Conditions and Maintenance of Certification Requirements Task Force

Transcript
March 21, 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

Transcript

Operator
Phone lines are now bridged.

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 had a very interesting and informative discussion from the full HITAC today, so we are ready to jump back into our task force level discussions. We'll start with a brief roll call. Denise Webb?

Denise Webb – Individual – Co-Chair
Present.

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

Raj Ratwani – MedStar Health – Co-Chair
Here.

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

Carolyn Petersen – Individual – Task Force Member
Good morning.

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

Ken Kawamoto – University of Utah Health – Task Force Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Great. Sasha TerMaat?

Sasha TerMaat – Epic – Task Force Member

Present.

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

Les Lenert? Don't think we have Les yet. John Travis?

John Travis – Cerner – SME

Here.

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

Thanks. Okay, I'll turn it over to Kate Tipping for just another quick review of the charge, and then we'll get right into it.

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

Sure. Thanks, Lauren. So, the Conditions and Maintenance of Certification Task Force is charged with providing recommendations on the API, real-world testing, and attestations, conditions and maintenance of certification requirements, updates to most of the 2015 edition Health IT Certification criteria, Changes to the ONC Health IT Certification program, And de-regulatory actions related to the certification criteria and program requirements.

Denise Webb – Individual – Co-Chair

Thanks, Kate. I will go ahead and get us started on this discussion on our first topic. This is Denise. Welcome, Ken, back from vacation. Thanks for joining us. There is in the preamble, which is up on the screen, a section that discusses self-developers. ONC is asking for comment on whether these – they are proposing that these conditions and maintenance of certification requirements to apply to self-developers, and they're seeking comments on which aspect of conditions and maintenance of certification may not be applicable to self-developers. So, that's what this preamble is about. With the information blocking task force, they are addressing information blocking, assurances, and communications. They already covered this for self-developers, and they have passed this over to us and asked us to address the remaining conditions and maintenance of certification requirements, to have a discussion on whether we think any of them are not applicable to self-developers.

A good example of a self-developer is where I came from, Marshfield Clinic Health System. They have their own ambulatory HER, which they have – last I knew, was presently certified to the 2014 edition. So, it would be a situation like that. Someone who is actually developing their own self-software rather than getting it commercially.

Ken Kawamoto – University of Utah Health – Task Force Member

And these are for folks who specifically want to be certified in the system, right?

Denise Webb – Individual – Co-Chair

I believe so. Right, Kate?

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

Denise Webb – Individual – Co-Chair
They would be seeking certification, and if they were going to have certified software, they would be subject to the conditions and maintenance of certification requirements in the rule. So, we have real-world testing, attestations, API… Let's see, am I missing one? Those are the three, right?

Kate Tipping – Office of the National Coordinator for Health Information Technology – Staff Lead
Those are the three.

Leslie Lenert – Medical University of South Carolina – Task Force Member
I just think this is a heavy list to start with for self-developers. They are just building it for themselves, right?

Denise Webb – Individual – Co-Chair
Right.

Leslie Lenert – Medical University of South Carolina – Task Force Member
Extremely anti-competitive, and it seems like a really heavy lift for self-developers.

Denise Webb – Individual – Co-Chair
I don't think we're here to judge that. I think probably most of us think that, in this day and age, who would to try to do this heavy lift? But that's really not what we are here to judge.

John Travis – Cerner – SME
This is John. Just one thing, and a little bit of devil's advocacy. Because that enables them to qualify on par with anybody using commercial-certified software, for federal program participation, there is an accountability point beyond you're doing it for yourself. So, I agree, I hear that perspective, and I'm not trying to say this as a commercial software vendor in any way, but there is that accountability point, whether – I know incentives are dead, but there are penalties still in place. There's participation, and MACRA, and alternative payment models that qualify for advanced status. So, it's not without consequence that you represent yourself as meeting those program requirements. Now, does that mean anything toward some of the requirements that we will talk about? I just invite you to keep that in mind.

Leslie Lenert – Medical University of South Carolina – Task Force Member
I think perhaps we could consider limiting it to be patient-facing requirements. But as you say, if they had a module, and it was not configured for interoperability and actually implemented information blocking, and it was self-created, that doesn't sound like a good outcome.

John Travis – Cerner – SME

Yeah, that might be the assurance point to just make sure is served by this, and maybe it doesn't mean everything has to be imposed, but enough to hold a par level of accountability for interoperability and information blocking.

Denise Webb – Individual – Co-Chair

Well, that's an interesting point, because if health IT developers, including self-developers, are subject to the information blocking rule, that goes beyond just modules that are certified.

John Travis – Cerner – SME

Yeah, I think that's an important point. So, if they are a provider, they're already subject to the information blocking provisions that are appropriate for a provider. What beyond that is really necessary here? I think the capability point – so, to separate it out a little bit. Real-world testing is not strictly about information blocking. Actually, I think it's much more underscoring the legitimacy and the validity of the certified capability. That actually may be one of the more important things, ironically, to retain, if your goal here is to assure that the module lives up to claims of being certified. So, there's that policy point that real-world testing is providing evidence of the real-world interoperability capabilities. If I separate that out from the information blocking considerations, for at least the moment, necessary to say that's a policy point unto itself. And then, are the information blocking concerns served by the provider obligations if the self-developers a provider – which probably they all are, given the nature of self-development.

Leslie Lenert – Medical University of South Carolina – Task Force Member

I have a comment here about testing in the real world if you're a self-developer. Does that mean that – you built it to deploy it yourself, so if you deployed it in your working environment, is that completion of that? Again, it makes sense to say that to make the distinction of real-world testing when there's a vendor involved, but if you're a self-developer and deployer in your environment?

John Travis – Cerner – SME

Here's a comment that may make that a little bit more palatable. If I understood Steve Posnack correctly, certified vendors can propose elements of their real-world testing plans to point to leveraging participation in health information exchange that proves the same point. Maybe I misheard that, but the question was asked in Tuesday's meeting that, can you point to participation in TEFCA or in a similar kind of exchange that requires at least the same level of interoperability as the certification requirement? That may be the way that they prove that without imposing a lot of burden of doing an additional round. It would be the same feeling, frankly, that we expressed in our committee. Can we point to production experience as meeting that point of value?

Denise Webb – Individual – Co-Chair

So, John, and all of the task force members, really what we have to first agree or disagree on is starting with real-world testing. Do we believe, and I think we do, that self-developers should be subject to the requirements of real-world testing? Now, how they demonstrate that… Obviously, they might have an easier time, since most of these self-developers, as I understand, are provider organizations as well, that they are actually using their own software, and if they are part of CommonWell or Carequality, certainly they could demonstrate it through some real-world testing. I think what we have to decide on today is, do we think real-world testing conditions for certification and maintenance apply to self-developers? And I think I'm hearing so far that we agree that it does.

Leslie Lenert – Medical University of South Carolina – Task Force Member

I think we agree that if the software is deployed within the organization, it applies. I don't think that they could claim that the software was certified before they had a period of testing through deployment in their organization. But if the standard really means that they would have to go through the battery of tests that a commercial developer would go through…

John Travis – Cerner – SME

I think we need to be careful there and distinguish it, and I certainly think there's a qualification on it. Remember, real-world testing is going to focus on only the interoperability criteria, so the proof point is not internal use. The proof point is interoperability in production. I have no issue at all with ONC making clearer – because I think if you were to read the real-world testing requirements as they are, you wouldn't get that. You'd think you had to do a lot of things that I agree, are probably overkill for a self-developer. I think that they need to elaborate on how those provisions could be applied for a self-developer. If we agree with the point, again, I think there is a point of more than your own use at hand that proves accountability to meet program requirements. If the market is being held to certified products that are capable in fact as proven through production use, then that should be the bar for them, no more.

That should at least be the bar if that's the expectation for vendor-certified products. And there, I do speak a little bit of a level playing field on that point, that it isn't just for your internal use. You're actually making a claim that enables you to benefit from certain incentives and conditions and penalty avoidance under federal programs. So, there is more than your own use at hand here. It can be met simply, but I think it does need to be met.

Leslie Lenert – Medical University of South Carolina – Task Force Member

I think you'd have to dramatically reduce it. There's so much opportunity to squash innovation through this type of regulation that we have to be very careful about this.

John Travis – Cerner – SME

No, I agree, but I'll play devil's advocate. I'll say a bit of "Amen, brother" to that because it's not without consequence on the commercial side either. I'm only after a par requirement where it matters for holding accountability for participation in programs that depend on those things being true, and if we're raising the bar on commercial developers…

Denise Webb – Individual – Co-Chair

John, I don't mean to interrupt, but I have personal experience with self-development of an EHR and going through the certification process. I can tell you, a self-developer is held to the same as the commercial developers are in that testing process.

John Travis – Cerner – SME

Oh, absolutely. I don't question that. I'm simply on this for real-world testing.

Denise Webb – Individual – Co-Chair

So, what I am suggesting is I don't think we should give a pass to self-developers in any way when it comes to real-world testing. They need to meet the requirements because providers do interoperate with other provider organizations, and if they've developed their own EHR, then they need to fulfill the interoperability requirements.

Leslie Lenert – Medical University of South Carolina – Task Force Member

This is Les again. What I want to say is that the thing that is different now is that term "EHR module." So, anything that has to do with the self-developer of a complete EHR, sure. But if the interoperability is out of the scope of the module, then it's out of scope.

John Travis – Cerner – SME

I agree. I think that's accomplished through the limited criteria set that is subject to the real-world testing.

Carolyn Petersen – Individual – Task Force Member

I agree.

Sasha TerMaat – Epic – Task Force Member

Sounds like you find specific criteria for what you would have to accomplish real-world testing, and that is already specific to interoperability criteria, so if a module only did, I don't know, order entry for example, there would be no obligation to do real-world testing of interoperability of order entry. And so, I think that's already built into the way it's proposed, Les.

John Travis – Cerner – SME

Yeah. And I do think – and this is part of Les's point, I do think if you just do a straight up read of the provisions as they are, you don't get the level of flexibility that I think Steve Posnack indicated the other day. So, I think if we are agreeing with it, it's important to highlight to ONC to maybe make that path clear.

Denise Webb – Individual – Co-Chair

Why don't we touch on that when we get to our recommendations on real-world testing?

John Travis – Cerner – SME

Okay.

Leslie Lenert – Medical University of South Carolina – Task Force Member

I would encourage everyone to focus on the idea of these EHR modules. I think this is consistent with both EPIC and Cerner's trajectories as well, but I think this is where the action is going to be. It's going to be that you're adding a module that enhances care for opiate abuse. It will be within these disease-specific lanes that we see these new modules that I think self-developers will come out with, and that they'll use standards in those things, as well as commercial companies that are seeking to create really high-performance additions to EHRs. I really hope this regulation could not discourage that kind of direction.

Denise Webb – Individual – Co-Chair

I don't think it is, and I think both Cerner and Epic have experience with their app – I don't know what you call them – galleries or whatever.

John Travis – Cerner – SME

App stores, Denise.

Denise Webb – Individual – Co-Chair

The App Store concept. There's a lot of organizations that are doing self-development on top of the commercial platform. They are creating health IT modules. They are not necessarily going out and getting them certified. I think if they wanted to lend credibility to their work and have others use it, they might get it certified, but it wouldn't be subject unless it involves interoperability to these conditions.

Ken Kawamoto – University of Utah Health – Task Force Member

I can comment on that a little bit, too, because I work with the FDA's Pacer program to pre-certify some of this kind of development, as well. I brought it up in that environment as well, but I share Les's concern of – and maybe it's just a matter of commenting to say this needs to be carefully done so it does not stifle innovation, while balancing against potential risk. Depending on how you look at the way folks have been thinking about the FDA regulation and review of these areas, it could potentially include things like an individual health institution developing an ordered set or developing an alert or reminder. That it could potentially be construed to be under FDA guidance. Specifically, the proposed regs, I think, even talk about, "Hey, should we use the FDA mechanism to certify these areas?" Perhaps we don't have to get into the nuances of what exactly should be and shouldn't be in, but I think at least commenting that we need to be careful to avoid a situation where folks just feel like as a health system, this could potentially be regulated, and we shouldn't get into it at all.

John Travis – Cerner – SME

People might give up the idea.

Denise Webb – Individual – Co-Chair

All right, so do we want to just say at this point that we do agree that the real-world testing should remain a condition of certification for self-developers? We are not recommending otherwise?

Ken Kawamoto – University of Utah Health – Task Force Member

Well, I think that caveat, however, we caution against taking the slippery-slope approach of regulating more and more what individual health systems may do in this area.

John Travis – Cerner – SME

I think if real-world interoperability remains the mainstay tactic for meeting and for self-developers, that's a good way to go. And the criteria that are included in this requirement focus on what is a fair evaluation. I agree it gets to be a different matter if you're beginning to get into intra-use cases, so to speak, for the self-developer. I take that as a very good point, that you don't want to get into judging their own production experience for their own internal use, as it were.

Denise Webb – Individual – Co-Chair

But then they wouldn't bring that forward – based on my past experience in my last role, we would not even bring something like that that we would develop for our own internal use forward for certification.

John Travis – Cerner – SME

True. Well, the only thing I'd raise is if you're doing it to serve a qualification point or a requirement under program participation. Yeah, you might go to the commercial market for that, or it might play a role, but in the past at least there's been the possibility. We have clients who built their own registration module and certified the demographic to fulfill that. That would not have been particularly an interoperability point, but it would have fulfilled a program participation requirement for meaningful use. So, I think we have to be careful about saying it never could happen, but I agree with where our recommendation is.

Raj Ratwani – MedStar Health – Co-Chair

This is Raj. Can we potentially strike a balance here? It seems to me like we would need some more information or data from some of the self-developers to understand some of the challenges that they experience now and potentially what they might foresee with these new proposed rules. Denise, thanks for making some great points from your experience, and there are probably several others that have some other additional insight. Maybe the recommendation could be that we think aspects of this may apply, but that we should get some greater feedback from those individuals.

John Travis – Cerner – SME

Yeah.

Denise Webb – Individual – Co-Chair

Well, I think they all have the opportunity to submit their comments.

Raj Ratwani – MedStar Health – Co-Chair

They do, but what I am proposing is that, for this particular piece here, more might be needed than simple text comments. There might need to be a little bit of work done to actually go and talk to some of those people and understand some of their concerns more deeply that what might be submitted via comment.

Denise Webb – Individual – Co-Chair

So, what are we recommending?

Carolyn Petersen – Individual – Task Force Member

I've just been listening to all this discussion, which I really appreciate because while I've heard in passing of many of the problems that Mayo had with its own EHR before it went with Epic, the nuts and bolts of all of this are not clear in my head always. The one thing that occurs to me is not everybody who wants to self-develop is necessarily going to be building the full-on sort of thing that's useful for a large multi-specialty kind of practice, or medium-size outpatient family practice clinic. It occurs to me that what you might see is that groups that do very specialized things, like

perhaps substance abuse treatment, or something other that's very specific, might be the groups that are interested in self-developing.

While I think that absolutely, all the patient-facing stuff has to be there, and you have to be able to do interoperability and all the rest of it, I am concerned that we don't do something that prevents people that have special and very specific needs that aren't well served by a large commercial product, that they're prevented from doing that, as long as they can be interoperable. That would be the one concern that I have.

Leslie Lenert – Medical University of South Carolina – Task Force Member

Just to clarify, this is Les. I really agree with that comment. I think that was the gist of what I was saying as well. The question is, when does the certification criteria become an undue barrier for this kind of innovation? Particularly when we think of this as an EHR module that works alongside a certified EHR. You wouldn't want to knock the organization out because they've innovated in one module that does something better than they can do anywhere else. So, how do we streamline that process so that we don't stifle innovation as people roll out modules that do these special tasks that are really too small for EHR or MACRA developers to build their own modules for, where it may precede their development of an EHR module?

Sasha TerMaat – Epic – Task Force Member

This is Sasha. Just to maybe chime in on some background on how certification works and how this criterion would be applied, there is a fair amount of flexibility to picking the particular certification criteria that would be applicable to a module. Which might have a very specialized setting, it might have a very narrow scope where it works in conjunction with other products to serve the full needs of a clinic or hospital. I think that is accommodated by the current structure, and I think that continues to be accommodated by what's proposed for real-world testing, with the sense that there's a narrow scope of criteria where real-world testing has been determined to be important. I think we would agree, as everyone has said, the products do have to be interoperable.

So, if one of these products, whether it is meant for a specialized setting or for a narrow scope of use, if it is going to be used for something related to interoperability, like exchange of information using FHIR, then it should be tested in the real world at the same level that a commercial product user exchange using FHIR would be. So, I think what the concerns I'm hearing the group articulate are actually accommodated by the proposal that Denise mentioned earlier. I'm wondering, just given time constraints, if we want to continue through the other requirements so that we don't end up losing too much opportunity to do that.

John Travis – Cerner – SME

I agree with you, Sasha. I think that is a good balance, knowing what is in the requirement in the program and how it would apply. I am fine to move on.

Denise Webb – Individual – Co-Chair

So, do we want to move on? The next one is attestations and then the APIs.

John Travis – Cerner – SME

Sure.

Denise Webb – Individual – Co-Chair

I mean, attestations are pretty straightforward. I think they need to attest that they meet the requirements of certification.

John Travis – Cerner – SME

In the same spirit of what Sasha just said, it's a par-level requirement of seeking to be certified.

Denise Webb – Individual – Co-Chair

Right, and that assumes that they would attest to the conditions of certification and maintenance, assuming all applied to them in the final rule.

John Travis – Cerner – SME

Yeah. Which, by the way, to the extent that they do, I think is already a requirement. Otherwise, you would probably be violating your certification agreement with your certifying body.

Denise Webb – Individual – Co-Chair

Right. Okay. And then APIs -- I don't know if there's going to need to be much discussion on that. I guess they apply.

John Travis – Cerner – SME

Yeah, they apply for the functional and technical capability.

Denise Webb – Individual – Co-Chair

Any thoughts on that from the group? Or concerns that it would not apply?

Sasha TerMaat – Epic – Task Force Member

Would all of the provisions apply? Would they be expected to perform registration and list endpoints? I would propose yes because if registration practices and listing endpoints are how the interoperability is planned to sort of know what apps are available and what endpoints are available, I think self-developers would have to do it also. But I guess I am just raising the question.

John Travis – Cerner – SME

I agree, Sasha. I don't think there is anything about self-development that says you're not otherwise exposed to the same kinds of needs that commercial APIs would, or that app developers wouldn't seek to work with you in the same way they work with commercial APIs.

Leslie Lenert – Medical University of South Carolina – Task Force Member

I'm very concerned about this trajectory. It sounds like any attempt at innovation that doesn't get certified where they have an app would knock the organization out of… Only in that area that if the program was using a certified app? I mean, it seems like it's fairly easy to break your certification process if you are an institution that is an app developer. And then you would be knocked out of the financial incentives and program participation that would come along with that.

Sasha TerMaat – Epic – Task Force Member

Les, I think there is a concerning direction the alternate way, too, right? I mean, I think yes, certification requirements are rigorous, and if anyone is pursuing certification, they have to be prepared for that level of rigor in participation. But, if we said self-developers and other apps don't have to meet those criteria, then we could end up with self-developers where there is no opportunity to use an app with their system because there's no method for registration. There's no availability of endpoints. The patients wouldn't be able to take an app of their choosing and connect it to that health system if those features aren't available. So, I think to some extent, the rigor is significant for self-developers or for any developer, that that's something we're agreeing is important as a matter of public good.

Leslie Lenert – Medical University of South Carolina – Task Force Member

It's also an entry to a barrier.

John Travis – Cerner – SME

Yeah, I think what Sasha and I both feel in response where we're – I can't say empathetic, we're not self-developers, but we are developers. But we would agree there is a lot of – burden's a funny term, I don't use it in a negative context here, and that's kind of hard to say, but there is a lot to doing this that, putting aside vendor versus private development if you will, there is a par that the program expects that is the public good that Sasha speaks of, and it can be focused on the things that are important to the public. I don't want to rehash the world real-world testing, but it's the notion that there is a fair bar –

Sasha TerMaat – Epic – Task Force Member

Hello? Hello? Did John get cut off?

Leslie Lenert – Medical University of South Carolina – Task Force Member

I think he did.

Sasha TerMaat – Epic – Task Force Member

Sounds like it.

Denise Webb – Individual – Co-Chair

He's going to have to dial back in.

Leslie Lenert – Medical University of South Carolina – Task Force Member

I think that this is a very challenging area because the public good is also – it's essential to preserve the ability to innovate at the point of care, for the public good.

Denise Webb – Individual – Co-Chair

Well, I think a number of health systems or provider organizations have gone from their homegrown systems to commercial vendor platforms and have still retained the ability to be innovative and develop in conjunction with having that commercial product. And, to your point earlier, Les, about the heavy lift? If you look at why a number of health systems finally decided to abandon – and

maybe Carolyn can comment on this, if she has any knowledge on Mayo – to abandon continuing to develop and keep their own EHR up to date, when a lot of these organizations created their software, there was not the regulatory landscape that there is today. And it's a huge lift to stay on top of this. Based on my research, I know Cerner and Epic invest $500-$700 million in R&D a year, and there is a lot of people invested in working at the regulatory aspect and what it will take to ensure the products that they deliver are safe for the patients and meet all of the federal and state requirements from a regulatory standpoint. I don't disagree with you on your earlier comment, but again, we are not here to judge if people should self-develop or not. That's their organization's personal decision.

Leslie Lenert – Medical University of South Carolina – Task Force Member

The regulations shouldn't prevent this idea of an ecosystem preliminary to commercializing the module, develop a module, and use it within the organization without the organization losing its ability to claim that it is using certified software. And what you described is exactly the point that I make about this, is that the regulatory burden is so heavy, that all of the academic developers of EHRs have dropped out, and the only innovation right now is in the commercial side of the market. I think we could be in a golden age where there is a lot of innovation going on within EHR modules if we don't have an overly burdensome regulatory environment.

Sasha TerMaat – Epic – Task Force Member

Les, I don't think that the self-development accommodations are going to change the concern you are expressing one way or another. Fundamentally, I think that there has to be a debate at a higher level to say is the regulatory burdens on health systems and health IT appropriate? Because if it is slowing the pace of development too much and placing too many restrictions on new entrants to market, I think we address that concern in a different way. The self-development provisions here, to me, seem tangential from the concern you're expressing, which I see as a much higher-level picture concern.

Leslie Lenert – Medical University of South Carolina – Task Force Member xyz

I don't see it as tangential at all, given the history of EHR development. Most of the innovations that came to the commercial space came from the academic environment by self-developers of EHRs. So, Warner Slack, the folks at Intermountain, Reamstreak. Those areas are where the infrastructure for modern EHRs was invented back in the '70s and '80s. As we move forward, this regulatory environment has essentially limited the ability for academic institutions to participate in the development of EHRs as brand tools, as these comprehensive tools. As we move on to an era where interoperability allows EHR modules to be brought into play in conjunction with certified EHRs, you don't want to penalize innovators who build their own modules that happen to work well with their overall certified system. I don't think anybody's going to walk away from certified systems in the future, but I think this has to serve the notion that EHR modules that are much more flexible and focus on in-depth care of one class of patients.

Sasha TerMaat – Epic – Task Force Member

Yeah, but I think the question is whether that needs certification, right? If someone is bringing out a new module that they're going to use for something related to opioids, for example, they can still start to use that, and try it, and it might not come into the scope of what's necessary from a certified health IT product. If it does come into the scope to do things that certified health IT does, then it

seems that we should hold that new module, no matter how new, to the same standard as any product that wants to do the functions of a certified health IT product.

Leslie Lenert – Medical University of South Carolina – Task Force Member

The main thing I would say is that if the healthcare institution develops a module for its own use and applies it, it cannot lose its overall certification status because it's developing a module for its own use. And if you make it go through a full certification as if it was marketing it externally and it's simply within its own use, you're going to stifle innovation.

John Travis – Cerner – SME

Well, unfortunately, we are already there, because you are. Forget this rule, that's the way the current certification program functions. I have not heard of anything that provides a tiered level of certification relative to the certification requirements themselves for a self-developed module compared to commercial one. I think we need to retain sight of that. If a different program needs to evolve, that's a whole different question, a higher-level one, but insofar as the same requirements are held to a certified module, I respect the point about self-development. But self-development doesn't mean internal use. Why these things exist are to hold a public accountability on both preserving the institution's ability, who is a self-developer, to participate in the federal program so there is a public point of accountability to avoid penalties, earn incentives, have particular status and benefits from use of certified EHR technology to go with it, and being a reliable point of interoperability in fact. So, I think that's all Sasha and I are saying, is that the same par needs to operate for both flavors of product. I appreciate the self-developer innovation needs to be able to be supported and promoted. So does the commercial developer. But it's a par that, as long as the program's constructed as it is, it's a par that should exist for both flavors.

Leslie Lenert – Medical University of South Carolina – Task Force Member

Well, I think we can agree to disagree on it, John. I represent the academic contingent of this group, and you represent the commercial, and we're always going to have a difference of opinion on that.

John Travis – Cerner – SME

Absolutely. I have no issue with that being conveyed. I think the thing I do want to express agreement and appreciation for is I don't think Sasha or I would seek to have things stifled, and especially not overextend provisions for things that are truly self- developed for the institutions' own use, but there is a place in there where it isn't just for your own use if it's for the purpose of interoperability and potentially engaging with external parties in the manner that a commercial vendor might. Setting aside whether or not you intend to offer it for sale, it's a point of dependency that connects in the ecosystem that has to perform in ways that hold up and are of similar rigor to what a commercial product would on the same point.

Carolyn Petersen – Individual – Task Force Member

If I could go ahead and interject one quick comment, I think you are both making important points that have merit. To clarify what I was talking about when I spoke earlier, I am thinking about the fact that in 10 and 15 and 20 and 30 years, it's not just health organizations and systems that have to evolve, it's communities. It may very well be that in a community, a non-profit consortium comes together to help manage the care and the well-being of elders in their homes. Because frankly, we are coming up on a large population of people who cannot afford assisted living, and senior

complexes, and all of those. And I can absolutely see where this sort of consortium would bring in technical assistance to build a product that overseeing providers like a couple of docs with a couple of nurse practitioners or PAs working together as a community resource manage what's going on with seniors in their homes through the use of sensors and PGHD and other things. Folks that are coming together with absolutely no interest in the EHR market, in developing a commercial product, in trying to compete with anyone, and wanting to do anything more than coming up with the module and the tools needed to make a module or to manage the care and health of a particular population locally in the community. And maybe at some point, some other group in another part of the country might say "Hey, that looks really cool what you're doing, can you help us set up something similar?" I would hate for that type of innovation to be stifled because this group now has to meet a whole set of standards that are designed to support a much larger product being sold on a commercial basis. Competition for existing vendors, I get that. When we talk innovation, we're not talking about another EHR by another company. We are talking about people who start with a problem and try to figure out how to deal with that specific problem on a much smaller scale. And that is what my concerns are when we say, "Has to be subject to everything else from the very large organization."

John Travis – Cerner – SME

I think if I can recommend to the co-chairs, that an important lesson here – I think we can agree to disagree. I certainly respect that, and I think we can make the recommendations to the extent that there is a fair par that doesn't stifle innovation, there are certain of these requirements that apply. I think what we're running into is an important point for ONC to take measure of on a more comprehensive level, and it maybe isn't cured in this rule, but this rule was designed to, let's be honest, very significantly regulate against bad behavior on the part of commercial vendors. It's an elephant in the room and I'm going to name it. I understand that there is a potential for great unintended consequence for self-developers if you literally applied it the same way. There are certainly parts of it that are aimed at providers. What ONC has not done, to me, is address a provider organization that plays both self-developer role and provider role that have different consequences under this regulation. And yet, here they may face both, and I appreciate that a self-developer probably doesn't desire to get into this for the sake of becoming as significantly regulated as they might under this rule. I think part of our point ought to be that ONC's got to go take a big step back and look at how this rule applies to self-developers if there is any different statement that they want to make. We could probably go on for a long time in this park of conversation about how these things apply. But I do believe there is a strong current in this regulation that was aimed at commercial vendors, but it nets in self-developers, and as long as it's written that way, that's a tension point that ONC is going to have to come to and figure out if there's a different applicability that we probably cannot do a lot about in our discussions.

Denise Webb – Individual – Co-Chair

Thank you, John, for that summary.

Leslie Lenert – Medical University of South Carolina – Task Force Member

I think that I'm probably suggesting a world where innovative EHR modules are used alongside certified products. I think that is probably the distinction here, that if it was intended as a replacement for an entire certified product, like an EHR program. But if it's a module that works alongside... This is where the future is going, I feel. This is where we really need to preserve innovation. If there was a way not to have organizations lose their status as complying with certification when they innovate in this module used alongside a certified

John Travis – Cerner – SME

I think that's an important point to register because it raises a different set of questions, and potentially a different standing. I am not trying to solve the problem that I think ONC's created, and their proposal has uncovered this. As long as the certification program was substantially focused on capabilities that were used in clinical workflow and were kind of intra-use, these things did surface. Not for interoperability concerns, but now that much of the aim of the program is towards interoperability, these questions arise.

Denise Webb – Individual – Co-Chair

Maybe we could make a recommendation that we agree that the conditions of certification and maintenance apply to all developers of certified HIT, whether it be commercial or self-development. However. And then, on the, however, we could specify some of these points.

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

Sorry to bridge the conversation here. We should probably take a quick break for public comment. And then I think we can just confirm that last, what sounds like we're proposing, recommendation. Operator, can you please open the public line?

Operator

Yes, thank you. 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 2 if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

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

Thanks. Okay. We've pulled up the number here for a few minutes, so hopefully, we have some public comments. Do we have any comments in the queue at this time?

Operator

Not this time.

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

Okay. Seeing that we don't have any comments, I think it's important that we kind of wrap up on this last point here. I will hand it back to you, Denise and Raj, and then we can wrap up.

Denise Webb – Individual – Co-Chair

Yeah, and I think we will have to take our second agenda item and push it forward to the next meeting to go over the recommendations. I didn't realize this was going to get into such a lengthy discussion. It was a good discussion. Do we want to propose any particular language related to the concerns that surfaced today?

John Travis – Cerner – SME

If I could suggest, I like the last statement that was made that we believe that there is, I don't know whether to say general or particular, but there is an applicability of the conditions of certification to all developers. I have a chest cold. I'm sorry. And enumerate, I think that we covered a couple of points here, that in particular, there should be – and I'll offer them, and we can have an agreement to disagree – that there's a par-level for real-world testing when it comes to interoperability criteria. ONC should probably reinforce the ability to point to production use and participation and health information exchange, like what Steve Posnack said the other day about TEFCA potentially being a proof point that a developer could point to under a real-world testing plan. That there is a need to look to maintain or provide for moderation of burden to a self-developer when applying the conditions of certification to them. I think it is fair to make a point that ONC needs to really evaluate the application of conditions of certification to self-developed products that are predominantly in the provider's own interest for their own use. And provide compliance path or set of guidance for them. I think, looking at them as they are, self-developers are going to be very challenged to understand how this isn't a very burdensome exercise. I certainly appreciate that. And that probably speaks to a need not to just leave it to the imagination, but to provide a clearer path of how they may comply. I will stop there.

Denise Webb – Individual – Co-Chair

Raj? I know you've been listening, I don't know if you would summarize this a way that could be succinct in our recommendation?

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

And just for logistical assistance, I was taking notes in the document I mentioned in the chat. I tried to capture what John said, and some of the other discussion points and proposals in the notes at the bottom of the document. So, if we want to use that to try to further refine the language, I do have a starting point captured there.

Denise Webb – Individual – Co-Chair

I would ask Les and Ken and Carolyn to take a close look at that to make sure that the notes reflect the points that they made.

Carolyn Petersen – Individual – Task Force Member

Can you re-send that out?

Denise Webb – Individual – Co-Chair

And then, if you all can add anything that you feel is missing that we would need to use to draft the final recommendation, I would certainly appreciate that. We all need to look at it and reflect.

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

I think I shared my screen so you could see where Sasha laid out the draft proposal, but I'll resend the link to this document as well.

Carolyn Petersen – Individual – Task Force Member

Thank you.

Denise Webb – Individual – Co-Chair

One thing I would clarify here on point three is self-developed health IT products seeking certification. I think they are referring to all modules now, Les, as HIT modules, not necessarily EHR modules. Some are EHR modules, some are just generally health IT modules that interact with the EHR.

Leslie Lenert – Medical University of South Carolina – Task Force Member

I might modify number three to say, "Seeking maintenance of certification of their environment with the addition of self-developed products. So, it's not the products that are seeking certification, we are saying, MSC builds a new EHR module, we don't want to lose our certification because we are use using that new module we developed.

Denise Webb – Individual – Co-Chair

Well, that's not how the program necessarily works. At Marshfield, we created plenty of modules that never went through certification that interact with the certified software. It is a function of the certified software that you cannot affect that has been certified.

John Travis – Cerner – SME

Yeah, exactly.

Denise Webb – Individual – Co-Chair

So, I am speaking from a self-developer perspective, and Sasha and John have the experience of commercial development and going through the certification process. There is nothing limiting self-developers, or nothing ever limited to us from deploying – we deployed a thing that was related to imaging that interacted with the EHR, and it affected the EHR certification in no fashion. But, if it breaks one of the functions that was certified in the EHR, then that is an issue.

Leslie Lenert – Medical University of South Carolina – Task Force Member

Okay. Maybe we'll work – maybe we'll distribute this language, and we'll all type in a variance of it, and we can try that.

Denise Webb – Individual – Co-Chair

That'd be great. The more eyes on this in the input, then the better job we'll do on crafting this. Okay, so Kate, you'll send out that link to everybody?

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

Yep.

Denise Webb – Individual – Co-Chair

Great, thank you. I was going to say, when is our next meeting?

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

Our next meeting is not until next Wednesday, I believe. At 4:00 p.m.? Sorry, wrong one. The next ones say next Thursday at 12:00 p.m., and next Friday at 4:00 p.m.

Denise Webb – Individual – Co-Chair

Okay, so we have two meetings next week. So, hopefully, we'll have the transcript and are able to look at the discussion that was had at HITAC on our recommendations so that we can step through those and refine them, as well as the one we were working on today.

Raj Ratwani – MedStar Health – Co-Chair

Yeah, and Denise, Sasha sent out some great notes on that one as well. Sasha, thank you for taking such great notes and sharing it.

Sasha TerMaat – Epic – Task Force Member

Oh, you're welcome.

Carolyn Petersen – Individual – Task Force Member

Yes, I second that.

Denise Webb – Individual – Co-Chair

Yes, thank you very much, Sasha.

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

Okay. Well, thanks, everyone. I think we'll adjourn for today. I think you've got our homework assignment for our next meeting, and I think Denise and Raj, we'll follow up offline right after this.

Denise Webb – Individual – Co-Chair

Okay, sounds good.

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

Okay, thank you. Bye-bye.

[End of Audio]

Duration: 58 minutes