

Transcript
April 11, 2019
In Person Meeting

# **SPEAKERS**

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

#### Operator

All lines are now bridged.

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

Thank you. Good morning, everyone, and welcome to the Information Blocking Task force meeting. Today, we're going to continue on with our discussion on recommendations for the rule. And I will officially begin the call by taking roll. Andrew Truscott.

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

Present.

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

Michael Adcock.

## Michael Adcock - Individual - Co-Chair

Present.

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

Steven Lane.

# Steven Lane - Sutter Health - Member

Good morning.

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

Good morning. Sheryl Turney.

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

Good morning.

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

Good morning. Denise Webb.

# <u>Denise Webb – individual – Member</u>

Present.

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

Hello. Aaron Miri.

## Andrew Truscott - Accenture - Co-Chair

He's running 10 minutes late.

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

Okay, he's 10 minutes. Okay. Arien Malec. Not here. Valerie Gray.

## Valerie Gray – New York eHealth Collaborative – Member

Here.

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

Anil Jain.

# Anil Jain - IBM Watson Health - Member

Here.

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

Hello. Cynthia Fisher. John Kansky.

# John Kansky - Indiana Health Information Exchange - Member

Here.

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

Lauren Thompson. Denni McColm.

## Denni McColm - Citizens Memorial Healthcare - Member

I'm here.

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

Okay, great. So, I'll turn it over to your chairs, Andrew and Michael.

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

Welcome, everybody. Thank you very much for joining us. Guys on the West Coast especially, thank you, given that you flew back overnight and got there very, very late, and then joined the call very, very early. I would have stayed up.

## Female Speaker

Stayed up all night, yup.

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

All right. Thanks ever so much. We've got two kind of focuses today to go through. One is the promise that your chair made yesterday just to touch upon the intellectual property and screenshots provisions inside 17403, communications. And the second is to go through the fees, and to use the vernacular, recommendations as drafted in workgroup two. Can you let me know as soon as Arien has joined? Because Arien will be driving that piece of the conversation.

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

Okay.

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

Okay. So, if we move straight to 17403 . . . let's just look upon that. Actually, is this the full task force? This is, isn't it?

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

Hm?

## Andrew Truscott – Accenture – Co-Chair

This is the full task force.

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

Yeah.

## Andrew Truscott – Accenture – Co-Chair

Yeah. Okay. Okay. So, yesterday, this did cause some degree of discussion in HITAC. I'll open it to the group. To what extent do we think that actually, we need to go back and modify some of the language, maybe something in the preamble? Fair use as a definition caused discourse.

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

Yay!

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

Oh. Huzzah! I was kind of [inaudible] [00:02:51]. Arien Malec has entered the room.

## **Arien Malec – Change Healthcare – Member**

Oh, I'm so sorry.

# Andrew Truscott - Accenture - Co-Chair

That's okay then. So, the discussion around fair use. I'll be interested to have Mark and Mike's feedback on that without me giving them curveballs over the table. So, guys, what do you think? You're all in the room. You heard the comments. Thank you much.

## Anil Jain - IBM Watson Health - Member

Yeah. Well, I mean, I'd try to understand it from the point of view of someone who might want to do usability research or looking at effectiveness of the technology, as well as the vendor who needs to protect their intellectual property. And was it Mark who mentioned the different reasons why there should not be any blocking of the screenshot?

## Andrew Truscott - Accenture - Co-Chair

Yes, he [crosstalk] [00:03:50].

#### Anil Jain - IBM Watson Health - Member

That list made sense. What I think vendors will be concerned about is when someone uses those screenshots for alternative purpose. So, I think revisiting those reasons for making sure that we're not missing any, and then making sure that we account for what – I think it was Raj -- was trying to get at, or maybe it was somebody else. But I didn't quite understand what the issue was with the current language. But maybe I'm –

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

Also looking at media coverage doesn't tell me what the issue was. Yeah. I think there was concern that fair use could be – here, could be used by a vendor who was trying to be unreasonable. I think that was Raj's concern.

#### Steven Lane - Sutter Health - Member

I think the other concern was that if somebody put it to fair use, that they would somehow be responsible for everyone's secondary use of that and assuring that was going to be fair, which doesn't seem at all possible.

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

That was the other one. That was the one I was going to sort of get to. I think that one's quite valid, and we all understand that, that we wouldn't either want to put the burden over anybody who was doing the initial fair use or downstream fair use they had to police.

# Anil Jain - IBM Watson Health - Member

That seems like a very – I'm not saying **[inaudible] [00:05:05]**, but it just seems like we already have examples of that. If I write an article and it gets published in a journal, and someone wants to use that article, they have to go back and look at the original copyright, so.

## Andrew Truscott - Accenture - Co-Chair

Yeah. It was the way that Alan drafted – we actually drafted it and said that any acts of disclosure in the screenshots are responsible for ensuring that each use is being put to fair use, we'd just be [crosstalk] [00:05:26].

#### Denise Webb – individual – Member

I mean, if they hand it to somebody, they should take the responsibility to tell them, you cannot just freely disclose this information.

## **Arien Malec – Change Healthcare – Member**

Yeah. Maybe the way to put that is that an actor that – we can't use the word actor – is that somebody, something that – using the example of a screenshot for use of safety critical evaluation, that merely by using it in that capacity, any subsequent use is not deemed fair use. It has to be tested for fair use. And it doesn't by that nature become public domain or non-copyrighted. So, I think this is all pretty standard under fair use law, that fair use is fair use is fair use. And I think all we're saying is that merely by using a screenshot or other copyrighted material in the context of the permitted activities, we're not thereby saying that they've escaped the original provision of the copyright law, right?

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

Yes. There're two sides. One is the side I think we all agree on, that you're not responsible for policing downstream use. You're responsible for communicating [crosstalk] [00:07:04].

## <u>Arien Malec – Change Healthcare – Member</u>

That's what I'm saying, is that's already contemplated in intellectual property law and fair use –

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

It absolutely is.

#### **Arien Malec – Change Healthcare – Member**

- is that if I use something and it is not fair use, that's an IP . . .

## Andrew Truscott - Accenture - Co-Chair

I think it was more an inadvertent over-reading of our drafting.

# <u>Arien Malec – Change Healthcare – Member</u>

That's right.

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

So, it was this group – so, kind of updated this –

## **Arien Malec – Change Healthcare – Member**

I'm sorry to infer – we don't need that in the drafting because it's . . .

# Andrew Truscott - Accenture - Co-Chair

Okay.

## **Arien Malec – Change Healthcare – Member**

If we feel we need to make it clear, we should make it clear that you're using **[inaudible] [00:07:37]** subjects here.

#### Denise Webb – individual – Member

You probably should put – well, or put it in the preamble, because if you want to explain, that explanation shouldn't go in the regulatory thing.

### Andrew Truscott - Accenture - Co-Chair

So, we've got to do that. Just insert the term "fair use" and then put the rest in the preamble.

## Denise Webb – individual – Member

And I know that Mike may have some issue with — was it Mike who brought up introducing that term in the regulatory text? But the thing is, it's already in the regulatory text, which I tried to point out, that it's already in sub one there. It's in the actual regulatory text.

## Andrew Truscott - Accenture - Co-Chair

It is in the regulatory text.

## Denise Webb - individual - Member

So, that would be a fair use of copyright work to use that word "fair use" or that term. So, I'm not sure why he had concerns or took issue with that.

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

Well, Mark, do you want to speak to that?

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

All right. So, the question is? I guess I don't remember – you're saying Mike said that fair use was not in regulatory text? Is that the comment?

## <u>Denise Webb – individual – Member</u>

I believe it was Mike who brought up a point that the committee – or excuse me, the task force – was introducing the term "fair use" in the regulatory text, and it was not in the regulatory text, but it is. It's in sub one above.

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

Yeah. Well, so I guess I don't remember – I mean, I trust that maybe he said something like that. My guess is, if he said that, he probably was just talking about specifically in the context of two. And I think what he probably meant was that we don't – maybe we don't define "fair use" in our definition because it's an established term in IP.

# <u>Denise Webb – individual – Member</u>

Right.

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

That might have been what he meant. I think it just comes down to, as far as the addition — and two, I think there's good conversation about it in the preamble — it comes down to whether you think, in addition to moving in regulatory text the language you had before, does having that fair use in two add value to — given the fact that there's this understanding in IP law?

# Denise Webb - individual - Member

It absolutely does.

#### **Arien Malec – Change Healthcare – Member**

If you don't say that, then you're saying that a health IT developer does not prohibit communication.

## Denise Webb - individual - Member

It just makes it crystal clear.

# <u>Arien Malec – Change Healthcare – Member</u>

It makes it crystal clear, yeah.

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

Okay, great. No, I'm not taking one side or the other. I just wanted to just pose the question.

## Ken Kawamoto – University of Utah Health – Member

Sorry, this is Ken. I'm on. Can you hear me?

# <u>Arien Malec – Change Healthcare – Member</u>

Yup.

# <u>Denise Webb – individual – Member</u>

I can.

## Ken Kawamoto – University of Utah Health – Member

Yeah. I think, even if it's in common use, I think it should be referenced, right? Just saying fair use reference. See this copyright law. Just so that the terms — maybe folks will commonly understand it, but I think that certainly helps, right, if you say this is exactly what we mean by fair use, and also, I think it's still this notion of — when I reread the regulatory text, it seemed like screenshots were called out as separate from all the other kinds of communications about health IT, about the other part that says unless it's one of these five or six things, then basically, this doesn't cover it. Health IT developers can put whatever IP restrictions they want, was sort of what I read.

But then the screenshots part, it seemed to take an opposite approach, where it says it's presumed to be shareable except in these circumstances or for these restrictions. I think getting some clarity there would be good, because in my assumption, it's actually – the screenshots are a huge part of what you'd want to potentially communicate. So, that's a little bit puzzling, where the language says as a default, you can't share, except for just these things, and then on the screenshot part, it seems to say as a default, you can share. And if in fact it is that as a default, you can share screenshots, I understand putting in these restrictions. But that seems like a puzzling way to put it in regulatory text.

# Denise Webb - individual - Member

And can I, I mean, just throw our a question to the group? When I was listening to the discussion, I heard several times that one of the instances where you could not share the screenshot is if there was PHI in it.

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

Yeah, well that's – well, yeah.

## Denise Webb - individual - Member

Well, that one kind of caught my attention because you have provider X talking to provider Y. They're in two different health systems, and they're –

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

They use the screenshots to communicate [crosstalk] [00:12:13].

### Denise Webb – individual – Member

And they're not necessarily sharing the screenshot. Maybe they're sitting there with them, and they're showing them the screenshot. Is showing the screenshot the same as sharing the screenshot?

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

No, no, no. There's a difference there. One is around effectively sharing a patient's record. And the only reason they're available to me is by taking a screenshot, because for some reason, I can't do anything else, and I will send that to you, whether it's hard copy, whether it's email, whatever. That happens. You don't like it. None of us like it. But it happens. [Crosstalk] [00:12:42] We don't want it to be. I think there was a —

#### <u>Denise Webb – individual – Member</u>

No, we don't.

## Andrew Truscott - Accenture - Co-Chair

I think what was being referred to was when a screenshot is shared, it's intended for some kind of fair use or research study, whatever, and it has PHI inside it.

# <u>Denise Webb – individual – Member</u>

Oh.

## Andrew Truscott - Accenture - Co-Chair

That's what's prohibited, because then that's a breach.

## Denise Webb - individual - Member

Okay. Well, I hope that's crystal clear, because -

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

Excuse me. Steven Lane has his hand up. I just wanted to let you know.

# Andrew Truscott - Accenture - Co-Chair

Who?

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

Steven Lane has his hand up.

# <u>Denise Webb – individual – Member</u>

Go ahead.

## Andrew Truscott – Accenture – Co-Chair

Mr. Lane, go ahead. We haven't got the presenter view at this end, so.

# Steven Lane - Sutter Health - Member

Oh, okay. No problem.

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

Just shout.

## Steven Lane – Sutter Health – Member

Yeah. I wanted to echo what Ken said, which is I think it's really important that we make reference to definitions of these terms, because these are critical questions on the part of end users, and I think on the part of HIT vendors. And I think it leads to some significant consternation between those parties, because people want to and feel a need to share screenshots amongst themselves, across the customers, across communities. So, again, I do not think we can assume a definition of a term like "fair use." And I think the more specific we can be, the better.

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

Well, if I could just -

## <u>Arien Malec – Change Healthcare – Member</u>

[Crosstalk] [00:13:58] fair use is essentially litigated, so.

# Andrew Truscott - Accenture - Co-Chair

Yeah. Well, no. Fair use is an identified term elsewhere in the legal canon.

## Steven Lane - Sutter Health - Member

And perhaps we should capitalize it also, in that case.

## Andrew Truscott - Accenture - Co-Chair

Okay.

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

This is Mark. Just wanted to say, I can't pull up on my screen right now the regulation because I'm sharing. But I do believe in preamble, and I know with Arien thinking it's preamble, but we do know cite where the definition of "fair use" comes from, and we have that. But if you all think that's not clear enough, you could make a recommendation that the definition or the reference be made in the definition section, or some recommendation like that. But I do believe it is in preamble. [Crosstalk] [00:14:49]

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

Can I ask a question? Yeah, can I ask a question real quick? This is Aaron. Real quick. I was thinking about it. The screenshots also include the ability for, say, CIOs or whatnot to be able to share their contracts and contractual language with each other, because one of the things that we have been interested about is looking at what terms and conditions, things like that, and trying to figure out what the market looks like and what allows us to be flexible. And a lot of times, you're forbidden to even share that – just contractual language.

# <u>Arien Malec – Change Healthcare – Member</u>

No. Not –

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

If I took a screenshot of my contract, is that fair?

## <u>Arien Malec – Change Healthcare – Member</u>

This is not a usual practice. So, this happens. Sharing of contracts happens. People discuss contractual concerns. They're not supposed to, and it's not a usual practice. This is not –

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

Got it.

## **Arien Malec – Change Healthcare – Member**

Yeah.

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

Okay. That's my question. I think that's going to come up. That's going to come up as what . .

# Anil Jain - IBM Watson Health - Member

I think what we're trying to facilitate here with the screen sharing, or the sharing of screens, communicating with screens, is if someone believes that there's a usability issue that's causing the patient harm, they should be able to do that without the vendor coming after them.

## **Arien Malec – Change Healthcare – Member**

I think we should narrowly target the information blocking provisions to the things that TEF people have significantly expressed concern about, which is that some people interpret the confidentiality clauses, contracts to prevent the use of screenshots for demonstrating safety issues and —

## <u>Denise Webb – individual – Member</u>

And education.

#### Arien Malec – Change Healthcare – Member

Education, usability issues, and the like.

## Denise Webb - individual - Member

Things related to the treatment of the patient.

#### **Arien Malec – Change Healthcare – Member**

Sure. Yeah.

## Andrew Truscott - Accenture - Co-Chair

Do we actually want to state and call that out, that these intellectual property considerations come second place to providing patient care? That seems to be the sense that I'm getting. And the preamble doesn't discuss that particularly. I don't know why that wasn't – Arien has gotten to making contortious faces.

## **Arien Malec – Change Healthcare – Member**

I am making contortious faces. I don't know what I think about it. I mean, I understand it's usual practice. I understand it's a workaround for the lack of interoperability systems.

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

The people who do it [inaudible] [00:17:13] it's the only way they can -

#### **Arien Malec – Change Healthcare – Member**

I understand. It's a workaround for the lack of interoperability systems. Do you want to codify it in practice? I don't know. Do you want to create an explicit safe lane for it? It is a practice that is frequently used to communicate information for the context of treatment.

# Cynthia Fisher - WaterRev LLC - Member

Arien, would you just simply say that screenshot use for intended purposes prohibited for development, developers using it for the purpose of developing software, competitive software, and just let it be with respect to, it is a workaround. It's how people may practice and be able to communicate until the systems are – we have interoperability, and then just address the –

## **Arien Malec – Change Healthcare – Member**

I'm advocating staying silent on it. It's a practice that's used. I'm not sure we want to say that it's either – I'm not sure that we [crosstalk] [00:18:15] either legal or illegal.

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

Yeah. Well . . .

## Andrew Truscott - Accenture - Co-Chair

Go on.

#### Cynthia Fisher – WaterRev LLC – Member

I think if you don't have interoperability, it's the only way you can communicate for communication.

# <u>Arien Malec - Change Healthcare - Member</u>

I agree. I agree, yeah. I agree.

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

And then if people get fearful that they are doing a copyright violation because they can't print over the pipes, they don't have it over the pipes together, it's wonky.

#### **Arien Malec – Change Healthcare – Member**

As a patient, I have gotten all kinds of screenshots, because that's the only reasonable way that somebody had to communicate some information to me.

## Cynthia Fisher – WaterRev LLC – Member

Yeah. Yeah.

## Anil Jain - IBM Watson Health - Member

But are you saying that we should explicitly say that that's allowed, or stay silent on it and let people do –

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

I think she was just saying this is a permitted use.

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

I would allow it for permitted use to the patient, except not for competitive – to have a copyright protection for competitive practices.

# Anil Jain - IBM Watson Health - Member

Right. I guess my take on it would be, I think it's going to happen, and it's going to happen in rural communities where they're using some EMR and they're not going to alter it. I get that and how to fix it. But if we say something about it, we're sort of implicitly saying that that's something that we think that this committee feels or this task force feels is appropriate action, as opposed to implementing some other mechanism to exchange. And so, if we stay silent on it, it's not a harm to stay silent on it, because it would still be – you could argue that it's fair use.

## Andrew Truscott – Accenture – Co-Chair

Given the discussion that went on yesterday, it feels like there is sufficient sentiment that to stay quiet and say nothing is a copout.

## Anil Jain - IBM Watson Health - Member

Well, then why don't we put some language in there saying that we should fix those **[inaudible] [00:20:03]** now, continue using –

## Andrew Truscott - Accenture - Co-Chair

And that's what I'm thinking. So, this particular statute is around permitted prohibitions and restrictions.

#### Anil Jain – IBM Watson Health – Member

I understand that. But I think sometimes, there are a lot of things that happen with information sharing that are going to happen. And I think if we explicitly put it in here, then there're other forms of information sharing —

## Andrew Truscott – Accenture – Co-Chair

And that's endorsing it.

# Anil Jain - IBM Watson Health - Member

Again, I'll defer to the consensus of the group, but staying silent doesn't meant that it's a copout if it means that — I think the most important thing to do is to think about why screens are shared. What are the appropriate reasons? What are the reasons that's going to happen because there's no alternative, and what are the reasons that are absolutely illegal and prohibited and should be illegal and prohibited? For example, I wouldn't want to see a screenshot of one of our solutions while I was in oncology so that I could tell the group to train themselves up and then do self-services on it, or a competitor could build it up. That's pretty straightforward. But we also shouldn't be advocating for two providers who find it easier to do screen dumps and share those instead of flipping a few switches and sharing information down the right route. So, I'll stop.

# Andrew Truscott - Accenture - Co-Chair

These are all good points. And . . . [inaudible] [00:21:31].

# <u>Ken Kawamoto – University of Utah Health – Member</u>

This is Ken. If I could ask clarification, is it the fact that this copyright part is in fact – you can do it unless we say here that we can't, or is it a subset of the earlier part that says that's basically the parts that aren't like the five or six specifically exempted communications. As in, is it a further restriction starting from a limited set, or is it a starting from everything's allowed except in these cases? Because I think that that is a really important point, right? Because otherwise, all this is still in the context of I'm reporting something for safety reasons, that kind of thing. The usability, I don't think, is even in there in terms of reporting on usability, unless it's safety.

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

Ken, it's the second one. It would still be bound by the purposes, but it's not restricted to the unqualified protection.

# Andrew Truscott - Accenture - Co-Chair

Correct.

## Denise Webb - individual - Member

Here, I can just – it says here, "We consider screen displays an essential component of health IT performance and usability, and their reproduction may be necessary in order for a health IT user or other health IT stakeholder to properly make communication. Subject matter is enumerated in 170.403A1." 403A1, which says, "A health IT developer may not prohibit or restrict the communication regarding the usability of its health IT, the interoperability of its health IT, the security of its health IT, relevant information regarding user experiences" –

# Andrew Truscott - Accenture - Co-Chair

And if you couple that with what I can see right now, the developer is not permitted to prohibit or restrict communications under the guise of copyright protection or under the guise of copyright [inaudible] [00:23:20] or NDA when the communication in question makes use of the copyrighted material in a way that will qualify as a fair use. It feels like that actually covers it. The question is whether we think the regulation text should also reflect that, or whether we're comfortable with just the preamble.

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

And just a note that I highlighted, we do cite specific to USC107, which has the fair use definition under the Copyright Act.

#### Steven Lane - Sutter Health - Member

That's great. I think getting it – as Arien reminded us, the preamble is not regulation text. And if we want it to be clear to both end users and vendors, it seems like we need to reiterate this in regulation text.

## <u>Arien Malec – Change Healthcare – Member</u>

Yeah. I would make exceptions for things or terms that have well established meanings, and "fair use" is one of those terms that has a well established meaning. It clearly doesn't have a well established meeting in the medical community, but in the legal community, I think anybody who looks at the word "fair use" knows what that means. [Crosstalk] [00:24:25] when we deal with a journal article, [inaudible] deal with education, absolutely, yeah, it does.

## Andrew Truscott - Accenture - Co-Chair

Is fair use a defined term? Have we defined?

## **Arien Malec – Change Healthcare – Member**

Yeah. You could say fair use has the meaning defined by [audio cuts out] [00:24:39].

## Denise Webb – individual – Member

Yeah. I've seen that regulatory text.

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

It appears six times in the regulatory text.

### Denise Webb – individual – Member

The regulatory text or the preamble?

## Andrew Truscott - Accenture - Co-Chair

Sorry, in the regulatory text and the preamble.

## <u>Denise Webb – individual – Member</u>

Yeah.

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

Well, so, in the Copyright Act – I can read it to you, what they define it as. But you could make the suggestion that we pull language from the Copyright Act to clarify, I guess.

# **Arien Malec – Change Healthcare – Member**

It's the usual thing that you've done, where you can say in the definition section that this term has the meaning ascribed to it by – in the same way you did for providers, providers has the meaning as defined by the Public Health Service Act.

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

Yeah. I mean, that'd be a fine recommendation, I think, if you want to do that.

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

So, I'm just calling attention that there's actually a reference there to 17USC107. What is 17USC107?

# <u>Denise Webb – individual – Member</u>

Yeah, but it's down there in a footnote.

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

It's the Copyright Act.

## Andrew Truscott - Accenture - Co-Chair

So, we have to reference it in all of it.

## <u>Denise Webb – individual – Member</u>

We do.

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

We'll just put it in the regulatory text.

## Male Speaker

Yeah.

### Denise Webb – individual – Member

Yeah. I think . . .

#### Ken Kawamoto – University of Utah Health – Member

So, this is Ken. I am personally less concerned after learning about exactly how it's referenced, because it seems like it's not just for the things that – so, anyway, I think it's fine personally to add in the fair use one. One question for usability and such. Is it implied anywhere that you're only allowed to talk about it when it's showing a negative? Like, oh, there's a usability problem or interoperability problem in the health IT? Because positive is okay, right? Because a lot of the times, what you want to share is what's good about what the EHR's letting you do in terms of – for publication, it's not that – compared to showing things that horribly didn't work, it's much more common that you're wanting to share how it did work well. [Crosstalk] [00:26:34]

## Anil Jain – IBM Watson Health – Member

Ken, I think the issue is, when are you going to — in a typical scenario, when would you have not gotten permission from the vendor? If you call up a vendor and say, look, I got some amazing results with this — let's call it an alert in the system, they're going to say, go for it. It's when they have a negative outcome that they generally are concerned, so I think it —

# Ken Kawamoto - University of Utah Health - Member

Yeah. That being true as well, I mean, even for things that are good, they'll often cut out a lot of things that I would think are relevant things surrounding it that shows more context, or

even for things that have been approved previously for public presentation, even for something that another task force in HITAC asked for, that I have gotten approval for like five times prior, to share those screenshots, I have to go through again seeking permission. Can I use these screenshots that I've gotten permission five times before because I can't get permission to use it indefinitely for similar kinds of presentations.

## **Female Speaker**

What kind of things? Is it -

## <u>Ken Kawamoto – University of Utah Health – Member</u>

It can be operatory, right?

## Andrew Truscott - Accenture - Co-Chair

Guys, okay, we need to stop this conversation at this point because we have a lot of other things to get to. I think I've got enough input from the group that I will try and distill this. I'll go back and look at this. The outstanding question around this section is the point that – I want us to consider this, about whether there are sufficient teeth in here to prevent and develop or actually say, well, that wasn't fair use. Okay? That was what he brought up, is this other point. And what is considered inside the preamble. There isn't anything deliberately called – specifically called out in the regulatory text apart from what we see here. Do we think this is sufficient? And with the preamble obviously saying, you can't do that. You can't send it away. Do we think there's something in the regulatory text that needs to reflect that in addition, or are we comfortable with this as it stands?

# **Arien Malec – Change Healthcare – Member**

Well, it might be worthwhile just enumerating the cases that people have complained about. So, for example, using screenshots for both positive and negative usability; discussing poor usability; discussing safety-related issues.

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

But those are protected communications already.

# <u>Arien Malec – Change Healthcare – Member</u>

Right. Exactly. So, I'm trying to get at what are the practices that somebody would be concerned about not be permitted under the [crosstalk] [00:29:05].

# Andrew Truscott - Accenture - Co-Chair

I think the consensus we need to come to on it is do we want to say something specific that a vendor cannot send it away outside the preamble, because the preamble already says that.

#### Denise Webb – individual – Member

I don't think you need to say that because of the enforcement provision. If I'm a provider organization, and my vendor's telling me that you can't share that. That's not fair use. And I know clearly it is fair use, and they take action against me, I'm going to go through the process to file a complaint.

# Andrew Truscott - Accenture - Co-Chair

Yeah.

#### Denise Webb – individual – Member

Vendors don't want that. That provides them teeth in this market, because they are certified under the program. They don't want to jeopardize their certification. So, if they really are being unreasonable, and you go, okay, fine, I'm going to take this —

## Andrew Truscott - Accenture - Co-Chair

Okay. Is that the general consensus?

## Anil Jain - IBM Watson Health - Member

I think it is, because allowed to completion, if we work to entertain Raj's position, would be that in every case where it's a small guy, I guess the bigger guy has deeper pockets, we'd be in the same situation, so why don't we deal with that expectation now?

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

On behalf of the task force, I'll go back to Raj directly and just fill him in on our position and why we think this is actually taken care of in the current drafting, if that's okay with everybody?

# Male Speaker

Yeah.

# Andrew Truscott - Accenture - Co-Chair

Okay. So, let's move on then.

## Denni McColm - Citizens Memorial Healthcare - Member

So, this is Denni. I just wanted to throw in, I mean, as a provider, we use screenshots all day long for training and everything. And if our vendor doesn't prohibit that, none of this applies, right? If our vendor doesn't take a hard line, like apparently some vendors do say you have to get our permission – we use them in presentations, everything. So, we're not putting some burden on us that we don't already have, right?

## Andrew Truscott - Accenture - Co-Chair

I think the question came in full committee based upon an experience, and we, having discussed it, believe that we have sufficient levers inside the regulation as it's currently expressed. And I'll go back and help guide Raj through that, because [inaudible] [00:31:16].

## Denise Webb – individual – Member

Yeah. I mean, if a vendor wants to provide more liberty, that's their prerogative. And so, charge on. [Crosstalk] [00:31:29]

## Ken Kawamoto - University of Utah Health - Member

I know you're trying to move on, but just a real quick comment for the screen distortion part.

Could we just make sure there's some language saying blurring to remove content is okay? Because that's something, for example, vendors oftentimes will want. And then trying to protect the IP, I think that's oftentimes what the vendors request. And I think it'd be kind of weird if this regulation makes it where you can't do that, where you might want to show more of a screen. But in order to — so you get the general sense of everything that's laid out. But you may want to blur things out, especially at the request of the vendor. And if it says you can't, then I think that would be kind of counterintuitive, but it might be baked into this. So, distortion, but excluding blurring to remove sensitive data or something like that. I think that would be [crosstalk] [00:32:15].

## Andrew Truscott - Accenture - Co-Chair

Appropriately redacted.

## <u>Arien Malec – Change Healthcare – Member</u>

Yeah, that's right. Distortion with the exception of appropriate redaction.

## Ken Kawamoto - University of Utah Health - Member

Yeah.

## Anil Jain - IBM Watson Health - Member

I think that's been introduced. I don't want to keep extending this conversation, but that's introduced another level of complexity. My definition of appropriately redacted may be different than yours.

## Andrew Truscott - Accenture - Co-Chair

Yeah. And a vendor could -

#### **Arien Malec – Change Healthcare – Member**

I think the intent here is that if you're sharing a screenshot and you're saying there's some horrendous usability issue in EHRX, then that does not cover effectively liable or creating a Photoshop version of EHRX that is wrong.

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

I'll make a note to have a think about the redaction one or how to go about it, because fair use would – if it's not redacted, then that's not fair use. And so, I'll have a ponder on that one. So, I do want to move on.

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

I think it's actually covered in D1, because it says that you cannot require alteration except to redact PHI.

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

In the actual screenshot section.

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

Yes. So, Ken, I don't think the vendor could require, under this provision, that type of redaction or blurring. But it's not eliminated if you wanted to redact for some reason . . .

# <u>Ken Kawamoto – University of Utah Health – Member</u>

Okay.

## Andrew Truscott - Accenture - Co-Chair

Yeah. But the screenshots -

### Ken Kawamoto – University of Utah Health – Member

I think that's good. Even if the vendor requests, if it's not actually necessary, please just blur it out, I think that's totally reasonable. But yeah. I mean, I think it'd be important to have the option for the sharer to redact out or blur out things like what the other buttons look like, or whatever that's included in that IP that isn't really necessary.

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

Yeah. And can I ask one more question? I'm sorry, one more question on fair use. Is there, within the definition of fair use – I don't have it in front of me – is there anything about length of time for review? So, if I ask a question to be able to share and whatnot, and I do have a question out there, and I have a situation where a vendor just waits forever to get back to me, and then suddenly, I just give up, frustrated. I mean, is there anything here about unnecessary delay here, something to that effect?

## <u>Arien Malec – Change Healthcare – Member</u>

In permission for fair use.

#### Denise Webb – individual – Member

Yeah. That's what this regulation is going to provide.

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

Yeah, I know. I just want to make sure that that's covered. I don't have it in front of me. I just want to make sure that that is covered in that. That's all.

## Andrew Truscott – Accenture – Co-Chair

And to Sasha's point, D1 covers this neatly. It talks about both redaction and conceding particular health information. So, I think –

## <u>Denise Webb – individual – Member</u>

I think [inaudible] [00:34:39].

## Male Speaker

Okay.

#### Denise Webb – individual – Member

[Inaudible] Well, you don't have to ask permission under fair use. You just need to make sure you're using it under fair use.

## Andrew Truscott - Accenture - Co-Chair

Fairly. [Crosstalk] [00:34:52] Let's move on. We're now going to move into something that actually came from workgroup two around the exceptions, and specifically, we're going to talk about fees and permitted fees that can be charged. For those of you not on workgroup two, there has been even more conversation about this topic than any other topic we've had across any of the workgroups, which may astonish you. More, yes.

### **Female Speaker**

More than money?

## Andrew Truscott - Accenture - Co-Chair

More than price transparency, even.

#### **Female Speaker**

More than money!

## Andrew Truscott - Accenture - Co-Chair

It actually is about money. So, I've asked our learned friend – he can't be on all the calls. He can't be sage of sages because they're already occupied by Mark and Mike. So, Arien is going to actually lead us through. He's done the lion's share of the drafting. Mark, can you switch to workgroup two, please?

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

Yes, I'm working on it. I'll get it up in a second.

## **Arien Malec – Change Healthcare – Member**

While you're doing that, let me just set up the discussion, because I think the workgroup appropriately deliberated on this topic. There was a fair amount of discussion. The sense of the workgroup, number one, was that the way that 171.204 and 206 were divided up made it hard to understand what fees were and weren't permitted. So, just for context, 171.204 covers costs reasonably incurred, and 171.206 covers IP considerations, or licensing for interoperability elements. And that it would be better to have a single section covering permitted fees. So, Andy and I had this lengthy discussion about this yesterday. But the way to think about this is that any fee is inherently a restriction on interoperability unless it is permitted. Just as sort of a —

# Andrew Truscott - Accenture - Co-Chair

That's a slightly contorted way of thinking about it.

# <u>Arien Malec – Change Healthcare – Member</u>

A slightly contorted way of thinking about it. But once you're in the frame of what are permitted fees, then it's a lot easier to wrap your head around the language. The second thread of discussion – we had a lot of very detailed discussions about the specific provisions in 204 and 206. But the second thread of discussion was to recognize that there is a distinction between activities for exchange or use that are value-added, for which market forces are a sufficient mechanism for establishing fair pricing, and other activities that are impeded by potential rent-seeking behavior, where market forces are not an appropriate mechanism for establishing pricing. So, we tried to get at – in our discussion, we tried to get at the distinction between appropriate pricing mechanics that address rent-seeking behavior and ensure the data flows, and distinguish that from other kinds of services where we believe that market forces are appropriate.

And the way that we did this was to make a distinction between, number one, access, and in particular, access to what the workgroup discussed as the legal medical record. So, there's a strong consensus that access to – and then this quasi-defined term of the legal medical record, and there's a little bit of difficulty with this term that I'll get into just to make sure people have the context for the discussion, but that access to the legal medical record should not be impeded, and that there are particularly forms of IPR that stand in the way of both access, exchange – or all of access, exchange, and use. And that the pricing regulation that we should be contemplating is focused on basic access and then activities that impede – our IPR that impedes access, exchange, and use.

An example of IPR that could impede access, exchange, or use is, for example, a code set that is not licensed by the U.S. federal government. Just for, again, purposes of reference, because I don't think many people understand this – many of the code sets that are called out in standards are licensed by ILM for blanket use in the United States. There are exceptions. One of those exceptions is a procedural terminology that is extensively used by the largest federal payer. And the way that the vendor or society that licenses that IPR often licenses that IPR is by not just licensing the use for the organization that is using that terminology in their software, but also licenses the downstream use of the terminology. And the way that copyright law works is that their code can't be copyrighted, but the description can be, which means that –

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

[Inaudible] [00:40:34] as diplomatic as you [inaudible].

# <u> Arien Malec – Change Healthcare – Member</u>

Which means that – yeah, if you're confused, yes, we're talking about 60. Which means that you could share the code, but you couldn't share the interpretation of the code to downstream users. So, that would be an activity where IPR could inhibit the access, exchange, or use of the information. So, that was the broad policy framework, or explanatory framework, or background.

## Andrew Truscott - Accenture - Co-Chair

The lens by which we consider it.

## <u>Arien Malec – Change Healthcare – Member</u>

The lens by which we consider it.

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

Let's just get Mark. So, Mark, can you just quickly go back to the group two, please, and search for the words "Mark – scroll to here 4TF meeting." Just look for the word "scroll."

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

Oh, you put it in there, huh? Mark.

## Andrew Truscott - Accenture - Co-Chair

Actually, there we go. That's that.

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

Was that it?

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

Just look for the word "scroll." It's definitely in there.

# <u>Arien Malec – Change Healthcare – Member</u>

It's under 204.

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

Okay.

# <u>Arien Malec – Change Healthcare – Member</u>

So, first of all, I just want to make sure that the broader group understands the perspective that the workgroup used and make sure that we have either consensus or discuss any lack of consensus with the policy framework. And then we can get the language that's being proposed to make sure that the language accords with the policy framework.

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

So, the policy framework you're proposing, Arien, is to combine the two different sections that would be there.

# <u>Arien Malec – Change Healthcare – Member</u>

Yeah.

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

And then also, within the new combined section, to distinguish between what you're calling basic access, the definition of which is hinging on this legal medical record concept that we have to discuss further, and then other types of activity that would be market-based in their

pricing?

# <u>Arien Malec – Change Healthcare – Member</u>

Yeah.

# Sasha TerMaat - Epic - Member

Okay. I follow.

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

Yes, because the original document did entertain the fact, it's literally [inaudible] [00:42:40], okay? And it's legitimate to do [inaudible], but we just wanted to make sure we differentiate between the two.

# Arien Malec - Change Healthcare - Member

Yup. Okay. So -

# Andrew Truscott - Accenture - Co-Chair

Great conversation.

## **Arien Malec – Change Healthcare – Member**

So, there is actually a large amount of discussion text and background in the recommendation that we can go back and refer to, to kind of motivate some of this. But if we actually look at the recommendations. So, first, some high-level recommendations that just establish the policy framework, and then some more detailed recommendations that address the more specific. So, first of all, we recommend combining the two sections into a single section, so that you can look at one section to understand what fees are and aren't allowed to charge.

Second recommendation is make sure that — and this was related to the regulatory text that described cost recovery and the preamble text that described that reasonable profits would be allowed. And the task force found that confusing. And so, there's some suggested language in terms of pure cost or expense recovery with no provision for margin of profit; cost-based pricing, where margin of profit's allowed; and market-based pricing, where the market sets the price as the appropriate terms to use. And let's make sure that those are distinguished. So, where cost-based mechanisms are required, rather than say "the task force," we should say "the committee."

There's a lot of text here basically saying we should allow for reasonable heuristics. So, many HIEs in practice use OE, or revenue, or other kinds of metrics as base proxy metrics for the size of organization, where the size of the organization tends to correspond to the exchange activity of that organization. And to the extent that you allow cost plus or cost recovery, pure cost recovery mechanisms, you should also allow reasonable heuristics. And right now, those would be prohibited by text.

All right. Now we get into the fun stuff. Task force recommends that ONC distinguish

between basic access – and there's a whole bunch of ways of getting at this concept – the data or facts about the patient or patients, legal medical record, designated record set. Just one little nuance here that I think ONC may need to go figure out or we could help ONC figure out, is that if you think about the designated record set, the designated record set already has the mechanisms for describing claiming remittance and any of the pricing associated with claiming a remittance. That's already covered under the concept of the designated record set. It's already established in regulation. I think the reason that ONC went to the definition of electronic health information that they did is that I think there's a legitimate question as to whether the designated record set would apply to prospective pricing information, where – and I think there's an argument to make that the designated record set would apply to prospective pricing information. But that's not a usage that's firmly established in regulation or in usual practice.

So, the designated record set is defined as effectively any data that's used to make decisions about the patient. And it specifically includes claiming and remittance associated with an encounter. It doesn't specifically include prospective pricing. And I think the reason that ONC chose the EHI definition that they did is to fall under the definition prospective price information. So, the way that we're framing basic access, we might want to consider or contemplate also access to prospective pricing information specific to the patient. Yeah?

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

So, a couple of points coming off that. One is that I think my feeling is that the – I recognize what was going on with the EHI definition around prospective. I think that is moving the ball forward, and it's allowing us to put the tracks in place to support future transparency efforts. And that's what we have been asked to do and discuss, and that seems right.

Going back to the use of the various different terminology and classification type sets, okay, we ought to have a conversation around standards essential.

# <u>Arien Malec – Change Healthcare – Member</u>

Yeah. We'll get there.

## Andrew Truscott - Accenture - Co-Chair

Yeah. You did wax very diplomatically about the downstream licensing of classifications and coding. Are we inadvertently or are we deliberately suggesting that they all are standards essential?

# <u> Arien Malec – Change Healthcare – Member</u>

Hold on. Yes.

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

We are. Okay.

## **Arien Malec – Change Healthcare – Member**

We'll get there.

# Andrew Truscott - Accenture - Co-Chair

I do like this dynamically editing it in real-time.

# <u>Arien Malec – Change Healthcare – Member</u>

Yeah. And then under term "basic access," I think a reasonable person would believe that basic access should include access through certified standards, reasonably required to enable access or implement the use of intended use of certified technology. So, there is a practice that is often used where, as an EHR vendor, I purchase a resulting interface, or I purchase resulting or ordering capability, and then I am going to need to go purchase the resulting or ordering interface on top of it. At least in this context, this language is contemplating that use of standards reasonably essential or reasonably required to enable access would be included in the definition of basic access and would therefore be included in the definition of . . . Okay. Would be included – and you'll see later where basic access gets hooked in. So, I just wanted to call that out.

# Andrew Truscott – Accenture – Co-Chair

So, just to amplify that, when we say basic access, what does that mean in terms of fees that you can, in that proposal, legitimately charge?

## <u>Arien Malec – Change Healthcare – Member</u>

Yeah. so, in this text, we are contemplating pure cost recovery for basic access. Not cost plus, but pure cost recovery for basic access.

## Andrew Truscott - Accenture - Co-Chair

And therefore, I think you're saying the additional interfaces which conform to certified standards would be considered basic access.

# <u>Arien Malec – Change Healthcare – Member</u>

Correct.

### Andrew Truscott - Accenture - Co-Chair

Therefore, cost recovery purely.

## **Arien Malec – Change Healthcare – Member**

Correct. Right. Now, if you offer another kind of interface that is not a certified standard, or it's not the interface that you used for gaining certification, or it's not a standard that's reasonably required to enable that form of access, that does not form the term of basic access. So, we're not trying to —

## Andrew Truscott - Accenture - Co-Chair

And that would also include localization, coding, and all that kind of stuff.

# <u>Arien Malec – Change Healthcare – Member</u>

There are some discussion points later on that we'll get to. But there is a nuance relating to

forms where it would be permitted to charge fees. And those would be relating to use of –for example, if a provider required the use of nonstandard terminology or data that was in the chart that was nonstandard, or example – these are real examples – examples where there are results that are in the chart that came from a lab that did not use LOINC, and there's custom mapping that's required, those kinds of things basically should be at market rates because if the vendor provides appropriate interfaces and access to that information, then the vendor could provide those services, or you could contract with a systems integrator. And there's already existing market-based pricing to establish it.

All right. So, that's the recommendation relative to basic access. So, second – yeah, go ahead.

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

Do we have enumerated out anywhere inside the regulations what the certified standards are?

# <u>Arien Malec – Change Healthcare – Member</u>

Sure.

## Andrew Truscott - Accenture - Co-Chair

We do? Do we actually have that exhaustive list?

## **Arien Malec – Change Healthcare – Member**

Absolutely.

# Andrew Truscott - Accenture - Co-Chair

And so, we don't need to have any of the examples in here.

# <u>Arien Malec – Change Healthcare – Member</u>

Absolutely. Now, there are some issues where ONC has removed standards because the corresponding meaningful use definition was removed. So, for example, ONC had a standard for LRI and now LOI, and then removed them because CMS declared the LRI standard – or described electronic reporting as top down.

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

That's what I'm responding to, as you used it as an example.

# <u>Arien Malec – Change Healthcare – Member</u>

Yeah. I did use it as an example very deliberately.

## Andrew Truscott - Accenture - Co-Chair

Wouldn't it be more helpful if we went back and made some recommendations to correct that list?

# <u>Arien Malec – Change Healthcare – Member</u>

Sure.

# Andrew Truscott - Accenture - Co-Chair

Yeah. I think, could we -

# <u>Arien Malec – Change Healthcare – Member</u>

We can make any recommend -

## Andrew Truscott - Accenture - Co-Chair

Could the task force request that we have access to do that, please?

# <u>Arien Malec – Change Healthcare – Member</u>

We can make any – oh.

## **Female Speaker**

Yeah. We've done [crosstalk] [00:52:45].

## **Arien Malec – Change Healthcare – Member**

Right. Yeah, yeah.

## Andrew Truscott - Accenture - Co-Chair

We'll increase our charter because we'll have time.

## Cynthia Fisher – WaterRev LLC – Member

Well, at 30,000 feet, part of the EHI is the patient have access to payment information, past, present, and future. And a big issue when we interview patients and understand their profit situations are they're getting fragmented bills months later, sometimes seven months later. And they're surprised billings. And they don't match up. And even sophisticated patients do their own Excel patients, and they have piles of bills that are overwhelming. And it's like having – yeah. So, the long and the short of it is that's part of the medical record. So, are we looking at, on the standards setting, why not just have HL7 include payment along with the clinical information, the payment information, so that also, the – my kids get Venmo, and they use Venmo –

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

So, that's probably going back to the list, because –

## Cynthia Fisher – WaterRev LLC – Member

Yes. And this could just be an HL7 FHIR standard for -

# <u> Arien Malec – Change Healthcare – Member</u>

Yes. There is one, actually. So, there's an EOB standard that CMS is using, and it's part of what they reference for MA plans. It provides access to the retrospective remit, not to the prospective payment.

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

Correct. But it's still in the HL7 FHIR.

# <u> Arien Malec – Change Healthcare – Member</u>

It's still in the HL7 FHIR standards document.

# Cynthia Fisher - WaterRev LLC - Member

Standards. So, why not - so that's not -

## **Arien Malec – Change Healthcare – Member**

And that's actually a listed standard [crosstalk] [00:54:35]. That's actually proposed as a listed standard, and it would be applied to the payer list that was described yesterday by Alex.

## Steven Lane - Sutter Health - Member

Hey, Arien? Can you take a moment and just clarify what you mean by prospective payment data? I understand retrospectives are what's been paid in the past, but what is included in the prospective? [Crosstalk] [00:54:58]

## <u>Arien Malec – Change Healthcare – Member</u>

Prospective would be I'm going to CPMC, or I'm thinking about going to CPMC, and I'm going to have a knee replacement surgery or hip replacement surgery. Prospective payment would be –

# Andrew Truscott - Accenture - Co-Chair

What is that going to cost me?

## <u>Arien Malec – Change Healthcare – Member</u>

What is that going to cost?

#### Cynthia Fisher – WaterRev LLC – Member

Why don't you call it price?

## Andrew Truscott – Accenture – Co-Chair

Cynthia.

## Cynthia Fisher – WaterRev LLC – Member

Why don't you call it the real price?

# <u>Arien Malec – Change Healthcare – Member</u>

Well, because healthcare's super complicated, and the real price is actually the post-adjudicated –

# Female Speaker

Contract.

## <u>Arien Malec – Change Healthcare – Member</u>

The post-adjudicated contract price is established between the payers, the providers, and –

# Cynthia Fisher - WaterRev LLC - Member

That's what I'm trying to get.

## Andrew Truscott - Accenture - Co-Chair

She wants to be able to say that we have put in place the tracks, so the patient, when they're going to receive care, would have an inkling – let's just say an inkling for the time being – of what that post-adjudicate cost might be. Because the payer would have done a preadjudication on it, etc.

#### Cynthia Fisher – WaterRev LLC – Member

Well, we took Les's big idea, right? We have a mobile device. We have it adjudicated. And we say, okay. The Brigham wants to a knee replacement. What's it going to cost there? And what's it going to cost if I go to Stuart instead?

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

So, if you look at what we can do here, we can put in place the conduit to allow that communication to take place if it's being supported. And from what you're suggesting here, the conduit for any event, whether it's past, current, or pre, to understand the pricing around that would be supported within basic access.

### **Arien Malec – Change Healthcare – Member**

Yes. That's right. That's right.

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

Okay.

# Cynthia Fisher - WaterRev LLC - Member

But hang on with me. Yeah.

#### Anil Jain – IBM Watson Health – Member

Just a quick question. I want to make sure I didn't mishear this. Did I hear that EOBs are part of the legal medical record? Because that's not my understanding.

# <u>Arien Malec – Change Healthcare – Member</u>

If you read the definition of designated record set under HIPAA, then the designated record set includes all of the payment information.

# Anil Jain - IBM Watson Health - Member

So, if a hospital gets an EOB, or the EOBs that are part of the care of a patient –

## **Arien Malec – Change Healthcare – Member**

So, an EOB is an explanation of benefit, where [inaudible] [00:56:59] get is a remit, but that's . . .

#### Anil Jain – IBM Watson Health – Member

Well, in order to get a prospective, they have some exchange happening, right? You're saying that if I were to request my legal medical record, all of those documents have to be provided at this point?

# Cynthia Fisher - WaterRev LLC - Member

That's in the definition, the payment information.

## Anil Jain - IBM Watson Health - Member

Well, I'm talking just legal medical record, right?

#### Cynthia Fisher – WaterRev LLC – Member

Yes, in the -

# <u> Arien Malec – Change Healthcare – Member</u>

Yes. So, the designated record set – we can go to the definition of designated record set under HIPAA. But the designated record set under HIPAA, we can pull it up.

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

I have it. I have it right here. It includes payment information, past, present, and future.

#### **Arien Malec – Change Healthcare – Member**

Right. It does.

### Denise Webb - individual - Member

Pre-adjudication can act on the individual right of access for all of that information.

## <u>Arien Malec – Change Healthcare – Member</u>

Yup.

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

So, this is the thing. Okay. We don't want the patient to have to ask, because the patient – it's part of their record. So, if you can get – what is the adjudicated price quote? Okay, wait.

# Andrew Truscott – Accenture – Co-Chair

[Inaudible] [00:57:58] you to be. Because it hasn't been adjudicated yet. I mean, it's not happened, so it can't be adjudicated because the event hasn't happened yet. So, the preadjudicated price.

# Denise Webb - individual - Member

But the adjudicated.

## <u>Arien Malec – Change Healthcare – Member</u>

And then, again, just to be super clear, unfortunately, the way that CURES was written, it applies to providers, health IT developers, health information exchanges, and health information networks. It does not apply to payers.

# Cynthia Fisher - WaterRev LLC - Member

It does apply to payers.

## **Arien Malec – Change Healthcare – Member**

It does not apply to payers.

# Cynthia Fisher - WaterRev LLC - Member

Well, wait a minute. Because if a payer is part of a health information exchange –

## Denise Webb - individual - Member

Or if they're part of an integrated delivery network.

# Arien Malec - Change Healthcare - Member

Or if they're part of an integrated delivery network.

## Cynthia Fisher – WaterRev LLC – Member

That's why the definition of health information changes. Very important. [Crosstalk] [00:58:39]

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

So that we can use HIN.

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

Well, a payer has to be included because they are exchanging information on that patient. And that's why I keep going back to the CURES Act, and I'm happy to provide this for you.

### Andrew Truscott - Accenture - Co-Chair

Hot coffee. This is almost information blocking, isn't it?

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

Okay, and you can read them all. You can read the CURES Act, you can read the reference from HIPAA. But sit with me on this. Because as a patient, what I was trying to go at on the payment information, even if they get – what's not working today is that payers are saying, oh, we have cost estimators. Go there for what it's going to cost you. Well, and guess what? An estimate isn't reality, okay? So, when a big hospital system –

# <u>Denise Webb – individual – Member</u>

What's it really going to cost me?

## Cynthia Fisher – WaterRev LLC – Member

What's it really going to cost me? Then the bills come in dribs and drabs, okay? And they come up to seven months, on average, later than the actual procedure, okay? And we are finding that time and time again, the patient has no idea what it's going to cost and what the real price is. They can't shop. They can't see, where can I most efficiently get my knee replacement to me and to my employer, okay? And then what we want to provide them, because by law, since 1996, this information is part of their electronic record. And you can say, yes, it is identifiable. If you want to take your identifiable definition, the payment is identifiable to the patient. And the adjudication goes back and forth, and they have the rate -- the rates are already negotiated with my TPA or my insurer upfront. So, it's in the electronic record. And now we have it that it's already standardized with FHIR and HL7. So, why can't the patients get – for the first start, they should get their payment information digitally, that they could get it on their mobile app, along with their [crosstalk] [01:00:43].

## Andrew Truscott - Accenture - Co-Chair

So, what we're seeking to and what Arien's doing with this drafting is to put that information set within this definition of basic access so that the track is there to allow that information to flow.

# <u>Arien Malec – Change Healthcare – Member</u>

Yeah. We're laying the train track.

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

Because right now, we've taken the hurdles out of the way, right?

## <u>Arien Malec – Change Healthcare – Member</u>

That's the right metaphor. We are laying the tracks.

# Cynthia Fisher - WaterRev LLC - Member

So, we don't have to go to HL7 and ask them for a standard because there already is one.

#### **Arien Malec – Change Healthcare – Member**

There already is one. [Crosstalk] [01:01:03]

# Andrew Truscott - Accenture - Co-Chair

This is already part of – there's a whole domain in HL7 for financial [crosstalk] [01:01:07].

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

Okay. So, can we confirm that if we appropriately utilize the definition of health information exchange, the payers are in this bucket too for being part of information blocking issue [crosstalk] [01:01:20].

# Denise Webb - individual - Member

CMS is going to require them.

## **Arien Malec – Change Healthcare – Member**

Yeah, CMS will require another mechanism, yeah.

## Denise Webb - individual - Member

Because they're requiring them to be a part of an exchange.

## Andrew Truscott - Accenture - Co-Chair

The definition of a network is one that's also used some issues across the industry. We will as a task force go back and look at the electronic health information definition to ensure that it's within the spirit of what CURES was looking to do. And I'll commit —

# Steven Lane - Sutter Health - Member

Excuse me.

## Andrew Truscott – Accenture – Co-Chair

That's not what we're looking at today, but we do need to go back and check this EHI definition. I'll put it here, and I'm going to go through this. Okay?

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

Can I just –Andy, this is Steven. Just again, what we heard from CMS was **[crosstalk] [01:01:59]**. I'm sorry.

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

You get permission because it's very early. Go ahead.

#### Steven Lane – Sutter Health – Member

Thank you. What we heard from CMS yesterday, Alex, was that the payers need to be part of a trusted exchange framework, not network. So, I think we just have to be clear on those terms to make sure that indeed, the payers get captured in all of this.

## **Arien Malec – Change Healthcare – Member**

Yeah. And also, just to be really clear, and this is just me in pedantic rules mode, and this is why I was trying to drive the distinction between the payers that CMS has regulatory authority over and the payers CMS doesn't have regulatory authority over yesterday. But the access provisions would be to the network the payer is part of, not to the payer themselves. So, there may be other legislative or regulatory mechanisms required to further open prospective price transparency from payers. But to Andy's point, the intent here is to open up many or most of the rails that are currently impeding access to both clinical information, prospective payment, and retrospective payment information. All right.

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

So, on that, aren't we just –

# John Kansky - Indiana Health Information Exchange - Member

Hey, Andy?

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

Cynthia, please.

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

Aren't we just looking for – since it's already been done on the payment for HL7, aren't we just looking for the pipe, and shouldn't it be very efficient to do the price in HL7 then too?

## **Arien Malec – Change Healthcare – Member**

The retrospective price, yes. Prospective price, there's not yet a standard for yet.

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

Yeah, no, but I'm saying, the standard exists for payment, financial.

## Andrew Truscott - Accenture - Co-Chair

But there's no policy to make it happen.

# **Arien Malec – Change Healthcare – Member**

That's right. There's no policy to make it happen.

## Andrew Truscott - Accenture - Co-Chair

The standard to convey the information. And we were in the – Cynthia said the pipes to enable that. But there's no health policy.

# <u>Arien Malec – Change Healthcare – Member</u>

Well, there actually are – because it's part of conditions of participation CMS is now also requiring hospitals to list their published – yeah.

## Andrew Truscott - Accenture - Co-Chair

This isn't for us to -

## **Arien Malec – Change Healthcare – Member**

We have a lot -

# <u>Denise Webb – individual – Member</u>

John's had his hand up.

## Andrew Truscott - Accenture - Co-Chair

Yeah. We put in place the framework to allow the information to flow. There is other machinations going on to force – to instruct that that information should flow.

# Cynthia Fisher - WaterRev LLC - Member

Yes. The question I have is, do we go to the HL7 route and say here, just as in payment is

supposed to be there, price needs to be there to HL7. And that becomes a recommendation from the task force –

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

And actually, I would invite you to come to the board of HL7 and would have that conversation there.

## Cynthia Fisher - WaterRev LLC - Member

Yeah.

## John Kansky – Indiana Health Information Exchange – Member

Andy.

## Andrew Truscott - Accenture - Co-Chair

And they will say it's already in the domain, and we're -

## Cynthia Fisher - WaterRev LLC - Member

It's already in the domain, so it should be very efficient, because –

# <u> John Kansky – Indiana Health Information Exchange – Member</u>

Andy.

## **Arien Malec – Change Healthcare – Member**

John's trying to get us.

# John Kansky - Indiana Health Information Exchange - Member

Yeah. If we're not going to use the raised hand function, could you at least pause occasionally for those who are the phone and just inquire? Sorry, it's just hard — I mean, the point I'm trying to make was like five minutes ago. I just wanted to clarify — I didn't want a misconception to keep being an important part of the conversation. So, with the disclaimer that the definition of HIE and HIN is currently very broad, what we traditionally think of as an HIE, when payers share data with them, it's, in my experience, uncommon for that information to include pricing or cost. It's claims utilization information, clinical information — but the financial information is stripped out. So, I just didn't want that misconception to be part of people's logic.

# <u>Arien Malec – Change Healthcare – Member</u>

And John, I have a perspective on that, which is why there's discussion later on relating to contractual provisions. Very often, even when – so, our legal counsel, Change Healthcare's legal counsel, had a fascinating example of a case where even where price transparency information was allowed under our BAA terms to be shared, one of the parties to the network sued us over confidentiality, saying that price information notwithstanding, that it was shared electronically, was confidential information not to be shared. And it got litigated and of course decided against that sharing. So, in many cases where price information's not being shared, it is not being shared because either, A, it's not from part of the BAA terms, or

B, confidentiality terms are being used to -

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

To make this crystal for everybody –

# <u> Arien Malec – Change Healthcare – Member</u>

- prevent that sharing.

## Andrew Truscott - Accenture - Co-Chair

The reason it's not being shared is procedural and policy-related, not capability of the sender to share.

## <u>Arien Malec – Change Healthcare – Member</u>

Correct. Exactly. Exactly.

## Cynthia Fisher - WaterRev LLC - Member

Oh, yeah. One could call it collusion among big players to be opaque.

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

We wouldn't call it collusion.

# <u> Arien Malec – Change Healthcare – Me</u>mber

And we discuss that point explicitly later on in the contractual provision section, because it is a significant term. Okay. I'm going to keep going.

#### Denni McColm – Citizens Memorial Healthcare – Member

So, wait. This is Denni.

## Cynthia Fisher - WaterRev LLC - Member

So, just a question. Out of this task force, if the OBM payment happens that way, what we want to do is empower the patient efficiently to get that billing data, the billing and payment data.

# <u> Arien Malec – Change Healthcare – Member</u>

Absolutely.

# Cynthia Fisher - WaterRev LLC - Member

And comprehensively.

## Andrew Truscott - Accenture - Co-Chair

Remove the hurdles.

# <u>Arien Malec – Change Healthcare – Member</u>

Absolutely.

## Andrew Truscott - Accenture - Co-Chair

That's exactly what we're here for.

## Cynthia Fisher – WaterRev LLC – Member

And if you have no pricing, you sit overwhelmed, because you are surprised.

#### **Arien Malec – Change Healthcare – Member**

Yes.

#### Cynthia Fisher – WaterRev LLC – Member

Okay, with a \$6,000.00 anesthesiologist out of the network for a colonoscopy. So, you have no voice to say, I didn't know. And now you're stuck with this bill, or an \$18,000.00 genetics test before [crosstalk] [01:08:14]. So –

## Andrew Truscott – Accenture – Co-Chair

So, we enable the information to flow so those kinds of problems can be addressed.

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

That's right. Okay. Great.

#### Denni McColm - Citizens Memorial Healthcare - Member

This is Denni. This is Denni. I just wanted to make sure we're clear that the provider doesn't have the EOB information. The payer has the EOB information.

#### Arien Malec – Change Healthcare – Member

The provider does have the remit when it comes back.

#### Denni McColm - Citizens Memorial Healthcare - Member

The remit, but not – we don't know how much of their deductible they've met.

#### **Arien Malec – Change Healthcare – Member**

Correct. That's right.

## <u>Denni McColm – Citizens Memorial Healthcare – Member</u>

Right? We don't have all that other information. We know what we got paid, and we know what our contract is, but we don't know the specifics on that individual. That's a payer thing.

## <u>Arien Malec – Change Healthcare – Member</u>

That's right.

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

Okay. It's not for this group to litigate through how to change health policy to make some of these things happen. That's for elsewhere. But we'll recognize that's going to be needed for

this to be used.

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

But this is the question, okay? In the food chain of the financial transaction, there is a time when the provider knows what they're going to get paid before they do the procedure.

## Andrew Truscott - Accenture - Co-Chair

No. Sometimes. Sometimes not. They know the cost that they have to perform the procedure.

## <u>Arien Malec – Change Healthcare – Member</u>

They don't know that either.

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

Potentially. [Crosstalk] [01:09:30]

## <u>Arien Malec – Change Healthcare – Member</u>

They know the procedure that they're going to – they know the DRG or the CPT code that they're going to charge. [Crosstalk] [01:09:36]

#### Cynthia Fisher – WaterRev LLC – Member

But they have a CPT code. They have it bundled and unbundled. But DRG, CPT bundled and unbundled, right?

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

Yup.

## Cynthia Fisher - WaterRev LLC - Member

And then they know the contractual negotiated rate with that insurer.

## <u>Arien Malec – Change Healthcare – Member</u>

If they're good.

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

They have a rate card.

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

It's more complicated than that, though.

#### **Arien Malec – Change Healthcare – Member**

If they're good.

## Andrew Truscott - Accenture - Co-Chair

Because we are off track and we are going to come back on track in about two minutes,

okay? But in terms of provider, there are many different routes by which what gets billed gets defined. And at the point a procedure is conducted, that may or may not be accurately known. Leave it at that?

#### Cynthia Fisher – WaterRev LLC – Member

Okay, this is on the standard setting on the pipe.

## Andrew Truscott - Accenture - Co-Chair

This has nothing to do with the standard on the pipe.

#### Cynthia Fisher – WaterRev LLC – Member

No, I have a question on the pipe. On the pipe, because you guys know – on the pipe of that standard now, on the financial negotiated rate between the provider and the payer, what is the standard that they're using now? S12.

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

Yeah. S12. 837 - [crosstalk] [01:10:51].

## <u>Denni McColm – Citizens Memorial Healthcare – Member</u>

That's not the contracted – that's not the standard for the contracted rate. The standard for the contracted rate is a contract in a file cabinet someplace that, if we're good, as someone mentioned, we can build into our system to try to estimate and anticipate what we should have gotten paid.

## <u>Arien Malec – Change Healthcare – Member</u>

Anyway, let's keep going.

## Valerie Grey - New York eHealth Collaborative - Member

Can we move on? I mean [crosstalk] [01:11:13] is that there is no such thing as a simple price that is available to answer all the questions that we're talking about right now.

#### <u>Arien Malec – Change Healthcare – Member</u>

And we're not going to solve that [crosstalk] [01:11:22]. We can open the pipes.

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

Was one of our other recommendations to set up a group that will spend time going through all of this? Because we've got a whole bunch of other things we're supposed to get here.

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

Yeah. No, I'm just looking at the pipe, the conversion to HL7 of that pipe. Laying the groundwork for the pipe. It shouldn't be a big deal, right?

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

I think we are going to move on, okay? The point is, the standards exist. The standards can be utilized. We need to make sure that they are going – everything is clear so they will be

utilized, and that information, there is no reason for that information to be blocked.

## <u>Arien Malec – Change Healthcare – Member</u>

Right. And having that information flow will enable many of the services that will establish price transparency.

## Andrew Truscott - Accenture - Co-Chair

And what we're going to discuss is what's legitimate to charge for enabling that information sharing.

## **Arien Malec – Change Healthcare – Member**

Correct. Okay. So.

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

That's what this conversation's supposed to be about.

## Cynthia Fisher - WaterRev LLC - Member

Charge whom?

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

Charges. Okay?

# <u>Arien Malec – Change Healthcare – Member</u>

So, the next paragraph was an agreement in the task force that there well may be value-added services. So, the example that's given here is a risk scoring service. There may well be value-added services that are then incorporated into the chart and used to make decisions. Under the definition of a designated record set, that's already part of the chart, and it's already related to basic access.

All right. Task force or committee recommends that ONC distinguish between IPR, intellectual property rights, that are essential or is essential to access – thank you – to access, exchange, or use, to use the basic facts. And essential IPR would include standards essentially IPR. So, that's any IPR that's named in a standard and reasonably required to use that standard. There's a well established amount of law relative and custom relative to standards essential IPR that's actually well named in the preamble.

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

Is this still certification standards or any standards?

## <u>Arien Malec – Change Healthcare – Member</u>

That's a great point. Mm, that's a great point.

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

I think it should be divided for certified standards [crosstalk] [01:13:41].

## <u>Arien Malec – Change Healthcare – Member</u>

Yes, that's right.

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

Follow-up question on this.

# **Arien Malec – Change Healthcare – Member**

Yeah?

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

Different standards have different remuneration models around them. So, something like SNOMED CPT is paid for as a countrywide license **[crosstalk] [01:13:57]**. Something like CPT is obviously, as we discussed. Doesn't this potentially have the – even though it's unintended – effect of saying actually – pushing people towards using something like a SNOMED to have an IT versus CPT? Because –

#### **Arien Malec – Change Healthcare – Member**

I think it would have the intended effect of pushing -

## Andrew Truscott - Accenture - Co-Chair

It's a consequence.

#### **Arien Malec – Change Healthcare – Member**

I think it would have the intended effect – this distinction of an essential intellectual property right would have the intended effect of making sure that the AMA licensed CPT in terms that met the RAND pricing terms, yes.

## Andrew Truscott - Accenture - Co-Chair

Okay.

#### Arien Malec - Change Healthcare - Member

Now -

## Andrew Truscott - Accenture - Co-Chair

It'd be interesting to see the AMA make conversation about that point.

## <u>Arien Malec – Change Healthcare – Member</u>

Well, I'm sure that they'll have comment, and they'll provide their comment at ONC. That doesn't mean that – if we think it's the right thing to do, it doesn't meant that we shouldn't recommend doing it.

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

It's all about the money, isn't it?

#### **Arien Malec – Change Healthcare – Member**

Yeah. All right. Okay. So, now we get to the money section of this discussion. We recommend that fees allowed for basic access be on a pure direct cost recovery basis only. In many cases where basic access is provided via widely deployed consent-based standards — that should be certified standards — built into health IT, such direct cost would be minimal. Task force does not recommend the cost to develop standards be part of the cost basis for fees for basic access and believes this provides a significant incentive to adopt standards.

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

Okay. So, [inaudible] [01:15:51] direct cost. When you say pure direct cost, that can have several different meanings. So, I could turn around and say, actually, the labor that I'm going to have to charge to make something happen for you, that's a direct cost.

#### <u>Arien Malec – Change Healthcare – Member</u>

That is a direct cost. So, what we're excluding as part of the calculation for direct cost is the development cost to develop the certified standard that's already required to get the application certified. And you'll see also, not including reasonable mapping to standards. So, reasonable mapping would be defined as mapping of proprietary terminology —

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

That's not basic access.

## <u>Arien Malec – Change Healthcare – Member</u>

That is part of basic access.

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

Mapping's a part of basic access?

#### **Arien Malec – Change Healthcare – Member**

So, just to be clear –

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

I like that.

## <u>Arien Malec – Change Healthcare – Member</u>

The intent of this section is to say, if I have, as an EHR developer, a custom code set that I used for procedural coding or for condition coding, and I'm required to make that access via SNOMED, I should not be allowed to charge for the one-time mapping of that custom procedural code to SNOMED. Later on, exceptions would include cases where data terminology sets exist that are not reasonable to include in mapping standards and where sufficient mechanisms to basic access exposing the nonstandard data exist. And I'm more than happy to make this clearer if this is not clear. So, the intent here is that as an EHR developer, if I have an internal proprietary code set that I use, and to make it available via a consolidated CDA, I've got to map to SNOMED, that that one-time cost of mapping between my internal code set and SNOMED is part of the cost of providing that standard.

If the way that I license my software, I allow each of my providers to customize, add additional procedural terminology or additional condition terminology or problem terminology, etc., etc., etc., then my obligation as an EHR vendor is to make the data available, and the costs incurred to do the additional mapping would be basically on the provider to achieve, either through the vendor or through a systems integrator.

#### Female Speaker

At market rates.

## <u>Arien Malec – Change Healthcare – Member</u>

At market rates.

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

We probably need to call this out a bit clearer. I think where a vendor builds a new feature to enable information sharing, if that new feature conforms to a certified standard, how would they charge for that as a product upgrade?

#### **Arien Malec – Change Healthcare – Member**

They would typically charge for the product upgrade associated with the certified module. I don't know – Sasha, you're closer for this, but in our experience –

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

Can you give the scenario again?

## Andrew Truscott - Accenture - Co-Chair

The way this is worded, they might not be able to.

#### **Arien Malec – Change Healthcare – Member**

So, I'll give a personal experience of one person's way of addressing some of this complexity, which is that in areas when I have sold certified, in this case, ePrescribing or resulting modules, the interfaces were included as part of the price. But if there was a new version of that software to be certified to edition 2015 and not edition 2011, or whatever it was, or 2014, or —

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

Okay. But these are exceptions to information blocking.

#### <u>Arien Malec – Change Healthcare – Member</u>

Yeah.

## Andrew Truscott - Accenture - Co-Chair

They're not in the maintenance of certification section, so they're not specific to -

## <u>Arien Malec – Change Healthcare – Member</u>

Nothing limits the EHR vendor's ability to charge for the EHR technology itself.

## Andrew Truscott – Accenture – Co-Chair

Agreed. But does this inadvertently say they can't charge for interoperability [crosstalk] [01:20:16]?

## **Arien Malec – Change Healthcare – Member**

What it effectively requires is to bundle the standards-based access as part of the certified technology.

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

Could we not use the word bundle? Okay. But these are in exceptions. They're not in certified health IT maintenance and certification.

## **Arien Malec – Change Healthcare – Member**

Nothing in this section addresses what anybody can charge for their software. This is purely about information blocking relating to access, exchange, or use.

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

So, if I understand this, and this is new to me – so, you're proposing that there might be a pricing model where a particular software product sold both – well, a software license, and then additional interoperability elements, such as an interface, some of those interfaces might fall under this basic access if they were, for example, the ePrescribing interfaces that are referenced in the certification standard, other interfaces, or interoperability elements that are part of that might be separate. And you're saying that the software license for the module itself, which would include any kind of upgrade, if those were something that were charged for, would be at market prices.

#### **Arien Malec – Change Healthcare – Member**

Yup.

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

It's the interoperability elements, particularly, in this case, the ones required for basic access, such as the interfaces that would be named in the certification standard, that would be a peer direct cost recovery basis.

## <u>Arien Malec – Change Healthcare – Member</u>

Correct.

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

And interoperability elements that would not be part of that basic access could then be charged at market rate.

## <u>Arien Malec – Change Healthcare – Member</u>

Correct.

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

I don't know if that example maybe helps clarify.

## <u>Arien Malec – Change Healthcare – Member</u>

Yeah.

#### Denise Webb - individual - Member

I have a question. So, I mean, if I was a health IT vendor, based on what you just described, then I can charge what I want for my EHR software, but I can't charge for the interface.

#### Arien Malec – Change Healthcare – Member

Yeah.

#### Denise Webb - individual - Member

I'm just going to build it into my price of my EHR software.

## <u>Arien Malec – Change Healthcare – Member</u>

Absolutely.

#### Denise Webb - individual - Member

So, how is that going to be regulated, what you chose to build in as the price of you EHR software, whether it was the actual cost of the interface?

## Anil Jain – IBM Watson Health – Member

Well, we can't figure that out now. So, the question will be, will the market then just decide, right?

#### Arien Malec - Change Healthcare - Member

Yeah.

## Anil Jain - IBM Watson Health - Member

I think the question is that you shouldn't charge anything incremental, because I don't think that is –

#### **Arien Malec – Change Healthcare – Member**

That's right.

## Denise Webb - individual - Member

Yeah, because -

## <u>Arien Malec – Change Healthcare – Member</u>

If I buy a results module, then the results is a particularly bad example, because we removed – so, ePrescribing is a great one. So, if I buy an ePrescribing module, my expectation should

be the price I pay for buying the ePrescribing module, and I should bill the conveyor of vendor A, vendor B, and vendor C, the expectation I should have is that I buy the ePrescribing module. If they certify the EHR module, it should include all of the costs associated with doing ePrescribing.

#### Denise Webb - individual - Member

I absolutely agree with **[crosstalk] [01:23:16]**. I had a number of small provider organizations that said, we bought the immunization capability.

#### <u>Arien Malec – Change Healthcare – Member</u>

That's a totally different issue.

#### <u>Denise Webb – individual – Member</u>

And now, we're getting charged and connected.

## **Arien Malec – Change Healthcare – Member**

That is a totally different issue, because the EHR module that you bought where there is a defined standard – in this pricing approach, that standards-based interoperability would be included in the price of the immunization module.

## Denise Webb - individual - Member

Right. That assumes you're [crosstalk] [01:23:51] the standard.

## <u>Arien Malec – Change Healthcare – Member</u>

But the state that uses a nonstandard mechanism -

#### <u>Denise Webb – individual – Member</u>

But we didn't. We used the standard. And then they said, oh, now we have to pay \$15,000.00 more.

#### **Arien Malec – Change Healthcare – Member**

Right. And that's pretty – so, that's a –

## Denise Webb - individual - Member

So, we're going to get rid of that problem, right?

## <u>Arien Malec – Change Healthcare – Member</u>

Correct.

#### Denise Webb - individual - Member

Okay, great.

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

The majority of EMR, EHR contracts I've ever seen have many different aspects to their

pricing. And interfaces integrate is always a separate carve-out. And there's sometimes a slim section, sometimes an extensive section calling out specific interfaces that require construction. And I'm not going to pretend to understand the intricacies of how EMR vendors wish to do their pricing. But I'm moderately comfortable with assuming that there are different pricing approaches, different clients who want to see pricing different places, whether that's a capex or an opex experience, and all sorts of other reasons why contracts are drawn the way they are. And we might inadvertently – that was very pleasant, the music [inaudible] [01:24:56]. We might inadvertently – the unintended consequence might be we actually start dictating how contracting could take place. So, I don't think that's our intent either.

## <u>Arien Malec – Change Healthcare – Member</u>

I'll just put it as simply as I can. The intent here is that if I buy certified module X, that any standards interface that's required for that certification are included in the price of X.

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

[Inaudible] [01:25:26] certification, because these are – we're in a section that isn't about certified health IT and [inaudible] health IT.

## **Arien Malec – Change Healthcare – Member**

Right. Well, there is an obligation, and I don't know if I wrote that, so we probably should make sure –

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

[Crosstalk] [01:25:40] has to interoperate.

#### **Arien Malec – Change Healthcare – Member**

So, there is also an obligation to provide – if there isn't a certified standard, there is an obligation at cost basis to provide basic access, independent of there being an existing standard.

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

We need to call that out very specifically. [Inaudible] [01:26:03]

## <u>Arien Malec – Change Healthcare – Member</u>

So, the first sentence is, what the TF recommends – and yeah, we can clarify this sentence. But this committee recommends that allowed fees for basic access be on a pure direct cost recovery basis only. Period. Second sentence. In many cases where basic access –

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

Where are you now?

# <u>Arien Malec – Change Healthcare – Member</u>

This is on the top of this paragraph that's being highlighted right now by Mark. So, period. In many cases where basic access is provided via widely deployed consensus-based certified

standards built into health IT, such direct costs can be minimal. And the intent here is that it is more expensive for a health IT vendor to make an ad hoc access to enable basic access than to enable that one time, particularly enable it one time via standards. That's the intent. You've got to provide basic access. The cheapest and easiest way to provide basic access should be through a certified standard.

Per this discussion, I think we need to clarify this nuance of what mapping is and isn't included, because the intent is to include anything reasonably necessary to use the module as purchased, but not to include any places where I'm shooting myself in the foot. Many EHRs allow for modification of the procedural terminology or modification. But the problem with terminology, many EHR users like to have problem lists defined just so. And in some of those cases, those modifications are going to require additional costs to map to standards. And that should not be the vendor's problem.

#### **Female Speaker**

Agreed.

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

Where mapping are being created between a standard and something else, that mapping, does that now enter some kind of public domain usage? So, vendor A and vendor B both need to conduct the same mapping between the same standard and the same localization, because they're being used in the same organization, but different reasons. Why would it be a legitimate cost for that organization to bear twice?

## Cynthia Fisher - WaterRev LLC - Member

So, are you saying open source?

# Andrew Truscott - Accenture - Co-Chair

Where you've got a mapping that been created between a standard and something local inside this hospital system. And vendor A has done it and charged for it because that's legitimate, okay?

## <u>Arien Malec – Change Healthcare – Member</u>

Yup.

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

Vendor B has exactly the same mapping to do, and they would charge for that again. Do we entertain that actually – and this does happen, repeatedly.

## <u> Arien Malec – Change Healthcare – Member</u>

Yeah. Sure.

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

So, should it only be something that the provider has to incur a cost for once?

#### **Arien Malec – Change Healthcare – Member**

That's a classic example. We've got FTB, Metaspan, GoldRX – all of them have proprietary medication terminologies, and they all sell mappings to RXNorm and NDC.

#### Denise Webb - individual - Member

But that's different. They're mapping to their proprietary – what you're saying is there isn't proprietary. There's a standard mapping.

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

Yeah, but localization – there's local code sections all over the shop, okay? And I've got many hospital clients who have their own specific things for specific reasons, which you've met to a standard. Another vendor working inside the same organization with a product which does something inside the organization would have to go and recreate the same mapping that they've already paid for once under another vendor.

## Anil Jain - IBM Watson Health - Member

Yeah, but they could negotiate to own that map if they wanted to. I mean, I think -

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

Yeah. I'm just wondering whether we should stay silent on that, or we should **[crosstalk] [01:30:10]**.

#### Anil Jain – IBM Watson Health – Member

I think we have to, because the alternative would be that we're going to have that organization try to figure out which vendor are you going to subsidize with the other vendor. So, the best way to do it is to simply say, if we went to a vendor and said, look, you're going to be performing this mapping for me for my institution. I want to own it.

#### Denise Webb - individual - Member

So I can use it with other vendors and save the money.

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

And then they can use it however they want.

## <u>Arien Malec – Change Healthcare – Member</u>

The intent here is to be surgical and make sure that access to health information flows without major cost impediments, but not to get into the details of negotiations or value-added services.

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

Yeah. I'm just wondering where we've – if there's something to be –

#### Anil Jain – IBM Watson Health – Member

And if a hospital is smart, what they'll do is they'll try to move their code sets, their internal codes, closer and closer to open source standards, or closer and closer to something that

might -

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

To an open standard, yeah. But not open source, but open standards.

## Anil Jain - IBM Watson Health - Member

Open standards, yeah. But the point is that I don't think we're going to be able to dictate through this how we want to have them do their business.

## <u>Arien Malec – Change Healthcare – Member</u>

Yup. Okay.

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

The onus is on us to eliminate information blocking. And I'm wondering whether this is actually an area where it's not address right now, and it's an area that we could actually facilitate an assist.

#### Cynthia Fisher - WaterRev LLC - Member

Looking at the world of open source, what level of this "mapping" can be more applied from open source?

## Andrew Truscott - Accenture - Co-Chair

Well, open source is a way of placing prior work into a more openly available way of consuming that without any additional charge.

#### Denise Webb - individual - Member

But it still costs to implement, but that's a misnomer.

## Andrew Truscott - Accenture - Co-Chair

There is an initial cost to create the -

## Denise Webb - individual - Member

To create it, but then also if you want to use it. It's like with red hat lining.

# <u>Arien Malec – Change Healthcare – Member</u>

Yup.

#### Cynthia Fisher – WaterRev LLC – Member

But if we want to get there to prevent information blocking in the fastest way, I mean, isn't that how the rest of the industry works to provide open sourcing, that you open the pipe from those mappings?

## <u>Arien Malec – Change Healthcare – Member</u>

Well, in many cases – yeah. So, for mappings, in many cases, ILM has solved this problem at a

nationwide level by licensing and making available almost all of the relevant terminologies. The one example, or I guess, the examples that exist, are Metaspan and FTB, GoldRX, etc., have a good amount of decision support that operate against – for historic reasons – not the RXNorm term, but their own GCN sequence numbers, etc., etc., etc. And CPT is a classic example of something that does not fall within ILN licensing. And then the variety of use is effectively proprietary codes. And so, what this is trying to address is to the extent – so, next paragraph.

So, I think we've got some good proposed modifications to this paragraph. Next paragraph is on IPR – again, intellectual property rights. Committee recommends that allowed use for access, exchange, and use essential intellectual property rights be sent on RAND basis. Such feats would not be reasonable if they materially discourage access, exchange, or use, or impede the development of competitive markets for value-added exchanges and use services. Recommends that access, exchange, and use essential IPR license grants be sufficient for actors to provide access and/or deliver exchange and use services. So, as an example, and here's the example, IPR grants for terminology sets that are access, exchange, or use essential should be sufficient to allow access, exchange, and use for permissible purposes. You can't restrict access to downstream actors through your IPR license grant.

## Sasha TerMaat - Epic - Member

So, logistically, you have earlier the term "basic access" and "essential access." Are those the same, or are you contemplating different things for essential and basic access?

#### Arien Malec – Change Healthcare – Member

Yeah. So, basic access is access effectively to a legal medical record and prospective pricing. Essential IPR is intellectual property rights that are reasonably required to expose the data and have it be interpreted and used. So, an example of an essential IPR is the example of CPT codes, or in cases where – unfortunately, in healthcare, we don't have many of these. This is much more prevalent in consumer technology and the like – in cases where the standard has an associated IPR license, so a patent license that used to be included.

#### Denise Webb – individual – Member

Now, are all of these recommendations clarifications that will go into the preamble? Because –

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

No, these are all recommendations just for ONC to consider to make our vote to reconsider regulations and preamble as appropriate.

#### Denise Webb – individual – Member

Oh, so we're not giving them -

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

There's no regulatory text drafting in workgroup two.

## <u>Denise Webb – individual – Member</u>

Okay. We'll want to make sure we –

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

It was felt that that was extensive and not the best [crosstalk] [01:35:28].

## Denise Webb - individual - Member

Are we making a recommendation just for them to take that recommendation and change the preamble or regulatory text?

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

Well, they'll obviously make that determination. And we obviously work with them –

## <u>Denise Webb – individual – Member</u>

Okay. Well, I think what they were asking us to do in our recommendation is to say that, that we're not.

## Andrew Truscott - Accenture - Co-Chair

Yeah.

#### Denise Webb - individual - Member

Fine. Now, your format is much clearer than what our task force did, because you actually show when it's regulatory text –

## Andrew Truscott - Accenture - Co-Chair

Oh, I was channeling my inner Cynthia, who said, I want to see the markup.

## Denise Webb - individual - Member

Okay.

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

And honestly, this stuff, I don't think we are suitably skilled.

#### **Arien Malec – Change Healthcare – Member**

I agree. I agree. We tried, and –

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

And failed.

#### **Arien Malec – Change Healthcare – Member**

Failed, exactly.

#### Denise Webb – individual – Member

No, they're better suited to –

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

Yeah. The other workgroups, it was more straightforward, but this is actually quite complicated.

## Denise Webb - individual - Member

And I think that's the case in a lot of our recommendations from ONC, that we're not trying to rewrite –

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

Yeah. What we want to do is to find the outcomes for Seton to achieve. I must confess, I'm a little bit – and this is not just me; it's also the humble vessel by which other members of the workgroup wish to express themselves through me. The mapping one is potentially a thorn, because with the spirit of CURES, which is looking to remove barriers to information sharing, if mappings are created, then why would they not be freely available?

## <u> Arien Malec – Change Healthcare – Member</u>

Yeah, they would be basically freely available if I provide –

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

Free in the [inaudible] [01:37:04] term, not openly.

## <u> Arien Malec – Change Healthcare – Member</u>

So, here's the way I would put this, and I welcome – at this point, we're discussing ways of addressing the text to potentially address this issue. Here's the way that I would put this. I would say a vendor has an obligation under basic access provisions to make the data usable. The easiest way to do that is through mapping to a standard, and the usual way for a provider or other systems integrator to interact with that vendor is via the well-defined standards, or if there aren't standards, via whatever mechanism the vendor provisioned to enable that basic access. That's number one.

So, the mapping would be included, because I could pull the data out of the EHR in the form, in a standards-based form. If you're asking for, well, we should also provide access to internal database terminology to external standard, what my software engineering had on, I'd say, wouldn't it be better just to offer an API that provides access to all of the capability and not get into brittle mappings into database structures that are going to change from version release to version release? And are you then putting yourself in the position of regulating basically version releases and database changes?

## Andrew Truscott - Accenture - Co-Chair

I think that's a different issue. I get where you're going on that. I think the provision of open APIs using open standards, I think, is well-litigated through [inaudible] [01:38:53]. I'm talking about where there is specific coding which is not necessarily a standards base, and it's not necessarily a complete localization, but it could be. And you and I know the ones. It's like where you've got provisions in the primary care system, and when they see a patient who is, I'm just tired all the time, TATT, TATT, TATT. Well, but unfortunately, under recoding, that means tattoo, okay? Well, that's just a localization that we'd want to pro-test a map of it

#### when that [crosstalk] [01:39:26].

## <u>Arien Malec – Change Healthcare – Member</u>

So, the obligation here is that if there is access, exchange, or use essential IPR, then that IPR needs to be licensed on a RAND basis. And if my local TATT code or my local HCTZ code – I can't tell you the myriad ways of spelling hydroclorothiazide – is essential to interpreting the data that I've got, then it's got to be licensed on a RAND basis. That's at least the way this framework works.

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

I agree with you. I'm working out whether we want to push the boundary that little bit further.

#### Steven Lane - Sutter Health - Member

Can I chime in? This is Steven, and I no longer have the hand-raising function because I had to get in the car.

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

We can't actually see -

## **Arien Malec – Change Healthcare – Member**

We can't see the hand-raising function anyway.

## Andrew Truscott - Accenture - Co-Chair

We can't see the task force, so we don't know if you've got your hand raised or not.

## Steven Lane - Sutter Health - Member

Very good. So, I'll say maybe I did. But I like where you're going, Andy. The idea that mapping a vendor's custom code, as opposed to a customer's custom code. The hospital system, the clinic, they may have custom codes. They're going to have to pay to get those matched. But if a vendor has specialized codes, the idea that the mapping of those two standard datasets should be kind of subsumed in the cost of the product as opposed to being a separate cost item sounds very appealing to me on the surface. So, I just wanted to throw that out there.

## <u>Arien Malec – Change Healthcare – Member</u>

That is, I believe, the proposal.

#### Denise Webb – individual – Member

That is the proposal.

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

Well, kind of the proposal.

## <u>Arien Malec – Change Healthcare – Member</u>

No, I think it's the proposal.

## Andrew Truscott - Accenture - Co-Chair

Well, when you use the term vendor custom codes, I'm trying to distinguish between what a customer does with their own coding versus what a vendor has done internally. What a vendor has done internally, they have an open API too. That's out of the scope of what I'm talking about. I'm talking about where a customer has put their own codes in. Because – you speak up for vendors here, because you see it all the time.

## Sasha TerMaat – Epic – Member

Sure. So, I think the example maybe, to give an illustration, is that if a product included a specific set of, I don't know, medications, right, and used a proprietary code set to identify those 100 medications, then it would be the responsibility of whoever's licensing that module to map those medications to something interoperable – RXNorm, presumably. But I think the challenging part that Andy's getting at, if I understand, is that it might be possible for a healthcare organization to add their own medication record within this medication module.

## Andrew Truscott - Accenture - Co-Chair

So, informally, we'd [crosstalk] [01:42:21].

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

Right. They said, we have a custom mixture that we used to represent this particular cream, and we've added it to our medication record. And it wouldn't be possible for the vendor of the product to know what the mixture they made at their organization, what should be represented in RXNorm. But there might be work involved to map those types of records, which might be used at just one site or potentially at multiple sites. And I think this gets to your "should it be shared" question, to some sort of code —

## Andrew Truscott - Accenture - Co-Chair

Here's another example. Labs, okay? The likelihood is that multiple providers use the same lab. It's highly likely that lab has some local coding, okay? And if provider A creates a map Arien's got that jaw open.

## <u>Arien Malec – Change Healthcare – Member</u>

No, no. I think this actually addresses that issue.

## Andrew Truscott - Accenture - Co-Chair

Do you?

#### <u>Arien Malec – Change Healthcare – Member</u>

Yeah, I do. So, this goes into the access, exchange, or use essential IPR RAND licensing, maybe.

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

Where I think it doesn't address it is if I've got four vendors from four different provider –

used by four different provider organizations, all using the same lab. Organization A with vendor one has created this map. Organization B with vendor two has to go and recreate that same map.

#### Sasha TerMaat – Epic – Member

Wouldn't the lab make the map, though, and license it on RAND terms?

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

No. Sometimes. But sometimes not.

#### **Arien Malec – Change Healthcare – Member**

Let's do some more – let's take this –

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

Let's take these offline and have a look.

## <u>Arien Malec – Change Healthcare – Member</u>

Let's take these notes. So, what I'm hearing – let me just state back what I'm hearing as the either expressed or implied consensus of the group to test to see whether this is true. I believe the task force believes that this is an appropriate way of striking the right balance between enabling access, exchange, and use, and not impeding the development of value-added services, and that the pricing mechanisms here are sufficient to ensure that information flows. I think there are additional examples that need to be put into this text to provide more color, and I believe that there's an issue related to mappings for proprietary terminology that we may need a little more discussion of and a proposal for.

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

Mm-hmm. Reword it so it's not an issue. Is there an opportunity here, and if there is an opportunity, should we embrace it, or should we stay silent? I think –

#### **Arien Malec – Change Healthcare – Member**

Well, the certification that's required relative to the intent, and then there's potentially an addition that we could contemplate relative to mapping some proprietary terminology to standard terminology that are effectively essential for basic access.

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

Correct.

#### **Arien Malec – Change Healthcare – Member**

Yeah.

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

Yeah. Anil, you had a point.

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

I did, but I think it's -

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

[Inaudible] [01:45:29] that work.

## Anil Jain - IBM Watson Health - Member

Yeah, we can move on to [inaudible].

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

Before we go to public comment, Arien's taken us to, or we've discussed some pretty intricate details of how this could manifest itself. And has anybody else got anything they'd like to say before we go to public comment?

## <u>Arien Malec – Change Healthcare – Member</u>

Sorry, I just want to be formal, because I expressed an implied consent. I just want to pause and make sure that I am expressing the intent of the workgroup appropriately. Hearing no objection . . .

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

I think the one thing that Andy said earlier was, could we – is there a way we could have something more freely available in the mapping? Open source, freely available.

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

Right. So, we've captured that in the notes, and -

## Cynthia Fisher - WaterRev LLC - Member

So you efficiently, cost-effectively, time-wise and money –

## Andrew Truscott – Accenture – Co-Chair

It's about reducing provider burden.

#### **Arien Malec – Change Healthcare – Member**

Yeah, that's right.

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

Pardon?

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

It's about reducing provider burden.

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

Pardon me?

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

Reducing provider burden. Mainly just the [inaudible].

## Cynthia Fisher - WaterRev LLC - Member

[Inaudible] lots of.

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

Yeah. We'll talk about that as well. And I think Sasha kind of sees where I'm coming from.

## Sasha TerMaat - Epic - Member

On the mapping question?

## Andrew Truscott – Accenture – Co-Chair

Yeah. But it's very different – it's not like there's one size fits all, because there's not just one scenario.

## Sasha TerMaat - Epic - Member

I think it might be helpful to talk about some more scenarios. Some of those ones we've talked about today have been very helpful for me to understand the intent of the recommendations, and maybe some mapping scenarios would help us.

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

Yeah, that point's a good one. I like that.

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

Yeah. That would be good.

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

Multiple providers using one map in multiple systems.

#### Sasha TerMaat – Epic – Member

Maybe that would be a good one to flesh out further in a subsequent conversation.

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

[Inaudible] [01:47:12] time. Okay. Let's go to public comment.

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

Anil has -

#### Anil Jain – IBM Watson Health – Member

30 seconds. [Crosstalk] [01:47:16] No, but another point. I like the idea of putting the patient in front, then the provider burden. But don't forget also that a lot of what we've done in the industry has been through innovation. And if we don't leave an opportunity for those to actually innovate, not just to make money, but just to be somewhat creative, we're going to lose out. So, think about that in the lens of where we're thinking about some of the – giving

the maps away, and who's the first vendor who's going to do it? I mean, [crosstalk] [01:47:45].

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

Everyone'll wait, then, for [crosstalk] [01:47:48].

## Anil Jain - IBM Watson Health - Member

Yes, exactly.

#### **Female Speaker**

It's like [inaudible] [01:47:51].

## Andrew Truscott - Accenture - Co-Chair

Okay. Public comment, please.

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

All right. Operator, can you open the line for public comment?

#### Operator

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

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

Okay. Is there anybody in the room, or - no - or on the phone who'd like to comment?

#### Operator

There are no comments at this time.

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

Okay, thank you. All right.

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

Okay. Have you got more to add?

#### Anil Jain – IBM Watson Health – Member

I just think it's really – we have to think about real-world cases. I liked Sasha's point. But we have to go through and play out some scenarios of where this is happening, and not having a theoretical – I mean, I'm not saying we've been theoretical all this time, but I'm saying that we have to look at what the clinical IT leadership in a hospital provider, how does the patient

- when they see this information be presented, how do they benefit from having some of this exchange be done in this way, and then how do we build the entire industry in a way that says that we're not going to use proprietary codes in the way of information blocking. But there are a whole host of folks who use proprietary codes to add value to their services, and maybe that mapping is what we focus on. But I just want to be careful we don't end up stifling innovation in the process of trying to make that happen.

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

And that's a good point. I think we're using the term "mapping" to cover multiple scenarios, and we probably need to distill that out into some real-world ones so we're clear what we're talking about. I need to think through the scope of basic access as we've got it right now, just for my own contribution to the group.

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

It might be helpful, I think, Arien, in your clarification on those to define each of those in the recommendation. I think basic access is defined in the fourth, fifth recommendation, but I don't know that essential access is.

#### **Arien Malec – Change Healthcare – Member**

Essential access.

## Andrew Truscott - Accenture - Co-Chair

It says TF recommends that ONC distinguish IPR of the essential to access, exchange, or use the basic [inaudible] [01:50:18].

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

Oh, okay. Got you. Thank you.

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

I actually think, Arien, we probably – I think once we talk to them re: the sentiments herein, we'll probably need to do a bit of a restructuring.

#### **Arien Malec – Change Healthcare – Member**

Yeah, yeah.

# Andrew Truscott - Accenture - Co-Chair

I probably need to define, this is the outcome we're seeking to achieve, and these are our recommendations to get there.

## <u>Arien Malec – Change Healthcare – Member</u>

That's right.

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

Before we have a good idea about what's going on.

#### **Arien Malec – Change Healthcare – Member**

That's exactly right. And I think it's more helpful to give in this – with something as naughty and difficult as this, it is more helpful to give ONC a clear policy direction and then some example, perhaps, to solve that policy direction. But they may want to take the policy direction, obviously, [crosstalk] [01:50:57].

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

But you'd need to work -

#### <u>Arien Malec – Change Healthcare – Member</u>

Yeah, yeah, exactly.

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

I would not want to draft it.

#### **Arien Malec – Change Healthcare – Member**

And we're not going to draft it for you. Sorry.

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

And to Anil's point, you've got to make sure that we're not burdening with protectionism. With today's existing vendors and system integrators speaking in the room, but I do think it is really important to move toward opening it up. Opening it up in whatever way, cost-effectively, open source, open up the pipes, let the tech innovators come into this field as well, and let us all compete to provide for the next –

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

I agree with you. And we also need to not forget that the term "mapping," you automatically jump to thinking it's a one-to-one thing. It is just completely not. Mapping is horrendously complicated. It has massive clinical governance burdens around it. And it's many to one, one to many, many to many, especially when you're dealing with something as granular as SNOMED versus something as coarse as ICD, etc. And those are about to exist.

#### **Arien Malec – Change Healthcare – Member**

By the way, I just want – because I did pull up designated record set. The definition of designated record set under HIPAA, designated record set means, one, a group of records maintained by our [inaudible] [01:52:23] that is, subpart I, the medical records and billing records about individuals maintained for or by a covered entity provider, a covered healthcare provider. So, the one piece this does not include is the prospective price, and I think we need to make sure that we're adding to that the prospective price.

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

And we need the definition of EHI, don't we?

## **Arien Malec – Change Healthcare – Member**

Yeah.

## Andrew Truscott - Accenture - Co-Chair

And EHI consumes the designated record set by inclusion.

## <u>Arien Malec – Change Healthcare – Member</u>

Right.

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

So, I think as long as this is feeding back to EHI . . .

#### <u>Arien Malec – Change Healthcare – Member</u>

Although I think, actually, subpart three – so, subpart two is enrollment, FEMA claims, adjudication, and case or medical management record systems maintained for or by a health plan. And by the way, have you ever seen a health plan actually give the enrollment, and its claims, adjudication, and case or medical records management system access to patients? I'd love to see that.

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

Arien, on that point, it was raised yesterday with Alex's testimony around the definition of a plan versus a payer.

# <u>Arien Malec – Change Healthcare – Member</u>

Yeah, which is interesting.

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

I think that would fall firmly into the commercial plan, versus -

## <u>Arien Malec – Change Healthcare – Member</u>

Yeah, yeah. Well, health plans are covered entities under HIPAA. Commercial health plans are covered entities under HIPAA.

## Andrew Truscott - Accenture - Co-Chair

But that's what we mean by that term, right? Payer or plan?

# <u>Arien Malec – Change Healthcare – Member</u>

In the definition, designated record set, subpart III, it's an "or." It's not an "and." It's "or used in whole or in part by or for the covered entity to make decisions about an individual." So, I actually believe the prospective pricing information, the charge master, for example, is used to make decisions about individuals and falls within that definition. But I don't know that ONC seems to think —

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

But they might have the same interpretation of that.

## <u>Arien Malec – Change Healthcare – Member</u>

Yeah.

# Andrew Truscott - Accenture - Co-Chair

Okay. Are there any public comments on the line?

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

Operator?

## **Operator**

No comments at this time.

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

So, we have to break up the party because there's another meeting coming in here right now at 11:00. So, we'll have to get back to this tomorrow.

## Andrew Truscott - Accenture - Co-Chair

And we are at the top of the hour. Task force, thank you very much. Members of the public, thank you very much for listening in. See you all next time.

#### **Arien Malec – Change Healthcare – Member**

I think we've made some significant progress.

## Steven Lane - Sutter Health - Member

Thank you. Great meeting.

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

Thank you.

#### Anil Jain - IBM Watson Health - Member

Thanks.

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

We have, because we've cranked through something which was really hoary before, because it was unhelpfully worded, and now it's more helpfully worded, by very hoary.

## <u>Arien Malec – Change Healthcare – Member</u>

Yeah, exactly.

## Sasha TerMaat - Epic - Member

I like combining the two sections into one. It's much more clear.

# Arien Malec - Change Healthcare - Member AJ

Are you saying that that record set is the same thing as the legal medical record, because I don't –

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

Sasha, [crosstalk] [01:54:52]?

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

Combining the two different sections on licensing and pricing into one section –