Conditions and Maintenance of Certification Requirements Task Force

Transcript
March 8, 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

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good afternoon, everyone and welcome to the Conditions of Maintenance and Certification Taskforce. Hard to believe this is now our fourth call in a week. So, we are making good progress here. Let's start with a brief roll Call. Denise Webb?

Denise Webb - Individual - Chair
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Raj, I believe, is going to be absent. Carolyn Petersen?

Carolyn Petersen - Individual - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Ken is absent as well. Sasha TerMaat?

Sasha TerMaat - Epic - Member
Here.

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

Leslie Lenert - Medical University of South Carolina - Member
Here.

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

John Travis - Cerner - SME
Here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Great. We are all set to go. I will turn it over to Kate from ONC before diving into our next discussion items around, I think, two of the 2015 certifications.

Denise Webb - Individual - Chair

All right.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Great. Thanks, Lauren. Oh, go ahead, Denise.

Denise Webb - Individual - Chair
No, I was just going to say – Kate, you're going to do the brief review of our charge and then we can jump into our discussion.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Sure. Just to follow-up, yesterday, we covered the attestations and API. We have a couple of follow-up items on the ONC side that we will get back to you all with. And then I just wanted to highlight – there will be like a specific API presentation that Steve Posnack will be giving on Tuesday, March 13th, at 2:00 p.m. And in order to register, you can go to – it's on the ONC website on the MPRM landing page.

So, a quick review of the charge for the taskforce – this taskforce will provide recommendations on API, real world testing and attestations conditions and maintenance of certification requirements, updates to the 2015 Edition certification criteria, including API, electronic health information export, e-prescribing, clinical quality measures export, and two privacy and security-related attestation criteria, also look at the modifications to the ONC Health IT Certification Program, and any deregulatory actions related to certification criteria and program requirements.

I'll turn it back to you, Denise.

Denise Webb - Individual - Chair
All right. So, I thought to go through – if we go to the next slide – we're going to go through these remaining updates to the 2015 Edition certification criteria.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
This slide is just like an overview.

Denise Webb - Individual - Chair
Oh, okay. Do you want to go over this slide for us, Kate? Maybe what we could do is pull up the regulatory text and step through it. That might be conducive for this discussion today and then we can reference the preamble. The preamble for this today is on pages – hold on a second so I can get everybody on the same place – it's pages 78 through 107.

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

And Denise, we have the Google Doc now too, right? We can take notes in it.

Denise Webb - Individual - Chair
Yeah. That's what I was suggesting.

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

Denise Webb - Individual - Chair
If we could share the Google Doc – are we able to do that, Kate?

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Yes, I can share my screen.

Denise Webb - Individual - Chair
Okay.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Do you want me to go ahead and walk through some of these slides? I'll just explain.

Denise Webb - Individual - Chair
Yeah, if you don't mind. That will launch us in to cover these items. I would highlight the ones that we're going to talk about today.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Okay. So, this slide here is proposed changes to the 2015 Edition certification criteria. This includes more than the few items we're going to discuss today. It goes over the base EHR definition criteria under the removed criteria, other criteria, and then we will get into more of these discussions when we talk about the deregulatory actions and proposals that ONC made to remove certain criteria.

And then the blue box here is the updated criteria. So, for instance, we'll talk about e-prescribing today and API. And then if you look to the right of that, there is the revised criteria. CQMs we will discuss today. And then new criteria – the first two are the two privacy and security attestation criteria that we will discuss and then the third one is consent management for application programming interfaces. Okay. The next slide…

Denise Webb - Individual - Chair
Just out of curiosity, I know we have to talk about the two new security criteria, but are we covering consent management for APIs?

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
So, we included that –

Denise Webb - Individual - Chair
Well, then we already covered that.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
That's more included in the discussion for the data segmentation for privacy, which I believe another taskforce is covering, but I can double-check on that.

Denise Webb - Individual - Chair
Yeah. I didn't see that one was on our list. Then the real big one today is around the data export changes.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Yes. Should we go through the slides or do you want to jump into the reg text and start the discussion?

Denise Webb - Individual - Chair
I think just so we make a good use of our time and get through what we have to discuss – because I think we're probably going to have a lot of discussion on the data export with our representatives from the vendor community.

John Travis - Cerner - SME
That's a good guess.

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

Denise Webb - Individual - Chair
So, if no one objects, why don't we start walking through? I think we're starting with data export. Is that correct? If I remember looking at the documents last night…

John Travis - Cerner - SME
Very basic. Do you know what page of the display copy you're starting on? I can certainly find it. I have it open.

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

Designated Federal Officer
88.

John Travis - Cerner - SME
88. Thank you.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Can you all see the…?

Denise Webb - Individual - Chair
Yes.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
You can see the screen?

Denise Webb - Individual - Chair
Yeah. All right. So, this update to the regulatory text would replace the existing data export regulation text. This is going to focus on two use cases, data export for a single patient and that would be all of the patient's EHI. We had quite a hearty discussion on information blocking and the definition of EHI. And then the second use case is around exporting all of the EHI to support a customer moving from one product to another product.

So, if we start here with the single patient electronic health information export, why don't we discuss A, B, and C here? My computer is going wacko here. So, why don't we discuss the first use case around single patient electronic information export and any comments, recommendations, or major concerns with this requirement? Go ahead, Sasha.

Sasha TerMaat - Epic - Member
Sure. So, this is Sasha. I've given extensive thought to this proposal and thinking with colleagues here about how to implement getting a patient all of their exported data. I think even though they don't necessarily tie to the regulatory text, there are several buckets I'd like us to consider kind of thinking about.

One – and this is, I guess, one where I'd just defer to the clinicians – but it seems to me that this criterion sort of implies that everyone has implemented open notes. Notes would certainly be within the export format. So, that would, I guess, from an implication perspective, any of the patient's historical notes would certainly be part of the content that was exported. So, I think that kind of is one thing that clinicians want to think about.

It leads to a secondary concern, which is partly about notes but partly about other content, which is that as a health system implements this export, how would they ensure that they weren't accidentally exporting electronically something that was not allowed by their state

law to be released electronically.

So, I think there's a question of how this export of all the data, which is much broader than other types of criteria we might have talked about and the standard for filtering those appropriately would be there and then how that sort of jives with compliance with other regulations and legislation.

I think there are some particular categories of data that will get tricky there. I can give a list, but I don't know if we want to dig into those first.

John Travis - Cerner - SME

I've got a similar point, Sasha, but it's kind of part philosophical and it's part pragmatic. I kind of was holding this for the Volt case, the second use case, but it really applies to both because they both have the same breadth.

So, if I'm not mistaken, basically, the concept is that the export needs provide for the ability to produce an electronic output of all the data that is held within the certified EHR module that is presented for certification. So, there is a terrific –

Sasha TerMaat - Epic - Member

John, is it limited to the certified EHR module or is it all data in the system that has a component presented for certification?

John Travis - Cerner - SME

That's probably a good point of conversation. So, the way I understand this, it is bounded to the certified system, I think, because that's what brings about the requirement versus the information blocking provisions that do extend everything. So, there's a difference, I think, between the export criteria that I think is practically limited with data held by CERT, which I want to get into a little bit. And the information blocking provision extends to everything certified or non-certified that the vendor, who is seeking certification or holds certification, offers to market.

So, I think there is a difference there. It's an important one because you have to produce the semantic reference information about what export requires. It seems greyer when you get the information blocking. I agree – in some ways, there's not a lot of tangible difference if you are approached to enable an export or to enable an electronic disclosure or an extraction, whatever you want to call it when you get to the information blocking rules.

But honing in on the data export, I'm not sure it extends to everything you do. I think it extends to all data types held by the certified EHR technology that you have presented for certification as a practical matter. I realize this intended to be more of an attestation. It's not very testable as it is, other than by that. It speaks to being able to be able to meet the demand to produce an export, but you actually have to produce the export inclusive of the reference map or whatever supports the semantic understanding of what the data is, but I do think there is a boundary on it.

Now, the existential question in here is they speak of it's not limited to the USCDI. It is all data held by CERT. So, the important question to me here is if that's correct – and that's probably worth finding out – but if it's correct, then there is a burden on the vendor practically to find that. So, for example…

Denise Webb - Individual - Chair
So, John, can I just interrupt for a minute?

John Travis - Cerner - SME
Sure.

Denise Webb - Individual - Chair
There is a definition of EHI. It refers to the EHI that's held in the certified technology.

John Travis - Cerner - SME
Correct. I understand that.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
I pasted it into the comment too just for reference, if that's helpful, or I could put it into the blue below if that's useful.

John Travis - Cerner - SME
Here's my point about that remark – it doesn't suddenly enable the presence of EHI that's not present. So, you use the definition of EHI to inform what information is held by CERT. But here's the problem I have – two problems – one is there still is a practical definition of what is held by CERT. So, integration doesn't mean inclusion. I think for both Epic and Cerner, we're integrated models. We have revenue cycle. We have supply chain. We have ancillary systems that are not part of CERT.

This is why this matters – if I accept it at face value to apply to everything in a physical sense held an integrated data model and I draw no distinction about what is within the scope of CERT and what is not, then Sasha, you're absolutely right. There's no distinction. It's everything. But that is a mighty distinction compared to the statement that it's held by CERT because revenue cycle, by in large, is not part of CERT. Many ancillary systems are not part of CERT. Supply chain is not part of CERT, ad nauseum. So, this matters. It's a big difference.

Sasha TerMaat - Epic - Member
Oh, it definitely matters. It's hugely important. I guess I was worried because – and I agree with you that the distinction is critical. But I was worried where they say the health IT's entire database, including but not limited to clinical, administrative, and claims billing data, there's no implication that claims or billing data would ever be part of CERT. So, the preamble language was making me think they intended a broader scope.

John Travis - Cerner - SME

I agree. On my first reading, that was my reaction. But it needs to be very cleared up.

Denise Webb - Individual - Chair

I think we're getting into – on the two use cases, there's the one for the patient. I don't believe you're going to give an export of the entire database to the patient.

Sasha TerMaat - Epic - Member

They say that the scope is for both of the use cases and then it would just be limited to data about the patient for the patient use case. But they say it would cover the whole database. So, in theory, I read it as saying if you had claims about the patient, you should export those too.

John Travis - Cerner - SME

I agree. I don't think they're drawing a distinction of scope based on use case.

Denise Webb - Individual - Chair

Okay. So, what I hear you both saying is that sounds like a concern that we should make a note on. While I can see this, I don't have a way to put notes in here. So, hopefully, Kate, you're capturing these notes or someone is.

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

I can add that.

Denise Webb - Individual - Chair

So, one of the major concerns here is the scope of this export. Is it data that is collected and retained in the certified portions of the product or is it really intended all data, whether the product is certified or not and does that fit within the authority of the certification program?

John Travis - Cerner - SME

That's essentially it. If there is a practical or at least, let's say, a conceptual definition of the boundaries of CERT, I have no dispute that it's all data held within that boundary. That's EHI. My issue is does it extend – which, by contrast, the Information Blocking Provision does, but it is a big difference – does it reach non-certified EHR technology?

I want to use the phrase and I suggest it to be used – integration does not mean inclusion, if that's true. But that does suggest there's a burden on the vendor to offer a practical statement of how they identify the boundaries of what's held in CERT. I understand the point that Sasha was raising. I had to think about five times about that, but the way I realized it is if there is a capability within the scope of the certified product, it depends on utilization of kind of an auxiliary table space or data mart, that's part of it as well.

So, for example, in our architecture, our main line product for our clinical EHR is most of what we do, but we do have measurement capabilities that actually will be in a distinct database, but within the scope of the same EHR module. So, when we present it, both of those are in play, but that doesn't mean suddenly our revenue cycle is in play and our supply chain is in play.

Those are integrated into those systems, but they are distinct tables, distinct data types, and they can't be parsed out from what we would enable for export here. So, that's the key practical difference that we need to have clarity about.

Denise Webb - Individual - Chair
Or they may not be integrated at all.

John Travis - Cerner - SME
Yeah, the integration doesn't matter. My reaction probably is a bias towards being integrated. That could be what's good for the goose is not good for the gander just by virtue by integration. It doesn't mean suddenly I'm in a different boat than somebody who's not, where clearly, there's a physical distinction and it's easy to say, "Well, that over there is not integrated and it's not certified. So, don't worry about it."

I don't want to be punished for the fact that it is integrated and it's not CERT. That doesn't make any sense. I'm not complaining. I'm just saying that's why the distinction matters. I think if somebody wants to go to the place of thinking, "Well, it's anything that's integrated with your CERT." No. It's not CERT. That makes a big difference to the way I would scope my response to this to go to test for it.

Denise Webb - Individual - Chair
Yeah. I was just going to comment – you know, the health system I came from happened to be on your product, but the revenue cycle was totally separate. So, it was a different product.

John Travis - Cerner - SME
And it certainly can be.

Denise Webb - Individual - Chair
Yet, it's interfaced. So, there are a lot of health systems that use a different revenue cycle product. So, that would have billing and claims-type information for a patient. All right. I don't know if we need to beat a dead horse here. I think the point is well made that there needs to be some clarification or some consideration about this issue.

John Travis - Cerner - SME
Yeah.

Sasha TerMaat - Epic - Member
Do we need to comment about the other provisions with both implications in mind? I guess

it's pretty different if it's CERT or if it's the whole system.

John Travis - Cerner - SME
I think we certainly can ask for clarity and if there are things to play out, assuming either, that's fair game, certainly.

Sasha TerMaat - Epic - Member
Okay.

Denise Webb - Individual - Chair
So, what I'm hearing too, though, is if there is clarity provided in the final rule, that, "Here's what the boundaries are," and it's further defined, then – we're having bleed over or somebody needs to mute their phone.

John Travis - Cerner - SME
Yeah. I don't know where that's…

Denise Webb - Individual - Chair
So, the function of exporting the data is still satisfied – could still satisfy whatever the definition is or boundaries are.

John Travis - Cerner - SME
Yeah.

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
If we could have everyone mute their lines, please. If not, we'll have the operator mute for us. Sorry, Denise. Go ahead.

Denise Webb - Individual - Chair
All right. So, Sasha, are you suggesting that we need to – I'm sorry. I got distracted on what comment you wanted to make.

Sasha TerMaat - Epic - Member
Yeah. I guess my question is we do need clarity about if the scope if CERT or if the scope is all integrated products for the reasons that John described. I'm wondering as we talk about the feasibility and challenges of some of the other components of this, should we be assuming it's one way or the other or comment on it with respect to both?

Denise Webb - Individual - Chair
Well, what would we – okay, considering the information blocking portion of the rule, would we want to recommend that this export function only was for EHI that is collected and retained by the certified technology?

John Travis - Cerner - SME

I would…

Denise Webb - Individual - Chair

I don't think that's their intent, to tell you the truth. It would be in conflict with the information blocking expectation.

John Travis - Cerner - SME

Well, not necessarily.

Leslie Lenert - Medical University of South Carolina - Member

So, what's the purpose?

John Travis - Cerner - SME

So, personally, I would favor that constraint on certified EHR technology is the data export criterion. I think the reason I say that is that I accept it as non-trivial to provide the semantic reference information about what is being exported. That needs to be computable. Here's where I go there.

The Information Blocking Provision, setting aside whether or not it's perfectly scoped or not, it pulls in, quite simply, everything that you have as an application or a product. At least in our thoughts about it, from what we'll comment as an organization, I think there are some things we'll look to raise there that are pragmatic problems with that assumption, but we do understand its scope that's proposed.

But it reaches legacy systems. It reaches systems that you might have deprecated. It reaches systems that may be old versions of currently commercially offered products. There are a lot of things that are challenging about taking it at face value if you're going to hold it up to the data export criteria.

While they don't propose a standard, which is probably wise, given the form of what the data would be in a lot of those older systems, to apply the requirement for semantic interoperability or a data map, whatever, to everything that's in an inventory of what an HIT vendor may have could be very challenging in any useful way because there is basically the requirement that it's computable.

Well, whether I'm embarrassed or not to say it, we still have some products that are original generation that are COBOL file formats that I'm not sure about the computable part of that on the part of a recipient unless they've got an ability to interact with some pretty old computing technology.

Denise Webb - Individual - Chair

Did you read that it had to be computable for the patient extract?

John Travis - Cerner - SME
For the bulk one.

Sasha TerMaat - Epic - Member
I did, Denise. I think the idea is a patient app might be able to parse it.

John Travis - Cerner - SME
The patient one too, I think.

Leslie Lenert - Medical University of South Carolina - Member
It's more than that. I think that a patient should be able to take their records on whatever portable electronic drive and essentially upload them to an EHR. I think that's what they're saying is the patient is the vehicle of interoperability.

John Travis - Cerner - SME
I agree.

Denise Webb - Individual - Chair
Les, was that you speaking?

Leslie Lenert - Medical University of South Carolina - Member
That's Les, yeah.

Denise Webb - Individual - Chair
Thank you. I didn't recognize your voice. Sorry.

Leslie Lenert - Medical University of South Carolina - Member
That would probably be the first time you heard it.

John Travis - Cerner - SME
So, I think the export criteria is written substantially with contemporary systems in mind that have more evolved capabilities, let me just put it that way. It is a significant reach. They do talk about, I do believe, in the export section whether or not it should have the same breadth of applicability as does in the information blocking provision. So, they do raise the question. But I think that speaks that they do understand there's a difference in what they propose and the information blocking scope.

So, I think to me, the right answer is it's all EHI held by CERT for purposes of export and it applies to both use cases and it does require a processable output that has the semantic reference information that accompanies the data. I don't have any – that is what it is. But that does not extend to everything that you do.

I think there's a large open or pregnant pause relative to the broader requirement of information blocking that puts the task to the vendor and the requester of the data to work out how the data will be provided without getting into saying how it will be provided. It doesn't get into speaking to the semantic reference information requirement the data export does unless I missed something. So, there's a difference.

Denise Webb - Individual - Chair
So, I think we have a good sense of what the concern is here and can capture that in a recommendation.

John Travis - Cerner - SME
Okay.

Denise Webb - Individual - Chair
There was a couple of things that Sasha said that I would like to respond to, some thoughts around what is in the export versus the breadth of the export. You mentioned open notes, Sasha.

Sasha TerMaat - Epic - Member
Yeah.

Denise Webb - Individual - Chair
So, notes – I think OCR and others have been pretty clear about this and patient advocates that the notes in a patient's medical record, those belong to the patient. I know some health systems, the providers have been forthcoming and provided to the Open Notes Initiative, provided notes to patients. And others refuse to provide their notes to patients because they don't have good hygiene in the terms of how they might write their notes and they might put things in their notes that offend patients.

So, on open notes – I don't know what the rest of the group thinks – as far as the notes in a patient's records, unless we're talking about psychiatric notes – and actually, you're correct about state laws being different in every state concerning mental health treatment and that's an issue and we should probably highlight that, that you can't necessarily export everything that a patient asks for. We do have to reflect on what the laws of the state are. So, how does that vendor handle that? That's probably the more salient point.

Sasha TerMaat - Epic - Member
Yeah. My thinking, Denise – this is just speculation to help folks have context – I think that my approach as a vendor would be to provide a query that could be used for this export that could be edited by a health system for several reasons. One would be if they need to restrict certain types of communication like psychiatric notes to be filtered out.

Another reason to edit would be if they have any usage restrictions on data that's stored, it maybe gets somewhat back to the debate John and I were having about what's in CERT or if it's all data, but sometimes people will import data like a claims set from a payer that has a

redisclosure usage restriction.

So, if there are other data sets that would have to be filtered out, if they live in a state where a certain piece of information like a sensitive test result is not allowed to be released electronically, they could edit it to filter that out. If there's a teenage privacy type of restriction, where the patient could see the teenage pregnancy test result, but the parents can't, but only in certain ages or certain states, the health system would have to accommodate those types of edits as well.

But then I guess the question is regardless of who's doing the edits, whether it's the developer providing standard tools or configuration methods or the health system trying to do that, is it practical to effectively restrict this broad of an export in compliance with what might be 50 permutations of state law? I think that's a reasonable question for us to ask.

John Travis - Cerner - SME
I agree.

Denise Webb - Individual - Chair
You mean in terms of making a recommendation that there needs to be further elaboration?

Sasha TerMaat - Epic - Member
I think the challenge part – yes. I think the way it is currently proposed, health systems will be at high risk of either restricting what they release too much and then they are at risk of information blocking. If they said, "I don't know if this PDF that I have in the system is a scanned psychiatric note from another system or contains a sensitive test result or not, so I'm not going to release it," then they're at risk of information blocking because they didn't provide enough information to the patient in the preferred format.

But if they don't restrict and they say, "I don't have discreet metadata about what's in this PDF. It might be a test result the patient wants. I'll release it electronically as apart of this export." Then they're at risk of being found in noncompliance with a state law that says you can't release that type of test result electronically.

John Travis - Cerner - SME
Yeah. There are many use cases like that, Sasha. One that seems to have come up in spades for me in my week here is the one where the patient – things that would fall under the privacy exception for information blocking that have to do with patient requests to withhold information from their health plan.

So, if the purpose of the export was to provide information to fulfill a payer request and they wanted to make use of it, they'd have to understand where those restrictions exist. There are just a lot of those types of cases. So, the practical use of this out of the box as is, unless it's the kind of approach that Sasha mentions, is going to be highly problematic to produce with fidelity what is being asked for, just as a matter of selection criteria, never mind scope of content.

Carolyn Petersen - Individual - Member
So, this is Carolyn.

Denise Webb - Individual - Chair
Carolyn, go ahead.

Carolyn Petersen - Individual - Member
It sounds like there's quite a lot of good points and important points to take into consideration as we frame this comment. One thing that we shouldn't ignore is the context in which the patient requests for information and expectations of information release. It's true that some health systems are not wanting to provide information in notes because of hygiene or whatever other issues, but the environment is such that I think the trend is going to be forward for more of that to be going on and for patients to be expecting that more.

It's not an environment in which that will be happening less and less, but maybe this is enough to take into consideration. Even with the later adapters, patient expectations of getting information are going forward and that's something that ONC needs to be thinking about as they clarify and pull these things together.

Sasha TerMaat - Epic - Member
Carolyn, I think one thing that would be helpful to that effect would be – in a parallel effort, perhaps, on harmonizing state restrictions and laws. Actually, I think if patients saw what their state policies were on restriction of electronic communication of certain things, they would feel, as you described, that the policy is not consistent with what they would demand as patients and as consumers.

But I think that it is a tough spot to try to provide what patients are looking for, which might be all the data right away, and be at risk of really other regulatory or legislative obligations as a health system.

Carolyn Petersen - Individual - Member
And certainly, there needs to be consideration to all of those types of jeopardies that health systems can be in and providers can be and the challenges for vendors. But even if consumers understood that there were very complex regulations across 50 states that made the technology hard to do the things that are required under law, it seems unlikely to me that consumers as a population would throw up their hands and say, "Oh, well, gosh, it's so hard. We just don't ask for our data anymore." I just don't think that's a realistic…

Sasha TerMaat - Epic - Member
No, I think we should go the other direction and say that if consumer demand is for the data, then we need to deal with the other policies like the state laws that make that challenging. Exporting all the data is much easier from a technical perspective than attempting to know what might be in this PDF an whether releasing it electronically is in violation of state law, right?

Denise Webb - Individual - Chair

Well, you know, I think – I'll just say just from my experience in my last role – all releases of information were handled through the Health Information Office because of things that you've brought up, Sasha, like state laws.

They do release an entire electronic record because I just moved from one health system to another and I asked for my entire record. It's in PDF. It does say here on page 94, no matter the electronic format, PDFs are included. The function of those HIM folks is to review the information before it's released to the patient so that they know they're in compliance with the law.

So, I think it needs to be acknowledged in the rule that this export has to be designed in a way or processes have to be in place that are – the release of the information is accountable to ensure that the information that's released is allowed to be released. I don't think we're going to solve this. I know the Federal Government is not going to get into the business of the states' laws. While we'd like to have them all harmonized, that's a state-by-state issue.

Sasha TerMaat - Epic - Member

I do think, Denise – I agree – but I think manual review is the process by which health information management departments handle this today. I think that that could be an answer to the, "How do I release enough but not too much?" question a health system will face, but it doesn't jive with some of ONC's other descriptions of this functionality, like the expectation that the export would be available in near-real time.

I guess that to me says that they're not picturing a step up and then it's queued up for someone in the Health Information Management Department to read over it and make sure it's not accidentally releasing something electronically that state law prohibits.

Denise Webb - Individual - Chair

Yeah. But it doesn't say near-real time, even. It just says timely does not mean real time. But if you're going to take three weeks to give your patient their data, well, that's not timely. I think if a patient makes a request for their data and they can get it within 72 hours, that's probably reasonable because of these manual things that are going to have to occur.

You're absolutely correct about the state laws and the filtering. You as a vendor can't just give an export function and say, "Well, here you go," and just let the patient go into the portal and download everything because your customer is going to have a problem because they're probably going to be violating some state laws.

Sasha TerMaat - Epic - Member

Yeah. Well, I think that would make sense. That would also help with some other data categories that I was thinking about with respect to the export, like if you have any shared data, like group therapy, notes that might be shared, linked mother and baby documentation, anything where there's shared information, I was thinking, "How do you

handle that with an export? That's going to be tough." I was also thinking about in progress stuff.

So, like if someone is halfway through a note when the patient says, "Give me my export," do you give the half-finished note? Do you have a time window to say like that wasn't done? How do you finish if someone is midway through their admission and wants their stuff but nurses might be like halfway through an assessment, people might be halfway through a procedure note, all of those types of questions.

Denise Webb - Individual - Chair

Well, I don't think those are considered part of the medical record until they're signed.

Leslie Lenert - Medical University of South Carolina - Member

I was going to say the same thing.

Sasha TerMaat - Epic - Member

It's the medical record. I guess I heard electronic health information as broader than the medical record.

Denise Webb - Individual - Chair

Well, there's another thing to clarify. It's something that is official and signed.

Leslie Lenert - Medical University of South Carolina - Member

Do we need to focus on this idea of distinctions of the types of data in the medical record between administrative, clinical, and research that those three categories are very distinct, that they all could be in electronic health information system, but the providence of those is very different. Was the intention here to include all the administrative data that might be relevant to the patients like the nurse who was on the patient's shift?

Denise Webb - Individual - Chair

Yes. It says, Les, on page 94, "For both use cases supported by this criterion, EHR export encompasses all of the EHI that the Health IT system produces and electronically manages for a patient or group of patients. This applies to the Health IT's entire database, including but not limited to clinical, administrative, and claims billing data. This is what launched this concern that John and Sasha have to begin with is that goes beyond CERT because a number of these data types are not generated via certified product that's governed by this regulation.

Sasha TerMaat - Epic - Member

Yes. They ask particular questions about that also. So, for example, there's a whole discussion of the value of diagnostic images for patient export, but ONC acknowledges that those are typically stored in a PACS system, not in an electronic health record, and would the health record be able to export it and, I guess – this seems like a straightforward answer – but I think the health record can only export data that's in the health record.

Leslie Lenert - Medical University of South Carolina - Member

That's a good point. I think this idea – I'm a little puzzled as to the rationale for needing to export the administrative data.

Denise Webb - Individual - Chair

Administrative data can include claims, billing. EHI is defined as to include payment, prior, current, and future expected. The kind of conundrum we're in here right now with this regulation text is that it refers to certified technology and what the EHR would have to be certified to to provide this export function.

But the export function seems to more broadly address the Cures Act in terms of providing all the EHR to the patient or to the health provider who wants to move to a different product. That extends beyond the product that's being certified. So, I think that's really kind of describing what the issue is here.

Sasha TerMaat - Epic - Member

Yes.

Denise Webb - Individual - Chair

And that would capture the issue about images, right, Sasha?

Sasha TerMaat - Epic - Member

I have them separately written down in the notes, but I think they are very interrelated. If we limit to certified EHR technology, that probably solves the images problem also. But I have two proposals, actually, if Kate scrolls down to the text box. I tried to organize our notes to say first what were we proposed – well, we had a question for clarity.

We had two proposals. And then I have a whole bunch of discussion notes just so that we remember what we talked about. There's the question, there are the two proposals I documented, and the discussion notes start there and go on to the next page.

Denise Webb - Individual - Chair

Okay. Thank you.

Sasha TerMaat - Epic - Member

Yeah.

Denise Webb - Individual - Chair

So, they do ask on page 96 – I want to make sure I got all the places where they were seeking comment. They did ask – I don't know if anybody has any thoughts on this – on who could ask for the patient's data and should that be limited. Carolyn, do you have any thoughts on that? This is on page 92 in the preamble, "We seek comment on whether this portion of the criterion should be made more prescriptive."

This is where they're saying the healthcare professional or his or her office staff or a sophomore program or service could interact directly with the certified health IT to provide and be the user to do this export on behalf of the patient. They're seeking comment on whether this portion of the criterion should be made more prescriptive to only allow the patient and his or her authorized representative to be the requester of their EHI.

Carolyn Petersen - Individual - Member

I think if you do make it more prescriptive, more restrictive in that sense, you can reduce the potential for fraud and for – I don't know that identity theft is the term – but for getting some information about someone out of a place where they think it's secure for purposes the patient doesn't support. At the same time, I suspect some providers would be concerned because they would find it inconvenient to have to actually contact the patient and get permission.

Normally, we all sign those forms when you go in for a website. But if someone has some kind of an emergency situation or perhaps there is a custody issue with a child, for example, and the dots are not being connected in terms of who can authorize release of information or request certain things. I mean, I think in general, it would works best for patients in the average case to be able to make those requests and decisions themselves, but the world is not made up of standard cases.

Denise Webb - Individual - Chair

Well, I don't think this precludes other releases of information or other release processes. Isn't this specifically referring to the EHI export of a patient's entire record at the patient's request?

Sasha TerMaat - Epic - Member

I sort of read this language, this question, as should a patient be able to go into something like a patient portal and say, "Give me my export," with a button or should the patient be able to ask their doctor or someone in medical records at the clinic like, "Hey, please provide me my export," or both.

Denise Webb - Individual - Chair

Yeah. That's a good point. I don't know if this has ever happened to any of you, but I've been in an office visit and I said, "Oh, could you print that off for me?" And I've been told, "No, you have to go request it and fill out a form," where the provider wasn't able to do it on my behalf. So, if that's what they're referring to here, then I think providers should be able to do it on behalf of the patient.

Carolyn Petersen - Individual - Member

Yeah. It's a conundrum. I think certainly, patients should be able to go into the portal and request that record and the information. But I don't know that that is necessarily a change from what they can request today, at least in some places, in some implementations.

Denise Webb - Individual - Chair

All right. Any strong feelings on this that we need to make a recommendation?

Sasha TerMaat - Epic - Member

The one thing – I guess going slightly earlier – Denise, you and Les had called out the difference between a legal medical record and this proposal. I didn't capture a proposal on this. Are we proposing as a group that this should only apply to electronic health information that would be part of the legal medical record?

Denise Webb - Individual - Chair

Yeah. I think that would be a good recommendation because, you know…

Leslie Lenert - Medical University of South Carolina - Member

No, it should be limited that way.

Denise Webb - Individual - Chair

Yeah. It would address that issue of a note that's in progress that hasn't even been signed.

Leslie Lenert - Medical University of South Carolina - Member

And it would address the issue of research information in electronic health records, which should not be released.

Denise Webb - Individual - Chair

Unless you're part of All Of Us or whatever that project is. They're actually providing patient information from the research project.

Leslie Lenert - Medical University of South Carolina - Member

Yeah. Again, that's a different type of release. But if you accidentally release research-related results and they're disclosed inappropriately that are not part of the medical record, then that's a liability issue too, for example, an HIV test that was performed as part of a research study.

Sasha TerMaat - Epic - Member

I agree with – I see why you're proposing that and I agree, it solves the problem of like a note in progress. From a technical perspective, it adds another layer of complexity to the export because the query has to differentiate. Again, it has to allow for some amount of editing and filtering for state law, but then also for organizational policy, determining what would be part of their legal medical record.

John Travis - Cerner - SME

This is John. I think since this is a certification requirement, not a user requirement, its intent is to set up kind of an outer bounds on what's possible to accommodate those differences. It doesn't dictate to us necessarily a technical design, but I think its spirit is definitely that it's definitely intended to be broad enough that the capability is there that can be configured and adapted to fit to those types of requirements.

So, I'd want to be a little careful about limiting – as much as I know what I said about scope of EHR and data held by and all of that, I think they are trying to make it broad enough to deal with the vagaries of difference that's going to occur at the state and local level or at the organizational policy level.

Sasha TerMaat - Epic - Member
Right. And no one EHR developer would be able to create one export query that would accommodate every possible state and local variance, every possible healthcare system definition of a legal medical record, any possible usage restrictions on data that might be in an EHR.

So, I think kind of implicit in the complexity of this proposal is that there will be a role for healthcare organizations to sort of define what they're putting into the export and then potentially, as Denise suggestion, have a medical records role in reviewing that. If it can't be automated, what should be in and should be out and needs to happen through manual review?

Denise Webb - Individual - Chair
And I know like Marshfield, they send PDFs, electronic PDFs. So, they were able to review it.

Sasha TerMaat - Epic - Member
Right.

Denise Webb - Individual - Chair
It was a useful format. As a patient, it's a useful format to then take to the next provider.

Sasha TerMaat - Epic - Member
PDF wouldn't meet this requirement, though.

Denise Webb - Individual - Chair
They mentioned PDF in here. They don't dictate the electronic format.

John Travis - Cerner - SME
But it does have to be processable.

Sasha TerMaat - Epic - Member
But it has to be computable in D, Denise.

Denise Webb - Individual - Chair
Oh, Okay.

Sasha TerMaat - Epic - Member

So, I'm picturing that it would be something like maybe a giant XML file. Who knows? I guess that's left open to whatever the developer would decide was most suited.

John Travis - Cerner - SME

Yeah. I could see that being a way. But that also gets back to some practical questions about the contemporary – I think an assumption made of it was it's a fairly contemporary level of technology and not some old 30-year old COBOL-based…

Sasha TerMaat - Epic - Member

Right. Well, and another –

Denise Webb - Individual - Chair

Well, that actually kind of contradicts what's on page 92 of the preamble, where it mentions PDFs – excuse me, page 94.

John Travis - Cerner - SME

That might be how it's provided. Again, I think what we need to remember – with certification, it's about capability, not prescribing use. That may be for a number of reasons. The patient may ask for it as a PDF. The patient may ask for it in a form that can't be provided and that's the negotiated settlement. Those are all things that are possible. But as to the capability that needs to be present in a certified system, they are after it being something that can be processed that carries with it the structured reference meaning of what is being produced.

Sasha TerMaat - Epic - Member

Yeah. I read this reference to PDF, Denise, to say something like if you have PDFs scanned into the database, those are also provided, not that you could convert to a PDF.

John Travis - Cerner - SME

Right.

Denise Webb - Individual - Chair

Got it. Okay. Thank you for that clarification.

Sasha TerMaat - Epic - Member

But I do think that –

Denise Webb - Individual - Chair

I just reread it and you're right.

Sasha TerMaat - Epic - Member

Yeah. I do think that including PDFs like other unstructured data is challenging from a perspective of the filtering that we talked about earlier, right? If a patient's record has a bunch of different PDFs that are pathology results from some other system attached, the

exact content of what's in the pathology result PDF is not sort of know to write a programmatic filter and will be a case that goes back to that manual review.

Denise Webb - Individual - Chair

Okay. All right. I'm watching our time because we do have some other things to get through. I want to make sure we cover some of the other comments that they're looking for here. They have a list of data that would not be included. I know there's probably other data we've already said we don't think should be included based on how broad this is, but this is on page 95 and 96 and they were seeking comment on whether…

"We also seek comment for consideration in finalizing this criterion and the subsequent final rule on types of EHI that may present challenges for meeting the intent of this proposed criteria." Other than what they've listed, they've listed metadata or things that would not be included.

Is there anything else we want to add or do you think we've covered our landscape in terms of our concerns on types of data?

Sasha TerMaat - Epic - Member

Well, one thing that hey asked about for comments, I think, was like audit trail data, which they said was not expected. If I recall correctly, audit logs are not expected in the export. They asked for comment on it. I think the challenge with that type of data, which might be in other parts of the EHI also, but it's the privacy of all the other parties who are working at the health system, for example. So, it's something to think about if we decide to recommend audit logs be in.

Denise Webb - Individual - Chair

And actually, I think –

John Travis - Cerner - SME

And I – sorry, go ahead.

Denise Webb - Individual - Chair

I was going to say that on the export for the database export, not the single patient, I would think that the health system would need the audit logs included if there were any investigations.

Sasha TerMaat - Epic - Member

That's a good point. Maybe we would recommend it for the transitioning systems use case but not the patient use case.

Denise Webb - Individual - Chair

Yeah.

John Travis - Cerner - SME
Yeah.

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

Sasha TerMaat - Epic - Member
I'll put that in as a proposal.

Denise Webb - Individual - Chair
Okay.

John Travis - Cerner - SME
I don't know that I noted anything else. I know they don't get into this. The only other thing that comes to mind is – I think the discretion is there and maybe it's a comment of support or a statement that assumes this and makes a supporting statement, but the provision of the semantic reference information is not a – as much as the data might not be a singular concept because of the form by which it's stored or sourced, so is the provision of the reference information about it. I don't believe they get into stating that it needs to be singular in how you produce it, but I think it's important that it's –

Sasha TerMaat - Epic - Member
Doesn't have to be posted proactively on your website, though, John? Which would imply to me that at least a superset or something is standard and available.

John Travis - Cerner - SME
It may be comprised of more than one reference. Like, if you're going to post it through a wiki –

Sasha TerMaat - Epic - Member
No, I agree. I mean, depending on what products a particular system had licensed, I guess, if it's not just the CERT thing, but even in that case, the documentation practices and integrations would vary the data that's going to be in any given export.

John Travis - Cerner - SME
Exactly.

Denise Webb - Individual - Chair
Yeah. So, there is a requirement to provide documentation about the export format. They do say you can protect your proprietary data model depending on what your export format looks like. And then one other area that we do have to address is timeframe. They are using the same two-year timeframe.

So, on page 98, ONC seeks input on EHI export and timeframes and particularly beyond

exporting all of the EHIs that the Health IT system produces and electronically manages. Should this criterion include capabilities to permit healthcare providers to set timeframes for an EHR/EHI export? Not for your development, but this is more for them to set timeframes.

Sasha TerMaat - Epic - Member

Yeah. I guess my understanding what if you wanted to say like, "Wow, your download is going to be super big. It's going to be like 100 megabytes or whatever," would you prefer to just get your most recent years' worth of data and that's only 20 megabytes instead of the whole thing, something kind of along those lines. I think it could be advantageous – I assume this isn't prohibited – health IT developers and providers might want to offer other options for patients.

So, you might want to say if you're really interested in a certain type of data or you don't care about the PDFs that are attached or whatever and you can get it faster either because it goes through manual review in the Health Information Management Department faster or the query runs after over a smaller data set or the upload is faster because there are not as many images, or whatever.

I think that could be advantageous. I could see why providers and health IT developers would offer it. I wouldn't offer time range-based filters. We know from the view, download, transmit criterion that time ranges are deceptively tricky that way because if you pick a time range that doesn't really jive with the time ranges of medical activities, it's really complicated. Like if you say, "Give me the time range of data that…"

And one of the dates falls right in the middle of an admission, do you parse the data from the admission to half be in and half be out? How do you even distinguish that? Is it even what they really wanted?

So, I think I would say don't require specific time ranges. We've learned from the view, download, transmit realm that that introduces more complexity, maybe, than was anticipated.

Denise Webb - Individual - Chair

Well, why don't we make that as a recommendation here, then, if everybody agrees.

Sasha TerMaat - Epic - Member

Okay.

Denise Webb - Individual - Chair

Not to have any specific set timeframes because of the complications that has caused in the past.

John Travis - Cerner - SME

Yeah. And as I recall, they did adopt kind of an intelligent response to that concern, that you do have an ability to provide what is a whole contextual response. And so, that may be the

way to word it.

Denise Webb - Individual - Chair
Now, what about the timeframe for you all to have developed and delivered?

John Travis - Cerner - SME
The two years – and that, as I recall, includes rollout and adoption as well as development certification.

Denise Webb - Individual - Chair
Yeah.

Sasha TerMaat - Epic - Member
Yeah.

John Travis - Cerner - SME
Oh, boy. That's two years from the effective date of the final rule. So, while that's effectively close to three years, it's still a lot of work to roll out. I don't know, Sasha. I feel like they tried to listen to the old EHRA comment of 18 to 24 months from final rule to adoption as a minimum and that they really – this is repeated in a couple of other places on other topics about things we have to do. I can never recall a time when we've ever asked for more than that. It's not going to be a trivial thing to get done and roll out.

Sasha TerMaat - Epic - Member
Well, ONC estimates that it would take between 160 and 1,600 hours. John, I don't know about you, but here, we've already spent probably close to 160 hours talking about design and there's still a lot of effort left ahead to actually further design and program it.

John Travis - Cerner - SME
That doesn't get into at all the effort of rolling it out, which is non-trivial.

Denise Webb - Individual - Chair
Right.

Sasha TerMaat - Epic - Member
Certainly, a huge project. I guess there is both a development cost and an opportunity cost. So, I think if it is rolled out over a relatively short time, like two years, which basically, you know, in my head gives like a year for development and a year for everyone to upgrade and implement it, then that will be the focus of health systems over the next couple of years. If we extend the timeframe, it might allow for more diversity of focus over that time, but then, you know, the export feature isn't necessarily widely available until later.

John Travis - Cerner - SME
And this update, by the way, is not happening in a vacuum either. It's going to be a major

potential driver for adoption of new capability. I couldn't tell you yet if this necessitates what order of magnitude of update compared to other things. By itself, would it compel you to take an upgrade? That's a pretty broad thing. I don't know.

Denise Webb - Individual - Chair

Maybe as a committee, we don't have – this might be better addressed by the public comment and the various vendors providing input on this.

Sasha TerMaat - Epic - Member

Okay.

Denise Webb - Individual - Chair

Unless you all have some strong – I'm sure you're all going to be hearing comments from your organization.

John Travis - Cerner - SME

We probably have to be a little careful about being too vendor-centric in this forum, so to speak, for that. You're right. It's not like we're not going to make –

Denise Webb - Individual - Chair

Yeah. I'd encourage you to do that.

John Travis - Cerner - SME

Or as an association that Sasha and I are both a part of.

Denise Webb - Individual - Chair

Okay. So, we have about 21 minutes left? Can we go ahead and jump to the – is prescribing next? Actually, I read through that and I have no background to make any comments personally.

John Travis - Cerner - SME

I have a few things that maybe I could start us off with, just kind of – I'm not getting much cooperation out of my…

Denise Webb - Individual - Chair

Fundamentally, it seems to make sense to align with what CMS is requiring in their program.

Sasha TerMaat - Epic - Member

It does. My big picture is that aligning with CMS makes sense. Some of the transactions that ONC has proposed, they propose all of them are required for certification. That does not make sense. Some of them are pharmacy to pharmacy transactions. Some of them are long-term care transactions. Some of them only are required if you have a certain architecture of your system, which many modern systems don't. So, we have to make a bunch of them optional.

John Travis - Cerner - SME

Yeah. That's exactly what I would say. Scale back what's required to match to what is the current B3 and treat it as a replacement of the standard and perhaps make the remainder optional. If somebody wants to seek them, great. But you said it very well, Sasha. That's exactly what we would say.

Sasha TerMaat - Epic - Member

I actually had a proposed edit here. I'll stick it in the notes. So, if people want to scroll down…

Denise Webb - Individual - Chair

I was going to say that various Health IT products can get certification. So, it's not just EHRs. And then for like long-term care products and those kinds of things. I would think that for those products to come in and get certification, then they would want to do these optional things. Otherwise what would be the benefit of their product if they're not going to provide –

Sasha TerMaat - Epic - Member

No, I agree.

Denise Webb - Individual - Chair

Yeah.

Sasha TerMaat - Epic - Member

What I tried to do with these edits, which are in red, was sort of say instead of doing all of these, do whichever subset are relevant to the domain of the product. Some of them haven't been piloted or new. So, I also put in "and are piloted ready." Then I went through each one.

So, A, I think it's only applicable in a certain architecture. So, I said make that optional. D is new and I think parts of it should be piloted widespread of adoption. So, NewRx, I think, is fine, but then NewRx request and NewRx response denied, I'd like to see pilots prior to adoption.

Then like some of these, like drug administration in K is a long-term care flow. That would only be relevant if you were a long-term care product. Some of these are pharmacy flows, like pharmacy to pharmacy communication, which would only be applicable if you were a pharmacy product. I don't know why a pharmacy product would be getting certified. And then the REMS things were new. I think those should be piloted before they're required for all products.

Then in II, they say, "Put the diagnosis segment in every transaction." But not every transaction listed above actually has a spot for diagnosis segment. So, I just added the, "If the segment is supported."

Denise Webb - Individual - Chair

So, generally, the way we would draft a recommendation on this, Kate, would be to say for these items, we recommend they be optional because they're new and they have been tested and then the ones that we recommend that be piloted. So, Kate's going to help draft some of this up, Sasha.

Sasha TerMaat - Epic - Member
Do you want me to put my transaction by transaction notes into the Google Doc?

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Yeah. That would be helpful. Thanks, Sasha.

Sasha TerMaat - Epic - Member
Sure.

Denise Webb - Individual - Chair
Sure. Other things on pharmacy?

John Travis - Cerner - SME
That was the main reaction that we had.

Denise Webb - Individual - Chair
And then the only other thing I thought about is the given the fact that this is going to require some development on the developer's part. These dates aren't necessarily going to coincide with the 24-month date. I don't know if that's an issue because CMS right now is targeting January of 2020.

Sasha TerMaat - Epic - Member
Yeah.

John Travis - Cerner - SME
Yeah. That's a good point. The recognition in retirement – I guess I didn't pick it up here because I was focused on that being more towards the retirement of the B3 criteria, which they've said they mean to coincide with the 2017-071 adoption. But they may want to – I think all we were really trying to say was to find some wording that – don't be premature with the setting of the sunset date of that criteria in favor of the new e-prescribing criteria because there still could be action taken. I think they're open to that by the way they speak of it.

Denise Webb - Individual - Chair
Yeah.

John Travis - Cerner - SME
Don't do a hard setting of the date yet.

Sasha TerMaat - Epic - Member

I think if they narrow the set of transactions to kind of the ones John and I are recommending, which is the scope of what was previously in certification, just the new transaction standard, then it is reasonable to do by 2020. People have been kind of planning that based on CMS's regs. But if they add these other transactions in that don't make sense in context or still need to be piloted, then it jeopardizes CMS's plan to switch standards on 1/1/2020.

Denise Webb - Individual - Chair

All right. We should say that as part of our recommendation.

Sasha TerMaat - Epic - Member

Let me put it in a note here.

John Travis - Cerner - SME

That's a good way to state it.

Denise Webb - Individual - Chair

All right. Can we talk about the clinical quality measure change?

John Travis - Cerner - SME

Yeah. There are others more expert. I don't know that we've done the work to necessarily assess this, but there's a strangeness that's introduced by the adoption of the CMS standard for C3 as the exclusive basis of standard. One reaction is they're not making any changes to the use of QRDA for C1 or C2. I don't know. It's a little bit in the realm of I'm not quite sure what that does, but that caught the attention of our quality team.

And also, just a note – there's a difference in what the CMS specification covers, which if I think correctly, that only impacted the CMS hospital, electronic clinical quality measure reporting. So, that adoption for C3 might be a strange impact to the ambulatory reporting of clinical quality measures.

Sasha TerMaat - Epic - Member

I agree, John. I put a table into the notes way down at the bottom if you want to scroll – sorry, Kate, to keep making you scroll – but I think this is what John is articulating. I had this table. So, I copied it in here. ONC is proposing that across all products, import use the impatient CMS implementation guide. Export for QRDA1 use the inpatient CMS implementation guide. And QRDA3 export, use the ambulatory implementation guide. I don't think that's going to work technically.

If you scroll down, I made a new table of what I think has to happen based on knowledge of the quality standard. There has to be differentiation based on the ambulatory setting and inpatient setting because it does not make sense to use implementation guide for the wrong

setting.

John Travis - Cerner - SME
That is it exactly.

Denise Webb - Individual - Chair
All right. We should probably consider this in our recommendations that this may be problematic and should be evaluated.

Sasha TerMaat - Epic - Member
The other question I just had about this one was what the timing was, like when does this take effect?

Denise Webb - Individual - Chair
Kate, do you know on this? Is this the 24 months or is this right away?

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
I will get back to you on that.

Denise Webb - Individual - Chair
Okay. So, we're coming up on public comment. Is that correct, Lauren?

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yeah. That's correct.

Denise Webb - Individual - Chair
Let's go ahead and do that. Then if we have a few minutes, we can talk about the two attestations that have to occur related to security and also to implement that in CERT. If we don't have time to do that, we'll add that to our agenda Monday. If you want to go ahead with public comment…

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yeah. We may still have a few minutes. I don't see too many participants. But Operator, can you please open the public line?

Operator
If you'd like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press *2 if you would like to move your comment from the queue. For participants using speaker equipment, it may be necessarily to pick up your handset before pressing the * keys.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Do we have any comments in the queue at this time?

Operator
Not at this time.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. I'll hand it back to you, Denise, for the last ten minutes or so if you wanted to wrap up on that last point on quality measures.

Denise Webb - Individual - Chair
Yeah. So, anything else on quality measures? Thank you for doing those tables, Sasha. Then if we could put a little more context on that about what the dilemma will be if they proceed as proposed. Anything else?

Sasha TerMaat - Epic - Member
The only other thought I had was they asked about migrating quality reporting to FHIR. ONC says they don't think FHIR is ready for that yet, but it's the future direction they'd like to move toward. I would wholeheartedly agree.

Denise Webb - Individual - Chair
Oh, yeah. It's on page 88.

Sasha TerMaat - Epic - Member
It's a good future direction, but it's not there yet. It's not ready.

Denise Webb - Individual - Chair
So, we can just confirm that and say that we don't believe this is ready, but we endorse the future directions.

Sasha TerMaat - Epic - Member
I'll add a note.

Denise Webb - Individual - Chair
Thank you for doing these notes. You have been super helpful.

Sasha TerMaat - Epic - Member
You're welcome. I try to take good notes.

Denise Webb - Individual - Chair

Okay. You do take good notes. All right. So, the last area is around privacy and security transparency attestations. They're proposing two new 2015 Edition transparency attestation certification criteria. One is for encrypt authentication credentials and the other one is for multi-factor authentication. These also have a different timeline that I notice here than the other timelines for meeting these attestations, I believe, or at least I thought I noted that.

Sasha TerMaat - Epic - Member
It's six months.

John Travis - Cerner - SME
Yeah.

Denise Webb - Individual - Chair
Six months.

Sasha TerMaat - Epic - Member
I had a question about that.

Denise Webb - Individual - Chair
Can you pull up, Kate, the actual regulatory text, what the regulatory text says?

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Do you see it here? Encrypt authentication credentials.

Denise Webb - Individual - Chair
Yeah. So, each developer is going to assess their capabilities and make one of the following attestations, yes or no?

Sasha TerMaat - Epic - Member
So, I'll start off. Generally, I think encrypting authentication credentials and multi-factor authentication are both important practices and assessing them in certification seems reasonable. Both of them have a degree of complexity that a yes/no answer doesn't necessarily get to.

So, I think in both cases, it will be valuable to have a description or a text box, where the developer can explain how do they support multi-factor authentication? The options might be different, whether it's the patient flow on the patient portal versus the provider who's accessing from home versus the provider in the clinic. Is it part of your product or a third-party offering? What level of the architecture is it at?

I think people want to describe that beyond like a yes and a no. The other question I have is if this takes effect, I can see the value, as ONC puts it forward, of a yes/no attestation for future products that come on to the market because if a provider is making a purchasing decision,

then they can look at this and say, “Oh, do I want to buy a product that supports multifactor auth or doesn’t?” right?

But if you think about the fact that this would be in six months applied to products that are already in widespread use, I’m wondering if it actually publicizes something that healthcare providers don’t necessarily want publicized. If you’re using a product, say, an old version of a product, that’s out there and then suddenly it’s up on the internet that that product doesn’t support multi-factor auth, for example, is that, I guess, making more widespread something a vulnerability about the software that you’re using?

I’m wondering if it should only be applied to future products to avoid unintended consequences for people who are already using things out in the wild, if that makes sense.

Denise Webb - Individual - Chair
That does make sense.

John Travis - Cerner - SME
“Here’s a vulnerability. You’re welcome to come exploit it.”

Denise Webb - Individual - Chair
Versus if you don’t provide this in your product and you have to say no, that’s just going to hurt you with selling your product because it’s going to be public.

Sasha TerMaat - Epic - Member
Right, for new products that aren’t already in use.

Denise Webb - Individual - Chair
Yeah. Isn’t the intent on this – Kate can chime in – isn’t the intent to actual get developers to modify their product so that they do support these capabilities?

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Sure. We note in the preamble and then the impact –

Denise Webb - Individual - Chair
Isn’t this a nudge?

Kate Tipping - Office of the National Coordinator for Health Information Technology - Staff Lead
Yeah. We included language in both the preamble and then impact analysis.

John Travis - Cerner - SME
That’s exactly the end.

Denise Webb - Individual - Chair
Yeah.

John Travis - Cerner - SME
I think it's something to at least raise the cautionary note. Does it rise strong enough, Sasha, to the level of saying there's a recommendation or, "Keep in mind," sort of comment?

Sasha TerMaat - Epic - Member
I'm drafting, I guess, in their proposals two of them, based on this privacy and security piece. One, don't just get a yes/no, but get like a description and then two, I think, apply the privacy and security attestations only to certifications that take place after this is finalized, not retrospectively to products that are already in use.

John Travis - Cerner - SME
I think that's fair.

Denise Webb - Individual - Chair
I think that's a good recommendation.

John Travis - Cerner - SME
That's a good way to put it.

Sasha TerMaat - Epic - Member
Les and Carolyn, are you good with that?

Carolyn Petersen - Individual - Member
I think so, yeah.

Denise Webb - Individual - Chair
These are draft recommendations. They're going to go before the whole committee to deliberate on.

John Travis - Cerner - SME
I had one – this is not a big deal. It's something that just – I'm pretty sure the answer is no, but Sasha's comment about the different authentication pathways, kind of two things. One, this goes towards your clarification, Sasha, and maybe it's something that we recommend that they do, but speak to all of your authentication capabilities or at least speak to wherever you do this and in what context you do this.

For the very fact you may have multiple pathways in, they may not all be at par for two-factor or for encryption. I think that's why the explanation is important. I know when we started talking about this, that came up. Not everything may be to the same level of ability,

much less use of the same method.

The other thing is does it strictly apply to a login use case or does it encompass other authentication use cases like signing electronic prescriptions for controlled substances or where else you may be using two-factor authentication for electronic signature or digital signature. So, I don't know if that's opening a can of worms and if it's clear enough to you that that is in no way their intent and they are limiting it to the same scope as to what basically the access use case or the login use case would cover. That's fine. I just raise it.

Denise Webb - Individual - Chair
So, I'm not sure what you're suggesting, John. Are you suggesting that they actually try to close it?

John Travis - Cerner - SME
Did anybody else read any other possibility than that this is strictly asking about user login types of use cases?

Sasha TerMaat - Epic - Member
I thought it was asking about all use cases, which is part of why I suggest the textbox. You might have some methods of multi-factor auth that are applicable to login, but those might not qualify for EPCS standards by the DEA. You might have DEA-supported standards that maybe are not the same as what a patient can use at home in the portal.

I guess the best answer I can come up with is have the developer describe it. Then you can elaborate on, "This is how our software supports multi-factor auth." And a purchaser could look at that and understand it. I don't think there is a number of questions that can get at the required level of detail.

John Travis - Cerner - SME
I also think it's good to make – sorry. Go ahead.

Denise Webb - Individual - Chair
I was going to say if they do go with the recommendation to add a text box, that would even more strongly support the idea that these attestations don't go out there for already certified products, that they are on newly certified products.

Sasha TerMaat - Epic - Member
Yes, good point.

Denise Webb - Individual - Chair
That's going to reveal a whole lot of information.

John Travis - Cerner - SME
Yeah. And I think that it's good that the instruction for it is very clear that it is – as to what its

scope of applicability is. So, to the point that it does include all authentication use cases, I think that needs to be part of the instructions so that's not misunderstood.

Denise Webb - Individual - Chair

Okay. All right. So, we're at the top of the hour. I want to thank all of you, especially all of you who have slogged through all four meetings this week. I really appreciate it, both on the taskforce and our ONC team. Thank you. So, next week, on Monday, we're going to talk about – is that on the slide, Kate, what we're covering next week?

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

Yes. It should be on the schedule of topics. Let me see if I can get back to that. Excel, is there a way to get back to that?

Denise Webb - Individual - Chair

We're there.

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

Okay.

Denise Webb - Individual - Chair

So, next week, we're going to talk about modifications to the ONC health IT certification program around corrections and principles of proper conduct for the certifying bodies and testing labs. We are also going to have one other topic that's going to be added to that around talking about the four options related to the API standard, FHIR standard. Thank you for the information, John and Sasha, that you provided on that. We'll discuss that on Monday. All right. I hope everybody has a nice weekend.

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

Same to you. Thank you for your time today.

John Travis - Cerner - SME

Thank you.

Sasha TerMaat - Epic - Member

Thank you.

Denise Webb - Individual - Chair

ONC team, I'll call on the other line for our de-brief.

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

Okay. Bye.