

Transcript
April 5, 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
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member
Cassandra Hadley		HITAC Back Up/
	Office of the National Coordinator	Support
Mark Knee	Office of the National Coordinator	Staff Lead
Penelope Hughes	Office of the National Coordinator	Back Up/ Support

Operator

Thank you, all lines are now bridged.

<u>Cassandra Hadley – Office of the National Coordinator for Health Information Technology – HITAC</u> Back Up/ Support

Thanks, and welcome to the Information Blocking Workgroup call and exceptions. We will continue our discussion today focusing on the rule recommendations. I will call the meeting to order now. We have with us Co-Chair, Andrew Truscott. Michael Adcock will be with us in a moment. We also have members Anil Jain and Arien Malec and we should have more joining shortly. But I'll turn it over to Andy right now.

Andrew Truscott – Accenture – Co-Chair

Thank you, very much indeed. Good afternoon everybody. Happy Friday. Welcome to... I think it's the last meeting of this task force this week. We're going to kind of step through the feedback that's being provided. Mark, could you bring your screen across?

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> Yeah, it should be up there. Do you guys see it?

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

No, it's just getting there. Move your mouse quicker. There we go. Okay, so I was going to propose our walking through the drafting. I think all the members have done a really good job of pulling together our discussions and reflecting the consensus across the workgroup, and this is very helpful, indeed. Shall we step to it? I think Anil, you drafted this one?

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

I did, and I already see a typo that I thought I had fixed. So, I think the bottom line on this one is that it's a very important exception to include because oftentimes we are dealing with the real-life use of technology and there could be any number of reasons why the data may be inaccurate. The patient's data that has been merged within the record is known to be the wrong patient, or the provider, who is taking note to take care of their patient, somehow finds that sharing that information could put their patient or someone else in harm's way. So, I think this exception is important. Our particular workgroup, when we are sort of reporting out to the committee, I think really focuses on a couple of different aspects.

I'm not going to read this word for word here, but I think that we are focused on making sure that the words 'corrupt data' replies to a technically corrupt aspect of the data rather than the inability to interpret the data, which may have everything to do with not having implemented standards, or using inappropriate software, or a wide variety of different things. If you scroll down, I think the best way to really talk about this would be to talk about the recommendations and then go back and explain why. One of the comments that the group had really focused on, which actually applies to multiple areas... and being an MD and not a JD, I think one of the comments that I find sometimes...that it is hard to know whether the text is referring to any of the following or all of the following when it comes to

requirements of conditions. We suggest that perhaps we ought to say that in bullet A.) that we ought to say "arising from any of the following conditions" before listing out the conditions themselves.

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

Anil, so we're clear, what you mean is any one of these, not all of them. It can be any one of them.

Anil K. Jain – IBM Watson Health – Member

It can be any of the following as opposed to all of the following. There are other parts of the regulatory text that could be enhanced to do this, but if it's about consistency than there are other areas. But specific to this exception, this is one recommendation we would make.

Arien Malec – Change Healthcare – Co-Chair

I think we should make this as a general recommendation because it's pretty broad in its intent. And so, I think we should contemplate having a general comment that regulatory text should consistently say any of the following, or all of the following.

Anil K. Jain – IBM Watson Health – Member

Yes, I think that is well said. I think the next item...we talked a little bit about the word corrupt and maybe thinking about it as technically corrupt data, and others in the workgroup that were involved in that conversation, please chime in if I've misremembered or mischaracterized any of our conclusions as a group. But one of the other comments that we discussed was why is it only about recording and incorporating into the EHR? I think what we discussed was any time we feel, or the user feels, that the data being accessed in the patient's electronic health record that is going to be used for access exchange or use, any time that happens, if they feel it is technically corrupt or inaccurate, that they should be allowed to use this exception to not share the data downstream because it would cause harm by definition.

Arien Malec – Change Healthcare – Co-Chair

I think in this case you did misunderstand the intent of the workgroup. Or maybe I'm reading this the wrong way. I think there is a principle that says if an item is part of the legal medical record, part of the designated record set, etc. even if it is thought to be not correct, the remediation is to correct it, not to not share it. And patients have a right to correction and the like, but this exception should be broad enough to, in cases where data is non-interpretable or obviously garbled, doesn't meet base sensibility requirements...that this exception should apply in those cases.

Anil K. Jain - IBM Watson Health - Member

Okay. Arien, I think that's fair. In the discussion section, I think I do mention summarizing our thoughts on uninterpretable data, but I did see comments from our group around thinking about it being technically corrupt versus just having corrupt data. And also comments around word choices around record and incorporating into the EHR versus thinking about the actual downstream intent of access exchange or use. Maybe I've misconstrued it and I'm happy to go back and review it so that we have the right language. But what I was trying to do was incorporate comments from two or three different discussions that we had on this particular item. What you're describing is discussed. It's in the discussion section and I also make comments in the preamble text recommendations to put some

examples, because I think one of the comments about uninterpretable data is – that's a good one. I just don't know whether that fits the definition of corrupt. Because if it's not interpretable because I haven't implemented a standards way of looking at what those codes mean then, it could be a challenge. But I'm happy to relook at this within the context of what you just described.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

A practical example of where systems that I've had oversite for or managed to do this is where, for example, you are trying to interpret a consolidated CDA and the data that's incorporated in the consolidated CDA is non-interpretable as a medication because it's not actually adhering to the standard and it's missing, for example, a medication name or medication code or anything that would allow it to be actually inserted as a valid medication. Those are the cases that I am referring to by non-interpretable.

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

So, normally when we talk about data corruption, we normally say we use it in terms of data that has lost its base integrity and is no longer understandable by the system that created it.

Anil K. Jain – IBM Watson Health – Member

I think that is a valid definition, yes.

Andrew Truscott - Accenture - Co-Chair

Because it could well be not understandable by the downstream system simply because the downstream system doesn't understand the semantic it was authored at...a bit of a different issue. It's when the creating system no longer understands it. So, Anil, it might work just picking that up and trying to incorporate that in. Is that okay?

Anil K. Jain – IBM Watson Health – Member

Yes. Sure. And also look at the discussion text. I do make comments about noninterpretable and if that's not sufficient I'm also happy to look back at that and review my notes and then review the comments that had been made on this document to summarize that, but sure, absolutely.

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

Cool. Well, I'd almost pick up that text and insert it where you've got technically corrupt.

Anil K. Jain – IBM Watson Health – Member

Okay. All right. If you can make a note of that so that I remember to review that, that would be great.

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

Lshall.

Anil K. Jain – IBM Watson Health – Member

Or I can even do it on the document.

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

I can do that for you, Anil.

Anil K. Jain – IBM Watson Health – Member

All right. Let me move on to the third item on the list. One of the areas where we thought that it would be important is that if you are going to use this exception to engage in this practice of not sharing because you believe that it would cause harm. Then that reasoning, that judgment why the user should be documented in the electronic health record by the appropriate user, and then, the reasoning that was used must be contained within it. And then, which criteria was used and so on. Otherwise, I think you run into a challenge where you can't understand why the information wasn't shared and no one can get back to the trail of what led to it and that could cause unintended consequences. So, having that documented within the EHR is important by the user. And then, making that available by the vendor so that it could be used subsequently, I think is important too.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

We are not always talking about cases where the data are contained within an EHR. It could be within an HIE, an HIN, or another system. I can't see the recommendations at this point because of the...

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> Yes. Sorry, I lost the connection for some reason.

Anil K. Jain - IBM Watson Health - Member

Yeah, that's a good point Arien. I think in some areas of this particular rule they do talk about within the patients' electronic health record. But you are right, in other areas they just talk about their EHI. So, I can certainly change the language to make sure that gets reflected. Is that what you are referring to?

Arien Malec - Change Healthcare - Co-Chair

Yes.

Anil K. Jain - IBM Watson Health - Member

Okay. So, for system recording the EHI. All right. The fourth bullet...do you guys want me to wait until the screen comes back?

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> I should have it up in a second. Sorry about this.

Andrew Truscott – Accenture – Co-Chair

Mark we need to sort out your IT.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> I'm having some real issues here.

Andrew Truscott – Accenture – Co-Chair

You're information blocking.

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

I think it is more of the product of working for the government but...what the heck? Katie, someone else might need to share their screen. I'm having issues clicking on the link. There we go. Great. Almost...

Anil K. Jain – IBM Watson Health – Member

You want me to keep going? Can you scroll down?

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> Yes. It's like frozen again.

Anil K. Jain – IBM Watson Health – Member

Okay.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> Yes, that is too far.

Anil K. Jain – IBM Watson Health – Member

Too far. That's good to know I am not the only one with technology problems once in a while.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u>
No. I have been having them quite a lot. All right. There we go.

Anil K. Jain – IBM Watson Health – Member

Okay, I added the 'need to define corrupt' under there and I also added on Number Three I added 'in the EHR or system recording the EHI'. Arien, is that...?

Arien Malec - Change Healthcare - Co-Chair

Yes, I think it's perfect.

Anil K. Jain – IBM Watson Health – Member

Okay. All right. So, No. Four is really about bullet B.) where...and I didn't even recognize this until we as a group started discussing this, but the language appeared to be confusing because the word practice was used in the same line as thinking about organizations. And I think the team wanted to make sure that we specified that the word practice in this particular item refers to the information blocking activity potentially occurring under the exception. And then, we recommended rephrasing it 'if the practice referring to the permissible information blocking activity relies on an organizational policy, the policy must be'. And if we want to go back to B.) to see what that would look like, we can do that. If you scroll up a little bit you can see how B.) might be a little confusing in the way it is currently written. So, it says right now, "if the practice implements an organizational policy, the policy must be". So, it can be confusing that some people may think the word practice is referring to a physician group practice or a group of providers as opposed to the potentially permissible information blocking activity and... any questions on that? It is just a clarification to the text to make it easier to understand.

Andrew Truscott – Accenture – Co-Chair

Yup.

Anil K. Jain – IBM Watson Health – Member

Okay. All right. No. 5 is recommending that we add a sub-item under B.) that the existing organizational policy should be reviewed for consistency with these regulations in order to prevent confusion and undue burden to providers who are going to be struggling to understand how their organizational policies, that may have been written in a time that predates these rules, get implemented and how they can leverage them. So, it's simply to say, as we have in other places in regulatory text, recommending that agreements be revisited. We're recommending that the organizational policies be revisited in order to be consistent. Otherwise, I think providers could have an undue amount of confusion and that could have a detrimental impact on patient care.

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

That makes sense. That seems to be consistent with what we agreed.

Arien Malec – Change Healthcare – Co-Chair

So, I kind of have...I think that's fine. As far as how that would work, it should be reviewed... is that by ONC? And I guess...

Anil K. Jain - IBM Watson Health - Member

The organization...most organizations, when they have organizational policies, have standing reviews of those policies and they have varying rules around how often those policies need to be revisited. But the organization that has the policy needs to review, and if we need to rephrase my recommendation to make it clear, it should be reviewed by the organization... sorry, I was about to write at the same time. Yes. So, it should be reviewed by that organization

Arien Malec – Change Healthcare – Co-Chair

Okay great, that helps. I just wanted to be clear.

Anil K. Jain – IBM Watson Health – Member

Okay and then the only other thing, and I think we discussed this once within our group around the preamble. And again, I apologize to the group if I misconstrued the nature of the conversation, but we did discuss a little bit about where this particular exception may interact or interfere or relate to other exceptions. And I if I recall correctly, we talked about how when would this particular exception be applied given the fact that it may not be feasible, and when would the exception for feasibility apply when we talk about data, and inaccurate data, and the inability to share because of those inaccuracies. And to me that there is a potential for there to be some confusion between those two. If it is clear to everyone else that is great, but because it could be that once the data gets corrupted, or if it is the wrong patient, it is not feasible to share, especially around patient matching. Then when is one to use this versus the infeasibility? And I would ask my fellow workgroup members to either say yes, this is what we were thinking, or no, this is not necessary. Okay. So, do we agree that we need some language in the preamble to help clarify which condition one might use?

Arien Malec - Change Healthcare - Co-Chair

I have a general preference that if we need clarification it should be in the regulatory text itself and that the preamble should be used for explanation, background, examples, and the like. So, if the regulatory text is confusing to read, I have a preference that the clarification be in the regulatory text itself.

Anil K. Jain – IBM Watson Health – Member

I agree with you that in some cases it is not clear where...so one of the examples that I have given is an example of a perfectly valid consolidated CEA being sent from a...so in our HIE activity a completely valid consolidated CEA being sent on auto-repeat from a physician or a hospital. And I think I put... maybe I didn't actually get this into the comments when we reviewed. We can remember if I got this into the comments on preventive maintenance, but I should be allowed in those cases where I've got effectively a denial of service attack to not exchange the data and not be an information blocker. I don't think that's an area of data corruption, I think that's an area of maintenance. And I should be clear when I am taking an action that is allowable and permissible, which exception I am falling under.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Okay. Maybe just to help me if I'm going to summarize that we can through that example...it's a good example...into our discussion thread above and we could throw that in there. Right now as a place holder I said, "Just recommend adding clear guidance of when this exception should be used versus the exception for infeasibility," and then we'll build that one up.

Anil K. Jain - IBM Watson Health - Member

Yeah, infeasibility and maintenance would be another one.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Right, that was the other one.

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

Anil, you know I have a preference when we're going through these if we can draft some proposed regulatory text. I personally prefer that because I think that removes some of the ambiguity from our 'suggest you look at this then suggest you look at that'. So, if that is helpful, then feel free to. If it's too much, then don't, obviously.

<u>Anil K. Jain – IBM Watson Health – Member</u>

Well, I am a lot more comfortable writing a prescription that I am writing regulatory text. So –

Andrew Truscott - Accenture - Co-Chair

That's fine. That's fine.

Anil K. Jain – IBM Watson Health – Member

Yeah, I mean I'm happy to do it, but I think it's just going to be more work for the next person who looks at it and says, "What the heck is this?" I think the recommendations, if they're not clear, I'm happy to work on them further. And I think Arien's example...I think I could put it into No. 6 in a way

that does what he's said. I think he is right. I think we want to clarify the regulatory text as much as possible, but I do think the preamble gives real-world examples of how this would be applied, and that's going to be important for people when they start to interpret these in the real-world setting... what degrees of freedom they might be looking at these with. Otherwise, I think the regulatory text may be too unwieldy for all the permutations, but that's just my thought.

Andrew Truscott - Accenture - Co-Chair

Yes, and that's a good comment too, especially in this section. I think other sections it's a bit easier, but this section is probably harder to do that. And Incidentally, you don't just willy nilly write prescriptions do you?

Anil K. Jain – IBM Watson Health – Member

Say that again? I'm sorry what did you say.

Andrew Truscott – Accenture – Co-Chair

I said you don't willy nilly...maybe that's an Englishism too far...write prescriptions. Anyway, moving on.

Anil K. Jain – IBM Watson Health – Member

Well, if you need anything, I'm happy to write you a prescription anytime, Andy. For almost anything... no, I'm kidding.

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

Moving on rapidly then.

<u>Arien Malec - Change Healthcare - Co-Chair</u>

We did not hear that comment.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> We did not.

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

Actually, the caption did pick it up. All right. Did you do the next one as well? The privacy...?

Anil K. Jain – IBM Watson Health – Member

No, I don't...that was not assigned to me, but I'd be happy to weigh in...

Andrew Truscott - Accenture - Co-Chair

No, let's just go to the suggestion.

Valerie Grey – New York eHealth Collaborative – Member

Hey, Andy, it's Val. I just wanted to let you know that I joined.

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

Hello ma'am, how are you?

Valerie Grey - New York eHealth Collaborative - Member

Good.

Andrew Truscott - Accenture - Co-Chair

Okay, so, who got privacy? Mark?

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

I think it might have been Stevens. I think he got privacy and security.

Andrew Truscott – Accenture – Co-Chair

Okay. Let's move on. Anil, what was the next one you did?

Anil K. Jain – IBM Watson Health – Member

Well, I was on the plane yesterday...I was about to do the next two that were assigned, but they had already been done. And based on the language, it looks like Arien did them. Yes, the additional exceptions that we should be thinking about which we discussed, and I thought his write...I'm assuming Arien you did those. I thought it was beautiful and it encompassed our discussions and the one on...I think the...what was the other one? The third one was...the other RFI one...

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Provider disincentive? Was that it?

Anil K. Jain – IBM Watson Health – Member

Yeah. Provider disincentives. Yes. And again, there is nothing that I could do to add to what Arien did masterfully in terms...not only of summarizing what we thought but clarifying in ways that...it's well-written.

Andrew Truscott - Accenture - Co-Chair

Okay. Is it worth us bumping down then to new exceptions and healthcare providers? I do want to, before we finish today, I want to spend time on...Arien, I want to look through your most excellent prose around the fees and I would like us to have a quick discussion about actually how we want to propose this up.

<u>Arien Malec - Change Healthcare - Co-Chair</u>

Valerie had some really good questions that hopefully I explained, but then I want to make sure that the words I wrote actually match the explanation that I did. I think they do, but if what I read wasn't self-explanatory to Valerie, it means that somebody else is going to misinterpret it as well. That is on me.

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

Okay. Shall we jump down to new exceptions? Quickly go through new exceptions and then I do want to discuss the request for comment on the information blocking complaint process to make sure that

any of our thoughts go into that because we have done nothing on that so far, and then we will go to the fees.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Yes. The intent here was to note that much of the preamble discussed contracts by presumably EHR vendors doing bad things that implement information blocking. There are many, many cases where BAA's or BA's are confined by BAA terms. I came across a great one in conjunction with legal counsel not to be named where we had access to pricing transparency information and we actually had BAA [inaudible] [00:27:06] agreements, but we were sued by an actor, a noncovered actor, through information blocking regulation because it was felt that it conflicted with the confidentiality provisions we had in our agreements. And that is another case where we would have been in the middle of adhering to a contract and adhering to information blocking requirements.

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

So, let's pick up on that one specifically because Mark, we have addressed that in one of the other workgroups, right? Workgroup three?

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> Yes, I think so.

Andrew Truscott - Accenture - Co-chair

Yes. We put wording in there around any contract which, Mark keep me on the straight and narrow, but basically saying any contract that contravenes the information blocking divisions, that those contraventions are immediately unenforceable.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u>
Yes, but it might be worth... I was going to say it might be worthwhile, to be clear, I think what we're talking about, Andy, is in the communications conditions and certifications.

Anil K. Jain - IBM Watson Health - Member

Yes, a little more general.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> So, that's specific to the...it is probably worth noting again if you want to make a recommendation.

Anil K. Jain - IBM Watson Health - Member

I probably should add to this section in the discussion area other contractual terms including confidentiality etc. where it's not the actor themselves who are putting the contractual requirements, but it's an upstream actor pursuant to BAA's. And the recommendation, really for ONC, is to make it clear either to add a contractual exception, or what I think is the preferred option is the notion of making contractual terms that conflict with information blocking provisions unenforceable. This is an area where I think ONC should be in consultation with OCR relative to HIPPA and data use agreements, and an area where we want to make sure that we have clear language on preemption or precedence.

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

Yes, and we have been working closely with OCR and we will continue to do so. I guess my question to you, Arien, and to the group is I think both those options, they're sensible options, but based on the conversations I remember it seems like...did anybody in the group, were they in favor of an exception for BAA?

Arien Malec – Change Healthcare – Co-Chair

I don't think anybody was in favor of an exception. I believe that the preferred option is preemption, but I also am stating that from the perspective of being primarily a BA and not from the perspective of being a provider organization, or payer PDM, or other actor that is not covered by information blocking that cares deeply and meaningfully about the data use rights, terms, or confidentiality terms that they've included in the contract. It's a reflection that I think is the sense of this task force that preemption is the right approach, but a reflection that other actors and stakeholders may feel very strongly about this area. So, I'm trying to be fair. I think in the spirit of information blocking, it's the spirit of this task force that preemption is the right approach.

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

I guess all I'd say to that is...well, 1) this is the recommendation for this task force. So, if no one represented...it feels that way, then I'm not sure...and also, if you do put that forward it would be helpful from our perspective to understand what that exception might look like. Because as I've said repeatedly, we have been very clear that contractual terms should not be used as an excuse for information blocking and will not be allowed. So, I would be curious what would be in that exception to kind of fit within that construct.

Arien Malec – Change Healthcare – Co-Chair

I think the task force would want to recommend and test this out...the task force would want to recommend that ONC be clear about preemption in areas where contractual terms conflict with information blocking requirements in particular, but not limited to BA's who may be confined by BAA terms.

Andrew Truscott – Accenture – Co-Chair

Arien, do you think that the ONC has not been clear about the intent there?

Arien Malec – Change Healthcare – Co-Chair

I do not believe that ONC has been clear about the intent. I did take the time to look through every mention of the word contract in the preamble, and all of the examples there refer to contracts where the actor themselves is the contracting party and where the terms are part of the actor's contracts. So, it's things like non-competes or restrictions on sharing intellectual property that can be construed as sharing screenshots and the like. But this particular issue of BA's confined upstream and downstream by terms that were explicitly put by the counterparties is not discussed and I don't think it is clearly represented. Our legal counsel essentially comes out I believe, I don't want to speak for him or her, but comes out on generally the same perspective and thinks this is the right outcome but does not believe that the regulatory text is adequately clear.

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

So, with respect to this conversation we did definitely talk about BAAs and we did definitely say in there that BAAs would require rediscussion within a timeframe. I know it is in the communication section. We should probably go back and look at that as well as try to make these all line up, at least so we have consistency.

Arien Malec – Change Healthcare – Co-Chair

Can we go to regulatory text recommendations? Because I think I was weasely and edgy because I didn't want to... deliberately because I know there are multiple parties. So, I think we are recommending explicit clarification and the simplest solution would be to preempt and maybe we can just strike the last sentence?

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

Does that work?

Arien Malec – Change Healthcare – Co-Chair

Yes.

Anil K. Jain - IBM Watson Health - Member

This is Anil, I think this is good. A quick comment on...again, not being a lawyer, but if... I sometimes will see language in our agreements where if any part of that agreement is in conflict with existing law that the entire agreement needs to be renegotiated or redone. It's basically invalidated. Is that...what we are writing here about preemption, which I think makes sense, is that going to force a flurry of activity of having to renegotiate or rewrite these BAAs or any other agreement that would deal with this issue in ways that could create undue burden? Again, I'm not sure how to write it any better than it is now, but I'm just putting it out there as a potential unintended consequence because if you preempt certain parts of that agreement, then once it's claimed that there are other parts of that agreement, that made them fall apart.

Andrew Truscott - Accenture - Co-Chair

We definitely had this conversation in communications because we actually went and looked at the burden that we placed upon contractual parties having to do all this renegotiation and we considered that the estimation of burden was probably underestimated for obviously when we had done that review, and we needed a longer time period for the renegotiations to be undertaken. Mark, I think that sums it up, doesn't it?

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

Yes, I think that is right. If I'm hearing what Anil is saying is maybe there would be some kind of clarification in your recommendation about how... similar to what we did, or you all did in communications as far as clarifying what would happen with those contracts. I don't want to put words in your mouth...

Anil K. Jain – IBM Watson Health – Member

Yes.

Andrew Truscott – Accenture – Co-Chair

Could we mix all of these two that are in lock step with each other between the two workgroups because they're going to come together under the task force? So, it would be prudent of us to make sure that they are saying the same thing and consistent with each other?

Anil K. Jain – IBM Watson Health – Member

Can I play devil's advocate a little bit and say...? I agree with what you just said, but this is under a section called additional exceptions, right? So, if we are saying that we do not think you need another exception, should we say that explicitly and say, "We do not need another exception around this to basically be proactive and say" —

Andrew Truscott - Accenture - Co-Chair

Yes, that is the point. That is a good point. We're sitting here discussing something we're all agreeing we don't need, and we want to say something else. So, Let's say we don't need it.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u>
Do you want to add that in, Andy? Are you able to do that?

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

I am just rebooting.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead I can... I mean I can do it. I don't want to type at the same time. But I will let you do it.

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

Arien, is that okay with you?

<u>Arien Malec – Change Healthcare – Co-Chair</u>

As long as this discussion ends up somewhere in our recommendations I don't particularly care where it goes. I do think that's the sense of the workgroup is that we...this was the one thing that we discussed, and this was the solution that we proposed addressing for it.

Andrew Truscott – Accenture – Co-Chair

Arien, can you do me a favor and look at the workgroup three drafting where this is discussed and just see whether that sentiment is aligned with the thinking here.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Can you point me to workgroup three material?

Andrew Truscott – Accenture – Co-Chair

Yes, I can. Can someone from ONC who is on the phone just send Arien the link to the workgroup three document, please?

<u>Mark Knee – Office of the National Coordinator for the Health Information Technology – Staff Lead</u> I can also pull it up on the screen potentially.

Andrew Truscott – Accenture – Co-Chair

Okay, go on then. I was going to give Arien homework.

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

But then if you guys want to keep moving on, then that's fine. This might take a minute.

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

Okay.

Arien Malec - Change Healthcare - Co-Chair

Let's keep going and we can give it to me for homework.

Andrew Truscott - Accenture - Co-Chair

Mark has already moved so we've lost the text.

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

All right, let me go back to the old document.

Andrew Truscott - Accenture - Co-Chair

Okay Arien, we'll get it to you offline. Okay, I think Anil's point is a good one. We do not propose any other exceptions.

Valerie Grey - New York eHealth Collaborative - Member

Hey Andy, it's Val. Could I just go back to one concept, and I can't remember where it was or where it would reside in all of this, but we had talked – I am sorry, I'm traveling so my reception may not be great. At one point we had talked about...ONC had asked should TEFCA be an exception? And I think that the group's thinking on that was that it is hard to say. It should be an exception when you don't know what 'it' is yet.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

We might want to go to that section because I did put some verbiage around that to react to.

Valerie Grey - New York eHealth Collaborative - Member

Okay.

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

Because we were talking about if you complied with TEFCA then you would, therefore, be effectively in a safe harbor.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Right. And so, I believe the sense of the discussion that we had is that we don't know what's in TEFCA, so it is hard to particularly point to a common agreement. But it was the sense of the workgroup that an affirmative set of obligations that should be presumed to address information blocking requirements would be helpful to help actors move in the right direction.

Valerie Grey – New York eHealth Collaborative – Member

Okay. Yeah. Because what I was trying to figure out...and I have had a lot of hats in my life. My current hat is HIE, but I think to myself without knowing what the TEFCA requirements are going to finally be and some of those...like TEFCA contemplated HIEs being required to share information for HIPPA permitted purposes. Some of that might not fit into all of the information blocking. I wondered what happens in the interim? Is that something to think about?

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Yes, the way that I tried to address that in these recommendations is to say that it was the sense of this workgroup that an affirmative set of obligations that would be deemed or presumed to meet information blocking requirements would be a good thing without pointing to something that doesn't currently exist or may have to go through another couple of rounds of specification.

Valerie Grey - New York eHealth Collaborative - Member

Okay. I totally agree with that recommendation. I just hope it is taken up... I guess because in between there will be a total lack of clarity about what HIE rules should be followed and all of that jazz. You guys know that.

Arien Malec - Change Healthcare - Co-Chair

Yes.

Andrew Truscott - Accenture - Co-Chair

So, before we move off of this one, Arien, for trade on the IPR licenses for the terminology techs, etc., What was your sentiment there?

Arien Malec – Change Healthcare – Co-Chair

So, I think it is better expressed in the pricing recommendations, but there are...among the many, and maybe I just need to take another pass at this language and broaden the set of contractual terms an intermediary, a BAA, might be a party to. There are...this issue of upstream and downstream requirements or flow down requirements is pretty common, and as an example of one of those requirements, I might...and name your terminology vendor here... I might be a licensee to a terminology set that does not allow me to exchange information with a counterparty who isn't already a licensee to that information. Again, that could be a case where I would be in conflict with my information blocking provisions and my contractual provisions. That is a specific area that when we get pricing, I think would be in the language that I proposed an exchange or use essential IPR, and so we would need to be licensed on a RAND basis.

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

Okay, we probably need to highlight the use essential classification there because that's going to have...you and I both know the terminology world is a slightly checkered one, and for certain terms that's fine. For other terms that are going to be more problematic.

Arien Malec – Change Healthcare – Co-Chair

Right. The easiest way to address this is the cases where ILM has purchased the licenses effectively on behalf of the nation, but there are definitely other cases where that has not happened and some of those cases the IPR and licenses in practice essential for any access exchange or use.

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

Yes, and something like SNOMED obviously with an actual license being procured, but others not quite in the same boat.

Arien Malec - Change Healthcare - Co-Chair

Correct. Okay. I think it would be more useful for me to just enumerate some other examples here of where these issues apply, and then with respect to the IPR just do a pointer back to the fee section.

Andrew Truscott - Accenture - Co-Chair

The major point here is we are saying these are not exceptions.

Arien Malec - Change Healthcare - Co-Chair

Exactly. I think we are saying these are not exceptions and that we recommend that ONC clarify preemption.

Andrew Truscott – Accenture – Co-Chair

Yes, okay. So, we move into the next section down here...the information blocking complaint process. We have not made any considerations here.

Arien Malec - Change Healthcare - Co-Chair

Do we want to go to the provider's incentives?

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

We can. I am conscious that we have at least made comment in the disincentives for healthcare providers. We have not made any comment on the complaint process.

Arien Malec - Change Healthcare - Co-Chair

Yeah. Who wants to volunteer for the complaint process? It's not something I've gone deep on.

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

We can volunteer Steve, since he's not here.

<u>Valerie Grey – New York eHealth Collaborative – Member</u>

Andy, it's Val. I think technically I was... am I on mute? Can you guys hear me?

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

No, you're still there.

Valerie Grey – New York eHealth Collaborative – Member

Okay. All right. Sorry. I think technically I was assigned the complaint process, but I do need the workgroup's help on some of the specific questions related to the kind of data that they collect and what is most useful. I did send around an email that had just some general concepts that I thought might be worth talking about and becoming general recommendations. And then I think there is still...I don't know. In my head, I still have a few questions on enforcement and consistency between the CMS law... I'm sorry, proposed rule, and then OIG and ONC and things like that. Do you want me to just throw out a few ideas?

Andrew Truscott - Accenture - Co-Chair

Please do because we're all starting to consider this one at this point in time because we have not talked about this as a group yet.

Valerie Grey – New York eHealth Collaborative – Member

Okay. I think the first thing that struck me was that through the course of the last couple of workgroup meetings a lot of people have brought up that ONC needs to consider industry standards, it needs to think about what is the norm in medical practice and things like that. So, that seems like a recommendation generally that as ONC goes through the complaint process, investigates, evaluates and all that jazz, there should be a big component of that there. I did think that sometimes it was not clear to me when OIG has referred a complaint or decides to pursue a complaint, have they fully signed on? With like the preamble and all of the intent above this? I know, Mark, you said you had talked to OIG but you couldn't speak for them. I just want to make sure that both agencies have affirmatively agreed that that preamble is the general intent as well as the regulatory language. I thought another recommendation... oh, sorry. I have two others and then maybe I can go back on mute because I'm trying to drive and read at the same time.

Arien Malec - Change Healthcare - Co-Chair

Oh yeah, I'm sorry about that. Yes, go ahead.

Valerie Grey - New York eHealth Collaborative - Member

No, no problem. I'm trying to drive and read at the same time so it's a little dangerous.

Anil K. Jain – IBM Watson Health – Member

Oh, don't do that.

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

Pull over. We are in no way endorsing you doing this.

<u>Valerie Grey – New York eHealth Collaborative – Member</u>

Understood. Understood. It also seemed like maybe another general recommendation could be that ONC really needs to issue guidance templates and other things like that. You go back to HIPPA and all

of the misinterpretations...it wasn't until a few years ago there were some really great documents that really made it clear what was allowed and not allowed. I think the informatics they put out there and things like that is a really great start. I would just encourage them to do more. And then, there was a specific question about how we can maintain confidentiality for the complaints themselves and to me, it felt like we should maintain an innocent until proven guilty and should maintain that level of confidentiality. But I do think that we should recommend though that if ONC sees some major trends or some really egregious stuff going on there might be less due process and a little less confidentiality especially if patients' safety is at stake.

So, those were just some quick initial broader thoughts, but I really did not have any good answers on some of the specific questions they asked in terms of what kind of data do they best need to investigate a complaint?

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

Okay. Mark, you were trying to interject.

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

I apologize and I hope I did not cause you to swerve at all Val, I apologize for that. I think there are a few questions in there that maybe I can address. If there are others just let me know. As far as the OIG piece, just for clarification, we have talked and consulted with OIG in drafting the prosed rule and also we are working on an ongoing basis on our referral process to OIG and how all this is going to work to make sure that OIG, as Anil has pointed out, needs to have the proper subject matter experts to help advise when these cases come through and the rule is final and we are able to act on them. We are working with OIG very closely. I guess in the context of what I was saying to you about I can't speak for OIG's processes is that they are in charge of enforcement. And once the case is on their desk, we are going to consult with them and provide that knowledge that we have based on the work that we have done and the rule, but really it is in their court at that point as far as discretion and how they go about investigating these different cases. So, that is what I was talking about there.

With the guidance piece, Val, that you are talking about maybe if you could provide a little more clarification? And I say that because under this administration we are a bit more limited in guidance that we are able to release. There has been some new guidance, but basically, we are not putting out guidance the same way that we may be used to, so I wanted to get more clarification on what kind of information you would have wanted in that guidance and maybe I could help provide it in another way.

Valerie Grey - New York eHealth Collaborative - Member

Okay. I could have used the wrong word...if guidance has a different meaning or implication. I think my only point is that the more tools that you can get out there to help people understand the rules of the road: checklists, templates. These things...and I don't know. I guess maybe that's not part of the complaint process, but it could reduce the number of complaints if there is a better understanding of these new rules.

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

No, that is a great point, and I think I misunderstood. We are trying to get the public as much information as much as possible right now during the public comment period. But also, for instance, there is a FOIA exemption for complaints of information blocking. So, there are special protections for the Freedom of Information Act if you are submitting a complaint of information blocking. And we are trying to be very clear about that for folks so that people will not be worried about submitting complaints. And we are trying to get out other such information as much as possible and are open to recommendations about ways we can better disseminate the information.

Andrew Truscott - Accenture - Co-Chair

Okay, cool. Also, Mark, something I know you may have had a bit of a sidebar on, and I kind of phrase it in two ways. One was "double jeopardy". So, a potential information blocking act or something that could implicate the information...I'm sorry. I'll start again. An act that could implicate the information blocking regulation...how would we ensure that it was not alerted to ONC and alerted to OIG. ONC looks at it and says, "Nope, that is fine." OIG looks at it and says, "Oh, absolutely...you are guilty of blocking." How would we deal with that?

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

I think that wouldn't really happen because OIG really has the enforcement authority for information blocking. If there is an issue with a developer with a certified product and it fell under the conditions of certification, then we would be reviewing that. We have authority to review that and it could be information blocking if it wasn't that condition of certification. As far as information blocking goes more broadly, OIG would be the entity that would be reviewing and investigating and ONC is providing technical experience and knowledge to help advise. But also, we are going to be working with OIG so that we have a common understanding. In the end, it would be in their court to make the decision about how they wanted to proceed, but we would definitely be open to conversations with them to help inform those decisions.

Andrew Truscott – Accenture – Co-Chair

Okay, so it sounds like that isn't an issue.

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

No, I don't think so. I can pull up preamble language, but I believe there is some language in there about how ONC will interact with OIG on these cases.

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

You don't need to. We know your computer is temperamental enough. Arien, have you got commentary here?

<u>Arien Malec - Change Healthcare - Co-Chair</u>

No. As I said I have not gone deeply in this area. I think with respect to Valerie's comments I think there is something to if there is a pattern or accumulation, the public probably should know about it, but you can't both include the complaints as secret and not secret at the same time. And you can't have a process reliant upon somebody saying, "I think there is something here." So, I wonder whether the raw number of complaints is...if there is some information that is worth sharing or reasonable to share

while an investigation is going on, clearly the details or particular findings of that investigation probably aren't unless there is an actual finding. So, again just wondering if the raw number of complaints is a reasonable thing. And I also recognize that that opens the gate for spurious or malicious complaints being used as anticompetitive behavior.

Andrew Truscott - Accenture - Co-Chair

Yes, do we have a sense for the level of anticipated complaints?

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

Yeah. There is a bit of guesswork there. I will say that I can't provide the number right now, but we have had quite a bit...many complaints come into this point and say that there is in an increase. Well, I can't really say that. I'd say that we've had a steady flow of complaints and I would suspect that we are going to be busy, is all I'd say.

Arien Malec – Change Healthcare – Co-Chair

I suspect that whatever OCR does for its wall of shame should probably be the equivalent response here. And I think it is only findings that appear on the wall of shame, is that right?

<u>Anil K. Jain – IBM Watson Health – Member</u>

Can you explain? I am not sure I understand the wall of shame that you are talking about.

Arien Malec - Change Healthcare - Co-Chair

So, OCR has a page where they list people who have been...who have had incidents, disclosures, breaches, etc. And it is somewhat jokingly called the wall of shame, but I believe it is only specific findings.

Andrew Truscott – Accenture – Co-Chair

It's a public publication of found incidents.

Arien Malec – Change Healthcare – Co-Chair

Yes. Equivalents would be FDA... I don't believe that FDA posts notification of investigations they do, but when there are findings, those findings are public information. CLIA only posts notifications when there is decertification or specific findings. So, I think that is probably the appropriate process to follow.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> Is there a recommendation... I guess I am still confused...

<u>Arien Malec – Change Healthcare – Co-Chair</u>

I think we are recommending ONC and OIG follow equivalent processes for OCR, FDA, CLIA and other similar regulatory oversights with regard to their publication processes because they seem to work and do the job that they are intended to do.

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

Okay. And one more part...so is that when whoever the individual or entity is found to have actually violated whichever...?

Arien Malec – Change Healthcare – Co-Chair

I believe in all of those cases the way it works is that only findings are published.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> Yeah. And I will say... and I think —

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

I am sorry, Mark, this is Morris. Just adding clarification... just a small clarification on the wall of shame just to make this quick point, which is it's in the regulation text...in the regulations for OCR that there is a duty to over 500 or more to publicly disclose. They have a duty to OCR to notify, but also, they have to notify, in certain situations, the media which is in regulation text. I just wanted to clarify that. And we don't have any of that in our proposed text the way we have it.

Arien Malec – Change Healthcare – Co-Chair

I don't know what is in the FDA regulation or law or what is in CLIA regulation or law but I generally think the principle here is it is appropriate to publish significant findings.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead Okay. Then I think then that is a good recommendation to make if you feel that way.

Valerie Grey – New York eHealth Collaborative – Member

Yes, and I agree with Arien and I struggled a little bit with trying to find a balance between confidentiality, but then what if something bad might happen? Maybe what would be helpful to me is what are the other...like if ONC got a bunch of complaints and it sounded like there were real implications for negative impacts on patients in a big way, are there other tools that you have where you would expedite your complaint investigation in a really big way? I guess I just want to be sure that there is some valve or mechanism you guys have if something really bad is happening to take care of it right away and not wait for a long findings process. Hopefully, you know what I mean.

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

Yes. I think...and I don't want to sound weaselly. I can't really speak to it too much. I will say that if it all fell in the scope of the certification program, like a certified product was involved or it fell under that scope, then the ball would be in our court and we would be able to try to expedite. As far as with OIG, we can weigh in. I think OIG will be relying on us to say this is a real public safety issue and this needs to be expedited, but again I can't really speak as to how they are going to structure their process. And again, as far as the shaming list or whatever, I think you all should make that recommendation if you think that would be an effective strategy, but it would really be more ONC. We can consider it, but we can't really tell OIG. I mean we can tell them it's a recommendation, but in the end, we cannot really tell them to take that approach. And I know they do have processes in place with monetary penalties

and in the cases they do now, but I am guessing they are probably going to follow. But again, that's their thing so I can only speak for ONC.

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

Mark, this is Lauren Wu - Office of the National Coordinator for Health Information Technology - SME. I wanted to respond to Val's question. So, Val, I understand we're really focusing on information blocking as a whole. As was mentioned earlier you're probably aware ONC has authority when it comes to the health IT developers that are part of our certification program. And so, for that one group of actors there is an associated information blocking condition of certification to participate in the program. If there are patient safety concerns arising from the health IT that is certified, we already have a process in the program where ONC can initiate a process called direct review where we would work directly with the health IT developer to try to remedy that issue. And so, that is already something that was finalized in a previous regulatory process.

Aaron Miri – Change Healthcare – Member

Yes, thanks, Lauren. That is all very accurate, and we are working in the conditions of certification workgroup three. One part of the conversations they are having is about enforcement and whether the same...basically what we are proposing is essentially, with some variations, the same enforcement process for direct review would apply for the conditions of certification as they do for direct review currently for nonconformity with health IT. And as Lauren said, one of the conditions of certification is information blocking. So, that was well said, Lauren. Thanks.

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

Sure. The other thing I wanted to suggest that as this workgroup thinks through this specific request for comment in the rule, you will notice in the preamble that we point to a form that is on HealthIT.gov. Today we call it the Health ID Feedback Form where our channel for all kinds of complaints and information to us and today it's kind of a free text form. One of the things that we are seeking input on is specifically for information blocking complaints or allegations in the future if we should structure the field a little bit more, rather than pretext, to collect specific pieces of information, and whether certain pieces of information are priority or you might feel are more necessary for ONC to collect in order to really investigate working with OIG any allegations of information blocking.

Anil K. Jain - IBM Watson Health - Member

Hey, this is Anil. I think that is something we could certainly think about the additional fields and all of that. But I have a question about the complaint process around information blocking. Is there an opportunity for the complaints to be around when inappropriate information sharing has occurred, or an exception should have been applied but wasn't? Is that in the scope of the complaint process that ONC is contemplating here?

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u>
Are you talking more about like a HIPAA violation?

<u>Anil K. Jain – IBM Watson Health – Member</u>

It wouldn't be a HIPPA violation because that would already be covered under another one, But let's assume I am a provider and I decide to use an exception that I feel that the data is corrupt. I'm sorry... I decide to share the information, but it turns out the data was corrupt, and the receiving organization says, "Hey you just sent me a bunch of corrupt data. You should not have sent it to me. You should have not sent it to me because you should have used this exception." Where is that complaint going to go? Because if you are going to have complaints about where information blocking has occurred, then... and we go through the painstaking process of laying out exceptions, there should be a way when information blocking has...when it was permissible to occur under one of the conditions it didn't occur and it should have.

Maybe I'm not making any sense here, but I don't know how you can have a process by which you can take complaints that information blocking has occurred, but not have a process by which you can have complaints of where information was shared, not a HIPAA violation, but inappropriately shared when an exception should have been used.

Andrew Truscott - Accenture - Co-Chair

I think you mean an oversharing. So, it was shared but it should not have been. An exception should have been used, but it does not rise to the level of HIPAA?

Anil K. Jain - IBM Watson Health - Member

Yes, exactly.

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

Okay. I think that... I don't know that that would really fall into the scope of what we are doing because the way that the whole construct of information blocking provision and rule is that we expect the sharing of information. This is in general terms, but if there is a really good reason for not sharing that information then you can... if a complaint comes that you are not sharing the information, then you can claim an exception and say this is why I am not sharing information because there is a really good reason and I have met all the conditions of one of these exceptions.

What you are describing is an actor or an individual or entity shared information that they should not have shared and I feel like that just falls under the responsibility of that entity. And that's almost the reason why we have these exceptions. We don't want different individuals and entities to feel an obligation to always share when they really should not be sharing. And we tried to identify situations when they would not get in trouble for not sharing that information. So, I think what you are explaining is one of the rationales for coming up with the exceptions, but I don't really see how necessarily it falls into our purview. Maybe you can explain more if I am misunderstanding you.

Anil K. Jain - IBM Watson Health - Member

I need to think through this a little bit more myself because I just thought of it when we were talking about a process of collecting specific data. And if you are going to collect specific data that's going to help us understand the patterns and trends around where information blocking is occurring to help refine our processes then... and you are only looking at one side of the equation, then how are you

actually going to understand what the false positive sharing that occurred was as opposed to the flip side of it. So, let me think about it some more and maybe I'll be more clear.

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

Anil, have a think, because I'm thinking about maybe some of the third party IP or something like that where a third party says, "Hang on a second, you shared my IP saying that you had to because it would be information blocking otherwise when you should have actually declared the exception of saying..." something like that. I could see that maybe.

<u>Arien Malec - Change Healthcare - Co-Chair</u>

Yeah, it could be any of these conditions and I think I get Mark's point that if the burden is on sharing and then you have to say why you didn't. So, if you shared okay great and maybe there are other mechanisms for you to be penalized when you inappropriately share whether it's HIPPA or some other contractual language. But I have a sense that the complaint process is going to be unidirectional. The FDA deals with it because they sponsor the clinical trials that show that the drug works so then they get complaints when it doesn't work, or it causes harm. So, there is a balance there. I'm missing out on what the balance here is.

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

Arien, just a point to note is that we have been getting complaints on an ongoing basis and they are not always necessarily about information blocking as we are understanding it in the rule. All I'm saying is if we get a complaint that has to do with HIPAA, we will forward it to the appropriate party which would be OCR.

Andrew Truscott – Accenture – Co-Chair

I get what you are saying, the point is not that you get complaints about blocking; you get a complaint about not blocking.

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

Right. I guess all I'm saying is I still stand by my statement that I think the scenario that Anil has described is outside what we are doing with this rule. All I was saying is that we do get a wide range of complaints and if it fell in the scope of OCR or another office that dealt with it, we would definitely forward it on to them. That's all that I was saying.

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

Yes. Okay, but if there is a complaint about non-blocking where a complainant believes it should have been blocked, you are the right people to handle that complaint, correct?

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

No, I would probably say, I think...I mean, again, the that fact and circumstances are key here. I can't speak to how we would handle it, but I think generally, and Morris can speak to this because he has much experience with OCR, but I think the Office of Civil Rights often deals with inappropriate disclosures of information.

Andrew Truscott – Accenture – Co-Chair

No, no, no. This is about exceptions under these regulations. So, there's a list of exceptions and if a complainant says you should have used this exception, but you did not.

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

Right, but what I'm saying is the way that the exceptions are is that they only would be used when there is an individual or an entity that does not share information and then a complaint is raised they should've shared that information and then they would say, "Look, I didn't share the information because of this exception."

Arien Malec - Change Healthcare - Co-Chair

So, the exceptions are not creating the obligation to not share, the only thing that is creating an obligation to not share would be at a national level this law including HIPPA and then potentially at a state level. And so, if you're violating one of those obligations to not share, then the complaint should be handled by the relevant agency which would not be ONC or OIG.

Anil K. Jain – IBM Watson Health – Member

This is Anil. I need to think about some more. I think I didn't mean to open up a hornet's nest here. I feel like we're going to have such a mandate to share that more sharing will occur, which is the intent, and that until everyone is educated about the exceptions, there's going to be more than a theoretical possibility that sharing will happen inappropriately. And perhaps it's a theoretical risk that, as you guys said, is going to be managed in other ways, but I'm just a little bit worried that there may not be...if ONC gets a complaint about oversharing and it doesn't fall under HIPPA where does it go? Forget it...

Andrew Truscott – Accenture – Co-Chair

No, it's a good point.

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

I guess all I'm saying is that that wouldn't fall under information blocking. I think we would have to asses what the facts and the circumstance are and see which other office is the appropriate place to send it.

Anil K. Jain - IBM Watson Health - Member

All right. That sounds good.

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

Okay. We have about 37 minutes left. I'm going to suggest that we move to the fees conversation now. Can we do that?

Arien Malec – Change Healthcare – Co-Chair

In seven minutes? In half an hour?

Andrew Truscott – Accenture – Co-Chair

Well, we've only got half an hour left. For the next 30 minutes.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Can we do fees in our face-to-face and cover everything that is not fees here. I feel like –

Andrew Truscott - Accenture - Co-Chair

Okay. I'm happy to take that direction. I have a dumb question, Arien, what if we kind of actually just say, "Look, we propose deregulation that sits outside of exceptions that covers fees?"

<u>Arien Malec – Change Healthcare – Co-Chair</u>

I thought we were going to propose to collapse 204 and 206 into a single exception that covers fees. That is the approach that I took.

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

I was going slightly further and say given we are going to collapse them together; do we actually think that they shouldn't actually be an exception...they should be a separate regulation around permissible fees?

Arien Malec – Change Healthcare – Co-Chair

It amounts to the same thing, I think, which is the way that information blocking works is that in any case where you are requested for...you are requested information for a permissible purpose that any obstacle that you place in the way of that request has to meet an information blocking exception. In general, I think we could clarify that that negative framing is confusing and that even though CURES asked for exceptions, it's better phrased as 'permissible reasons to place barriers to information flowing', but it all amounts to the same thing. So, I don't think it gets you anything except for... and it actually may exceed what authority was granted under CURES because what CURES did is it requested ONC to create exceptions.

Andrew Truscott - Accenture - Co-Chair

Okay. I must admit, I do find it a bit confusing.

Arien Malec – Change Healthcare – Co-Chair

It is confusing.

Andrew Truscott – Accenture – Co-Chair

And I am not sure it was intended to be confusing. I think the exceptions were intended to be reasons why you might block information, or it might be acceptable to not share. That's what the exceptions were for. I don't think I read it that the exceptions were reasons why you might charge for —

<u>Arien Malec - Change Healthcare - Co-Chair</u>

Yeah, well put it the other way which is that I am not sharing unless you pay me this fee. And then the question becomes, is that permissible?

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

And that is why I was thinking that we maybe recommend that fees could be a separate regulation that just says permissible fees.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Yeah, and when we get to that section you will see that I tried to frame it in terms of permissible fees because I think the permissible is easier for people to wrap their head around than the allowed variance to an exception.

Andrew Truscott – Accenture – Co-Chair

Can we quickly ask the man who knows all these things? Mark or Morris, either of you, is it like verboten we wouldn't be able to... it's not anything that would ever happen around having a new regulation around permissible fees that sits outside the exceptions? Don't both answer at once.

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

I was just talking to myself then. I was saying, first I want to be clear that I understand what you mean by regulation. Are you saying you want to add a provision within this regulation or proposals? Or a separate stand-alone document?

Andrew Truscott – Accenture – Co-Chair

No, within this set of regulations, if we're going to propose final rule, taking the elements around fees, which Arien has done a masterful job of collapsing into one, and actually casting it not as an exception, but as permissible fees that can be charged in enabling information state, only because it can get a bit confusing when you are saying, "Okay, it is an exception that we can charge a fee." I don't know, it just feels like it is the wrong place.

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

Yes, I think if I talk too much, I'll probably just go down the road of starting to discuss fees, but I guess I don't totally understand. I think that the fees, whether it's two exceptions or one exception, at least in my mind it makes sense and that's why we proposed it that way, that that is an exception. Because like Arien said, the situation is...and we've heard about this quite a bit from stakeholders and from the public, that there are fees being charged and the data is not flowing...the information is not flowing unless a certain fee is paid. And we are trying to say that there are certain reasonable fees that can be charged both for access to the information, but also for the interoperability elements and for licensing that are okay and that would be allowed. And so, that would be considered an exception. I guess I am not fully clear why it would not be an exception and how it would be structured otherwise.

Arien Malec – Change Healthcare – Co-Chair

I think the general comment is that it is easier to think about permissible practices than it is to think about exceptions. It's just that CURES asked for a list of exceptions. And to the extent possible, writing the exceptions in terms of permissible practices is just cognitively easier to wrap people's heads around.

Andrew Truscott – Accenture – Co-Chair

Yeah. An exception by definition is an exception to the information blocking rule. So, it is saying, "It's okay for you to block if you are doing this."

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> No. No –

Andrew Truscott - Accenture - Co-Chair

Well, I don't know. That's why there's cognitive dissonance with it.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> Well, no. Just to be clear, it's saying it's okay to not share the information. I don't think we want to say...I mean...essentially yes, but...

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

I know. That's the whole point.

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

And again, I look forward to the conversation. I don't know that... I guess I would like to hear more from Arien and the group about why it makes more sense to combine them into one exception, than to leave it as two. But again, that might be for another day.

Arien Malec - Change Healthcare - Co-Chair

Yes, let's see how much we can get through that's not that and then when we are face-to-face, we can spend our time working through the fun stuff.

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

Yeah, sounds like a lovely plan.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> Just a note I'll probably... I think I'm going to be calling in for that, but I will be on for the face-to-face.

Anil K. Jain - IBM Watson Health - Member

Well, I'll be in DC so... anyway...

<u>Arien Malec - Change Healthcare - Co-Chair</u>

Should we go to provider disincentives?

Andrew Truscott - Accenture - Co-Chair

Yeah, because Steve wanted this by close of business this evening. Provider disincentives...what number was that?

<u>Arien Malec – Change Healthcare – Co-Chair</u>

It's not a number.

Andrew Truscott – Accenture – Co-Chair

It's the preamble, 501 and 502.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

And there was also something else that appeared to be garbled that you said I should take a look at, but I didn't know what I was taking looking at, so, I didn't. I had a question and then I answered my own question when I was thinking about disincentives for providers. So, I will just describe maybe my journey.

It always seemed to me curious that Congress puts a specific penalty structure for HIT developers but didn't put a specific penalty structure for provider organizations. And as I was thinking about this and thinking about this section, it occurred to me that the federal government already has the mother of all disincentives which is Medicare, fee-for-service, Medicaid, contractual requirements, ACO's and other value-based care programs, and then contractual requirements with DHA, DOD, IHS, CDC, SSA, and on and on. So, as I was thinking about that, I thought the simplest thing to say in all these programs that the appropriate disincentive is to include anti-information blocking provisions as conditions for participation, conditions for coverage contracts, and other similar relationships with provider organizations.

And then that anti-information blocking attestation provides sufficient incentive to comply with the investigation, as well as sufficient incentive to comply with information blocking provisions. And in the rare event where, in the same sense that OCR very rarely levees fines for HIPPA, but when it does it levees big fines. And in the very rare exception where practices cannot be modified or appropriately addressed, it provides adequate tools including barring from programs that provide inadequate disincentives for providers.

I came out of this thought process saying actually the US Federal government has all the tools that it needs to apply disincentives. The one question that I had, and I didn't include this in the text, is my assumption is that the CAdES are part of the anti-information blocking. And I have to admit that I don't know exactly how the regulatory flow down for CMS works for the CAdES but I thought about a...and, to be honest, primary care practices or pediatric practices are just so far down the list of information blocking bad behavior that it is probably not that worth thinking about. But my assumption would be that the CAdES would be...almost all organizations receive a significant amount of reimbursement through either Medicare fee-for-service, Medicare ACO, Medicaid, whether fee-for-service or managed, or other programs that ultimately flow through Medicare. I just don't know how conditions for participation for the CAdES actually work. So, I will just pause there.

That was the thought process and the recommendation is basically to include information blocking attestation as conditions of participation, condition for coverage, contracts, and other similar relationships.

Andrew Truscott – Accenture – Co-Chair

Don't the CMS regulations cover CAdES on this?

<u>Arien Malec – Change Healthcare – Co-Chair</u>

That would be my assumption. I just don't know exactly how conditions for participation or conditions for coverage flow down through the CAdES, whether that's a state-administered or CMS administered.

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

But I think we have the same views on that, which is good because it is covered, and we don't need to say anything.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

I think that's right. And also, as I mentioned, I don't think that primary care practices or particularly pediatric practices are on the top of the list of organizations that have engaged in problematic behavior.

Anil K. Jain - IBM Watson Health - Member

Not by choice.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Yes, exactly. That's right. They tended to be on the receiving end as opposed to the giving end, yes.

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

Or on the technically unsavvy end where they just don't have the ability.

Andrew Truscott – Accenture – Co-Chair

Right. The other set of questions is around pediatric systems, isn't it? Okay.

Anil K. Jain – IBM Watson Health – Member

I was just going to say I am struggling with this one a little bit because there are already disincentives in place and the question I think they are asking us is that should there be additional, as you were just discussing, additional things or different things? And they already talked about the HHS programs which are already covered under the CMS rule. I'm failing to understand exactly what they are asking for here.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

I am not, maybe I didn't read the CMS rule adequately, but I am not aware that the CMS rule included anti-information blocking attestation as conditions for participation or conditions for coverage.

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

I thought...maybe I'm thinking of programs like MIPS and MACRA and all those where you have to have the information sharing in order to get paid. Otherwise, you get penalized.

Arien Malec – Change Healthcare – Co-Chair

Yes, it's pretty at the margins whereas fee for service and ACO payments are definitely not with the margins.

[Crosstalk]

Andrew Truscott – Accenture – Co-Chair

Is there any information that ONC can provide us just so we -

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Just factually what is in the CMS rule and what disincentives were included in the CMS rule or not included in the CMS rule?

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> Sorry, that was a question. Sorry, repeat the question one more time.

Andrew Truscott - Accenture - Co-Chair

Can you provide us with any factual information around the CMS disincentives so that we are not simply replicating something that already exists and putting brain power into something that doesn't really require us to comment?

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

Right. So, without getting in too much into details of CMS, I don't believe... I mean there's existing CMS policies. I don't believe, and I can't speak to their rule, I don't think they address specifically information blocking penalties in their rule. And I think looking to what the existing penalty structures are for CMS programs might be something to do to look as far as recommendations go. What I'm saying is that I don't believe this same question is posed in any way in their regulation. I'll say that.

Arien Malec - Change Healthcare - Co-Chair

Okay. Then I think we should stand pat with the language proposed unless there's strong disagreement with it.

Valerie Grey - New York eHealth Collaborative - Member

Since I'm driving, I just wanted to make sure that I understand the recommendation. So, we are recommending that as a condition of participation for Medicare, maybe Medicaid...we've got to do a little more homework on that, that it is a requirement that you attest to not information block.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Yes.

<u>Valerie Grey – New York eHealth Collaborative – Member</u>

Okay.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

And again, just to be clear with the questions that you raised, that does not imply that any finding of information blocking thereby disqualifies you from fee-for-service payments. It just provides a range of tools up to and including disqualification for programs for egregious behavior. And if you look at the practices, for example, in OCR what you find typically is that OCR seeks to modify behavior wherever possible and only goes to a fine structure when despite repeated attempts to modify behavior, there has been a finding...repeated findings of failure to address the requirements.

<u>Valerie Grey – New York eHealth Collaborative – Member</u>

Okay. That's helpful because part of the reason I am a little sensitive to it is that we have done a bit of work on the CMS rule and I know the AHA and some others are not necessarily...have some concerns with...they have some concerns with the requirement of...like the ADT requirement. And part of what I have heard from some of the hospitals is that it is a very blunt instrument...the certificates of participation and it has been characterized to me as so if I don't do alert sharing then I am not allowed to have Medicare payments anymore and you are going to bankrupt all sorts of hospitals. So, as long as it's a progression so that there is some degree of magnitude for whatever bad behavior there might be...if it's just a tiny bit bad and maybe a mistake, there is one penalty within all of that versus purposely doing really bad stuff and maybe they do get kicked out of the program.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

So, maybe...and I think I wrote this, but maybe I should be more explicit that we recommend that ONC works with CMS to establish reasonable and progressive approaches that should primarily address modification of behavior.

Valerie Grey – New York eHealth Collaborative – Member

Yes, I think that seems good.

<u>Anil K. Jain – IBM Watson Health – Member</u>

As opposed to what it is today which you guys believe is a one-size-fits-all.

Arien Malec – Change Healthcare – Co-Chair

I don't believe that. I believe that's a little bit hyperbole and I think it's also... again, I think if you look at HIPPA, that's not the way that HIPPA has worked in practice. I think there is a concern that one violation and you hit us with a million-dollar fine and in practice, regulatory oversights tended to work on behavior modification as its first level and then on...but only reach for the big fines when there is repeated and egregious behavior. I suspect that would be the way it would play out and that maybe we should recommend that that's the way that it actually plays out.

Anil K. Jain - IBM Watson Health - Member

Okay. That makes sense.

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

Maybe we have to go back and read the CMS regulations.

Anil K. Jain - IBM Watson Health - Member

Yes, I thought there were penalties, but they may be carrying on those that were already in the existing programs like the quality initiatives and all of that. I'll go back and read it too. I thought that those existed and, in fact, CMS points to the ONC rule to say here are the exceptions and all that. So, I am not sure what I'm misunderstanding here, but it didn't have a gradual process from what I recall. It was

basically you may lose your ability to take care of these patients and get reimbursed for them if you engage in these behaviors.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u>
So, just to be clear, I think the CMS rule speaks about attesting that you have not been information blocking. They talk about that and the implications of a negative attestation, but that is different than what we are asking for here. Does that make sense?

Arien Malec - Change Healthcare - Co-Chair

Yes, I think you need to explain a little bit more to us.

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> Okay. And again, I am not an expert on the CMS rules, so I don't want to just –

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

Okay, please explain first.

Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead Basically, there is an attestation requirement for CMS programs regarding information blocking and they discuss the implications of attesting in the negative or saying that you are not affirming that you are not information blocking. And I believe that they discuss posting that information publicly and other such potential proposed disincentives. What I am saying is that what we are asking for are the actually proposed disincentives that would be for information blocking. But what they are talking about, I believe, in their rule is specific to the CMS program.

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

So, you are asking for more general sanctions that could be applied to a provider who has a finding of information blocking?

Anil K. Jain - IBM Watson Health - Member

What we are asking for is in CURES, as we've talked about, there is a penalty structure laid out by Congress for developers, networks, and exchanges there are penalties up to \$1,000,000 per violation. They just say appropriate disincentives for providers. So, we are asking what those appropriate disincentives could be.

<u>Arien Malec - Change Healthcare - Co-Chair</u>

And I think we are saying in our comments that the appropriate disincentives should be anything up to and including removal, violation of condition of participation, but that we believe that the disincentives should be gradated and seek to address behavior modification wherever possible.

Andrew Truscott – Accenture – Co-Chair?

But the removal of certificate of participation in what, Arien?

<u> Arien Malec – Change Healthcare – Co-Chair</u>

Fee-for-service, ACO...so...let's posit a hypothetical which is a hospital system that refuses to share information with a competitor who is...or within a local ACO who is attempting to provide value-based care payments that may limit future hospital revenues. This is, I think as everybody knows, not a hypothetical example. And so, let's presume again, for cases of the hypothetical, that there has been a complaint and investigation and a finding that this was a permissible use and does not meet one of the exceptions. Then the question is what is the appropriate disincentive? What we are proposing in the language that I've written is that 1), CMS should seek to modify behavior, so let the hospital know there has been a finding of ...that OIG lets the hospital know there has been a finding of information blocking and ask the hospital to change its behavior, but then repeated and egregious violations of information blocking provisions that the final tool in the toolbox is to disqualify for fee-for-service and ACO payments.

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

And I guess I wanted to say that I don't believe that any of that is in the interoperability CMS rule.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

I didn't read it either so, I think it is worthwhile restating it if it's something we believe.

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

Is an unintended consequence of that, essentially you disincentivize people from participating in those programs completely?

<u>Arin Malec – Change Healthcare – Co-Chair</u>

Any hospital that doesn't want to receive Medicare reimbursement or Medicaid reimbursement is already free to not do so.

Andrew Truscott - Accenture - Co-Chair

So, where an organization is not receiving Medicare or Medicaid reimbursement, what would you propose the disincentive is for them?

Arien Malec – Change Healthcare – Co-Chair

I don't believe there is any regulatory mechanism for providing a disincentive. It's a good question and this is probably deep in the bowels of is a hospital that is serving a local area in the confines of the state that is not dealing business with the Federal government...this is almost a constitutional issue?

Anil K. Jain - IBM Watson Health - Member

Uh, I'm trying not to frame it that way.

<u> Arien Malec – Change Healthcare – Co-Chair</u>

I don't think it is a practical issue because I don't – [Crosstalk] [01:43:33]

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Yeah, sorry. Go ahead.

Valerie Grey – New York eHealth Collaborative – Member

Oh, it's Val. I think I'm gonna...that is a little bit contrary then to my understanding, having worked in a hospital sector for four years and it was rare to find a hospital that wasn't somewhat reliant on government funds. You have some specialty hospitals where they definitely have a much higher commercial mix and they sort of don't pay as much attention to the government programs, but it's unusual. But I guess to see your point, even the unusual circumstances we should ask ourselves is there anything else we can do.

Andrew Truscott – Accenture – Co-Chair

And what the point is that 1.) it is not so unusual that we can't think of any because we can, and 2.) do we want to provide a push that is going to disincentivize other organizations who have a dwindling Medicare/Medicaid capability to actually back out even fuller from those programs?

<u>Arien Malec – Change Healthcare – Co-Chair</u>

I would then recommend that ONC and CMS work together to address information blocking. We believe these are appropriate tools for providers who receive a significant proportion of revenue from government programs. We would ask ONC and CMS to work out approaches for addressing actors who do not participate in government programs.

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

As OIG...

<u>Mark Knee – Office of the National Coordinator for Health Information Technology – Staff Lead</u> Yes, you definitely want to include OIG in there.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

I don't think we have a solution for it and I think we just need to recognize that for the vast majority of organizations this is a sufficient disincentive and that there are rare cases where there are no appropriate disincentives.

Andrew Truscott – Accenture – Co-Chair

What we don't want to do, Arien, is inadvertently encourage organizations to stop participating or dwindle participation more in government programs.

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

There is another way we can do this. It's not as strong, but we could tie in the state medical boards. They have done that with opioids, right? So, it's essentially adding something to state medical licensure that says you're going to attest that you are not going to be engaging in information blocking as a provider.

Arien Malec – Change Healthcare – Co-Chair

That is not an ONC tool or a CMS tool, right? It is not a Federal government tool, is that right? [Crosstalk] [01:46:13]

Anil Jain – IBM Watson Health – Member

Yes, suggest that ONC work with state medical agencies to provide implementation tools kits, or whatever it might be, to help educate on information blocking and promote some attestation at the medical licensure level like I do for opioids right now.

Arien Malec – Change Healthcare – Co-Chair

Great suggestion.

<u>Cassandra Hadley – Office of the National Coordinator for Health Information Technology – HITAC</u> <u>Back Up/ Support</u>

Andy, you want to open the line for public comment?

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

I'd say we have to.

<u>Cassandra Hadley – Office of the National Coordinator for Health Information Technology – HITAC</u> Back Up/ Support

Operator, can you open the line, please?

<u>Arien Malec – Change Healthcare – Co-Chair</u>

And if AHA doesn't comment, it's because they weren't listening.

Operator

If you would like to make a public comment please press star one on your telephone keypad, a confirmation tone will indicate your line is in the queue. You may press star two 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 key.

<u>Cassandra Hadley – Office of the National Coordinator for Health Information Technology – HITAC</u> Back Up/ Support

Do we have any callers in the public comment?

Operator

There are no public comments at this time.

<u>Cassandra Hadley – Office of the National Coordinator for Health Information Technology – HITAC</u> <u>Back Up/ Support</u>

Thank you. Andy?

Andrew Truscott – Accenture – Co-Chair

At one point someone from the public is going to make a comment on one of these calls and we'll be completely unprepared. It will be wonderful. Okay. Arien, do we want to move on to another section for the last ten minutes?

Arien Malec - Change Healthcare - Co-Chair

Is there another section we have not reviewed yet? I forget what we have and haven't reviewed.

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

Yes, go on Mark.

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

All right where am I going? Which section do you want to see?

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

Well, one of the ones we have not reviewed that isn't the fees.

Arien Malec - Change Healthcare - Co-Chair

And isn't Steven Lanes'.

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

Okay, an easy one. What about the maintenance? Did we talk about maintenance?

<u>Arien Malec – Change Healthcare – Co-Chair</u>

No, we haven't talked about maintenance yet.

Valerie Grey - New York eHealth Collaborative - Member

Yes, we did.

Arien Malec – Change Healthcare – Co-Chair

We did?

Valerie Grey – New York eHealth Collaborative – Member

We did. And Andy, I owe you some revisions and polishing on both that section and the other section... infeasibility to reflect the group's discussion, but we did talk about both of those.

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

You owe the group now, you don't owe me anything.

<u>Valerie Grey – New York eHealth Collaborative – Member</u>

Okay, the group.

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

Okay, cool that's...okay, so we'll part that. Any of the others?

<u>Arien Malec – Change Healthcare – Co-Chair</u>

It sounds like for, what is it Thursday? We have an agenda to talk about fees and then the remainder of Steve's suggestion.

Andrew Truscott – Accenture – Co-Chair

I must confess this conversation over disincentives for providers who are outside of government programs has got me thinking actually...not with a tangible answer yet, but more of and I want to make sure we are not missing something here. And it might mean, Arien, to one of your points, something that we have absolutely no listed mandate to even address.

Arien Malec - Change Healthcare - Co-Chair

Perhaps... I think we can cover this with handwavey comments back to ONC, CMS, and OIG. Those are the best kind of comments. We could not figure it out so you could solve the hard stuff?

Andrew Truscott - Accenture - Co-Chair

We made a good attempt at some of the other stuff.

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

This is Morris. Can I ask just a quick question for clarification? So, we understand...is a disincentive where any federal dollars touch an actor?

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Yes.

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

Okay. That includes grants, research...anything where Federal dollars are received by an entity?

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Yes, and I should broaden the language. I included COP's and conditions for whatever...grants absolutely. We should make sure the language is broader and clearer.

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

Okay. Thank you.

Andrew Truscott – Accenture – Co-Chair

That is a good point, Morris, because that's going to then broaden out sufficiently so complete organizations that aren't participating in one of the paid programs, but actually receive partial funding.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Hey, Andy, if I go home tonight and make some modifications, am I still modifying the same document?

Andrew Truscott – Accenture – Co-Chair

Yes, keep going. The first one I used in the task force was a one-off just because, so people could see changes and track changes because I so enjoy creating one-off documents.

<u>Arien Malec – Change Healthcare – Co-Chair</u>

Yes.

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

Okay. Operator do we have any public comments?

Operator

There are no public comments at this time.

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

Thank you, sir. Okay, team, I am going to propose rather than starting up on something fresh at this point, we close for the weekend?

<u>Arien Malec - Change Healthcare - Co-Chair</u>

Sounds good.

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

Cheers.