Conditions and Maintenance of Certification Requirements Task Force

Transcript
March 7, 2019
Virtual Meeting

Members/Speakers

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

Operator
All lines are now bridged.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning, everyone. Welcoming to the Conditions in Maintenance and Certification Requirements Task force. This is now our third meeting this week. So, we are pushing through at a rapid pace here. We will call the meeting to order starting with roll call. Denise Webb?

Denise Webb - Individual - Chair
Present.

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

Raj Ratwani - MedStar Health - 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 still on vacation. 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, I believe, is going to be a little bit late. So, with that, I will turn it over – I'll turn it over to Kate for another quick review of the charge and then we'll jump into discussions around attestations.

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

Sure. Thanks, Lauren. So, the Conditions in Certification Task force, we're charged with providing recommendations on the conditions and maintenance of certification requirements, including the application programming interfaces, real-world testing, and attestations. The updates to the 2015 Edition certification criteria, modifications to the ONC Health IT Certification Program, and deregulatory actions related to the certification criteria and program requirements.

Denise Webb - Individual - Chair

Thank you, Kate. So, let's go to the next slide. So, we're going to spend the first few minutes – we're going to try to get this wrapped up in less than ten minutes – to talk about attestations. That is the regulatory part 170.406.

So, under the condition of certification regarding attestations, the health IT developer will initial have to certify that they are in compliance with all of the conditions and maintenance of certification that are provided within the regulation except the EHR reporting criteria submission, which is going to be addressed at a later date. In this requirement, health IT developers are going to have to submit their attestations every six months or semi-annually as a part of the maintenance of certification.

In the preamble, it does provide that there's going to be a process to support this that ONC would publicize and prompt developers to complete their attestation, but they would provide a method for them to indicate their compliance and they would also provide health IT developers the flexibility to specify noncompliance with any particular certified health IT module, if necessary.

So, I'll open it up to the group to make any comments or concerns or particular recommendations regarding these attestations. Go ahead.

Sasha TerMaat - Epic - Member

This is Sasha. So, there's language that says there's a 14-day attestation period. I wasn't entirely sure what that meant. Is that the window during which paperwork could be submitted? It seems quite specific to specify that paperwork has to be submitted in 14 days instead of just saying there's a deadline.

Denise Webb - Individual - Chair

Kate, do you have any clarification on that?

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

Sure. There are 14 days for the submission of the attestations. The question was why it's not like a specific date as opposed –

Sasha TerMaat - Epic - Member

What is the 14-day attestation period? Are you saying that it would be impossible to submit your attestation earlier than that and it has to happen within that 14-day period?

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
I'll have to double-check with the drafter on that section. I can get back to you.

Sasha TerMaat - Epic - Member
I guess my thinking would be it seems like ONC could set an end deadline but that the process and timeline for collection of that data could be left to the ACBs that are collecting it from developers and saying it has to happen in a certain 14 days seems awfully prescriptive and kind of unnecessary.

Carolyn Petersen - Individual - Member
Yeah.

Denise Webb - Individual - Chair
Let's note that.

Carolyn Petersen - Individual - Member
This is Carolyn.

Denise Webb - Individual - Chair
Was somebody trying to speak?

Carolyn Petersen - Individual - Member
Yeah. This is Carolyn. I was going to say if you specify a specific 14-day period, then you put yourself in the position of having to issue changes and extensions and what not when you have natural disaster issues, hurricanes, massive tornadoes, snowmageddons. It seems like the NIH goes through this constantly where they have to change deadlines for grants because weather events prevented people from being able to file. You would create a lot more hassle for yourself if you get extremely prescriptive, like a 14-day period.

Denise Webb - Individual - Chair
Yeah. That does seem to make sense. It seems better that they set a deadline in the middle of the year and the end of the year and then by that deadline, those attestations have to be submitted. Then that gives them flexibility, like Sasha said, for the certifying body to work with the developer to get those in. Okay. So, Kate, do you have that noted?

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

Denise Webb - Individual - Chair

Okay. And then if you would, follow-up with us to what was intended in that 14-day attestation period, why 14 days and not just a twice-annual deadline. Okay. Any other comments on attestations? If not, we can move on.

All right. So, let's dive into the APIs and we'll start with – if we could go to the next slide… So, the first is related to changes in certification criteria. This just specifies that the rule is proposing to adopt a new API criterion in 170.315 G10. This would replace the application access data category request certification criteria that was in the same area, G8. This new criterion would require the use of Health Level Seven FHIR standards. Then there are some various implementation specifications discussed and included.

As part of this discussion, there is a part of the preamble that asks us to look at four options in terms of what release we would recommend. The rule is proposing the FHIR Release Version 2. There are two types of services that will be enabled through this API criterion. That's services for a single patient's data and services for multiple patients' data.

So, there's quite an extensive section in the preamble that discusses the details of all of this. So, what I thought we might do is start with whether there are any concerns related to – if you'll move to the next slide, Kate, I think this has more explanation. In Section 404 of Part 170, it talks about the various roles and definitions and the goals of this regulatory text around transparency, permitted fees, and pro-competitiveness.

So, as I said in the preamble, there's quite a bit of extensive discussion around these areas. So, if we could kind of step through those and start with the roles and the definitions around the roles and then we could go through the areas related to transparency permitted fees and pro-competitiveness.

Sasha TerMaat - Epic - Member
Denise, are we coming back to the question of the single-patient case and multiple-patient case? I know that was on the previous slide. I just didn't know if we were going to discuss that now or later.

Denise Webb - Individual - Chair
Let's go back to the previous slide and let's talk about that. The updates to the certification criteria reflect those two conditions. So, if we could move back to the previous slide…

Sasha TerMaat - Epic - Member
And then I'm just searching for the correct page…

Denise Webb - Individual - Chair
Yes. This is first mentioned in – I've got my pages marked here.

Sasha TerMaat - Epic - Member
101, I think?

Denise Webb - Individual - Chair

It's mentioned on 101 and then that refers us to Section 74, where all the detailed preamble is.

Sasha TerMaat - Epic - Member

Okay. I'm scrolling further to seven. Does anyone have a page reference for when the preamble for part seven starts?

Denise Webb - Individual - Chair

I'll give it to you. It's 204.

Sasha TerMaat - Epic - Member

Thank you.

Denise Webb - Individual - Chair

Excuse me, 203 – bottom of the page. Do you have a specific comment or suggestion related to the two types of API-enabled services?

Sasha TerMaat - Epic - Member

The one thing that I guess is notable about the multiple patient data requests is that there's not a standard way to do that. While most of what's being proposed related to API programming interfaces is very focused on identifying a standard way that it would be done across all different products that would be certified, the multiple patient data, there is not sort of an existing standard approach for doing that and it is included without that. That seemed unusual to me, I guess, in the scope of everything else that's proposed and potentially meriting conversation.

Denise Webb - Individual - Chair

So, do you have a specific suggestion or recommendation that our task force might make related to the multiple patient data? Are you suggesting that possibly be deferred until there is a standard that could be applied across the board?

Sasha TerMaat - Epic - Member

Well, I understand it's an important use case that people are interested in. But I guess I do question if it's appropriate to spend time implementing it in non-standard ways or if it would be a better investment of the industry's time to develop a standard approach and then implement it at a later date.

Denise Webb - Individual - Chair

Okay. Any comments on that from the rest of the group – Raj, Carolyn? I see John is on.

Carolyn Petersen - Individual - Member

This is Carolyn. The statement that Sasha made strikes me as something that seems

reasonable on its face. But then when I think about the long history of inability to agree upon standards and new standards proliferating with new products, it kind of feels like we're going to still be in the same place we've been for a long time. That hasn't always been helpful or meaningful for users.

I'm just trying to think of if we go with that approach, then we're left with – how do we get to the point down the road where we can all adopt it? How long does that take? What is all of the regulatory stuff around doing that? It just kind of feels like we're kicking the can down the road.

Sasha TerMaat - Epic - Member

You know, Carolyn, I certainly respect that it could take time to finalize a standard. I guess what would likely play out if we require it now is that because there is no standard, each developer will implement it differently. I guess that, unfortunately, makes it harder for – I forget the term; it's on the next slide – but the API users to take advantage of that multiple patient data services because each developer has implemented it in a different way because there was no standard to follow.

So, I think if we move forward with it now, we will see everyone investing R&D time into something in non-standard ways and we'll see it be reduced in its efficacy because of the fact that there was no standard identified. That might move faster in some ways because it would be available, even in a non-standard way.

But it would also, I guess, introduce waste in the sense that at some point in the future, we're presumably going to want to move to a standard way to do it to make it more effective and efficient for the API users and for developers to be able to take advantage of a standard FHIR approach, for example. If they've already invested in different ways, then the transition could be harder than just investing in the standard way in the first place.

So, I guess we have to decide how much value we get from a non-standard implementation and is it worth the increased cost of switching later or would we be better served by putting the effort that we lose in that switch into faster adoption of a standard method.

Raj Ratwani - MedStar Health - Chair

This is Raj.

Carolyn Petersen - Individual - Member

All of that sounds good, but when I look at the history of how we've gotten down the road, the result feels unsatisfying.

Denise Webb - Individual - Chair

Raj, did you have a comment?

Raj Ratwani - MedStar Health - Chair

Yeah. I was going to say – I think Sasha is bringing up some really good points. I think this is a

difficult issue that we have to grapple with. But I think the big point is there's an immediate need here. If we sort of all agree that there's an immediate need, then I think Carolyn is making a really good point, which is we're just kicking the can down the road and we don't really have a great history of executing on these things when we do that.

Denise Webb - Individual - Chair

Right. Well, I'm trying to recall – I thought I had read – maybe I'm confusing this – but on the four options on the different releases for FHIR, that Release 4 would facilitate this. Did I read that wrong? I don't know. Someone who is familiar with the release versions – it gets pretty technical beyond that point. I don't have that expertise. Go ahead.

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

Hi. Yes, we do have a request for comment regarding some different paths regarding either FHIR 2, FHIR 3, or FHIR 4, which recently came out. So, maybe that's something that this group can discuss in this conversation as well.

Sasha TerMaat - Epic - Member

Denise, I think what you brought up is on 232, where they say, "We expect that FHIR Release 4 will have such specificity."

Denise Webb - Individual - Chair

Yeah. I thought I had read that. Thank you for getting me to that page.

John Travis - Cerner - SME

This is John. I know –

Sasha TerMaat - Epic - Member

I don't know what that means from a technical perspective, if that means like, "We hope it will," or if that means it does.

John Travis - Cerner - SME

This is John with Cerner. I joined late. I probably can go back and talk to our API services folks, but I know there's a lot of support here for R4. We can probably get more substance around that if we want. I can ask them if we're going to get more into that in our next call.

Sasha TerMaat - Epic - Member

I can ask some colleagues too if we want to take a follow-up.

John Travis - Cerner - SME

Yeah.

Denise Webb - Individual - Chair

Yeah. I think we can do a follow-up because we were going to try to get through all of the

aspects of the API language in these two hours, if possible, including discussing those four options.

John Travis - Cerner - SME

Yeah. Sorry to kind of come in late. So, I'm out of context. I did ask them for a lot of reflections on some of the policy areas that maybe I provide these after the call or I can try to offer them in the context of the conversation. They deal more with what are probably some policy matters around some of the proposals or questions that are more functional in nature than technical.

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

Well, let's put a note on this and keep going, as folks have suggested.

John Travis - Cerner - SME

Okay.

Denise Webb - Individual - Chair

Okay. So, those were really great points. Thank you for bringing those out. We definitely have both sides that Carolyn presented and then that Sasha presented. They're both salient points.

All right. So, let's move to the next slide. So, the preamble is broken up to discuss – actually, the first part of it discusses the actual statutory requirements around a standardized way, transparency, and pro-competitiveness. Then there is a pretty significant section in here on D.

But before we launch into a discussion around the proposed standards in particular, let's talk about the API technology role and whether there are any suggested changes in those definitions or whether those definitions are clear in terms of who the actors are regarding APIs. Any concerns or comments? All right. I guess hearing silence, I guess everybody is pretty good with what those goals intend.

John Travis - Cerner - SME

There is probably one thing or a couple of things that I think I could throw out there for comment. So, these might be more observational than comments, but they could lead to something. The first one is the regime does seem to set up a presumption that the API user as a developer of an app is going to be working with and through the API data provider.

While they need access to the API technology supplier to get things done, if you will, to prove secure connection to be able to engage in obtaining access to the API services, it seems to presume that invalid may not be the right word, but there's not a support for the API user and API technology supplier working together to support development of application offerings without an API data provider being in the mix right away.

It seems to rule out or maybe it doesn't give much treatment the case of an API user as developers seeking to develop a commercial offering by collaboration with the API technology supplier. I'm not sure that's true. It certainly shouldn't be ruled out by the way this rule is structured. It kind of seems to be. I think that's relevant to this.

Denise Webb - Individual - Chair

Or maybe it's just more silent to it. I see your point. As I read through this, it is permitting the data provider to have the exclusive control over the domain of who connects their data.

John Travis - Cerner - SME

Since we're talking about conditions of certification, maybe that's a presumption. But when we get to the context of the parallel provisions in the exceptions, it's kind of dangerous if it's left that mum or at least to make an explicit statement, it's not considered information blocking or it's out of scope to any conversation here. I think that would be a fine way to deal with it. Maybe that doesn't belong here, but down in the exception conversation.

But at any rate, I think it would be very helpful to make an explicit statement somewhere. Either it's out of scope to the intent of this regulation or it's a permitted activity that doesn't want to follow this regulation.

Denise Webb - Individual - Chair

I think that's a point worth noting that we could consider including. I know that a number of the vendors have app stores or app galleries where third parties can work with the vendor to develop an app that works with the health IT technology supplier's products through an API and that often times, the data provider who eventually is going to provide data is not involved in that development, per se, until the third party has completed building their application and working in a sandbox environment to ensure it works and interacts for a particular function.

Then at the point where, let's say, the patient – let's say it's a patient app and the patient wants to use that app, they would be interacting with the health system for which they want to obtain their data to bring into that app, I assume. Then that would involve that other API user, the third party that owns the application or is providing that application to the patient would be interacting again with the data provider at that point.

John Travis - Cerner - SME

Yeah. I think the point is that – and it's kind of true – the current model, it presupposes the application exists. The application may have come into existence through no specific involvement – I guess there is a difference between the development activity, which may not require the API data provider's involvement at all, and then yes, as a practical matter, the API data provider is going to be involved when it comes to the actual – whatever you want to call it, but I don't want to use the term – whitelisting for actual production access.

Denise Webb - Individual - Chair

Okay. So, Kate, I think you've probably captured a note on this that maybe we could

recommend some more explicit statement of the acceptable relationship for what is expected between an API technology supplier and an API user, that there are multiple relationships that are supported in this environment.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Got it. Thank you.

Denise Webb - Individual - Chair
Okay. Anything else on key terms? All right. Then the next part of the preamble discusses the actual proposed standard implementation specifications and certification criteria. So, this is along the particular FHIR standard release, the proposed adoption of FHIR DSTU2, Standard Release 2 – that's what they're proposing.

ONC does ask us to contemplate four different options. So, this is the next part of the preamble. For the actual standard, option one is what's proposed, Release 2. Option two is adopt Release 2 and 3. Option three is to adopt Release 2 and 4. And then option four is to adopt Release 4.

Hopefully, you've all had a chance to look at the actual text on that. Can we spend a little time discussing the actual standard and what ONC is proposing versus what we might recommend along the lines of those four different avenues? Or was this something, I know John and Sasha, that you wanted to do some reach-back to your technical folks?

John Travis - Cerner - SME
Yeah. I think if the ask is what's the feedback on the major merits of adoption of one versus another, I think that's what we were offering to do by talking to our API services team. I know that we have a general advocacy for our four here, but I would want to get a little more substance from them on why they favor that.

Sasha TerMaat - Epic - Member
I agree. I'm happy to gather more information from the folks who are in the weeds of the differences between 2, 3, and 4.

Denise Webb - Individual - Chair
Okay. Raj, do you have any particular opinion on this or Carolyn?

Carolyn Petersen - Individual - Member
I would benefit from further discussion and explanation of some of the technical details.

Denise Webb - Individual - Chair
I would too.

Carolyn Petersen - Individual - Member

I'm looking at pages 211 to 213 right now thinking, "Okay, should I really express an opinion this?" I think for me, at least, it would be helpful to know more.

Denise Webb - Individual - Chair

Okay. If it's okay with the group, why don't we table that? Of course, I don't know who's on from the public. They might have some comments when we do the public comment period.

Sasha TerMaat - Epic - Member

Can we set a date for when we will revisit it so that John and I know when we have to have our follow-up ready? Will we discuss tomorrow or next week?

Denise Webb - Individual - Chair

Well, what I'm going to suggest – when I was looking ahead on the schedule, I think for our meeting, I think we have an hour on Monday or maybe it's an hour and a half, but when I looked at what we're going to cover, it seems like we could squeeze something in on the agenda there. Would you agree, Kate?

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

Yeah. We do. We have an hour and a half on Monday morning.

Denise Webb - Individual - Chair

Okay. So, if we could revisit 1 through 4 for the DSTU standard.

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

Okay. I'll add that to Monday's agenda.

Denise Webb - Individual - Chair

Okay. Thank you. All right. So, this may apply too as well since we may not have the technical depth to reflect other than on a policy perspective around the actual implementation specifications that are being proposed for adoption, which starts on page 214. They're proposing in the regulatory text an implementation specification that would list a set of based FHIR resources for health IT modules certified to do this standard that will be proposed. They're proposing API Resource Collection in Health or the ARCH.

John Travis - Cerner - SME

Yeah. I think what I'm hearing from our folks is we wonder what the purpose or value of ARCH would be. It's our API services folks' thoughts that it's got a lot of redundancy to the USCDI required data classes for Version 1 and that systems are probably already able to find what the correct resources are to match to the USCDI-required data classes under Version 1.

There's something under FHIR resources that's called medication and we use a resource called medication statement to expose medications. I think those are probably the

underpinnings of what was used to certify for the 2015 edition as it is, as the API resource. So, I guess there's a feeling, at least for us, there's not a lot of purpose or value added by adopting ARCH versus asking vendors to develop the resources aligned to the USCDI-required data classes under Version 1.

Sasha TerMaat - Epic - Member

Do you think it would be helpful to be consistent, though? I agree they may not have to be the correct service, but does it seem like there's value of everyone adopting the same service rather than some variation in which med services folks use?

John Travis - Cerner - SME

Yeah. I think that's a fair point when you're looking at people harmonizing to a release in a version basis versus what we saw with the certification regime so far.

Sasha TerMaat - Epic - Member

Right.

John Travis - Cerner - SME

I think what our comment came from was for us, having done what we've done, it doesn't provide us much value and it feels like it would be work to go and do for that sake, but that's a fair point. I can raise that to them to say, "Think about it from a standpoint of does that cause us any issue from an interoperability standpoint if we were not to move to that?" That's a good way to raise it back to them.

Denise Webb - Individual - Chair

Well, it does show here in ARCH's first version, it does show medication statement at the bottom of page 215.

Sasha TerMaat - Epic - Member

Yeah. It has medication, medication order, and medication statement. My take is that conceptually, I think it is useful to interoperability to specify the resources that are expected and the implementation guides that should be followed. For specific details on, "Hey, there's a problem with this implementation guide," or something along those lines, I'll have to come back with some input from our FHIR team.

Denise Webb - Individual - Chair

Yeah. And then it's specifying three implementation specifications or guides that would be followed here. This was the first one. The second one was around the Argonaut Data Query Implementation Guide Version 1. The third is around the specific portion of the Argonaut Implementation Guide referring to the data query implementation guide service conformance requirements.

Generally speaking, I think having specific implementation guides specified does assure that everybody's all on the same page. I know when I was in public health, I experienced the situation where there were different versions of implementation guides and really, different

entities were using different guides. That really created a lot of issues. I would recommend that this go forth with specified guidance for implementation. Raj, do you have anything to add?

Raj Ratwani - MedStar Health - Chair
No. I do not at this time.

Denise Webb - Individual - Chair
Then the last – I think this is the last part of the criteria – it's around the adoption of standards and implementation specifications to support persistent user authentication and app authorization. That starts on page 220. It speaks around the SMART Guide specification and the use of refresh tokens. Are there any comments or concerns in that area?

Sasha TerMaat - Epic - Member
I have a technical concern or question for the group. When you have a persistent refresh token, the best practice, which is included in the SMART Implementation Guide, would be to only provide a token that allows persistent access to an application that's capable of keeping a secret, right? If you're providing a secret token to an application that has no security, then you're opening up persistent vulnerability because that application can't guard the secret as it should be protected.

I'm trying to puzzle through here – there's no process for – which we haven't gotten to yet – setting the security of an app that would be provided this token, at least not that I've seen. But it would seem to be best practice in implementing the SMART Implementation Guide to say, "I'll only provide this token if the app can guard it securely." So, how would that be handled?

Denise Webb - Individual - Chair
That's a good question.

Sasha TerMaat - Epic - Member
It seems that there needs to be a provision for either prior to providing a token, ensuring the app can keep a secret. It's technically capable that way. But that's not really provided for in the current process.

Denise Webb - Individual - Chair
Well, I can say having been a CIO for a time, I would certainly support that. So, we could make a recommendation along the lines that this was specifically addressed as a legitimate and expected activity in implementing a smart guide that protects patients' data.

Sasha TerMaat - Epic - Member
Okay.

Denise Webb - Individual - Chair

We should be clear that this is something that we'd expect the health IT developers to do so that when the data providers actually –

Sasha TerMaat - Epic - Member

Or if it's something the data provider does, I guess – maybe we need clarity. If the technology supplier is doing it, then the process has to accommodate them knowing that the app can keep a secret or can't keep a secret and how would they know that? An attestation from the API user, some sort of third-party validation, other methods? Or if the API technology supplier is not supposed to play that role, would the API data provider play the role of saying, "Oh, this app is capable of keeping a secret or not?" How would they make the determination?

Denise Webb - Individual - Chair

Okay. Thanks, Sasha. That's a good catch. Okay. I think that is, I believe, the last part of this. No, there's more here. There's a lot of technical stuff in here. So, page 226 through 232 is actually looking for any specific comments we would have on the proposals related to data response, search support, app registration, and secure connection authentication and authorization.

Sasha TerMaat - Epic - Member

So, data response is on 227 and simply says that any data elements that are mandatory would have to be returned in certification testing, right?

Denise Webb - Individual - Chair

Yes.

Sasha TerMaat - Epic - Member

Generally, that seems reasonable. From my perspective, I guess, the tricky part could be if there are any mandatory data elements that would not be commonly available within EHRs and we could ask that of some of the FHIR experts to flag any concerning areas.

Denise Webb - Individual - Chair

I think, though, initially, isn't this being constrained by the USCDI? While ONC acknowledged that the Cures Act expects that any data that's in the EHR would be made available, aren't we initially constraining to the USCDI version one?

Sasha TerMaat - Epic - Member

For this, we are. I guess my point – maybe I didn't articulate it well. Let's say there's a new data element that's part of the, I don't know, patient goals FHIR service that says the exact time the goal was made is mandatory. Previously, folks had only captured the day the goal had been made.

Then making it mandatory here would have other implications for capturing the time the goal was made in the EHR beyond just delivering it in the FHIR service. If all the data is in the EHR, I think testing it in the FHIR service process seems reasonable, from my perspective. John,

would you agree?

John Travis - Cerner - SME

I would agree. Actually, I think what you trigger is a different and maybe out of the scope of this particular conversation, more one for some other things, but USCDI does grow and we will get into that situation. I have to be honest – maybe I'm just being dense – I'm not quite sure what that does when Version 2 is adopted and they begin to incorporate more administrative and other demographic data that's not a current requirement.

I think that really comes into play, Sasha. I don't know that I see what exactly the growth path is for what the vendor is to do from a certification standpoint with the USCDI, which, after all, itself is a standard, really, as a whole and then certainly in part. As it grows and they adopt Version 2, exactly what is expected and exactly how those things go and get expressed, what we see in the current proposal governs that.

Let me give you a particular example. This may be just, again, my own thickness of mind. We have the ability to adopt higher levels of a version of standard. I don't know that the USCDI itself is exposed to that, but I'm not sure they explicitly say it isn't. It certainly can add in a new data element that will bring in both new nomenclature standards and potentially imply new resource requirements for the API services.

I think what you mentioned is it's going to happen. There will be new requirements. I'm not certain I understand how we are to go about their incorporation and how we proliferate the impact of that out to all of the interoperability standards, including API.

Denise Webb - Individual - Chair

John, I think that probably the discussion on the USCDI is out of the scope of our task force because there is another task force devoted to that specifically.

John Travis - Cerner - SME

That's fair. I bring it up in the context that it will introduce new requirements here, to Sasha's point, that are going to be exactly of that kind. They are going to be net new. I can't sit here and say that the existing requirement imposes things that aren't already captured in the EHR or aren't already things that would have to be otherwise enabled to be captured because the USCDI requirement applies across modalities of interoperability, if you will. So, the point on the patient goal is going to be as much an issue for CDH-based interoperability as it is going to be for API.

Denise Webb - Individual - Chair

Right. I think they're going to have to address some of these points in the USCDI task force. Hopefully our ONC team, if that isn't brought up, they could push that over to that group.

John Travis - Cerner - SME

I didn't mean to get off-topic.

Denise Webb - Individual - Chair

That's okay. So, let's move on and see if we can get through the rest of these certification requirements. Anything on search support?

Sasha TerMaat - Epic - Member

Search support brings up the same no standard for multiple patients question that we talked about earlier. So, we can touch on that again maybe after we've followed-up.

Denise Webb - Individual - Chair

Okay. All right. And then app registration?

John Travis - Cerner - SME

Yeah. That one gets into a few things. We're assuming the health system has the real and sole authority to approve the use of an application. Is that clearly enough stated? While dynamic registration is not automatically called out, is that anything to raise as a requirement?

Sasha TerMaat - Epic - Member

John, I guess I had a different understanding because I did not think that the API data provider was making a decision about patient applications.

John Travis - Cerner - SME

Yeah. I think that – well, maybe that needs to be expressed as provider and patient. Maybe I need to re-read it. I'm trying to have several things open. Doesn't it state that there is a process of – I try to be careful with the terms. Registration, to me, is a bit of a loaded term. There certainly is a process of proving out secure connection and the ability to state compliance to a given API technology supplier's terms and conditions.

Then there is a process by which the health system ascent – let me use that term – to the use of that application in their environment. I thought that was generally true, as kind of the rough description of the process.

Sasha TerMaat - Epic - Member

That would be good to clarify because my understanding was that there should not be a step for patient apps –

John Travis - Cerner - SME

I'm trying to be really careful how I say it, not to use the vetting word.

Sasha TerMaat - Epic - Member

Right.

John Travis - Cerner - SME

There is a general proof point of being able to show that secure connection can be achieved.

I thought that there still was a – on the part of the data provider – to be able to have an acceptance step, if you will, that an application was able to be used to access their production domain. I don't know – I'm careful about my terms. I'm probably describing it more for what the action is than the label used.

I'm very careful not to say I think it's clear there's not really a prior vetting step, if you will, not by the API technology supplier, necessarily, but there still is a step that focuses on assuring that there's not a security risk by the introduction in the application that the API data provider has the ability to exercise.

Denise Webb - Individual - Chair

At the end of the section, it does say that ONC believes the discretion that's provided is warranted as API technology suppliers and API data providers are best-poised to innovate and execute various methods for app registration within a clinical environment. So, they're not being specifically prescriptive of how this is done while they thought about proposing –

Sasha TerMaat - Epic - Member

I think that's true with the registration process in particular. I think the challenges that John and I are articulating are not necessarily specific to what they describe about app registration on 228 but are more about the overall process of where app registration would feature and some of the conversation that happens in the 240s, as far as pages.

Maybe I'm confused too. I'm trying to map out like what would be the process for app to go from, "I've made this app based on the publicly available documentation," then the app needs to register because that's the next step and that's why we're talking about app registration, and there is a permitted time period to verify the identity of the registering organization or user but not to vet the app on the part of the technology supplier.

John Travis - Cerner - SME

Exactly.

Sasha TerMaat - Epic - Member

Then after that, I didn't see – I guess maybe this is the part that John and I are debating – I didn't see – I thought based on the provision of endpoints by the API data providers, which is also required, that the app would then effectively be live. I didn't see a step where the API data provider could approve the app or take other steps. Maybe that's what I'm missing and need to re-read.

John Travis - Cerner - SME

Let me see if I can…

Denise Webb - Individual - Chair

I don't think there is a process about approving the app. I think the regulation or the proposed rule makes it quite clear that data providers are not supposed to get into vetting what apps that a patient chooses to use.

Sasha TerMaat - Epic - Member
Right.

Denise Webb - Individual - Chair
If the technology supplier, API technology supplier verifies that the entity providing the app is not some malicious third-world country, they must register and allow the connection. We talked about this quite a bit in the CARIN Alliance that it's not the role of the health system to be the guardian of what a patient chooses to do and where a patient chooses to send their data. However, it is important to provide sufficient education and information to patients so that they understand the risks that may exist but not to prevent them from using whatever app they want to use.

John Travis - Cerner - SME
Well, I read this statement again that I think you just mentioned on 229 and I'm really trying to describe in practical terms what that is saying. That's probably where I'm picking that up, that, again, really trying to ask for comment on the perspective. Again, "We don't intend to test registration capabilities…" Understood. "…That would be executed within an API data provider's clinical environment."

What we're really talking about is making an application available and probably for its first instance of use to access a given data provider's clinical environment. Once that's done, there's no question. It's there. It's available. If anybody were to present with it, it would be able to be used without any such step.

It's to that first instance of access as a novel thing to a given API data provider's clinical environment and then they say the discretion is warranted. I reflect on statements that CMS had made – and I want to say it accrued back to one of the promoting interoperability rulemaking preamble discussions in either the 2019 IPPS rule or in the 2019 MACRA QPP rule. They made a point similar. I'm just trying to reconcile all of that.

Sasha TerMaat - Epic - Member
Yeah.

Denise Webb - Individual - Chair
So, John and Sasha, can I suggest – because we have a lot of material to cover – can I suggest that if you want to come back with a specific recommendation for our task force as a group to consider, why don't we do that – maybe enter it in on the Google Doc?

Sasha TerMaat - Epic - Member
Sure.

Denise Webb - Individual - Chair
Because I just don't think we have the time to deliberate all the points.

John Travis - Cerner - SME
No, that's –

Carolyn Petersen - Individual - Member
This is Carolyn. I just had one thought listening to you all and re-reading this text. Back at the bottom of 228, it starts out, "While requiring dynamic registration could create a more consistent registration experience for health IT developers…" What if we make a comment that gets to how this process should be – ONC should be doing things to facilitate the greater adoption of that to create this more consistent registration experience? It seems that perhaps rather than arguing about those nitty-gritty details on 229, we could be encouraging development and adoption of the process to get where we want to be.

Sasha TerMaat - Epic - Member
I think we certainly support advancing standards like dynamic registration, Carolyn. It's not a standard that's widely ready for adoption today. So, we do need to figure out the details on 229 for the timely implementation of the features that everyone is planning.

Carolyn Petersen - Individual - Member
But can we also encourage work on dynamic registration so that we can eventually be there?

Sasha TerMaat - Epic - Member
I'm not confident that dynamic registration solves the problems on 229 that we're discussing, but I would certainly support advancing the standard.

Denise Webb - Individual - Chair
I think that would be a worthwhile point in making, Carolyn. All right. So, this moves us to the last part on secure connection authentication and authorization that's being proposed in the regulation text. It's saying the health IT presented for testing and certification must be capable of demonstrating supportive user authentication according to OpenID Connect Core 1.0, incorporating the errata set as well. It does talk about testing in two modes, standalone launch and the HR launch.

So, are there any specific suggestions or comments related to this? It also does talk about the three-month expiration period for the token.

Sasha TerMaat - Epic - Member
Yeah. I still have the token question raised earlier, but otherwise, I think the testing that's described seems reasonable.

Denise Webb - Individual - Chair
Are there any thoughts about whether ONC should specify a reasonable upper bound from the timing perspective on when users should be required to reauthenticate or reauthorize?

Sasha TerMaat - Epic - Member
Like at least one year or something?

Denise Webb - Individual - Chair
Yeah. They gave an example of one year. Does anybody have any specific druthers around that? I know as a patient I often times find if I use an app regularly, I don't see why I have to reauthenticate and reauthorize once a year. I guess if I don't use it, the token would expire then. I would be having to reauthorize, but I don't know.

Sasha TerMaat - Epic - Member
Well, the app could potentially be renewing the token even if you weren't using the app depending on the app architecture, I guess. But if it was completely expired after, say, a year, then even if you weren't using the app, it couldn't still be like pulling your data without you reauthenticating to the EHR.

My sense is that API data providers – maybe, Denise, you have a perspective as a CIO responsible for an EHR database would want to try to balance the, I guess, the risks associated with persistent access by an unknown application to the database with the patient convenience that's offered by less frequent reauthentication.

Denise Webb - Individual - Chair
Well, I know in my previous role that I just left, we didn't require patients to reauthenticate on an annual basis. Their credentials did not expire. Raj, do you have any comment on that?

Raj Ratwani - MedStar Health - Chair
No, I don't. I don't have enough insight to say whether a year is appropriate or not.

Denise Webb - Individual - Chair
All right. Maybe we should leave that to the broader public to make a comment on. So, that takes us to the end of all of the particulars related to standards and specifications. Now, we would launch into the portion around transparency through the publication of API documentation.

So, on pages 232 all the way through – this section is not large because then it gets into **[inaudible] [01:01:17]**. It looks like it's 240. Do I have that right? No, excuse me, 244. So, any recommendations around the requirements for the API technology suppliers making their documentation available in the timeframes and the methods in which they must make this documentation available?

Sasha TerMaat - Epic - Member
I don't have any comments on 232 through 236. I'm not seeing the timeframe piece. Is that on one of the later pages?

Denise Webb - Individual - Chair

I thought there was. I may be confusing this. Maybe this one didn't have a timeframe.

Sasha TerMaat - Epic - Member
Right.

Denise Webb - Individual - Chair
There was a timeframe on 240 related to compliance data six months from the final rule's effective date to revise their existing API documentation to come into compliance with the final rule.

Sasha TerMaat - Epic - Member
So, just so I understand that – the actual development to create some of the new APIs that are required is not six months, right? I'm assuming the documentation updates would be to reflect some of the changes around not requiring a click-through agreement or something. What would be different after six months since the new APIs might still be being developed?

Denise Webb - Individual - Chair
Yeah. This is referring specifically to existing API documentation. Come into compliance with the final rule… It might be worth noting that the 6 months might conflict with the 24 months deployed in production. How could you revise your existing API documentation when you're in the process of doing development to come into compliance? We might recommend that they look at this date or this time period.

Sasha TerMaat - Epic - Member
Yeah, or clarify what happens in 6 months and what happens in 24.

Denise Webb - Individual - Chair
Yeah. All right. Anything else on documentation transparency? If not, then we'll get into the meaty discussion of permitted fees.

Sasha TerMaat - Epic - Member
Don't we next have, Denise, just scrolling through, the verifying authenticity?

Denise Webb - Individual - Chair
Oh, yeah, the five-day process.

Sasha TerMaat - Epic - Member
Right.

Denise Webb - Individual - Chair
Yeah. They were seeking comments. We already talked about dynamic registration. You're correct. On page 243 –

Sasha TerMaat - Epic - Member
I think it starts on 241.

Denise Webb - Individual - Chair
Yeah, the bottom of 241. So, I was curious whether the health IT vendor community, what your thoughts were on the five-business-day process because I know that does not seem like a very long time. You have to have dedicated resources to be doing that work.

Sasha TerMaat - Epic - Member
I had several questions. Maybe they would feed into some suggestions. First, ONC is clear that API technology suppliers are not obligated to verify identity. I guess that left open a question for me to say if no one verifies identity because there's no obligation to do that, can it be clarified that choosing not to verify identity removes liability a bad actor?

If the five-day business process seems onerous, like, gosh, not really a lot of time to really a lot of time to effectively verify someone's identity – how do I know this person is who they say they are or not in a process that has to be executed in a very short amount of time? Then if I choose not to do that and to let them proceed based on who they say they are, can I be excused from consequences that might emerge from someone not being who they said they were? Does that make sense?

Denise Webb - Individual - Chair
Mm-hmm.

Sasha TerMaat - Epic - Member
I think one of the questions is the liability that comes out of this. If there's no responsibility for performing this authentication process, I think that – if the authentication process has to happen, I guess I struggle to know how would it effectively happen with high confidence at all, much less in a very short period of time?

Denise Webb - Individual - Chair
All right. Others, do you have any thoughts? It does note that if you chose not to vet an app developer – this is at the bottom of 243 – apps still don't have carte blanche access to the healthcare provider's data.

Sasha TerMaat - Epic - Member
Right. Someone would have to choose to use it, a particular patient or if it was going to be enabled in the clinical setting, like a particular user of the EHR, presumably.

Denise Webb - Individual - Chair
And they are able to have their access activated if there is any anomalous or malicious behavior.

Sasha TerMaat - Epic - Member

Correct.

John Travis - Cerner - SME

That, again, is – I'm not trying to overread our prior discussion – Sasha, I'll send you something.

Sasha TerMaat - Epic - Member

Sure.

John Travis - Cerner - SME

I'm really trying to pick my word carefully. I'm trying to find the most nominal, minimal word that says the API data provider has said it's fine for an application that's new to my experience to access my production environment. I just wondered if that's part of what is expected to go on in the five days – I think so –

Sasha TerMaat - Epic - Member

I didn't think it was.

John Travis - Cerner - SME

It's part of what may be – well, the five days, someone has presented to the API technology supplier and you've got that time period to – and they've passed all your tests – you've got that time period to make – whatever is the right term – that application has met your test.

Denise Webb - Individual - Chair

They can make production connections to the API.

Sasha TerMaat - Epic - Member

I don't think there are tests, though. Are there, John? I don't see the opportunity for the API technology supplier to conduct any tests. I thought that they –

John Travis - Cerner - SME

No, you're not vetting. I'm trying to stay away from the vetting word. It's not vetting. By whatever means, I think the five days is the time period you have that once they've done what's necessary to be able to comply with your terms and conditions and have a production connection, you have to make it available or sustain a connection.

Denise Webb - Individual - Chair

Right. You're not verifying validating their app. You're validating –

John Travis - Cerner - SME

What was in that – and these are the two things that I'll share – there are two statements made – one of them was in the 2019 IPPS Rule – and this was when the world was the consumer app of my choice – well, the statement reads as follows. I don't want to slow us down, but it ties in, I think, to what we're talking about here. "It was not our intent to imply

hospitals and their technology suppliers would not be permitted to take reasonable steps to protect privacy and security of their patients' information."

Now, they actually use the vetting word. But even in cases where a healthcare provider or CERT developer chooses not to vet app developers, very much echoing the word here – it's exactly the same wording as is used here. But it was done in the context of saying, "We weren't saying that you're not going to take any reasonable steps."

I guess I'm trying to roll that all up into there's a discretionary action that ultimately is a literal statement, in a way, that the API data provider is going, "I'm good with this application making a connection in my production environment." That's really all I'm trying to say. It's not vetting.

Sasha TerMaat - Epic - Member
Yeah.

John Travis - Cerner - SME
I don't think it's ruled out by anything I've seen. You don't have to do it, but nor is it telling you that you can't do it and that's really all I'm trying to say. So, what's funny is the quote I have is exactly what's said at the bottom of page 243 and top of 244. However, it first appeared in the CMS rule in the 2019 IPPS Final Rule in the context of consumer access. So, they're reusing something here that was used in that context.

Denise Webb - Individual - Chair
All right. I don't think we're going to solve this debate about this now. So, do we want to just put forth a specific comment or recommendation?

Sasha TerMaat - Epic - Member
Could we request that either, I guess, if there is clarity on this and John and I aren't finding the right references, maybe someone from ONC can point us to the right parts at a future call and we could review? Or if there's not clarity, I think maybe our comment as a task force is that we think it needs to be clarified.

John Travis - Cerner - SME
I would go with that. What I can do, Sasha, I'll copy – there's no reason not to copy other people. What I'll do is take the statement from the 2019 IPPS Rule, take the statement made on page 229, and take this statement, which you'll see when you see it, almost as a verbatim lift from the 2019 IPPS rule. I'm just simply saying does that say there is some simple exercise of discretion by the API data provider to say, "I'm good with this now having production access to my environment."

It has nothing to do with the API technology supplier other than it's met all the tests of proving production connection or being able to be compliant with the API technology suppliers, not vetting. It's exactly what's there. But then is there a discretionary act? I feel like CMS and ONC have not been quite on the same page and now they're trying to be, but I

don't know quite what they're trying to say. So, sorry to be dense, but yeah.

Denise Webb - Individual - Chair

Well, my understanding from the discussion on this is that a health system could not put up any barriers – this is coming from OCR – to patients using the app of their choice to get their data unless that app is going to put their health technology infrastructure at security risk or that it's malicious in some respect. I think they were pretty clear that a health system could deny app access if it operated in a malicious way that would bring harm to the health system security infrastructure that protects the EHI not from the patient getting their data, but from others that are not entitled to that data.

John Travis - Cerner - SME

What is really interesting – and I'll drop it. I apologize for being such a stick in the mud. In the 2019 IPPS quote –

Denise Webb - Individual - Chair

Well, we'll just have to have more meetings that we hope move along.

John Travis - Cerner - SME

Yeah. Just the last thing – what's really interesting – and I'll speak to it – in the IPPS Rule, "CMS makes a statement such measures might include vetting application developers prior to aligning their apps to connect to the API functionality of the provider's health IT." in the quote in the ONC rule here, they drop that statement.

Denise Webb - Individual - Chair

Okay. All right. Well, we probably just need to request clarification. I like Sasha's idea to have the ONC team, if there are other places they can point us to that can clarify this for us, great. If they can't, then let's go ahead and make a comment, a recommendation. All right. Can we move into fees?

John Travis - Cerner - SME

Sure.

Denise Webb - Individual - Chair

There are several pages on fees. The fees section talks about general conditions. What they're proposing as permitted fees, what they're proposing as prohibited fees. That is covered on pages 244 through 262 of the preamble. So, do we want to start with those general conditions?

Sasha TerMaat - Epic - Member

Does that start then on 247, Denise?

Denise Webb - Individual - Chair

Yeah. The introductory portion just discusses that technology suppliers obviously need to

cover their cost and earn a reasonable return and that regardless of what's decided about fees, there would be no fees related to patient-related access to his or her EHI. So, on page 247, there are general conditions. There are one, two, three, four pieces of regulatory texts that are discussed here.

The first is around in order to be a permitted fee, a fee imposed by the supplier must be based on objective verifiable criteria and uniformly applied for all substantially similar or similarly situated classes a person can request. That would be number one. Number two is the fee imposed must be reasonably related to the cost of supplying and, if applicable, supporting the API technology or at the request of the API data provider to whom the fee is charged.

Number three is for a fee to be permitted, the cost is supplying and, if applicable, supporting must be reasonably allocated. So, this has to do with allocation across to whom this technology is being applied to or supported. Number four is that in order to be a permitted fee, the fees cannot be based in any part of whether the person requesting access or another person as a competitor, potential competitor will be using API technology in a way that facilitates competition with that supplier.

So, those are the four provisions in the general. I thought they were fairly specific. Raj, are you still with us?

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denise, if I remember, I do believe he said to drop off early in one of our conversations.

Denise Webb - Individual - Chair
Okay. If there aren't any specific recommendations for this area, we could move on to submitted fees –

Carolyn Petersen - Individual - Member
It starts at the top of 250.

Denise Webb - Individual - Chair
Pardon?

Carolyn Petersen - Individual - Member
It starts at the top of 250.

Denise Webb - Individual - Chair
Yeah. These are the permitted fees. The first one is around developing, deploying, and upgrading the technology. Any concerns with that? Then the next one is on page 253. It permits fees to recover costs of supporting the usage for purposes other than patient access exchange and use.

Sasha TerMaat - Epic - Member
So, this is maybe very in the weeds, but would the process of certifying the API be considered as part of the development or as part of the support or it doesn't matter, one of the places in there?

Denise Webb - Individual - Chair
You mean with the accrediting body, the actual certification process and the cost of that?

Sasha TerMaat - Epic - Member
Right. Yeah.

Denise Webb - Individual - Chair
ONC, can you clarify whether that's considered part of development?

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Sure. Stephanie, are you still on? If not, I can follow-up.

Stephanie - Office of the National Coordinator for Health Information Technology
I am on the line, but I would have to follow-up.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
We should double check.

Stephanie - Office of the National Coordinator for Health Information Technology
Yes.

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

Denise Webb - Individual - Chair
Thank you. All right. And then let's see here… Those are permitted fees. Then the last one is for value-added services. Any comments? All right. How about prohibited fees, which starts on 261? And on 262 is three bulleted items that discuss specific fees that a supplier would be prohibited from charging. And then finally, I would ask are there any –

Sasha TerMaat - Epic - Member
One question that I had –

Denise Webb - Individual - Chair

Go ahead, Sasha.

Sasha TerMaat - Epic - Member

Sure. This is maybe back to some of John's questions earlier, but in 262, they make it sound like sandboxes – I guess I'm ambivalent about what the sandbox information is. It says it could include access to test environments if the expectation would be that APA data providers would be testing with apps that they wanted to work with, is that then – I'm trying to understand what is actually expected on 262.

John Travis - Cerner - SME

Yeah. I'm looking at that as well, Sasha. I think it fits within some of what we were talking about earlier and it speaks to – the notable thing isn't necessarily the fee. It's the activity.

Sasha TerMaat - Epic - Member

Yes. The fee piece is kind of just where it appears in the section. If someone was making an app that launched in the middle of your EHR and they wanted to work on that app with a certain health system, maybe like the scenario John described earlier, then my expectation would be that the test environments for that app would be provided by the health system that they were working with.

So, the API technology supplier would be publishing the documentation that's earlier. They would be making available the APIs for specifications for the API user and the API functionality for the API data provider, but the testing tools, in that case, would be provided by the API data provider.

John Travis - Cerner - SME

The way they phrase it here, I agree with you. I think it does hearken back to the question I raised earlier. It's just a clarification question whether or not any direct work between the API technology supplier and the application developer as the API user is at all dealt with this. This is why I was asking that question, at least in part.

I think for what it's raised here, there's also probably a difference between what is a development activity, where there's this kind of give and take. That's the purpose of the test environment or the sandbox. Maybe it's not the same kind of purpose or process that would simply be a new application connecting to a production domain of an API data provider that's already proven its ability for a secure connection and for meeting the terms and conditions of a developer.

I think there are different purposes there. This seems to speak to a development activity that is a deliberate engagement between the API data provider and the API user to develop a new application for use that the API data provider may want to make available. They may be playing both of those roles.

Denise Webb - Individual - Chair

I think that development, John, is outside of the scope of this. I think when they're speaking

about development here and the costs of doing development, it's specifically around the API technology, not the app that you might develop with somebody that accesses the API technology to get to the data.

My read of this, where they use this example of you cannot charge a fee to access the test environment but to build that test environment for an API technology, that would be part of the development cost that would be permissible in a charge to recover the costs and the fee you would charge and allocate fairly across all those that would be benefitting from that.

John Travis - Cerner - SME

I agree with you. I don't think what I was saying was ruled out either. I'm looking at the second statement in that paragraph, which could entirely be for the purpose of the app developer working with anyone. We're speaking specifically of being able to access –

Denise Webb - Individual - Chair

Just the documentation for the API technology. That second bullet is just the documentation to use the API technology in the process of developing this app.

John Travis - Cerner - SME

I don't think it's speaking to where the development is – I'm not trying to quibble. I'm not sure it –

Denise Webb - Individual - Chair

Oh, no. I know you're not.

John Travis - Cerner - SME

I don't think – what I read here is they're not trying to prevent business relationships between health IT vendors that may supply the suppliers of API technology. In general, their business dealings and partnering to build an app together that might use the API technology, but if we need clarification on that, certainly we can make that recommendation, but for me personally, I thought this was pretty straightforward.

Carolyn Petersen - Individual - Member

Yeah. I read it as you did, Denise.

Denise Webb - Individual - Chair

If there's something specific, John and Sasha, that you would like to recommend to get further clarity, we as a task force can certainly deliberate on that. All right. I'm watching our time. It looks like the one remaining part I want to mention on page 263, there is a recordkeeping requirement. They want to align the record keeping with the period of time that was also specified that we discussed – was it yesterday? On record keeping.

I don't know. The one question I would have, because this concerns financials, does it align with the general accounting principles and IRS requirements to align that timeframe? The

ten-year or the three-year based on certification, I believe, is what it's referencing on page 264 or duration of record, maintaining record. Do you think we need to get some clarification on that to make sure this doesn't conflict with GAAP or IRS requirements? Sasha and John, any thoughts?

John Travis - Cerner - SME

So, this is the record keeping that's general – and it kind of echoes also the record keeping that's more broadly applied to certification.

Sasha TerMaat - Epic - Member

I noticed it aligns with the rest of the certification as far as the proposal, but I didn't check it against accounting principles.

John Travis - Cerner - SME

I didn't either. Although, the IRS, what is that generally, seven years?

Denise Webb - Individual - Chair

Yeah.

John Travis - Cerner - SME

Other CMS requirements are also seven years for what substantiates a claim. Maybe it's six.

Denise Webb - Individual - Chair

Would that conflict with the three-year provision? If you're charging fees for a particular version that is no longer going to be part of certification – there was the ten-year and the three-year provision.

Sasha TerMaat - Epic - Member

I don't think it would conflict. It's possible you would keep records longer for financial reasons.

Denise Webb - Individual - Chair

Yeah.

John Travis - Cerner - SME

I didn't take any particular reaction to this. I think other things could be said for articulating which – here, it's fairly specific on stating which records. I think there is some fuzziness to the statement more generally applied for the ten-year requirement as to which records. They don't get into a lot of detail there, but that's not here.

Denise Webb - Individual - Chair

Okay. This brings us to pro-competitiveness – openness and pro-competitiveness conditions. This section discusses, beginning on 264 at the bottom through the end here, up to 272 – or actually up to 270 – and it covers non-discrimination, rights to access and use API technology.

Then there are some additional obligations. I thought this was pretty straightforward. It does refer back to some areas that are within information blocking.

I did point out to Kate earlier I think there is an incorrect reference on here. It appears on 268, 269, and again on 271. It references VIII V.3.C, which doesn't exist. I think they really meant V.6, which covers these same terms in the information blocking section. Any specific concerns –

Sasha TerMaat - Epic - Member

That's very detailed. I'm impressed you caught that that was an invalid reference.

Denise Webb - Individual - Chair

Well, I wanted to see – when they said it mirrors or reflects what's in that section, I just wanted to see if it did and it didn't. So, I was like, "This must be the wrong reference." Actually, on page 264 where this starts and it says IV: Openness and Pro-Competitive Conditions, that should really be V because IV is permitted fees. So, that's another one I caught, Kate.

Carolyn Petersen - Individual - Member

We're putting you on the Annual Report Committee next year, Denise. Thank you for proving your service.

Denise Webb - Individual - Chair

Wait until you see my hard copy. I've got these color-coded tags all over the place just so I can find things in this huge document. All right. We're doing pretty good on time here. It looks like we will get through all of – this is the last area, right, Kate, the pro-competitiveness?

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

I believe so. Let me scroll down.

Denise Webb - Individual - Chair

I know we did this a little different.

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

And then base EHR.

Denise Webb - Individual - Chair

Which?

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

The base EHR.

Denise Webb - Individual - Chair

Oh, yeah, base EHR. That one is just one small – well, not small provision, but it's just one paragraph. All right. Anything on this for the group? If not, we can talk about the changes in the base EHR definition on page 275 and then we can probably go to public comment and then talk about what we're going to do next and wrap up. So, base EHR definition – they intend to replace 170.315 G8 with G10, which is the FHIR DSTU2, and proposed as Release 2. I'm hearing silence.

Sasha TerMaat - Epic - Member

This seemed to make sense to me unless there's a flawed reference, which I didn't check as rigorously as you, Denise.

Denise Webb - Individual - Chair

The only thing I noticed – it says that it's going to replace the current criterion, but I noticed back where the regulation text is, it shows eight is now reserved like it's been replaced, but it doesn't say it was specifically replaced. The way they have this laid out, they talk about what they're changing in the regulation and then they show you the regulation text.

Just for your reference, Kate, on page 630, it does not say remove and reserve for G8. Where you actually see the regulation text, it doesn't exist any longer. Can you confirm – are you proposing that it actually be taken out or that they'll exist together until everybody's on 10?

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

They will exist together for a period of time. I can clarify that. What you're saying here is what we have as replaced may be confusing.

Denise Webb - Individual - Chair

It is because if you look at page 638, it shows 8 as reserved, meaning that it's been replaced. And then 639 goes into the discussion, the new text for 10, G10. So, G9 and G10 are the two new – I think 9, 10, and 11. No, 9 stayed the same. Ten and 11 are new. Ten is the standardized API for patient and population services and 11 is the, I believe, consent management for APIs. Okay. So, that –

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

I'm just going to point you to the definition section for base EHR. That's where it's added, section 17315 G8 or G10 until 24 months from the final rule's effective date.

Denise Webb - Individual - Chair

Okay. So, it's an intention to replace that but not until that date. Okay. So, that brings us to the end of the topics that we needed to cover today. Are there any items that we did not talk about in this area of APIs that anybody on the task force would like to bring up?

John Travis - Cerner - SME

Not at this point. I think Sasha and I have our homework to do more exploring the pros and cons around the versions of the FHIR standard.

Denise Webb - Individual - Chair

Yeah, options one through four.

John Travis - Cerner - SME

And then I'm going to send along an email that just states my confusion in support of Sasha's suggestion for clarity on what to me I feel is an almost cavalier use of terminology of words "registration," "vetting," and "access" that I'm having my struggle with and maybe it's just mine. You'll see why when I send the email.

Denise Webb - Individual - Chair

Okay. If you'll just copy everybody that's on the meeting appointment with materials that we got, that would be good.

John Travis - Cerner - SME

I will.

Denise Webb - Individual - Chair

All right. Great. Thanks. Anything else? So, Lauren, should we go to public comment now?

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

I think we can. We pulled up the phone number just to give folks time to dial in. But yeah, if there's nothing else, we'll go to public comment. If we've gotten through all the topics, I guess we can break for today. So, with that, Operator – sorry, go ahead.

Denise Webb - Individual - Chair

I was just going to say after public comment, we can just do a little wrap-up in terms of our next steps and what we're going to be doing in the next meeting.

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

Sure. Absolutely. Operator, can you open the public line?

Operator

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

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

Operator
We have none at this time.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. I will hand it back over to you, Denise.

Denise Webb - Individual - Chair
So, we do have a meeting tomorrow. We're going to be covering – let's see, is this on the next slide? We can go to the next slide. So, tomorrow, we're going to be covering the other updates of the 2015 certification criteria. We already covered the updates for the API. So, we have these four remaining areas to talk about. Besides looking at the changes in the regulation text, I was going to help you all out by pointing out where this is in the preamble.

It actually starts on – it's not in this order that's listed on the slide. So, not to confuse you, but if you start on page 77, at the bottom of the page, it starts with the electronic prescribing standard and certification criterion and then it goes through page – hold on a second – page 116, I believe.

Sasha TerMaat - Epic - Member
If we want to put in notes for tomorrow's meeting, is there a Google Doc we should put them into?

Denise Webb - Individual - Chair
Kate, we have the regulation text for API set up in the Google Doc, right?

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

Denise Webb - Individual - Chair
I know we didn't pull it up today.

Sasha TerMaat - Epic - Member
Then we have the EHI and electronic prescribing and CQMs and stuff in there too. So, we can add comments. That will certainly facilitate tomorrow's conversation, I imagine?

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Yeah. I will – the criteria one is not up yet, but I'll get that up by the end of the day.

Denise Webb - Individual - Chair
And then our meeting, I believe, is tomorrow afternoon, correct?

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Right, 3:00 to 4:30.

Denise Webb - Individual - Chair
Okay. All right. Anything else before we close out our meeting? I thank everybody for making yourselves available.

Sasha TerMaat - Epic - Member
Thank you for keeping us on task, Denise.

Denise Webb - Individual - Chair
You're welcome.

John Travis - Cerner - SME
Yeah.

Denise Webb - Individual - Chair
There is a lot of material here. It can get pretty thorny. All right. So, we'll plan on convening tomorrow. We're doing well on our schedule. I know we have two meetings scheduled next week on Monday and Tuesday and then hopefully we'll be getting some draft recommendation comments that Kate is putting together for us to review and discuss so we can finalize some draft recommendations to be prepared for the meeting on March 19th in Washington.

Sasha TerMaat - Epic - Member
Great. Thanks so much.

Denise Webb - Individual - Chair
So, we will likely try to schedule one more meeting at least prior to the in-person meeting in Washington to go over those, just to look ahead.

Sasha TerMaat - Epic - Member
Sounds good.

Denise Webb - Individual - Chair
Okay. Well, thank you, everyone. I'll dial in for our debrief, Kate, in just a minute here.

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

Lead
Okay. Thank you. Bye, bye, everyone.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Bye-bye.

Denise Webb - Individual - Chair
All right. Bye.

John Travis - Cerner - SME
Bye- bye.