences back-to-back. And so, my plan is to do a little bit of that this afternoon and tonight here in California, and then on my way back to Cleveland tomorrow, so if I do I have them, I'll email the group. But right now I don't; I don't have any questions –

**Andy Truscott – Accenture – Co-Chair**

Okay, that's fine.

**Anil K. Jain – IBM Watson Health – Member**

– in those two areas that....

**Andy Truscott – Accenture – Co-Chair**

That's fine, no worries. Arien, have you got any questions that you're looking for clarity from the group?

**Arien Malec – Change Healthcare – Member**

Well, I would love it if people could read the language, and I really appreciate that Valerie read the language and had a bunch of comments on it. On pricing, I tried to take the discussion that we had that we agreed on, and manifest itself in clear recommendations, and I know from history that my attempt at getting that right the first time is limited. So, I would really, really, really love for people to read what I wrote, and think about it, and think about whether I solved the problem that we articulated as a sub-workgroup.

**Steven Lane – Sutter Health – Member**

And this is all in the Google Doc, Arien?

**Arien Malec – Change Healthcare – Member**

Yeah, it's all in the Google Doc.

**Andy Truscott – Accenture – Co-Chair**

Yep. So, Arien –

**Arien Malec – Change Healthcare – Member**

And the way that I did it, by the way, since we recommended combining the pricing into one section, is I put it all under 204. So, if you look in 206 and wondering where all that stuff is, I just mashed it all into 204.

**Andy Truscott – Accenture – Co-Chair**

Okay. Arien, were you going to make an attempt at actually drafting the regulation, or were you going to leave it as a narrative commentary?

**Arien Malec – Change Healthcare – Member**

I put in a set of recommendations. I generally feel like I should leave the reg text itself to the reg-writers, but provide...as you know, in the past we've thrown some language back-and-forth, and it just



gets confusing. I'd much rather stay at the level of intent and goal, and let the reg-writers do their thing.

**Andy Truscott – Accenture – Co-Chair**

We're not holding back elsewhere, just so you know.

**Arien Malec – Change Healthcare – Member**

Put Lipinski on it and let Lipinski do his magic.

**Andy Truscott – Accenture – Co-Chair**

Okay.

**Steven Lane – Sutter Health – Member**

Arien, you're amazing. I have to tell to you. This is incredible.

**Andy Truscott – Accenture – Co-Chair**

What? The content?

**Steven Lane – Sutter Health – Member**

Yeah.

**Andy Truscott – Accenture – Co-Chair**

The thought or the plaudit? Oh, no, it's amazing content, I agree.

**Arien Malec – Change Healthcare – Member**

It is almost certainly confusing, and almost certainly wrong in areas, and please read it. I'm blushing over here.

**Andy Truscott – Accenture – Co-Chair**

That's okay, it's good. I've always said you're amazing, but I think it's a good concept.

**Arien Malec – Change Healthcare – Member**

[Laughs] I love you too, Andy.

**Andy Truscott – Accenture – Co-Chair**

Oh, I meant it with all the love in the world. Okay, cool, so we've got that to go to as well. Are there any areas which nobody is touching?

**Arien Malec – Change Healthcare – Member**

I'm sure there are. I've had blinders on; I might do a pass prior to our meeting next week to see if I can't just do a sweep-through.

**Andy Truscott – Accenture – Co-Chair**

Okay. Fine, thank you. I'm going to go through some of the other ones which we've got. Just so you know, we're trying to by next week get all the content pulled into a single document that has a current document of the reg text, proposed redrafting as appropriate, and/or recommendations—plus any discussion points, et cetera—across everything we were tasked with working through. Just so you guys know that's going on, so these kinds of documents we're working on will be retired, and [inaudible]



[01:09:35] get their comments into it, that's going to – that will be the basis for the next draft. If no one has any commentary, I'm happy to say that we – Lauren, we could actually open up for public comment.

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

Sure. Let me pull up the prompter.

**Operator**

If you would like to make a public comment, please press \*1 on your telephone keypad. A confirmation tone will indicate your line's in the question 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 star keys.

**Andy Truscott – Accenture – Co-Chair**

Thank you. So, Amazing Arien, have you anything else that you want on any of the other ones you would like to go and look at? Or do you feel that you've contributed very meaningfully?

**Arien Malec – Change Healthcare – Member**

No, I'm more than happy if you point – if you point me at something I'm more than happy to go vector in.

**Andy Truscott – Accenture – Co-Chair**

Okay, so...yeah. The request for information on disincentives for healthcare providers. We've touched upon that but haven't really had I would say meaningful discussion to pull together clear recommendations. Is that something you could start to go with?

**Arien Malec – Change Healthcare – Member**

Sure.

**Andy Truscott – Accenture – Co-Chair**

I think something that's worth picking up inside there would also be where a provider could also be considered a health information network.

**Arien Malec – Change Healthcare – Member**

Yep.

**Andy Truscott – Accenture – Co-Chair**

And how we could actually give some guidance on how that should be considered.

**Arien Malec – Change Healthcare – Member**

Okay. Let me grab some time tonight and do a pass.

**Andy Truscott – Accenture – Co-Chair**

Thank you, sir.

**Arien Malec – Change Healthcare – Member**

Or just leave work and go home, and work from my home so I can actually get access to the document.



**Andy Truscott – Accenture – Co-Chair**

That's a good excuse.

**Arien Malec – Change Healthcare – Member**

Oh, data loss prevention [chuckles].

**Andy Truscott – Accenture – Co-Chair**

Yeah. Okay, any questions on the line?

**Operator**

There are no comments in the queue at this time.

**Andy Truscott – Accenture – Co-Chair**

Okay. On that basis, we'll let Steve go back to his conference. I'm going to start working on some things as well...we can all get 45 minutes of our day back.

**Steven Lane – Sutter Health – Member**

Sounds good.

**Michael Adcock – Individual – Co-Chair**

Thank you.

**Andy Truscott – Accenture – Co-Chair**

Mark –

**Anil K. Jain – IBM Watson Health – Member**

Thank you.

**Andy Truscott – Accenture – Co-Chair**

Mark, Lauren, any comments as we sign off?

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

No, that's it for me. Thank you all.

**Andy Truscott – Accenture – Co-Chair**

Okay.

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

Nope, that's good.

**Arien Malec – Change Healthcare – Member**

Thanks, everyone.

**Andy Truscott – Accenture – Co-Chair**

Thank you, guys. Thanks, team.



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

Thanks, bye-bye.

**Andy Truscott – Accenture – Co-Chair**

Take care.

**Michael Adcock – Individual – Co-Chair**

Thank you.

**Arien Malec – Change Healthcare – Member**

Bye-bye.