# Conditions and Maintenance of Certification Requirements Task Force

Transcript March 29, 2019 Virtual Meeting

## Members/Speakers

Name	Organization	Role
Denise Webb	Individual	Chair
Raj Ratwani	MedStar Health	Chair
Carolyn Petersen	Individual	Member
Ken Kawamoto	University of Utah Health	Member
Sasha Termaat	Epic	Member
Leslie Lenert	Medical University of South Carolina	Member
John Travis	Cerner	SME
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
Kate Tipping	Office of the National Coordinator	Staff Lead
Christopher Monk	Office of the National Coordinator	SME

### <u>Cassandra Hadley – Office of the National Coordinator for Health Information Technology -</u> <u>Acting Designated Federal Officer</u>

Thank you. Good afternoon everyone welcome to the Conditions and Maintenance of Certification Requirements Task Force Meeting, under the HITAC, thank you for joining us. We are going to be continuing on with some discussions around the NPRM recommendations. The rule recommendations. Recognizing that we have a small group here of our HITAC member. The chair here, Denise, of the task force, along with members John Travis and Ken Kawamoto. So, I will just had it off to you Denise, so we can begin. No need to call role at this point.

#### Denise Webb – Individual – Chair

Okay, so we've got roll done, right? Or do you need to call roll?

## <u>Cassandra Hadley – Office of the National Coordinator for Health Information Technology -</u> <u>Acting Designated Federal Officer</u>

No need.

#### Denise Webb – Individual – Chair

You've got that covered. Okay, Kate, do you just want to quickly review the charge that we're going to continue deliberating on.

#### Kate Tipping – Office of the National Coordinator – Staff Lead

Yes, for this task force is providing recommendations on the application programming interfaces, real world testing, and attestations, conditions and maintenance of certification requirements. Updates to most of the 2015 edition, Health IT Certification criteria and changes to the ONC Health IT Health Certification program, as well as the regulatory actions related to certification criteria and program requirements.

#### Denise Webb – Individual – Chair

Thank you Kate. So, yesterday we went through a debrief of the discussion that we had at HITAC when we presented our draft recommendations. I know we had one-time Kate, that I think you were going to follow up on. Let me see if I can –

#### Kate Tipping – Office of the National Coordinator – Staff Lead

The timing piece.

#### Denise Webb – Individual – Chair

Yeah, on the timing piece. Was there any coordination with the CMS regulation and whether there was an allotment of time, or a date certain for the providers to have their 2015 updated, 2015 Edition and in use, because we were going to entertain a recommendation on providing some guardrails around how much time the developers are going to use or need versus the healthcare provider organizations or the customers that are using that Health IT, Certified Health IT.

#### Kate Tipping – Office of the National Coordinator – Staff Lead

Yeah, and I did reach out and I will probably have an answer probably by our meeting next week. Or I can email it to you if I can provide further clarification. I don't have it right now.

#### Denise Webb – Individual – Chair

Okay, great, and then what we should do is slop that as an item to discuss to form a recommendation around next week, at our next meeting.

#### Kate Tipping – Office of the National Coordinator – Staff Lead

Okay.

#### Denise Webb – Individual – Chair

Okay, so anyway we went through all of the notes, Sasha took notes while we had the HITAC meeting and we went through the notes to see what areas were highlighted, in terms the recommendation, and I believe we got through all of the notes yesterday. Ken, we could back up, and like I said I don't have the screen in front of me but there's a recommendation we added based on your feedback that you gave prior to the HITAC meeting. Kate can you call that up?

#### Kate Tipping – Office of the National Coordinator – Staff Lead

Yeah, I'm going to share my screen right now. Okay, can you see it Ken?

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

l can.

## Kate Tipping – Office of the National Coordinator – Staff Lead

Okay, sorry Denise, what was the recommendation? Is this the one that Ken had added?

## Denise Webb – Individual – Chair

Yeah, that didn't have a number on it yet.

## Kate Tipping – Office of the National Coordinator – Staff Lead

The Argonaut one? I think we...

#### <u>Denise Webb – Individual – Chair</u>

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Yes.
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## Kate Tipping – Office of the National Coordinator – Staff Lead Okay.

## <u> Denise Webb – Individual – Chair</u>

That was the one. So, Ken we discussed this yesterday and everybody was in agreement with the recommendation so we're going to carry that recommendation forward that the regulation shouldn't be specifying Argonaut, but rather the HL7 specs which derive information from the Argonaut work.

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

Sounds good. Well I'm obviously in agreement. Thank you.

#### Denise Webb – Individual – Chair

Okay, we just wanted to let you know that, and the only person that is not aware of that discussion would be Sasha and we can check in with her next week.

#### Kate Tipping – Office of the National Coordinator – Staff Lead

Okay.

#### Denise Webb – Individual – Chair

So, I believe we got through all of our recommendations, we had some discussion again around the duration of time being made available and the regulation for the developers to get all of the work done, tests to deliver the product to the customers, and then for the customers to have the time they need to implement the release, do the build, implementation and training, and they'll roll out. Particularly for really large health systems that have a lot of sites, and then for smaller providers who have limited resources, that they have the flipside of the issue. So, we are going to discuss that next week. The other item that we're deferring to next week, John has proposed a revision to the recommendation on the E-prescribing, ERX transactions and the implementation of the MCPDP, I believe it was...

## Ken Kawamoto – University of Utah Health – Member

Yeah.

#### Denise Webb – Individual – Chair

I don't have my notes right here in front of me. But I'm looking at our recommendation and we had specified a number of elements that we thought should be optional, and then John pointed out that there is some issues with doing that, in terms of how certification works, and made an alternate proposal. And so, I don't know if everybody on the Task Force got that information, but if they didn't then we can have Kate send it out to the rest of the Task Force members to take a look and be prepared to discuss that next week.

## Ken Kawamoto – University of Utah Health – Member

Yeah.

#### Denise Webb – Individual – Chair

Okay. That brought us down to, there was no real discussion on the clinical quality measures except the fact that it would preferable to go to FHIR, except that we're not ready to go to FHIR. I think that as a comment during the discussion at HITAC. And then the last part of this is around the two recommendations we had on privacy and security related access station criteria and the regulatory actions. So, and one thing I'll mention to Ken, just to bring you up to speed, I was talking with some of the CIOs from Chime, I was on one of their calls. And they were in full agreement about our overarching recommendation that the 2015 Edition, rather than being updated, we should continue with our recommendation that ONC consider titling or labeling a new edition.

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

Yeah. Pretty soon it will be 2020.

#### Denise Webb – Individual – Chair

And while I think there was some sensitivity around the fact that 2015 just came out for enforcement this year, and I think ONC, at least what I heard was concerned about throwing out yet another new edition. But when you look at it under the covers, it sure feels like a pretty substantial amount of changes. So, the CIOs did not have that reaction, that oh no, here's another new edition. They actually thought the idea labeling or specifying the new edition would make things a lot cleaner and less complicated than knowing, okay well, which 2015 edition is this running on right now? Are we on the new one? So anyway, they overwhelmingly supported that idea. So, I just wanted to let you all know that. And so, is there anything else that is burning on your mind Ken or John, that the three of us can discuss today, or any questions you might have about what we covered yesterday?

<u>John Travis – Cerner – SME</u>

No, nothing that .

Ken Kawamoto – University of Utah Health – Member

I did have –

#### <u> John Travis – Cerner – SME</u>

Go ahead, sorry Ken.

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

Thanks John. I did have one comment earlier on the security and HIPAA things, I started in off-line conversation with some folks to just provide some more clarification on what I mean by that. But I did have proposed language in there, I'm not sure it quite fits with what comments being sat on, but it's a deep and long topic that I am happy to provide a little bit more info on. Is that one, only so we can provide former grants on compliance with relevant privacy and security regulations.

#### Denise Webb – Individual – Chair

And that's your recommendation?

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

I can go into further detail on that, but yeah, I have put in some draft language that I suggested. If it hasn't been discussed before and obviously it will require some more focused discussion, but I'm happy to sort of discuss that in a little bit more depth, and why I think it's an actually pretty important issue for us to discuss. At the height of it at least.

#### Denise Webb – Individual – Chair

So, is that recommendation actually drafted in the Google Docs?

## Ken Kawamoto – University of Utah Health – Member

lt is.

Denise Webb – Individual – Chair

Everybody can go look at it and the put it on the agenda for our next meeting.

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

Yes, sure. It's right before 3.2.3.4, yeah.

#### Kate Tipping – Office of the National Coordinator – Staff Lead

Yeah, I have it on the screen now, but I can add it for next week's discussion.

#### Denise Webb – Individual – Chair

Okay. I kind of want to get to down to the point where we have the final items that we need to agree on: massage, change, one of the other ones I know we need to do a little bit of polishing on is around our recommendation for FHIR release four. We did discuss that yesterday too as well, and again I got some input and feedback from a group of CIOs that formed the policy committee with Chime and they have the same concerns that our task force does, where there is smaller provider organizations who are more limited in resources as well as developers, may be challenged. Particularly, the developers. So, one thing we are going to discuss next week is related to the timeline that there should be some variance in the timeline, the 24- or 25-month timeline, but everybody in that CIO group landed on endorsement that the first release of the version of FHIR, normative version of FHIR really is poor, and they think we should drive for that.

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

I think that make sense. I think my only comment might be if there's errata or whatnot that it doesn't have to be 4.0.0 though, just like in four that would leave so unseen what's for the significant leeway. Which I think it's appropriate just like with version 3 there was an errata version that was published. I think if some actual breaking issues found in by the time ONC is ready to regulate on it, there is a version that's considered the latest stable that everyone agrees it's the latest stable version of four, I think we should go with that. I don't think there's anything that prevents that from happening because it definitely goes down into the minor versions, in the rags as far as I could tell, but anyways that's a thought. And if we want to put a recommendation online we should choose the version to require as the version within four which is most recent stable release that's accepted by the community or something along those lines. I think that wouldn't be bad either.

#### Denise Webb – Individual – Chair

Well, we should get clarification from ONC on whether that kind of language is permissible because they do have some drafting requirements that have to comply within the regulation. I do know Elise has mentioned a couple times about the standard advancement process. So, if for some reason there is some issue or concern with publishing a release but then with the understanding that they could put it in the preamble. We can recommend they discuss what you are suggesting about errata. And I did have those notes –

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

And I did have – I'm sorry go ahead.

#### Denise Webb – Individual – Chair

I was going to say Sasha had your notes in here about that.

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

If they just said release four, it probably doesn't need the specific clarification because release four will include within it any versions within four, I think.

#### Denise Webb – Individual – Chair

For absolute clarity maybe we want them to say that in the preamble, and we recommend that they say that. So, if you can capture a note on that Kate, under the recommendation under API recommendation number – hold on a second, I'm finding it. It's recommendation 17. So, we're standing with our recommendation, but just we might want to reflex on this suggestion of Ken's – in the preamble, just to make it clear it includes the minor version within four. All right, anything else? So, Kate, can we send out just a little summary, a homework assignment to ask everybody to completely review either I would say either the Google Doc because that has the most recent comments, correct?

#### Kate Tipping – Office of the National Coordinator – Staff Lead

Yes.

#### Denise Webb – Individual – Chair

And then highlight, I think we have three areas we are going to discuss.

#### Kate Tipping – Office of the National Coordinator – Staff Lead

Yes, and let me just clarify or make sure I'm clear on what those three items are. So, one is with regard to the recommendation 17, the FHIR release four, both polishing and considering Ken's recommendation. I know the Argonaut one that Ken had added we just want to run that by Sasha.

#### Denise Webb – Individual – Chair

And probably Carolyn, I don't think was – Carolyn wasn't on the call yesterday either.

#### Kate Tipping – Office of the National Coordinator – Staff Lead

And then the other two is the timing, ONC versus CMS and provide the developers to the providers, and then the E-prescribing.

#### Denise Webb – Individual – Chair

Right. I and then I just thought of one other that we just briefly touched on, but I thought we needed a broader group to discuss was around recommendation 22, and the whole app registration recommendation. Some of the feedback I got from healthcare providers, CIOs, is they are kind of concerned about bad actors, even at an entity that's been verified or authenticated, whatever we want to call it. Because, the way we understand the rule is that the way the Health IT developer or the API data provider, they can – that the organization but not necessarily the app. I did read in the rule and I don't remember which page it was on but – oh, it was under information blocking the preamble prior to the seven exemptions. That talked about this idea of it being, it would not be appropriate for vetting for security purposes that were extensive amount of time or owners to put up roadblocks to connecting to an API. And it said if it did do that it would – could be considered information blocking. But just the fact it was mentioned that the Health IT developer may, which seems appropriate, it made that app to make sure the security is appropriate and functioning. I think we all want that. And these were the comments of the CIOs, yesterday. They're really nervous about this idea of just

anyone plugging in. What if someone quit an organization and had the keys to the kingdom, essentially wouldn't they still be able to plug-in? And I said yesterday I don't have enough technical knowledge to understand whether that could happen or not. So, anyway we might discuss recommendation 22, just review that together as a group.

#### Male Speaker

That's good.

#### Denise Webb – Individual – Chair

It may not change our recommendation but at least we can make sure we've covered the bases. And then that's all I had on my list. Unless anybody else has anything?

#### Male Speaker

No.

<u>Ken Kawamoto – University of Utah Health – Member</u> Do we just go early to public comment?

#### Denise Webb – Individual – Chair

Sure.

#### Raj Ratwani – MedStar Health – Chair

This is Raj I just want to let you know I was on, been on for the last 15 minutes, thanks for leading everything.

#### Denise Webb – Individual – Chair

Oh good. Anything to add or are you good with the plan?

#### Raj Ratwani – MedStar Health – Chair

No, it sounds like a great plan. Thanks again for your leadership here.

#### Denise Webb – Individual – Chair

No problem. I know how things can happen.

<u>Cassandra Hadley – Office of the National Coordinator for Health Information Technology -</u> <u>Acting Designated Federal Officer</u> Are you ready for public comment?

## <u> Denise Webb – Individual – Chair</u>

Ready to go whenever you guys are.

## <u>Cassandra Hadley – Office of the National Coordinator for Health Information Technology -</u> <u>Acting Designated Federal Officer</u>

Operator, can you open the line for public comment please.

#### **Operator**

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

#### Denise Webb – Individual – Chair

So, while we are waiting, Kate is there anything you want to share with us in terms of – do you want to just review the timeline? If the operator could let us know if we have someone in the queue.

#### Kate Tipping – Office of the National Coordinator – Staff Lead

Sure. So, as far as the April 10<sup>th</sup> full HITAC meeting, that's the in-person one. If we are ready, if the task force is ready to present and have the full committee vote, that is welcomed. If or whatever recommendations are ready to put forward to the full committee to vote on, we can. And if not, there's April 25<sup>th</sup> is the virtual of another full HITAC meeting that we will have to have the final vote on. So, I think since this task force has most of the recommendations in place and we're doing some finessing, hopefully we'll be able to put forward what has been agreed upon on the task force for the April 10 meeting.

#### Denise Webb – Individual – Chair

So, is it possible for you to start transitioning our text into the transmittal letter format?

#### Kate Tipping – Office of the National Coordinator – Staff Lead

Sure, yes.

#### Denise Webb – Individual – Chair

Working out of that so we can get a jump on this because I think what Elise said, and the information blocking work group call yesterday is that, if we are at a point where we are close to where we will think we will land on a recommendation to then have ACEL and our ONC leads to help us get that into the transmittal letter format. And we could then publish that on Google Doc and work out of that and once we get everything finalized and we have it ready to go.

#### Kate Tipping – Office of the National Coordinator – Staff Lead

Yes. Absolutely.

#### Denise Webb – Individual – Chair

Yes. Then we can have our final vote as the task force and then Raj and I can sign off on it to go forth to the full committee, for a vote.

## <u>Cassandra Hadley – Office of the National Coordinator for Health Information Technology -</u> <u>Acting Designated Federal Officer</u>

Operator did anybody -

#### **Operator**

There are no comments in the que at the moment.

## <u>Cassandra Hadley – Office of the National Coordinator for Health Information Technology - Acting</u> <u>Designated Federal Officer</u>

Thank you.

#### Denise Webb – Individual – Chair

I think we are in good shape to possibly conclude the majority of our work and be ready for April 10<sup>th</sup>. We have a meeting Thursday and Friday, correct? Next week, or is it Wednesday and Friday? I don't recall. Let me pull up my calendar here.

#### Kate Tipping – Office of the National Coordinator – Staff Lead

It is Wednesday April 3<sup>rd</sup> and Friday, April 5<sup>th</sup>. Wednesday it's at 9:00 a.m.

#### Denise Webb – Individual – Chair

Okay. Friday, I am in an airplane, so I would not be able to participate. And I didn't think you are available either, Raj because I went to look at your availability that you had submitted, or maybe I was just looking at the wrong date maybe you are available?

<u>Raj Ratwani – MedStar Health – Chair</u> What was the day again?

Denise Webb – Individual – Chair The call that's on Friday, and it's at 3:00 p.m. EST, April 5<sup>th</sup>.

Raj Ratwani – MedStar Health – Chair

Yeah, I'm available then.

#### Denise Webb – Individual – Chair

Oh, good. Well back at you, I need to you to lead.

<u>Raj Ratwani – MedStar Health – Chair</u>

Okay, good. No problem. Done.

#### Denise Webb – Individual – Chair

So, we really should encourage in the message that you get out, Kate, encourage the entire task force to do whatever they can to be available at 9:00 on Wednesday, so we can make sure we're all good to go on those remaining items.

## Kate Tipping – Office of the National Coordinator – Staff Lead Okay.

<u>Denise Webb – Individual – Chair</u>

And then Raj can get my email vote from me and then maybe you can take a vote Friday.

Raj Ratwani – MedStar Health – Chair Sure.

Denise Webb – Individual – Chair Sound good?

#### <u> Raj Ratwani – MedStar Health – Chair</u>

Sounds great.

#### Kate Tipping – Office of the National Coordinator – Staff Lead

That sounds good. I will send a note highlighting the few areas that we mentioned and the link to the Google Docs, and the reminder about Wednesday. And then I will get started on the transmittal memo – letter.

<u>Denise Webb – Individual – Chair</u> Any final words Raj, or anyone else on the task force?

#### <u> Raj Ratwani – MedStar Health – Chair</u>

Nothing from this end.

Male Speaker

No.

<u>Ken Kawamoto – University of Utah Health – Member</u> Thank you.

<u>Denise Webb – Individual – Chair</u> All right, so I guess we can conclude early and give people back the gift of time on Friday afternoon.

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

Thank you. Have a great weekend.

#### Kate Tipping – Office of the National Coordinator – Staff Lead

Thanks, you as well.

#### Denise Webb – Individual – Chair

Have a great weekend. Thanks everyone.

[End of Audio]

**Duration: 27 Minutes**