



Conditions and Maintenance of Certification Requirements Task Force

Transcript
April 12, 2019
Virtual Meeting

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

Operator

All lines are now bridged.

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

Good afternoon, everyone. Happy Friday. Welcome to the Conditions and Maintenance Certification Taskforce. Of the taskforce members, we have Raj Ratwani, Carolyn Petersen, and Sasha TerMaat so far. Have any other members joined? Okay. Hopefully others are just running late. With that, I will turn it over to Kate and Raj to get us started on continuations of discussion of draft recommendations.

Kate Tipping – Office of the National Coordinator for Health Information Technology - Staff Lead

Sure. This is Kate. I was just going to say I've provided some editorial updates to the Google Docs document and I left some comments in there that I heard from the full HITAC committee meeting this week. Raj, do you have anything else?

Raj Ratwani – MedStar Health - Chair

No. This is good. Thank you for doing that. I think what we should spend our time doing now is going through each of these recommendations, starting with recommendation two, I believe, since one was voted on, and work through each of them. Does that work for – who do we have on the call now? Sasha...

Carolyn Petersen – Individual - Member

Carolyn.

Raj Ratwani – MedStar Health - Chair

Carolyn, great. Thank you. Does that work for everybody?

Carolyn Petersen – Individual - Member

Yeah.

Sasha TerMaat – Epic - Member

Sounds good.

Raj Ratwani – MedStar Health - Chair

Okay. So, I think general feedback was there was a couple of editorial things like not saying the taskforce in there since it will be coming from the committee, but the other thing was teasing out the editorial part of the recommendation and being clear about what we're actually recommending. We may want to think about a format change to how we're doing this so that we clearly state the recommendation and then maybe have background or something like that. Does that work for people?

Sasha TerMaat – Epic - Member

Yeah. I think the other taskforces had helpful approaches where they separated regulatory text edits from discussion considerations. We could maybe see if there was a model that made the most sense.

Raj Ratwani – MedStar Health - Chair

I think that's a great point. I think some of the ones that were presented the other day were good models. I like the idea of having the considerations piece separate. So, as we go through and we're making edits to this, maybe what we can do for now is try and make that distinction and call it considerations for now. Then at least that text would be segmented out and then we can format it however we want to.

Sasha TerMaat – Epic - Member

Okay.

Raj Ratwani – MedStar Health - Chair

Okay. So, starting with recommendation two changes here...

Sasha TerMaat – Epic - Member

It looks like Denise went through and did some editing, which seems fine to me. I don't understand, actually, why Denise took out the pilot year supportive comment. Was that just because that would go into a discussion?

Raj Ratwani – MedStar Health - Chair

Yeah. I guess so. I think you're right. We want to probably have that in there. So, maybe what we can do is add considerations there. You got it, Sasha. Thank you.

Sasha TerMaat – Epic - Member

It also looks like Denise is actually editing right now.

Raj Ratwani – MedStar Health - Chair

Yeah. I was trying to see on Google if there was a way to ping her. I sent her an email. I know that the calendar invite for me was removed and I'm wondering if the same thing happened for her. Does anyone have a cellphone number for her?

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

Katie, do you mind just reaching out to Denise?

Accel Solutions

Yes, no problem.

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

Either by phone or email.

Raj Ratwani – MedStar Health - Chair

Okay. So, recommendation two, we're going to move that to discussion considerations – sorry, move that part to considerations. Recommendation three – any additional thoughts on recommendation three? That's a good way to do it.

Sasha TerMaat – Epic - Member

I'm having real-time chat with Denise in the document.

Raj Ratwani – MedStar Health - Chair

Was that you that just typed that. I like that.

Sasha TerMaat – Epic - Member

Under recommendation time, Denise and I are discussing whether she's going to join the call. I don't know why my text – oh, I have all caps on.

Raj Ratwani – MedStar Health - Chair

You're yelling at her. There we go. She had the wrong time. Okay. So, while she hopefully dials in, any other modifications to recommendation three? I don't see much consideration and discussion language.

Sasha TerMaat – Epic - Member

I have a super trivial one, but I don't – this is maybe to Dr. Rucker's point about not locking too much into the regs. I don't even know that the clarity that we requested in this case – I think John had brought this up originally – needs to be in the preamble of the final rule. So, if ONC wanted to provide guidance for the test plan through, for example, the certification materials for this criterion, that might also be acceptable.

The only factor I would have that would say we need to have it in the preamble is they have to accurately estimate the impact of the regulation. The cost of this proposal will be very much related to the number of care settings and menus. So, maybe they do have to have it. I kind of talked myself out of that point.

Denise Webb – Individual - Chair

Hey, everyone. This is Denise. I'm on. I apologize. I thought the meeting was at 3:00 and I was starting to work on the recommendations to put them in the wording so that they could be final for the committee to vote on.

Raj Ratwani – MedStar Health - Chair

Hey, Denise. No problem. Sasha did a great job finding a creative way to grab you.

Denise Webb – Individual - Chair

Get my attention?

Raj Ratwani – MedStar Health - Chair

Yeah.

Denise Webb – Individual - Chair

That was creative. So, just catch me up on where you all are at – are you all going through the specific items that we need to update or change besides just doing general – I was trying to generally reword these so that they were more specific to what we were referring to in the preamble or the regulatory text.

Raj Ratwani – MedStar Health - Chair

Yeah. So, we were going recommendation by recommendation.

Denise Webb – Individual - Chair

Okay. All right.

Raj Ratwani – MedStar Health - Chair

If there were ones that you flagged that you know we need to rework – I know there was the one around the use of exchange data that we need to rework.

Denise Webb – Individual - Chair

Oh, yeah.

Raj Ratwani – MedStar Health - Chair

I don't know what the most effective use of our time is.

Denise Webb – Individual - Chair

I don't think we should spend time going over what I was doing. If you just look at an example, for recommendation three, I said, "The Committee recommends..." They asked us to – I heard a couple of people say to taskforce out of here because when they vote on these, these are the Committee's recommendations. Is that right, Kate, in terms of how we advance this, or Lauren?

Kate Tipping – Office of the National Coordinator for Health Information Technology - Staff Lead

I think... Lauren, do you have an answer?

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

You mean in terms of – what was the question again, Denise?

Denise Webb – Individual - Chair

So, what I heard Arien and I think one other person says is that these recommendations needed to be reworded to say, "The Committee recommends..." Then the committee votes

on that and agrees or disagrees with what the taskforce was putting forth. Then they get cut and paste into the overall transmittal letter to Dr. Rucker. So, look on the screen there where I said, “The Committee recommends ONC provide...” not should provide. We should just say, “ONC provides...” more clarity.

So, I just did some finessing not to change our context or content. I did say like minimum expectations – setting a floor is, I think, what we’re trying to say here. So, I’m not trying to change anything we’re recommending. I’m just trying for us to be clearer about what we’re asking ONC to do.

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

Yeah, I understand. I think Arian’s right. He may have just been one step ahead of us in that the initial transmittal is from the taskforce to the committee and then the final transmittal will be from the committee to ONC. Just to be clear, I think he’s right, but I think for the initial transmittal, we can clarify that this is from the taskforce and not the full committee just yet.

Denise Webb – Individual - Chair

Oh, okay. All right. Then I will change it back to, “The Taskforce recommends...” But I’m still going to help to finesse to help some of this in a way that makes it clearer. Okay. So, anyway, that’s what I was doing. But absolutely right, Raj. There was that item that definitely we need to work on. I think I have notes on a couple of others. Let us proceed, Raj, wherever you had left off.

Raj Ratwani – MedStar Health - Chair

So, I think we were just moving on to recommendation three. What we decided was we would parse out the text that’s more of discussion or considerations. So, Sasha did that already for number two. For number three, Sasha, you were raising a point about preamble versus language somewhere else.

Sasha TerMaat – Epic - Member

I think I think the preamble is the right place. I convinced myself. The second sentence of recommendation three could probably go into the discussion.

Raj Ratwani – MedStar Health - Chair

Yeah.

Denise Webb – Individual - Chair

Yeah. I actually made it all one. I just said that the –

Sasha TerMaat – Epic - Member

Oh, you did. I see that. Okay.

Denise Webb – Individual - Chair

What's the goal of making minimum expectations clear and setting a floor concerning which settings and number of settings for the applicable certified health IT modules? I actually changed some of our wording to match what's in the – I actually opened the regulatory text. The regulatory text is very general. It just says care settings, but the preamble mentions it, but doesn't go into much detail. I really think we're trying to get them to say in the preamble what kind of floor they are setting. Does that make sense?

Raj Ratwani – MedStar Health - Chair

Yeah.

Sasha TerMaat – Epic - Member

I'm comfortable with three.

Denise Webb – Individual - Chair

Okay.

Raj Ratwani – MedStar Health - Chair

Carolyn, are you good with three?

Carolyn Petersen – Individual - Member

Sorry, I was on mute. Yeah, I'm fine.

Sasha TerMaat – Epic - Member

If we're getting nitpicky, I would avoid saying, "Setting a floor" when we're talking about setting, like cure setting, because it's kind of confusing.

Denise Webb – Individual - Chair

Okay. We could just say establish which setting and the number of settings. That makes sense. We said we want minimum expectations. So, that is kind of like a floor without saying a floor.

Sasha TerMaat – Epic - Member

Is there a reason in four that we're having the ONC ACBs provide a template rather than having ONC make a template?

Denise Webb – Individual - Chair

Wasn't it John that said that the ACBs have done this for other things? The ACB provided it? I don't care who provides it.

Sasha TerMaat – Epic - Member

It would just be strange if your template varied based on which ONC ACB you picked, in my mind.

Raj Ratwani – MedStar Health - Chair

I totally agree with you, Sasha. I think the same thing. I think we can be agnostic about who creates it, but maybe what we can say is that it's a standard or standardized template that's created.

Denise Webb – Individual - Chair

And also provide a standardized – also suggest the creation of a standardized template.

Sasha TerMaat – Epic - Member

I think in the safety-enhanced design corollary, we actually have the template coming from NIST.

Denise Webb – Individual - Chair

Oh, okay.

Raj Ratwani – MedStar Health - Chair

Yeah. But I don't think we need to call out who creates it unless you want to.

Sasha TerMaat – Epic - Member

No, I think it would be fine. And then I think you can probably cut the second sentence because it's not really adding much.

Denise Webb – Individual - Chair

No, it's not. It is the ACBs that are going to be reviewing the test plan. So, wouldn't they be expected to inform what should go in the template? We kind of talked about that after they assessed the plans from the pilot year. We could just say that should inform the minimum requirements for an acceptable test plan.

I was just trying to take all of what we had in there and kind of say who we're asking should do what and where. Obviously, this was not in the regulatory text. It really just tells the ONC ACBs to comply with – or to ensure that the health IT developers have complied with what are specified elsewhere in the regulation concerning certifications.

Sasha TerMaat – Epic - Member

I'm just editing, trying to be clear. I think that uses fewer words than we had before but makes the same point. Did I get cut off?

Denise Webb – Individual - Chair

No, I hear you. That's a lot more succinct. What do you think, Carolyn? You're the tech writer.

Carolyn Petersen – Individual - Member

I think it's good. I think it's fine.

Denise Webb – Individual - Chair

Okay.

Carolyn Petersen – Individual - Member

I don't know that the regular rules of normal communication apply in this kind of a situation anyway. So, I'm happy to defer to the experts on the terminology.

Denise Webb – Individual - Chair

All right. Obviously, we'll have to change it back from Committee to the CMC Taskforce. I misunderstood what was being said at the meeting. It seemed like some of the members felt that when they vote on this, it should say the committee. But I get it. It's a procedural thing.

Sasha TerMaat – Epic - Member

I think we're on five, right? I'm okay with how Denise has updated five.

Raj Ratwani – MedStar Health - Chair

Yeah, I agree.

Denise Webb – Individual - Chair

Is that clarity? Do we want to say when we're talking about the preamble – I don't believe there's anything said in the regulation. There we go. I think you might need a space there. There we go. Okay. Do we want to specify which paragraph in the regulatory text? I know the other taskforce is doing that. I have it in front of me if you want it.

It's 170.405 B1 – they actually have a typo in here. They have numeral II twice. I found one other typo in the regulatory text too where they had a letter referred to that didn't exist. This was on page 654 of the PDF version. It should be a Roman numeral, in open and closed paragraph, Roman numeral III and then capital A. So, B1 – am I able to type in there or just you? Oh, there, you've got it.

Sasha TerMaat – Epic - Member

This is the one where it's labeled as –

Denise Webb – Individual - Chair

I don't know if Kate if you have access to this, but it has Roman numeral II twice in the regulatory text.

Kate Tipping – Office of the National Coordinator for Health Information Technology - Staff Lead

Okay. Thanks, Denise. I know there were a couple we've already caught. I'm going to flag that one as well and I'll double-check. Thank you.

Denise Webb – Individual - Chair

Yeah. We should be referring to Roman numeral III and then in parenthesis capital A. That's where it talks about scenario and focus testing. They'll need to update the preamble as well because I think they use the same terms in the preamble. So, if you'll say in the regulatory text and in the preamble at the end of your sentence there, Sasha.

Sasha TerMaat – Epic - Member

Apparently, I'm Anonymous Kraken.

Denise Webb – Individual - Chair

Yeah, whoever that is. You must not be logged into your Gmail.

Sasha TerMaat – Epic - Member

I am logged in, though. When I comment stuff, it becomes me. I don't know why I'm a kraken.

Denise Webb – Individual - Chair

When that first came up, I was like, "Who is that?"

Carolyn Petersen – Individual - Member

I usually come up as the Anonymous Hippo or something.

Denise Webb – Individual - Chair

Oh, really? Google must give us funny names.

Carolyn Petersen – Individual - Member

Sometimes it uses strange animals that you've never heard of or that you don't hear about often.

Denise Webb – Individual - Chair

So, on recommendation seven, are we asking them to incorporate this in their preamble? Say that they have some discretion.

Sasha TerMaat – Epic - Member

In III, it says that the –

Denise Webb – Individual - Chair

Oh, we're still on No. 6?

Sasha TerMaat – Epic - Member

No, in seven, they say that the testing methods and methodologies must include scenario and use case-focused testing. So, we were saying in addition to scenario and use case-focused testing.

Denise Webb – Individual - Chair

Okay. So, we want them to add that to 170.405B1(III)A.

Sasha TerMaat – Epic - Member

Right. I guess we could just say we recommend modifying.

Denise Webb – Individual - Chair

Yes, to also include because they've got to resolve the issue about scenario and use case. So, we probably don't want to confuse matters. What about the little thing in the paragraph, also possibly automated? That came from John, I think.

Sasha TerMaat – Epic - Member

I think that's just a clarification. I think if we include automated testing and regression testing, it's clear. Multiple types of testing might be automated.

Denise Webb – Individual - Chair

Yeah. The more specific and crystal clear we can be here without extra fluff in here is going to be easier for the rest of the committee to vote on.

Sasha TerMaat – Epic - Member

Right. I'm going to clean this up just so that it's readable. We could actually, just for clarity... I don't know. Is that helpful?

Denise Webb – Individual - Chair

Obviously, we're going to have to do something with scenario and use case focus, but those are not two different things, right?

Sasha TerMaat – Epic - Member

I would assume that would come out of recommendation six, yeah.

Denise Webb – Individual - Chair

Okay. Everybody else okay with that?

Carolyn Petersen – Individual - Member

Yeah, I think so.

Raj Ratwani – MedStar Health - Chair

Yeah.

Sasha TerMaat – Epic - Member

Also, maybe this is just me looking at the wording, I think we actually mean or here, right? When they said scenario and use case-based testing, since those seem the same, it didn't flag me. But when we're talking about this whole list, I don't think we mean every case has to use

all of these, it's like there's more to pick from.

Raj Ratwani – MedStar Health - Chair

You're right, Sasha. I think that's right.

Denise Webb – Individual - Chair

Then that takes care of that recommendation where we say provides some discretion.

Sasha TerMaat – Epic - Member

Right.

Denise Webb – Individual - Chair

And or allows them to do that.

Sasha TerMaat – Epic - Member

Okay. Eight?

Denise Webb – Individual - Chair

Are the criteria there a typo or is that the way it is in the text?

Sasha TerMaat – Epic - Member

I think it's probably from the rule.

Denise Webb – Individual - Chair

Okay. Criteria's requirements – yeah, it's got a squiggle under it. All right. That came right out of the rule. Okay. All right. This is the messy one that we have to figure out what we're doing with. We got a bit of feedback on this.

Sasha TerMaat – Epic - Member

Yeah. It seems like we want to, I guess, divide it up and I'll just start editing to put into the recommendation portion and the discussion portion.

Denise Webb – Individual - Chair

Rather than the "ONC should provide," why don't we say, "The CMC Taskforce recommends ONC provide...?" That's a lot stronger than just should provide. We're telling them "recommends ONC provide." That would be in the preamble? Let me look at the regulatory text. I don't think there's anything specific in the regulatory text. I don't think they want to put that kind of detail in there anyway. That's all in the preamble. The preamble is not clear.

Sasha TerMaat – Epic - Member

I think most of this second paragraph is discussion. The recommendation I think the taskforce wanted to make was actually that the taskforce recommends that ONC **[inaudible]** **[00:29:14]** that if health IT developers are testing usage data received through exchange,

there should be users involved. The rest of it is just sort of discussion as to why.

Denise Webb – Individual - Chair

What about the part where we said the CMC Taskforce recommends that use of data testing validate...

Sasha TerMaat – Epic - Member

I read that. I guess maybe I'm just misreading it as sort of why this is important, not a separate recommendation, what would be the action step based on that?

Denise Webb – Individual - Chair

Well, this comes from feedback from a lot of different failures at health systems and provider organizations. They believe that the program up to this state until this rule came out has really focused on getting information – like on view, download, and transmit, it's focused on getting information out of the EHR and sending it somewhere with not enough focus on what happens when it's received in the EHR and that there are no guardrails around them getting usable information into their EHR that they can actually view, take action on, be able to report along with their own native data.

Sasha TerMaat – Epic - Member

I understand and I share that concern, but I don't think it's the role of this taskforce to dictate a particular design approach. What we're talking about here is what would be the expectation of testing that might further that goal. I think it's fine in the discussion to say this is the concern that we heard in feedback that motivated our recommendation.

The recommendation that I'm seeing actually has actual users involved in testing the use of data received through exchange. Then the goal of that would be that that would focus on the usability of the data that's exchanged by involved the users in the design and testing process.

Denise Webb – Individual - Chair

You do say that providers can process that data. Users can process and use that data.

Sasha TerMaat – Epic - Member

Users just in general.

Denise Webb – Individual - Chair

Yeah. And then we left that down in the discussion. Thank you for adding that. We were missing that.

Sasha TerMaat – Epic - Member

Then down in the discussion...

Raj Ratwani – MedStar Health - Chair

So, up above in the second paragraph under the recommendation, can we say usability

testing? I think it's still not as strong as it could be. If we say usability testing, we're not mandating or being prescriptive about the specific methods, but I think it gets at what we're trying to get at in a stronger way.

Sasha TerMaat – Epic - Member

Raj, I guess one of my questions is whether that term usability testing is consistent with how I understand the real world testing definition to be. What would you perceive as the meaning of putting the word usability there?

Raj Ratwani – MedStar Health - Chair

I would think that that stresses that we want to understand whether the intended user population can process that information with efficiency, effectiveness, and satisfaction, kind of coming back to that core definition of usability that ONC relies on.

Denise Webb – Individual - Chair

Well, we could just say, rather than using that term, that users can use that information in an efficient, effective manner or something like that. Would that be...? Or use some of those adjectives that you would normally see in usability.

Raj Ratwani – MedStar Health - Chair

What are the concerns in using the term usability?

Sasha TerMaat – Epic - Member

I guess just in my head – and this is perhaps why I'm asking for clarification – I think of that as very lab-centric when you are doing those types of measurements of a user's effectiveness, for example, when the emphasis on real-world testing, which imagine happening in a much less controlled environment because of the emphasis on it being real world.

I was trying to put together in my head if it would be possible to use the same sorts of measures of, for example, effectiveness in that setting. It's maybe possible. That's what I was trying to process. So, I was trying to reconcile in my head what I consider to be typically a more lab-centric type of measurement with my vision of what was intended by real-world testing. Does that make sense?

Raj Ratwani – MedStar Health - Chair

It does make sense, yeah. I don't think that – I think you can have – and people do usability testing in real-world environments. So, I don't know that those are necessarily contradictory to each other. I take your point. I think people might have that perception. I think you can do and people do usability testing in the real world. In fact, it's recommended that you do that because that's where you can really see a lot of these issues unfold. You're absolutely right. You lose a lot of control compared to laboratory testing.

Sasha TerMaat – Epic - Member

Right. So, where would we put the usability word here?

Raj Ratwani – MedStar Health - Chair

We could say something like – after the comma after exchange that the health IT vendors conduct usability testing with intended users to validate their ability to process and use that information.

Sasha TerMaat – Epic - Member

If we're saying usability testing, the validate [inaudible] [00:36:04].

Raj Ratwani – MedStar Health - Chair

Yeah, I agree. I think if there's discomfort either on this taskforce or more broadly on the committee with the term usability, then Denise, I think we can say, "Okay, let's remove that term," and then we could say effectiveness, efficiency, and satisfaction. If we're going to say those, we might as well start by saying usability. Like if we just say you have to test with intended users or users, you're still not saying what you have to test, like what are you actually testing for. So, I think we do need to bring some concreteness as to why this testing is being conducted with users.

Denise Webb – Individual - Chair

I like that change that Sasha just made.

Carolyn Petersen – Individual - Member

I like the way that sentence reads.

Sasha TerMaat – Epic - Member

I think it's okay. I do have reservations that the cost of involving users at all, I guess, irrespective of the most recent edit, the cost of involving users in this type of testing definitely implies a very significant expense that wasn't –

Denise Webb – Individual - Chair

Hey, Sasha.

Sasha TerMaat – Epic - Member

And that we have to think is going to be worth it. But I think this edit is kind of irrespective of that overall concern that I'm still working through in my head.

Denise Webb – Individual - Chair

Was this a place that Aaron was suggesting the use of synthetic data?

Raj Ratwani – MedStar Health - Chair

No. I think that was elsewhere where we called out some of the testing and he suggested that we look to some existing resources on synthetic data.

Denise Webb – Individual - Chair

Okay. Then the other thing I was going to say here is I know Ken – I don't know if Ken is on.

Ken Kawamoto – University of Utah Health - Member

I'm on.

Denise Webb – Individual - Chair

Oh, hi, Ken. Ken had a lot of concerns about the cost and the burden on the users, particularly the providers, I would say. So, when this came up at the meeting – I'm going to throw this out at you, Sasha – are you still the Chair of the EHR Association under him?

Sasha TerMaat – Epic - Member

I am the Vice Chair, yes.

Denise Webb – Individual - Chair

You're the Vice Chair?

Sasha TerMaat – Epic - Member

Yeah.

Denise Webb – Individual - Chair

I don't remember who suggested this idea, to maybe have the association consider how they might enlist him to get involved in setting up some real-world testing framework that would satisfy – that would minimize the cost for everybody by doing it together, get all the vendors together to set this up. Obviously, ONC can't afford to do it, just a thought.

Sasha TerMaat – Epic - Member

I do think it's likely that vendors will want to cooperate with each other to test because if you're testing interoperability between two products, that makes sense. John and I used that as an example in a previous meeting. We could test our products together. I don't know that that significantly changes the cost, thought, Denise, because the cost component – I'm taking the involvement of vendors as a sunk cost into this whole proposal. It's the provider investment.

So, if the vendors are testing and it's only the problem of scheduling the two different or five different or however many vendors participate, that's different than if there needs to be a certain quantity of users involved. If each of the products from five different vendors needs to have ten different users involved in their usability reactions to each of, for example, the received messages or incorporated data needs to also be measured, it's the provider involvement or the user involvement that dramatically changes the cost.

Denise Webb – Individual - Chair

Yeah, I see your point. Absolutely. [Inaudible] [00:40:33] exchange versus testing of use.

Raj Ratwani – MedStar Health - Chair

I think the cost point is really big and important one. On the vendor side, also, I understand that you're considering that a sunk cost. I wonder if, in the discussion, we can articulate the breadth of the testing that should happen and the number of participants and so forth. I think if you look at what they've done with safety-enhanced design, where they've constrained it, originally I think it was 8 key functions that had to be tested and now it's 12 or whatever the number is, I wonder if we can couch this in a similar fashion and have it stratified by potential risk to help that selection process.

I still think there's too much ambiguity to know to what extent that testing needs to be conducted. Maybe we can stress that we believe it should be only for some high-risk functions and perhaps it's a reduction in the sample size or something to that effect to help control some of those costs. Then potentially, also, not occurring at every site.

It's unclear to me how overall that real-world testing is going to unfold, how many sites, etc. I think to alleviate the – I think all of us are sort of – we talked about this the last time – we think the testing is important but the cost burden is significant. I'm wondering if we can find a happy medium there.

Sasha TerMaat – Epic - Member

Yeah. I started to – slightly below what's showing on the screen in the discussion section, say we did significantly discuss the cost of proposal for multiple players. There are other interoperability partners who would be [inaudible] [00:42:17], provider organizations concerned like maybe, as Raj just said, with how to prioritize where testing is helpful without unnecessarily increasing burden. I don't know that we have a total answer to this, I guess.

Denise Webb – Individual - Chair

No.

Sasha TerMaat – Epic - Member

It is helpful to kind of capture that we've spent a lot of cycles talking about that and include that in the discussion.

Denise Webb – Individual - Chair

Yeah. And you know, I think we all recognize that this is really important. It was a huge concern for the CIOs. They said we're just not there yet. I think they recognize that they have to have their organizations involved, to some extent, with their vendor in doing some of this testing. They didn't seem against it. They see this as necessary too.

Raj Ratwani – MedStar Health - Chair

I wonder if we can add another line there, Sasha. I like what you have, but I wonder if we can add another line in there that says something like, "ONC should really consider really titrating the testing by the risk of the actual function or usage of the data."

Sasha TerMaat – Epic - Member

I wonder if that would actually be a recommendation and not a discussion consideration.

Denise Webb – Individual - Chair

Yeah.

Raj Ratwani – MedStar Health - Chair

I agree. I'm not sure exactly where that fits. I'm not sure.

Sasha TerMaat – Epic - Member

Is that a fair summary? I'll be clearer. I guess to reduce cost in general, not even necessary cost – the taskforce recommends ONC prioritize real world testing.

Raj Ratwani – MedStar Health - Chair

For the taskforces, you need a committee. We could do all those changes later.

Sasha TerMaat – Epic - Member

They're going to do it all later with Ctrl + F.

Raj Ratwani – MedStar Health - Chair

Okay. I think that makes sense.

Sasha TerMaat – Epic - Member

Okay. Then the sentence in the paragraph above it, I just moved into the discussion because it was more of a discussion consideration than a recommendation. So, I will [inaudible] [00:45:03] these so we have it clean.

Denise Webb – Individual - Chair

Yeah. I'm glad we got through that one. I would say, "The Taskforce recommends ONC clarify..." I think that's in the – yeah. Why don't you say in the final rule preamble and we'll have Kate or Excel go back and catch it where we didn't do that elsewhere.

Sasha TerMaat – Epic - Member

[Inaudible] [00:46:02] on the next sentence here. So, it says the provider should be involved. We have that in recommendation eight. Is it okay if I cut it here?

Denise Webb – Individual - Chair

Yeah. That seems redundant. But the final rules need –

Raj Ratwani – MedStar Health - Chair

Yeah, I think you can cut it.

Sasha TerMaat – Epic - Member

We'll stay here instead. But yeah, recommend ONC provide guidance on testing options.

Denise Webb – Individual - Chair

Do we want that in the preamble as well?

Sasha TerMaat – Epic - Member

I think this that I have highlighted that's going right on to the top of page six was also accommodated in the previous one.

Denise Webb – Individual - Chair

We have to go to public comment and then we can come right back to this.

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

Thanks, Denise. Operator, can we please open the public line?

Operator

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

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

Okay. I don't see a lot of guests today, but do we have any comments in the queue?

Operator

There are no comments at this time.

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

I think we have plenty of time to wrap up on this last edit.

Sasha TerMaat – Epic - Member

We do have a commenter in the chat. I don't know if – Didi, are you planning to make an official public comment?

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

Even though she only typed it here, it will still be captured in the formal record.

Sasha TerMaat – Epic - Member

Just to read it off if anyone is just on the phone, Didi in the chat says, "The Sequoia Project performs real-world testing today for the e-health exchange network that exchanges data

with 75% of US hospitals with federal agencies. It might be good to include comments that industry programs should be assessed. The testing that is performed today covers transport, security, and content for data quality.

Denise Webb – Individual - Chair

That sort of relates to – I don't remember if it was John who said it. Actually, I think I heard this from Steve Posnack, that it was the intention of ONC that some things that would be acceptable are like care quality, commonwealth, some of those avenues for testing in the test plan would be acceptable. But they don't really call those things out in the preamble. What Didi is saying here I think applies more to the actual exchange of the information, not the use of the information, right?

Sasha TerMaat – Epic - Member

I wonder if we went back to earlier when we were editing 170.405B1(III)A to talk about testing methods and methodologies and we added automated and regression testing, I wonder if that would be a place where we would want to say something like recognizing other industry activities would also be acceptable. Or maybe that's more of the discussion around this edit. I don't think it would necessarily happen in the regulatory text.

Denise Webb – Individual - Chair

But we should have it in the preamble. I think that would be a good place to reference that.

Sasha TerMaat – Epic - Member

Maybe if we're clarifying the terms in six, we would add to six to say that the taskforce recommends that ONC also acknowledge in the preamble where it's [inaudible] [00:50:36] industry-wide testing such as that performed by the Sequoia Project in this example might already exist?

Denise Webb – Individual - Chair

Right, or interoperability testing.

Sasha TerMaat – Epic - Member

Okay. How does that sentence look?

Denise Webb – Individual - Chair

I would take that out in front of ONC and put it – the taskforce recommends ONC clarify in the preamble where existing interoperability testing –

Sasha TerMaat – Epic - Member

I think it's better without the [inaudible] [00:51:56].

Denise Webb – Individual - Chair

Okay. Right. You want to put the final rule preamble. Now, is this expectation for all testing? Would that include the use testing? Probably not, right?

Sasha TerMaat – Epic - Member

I guess if an existing network did use-based testing, maybe I t could. Thought, I would expect that in most cases, it would be not use-based.

Denise Webb – Individual - Chair

Okay. I would say, “Can satisfy expectations for real-world testing.” It can stand on its own.

Sasha TerMaat – Epic - Member

Are there other public comments that we need to take before we move on?

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

I don’t think so. Operator, do we have any comments in the queue?

Operator

There are no comments in the queue at this time.

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

Okay.

Sasha TerMaat – Epic - Member

Okay. So, my only comment on nine, which is where we were when we left off was the final sentence, which is yellow and just sneaking off the end of the screen seems to be already covered in eight. So, I think we can cut it from nine.

Denise Webb – Individual - Chair

Right. In fact, I think that was a little disjointed. I noticed that was down there and I thought, “That needs to be up with the other part where we talk about this.”

Sasha TerMaat – Epic - Member

Okay. So, we’ve got that cleaned up.

Denise Webb – Individual - Chair

I made a note to myself on that, as a matter of fact.

Sasha TerMaat – Epic - Member

Okay. Do we want to keep going on ten?

Denise Webb – Individual - Chair

I’m good. Then let’s make this affirmative the taskforce recommends ONC allow for. Now, where are we suggesting this goes? Are we saying the CMC taskforce suggests the final rule

preamble address the following or is this going to be regulatory text?

Sasha TerMaat – Epic - Member

I'm looking at the regulatory text again.

Denise Webb – Individual - Chair

I have that page open too.

Sasha TerMaat – Epic - Member

I don't know that the regulatory text is specific enough that it addresses this and I don't know that it has to. I suspect it's preamble.

Denise Webb – Individual - Chair

Yeah. I wouldn't think this would go in the regulatory text.

Sasha TerMaat – Epic - Member

In the regulatory text or the preamble?

Denise Webb – Individual - Chair

No, I was agreeing with you. Raj and Carolyn, are you in agreement?

Raj Ratwani – MedStar Health - Chair

Yeah, it works for me.

Carolyn Petersen – Individual - Member

Yeah.

Denise Webb – Individual - Chair

Do we want to say, "The CMC Taskforce suggests the preamble address the following..." up above? Back on ten...

Raj Ratwani – MedStar Health - Chair

Yeah, I think that works.

Denise Webb – Individual - Chair

And recommendation 11, yeah, that's definitely preamble. There's only one line in the regulatory text about having the measurement. So, folks, we're at the top of the hour. Do we want to continue with this? Our next meeting is on Wednesday.

Sasha TerMaat – Epic - Member

I think we could keep going through ten now or adjourn and pick it up – sorry, we finished ten – next week. We could certainly look at it a bit offline and make some of the editing suggestions that might help us move a little bit more quickly next Wednesday too.

Denise Webb – Individual - Chair

Yeah, that would be good. Then Raj, are you available next Wednesday? I do have an 8:00 conflict right now I'm trying to get changed. I mean 8:00 Central time. I believe our meeting is at 9:00.

Raj Ratwani – MedStar Health - Chair

I'm actually out next Wednesday through Friday.

Denise Webb – Individual - Chair

Oh, you are? Okay. Well, we'll talk about our debrief meeting about whether we can move a meeting.

Raj Ratwani – MedStar Health - Chair

Okay. I think Sasha's point is exactly right about us doing a lot of editing offline so we can move faster on the calls.

Denise Webb – Individual - Chair

Yeah.

Raj Ratwani – MedStar Health - Chair

Great. Thank you, everybody. I appreciate everyone joining.

Denise Webb – Individual - Chair

Thanks, Sasha, for your help.

Sasha TerMaat – Epic - Member

Thank you, bye, bye.

Denise Webb – Individual - Chair

Thanks, Carolyn.

Carolyn Petersen – Individual - Member

Bye.

Denise Webb – Individual - Chair

Bye-bye.