Conditions and Maintenance of Certification Requirements (CMC) Task Force

Transcript
March 5, 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
Christopher Monk	Office of the National Coordinator	Back Up/ Support
Kate Tipping	Office of the National Coordinator	Staff Lead

Operator
Thank you. All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Good afternoon, everyone. And welcome to the HITAC Conditions and Maintenance of Certification Requirements Task Force. I know that's a long title. This is our official kick off meeting. As you all are probably aware, the HITAC was charged with providing recommendations to ONC's proposed rule of 21st Century Cures Act. And as such, we broke the committee up into four smaller task forces. And so, this is the third, I believe, kick off meeting of the task force. So, with that, we only have an hour today. I will go ahead and call the meeting to order starting with 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 - Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Ken I believe is absent. Sasha TerMaat. Maybe not yet. Les Lenert. And John Travis.

John Travis - Cerner - SME
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
All right. With that, I will hand it over to our co-chairs, Denise and Raj, for welcome and introductions. And then, we'll dive into the charge and work plan.

Denise Webb - Individual - Co-Chair

I'll start. This is Denise Webb. And I am going to be working with Raj and we're going to be sharing duties on in terms of covering the different topics that this task force is going to be charged with covering. And I most recently was with the Marshfield Clinic Health System and now am working independently.

Raj Ratwani - MedStar Health - Co-Chair

Great. Thank you, Denise. I'm Raj Ratwani. I serve as the director of Metzger Health National Center for Human Factors in Healthcare and also an associate professor of emergency medicine at the Georgetown University School of Medicine and I'm really looking forward to working with this group to tackle some of these issues here. And I think since we have time, we'll through and do intros for everybody else. Is that right?

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

Yeah, that's fine.

Raj Ratwani - MedStar Health - Co-Chair

Okay. We can just go down the list here. So, Carolyn?

Carolyn Petersen - Individual - Member

Yes, thanks. This is Carolyn Petersen. I am a co-chair of the full HITAC. I work in my day job as a senior editor at Mayo Clinic but I participate in the HITAC as an individual representing the patient and consumer perspective. And the views expressed are my personal views and do not reflect the policy or position of Mayo Clinic.

Raj Ratwani - MedStar Health - Co-Chair

Great. I know Ken is out for the next couple of weeks and will get caught up later on. And I think Sasha is working to get on. So, are we over to John?

John Travis - Cerner - SME

Raj, do you think that's me or John Kansky? I didn't catch if he was on. I'm sorry.

Raj Ratwani - MedStar Health - Co-Chair

Yeah. I don't think John Kansky is on.

John Travis - Cerner - SME

Okay. John Travis. I'm with Cerner. I'm vice president over our regulatory research and strategy group. We also own all of the EHR certification activity for Cerner. And I've been involved in a number of prior task forces and work groups under the former regime of the Federal Advisory Committees that were under our HITAC. Also, it's a pleasure to be involved in one under the Cures Act.

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

Thanks. And Raj, this is Lauren. Just make a notation that John Kansky who was still on the roster here will not be on this task force. I think we may have just missed this edit but we'll correct that moving forward.

Raj Ratwani - MedStar Health - Co-Chair

Okay. Great. Thank you so much. Okay. So, we can –

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

Just really quickly, did Sasha dial in yet? Okay. You can proceed.

Raj Ratwani - MedStar Health - Co-Chair

Great. And we have lots of wonderful support here, which is great because we're going to need it. It's a pretty rapid timeline. So, if we can jump to the next slide here, we should have the ONC's support introduced as well. Lauren, do you want to start?

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

Sure. So, I'm Lauren Richie, the designated federal office for the full ONC also supporting all of our public task force meetings.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology - HITAC Back Up/ Support

Hello. I'm Cassandra Hadley. I'm Lauren's backup for the HITAC and the task forces.

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

And I'm Kate Tipping. I am a branch chief in the regulatory affairs division at ONC. Mike Lipinski is the director of the regulatory affairs division. And he won't be on every call but he'll dial in as needed.

Chris Monk – Office of the National Coordinator for Health Information Technology - Back Up/ Support

And I'm Chris Monk. I work in our certification program primarily for **[inaudible] [00:05:35]**.

Raj Ratwani - MedStar Health - Co-Chair

All right. Thank you. I think with the pace of things, we're going to be needing a lot of help from this team here. So, we appreciate the support you've already provided and the forthcoming support that will be much needed. I think we should jump in to start talking about the charge of this task force. And both Denise and I have been working to wrap our heads around a lot of this content. And Kate is the true expert here. So, Kate, I'm going to turn it over to you to help us kind of describe this. I could certainly read the slide but I think

you probably have a more articulate way of describing things here.

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

Sure. So, in the proposed rule, we have a number of conditions and maintenance of certification requirements. This task force, part of the charge is to focus on the application programming interface, condition, real world testing, and the attestations. We'll also be charged looking at the updates to the 2015 edition certification criteria, any modifications to the ONC health IT certification program, and deregulatory actions. And then, specifically, as you see on the slide, as I mentioned, we'll be looking at those three conditions and maintenance and certification requirements, the API, the real world testing, and the attestations. For the updates to the 2015 edition criteria, we'll mainly focus on the standardized API for patient and population services, the electronic health information export, E-prescribing, clinical quality measures export.

And then, there are two privacy and security related attestation criteria, which are titled the encrypt authentication credentials and multifactor authentication. And then, we'll also be looking at modifications to the program. Mainly, this is the principles of proper conduct section. And then, any deregulatory actions related to the certification criteria and the program requirements. So, we have a ton of work ahead of us related to our charge.

Raj Ratwani - MedStar Health - Co-Chair

Thank you, Kate.

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

Sure.

Raj Ratwani - MedStar Health - Co-Chair

Go ahead.

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

I was just going to say do we want to go ahead and look at the timeline and then, where we kind of set out the schedule of the topics?

Raj Ratwani - MedStar Health - Co-Chair

Yeah. Absolutely. And I think if you don't mind walking us through this timeline as well, I think that would be great. And then, we can talk about the next set of meetings we have this week with a pretty intense week and then, talk about what's going to be coming the following week as well.

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

Sure. So, this week, we're in, according to this draft work plan timeline, date wise we're in

Week 3. We scheduled our kickoff meeting last week. We're holding the kickoff meeting today. And then, we have a number of other meetings scheduled for this week. Week 4, we'll schedule some other meetings that we need. We'll finalize the draft recommendations for the HITAC review. And then, the week of March 18 to March 22, on March 19, we'll be presenting the draft recommendations to the full HITAC. And then, Weeks 6 and 7, we'll update and revise the recommendations. Week 8, present the progress on the draft recommendations to the HITAC. Week 9, revise and update recommendations. And then, Week 10, which is April 22 to 26, the task force will present recommendations to the HITAC if we don't finalize that sooner.

And then, Week 11, the week of April 29, the final transmittal letter from the HITAC. And then, May 3, which is when the public comment period closes, the HITAC recommendations are submitted to the national coordinator. And the next slide here is basically the schedule of topics that we've identified. Raj, did you want me to walk through those?

Raj Ratwani - MedStar Health - Co-Chair

I'm happy to walk through this and then, maybe you can kind of chime in if I'm not getting things right here. So, today is the big kickoff. We had an external kickoff. And what we thought is we have a meeting scheduled I believe tomorrow afternoon Eastern time. And in that meeting, we would go through and segment this by talking about the real world testing and attestation components of the conditions and maintenance for certification. And on Thursday, I need to pull up the calendar and make sure I'm getting this all right, Thursday morning we have a two hour meeting planned. And during that two hour meeting, we thought it would be good to go through the APIs given that that's really the bulk of this and we anticipate a lot of discussion and comment on that.

And Denise and I are going to sort of tag team who is running these. And so, I'll run tomorrow's and Denise will take Thursday and Friday. So, Friday will be the third meeting that's up here on the schedule. And that will be talking about the updates to the 2013 certification criteria, which will include the EHIX for electronic prescribing, the CQMs, and then some of the privacy and security attestation criteria. So, that will take us through this week. It's an intense week with roughly another four hours of actual meeting time, I believe, scheduled out. And then, going into the following week that leaves us two other big kind of meetings to walk through a lot of the content here. So, I'm looking at Week 4, March 11 through 15 that the first meeting we will talk about some of the corrections and then, the principles of proper conduct, I think it is.

And then, the second meeting we'll bet getting through all of the deregulatory actions. So, this is a bit out of order from the way things appear in the proposed rule but I think this structure seems to make sense for us given the time that we have this week and next week.

Denise Webb - Individual - Co-Chair

This is Denise. I'll just add that we structured it this way because we thought in terms of priority that the conditions and maintenance of certification topics were pretty important to give a sufficient amount of time to first.

Raj Ratwani - MedStar Health - Co-Chair

Good point, Denise. Kate, anything else to add here or any clarifications?

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

No, not on my end.

Raj Ratwani - MedStar Health - Co-Chair

Okay. So, that takes us to, I think, time to discuss here internally about the overall timeline, these particular topics, to hear from other committee members. Any questions, folks?

Denise Webb - Individual - Co-Chair

I assume everybody has gotten the appointments on their calendars. Sasha and I were together in the work group this morning for one of the other task forces. And the template that we were provided was really helpful. So, hopefully, we can get a similar template with the help of ONC and ourselves out to the task force members. It will help you get through the rule text and then, the actual supporting information that's in the overall rule.

Sasha TerMaat - Epic - Member

That was one of my questions. First of all, am I connected now? This is Sasha.

Raj Ratwani - MedStar Health - Co-Chair

Yes.

Sasha TerMaat - Epic - Member

Okay, good. So, I was going to ask if we would have a template. And then, I know one of the calls this week, for example, I don't know that I'll be able to be there. But I was hoping to provide some written comments and I didn't know what the best way to do that was. Should I send it to Denise and Raj ahead? Should I put it into the template?

Denise Webb - Individual - Co-Chair

So, Lauren or Kate, do you want to comment on how we should do that?

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

This is Lauren. I think you're certainly welcome to send your comments to either Kate or the chairs. But just another tool that we've used with other task forces, we can also set up like a Google Doc where everyone can have access to the document and can see other comments from the other task force members. But I'd defer to Kate on how she'd like to process those comments.

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

Yeah. I think a Google Doc would work. And I've pulled together the – Mark had shared with

me what he had used for the info blocking work groups. So, I've pulled together, at least I started pulling the real world testing and attestations, into that template so I can share that.

Denise Webb - Individual - Co-Chair
Does that work for you, Sasha?

Sasha TerMaat - Epic - Member
Yes, that's great. Thanks.

Denise Webb - Individual - Co-Chair
Okay. Good.

Raj Ratwani - MedStar Health - Co-Chair
Great. Any other questions or thoughts on the plan we have here? All right. Well, with that, I think we can move on.

Kate Tipping – Office of the National Coordinator for Health Information Technology - Staff Lead
What does moving on look like? Are we going to dive right into real world testing?

Raj Ratwani - MedStar Health - Co-Chair
Yeah, I think we should. Does that work for everybody, start getting into some of that content?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yeah. You've got plenty of time. We've got at least another 30 minutes before public comment.

Raj Ratwani - MedStar Health - Co-Chair
Okay. Great. Let's do that.

John Travis - Cerner - SME
Is there a protocol of sorts for – they've always made use of raised hand feature and things like that just to ask so we don't speak over each other.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
This is Lauren. Generally, if you're on the Adobe, we do try to use the hand raising function. But I know sometimes members are just on the phone only. So, if you're just only on the phone, feel free to **[audio interference]**. But, generally, the hand raising has been –

John Travis - Cerner - SME

Okay.

Denise Webb - Individual - Co-Chair
So, Kate, do you have your template available?

Kate Tipping – Office of the National Coordinator for Health Information Technology - Staff Lead
I do but I have the federal register page numbers. I'm just trying to gather the page of the real world testing.

Sasha TerMaat - Epic - Member
In the old version, it's 276.

Denise Webb - Individual - Co-Chair
Yeah.

Raj Ratwani - MedStar Health - Co-Chair
Oh, thank you.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Kate, are you planning to screen share or are you just sending the page numbers as a reference?

Kate Tipping – Office of the National Coordinator for Health Information Technology - Staff Lead
So, I pulled the information that we have from the public comment template kind of how Mark had. So, I was just going to put in the page numbers. I don't know. What would you suggest? I can send it to the group to be put up on the screen. Would that make sense?

Raj Ratwani - MedStar Health - Co-Chair
Yeah, I think so. Why don't we do that?

Kate Tipping – Office of the National Coordinator for Health Information Technology - Staff Lead
Okay. Let me just –

Sasha TerMaat - Epic - Member
So, we're going to get something over email, is that it?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
I think we're trying to get the specific page numbers and references pulled up on the screen

here. And, Katie, does Kate have the ability to share her screen briefly as a presenter?

Accel Solutions

Yes. There's a share my screen pod to the right that she can share. Or if she sends it to me, I can share it as well.

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

Okay. Let me just send it to you, Katie. I'm going to go ahead and just send it and I'll upload the page numbers as we speak. So, let me get this over to you.

Sasha TerMaat - Epic - Member

Could I suggest maybe some topics for our conversation while we're getting this pulled up?

Raj Ratwani - MedStar Health - Co-Chair

Yes, please, Sasha.

Denise Webb - Individual - Co-Chair

Absolutely.

Sasha TerMaat - Epic - Member

So, one of the initial parts of the proposal about real world testing is that ONC says successful real world testing shows three things. And they are, I guess, paraphrased, 1) continued compliance with certification including standards and code sets, 2) exchange in intended use setting, and then 3) receipt and use of electronic health information in the certified EHR. And so, I think that as we think through the real world testing, thinking about those three success criteria makes sense. One thing that popped into my mind about the third one, receipt and use in the electronic health information in the certified EHR is that not all of the criteria that are proposed to be real world tested actually involve bidirectional exchange.

And so, if the criterion is sending information to a Syndrome X surveillance registry, it wouldn't really be able to have use of the electronic health information in the certified EHR real world test of that because it's an outgoing export only. And so, I think there might need to be some adjustment to the success criteria or the criteria that are expected to be tested to make sure that those sort of overall are in alignment as we're thinking about what's expected.

John Travis - Cerner - SME

Yeah, Sasha, this is John. I agree. We noted that as well. And I might extend that to say as there is guidance developed on the development of test cases, I know there's a lot of latitude given to the vendor to probably design those things for themselves certainly ingesting the whole spirit and letter of the certification criteria. But is part of the test case designed to deal both with capture the USCDI required data classes as well as incorporation. So, kind of the frontiers of what the test case boundaries are, I think, would be very useful to have more specificity around it.

Sasha TerMaat - Epic - Member

I agree, John. And I think it kind of ties into something that's maybe not about a particular regulatory text but as an overall expectation making sure that everyone is on the same page about sort of the expected scope of testing. I tried to use ONC's estimates of time spent to get a scope. And if you assumed that you were going to test in 10 settings, which they say test in a representative sampling of settings for your user base. So, I said pick 10. I don't know if that's representative or not. It's probably various biproducts. But if you were testing in 10 settings then, with the amount of effort that ONC says it would take to perform the tests, it seems like you would be spending less than an hour testing each criterion as I'm doing that.

And so, then it's hard for me to imagine what is encompassed if you spend 45 minutes testing a particular criterion? Is it envisioned that there's a lot of data entry and then, only a limited amount of exchange? Is it primarily spent doing exchange? Am I totally misconceiving, I guess, how this would work? But I just wanted to sort of make sure that all of us had a similar sort of expectation set of what was envisioned so that we could comment on it in that light.

John Travis - Cerner - SME

Yeah. And let me offer a friendly amendment to that that is a big variable to it that I don't think there's a really effective answer in the proposed rule for and that is the whole definition of I believe the term is used care and practice setting. So, what in the world is that? So, for example, under the old regime of the 2014 and 2011 editions, we had ambulatory and hospital, which probably is not what they mean. But nor is if you go and ingest something like the provider taxonomy and go pick off some credible level of specialty. You could wind up with a pretty good multiplier effected venue depending on how you define it. And I think that needs to be a normalized concept that we all apply consistently. So, the level of effort is pretty par level. We're all, as you say, defining test cases at about the same level. And I think that's going to be a real key area definition that I just don't get a lot of satisfaction around from what's in the proposed language.

Raj Ratwani - MedStar Health - Co-Chair

This is Raj. I think those are really good points that we should make sure we're capturing and then, continue the conversation on. I think that it's a really big challenge of trying to bring more clarity to what some of these cases would look like and then, Sasha, to your point the time requirements here. And I think one concern I would have would be the level of rigor of those cases if they're not some example cases or guidelines put around as to what those should look like within key criteria that should be embedded in each of those cases. And I certainly think that we don't want to be too rigid here. I think it's really important for vendors and others to be able to shape those cases to best fit their product. But we certainly want some base level of rigor to ensure that there's actually kind of teeth and meat behind these.

John Travis - Cerner - SME

I think, too, to make sure, and this is John, again, that the test cases are defined in the level

of effort is good that probably one of the things that we should look into or ask ONC to look into are they do some good things in this area. They introduce the concept of, for lack of a better term, test once across the use cases or across the test cases. There are a number of things that may not be very variable. For example, secure communication probably doesn't depend on a test case. The format for some of the test cases as for the specification used probably does not vary. And there probably used to be allowance that if you're a vendor that has more or less a common capability, technology, method of addressing the requirement, there is recognition explicitly built into this to allow for that.

And I think there is room for that given what ONC proposed. It probably could be expressed at a criteria level given the requirement and how variable the implementation really is by care setting. Some of the documentation templates, for example, for some of the interoperability that is CDA based may not be common in every care setting you use. So, there is some tailoring of that. So, just along those lines that vendors need to be able to fairly look for leverage where there's no distinction of capability based on the care setting and venue, which is the variable by which the test cases are supposed to be defined.

Sasha TerMaat - Epic - Member

I think that makes sense, John. Another, I guess, question for the group, I was struggling to balance the expectation that the testing happens in production or in production like settings. And I know I would always discourage testing in production for data integrity reasons. But thinking about a production like setting with then the assertion that provider participation in testing should be minimal and trying to figure out, I guess, what the expectation was if production like settings are to be used, it seems like providers will certainly be involved in provisioning access to environments making sure that the access is probably recorded. That if they're provisioning test environments, having those be available and so forth. Whereas on the other side of that spectrum, if providers are less involved and shouldn't have to provide access and so forth then, the setting of the environment will end up being more simulated because of that.

And I wasn't clear, I guess, where on the spectrum is it supposed to fall. How do we balance not overburdening providers with this testing but also using realistic data and production like settings?

Raj Ratwani - MedStar Health - Co-Chair

Sasha, this is Raj. And I think one of the things that I was sort of grappling with, and this might sound silly, is if we think about a production like environment that involves the provider, are there human computer interaction usability elements that come into play here as well, which is not discussed and not part of this real world testing component. This is very much focused on the interoperability piece. So, does that get in the way on what we're trying to focus on testing? And do we foresee that as a potential challenge?

Sasha TerMaat - Epic - Member

And that's maybe a good question because I understood this testing because, I guess, they said they expected providers to be minimally impacted as being conducted by staff of the vendor. Because they're supposed to assume the expense of the testing. But if we are trying

to also test some elements of a real world setting, the staff of the vendor is not going to be the users. And so, again, I guess I'm trying to balance how much do providers need to be involved, how much should they be involved in this type of testing? We still have separate usability testing, of course. And then, if providers are expected to be involved, I think ONC needs to adjust the estimates to estimate the provider impact on that side because there's no provider impact estimated at the present.

John Travis - Cerner - SME

Yeah, I agree. It's almost kind of an ironic comment by the title of it. I actually think it's good to permit the idea of use of simulated data because I think that's going to alleviate a lot of concerns by providers who you might approach about helping with this effort. But I think that whole engagement side of things is a bit unclear. Who drives the roles of conducting the test and is it a hard wired condition that it has to be done with a provider partner? A little more on the test case design because, left as it is, is it strictly a unit test built on the certification criteria or are you trying to do more of a string test that's, as we said earlier, having the interactive components that go on for either recording information or incorporating information and reconciling it is that part of what goes on. And I suppose that's discretion to the vendor.

Sasha TerMaat - Epic - Member

And similarly, John, I guess with third parties as well. So, there's a question about provider participation. They also mention that you might test with others. So, we might test together and that would make sense both of us have this testing obligation. And we could work together to test our systems in that way. But there are other criteria that are proposed to be tested like submission to a Syndrome X surveillance registry. The Syndrome X surveillance registry in Ohio or in Michigan or in California doesn't have any obligation to participate in real world testing and might be approached by any number of vendors wanting to conduct tests. How will we work with those parties to make sure that the testing can happen on the timelines that are necessary without overburdening any one participant?

John Travis - Cerner - SME

Yeah. I think you hit on something as we looked at it. That was an open question, especially if you go the simulated route and on anything that's kind of a one way interoperability point. You need someone still to stand in the role of the recipient and maybe to stand in the role of applying conformance testing. We know of, to what you just said, I think it's Altarum who actually does some of that for some of the states on some of the public health reporting criteria for their deployment for doing onboarding. Is there going to be literally someone set up to be playing the role of the neutral convener and test harness to support playing in that role? Or are you going to have to bring other third parties, training partners of your provider clients to bear to be willing participants if you can't find them through a collaboration? So, there are just a lot of loose ends to that end about who is playing that role.

And something that kind of hit that's a little bit similar in the vein that we were kind of running across that can be a complexity is tying in the role of standards version advancement process because that's a requirement with real world testing that if you claim a higher version of standard and particularly that instance where they talk about a version of standard

that for which **[inaudible] [00:36:00]** doesn't exist for certification purposes and it's an out of station method, it just seems like some interesting things could happen with proving that through the real world testing process because, if I read it correctly, that's a requirement of real world testing that any version you claim needs to be incorporated into your test case development. And just some interesting things there.

And maybe the last thing to try to – we're kind of in the realm of getting things out on the table a bit but maybe the last thing to touch on is the idea of a pilot year for 2020 given the timing of a potential final rule. I think that's actually a pretty good idea and probably a good idea regardless of a final rule in 2019 to get people used to a rhythm of doing this.

Sasha TerMaat - Epic - Member

One question that I had, and I agree with your comment about a pilot John, one question I had was about the focus on scenario and use case space testing. There's a required focus on that in the proposed regulation. It seems like it merits conversation because I can see certain types of value from other types of testing. One of the things that is a goal of testing, for example, is standards and terminology usage of code sets. And that could be tested with any number of automated tools that are not necessarily scenario based tests. And so, I wanted to raise for our group a conversation about what are the advantages in cases where a scenario based test will be the best method versus when would developers want to be able to exercise discretion to use other types of testing methods that might be more applicable to the nature of what would be being tested?

John Travis - Cerner - SME

Yeah. Especially where that kind of plays into something, too, that I think it comes back, and I can maybe direct this to Raj a bit, that there just needs to be better elaboration on test case design to make sure it's efficient and how much discretion is really being given, to Sasha's point, to the vendor to design test cases that can be highly efficient on automated testing where it's possible. Something else that plays into that is the way it seems to read, there's an annual requirement to apply a testing plan for all of the practice settings and venues that you purport to offer certified EHR technology to in that.

If the capability doesn't change and the requirement doesn't change, it seems there should be a recognition for granting, I don't know, either there's a clear statement of need for doing regression or recognition granted or the fact that there was no real change in capability on something where the requirement didn't change and the capability didn't change. In other words, there wasn't anything advanced through the standards advancement process that the vendor is laying claim to and they were successful at their testing effort in the prior year. They don't seem to give any treatment for that and yet, I'm not sure that's entirely right.

Denise Webb - Individual - Co-Chair

So, John and Sasha, do you have some specific concerns around the timeline that's set up for submitting the test plan each year and then, subsequently, submitting test results?

John Travis - Cerner - SME

I don't know that there's an objection to it being an annual requirement where there is an

outright new capability. We may have progressed on certifying to something that wasn't there before. We may have progressed to adopting higher versions of interoperability standards. And all of those, I think, are fair game for that. I think what I would say is there needs to be recognition for the potential of either define a regression requirement or give recognition to a process that would give assurance and commit us to that, whether that's part of the attestation that we have maintained a capability at par level without any real substantive change year over year, if that's true. So, I think it's fair to test what is new. I think you need to account for regression. It gets to Sasha's point that there needs to be a good elaboration of the structure of this program that differentiates the kinds of testing that are expected. And that's not really very developed in the proposed language.

Sasha TerMaat - Epic - Member

I agree with John's point. I thought the annual schedule was reasonable. The deadlines fall right around the end of the year, which, I guess, has some advantage in terms of just centralizing all of the testing activity around a calendar year but then, also puts major milestones for test plans and submitting test results right around holidays, which is maybe slightly inconvenient. We could rotate around a different deadline of the year and avoid that. I think to John's point there's maybe a bigger picture question, which is what are we testing as far as things that have already been live and have not changed?

And overall, the clarity around all of these other components, some of the things that we've mentioned, for example, how many third parties are going to be involved in coordinating testing, whether it's customers or other interoperability entities or other developers who are required to do this testing or all three of those combined if an organization is coordinating with five other groups doing it annually is probably very reasonable. If you end up coordinating with 20 clients and each of them has 10 interoperability partners and you're suddenly trying to manage a schedule of 200 testing sessions with different entities, it is a much different sort of schedule if that makes sense. And so, I think we need some of that clarity to understand what really we're proposing.

Raj Ratwani - MedStar Health - Co-Chair

Yeah, Sasha and John, those are good points. Sasha, I wanted to come back to one of the things that you said earlier. And I'm wondering whether I just missed it in the text. But is scenario versus use case defined somewhere? Or is there a common definition for those two types of testing.

Sasha TerMaat - Epic - Member

Oh, I don't know if they were defined. I guess I had sort of an expectation in my head for what that meant and thinking of it as running a test scenario or running a test use case rather than something that would be more automated. But perhaps that's a mistake on my part. Would you read it differently?

Raj Ratwani - MedStar Health - Co-Chair

No, I read it that way, too, is that the scenario maybe has a little bit more context and is based on an actual – mimics something that we see in the real world versus a more scripted way of testing this. I'm confused by the use of both scenario and use case. So, that's including

a mandatory focus on scenario and use case focused testing. And from my background in the human factors usability world, sometimes, we use those two terms interchangeably. And here, it sounds like those are two different kinds of testing.

Sasha TerMaat - Epic - Member

They also say slightly below that the intended testing method/methodologies, would need to address testing scenarios, use cases, and workflows associated with interoperability.

Raj Ratwani - MedStar Health - Co-Chair

I saw that.

Sasha TerMaat - Epic - Member

Which is another and.

John Travis - Cerner - SME

It kind of answers the boundary of the testing question, Raj, but I think it's still a little bit vague. We're in an interesting situation where the primary proof point is the interoperability point. And it may be that the workflow component is there only if it's necessary to support the data capture or the data incorporation. If that's a fair assumption then, that probably should be pretty clear. Left as it is, I probably would assume that. Go ahead, Sasha, sorry.

Sasha TerMaat - Epic - Member

There's also a separate conversation at a different portion where they talk about the use of metrics, which isn't totally clear what's meant there. There is discretion to define. And also, the use of standardized metrics from existing networks like care quality, for example. And then, I wasn't sure, I guess, how that fit with the focus on use case or scenario based testing. I can see that participation metrics with a network might be very good evidence of the interoperability capabilities functioning in the real world. But it doesn't necessarily jive with the focus on use case based testing.

John Travis - Cerner - SME

Yeah. It seems a bit disconnected like an HIT vendor might have some capability to record metrics that something is being used or that a particular workflow is being followed, whether timer data or evidence trails that a capability is in use in the production world. But that really doesn't tie into scenario based testing that's more qualitative. We were a little puzzled by that.

Sasha TerMaat - Epic - Member

The same.

Raj Ratwani - MedStar Health - Co-Chair

This is challenging because if you have the provider interacting with the technology in the real world testing component of this then, I think it makes a lot of sense to have it scenario based or use case based. And I'm sort of using those terms interchangeably. But to have

different scenarios that mimic real world use and bring some reality. I think it certainly makes sense to have those as part of the testing if you're looking at the variability and human interaction with the technology itself and then, with the actual interoperability and exchange of information. But if you're not focused on that human interaction piece then, I'm not sure how much the variability and scenarios and use cases matters versus more isolated ways of testing interoperability and exchange of information.

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

This is Lauren. I think we should probably just take a break for public comment since we've got just about 10 minutes left of the hour. And then, if we don't have any comments, we can always come back and wrap up the discussion with the last 10 minutes or so. So, with that, operator, can you please open the public line for comment?

Operator

If you would like to make a public comment, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in the cue. You may press star 2 if you would like to remove your comment from the cue. 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

And while we're waiting for any members of the public to dial in, Kate, did you have anything else before we begin to wrap up? I just want to make sure we hit on all of the intended agenda items for today.

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

No, I don't have anything else. Tomorrow, as we continue the real world testing discussion, I can have the updated page numbers as well as the attestations and the **[inaudible] [00:48:30]**.

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

Okay. Great. Operator, do we have any comments in the cue at this time?

Operator

There are no comments at this time.

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

Okay. So, we can resume. Raj, I'll hand it back to you just to kind of wrap up on this last point and then, we can make sure we're clear on the next steps.

Raj Ratwani - MedStar Health - Co-Chair

Great. Thank you, Lauren. So, I think what would make sense to do in the last eight or nine minutes that we have here is to maybe recap some of the issues that were brought up to make sure we have those captured appropriately. So, I know Sasha and John, I think we went in lots of different directions. But I want to make sure that we can at least kind of get a bolder list of items that we need to document and revisit and figure out how we can handle those. So, I think for things that, and I was only capturing a few of these, so I don't know on the staff support if there is someone that captured some of the topics that were being discussed. But, certainly, for me, one of the key things was overall greater clarity.

But to get more specific about that, what does real world testing actually mean in terms of is that the provider working closely with a provider organization that is going to be in many ways the participants in executing on the testing? Or is this the vendor driving a lot of this testing? And so, I think that's a big piece that we have to figure out and talk through. And then, the second big –

Denise Webb - Individual - Co-Chair

Raj, can I just add to that? Because as I'm looking at the actual regulation text, I really do think John and Sasha have a valid concern. And I guess we'll have to figure out as a task force what sort of recommendation we want to make to ONC. But when you read the actual regulation text on conditional certification, it does clearly say must successfully test the real world use of the health IT modules for interoperability in the type of setting in which such health IT modules would be is marketed. So, that almost does imply that how could you do that without having the provider organizations involved in some fashion. So, I think that's a really bold point.

Raj Ratwani - MedStar Health - Co-Chair

Yeah, Denise, I think that's a good point. I'm still grappling with does that mean using production like systems where you're having the providers actually interact with the technology to test interoperability components? Or you could still use a production like system but have that still driven primarily by the vendor side of things or the vendor side.

John Travis - Cerner - SME

Raj, if I can kind of roll that into a statement, I think the things Sasha and I were speaking of are kind of as follows. How is care and practice setting defined? So, at what level of granularity? Yes, we understand we're marketing. Again, I give you the example of hospital and ambulatory governed the original conception of differentiating venue for certified EHR technology. Some examples for the reported rule that were kind of the levels at which statistics of adoption were reported, the old FACA structure. But I'm left wondering do I go look at the provider taxonomy code set, pick off a mid-level of the hierarchy and say that's level because there's a multiplier effect. And then, how are the test cases defined? We talked a lot about that one. Who would be the testing partner that would help play the role of either conformance validator or recipient or whatever is called for?

And how much can the testing be leveraged if the requirement doesn't really vary depending on care and practice setting? And I guess neither does the capability that's being subjected to the testing. I may have missed some things but I think those were a number of the major

areas of questioning we were raising.

Denise Webb - Individual - Co-Chair

John, I also think that because they use in the regulation text scenario and use case focused testing, what's the difference between those two? And I guess they need a definition because if they're really the same thing then, they should just use the term use case focused testing or one or the other, don't you think, Raj?

Raj Ratwani - MedStar Health - Co-Chair

Yeah. I agree and then, I would add to that that other line that Sasha pointed out further down in the document that says scenario work case, workflow, and there may even be another element there. So, I think greater clarity on what the type of testing should look like in a use case, workflow, something else.

Denise Webb - Individual - Co-Chair

Yeah. Because this is actually in the regulation text on Page 654. It uses those two terms.

Raj Ratwani - MedStar Health - Co-Chair

Okay.

Sasha TerMaat - Epic - Member

And how to accomplish all of the goals while doing those. So, they talk about realistic system load being one of the factors of real world testing. But if you are trying to simulate realistic system load, you're, practically speaking, going to have to approximate it based on automated things. You're not going to have a realistic system load of test users. Or you'd have to actually measure actual usage, which isn't testing but could still be useful to this potentially. So, I think those are a few examples. And I'd be happy and I imagine John would be, too, to jot down some bullet points for the record just to make sure that all of these are captured for further conversation.

John Travis - Cerner - SME

Yeah, absolutely.

Raj Ratwani - MedStar Health - Co-Chair

I think anything that you send over I think would be really good. And I think we just have to be careful with planning our time of not ending with a thousand questions and no recommendations or thoughts on how we can address those issues. And I just want to make sure that we're thinking of proposing some solutions here as well.

Denise Webb - Individual - Co-Chair

One other thing I'll mention when you were talking about care settings, John, it does say that the IT developer specifies what care settings and an explanation for their choice. So, it sounds like they're giving the choice to the IT developer on the care settings. But your point about what is sufficient –

[Crosstalk]

John Travis - Cerner - SME

It's more guidance on how to establish that choice. Yeah, exactly. And if you leave it that loose, you're going to wind up with – I could go do hospital and ambulatory and Sasha could do neurology and ophthalmology and podiatry and cardiac subspecialties. Yeah, exactly.

Denise Webb - Individual - Co-Chair

Right.

Raj Ratwani - MedStar Health - Co-Chair

Okay. So, we are just about at the top of the hour here. So, I think we have a good start here. John, Sasha, do you have other materials that you could send over? Clearly, your respectable organizations and you've been thinking about these important issues so please, send those over and we can continue the discussion tomorrow as we also bring on some new topics that we're going to need to focus on.

John Travis - Cerner - SME

Very good.

Sasha TerMaat - Epic - Member

Okay.

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

Thanks, everyone, for your time today. And we'll talk again tomorrow.

Denise Webb - Individual - Co-Chair

All right. And I believe we have a debrief, right, Raj?

Raj Ratwani - MedStar Health - Co-Chair

Yes, we do.

Denise Webb - Individual - Co-Chair

Okay. All right. Sounds good.