Conditions and Maintenance of Certification Requirements Task Force

Transcript
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Virtual Meeting

Speakers

Name	Organization	Role
Denise Webb	Individual	Co-Chair
Raj Ratwani	MedStar Health	Co-Chair
Carolyn Petersen	Individual	Member
Ken Kawamoto	University of Utah Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Sasha TerMaat	Epic	Member
John Travis	Cerner	SME
Lauren Richie	Office of the National Coordinator	Designated Federal Officer

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

Good morning, everyone. Welcome to the Conditions and Maintenance of Certification Requirements Task Force. We have Denise Webb, Raj Ratwani, Carolyn Peterson, Ken Kawamoto, Sasha TerMaat, and John Travis. With that, we can go ahead and get started. We only have really one recommendation to talk through today, and, hopefully, we can get that resolved. With that, I will turn the call over to Raj.

Raj Ratwani – MedStar Health - Co-Chair

Thank you. As Lauren mentioned, recommendation 25 is the key one to discuss, and I know, Ken, you had some thoughts on this I believe. And I don't know there are others that are on the call that want to weigh in, but we can open up the discussion here.

Denise Webb – Individual - Co-Chair

I'm online now. This is Denise, and I'll just jump in if we can put up the document that I had sent out. We actually got a written recommendation from Les, and then John followed up with a written recommendation. And then I followed up with one that's in this document. I think everybody has seen Les's and John's because they did that through email. Maybe we can look at that. Oops.

John Travis – Cerner - SME

This is John. Maybe I will start it off. I think that Les was raising a fairness point that my suggestion was trying to balance the two. The one thing that I think is important is, well, the two things, and they're not necessarily competing. I think they define the fairness balance we're trying to find here that certified HIT regard less of its nature needs to meet program requirements or needs to enable the participant that's relying on that status to meet program requirement. So, those things that establish that are probably fair to apply to any certified product. However, you want to characterize, that Les fairly raises is that you don't want to create an undue burden on self-developers who are seeking to meet their own need to meet that certified product prerequisite for program participation but also have an interest in building something for themselves, whatever their reason may be, to make use of beyond- the-certified-product aspect of it. I'd venture to say, Les, and you can speak to this, that kind of the rank order of how you view it is, number one, the value of the self-development for a provider's own use. Number two is the value of it as a certified product. Those are always going to really be in the order of things.

Maybe not in every single case but as a general motivation, that's probably the case, and you want it to stand up and meet the certification requirements. And probably the biggest one that remains after that is dealing with approving it out for whatever its capability may be if it's subject to additional capabilities that focus on the capability of the solution. I use capability a lot there, but real-world testing is probably the biggest one that enters in. But other conditions of certification or maintenance of certification that have to do with commercial market presence, fee structures, engaging in fair business practices regarding it, things of that nature, don't really enter in. If you make the decision to commercialize it, it's a

different matter, but assuming you don't, those don't really play in. So, definitely, there needs to be a modification of the applicability of the requirements to recognize that, and for our purpose, I think that's what I tried to balance. And I think, Denise, you did a pretty good job of merging in my suggestion at least. I wouldn't offer my language in favor of yours because yours, I think, broadens it a bit and makes additional points about it.

Denise Webb – Individual - Co-Chair

So, could we scroll up to what I'm suggesting? Because the one place where I really think it's important for the task force to provide specific guidance to ONC, excuse me. Scroll down. I meant down. Move the page up so we go down. Yes, thank you. All the way down. In the spaces that you see there, I just want to remind all of us that our charge is to specifically look at the applicability of the conditions and maintenance certification as it applies to self-developers for certified health IT modules and that that certification criteria that are being addressed here is around real-time testing APIs and attestations. On real-time testing and APIs, those criteria are all focused on interoperability. So, if a self-developer organization decides that they need to have something certified to be able to participate in a federal program, whether it be voluntary or it's mandatory they participate in that federal program, we're really focusing in here on the modules that they have to have certified that have these interoperability criteria. What I'm asking us as a group to consider is what is it that we have - those who have some real concerns with this - what is it we are concerned about specifically under real-time testing API and attestations?

I know you just got this last night, and maybe people need to think about this. I know Les was proposing that we narrow our recommendation to say that this should only apply to self-developers of commercially offered certified Health IT. I know if we put ourselves in the patient's shoes, I think, as a patient, a patient would want a self-developer to be put under the same level of scrutiny when it comes to my health information and the exchange of that information to make sure that that function all operates properly from a patient's safety perspective. So, that's sort of where I took this a little bit further, and if you'll go down a little bit more in the document I have a parenthetical note here. Everything in italics is what I'm suggesting. I think we are concerned about universally applying all aspects of CNC for these three areas to self-developers. And, yes, we don't want to stifle innovation in these areas when certified health IT is required, but I don't think that differs for a commercial developer than it does for a self-developer because certainly, we want our commercial developers to not be stifled either. I would think we would all agree on that. So, I'm offering an alternate recommendation that hopefully captures the concerns of Les and builds on what John has put forth for consideration.

Carolyn Peterson – Individual – Member

This is Carolyn. In listening to you all and thinking through all of this, especially over the last couple of days, I think for me, first of all, it's of note to me that when John started the discussion talking about the priority concerns, he did not mention patients. He also did not mention the physicians, who might be receiving data from a self-developed piece of something, who have to figure out what is going on here and sort of guess at the reliability of it when their patient is treated in some place away from home and that information is sent

back to them. I think as a patient it's important to know that the system met some kind of standard criteria and someone is watching over and paying attention to it. Firstly, of course, because you want to have confidence that the information that comes out of the system is information that's about you and not somebody else so that the decisions your doctor makes about how to care for you are based on accurate information.

I can see where, for example, if I was on vacation someplace else and I went to a facility that used some self-developed thing and I became ill and some tests were run that I had to pay for probably at higher out-of-network pieces and those test results came back to my doctor here at home and they were significantly different on many parameters from what he or she was used to seeing in terms of my numbers on tests run here, I can see where he or she would like at that and say this doesn't seem like you at all. I think we need to rerun all these tests. And then I could have my insurance company saying, well, we've already done all that, so you've got to pay for all of this yourself. That would be really distressing on top of the concerns that I'm getting a whole set of test results that are not in the ballpark of what my numbers usually look like. I would certainly wonder what was coming out of that box in somebody else's shop. In M-Health, kind of an area that I'm more familiar with in some of the testing and stuff that relates to some of the EHR products, it's becoming apparent that as a consumer you hear one thing about a product, and then you find out later about a lot of other stuff that it's also doing, which can be things you didn't expect.

For example, recently there's been some discussion about how women use menstruation apps to track their cycle and perhaps help them get pregnant or help them avoid pregnancy. And now we find out that this is being sent to employers and other people who have access to information, for example, through wellness programs. We see with social media there are all kinds of effects that people didn't know about, weren't made clear to them, despite whatever extremely difficult to understand language is in a terms of service. And I think that there is some pretty well-justified skepticism on the part of patients and consumers about what is really going on with technology. When something that hasn't been certified is introduced, I don't think that really makes people feel comfortable particularly given some of the kinds of events we've seen. So, perhaps maybe another place to take this conversation is exactly what is one missing when one doesn't certify in a test. As a patient, what sorts of assurances am I not getting if I am subject to your product that hasn't gone through the CMC process?

John Travis – Cerner - SME

This is John. I certainly wasn't suggesting that there weren't other interests in the reliability of the product. That was exactly my point. I was merely suggesting the interest a provider organization would have in seeking self-development under their own motivations. But I think the point that we're all raising is the key is the reliability of the certified product to meet its reported capabilities. And ONC has clearly said in this rule that certification itself is not enough. There have been problems with that. It's a laboratory test found to be insufficient. That's what they proposed real-world testing so that perhaps leading among all of these is a proof point that can be subjected to broader daylight and more transparency. I

think that is one that I would certainly argue remains effective. Anything that accrues to certification is already present because that's inherent in the certification itself.

So, I think we are really talking about what is it that establishes confidence and reliability of the software? For me, I've previously spoken to the fact that I accept and absolutely respect the points of the public interest in terms of consumer access. That was not one I had raised, so I appreciate very much that perspective. My main point of insistence before has been around these are products being used to qualified providers for program participation under Medicare and Medicaid and under innovation center models and other things that are claiming the standing of other certified product. Therefore, there is a public interest that way as well that those products hold prior to any other certified product. I suggest we should call out this particular condition of certification and maintenance of certification that are relevant to that trust. Those that go towards the commercial interest that would be appropriate for Cerner or Epic or any other certified vendor HIT, really are not nearly as relevant. I don't know if there's a way we can go through those and say these are the ones that matter and these are the ones that don't to both address the reliability point you raised and the point of assuring a prior-level capability to a product claiming to be certified that enables program participation with the public trust in mind. So, I think that'd be my suggestion.

Denise Webb – Individual - Co-Chair

John, that's where I was going with my fill in the blanks. I think it's easy to say, yes, all the conditions of maintenance of certification should apply to self-developers, except in the case of the following aspects of real-world testing of APIs and of attestation. If we can specifically identify what is in the rule that is problematic with those 3 CMC, I think there's some discussion in APIs around fees. Obviously, we would want to state that that would not be applicable to a self-developer unless they took it to the market. But I think the kind of technology that a self-developer would have to bring forth to get certified to participate in federal programs, either voluntarily or because it's mandatory, the CMC focuses on the interoperability aspects. I think you stated it well, John, that we probably need to identify what it is that we don't think is applicable. Otherwise, we're not being helpful to ONC in honing it down for self-developers.

John Travis – Cerner - SME

No. And then we're giving them the full task. I think in some cases, and you hinted at it with the API, the parts of that that had to do with the fee structure really don't apply. I think that there might be a specific call out in real-world testing as well that a self-developer can point to their production experience. If they don't have it, they can't point to it, but if they do have it, maybe there's a reduction in burden there that you really highlight that they can leverage their own production experience presuming it measures up to real-world testing would apply. For example, while a commercial developer might have eight venues that their certified software is used in, the self-developer is going to have their own. Whatever it is, it may strictly be a hospital, or it might be some ambulatory venues where they've actually deployed it. And then it's the production experience they have in those venues to do transitions of care or to do API service offerings. Pardon?

Denise Webb – Individual - Co-Chair

They can rely on their production experience for how it's working within their health system, but their module is going to interact with modules of other products outside of their health system. **[Inaudible][00:19:23]**

John Travis – Cerner - SME

It wasn't reducing the requirement of real-world testing, which we have already said involves proof of the ability to receive and incorporate information from those other systems. So, the requirement as prior level, my point was it's based on their actual experience. Who are their trading partners? They're not having to go out and create and contrive a laboratory test, if you will, or testing. They could have the opportunity more succinctly to use their production experience with whoever that is in whatever scope of operation because that is actually what they use it for. They are not going out to commercialize it otherwise. So, maybe there's an opportunity there to be clear.

Denise Webb – Individual - Co-Chair

Well, just to be the devil's advocate based on what Carolyn had presented, I'm traveling. I have a situation. I'm in the emergency room and that may not be a trading partner. I think everybody who develops software that is certified for these interoperability requirements has to contemplate the situation whether or not necessarily they're going to be trading with their typical trading partners.

John Travis – Cerner - SME

I'm going to go back to the framing of the requirement though. That is the vendor selects the appropriate venues, and that might be a part of a testing scenario design. But I think we have got to be careful about suggesting you've got to account for - and I don't mean to insult the suggestion - derivative cases that are not mainline cases. We're really getting into the details of how you would do test case design in that case, in which case we have a lot more to have a conversation about ONC with it needing to be very specific in their guidance. So, I'm just trying to simply say taking the requirement as it is, I'm not trying to change the requirement. I'm trying to suggest there may be particular statements that mollify the concern that, look, I built a component to do a hospital-based transition of care. And I have my trading partners that I do actually work with. If you're going to tell me that I've got to also do go do other things that are irrelevant to my own production use of the system and my experience with who my the trading partners are, accepting the requirement as it is, I'm constraining it to where I actually operate the system and what my own production experience actually is with it. Don't tell me I need to go off and do other things that are academic to the way I would define venue and I would define where I have my production experience if I'm going to leverage that as proof of testing. So, Steve possibly would say you can do that. That's what I was after.

Denise Webb – Individual - Co-Chair

I did capture that the API fee structure does not apply unless they're going to commercialize, and I think this is a great recommendation to add under the real-world testing - the point about the self-developers being able to rely on their own production experience in their test plan. We have not heard from Ken and Sasha, and I believe Les just sent a message. And he's trying to get on. So, Ken?

Ken Kawamoto – University of Utah Health - Member

Sure. Big picture, I think it is in front, of course, to think about the end-user patient experience. That's for sure really important. From a healthcare system perspective, I think it's really important to keep in mind that a healthcare system in general if there's something that's going to require a lot of regulations, we're probably going to stay away from it because it's just going to be too much effort. In terms of the things we already do in implementing EHRs, a ton of what an EHR does is done through local configuration and local development. Right? Practically every order set, documentation template, distance support, we provide in the system. It's not something like it's certified by some government entity or regulated by the FDA. I think if that were the case, it'd be a net negative for the patient because we would never put in those capabilities if we had to go through those kinds of regulation. Of course, we mean well when we say we'll just make sure we'll regulate, but I think you have to also keep in mind there can be unintended negative consequences.

I think my main question with the certified modules of Health IT is what are the places where they could be used in federal programs? My assumption is federal programs in deciding the requirements for participation aren't necessarily looking through hundreds of pages of regulation and saying, well, because of these particular capabilities that are important for this purpose, we are going to require certification. I think it's simply going to be, oh, well, it's using EHR, so we need to say it's a certified EHR product. In that perspective, I think if there are requirements that are not relevant for the purposes for which the module is being developed, I think it's something that is certainly a concern because you basically gain nothing but you cost innovation. I think it's much trickier when there's a balance of there are these potential downsides of not regulating, and there are these potential benefits. And then it becomes sort of like, well, we need to really look into it. But I think there's also potentially cases where the only thing that is present is a downside because the regulations aren't even really needed for those cases. But an administrator basically said, well, ONC has defined these, so let's just see them. And I think Les just joined as well.

Denise Webb – Individual - Co-Chair

Let's go to Sasha next.

Sasha TerMaat – Epic - Member

Sure. I think I agree with a lot of the points that have been made so far. There is clearly categories of certification requirements which are important for ensuring performance to users of the product, the users of other products who interact with it through interoperability, the patients whose data is stored within the product and have expectations

as users themselves through their own access. And there are on the spectrum, clearly, things that would not be relevant for self-developers. We've thrown around the pricing expectations as one example. It does seem like going through the items that are within our scope particularly one by one and sort of classifying them would be the most effective way. I think because we have a pretty small scope of what's in certification, conditions, and maintenance within this task force, my sense looking at those requirements is that most of them fall into the ones that would be important from the assurances provided to other users and to patients. But I philosophically agree. If there are ones that are relevant, it's not appropriate to burden any actors within the marketplace with irrelevant requirements.

Denise Webb – Individual - Co-Chair

All right. Is Les on?

Leslie Lenert – Medical University of South Carolina – Member

Yes, I'm on. Thank you. Again, it sounds like we've had a great discussion on this and a wide variety of subjects addressed with it. Again, I think we are entering a new era of innovation in EHRs with our APIs and SMART on FHIR and that the diversity in the EHRs system is going to expand with these eras within this era. But it's important for people to maintain certification to be eligible for federal programs, particularly programs that are addressing things like the opiate epidemic or that are addressing needs for national security like BioSense other things. If these are conditioned on having a certified EHR in that there are user-developed blocks that have to be certified to the same extent, then this is an issue. I agree that our focus should be on maintenance of certification issues. Maintenance of certification is different than certification one time in my opinion because it says maintenance. It's designed to be an ongoing process, which is going to require some attention from the institutions that are involved.

Therefore, it's particularly important to address the issue of ongoing burdens of certification for people who are self-developers and allowing them to participate in key federal programs, to advance the agenda for that, and to be eligible from the big picture perspective of those programs. I also think that we are here to really talk about the maintenance of certification. So, things that are outside of maintenance of certification are not in scope for us. So, if we had recommendations on other aspects of the document, I'm less excited about our committee making those because we are really stepping out of our lane when we do that. My concerns were addressed by John's modifications. I think that maintenance of certification and certification, in general, is about creating a market for certified products. We want to ensure that that is protected for people who are selling things. If you're building something for sale, even if you use it yourself, you shouldn't have any advantages in doing that. So, I think that the dividing line on this is really whether the product is for sale or not, and I absolutely believe along with the rest of us probably that anything offered for sale has the same floor as far as performance.

But I do think a caution to ONC in that our advice is not really to write the regulations but sometimes to advise ONC where to pay more attention to the regulation. We would do well

to advise ONC to pay attention to this nuance of self-developers and with ongoing maintenance of certification to avoid creating a situation where we inadvertently stifle innovation and that as long as we tell ONC staff, which did a fantastic job writing the initial regulations, what the path should be to be careful in this area because there is the possibility of unintended consequences. I think we've done our job. Then we can see what happens as that comes out from our cautions. I believe that ONC will do the right thing.

Denise Webb – Individual - Co-Chair

Raj?

Raj Ratwani – MedStar Health - Co-Chair

I don't think I've got too much to add in the discussion. I think I agree with all the points that are made. I agree with Sasha's point about in general there should burden reduced across the board. So, anything that seems like it's extraneous and burdensome for a self-developer, I think we should really be questioning whether that holds true for commercial vendors as well, and then those should be eliminated. I'm having a hard time seeing some of the distinctions here. I will say that one of the key pieces from a safety perspective is that there needs to be the base level minimum standard for safety that all products are adhering to, and that certainly shouldn't waiver whether it's self-developer or commercial.

Denise Webb – Individual - Co-Chair

On that particular point, I was going to make a similar point that regardless of whether something is offered commercially, there's a base level of standard that needs to be met in the of interest public and patient safety. That's kind of the point I was trying to make in my comments. So, I guess Raj and I need to understand where the task force is in terms of what version of this recommendation do we want to finesse and go forward with? I know I heard that Ken, I think, is in favor of what John has put forth. He's also in favor of what John has put forth. Is there someone who'd like to volunteer to tweak that recommendation or shall we put it on Google Docs and everybody can propose their edits? I think we at least need to decide which of these forms of recommendation we are going to edit.

Carolyn Peterson – Individual – Member

If I could ask for a point of clarification thinking about Les's comment, at the 35,000 foot level, it's easy to agree with the things that you have said and things that some other people have said about, for example, not putting requirements on self-developers that aren't also there for non-self-developers in terms of safety. But from Les's general comments, I'm not clear what actually is being advocated for. If I agree with the statements that were made, what is that actually committing me to? It would be helpful to get clarity around that.

Leslie Lenert – Medical University of South Carolina – Member

You've got it backward. Your statement is exactly backward, which was there are certain requirements that self-developers should not be imposed on that commercial developers, people who intend to sell the software should have. That's what I've been advocating for and

that maintenance of certification is a particular area that we need to be sensitive to this. I think John's language cover that.

Denise Webb – Individual - Co-Chair

Can you be more specific though, Les? What particularly aspects under real-time testing APIs and attestations in the maintenance of certification do you have the greatest concern with that we could call out ONC to pay special attention to? I mean, because, otherwise, it's all over the place.

Leslie Lenert – Medical University of South Carolina – Member

What I say is once, and then let it run for 5 years. Let's them certify it once, and then get it by the maintenance of certification for the life of the product after the one-time certification.

Denise Webb – Individual - Co-Chair

Hold on. I just want to ask a question of clarification. Are you suggesting that the self-developer will do their real-time testing once and not have to submit a test plan for five years?

Leslie Lenert – Medical University of South Carolina – Member

Yes, that's probably what I'd suggest, but I'd be open to other options with it. I just want to see that toned down a bit from a commercial developer would have to do because it's way more burdensome. If I have to spend 50% of my resources maintaining the certification of a self-developed app, if that's the tail for any development is 50 percent of the time and is that much, that's really a big burden.

Denise Webb – Individual - Co-Chair

What does the rest of the task force think about that? Would others be in agreement with specifying that - that they would not have a test plan for a particular period of time? They'd only have to test every five years.

Raj Ratwani – MedStar Health - Co-Chair

This is Raj. For me, the devil would be in the details. If there are conditions of maintenance of certification that are touching safety, then those absolutely need to be maintained no matter what, whether it's a commercial vendor or homegrown system. If it is touching a patient, we have to ensure it's safe. If there are other conditions that are not perhaps touching safety and are more about the commercialization of the product, I think I would agree with Les's point.

Ken Kawamoto – University of Utah Health - Member

This is Ken. I think, again, I like Les's point that the ONC folks have done a really good job putting these together. I'd be certainly in favor of saying, okay, these are particular things

that we thought of. I think if we are going to make detailed recommendations about this one particular should be edited this way for self-developers, etcetera, we probably need more time. We probably cannot get it done just in this call.

Denise Webb – Individual - Co-Chair

Yeah, I don't think we're going to get it done in this call. I think we are going to need to all contemplate this and think about filling in the blanks here. I completely agree Les about taking caution. ONC should take some caution and think about what the unintended consequences are with self-developers, but if we can help them out by calling out some specific areas we want them to look at under real-time testing in APIs, I mean, attestation is pretty straightforward.

Sasha TerMaat – Epic - Member

I don't dispute that we want to think this through. It's a pretty critical recommendation, but I wonder if this is actually something that would have to do with the volume of users independent of status about commercialization versus private development. In my mind, if you have a very small number of users for a particular product, the burden of real-world testing is high. For example, if ONC says that there should be ten participants in real-world testing and your product only has 20 users because it's used in one department at a particular facility, that's a high burden, whether it's a commercial product or a self-developed product. That scenario is probably more likely for self-development. But in contrast, if a self-developed product because it's used at a large health system actually has a comparable number of users to some commercial products, it seems like the importance of other interoperability participants, patients, and so forth being able to rely on the usability and interoperability of that product is more significant.

And I wonder if maybe in our existing recommendations about guidance on sort of how are the settings that are used in this testing going to be determined, what does that mean? How should they be selected? How many of them should there be? Maybe we want to incorporate into those existing recommendations a thought about products that have particularly small volumes of users, which would mitigate burden for probably many self-development situations given that they are likely to be more targeted in their usage but then also address other scenarios of the same constraints of I cannot involve half of my users in a real-world testing every year from a practical perspective, might influence products.

Leslie Lenert – Medical University of South Carolina – Member

I think it's a good point Sasha, but I'd just add there is a burden for the infrastructure to maintain the testing as well. For me, I think a lot of this is really about not making it so expensive to innovate that no one can afford to do it. When we started this discussion, I believe my opening remarks were we used to have a lot of people innovating in the space of EHRs. It's all gone. All University, all academic innovation, all have been collapsed into a market which is dominated by just a few players. And now we are in a new era where there will be a lot of modules that are developed based on FHIR capabilities. Again, we want to be able to protect innovation in the setting of individual organizations, and my interest is in

protecting them in the setting of academic institutions, in particular, that study informatics and also in the areas of public health where the resource levels are just much, much lower.

Denise Webb – Individual - Co-Chair

So, Les, you tend to lump things into a general category of EHR, but if I'm not mistaken, I'm also the program's NCMS, at least based on past experience have been around a base EHR. I think there's tons of development going on on top of base EHR that doesn't require certification because it's not base EHR. It's what you're doing with the data. So, the base EHR is the platform for selecting data, features, and functions around the base that then it's what you do with that data with APIs. Where the innovation comes is where you're developing on top, and those would not be subject to certification necessarily. I mean, I think that's a broad statement when we say that we think we're going to stifle innovation to have those who want to stay in the business of developing base HER, which includes these interoperability requirements. I think there's a balance on this.

Leslie Lenert – Medical University of South Carolina – Member

Exactly. You cannot go all the way over to favored commercial developers in this space. There has to be room for innovation that is protected for self-developers because that is really the roots from where all of this has come. Everything that we do today really comes from the self-innovation of different help situations that then we subsequently picked up and commercialized. But we have a 30-year history of this field where self-innovation has really been the core of how the field has advanced.

John Travis – Cerner - SME

I just sent this quick and dirty effort. You all got the email. If we were to try to take the conditions certification as they are, these are high-level statements of what should probably be removed or qualified in terms of how they apply to the self-developer just a strawman to put it out there to give maybe a start to practical statement of what we mean by fulfilling Les's statements and Ken's statements of what should not apply. I don't know if it's worth going through that real quickly but maybe tease up for follow up conversation. I sent the email to everybody that Denise sent it to earlier with materials for today's call. If anyone were to want to bring that up, I'd be happy to walk through it quick.

Denise Webb – Individual - Co-Chair

Is there a number, Accel, that can be put up on the screen that received the email?

John Travis – Cerner - SME

I don't know if I can share or be interactive on it.

Denise Webb – Individual - Co-Chair

Just to let everybody know where we are at on a public timeline, we are going to go to public comments in three minutes, but we can certainly go over this. Then if we get to the end of

the call, what we can do is Raj and I can work with Kate to add this to the document that I started. And let's move this document out to Google Docs and see if we hook them up with **[inaudible][00:45:31]**. Yeah, we'd combine a meeting of minds to come up with a recommendation that we can all weigh in on. Is anybody able to put up John's email?

Accel

Yes, this is Accel. Just give us one moment.

Denise Webb – Individual - Co-Chair

Okay.

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

Denise, maybe while we're waiting we can go to public comments.

Denise Webb – Individual - Co-Chair

Sure. That'd be great.

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

Operator, can we open the line?

Operator

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

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

And 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

Okay, let's go ahead and pull over John's email, and then we can use the last ten or 11 minutes.

John Travis – Cerner - SME

All right, I see it in view. Let me walk through it real quick. Pardon a few typos. I was trying to get it down so we could quickly talk through it. For information blocking, providers are already subject to information blocking provisions under the Cures Act, and they are already attesting to those in any attestations they make for things like promoting interoperability or for submission of their attestations from MACRA, QPP, MIPS. And while there is a distinction of the provisions applicable to developers, I would point out for what matters to the provider they're already using their self-developed product in a manner that would expose them as a provider. So, I don't know if there's additional value or purpose in applying information blocking provisions to them for self-developers who are using their own software.

Denise Webb – Individual - Co-Chair

Forgive me for interrupting, on the first two conditions those are in information blocking task force. Or first three and they've already addressed those. And they are bringing those forth for the whole committee. We need to focus on API real-world testing and attestations. I don't mean to cut you off.

John Travis – Cerner - SME

Okay, I took it more generally. That's fine. APIs, I think as we said before, provisions that apply to these likely do not apply to self-developers if they don't commercialize their product. The parts of them that deal with making information accessible and anything not related to commercializing the product or charging reasonable fees and things like that really don't apply. Real-world testing I had mentioned before to really focus on the specific value that their own production experience may play for the venues where they've actually deployed their software. Recognizing your feedback, Denise, for the training partner experience they actually have, assuming the certified capabilities, otherwise all measure up. For whatever is relevant for them that falls within the real world testing requirement really emphasized the ability to use their production experience as evidence and as a basis of their testing plan development. Really that is it because attestations are largely general statements made about the things that apply to you, and the EHR reporting criteria is a future state item that we really have no ability to speak to right now.

Denise Webb – Individual - Co-Chair

So, in real-world testing just hearing what Les, maybe we could say something around having ONC carefully consider the annual requirements for test plan and so forth as that would apply to self-developers and create an undue burden, particularly when there's a low-volume of users.

John Travis – Cerner - SME

I will highlight that in our own recommendations for commercial developers on real-world testing, we made a lot of comments about being able to leverage prior year results were nothing has changed or to not have to repeat testing where nothing has changed. Even there we are making the point that Les is making about allowing those results to stand for a period

of time and not qualifying it like we are for the commercial developers. But we are already on that path relative to commercial developers, so it's not a huge leap to support letting results stand for self-developers. But there may be more concession there than for a commercial developer.

Denise Webb – Individual - Co-Chair

Others? Sasha, Les, Carolyn? Ken, Raj?

Sasha TerMaat – Epic - Member

I think these are reasonable.

Leslie Lenert – Medical University of South Carolina – Member

Yeah. I think this is very reasonable, and it seems that we want to focus on this real-world testing requirement as the place where it needs to be mitigated slightly and that it needs to be mitigated. I like the idea that if nothing has changed, then you don't need to retest, certify that nothing's changed and that real-world experience when you've got minor changes just enough to certify.

Ken Kawamoto – University of Utah Health - Member

This is Ken. One thing with APIs, from the regulations, I think it just sets a minimum floor, but I want to make sure that additions to APIs that are done for internal purposes aren't affected. I don't think the regulations read that way, but what we find is oftentimes the vendor supply guys don't quite get us everything we need. So, we do add to the APIs that we use.

Sasha TerMaat – Epic - Member

Would you be adding in the USCDI or outside of USCDI?

Ken Kawamoto – University of Utah Health - Member

I think outside. The example might be, say, USCDI says you need to tell us whether the patient smokes, but in order to meet lung cancer screening guidelines, you need to actually know how many packs the smoke, etcetera. So, we create an enhanced version that provides that so we can take care of that. I don't think there's anything in the regulations that say you can't do that or health systems can't do that, but I'm just bringing it up again with the issue of the unintended consequences. I just want to make sure. It would be a travesty for us if somehow these regulations got interpreted to mean we can do that.

Sasha TerMaat – Epic - Member

My sense is that these particular conditions of maintenance are independent of that broader question, which is if we are enhancing something that is part of certification, does that prompt us with the need to recertified ourselves? I think that that is a question worth asking,

but I don't think the conditions of maintenance certification attestations here would actually change that one way or the other.

Ken Kawamoto – University of Utah Health - Member

Something Beth said really struck me which was, yeah, we are sort of entering a new, exciting era of being able to innovate using vendor supplied platforms like FHIR and CGAS OpenSmart. Again, I don't see anything in the regulations that don't allow it, but if the unintended consequences are that now we have to go to the equivalent of EHR certification to provide additional features or whatnot, I think that would be unintended. Unless it's intentional. It's one thing if it's intentional to say, hey, this particular aspect you can't build a smart app for, but we think of things like CMS funded efforts we have now to take HIE integrated data that looks like a mess sometimes. And providers have a hard time wading through and helping simplify the visualization of it. If, for example, that becomes something that requires ONC certification in order for us to be able to use it, I think, again, I would assume that's unintended stifling of innovation. I would assume that that's not the intent of any of these regulations. I don't think there's anything in it, but I just want to be careful so that doesn't happen.

Sasha TerMaat – Epic - Member

Well, Ken, I think the intent is to be a floor and not to be a ceiling. If your attempt to innovate messed with the floor, right, and meant that a patient was no longer able to get the data that they were entitled through that API because you made modifications to it in some fashion, then I think the intent of certification is that your modification would make you no longer eligible for the programs because it was no longer meeting the floor needs that are established through regulation. I don't think certification is intended to be a ceiling. That's been historically how ONC has talked about it, and so I don't think it's intended to limit the ability of anyone to innovate, whether the innovation is happening on the part of the health IT developer, the health system, or another party. As long as the floor is met, I think the intention is that all parties could innovate on top of that floor. I guess your question of intention is one of what the modification is. If your modification is interfering with the floor, I do think the intention is that this provides an assurance that the floor is available to the users of the product and to patients. But I don't think the intention is to limit anyone's ability to innovate, and I would certainly strongly support the ability of all parties to continue to build. And I would hate to see this be a ceiling.

Ken Kawamoto – University of Utah Health - Member

That makes sense. In essence, whenever we do something, we leave the existing stuff alone. We just create an addition. I think assuming things are implemented the way you are describing them, I think everything will be good.

Denise Webb – Individual - Co-Chair

Also, that addition that you're creating, Ken, would not have to come forth for certification. It's being used for a specific purpose that's an enhanced functionality, and nothing limits enhanced functionality as Sasha states. For instance, if you are using a commercial EHR

platform that is certified and you have self-developers that then do something that affects the certification ability of that platform you brought, yes, but you're jeopardizing, you're changing, the certified product that you bought with your own self-development for information blocking if the patient can no longer get the information they are supposed to get.

Ken Kawamoto – University of Utah Health - Member

I think I'm in agreement. Generally, anything we do, of course, we don't touch existing stuff. We add. So, I don't think it would come into play. But, again, just depending on how things are worded, I just want to make sure unintended consequences don't happen.

Denise Webb – Individual - Co-Chair

We are at the top of the house. How about if I take these comments of John's? Where is my note? I don't know if others are in favor of us stating that we want ONC to evaluate the appropriateness of requiring self-developers to Health IT to meet the following aspects of conditions of maintenance and then state these kind of like I'm suggesting. So, I'll put this out here, and actually, I'll add it under fill-in-the-blank. Then, if everybody could please go in and make their changes to this and what they like to see in the discussion in the next day or so, then at our next meeting we will go over this and finalize this.

Ken Kawamoto – University of Utah Health - Member

That's good. Thanks.

Denise Webb – Individual - Co-Chair

Any last comments before we end our call? I want to thank you, everybody, for the great dialogue today. It was really helpful in getting this to a place where we can come to some consensus. All right, bye. And, Raj, we'll call in for the debrief?

Raj Ratwani – MedStar Health - Co-Chair

Yes. That sounds good.