Conditions and Maintenance of Certification Requirements Task Force

Transcript
April 3, 2019
Virtual Meeting

Members/Speakers

Name	Organization	Role
Denise Webb	Individual	Co- Chair
Raj Ratwani	MedStar Health	Co- Chair
Carolyn Petersen	Individual	Member
Ken Kawamoto	University of Utah Health	Member
Sasha TerMaat	Epic	Member
Leslie Lenert	Medical University of South Carolina	Member
John Travis	Cerner	SME
Lauren Richie	Office of the National Coordinator	Designated Federal Officer
Cassandra Hadley	Office of the National Coordinator	HITAC Back Up/Support
Mike Lipinski	Office of the National Coordinator	Staff Lead
Kate Tipping	Office of the National Coordinator	Staff Lead
Christopher Monk	Office of the National Coordinator	SME

Operator
All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning, everyone. Welcome to the conditions in maintenance and certification taskforce. We are nearing the finish line here. So, we'll go ahead and get started to continue our discussion of our draft of conditions. Quick 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? Ken Kawamoto?

Ken Kawamoto - University of Utah Health - Member
Here.

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

Sasha TerMaat - Epic - Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Les Lenert? And John Travis? Okay. Hopefully the others will join us soon. I will turn it over to our Co-Chairs, Denise and Raj, to get us started.

Denise Webb - Individual - Co-Chair
Good morning. If we can just start with Kate doing a quick review of the charge that we're going to cover in our draft recommendations today…

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

Lead
Sure. So, the charge for the Conditions of Certification Taskforce is to provide recommendations on the application programming interfaces, real world testing, 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 deregulatory actions related to certification criteria and program requirements.

Denise Webb - Individual - Co-Chair
All right. Great. Thank you. Do we want to bring up Conditions in Maintenance of Certification Taskforce draft recommendations document to walk through that? I think we need to hit the highlights. We sent a message out to all the taskforce members about some items we need to resolve within our recommendations. Kate sent that out last Friday. I did go in, not in this document, which I should have –

Kate Tipping – Office of the National Coordinator for Health Information Technology - Staff Lead
Which one should I work from?

Denise Webb - Individual - Co-Chair
Well, we probably should work from the one that you prepared. I did make some changes. I can just read them to the taskforce under real world testing because one item that we were discussing was around recommendation eight, I believe – let me bring up my notes here. Yes, this had to do with testing the use of data and real world testing.

So, I don't think I changed this in your actual letter, Kate. This is the original Google doc, but we would want to discuss this. This is what I'm proposing. I tried to edit this. I don't know if you want to go ahead and just accept it since we carried over the original to the letter. It might be easier to read.

Kate Tipping – Office of the National Coordinator for Health Information Technology - Staff Lead
All right. Let me see…

Sasha TerMaat - Epic - Member
So, are we starting on recommendation eight then?

Denise Webb - Individual - Co-Chair
Yeah. I should ask – does anybody have anything before recommendation eight? Raj, we didn't discuss, I believe, anything else on real world testing.

Raj Ratwani - MedStar Health - Co-Chair
Right.

Denise Webb - Individual - Co-Chair

I know Ken is on. He wanted to add something. I didn't try to add his point while the preamble, where it covered the estimates for real world testing, it didn't consider the involvement of providers, but Ken had a comment in here related to not placing any undue burden or unfunded mandates on providers. I'm not sure how this would be handled and what we would recommend. Then I think Carolyn agreed with that.

But if we could start with just the suggestion – what I'm suggesting is where use of data testing would be pertinent and we're seeing that it would be pertinent to the receipt of data in the EHR – I changed this from we because there are a few places where we said we should do this or that and we needed to specify who we was, which is the health IT developers here.

So, if the health IT developers are testing the use of data received through exchange, that should be comma, the health IT developers should have the providers involved in the testing to validate providers can process and use that information. When certified health IT products receive foreign data, it needs to be presented in the same view as the native data to be useful and reduce burden on providers using the technology.

The CMC taskforce recommends use of data testing, validate the data provider receives in the certified health IT be viewable, actionable, and reportable. There's a typo there. It should just be singular reportable alongside the provider's native data. Then the providers were not considered in the cost estimates with real world testing in the proposed rule preamble.

At that point, I'm just wondering, Ken, what you might want to recommend there.

Ken Kawamoto - University of Utah Health - Member

Yeah. I think I have some – I think it was just a comment, maybe something along the lines of unfunded mandates that require provider effort should be avoided. I think there's a lot of talk about real world testing, but another way to put it is it's rigorous to validation, potentially and that's usually a pretty expensive endeavor.

Denise Webb - Individual - Co-Chair

Well, one thing I'm concerned about after talking to a number of CIOs is this was a big deal to them. They felt that the focus has been just on getting data out of the system and sending it to other places with no sufficient consideration given to validation and testing around the ability to use the data they receive through exchange through the interoperability requirements.

So, it's sort of a balancing act. On one hand, if we say no unfunded mandates in the providers, yet the provider organizations are saying we need this kind of testing done. So, what is the balance on how that testing gets done? I know we have Sasha – welcome back Sasha, by the way – I know she's inserted a few words in here. Yeah, user.

Sasha TerMaat - Epic - Member

Yeah. I agree that –

Denise Webb - Individual - Co-Chair

We are talking about the user. Thank you.

Sasha TerMaat - Epic - Member

The use of incorporated data – I do think it's going to be any user, not just providers. So, I put that language in. I agree with Ken's concern that there was no effort estimated for involving users in **[inaudible] [00:08:16]**. It would be significant. We know that from doing other types of user-centric testing, like the safety enhanced design testing that happens for other criteria. It's a pretty dramatic cost. So, definitely, it should be accounted for. If it is expected, I agree with Ken, there should be some sort of way in which that's not placing an undue burden on users who would participate.

The one thing that I highlighted in here that I'd like to revisit is the mandate that foreign data needs to be presented in the same view. That's exactly the kind of really definitive language that worries me because I don't think we want to make that recommendation. If someone did a test that said in a particular use case it was more effective to present data alternatively, you would want people to design based on that user feedback and that usability testing, not based on this mandate.

Denise Webb - Individual - Co-Chair

Maybe we could word it differently to suggest that where appropriate it needs to be because that was a major complaint of the users of the certified health IT products. I heard a resounding – I'm getting a lot of this feedback from members of CHiME. Plus, I know just using some of these technologies, having to go look for information elsewhere to look at htat information alongside your own information like medications or like allergies, those are examples.

Raj Ratwani - MedStar Health - Co-Chair

I think Sasha's calling out a really good point here potentially being overly prescriptive. Perhaps that language can say something about meeting users' needs in the context of use because there may be times where you do want the foreign data to look different or be presented differently from the native data.

Denise Webb - Individual - Co-Chair

That's a really great point.

Sasha TerMaat - Epic - Member

That's good clarification too. That maybe accomplishes what Raj and I were just suggesting.

Raj Ratwani - MedStar Health - Co-Chair

I think that's a good way to do it.

Denise Webb - Individual - Co-Chair

I like that. That looks good. Ken, Carolyn, are you good with that change? In general, are you all okay with this overall change to this recommendation?

Raj Ratwani - MedStar Health - Co-Chair

I still think that at the top, just after it says recommendation eight that we can strengthen that language. I thought there was a previous conversation that we had on this call that we had about encouraging the testing of the use of information. Maybe that touches more on Ken's point or Sasha's point. I think the way the first paragraph sort of reads there is that we're sort of saying some of this should be clarified, as opposed to coming out and saying we highly encourage the usability and human factors approach to testing and use of information.

Ken Kawamoto - University of Utah Health - Member

Yeah.

Denise Webb - Individual - Co-Chair

Oh, yeah. That part needs to be changed too. That part says should provide and we want to say that – yeah. Should we change that first sentence, our opening sentence? Raj?

Raj Ratwani - MedStar Health - Co-Chair

I think we should. I commented on the 4.2 version. So, I'm just trying to pull that up to see what we could take from there.

Denise Webb - Individual - Co-Chair

I think this still is the – oh, you mean the CMC – oh, yeah, gotcha. Maybe we can cut and paste it over, Kate.

Raj Ratwani - MedStar Health - Co-Chair

We can probably just as easily rewrite it. I think I modified it to say when testing the use of information, human factors and usability should be tested by assessing the ability for intended users to efficiently and effectively use the presented information and then maybe we could modify that first sentence as well. After the first sentence, we could add in there, "We believe rigorous testing of the use of information should be included," and then go into the consideration of human factors and usability.

Sasha TerMaat - Epic - Member

Sorry. I didn't get the words exactly right.

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

If everyone can mute their phones, I think there is a bit of background noise.

Ken Kawamoto - University of Utah Health - Member

Small point, but there's a typo in the second-to-last sentence, where "reportable" has an S after it.

Denise Webb - Individual - Co-Chair

Yeah. Thank you, Ken. I had mentioned that, but we missed that one.

Ken Kawamoto - University of Utah Health - Member

I think this is a balancing act because we do want this kind of testing. It's just expensive. I think of a study we're doing now where we're looking at HIE data in Epic from the CCDs. There are tons of differences between the providers, whether it's EHR vendors or just healthcare systems, of what they send, whether it's coded, whether they even send certain sections.

The question is obviously those things should be fixed, but who would be responsible for doing it. I would hate it if it's sort of the kind of thing where it's like, "Well, you need to get two informaticists in your health system assigned to work on this because it's now required." The ideal is someone funds those two health informaticists to do that work, but I don't think that's going to happen.

Sasha TerMaat - Epic - Member

Ken, I agree. When I think about doing this type of testing, I anticipate that a lot of the outcome is going to be around site-specific mapping and configuration. So, I would anticipate that if we did this type of testing, we'd end up with a lot of suggestions for Epic-using organizations to say, "Hey, maybe you want to revisit these different things."

Overall, I do think that could result in a lot of standardization and improvement, but it's certainly a fair amount of work for us to kind of design tests to look at that and then for the organizations to implement any recommended changes that come out of it. If that means changing how they nap, certain workflows, or capture certain data elements, the interoperability experience is standardized and improved.

Denise Webb - Individual - Co-Chair

So, Raj, did you want to change – I know this is in the previous document – did you want to capture those other changes in that first paragraph that you had suggested?

Raj Ratwani - MedStar Health - Co-Chair

I just had modified the third sentence there, but I think it reads fine as it stands now.

Denise Webb - Individual - Co-Chair

Okay.

Raj Ratwani - MedStar Health - Co-Chair

To Sasha and Ken's point, I completely agree. I think this is something that's critical that we test this because we've seen, heard so many challenges with this and there's a lot of safety implications to this that can be associated with the usability and human factors components. Yes, it's expensive and difficult to do at scale. I'm not sure there's an alternative.

Denise Webb - Individual - Co-Chair

I know the CIOs that represent these provider organizations are really looking for along the lines of what rather than all of the site-specific mapping, they did acknowledge there's a lot of that going on. They want to get to the point where there is a standard way of data coming in and data going out within the products.

I get it. Having been a CIO, I know a lot of times our organizations drive uniqueness they want and it's a balancing act for the health IT developers because on one hand, you do have to have a degree of standardization. On the other hand, there needs to be some modicum of flexibility. It's a challenging endeavor.

So, if everyone is good with this recommendation, what we're trying to do is get to the point where we can say by tomorrow afternoon, calls end, everybody's good with these recommendations and votes to move them forward to the full committee to vote on. So, can we move on now on this one? Are we good?

Ken Kawamoto - University of Utah Health - Member

Good with me.

Carolyn Petersen - Individual - Member

Yes.

Raj Ratwani - MedStar Health - Co-Chair

Yeah. I'm good with it.

Denise Webb - Individual - Co-Chair

Okay.

Sasha TerMaat - Epic - Member

I'm good with it too.

Denise Webb - Individual - Co-Chair

I know John joined us.

Sasha TerMaat - Epic - Member

[Inaudible] [00:18:11] tomorrow afternoon?

Denise Webb - Individual - Co-Chair

Pardon?

Sasha TerMaat - Epic - Member

I don't see a call tomorrow afternoon.

Denise Webb - Individual - Co-Chair
Oh, I'm sorry. Friday afternoon.

Sasha TerMaat - Epic - Member
Okay. Thank you.

John Travis - Cerner - SME
And yes, I did.

Denise Webb - Individual - Co-Chair
All right. Okay. So, I think the next – let me look at… The next one where we needed to do some refinement was around recommendation 17. So, does the taskforce, do any of you have any other changes or anything you want to discuss between 8 and 17?

Ken Kawamoto - University of Utah Health - Member
Maybe along the lines of the comment I had there, I wonder if we should say we recommend something like ONC have flexibility to specify any specific sub-versions within FHIR Release 4 in case there's a errata release or something. If it's unstated, maybe it goes without saying, but if there's like a 4.0.1, which has errata changes, I think they should be able to point to that.

Denise Webb - Individual - Co-Chair
I recall we talked about this. We were going to suggest them saying something in the preamble that while the regulatory text is going to propose a particular release or releases, what this means is that within that release, there's – what did you call them, sub-versions?

Ken Kawamoto - University of Utah Health - Member
Yes. I would consider 4 to be the major version and they have like dot –

Denise Webb - Individual - Co-Chair
Oh, minor versions.

Ken Kawamoto - University of Utah Health - Member
Yeah. Thoughts from the others on that?

Sasha TerMaat - Epic - Member
Are we adding something to the recommendation?

Denise Webb - Individual - Co-Chair
This is what Ken's recommending. We want to go ahead with our original recommendation that ONC should adopt solely FHIR Release 4 in the final rule. We also want to recommend that it be clarified in the preamble that this would include any minor versions that that would

be acceptable for health IT developers to adopt the current minor version of that release. I think that's what you're saying, right, Ken?

Ken Kawamoto - University of Utah Health - Member
I think so. I think it might be implied.

Denise Webb - Individual - Co-Chair
You know, Sasha and John, they might help with the wording.

Sasha TerMaat - Epic - Member
You're saying, Ken, that if ONC adopts release four, then it's okay if different vendors do 4.1 versus 4.3?

Ken Kawamoto - University of Utah Health - Member
I guess I'm saying that when they say Release 4, I'm thinking specifically of the example of Release 3, where there was errata version that I think was like 3.0.1. I'm assuming most people are implementing 3.0.1 instead of 3 or 3.0.0. I'm saying I just want to make sure 4 doesn't imply it's 4.0.0, which has to be specified that if by the time they're specifying this, there's an errata version that we should obviously use the version that fixes those obvious errors.

Sasha TerMaat - Epic - Member
Okay. I agree. I think it would be unfortunate to use the standards version advancement process to that. So, I guess what we're really saying is that ONC should adopt FHIR Release 4 or a subsequent version if one is identified to fix errata in that version.

Ken Kawamoto - University of Utah Health - Member
Yeah, that sounds good.

John Travis - Cerner - SME
If I'm not mistaken, they've done that before with other things.

Sasha TerMaat - Epic - Member
Then we would takeout this.

Ken Kawamoto - University of Utah Health - Member
That's good.

Denise Webb - Individual - Co-Chair
So, obviously, Kate, on these ones that we're changing, you'll have to move them over to the letter.

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

Lead
Yeah. I'll update the letter, make that final before our call on Friday.

Denise Webb - Individual - Co-Chair
Okay. Anything else on this, on 17? Let me just give everybody a change. Was there anything before 17 but after 8, recommendation 8? Are we good up to this point? I know Sasha, you can probably see all the comments. I reviewed them last night, but I can't flip between multiple screens here.

Sasha TerMaat - Epic - Member
I just arrived back last night. So, I haven't had a chance to look through everything else, but I can do that.

Denise Webb - Individual - Co-Chair
We have not changed. The things that we're hitting with the whole group today, these are the things where we had discussion after we did the debrief from the HITAC. The one thing I mentioned before we all got on the call this morning is that one area that we haven't concluded is around self-developers, whether we have a recommendation. I know we agreed that all the conditions of certification and maintenance should apply to the self-developers, but I think we might have talked about saying something about that, but we can do that at the end.

Okay. I think the next one that we wanted to talk about was this one that doesn't have a number yet and only to the extent that there's – the folks that were on the taskforce call when we discussed this recommendation that Ken suggested, everybody was good with it, but we wanted to make sure that you were and Carolyn put a comment in because I think she was not there on that call when we discussed this. She says she's good with it. Sasha, we just want to make sure you're good with this. I think you're the only other person that did get to weigh in on this unnumbered recommendation.

Sasha TerMaat - Epic - Member
I would want to use the US Core Implementation Guide still. I agree. Yes.

Denise Webb - Individual - Co-Chair
Okay. Good. Then there's a comment below – that had something to do with John. What was that. John, did we address that?

John Travis - Cerner - SME
I'm trying to catch up with the reading. My computer crashed in the middle of things.

Denise Webb - Individual - Co-Chair
Don't agree to Argonaut FHIR 4. That wouldn't exist. It has to be HL7.

John Travis - Cerner - SME

Let me look back. I did get that. I was talking to our interoperability lead and he has answered.

Denise Webb - Individual - Co-Chair

I think we were going to follow-up just to make sure that when the Argonaut group advanced something –

John Travis - Cerner - SME

It was going to be balloted and he did answer that and he defined that.

Denise Webb - Individual - Co-Chair

I think I recall that email. It said that they believed that was already advancing or going to advance through that process and that they believe these changes would be within the HL7 specifications.

John Travis - Cerner - SME

I believe that was the point. And then you'd ask when are they balloting it. I think he said in this next technical committee meeting cycle and I'm just trying to find his response.

Denise Webb - Individual - Co-Chair

Right. I think we were concerned about whether these would be actually – could people rely on what Argonaut is doing that's not yet in the specs for HL7 knowing that they are going to be? Obviously, the health IT developers want to get or already are working on this. So, I want to make sure we touch on all these comments so Kate can remove them. We don't want to carry those over into the letter. I just want to make sure we addressed it.

John Travis - Cerner - SME

Yeah. He said Argonaut is not planning to have another implementation guide based on FHIR Release 4 per se, rather FHIR US Core will include and cover Argonaut. HL7 will ballot HL7 FHIR US Core. Argonaut might have developed additional guidance, which then could be included in the next version. So, it basically works as a feeder. So, don't adopt something like Argonaut on FHIR R4. It doesn't exist. It wouldn't go through a ballot.

Denise Webb - Individual - Co-Chair

Okay.

John Travis - Cerner - SME

HL7 while not updated – yeah – should stand. Go ahead. Sorry.

Denise Webb - Individual - Co-Chair

So, it sounds like our recommendation addresses the concern with using Argonaut in there. Okay. Then you were going to say, to the last point…

John Travis - Cerner - SME

I believe the other question we had was when they may ballot next. They are doing so in the May technical committee meeting series for HL7. So, it would be plenty timely. If there's anything right now. It would be plenty timely to a final rule, should be through its balloting.

Denise Webb - Individual - Co-Chair
All right. Good.

John Travis - Cerner - SME
As a matter of fact, balloting is going on right now. Settling of the balloting result will happen, I think, in the May cycle.

Denise Webb - Individual - Co-Chair
So, I think the final point we need to discuss on this particular recommendation relates to concerns. I know Carolyn had surfaced it. A number of CIOs that I've talked to have surfaced this concern around smaller companies, less resource-rich companies that have to come up to the standard. I know we just briefly touched on this idea in terms of the timeframe. So, there are two years or 25 months to have all of this in place.

Of course, we had some discussion about how much of that time goes to the developers versus the users of the technology. Did we want to make any recommendation around some waiver process to request additional time for legitimate reasons or do we want to stay away from that and just have one standard timeframe?

Carolyn Petersen - Individual - Member
I think the waiver might be – if we don't become too prescriptive about that, I think that offers a pathway for discussion with ONC when organizations are in situations where this is a stretch or they just simply don't have the funds.

Denise Webb - Individual - Co-Chair
Maybe we could say in our recommendation that the CMC taskforce acknowledges that moving to any new standard within a product could be a larger lift for some smaller health IT development companies and then the subsequent adoption by their customers and would suggest ONC consider some reasonable waiver or exception process on meeting the timeframe specified in the rule.

Carolyn Petersen - Individual - Member
I wouldn't say consider. I would say formulate, something that's stronger than consider. Consider really means nothing.

Denise Webb - Individual - Co-Chair
Should – should provide.

Carolyn Petersen - Individual - Member
Yes, that would be better.

Sasha TerMaat - Epic - Member

I guess just thinking through – certainly, I think there's a big lift for many parties in what's proposed here – what's the consequence of some organization taking advantage of the waiver? So, if a certain healthcare organization says, "We aren't able to upgrade our system in time to meet this deadline, then the practical impact of that is that their patients can't take advantage of applications or their providers can't take advantage of applications that are written based on FHIR 4.0.1 because they haven't upgraded their systems yet, right?

Denise Webb - Individual - Co-Chair

Right.

Carolyn Petersen - Individual - Member

That can be an implication. Another one can be that additional fees get placed upon patients, that costs increase because the immediate budget for the next two years, three years doesn't have a place to hold this upgrade and the subsequent costs for the developing company as well as all the other things that the provider is mandated to ensure happen.

Thinking about the budgeting process, things don't happen instantly and just because a government agency comes along and says Company Y has to do this new thing that we haven't talked about before, that doesn't magically cause dollars to appear in the bank. Providers have to make decisions about how to fund different things and if they have too much that has to happen at once, if they're developing companies that they're working with that say, "We were told we have to do this. So, we have to pass the cost on to you now," we can't spread it over a longer period, then ultimately, that all rolls down to patience.

For the patient purposes, while it's important to keep up with new technologies and keep advancing, that's absolutely a fair point, it's not necessarily the case that all patients feel the benefit from moving to the new standard or the new technology in a very short timeframe. But when they get **[inaudible] [00:34:52]**, then everybody has a say.

Sasha TerMaat - Epic - Member

Yeah. I wholeheartedly agree. I'm wondering if a waiver is the best way to address that concern. The fear I have about waivers is it introduces an expectation and then an exception process which complicates the process for everyone because a patient or an app developer or another EHR can't rely on one of the assurances of certification, which is that any certified system will meet a certain technical standard.

That's tough, right? Then if you want to interoperate with the system that has a waiver, it places a burden on everyone else to attempt to be backward compatible or to explain why interoperating with that other system isn't available.

I wonder if a better approach to the concern that we're moving too quickly and increasing cost because we're exceeding the pace of reasonable adoption would simply be to suggest a different timeframe or that a different timeframe be evaluated to avoid that consequence

because I think the consequence of people being on different versions is also challenging to the industry. I would want to avoid introducing that side consequence in the attempt to mitigate the consequence of moving too quickly. Does that make sense?

Carolyn Petersen - Individual - Member

Yeah. It does. I think that is potentially a solution. I certainly can't speak to promote things that make it all more difficult, but if two years is a constraint, then that kind of creates its own problems.

Denise Webb - Individual - Co-Chair

So, through our dialogue through the weeks, universally, I think we all agree that there are likely problems with the timeline. Listening to both of you, I absolutely have been thinking about this and agree that setting an exception for one group of folks creates complications and burdens on other groups within the ecosystem and ultimately, it raises the overall cost for everybody.

So, maybe we would be better served to recommend how this timeline gets broken up, how much time goes to health IT developers to get done what they need to get done, and not specific just to this recommendation but to all the changes that have to occur I the certified health IT, the other 2015 Edition updates, this particular standard. I should ask Kate – Kate, do we have any more information related to what's in CMS's rule and when they're expecting the using organizations of the technology to actually have it in production use?

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

So, not for each specific criteria, but at least for the EHI export and API. In the ONC rule, through the conditions, which are on the developer, there's a requirement, obviously, to – they have 24 months to provide that certification. Then on the provider end of it, also, those two are included in the base EHR definition, which is 24 months and then therefore, they would be required within the third definition. So, be required to meet those two to comply with the CMS requirements.

Denise Webb - Individual - Co-Chair

At the same time?

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

I don't have it broken up by –

Denise Webb - Individual - Co-Chair

So, what I think I hear you saying, the time that's provided in the ONC rule, I think I hear you saying that does include actual deployment and production use in the healthcare organization?

John Travis - Cerner - SME

That's my understanding.

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

So, in a sense, because they have to meet the base EHR definition, which is included in the cert definition for CMS.

John Travis - Cerner - SME

There might be a little bit of very mild wiggle room with that depending on reporting period starts for whatever people need to do. But by and large – kind of like this year, promoting interoperability is 90 days, but if you participate in CPC+, you're worried about start of year. So, you need to meet that definition by the time your reporting period rolls around for whatever your interest is. That's a complicated intersect, but conservative would be get it in place by the start of that calendar year, whatever that falls. You first require that cert definition to be met.

Denise Webb - Individual - Co-Chair

You can see on the screen that Sasha put up a recommendation. Can you scroll up just a little bit, Sasha?

John Travis - Cerner - SME

Before I forget because I think it's relevant to this, I don't know if we covered it already, but the e-prescribing situation, I think we need to fold into this. If we're dealing with it in turn, I'll wait.

Denise Webb - Individual - Co-Chair

Right. She mentions in here not just these FHIR updates, but the other changes, which would include the e-prescribing. One thing that I would say, though, when you have particularly small developers and small practices, I would agree with the particularly small developers, but actually, it's a huge lift for these large integrated healthcare delivery networks that have hundreds of sites that they have to deploy and train their users.

So, I think there's going to be a challenge not just for small practices, but I think for large integrated healthcare delivery networks as well. That gets to the point Carolyn made about budgeting and scheduling these changes – when you think about all the different clinical systems that a healthcare organization runs, this has to be fit in to their release cycle and their budget. It's not as simple as one may think.

Okay. So, I'm just reading the rest of the recommendation here if everybody can take a look at this. I like that recommendation.

John Travis - Cerner - SME

Yeah, I do.

Carolyn Petersen - Individual - Member

I think that offers guidance and brings up the point in a way that perhaps allows for some creative thinking on ONC's part and hopefully some other solution that we're not going to come up with in the next five minutes.

Denise Webb - Individual - Co-Chair

Yeah. Ken? Ken, I see you're on last. Is this good with you?

Ken Kawamoto - University of Utah Health - Member

I guess my only potential update would be the beginning part of 9.3, instead of "is going to place," maybe say "may place an unreasonable burden," with the rest intact. I'm thinking it might depend on when this regulation actually goes into force because doesn't it say from the time this goes into force and if it doesn't go into force for a long time, maybe – it might end being reasonable, it may not, but I'm not sure.

Raj Ratwani - MedStar Health - Co-Chair

I agree with changing it to "may."

Denise Webb - Individual - Co-Chair

Okay. All right. Good. This was one of our major things to talk about. Check that off our list.

Raj Ratwani - MedStar Health - Co-Chair

We should have been using Google docs like this all along. It's really helpful.

Denise Webb - Individual - Co-Chair

So, let's see, where are we? Raj, do you know where the next item of discussion was? I see in the notes that went out to the taskforce members recommendation XX added by guidance on compliance with privacy and security regulations. Which recommendation was that? There it is.

Sasha TerMaat - Epic - Member

Between 19 and 20.

Denise Webb - Individual - Co-Chair

Yeah. We just want to make sure the new taskforce is – this is a new recommendation.

Ken Kawamoto - University of Utah Health - Member

I can explain it further if that would be helpful.

Denise Webb - Individual - Co-Chair

So, the folks that weren't on for the original discussion on this, further explanation? Is that needed or do you all understand what this is proposing?

Sasha TerMaat - Epic - Member
I'm comfortable with it.

Raj Ratwani - MedStar Health - Co-Chair
Yeah. I'm okay with it.

Carolyn Petersen - Individual - Member
Me too.

Denise Webb - Individual - Co-Chair
Okay. I think, Les, you were on that call with us. I think we're good to move, then? That recommendation is good, Kate. We have a comment on 20. So, on this one, my point we're saying that recommend ONC specify a standard approach. My comment was just do we have a specific approach we want to propose. Are we saying which is available on FHIR Release 4 and that covers it?

Ken Kawamoto - University of Utah Health - Member
I thought we said we want to use the version release for our – did we not say that?

Sasha TerMaat - Epic - Member
I think that was the intent. John, do you remember?

John Travis - Cerner - SME
I turned it away.

Denise Webb - Individual - Co-Chair
Maybe if we take the parentheses off the comment so it's less than just a parenthetical.

John Travis - Cerner - SME
I think our point was this was a major argument for R4, which is why the parenthetical note may be for emphasis. It doesn't matter. The sentence form is fine. The way it's worded is the way I remember it, which is we had concerns about supporting the bulk date use cases and having developers going off and doing different things at different levels of standards. I know we take it as a major argument for R4.

Ken Kawamoto - University of Utah Health - Member
Was there a comment somewhere earlier about not doing the population level of things in this requirement. I thought I saw them somewhere in the recommendations earlier. We might be contradictory if we say somewhere we should only do per patient things in this.

Denise Webb - Individual - Co-Chair
Oh, no. We didn't make that recommendation.

John Travis - Cerner - SME

No, I don't recall that. I think we were using that as a – yeah.

Denise Webb - Individual - Co-Chair

So, on this – I have concerns over – we can say it recommends ONC specifies standard approach and adopting in FHIR Release 4 in the regulation would address this concern. Pardon, Ken?

Ken Kawamoto - University of Utah Health - Member

I had thought bulk data was still pretty early in the process. I know we had one of our folks look at trying to use it for some of the things we're doing for population health management and we concluded it was too immature to start adopting for real use. Are there folks who have been engaged that bulk data is mature enough to really specify and say everyone should do this?

Sasha TerMaat - Epic - Member

Well, Ken, I think it has a lower degree of maturity and adoption than other uses of FHIR because in part, there isn't even a standard way to do the bulk access until Release 4, I believe and no one is using Release 4, I believe, and no one's using Release 4 because it was like just balloted recently or is about to be balloted. I am blanking on the details.

So, it's something that I think people are looking toward in the future, but I don't think it has real world use yet. I know that there was a demo of some of the prototypes using the bulk data at ONC's interoperability event last year and it seemed as you say, to me – that demonstration seemed to indicate to me it was very early on in it's development. So, I think there's kind of balancing act here.

Some people have been giving feedback even in our past discussions that the bulk data use case is critically important, but at the same time, it is clearly further from prime time than the single patient use case and potentially worth putting on a different timeline.

Ken Kawamoto - University of Utah Health - Member

I don't know. I'm always nervous about recommending everyone's required to use a standard no one has really tried in a real setting yet. That would be my only concern. I guess recommendation-wise, it might be to maybe say I know consider doesn't mean, but like take into account the current maturity of bulk data, perhaps, but I felt like it was primarily standard to say if you wanted to grab everyone or a very core-screened population to pull, that's how you do it was sort of my sense, not anything like for these particular populations I want to know their weights and A1Cs kind of thing.

I can just imagine this would be a very expensive computational process if we say we don't have those fine grain features, etc. I don't know. I'm always nervous about things that are only in a demo environment because demos will always work.

Denise Webb - Individual - Co-Chair

So, rather than us trying to make a final decision since we only have a few minutes and we will have to go to public comment, I think probably we should defer resolving recommendation 20 on Friday. I will say that a number – there seemed to be a lot of confusion on the rule amongst some CIOs I talked to.

They were kind of mixing up this API requirement for multiple patients versus individual patients and that these requirements required any data and I had to help explain to them that this is a round that's starting with the USCDI and that it's the EHI export, which is a different requirement that requires all of the data and that wasn't via API.

So, I just wanted to bring that up out in the field. There's some confusion on all of this. If we don't think the standard is going to be ready. Or there's a chance it might not be, we might want to think about adjusting our recommendation and then conclude on that discussion on Friday.

John Travis - Cerner - SME
That sounds good.

Denise Webb - Individual - Co-Chair
Are we due to go to public comment now?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
We are just about out of time. So, Operator, can you open the line?

Operator
Thank you. I'm sorry, please go ahead.

Denise Webb - Individual - Co-Chair
Then I was going to say after we do this, we'll do a little summary on what we are going to cover on Friday.

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

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Do we have any comments in the queue?

Operator
Not at this time.

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

Great. Denise, I'll hand it back to you.

Denise Webb - Individual - Co-Chair

All right. So, in my notes, I'll see that we have to conclude our discussion on recommendation 20. We also had some discussion that we needed to have on recommendation 22 relating to app registration, recommendation 27 related to the e-prescribing, and then one other final is whether we want to make any recommendation regarding self-developers or just make a statement that we agree that the conditions of maintenance and certification apply equally to self-developers.

If you'll all look at the bottom of this document as part of your homework on page 13, there are four items related to not just self-developers, but all developers, but it does clarify some things related to what we expect with self-developers. So, Raj will be running the meeting on Friday because I will be in an airplane, but I think our goal, Raj, by the end of the meeting Friday is to be able to advance the letter to the HITAC committee that includes all of our recommendations for the overall committee to vote on if possible.

Raj Ratwani - MedStar Health - Co-Chair

Yeah. I deliberately put it for Friday afternoon knowing that everybody would want to make it to happy hour, so, people will be efficient.

Denise Webb - Individual - Co-Chair

I may have missed some areas and now, Sasha, you're back from your trip. So, if everybody can take a look at the version we've been working in today because that one includes the comments, Kate has transferred everything over as far as what we've done up to today, but not including today, but she's going to move those items over that we've already deliberated on.

Sasha TerMaat - Epic - Member

So, the 3/12 version is the one to put further comments into and do our homework in?

Denise Webb - Individual - Co-Chair

Yeah. I would say so. That way, Kate can keep our letter clean and we're not making a bunch of changes to that. She can then transfer the changes over. Does that sound good, Kate?

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

Yeah, that works.

Carolyn Petersen - Individual - Member

Kate, can you send out that link wherever you'd like us to make the comments so we are sure

we get that right?

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

Yes, I'll send that out.

Denise Webb - Individual - Co-Chair

All right. Anything else we want to do in the last minute or so or are we at time? I lost my clock here. Oh, we have three minutes.

Raj Ratwani - MedStar Health - Co-Chair

I think we're good to hold it Friday, if that works for everybody.

Ken Kawamoto - University of Utah Health - Member

That sounds good.

Denise Webb - Individual - Co-Chair

All right.

Ken Kawamoto - University of Utah Health - Member

Just a quick suggestion – if anyone has access to folks who have tried the FHIR bulk data at their organizations, etc., if they can ask and get their input for Friday, that would be really useful.

John Travis - Cerner - SME

Ken, I would suggest that we probably ought to get them on the agenda for the full HITAC. That seems like a pretty advanced capability.

Ken Kawamoto - University of Utah Health - Member

That's true. I don't know who are the folks engaged, but if the ONC folks know, I don't know.

John Travis - Cerner - SME

I think that we should kick this up and say the HITAC should discuss the readiness of the bulk data 4.0 spec. This is clearly at the centerpiece of what's going on. If we're saying it's got to be ready in two years and there's not a lot of implementations of it, it's not really something that's been specified with the design that an EHR performance-wise could meet the requests for this without a heavy load on it, right? I don't know what you think would do to your system, Ken, to ask for the records of 10,000 patients.

Ken Kawamoto - University of Utah Health - Member

I just know that when we want to pull one typical patient's medication data, it can take like ten seconds.

Denise Webb - Individual - Co-Chair

Yeah. This may be something that has to be maybe near real time and not real time. There have got to be considerations of the burden on the infrastructure and the system and the – I have concerns. I know we're only talking about a subset of data with USCDI, but when you're talking 10,000 patients for a subset of data and it takes 10 seconds to just get the med data on one patient, maybe this requirement just needs to be held for a future date. I just don't like the idea of even all the developers using whatever approach they think is best. That just drives us further away from having standards around interoperability.

Ken Kawamoto - University of Utah Health - Member

I think the only time-sensitive question might be whether to invite somebody for next week's HITAC. So, maybe ONC can consider whether that might be appropriate.

Denise Webb - Individual - Co-Chair

I'll leave that up to Lauren and Kate to investigate.

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

Yeah. Ken, we can follow-up offline and see if that's possible for next week.

John Travis - Cerner - SME

That's great.

Denise Webb - Individual - Co-Chair

I know it's going to be a concern. It did come up at the last HITAC. There were concerns about this particular requirement and it would be helpful for us probably as a committee to be able to make a decision on this by hearing from a subject matter expert that can speak to actual real use of this.

All right. We're at the top of the hour. To be respectful of everybody's time, I think we're ready to conclude.

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

Thanks, everybody.

Denise Webb - Individual - Co-Chair

All right. We're dial in, Raj and I, for our debrief.

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

Okay.

John Travis - Cerner - SME

Bye, bye.

Denise Webb - Individual - Co-Chair
Thanks.

Ken Kawamoto - University of Utah Health - Member
Bye, bye.