Conditions and Maintenance of Certification Requirements Task Force

Transcript
April 18, 2019
Virtual Meeting

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 and welcome to the Conditions and Maintenance of Certification Requirements Task Force. We'll get started with a brief roll call. Denise Webb?

Denise Webb – Individual – Co-Chair
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Raj Ratwani, I don't believe is on yet. Carolyn Petersen?

Carolyn Petersen – Individual – Chair
I'm here.

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

Ken Kawamoto – University of Utah Health – Member
Good morning.

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

Sasha TerMaat – Epic – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Les Lenert? Don't think so. John Travis.

John Travis – Cerner – SME
Yes.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denise, I guess I will hand it over to you to get us started.

Denise Webb – Individual – Co-Chair
Good morning everyone. We're going to continue just about from where we left off yesterday to finish going through the recommendations in our transmittal letter for the conditions and maintenance of certification charges. Before we begin recommendation 25, I just want to make sure everyone, especially Kim, because he actually originally put forth this recommendation, recommendation 21, I

actually flipped the order of the –Hello?

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

Denise Webb – Individual – Co-Chair
Hello?

Ken Kawamoto – University of Utah Health – Member
[inaudible] [00:01:28]

Denise Webb – Individual – Co-Chair
Is everybody still on? I just heard a telephone ringing.

I flipped the order of the sentence because the way it read, I kept thinking whether we want ONC to work with these other agencies on compliance such as HIPAA. I think what we want to say is we want to have them work on the current use of the FHIR API such as Smart on FHIR applications or CDS Hooks services with respect to compliance with relevant privacy and security regulations. Was I correct in that interpretation when I flipped this content?

Ken Kawamoto – University of Utah Health – Member
It looks good to me.

Denise Webb – Individual – Co-Chair
Because I tripped over it several times when I read it and I just went, "Something is not structurally right about this sentence." Okay good. And then you will notice below – Carolyn, thank you for looking up information on the API task force. I actually found the page that had the comments and recommendations. It was actually a joint task force. They might have had working groups, but it was a joint task force that issued the recommendation to the policy and standards committee – the previous one. I put that link in there. Is everyone good with that?

Carolyn Petersen – Individual – Chair
Sure.

Denise Webb – Individual – Co-Chair
I just wanted to back up to 21 because I made some changes. On all of the other recommendations, I went, as I said in the email, and just accepted all of our revisions so you would have a clean read. Did anybody have anything before we go on to 25? I know sometimes when we accept revisions, things might happen. I'll just assume you all read it and agree with it if I don't hear anything.

Why don't we start with 25? Do we have Les on?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
I don't think so. I'll shoot him a message.

Denise Webb – Individual – Co-Chair
If you can shoot him a message, Lauren, what we'll do is we'll hold on 25 and see if he joins us. Then we will come back to it. That takes us to 26. I added a highlight there. Did we intentionally want to change "collected and retained" because – let's see. Where is my comment? I think in the actual document, it is -- Do you see my comment there? It's going to open up. Hold on a second, here. I should've printed these off. I think it's not "collected and retained." Isn't it "managed?"

Sasha, do you see my comment there?

Sasha TerMaat – Epic – Member
I am…

Denise Webb – Individual – Co-Chair
If you just hover over my highlight, I think I have a comment.

Sasha TerMaat – Epic – Member
I'm just seeing highlights. We can look up the text in the rule.

Denise Webb – Individual – Co-Chair
I'll pull open that page. I don't know how we lost those com – I think I had the experience you had, Kate, where I put comments in and then they disappeared. It must have something to do with the version. I don't know. Unless it's in the…

Scroll down a little bit and look at the second highlight there. Is there a comment under that? On the right side?

Sasha TerMaat – Epic – Member
I'm not seeing any.

Denise Webb – Individual – Co-Chair
It doesn't look… No, no, no… I guess not. That's very odd.

Sasha TerMaat – Epic – Member
I think the language is "produced and electronically managed."

Denise Webb – Individual – Co-Chair
Yes, there you go. Thank you. You got there. I was trying to find my page here. That one,

I don't have marked.

My question for the team is: Is that what we want them to change it to? "Collected and retained?"

Sasha TerMaat – Epic – Member
I think the concept of retention is important because we talked about the challenge of things that live in other places. If you have, for example, a document management system that stores things, they might be linked in the electronic health record but they're not really retained in the electronic health

record and it would be infeasible for the developer of the electronic health record to export data that's in a different product in a different system.

Denise Webb – Individual – Co-Chair
Right. I think the "retained" was good.

Sasha TerMaat – Epic – Member
"Collected" seems –

Denise Webb – Individual – Co-Chair
Collected versus produced. I don't understand what they mean by "produce." We considered alternative language – produce and all that, which would encompass more data. What we're saying we don't agree with "produce" because "produce" would mean all those other systems because if you produce data and then store it someplace else, using the EHR data as your source…

Sasha TerMaat – Epic – Member
Yeah, "produce" has that challenge. You could produce a CCA XML document from the EHR and transmit to an HIE, but no longer have any ability to control what the HIE does with that XML.

Denise Webb – Individual – Co-Chair
Then we would – then the producer wouldn't be retaining the data.

Sasha TerMaat – Epic – Member
The retention issue –

Denise Webb – Individual – Co-Chair
I just wanted to highlight this. I wanted to make sure this is what we really intend. We can take that highlight out of there and just reject the highlight. We remove that.

Then, my other comment that was in here that disappeared is the suggestion that we think about reordering this information so we can consolidate what is our overall recommendation. What's the discussion? Then at the end, my last highlight has to do with – what are we referring back to when we say original proposed recommendation? We have an alternate proposal. Is it really an alternative proposal or alternative recommendation, this last paragraph?

[Crosstalk]

Sasha TerMaat – Epic – Member
– different way to approach the same problem. I think, if I recall correctly, in the first review at the HITAC, Arien Malec raised the question about – Is "legal medical record" a defined term with a consistent meaning? There was concern that it is not necessarily.

There is the designated record set under HIPAA, but there is a degree of interpretation that each healthcare system put into what they consider their legal medical record. Arien was worried about introducing a recommendation that referenced a term that didn't have a clear definition. We talked

about an alternative being that the developer could just explain what electronic health information is held – or maybe would use the word "retained" if we use that above – by their certified health IT module. Include that in the export documentation they are already required to provide.

Then, the description could also have the flexibility and the discussion to exclude things that would not be part of a legal medical record. I guess you could describe in some sense the pertinent legal medical record element.

I feel that this proposal also has a lot of inelegance to it. I'm not sure it fully addresses Arian's concern because it similarly dependent upon a number of things that would be interpretive.

That was the background. The original proposed recommendation would have been what we had taken to the HITAC back in March, I think.

Denise Webb – Individual – Co-Chair
I am recalling that discussion that was in – I believe it was in March were we challenged this. What if we – just a thought – what if we did not use the term "legal medical record" in here and then combined the thought of this alternative up above in our recommendation to say something like, "and apply only to the EHI–" that we would take that out and then say that the developers would have to provide in plain language definition of EHI held by their certified health IT module and use that as part of their export documentation. We just – the export should not – we should say what it should not include, like research data.

Then, don't we get out of that conundrum of having the term legal medical record in there? Basically –

Sasha TerMaat – Epic – Member
Yeah. I'm not sure if we do, because –

Denise Webb – Individual – Co-Chair
– incorporate the alternative.

Sasha TerMaat – Epic – Member
I think we had a subset of the things we thought should not be included, but I don't know if we had a comprehensive list. We were always saying what should not be included in the export. Well, the stuff that's not in the legal medical record, but we never made a full and comprehensive list of what those things would be. It will be incomplete information, research information, and it could also be items that –

Denise Webb – Individual – Co-Chair
The law prevents.

Sasha TerMaat – Epic – Member
– or Communications between providers that are not part of the legal medical record. All of those different pieces, I feel like, were part of our conversation but we never came up – and I think this is the fundamental challenge. The only way we've been able to describe those is things that are not part of the legal medical record. I think the alternative fails because it still relies on this concept of "legal

medical record" from a definitional perspective.

John Travis – Cerner – SME

I think what is key is that that the concept that's defined by policy and there is not a widespread – I agree with Sasha in the following – You are practically going to have to enable some concrete definition, the exportability of EHI that recognizes that an individual data holder is going to reach a definition of that for themselves that fits their policy understanding of what is a complete medical record.

The terms are troubling but from a certification standpoint, we are enabling a particular set of data. I mean, in the end, it's not vague to the vendor seeking certification about what they'll enable export of. It is certainly variable in any given instance. I think the key to the process is something that can be flexible as it's actually used to support a given instance of requirement. That's where that gets resolved.

Now, that may also include some, as a practical matter, tailoring of the export to fit the purpose. I may not need to export everything. It's not going to be a uniformed thing each and every time. Inevitably, there is going to be adjustments of the content and the form of it. Potentially, that can add to or take away from what is normally enabled for export.

I think the key here is developers are going to have to provide a plain language statement. The first sentence is absolutely right to me. That's very important, and I think we have to take a stance for purposes of demonstrating this capability, in whatever manner we do for certification, to state what it does not include. ONC has made some proposals in there. I think we simply want the flexibility to be able to say things that it does not include and we have an example list. We don't have to be exactly precise about it. This is from the perspective of the HIT developer saying for themselves, "This what EHI means to our certified module and what we enable to be exported as our jacks to open position, to be honest.

Denise Webb – Individual – Co-Chair

You could actually enable more to export – Let's say a health system has a policy they have to have in place because of local laws about what can be exported. They would have the ability to exclude that from a technical perspective. As you note here, there are certain things that the developer would consider not appropriate to export and would document that, such as in a complete note or research information.

What we want to avoid the healthcare provider that sets the policy that actually ends up being information blocking rather than being a policy to comply with a particular law. When we say there's variability in what a health system or a health care provider defines as their legal medical record, that variability I would hope would be because of legal reasons and not because they're trying to information block or keep –

John Travis – Cerner – SME

No. And as a matter of fact, I think the way the exception conditions are defined –

We're kind of expanding on what the HI export is about. I want to take a little bit of care. It still is fundamentally about what a – the problem here is for an HIT developer to make a statement that is

informative and guiding as to what is EHI held by their certified module that they represent is enabled to be exported. That, I think, we have to confine ourselves there.

The other stuff is absolutely true, but it's a function of any given effort to port data from a given EHR to another EHR to make the data available to the patient. I think because they have not written this with any type definition, you kind of have to come up with one that serves as a pragmatic functional scope. They could have said it's the USCDI. They didn't. They left it like this, so we still have to define the scope.

Denise Webb – Individual – Co-Chair
Because the USCDI is being handled – is the scope of the API.

John Travis – Cerner – SME
Right. I'm not making an argument. I only use that as an example that they did not give any real, pragmatic definition of it. They give a general definition and then some instances stuff that's and the in it. Even so–

Denise Webb – Individual – Co-Chair
John, one thing I do want to tell you and the rest of the group is that Sasha and I are on the information blocking task force. Where the task force is lending on the recommendations for definitions – two definitions. One is around health IT developer and we are going to be recommending that that not be just those who have the certified technology – one or more products.

The second is around EHI. EHI is very broadly defined. I think it is – at least my interpretation that the proposed rule is expecting that if a provider wants to move from one vendor's platform to another's, that vendor is going to be required to support getting that data moved even if the modules are not certified.

I think what we are saying here in this recommendation that for the certification portion of this, we are saying that the certification should only apply and be tested for those portions of the EHI that are retained in certified technology. That does not relieve the vendor from working with the healthcare provider to get the rest of the information out that may be required to be given to the patient or for the healthcare provider to move to a different platform, and if that is not accommodated, that would fall under –

John Travis – Cerner – SME
Information block?

Denise Webb – Individual – Co-Chair
Information block.

John Travis – Cerner – SME
I appreciate and agree with that. Actually – the information blocking provisions are where that greater discussion comes into play. It's a bit **[inaudible] [00:21:46]** because information blocking regime is set up to enable those conversions to happen without stipulating that they must happen until somebody asks them to happen. Whereas here, this is a certification requirement a requirement. It is a

requirement of CHIT vendors and developers.

Really, I'm trying to get this defined so that is something we could go and operate and respond to in a manner that can be tested under certification as a criterion as it is, and accorded to and complied to as a condition of certification as it is.

I realize there is a significant permeable membrane between conditions of certification and information blocking because the rest of it opens up because you are a vendor or certified HIT. Although I realize that the way HIT developer provisions may come about, but my understanding of them is, in essence, if you are subject to this rule as a vendor of certified HIT and everything else you do is also subject to it – whether or not certified – but the root still is that you are a vendor, you start out and are exposed to this rule because you are a vendor of certified HIT.

Denise Webb – Individual – Co-Chair
What if we put here as part of our discussion that we discussed and acknowledged that depending on the final definition of health IT developer, regardless of what the scope of EHI data is for this certification piece, that those who meet the definition of health IT developer will be accountable to support export, whether the export function is certified or not, for a patient request for their data in the products – health IT products of health IT developer – or for the provider to move to a different platform.

John Travis – Cerner – SME
I would recommend a simpler expression that we acknowledge that other considerations for noncertified HIT and for other – I'm really just trying to say we acknowledge there is greater circumstances here that accrue to information blocking. I don't know that we need to say a lot more in here. That way, it could be whatever it is.

Denise Webb – Individual – Co-Chair
[audio cuts out] [00:24:34] important to acknowledge that.

Sasha TerMaat – Epic – Member
I'm live-editing here. We can reject this if necessary, but this piece seems like the recommendation. Sorry, lost my edit in copy/paste. The recommendation is that there should be clarity and we propose this EHI collected and retained apply only to the part of the legal medical record and that developers can provide that definition in their materials.

The rest of this seems like discussion which I condensed into a shorter phrase by moving some of it up and taking some of it out since it seems duplicative. But the reasoning for why we propose this had to do with research, half-finished notes, and other considerations around legal medical records.

I think the concern we had before about where the legal medical record might be broader than a particular product's scope is addressed by the phrase we have: "limited to EHI collected and retained by that technology." I don't think we need that sentence anymore which is why I cut it.

Denise Webb – Individual – Co-Chair
Do we really even need to say legal medical record?

John Travis – Cerner – SME
No. I don't think we –

Denise Webb – Individual – Co-Chair
– silence on that that we thought about having this apply only to the EHI that is part of the legal medical record rather than have that in our recommendation and put a period before that and take that out.

Sasha TerMaat – Epic – Member
How would you distinguish the research data then, Denise? Because if a patient is on a placebo med for a research study, that would still be electronic health information collected and retained by certified EHR technology. If we put a period there, it seems like the export still has to include the placebo med.

Denise Webb – Individual – Co-Chair
Are you saying that the placebo – What I'm hearing you say, Sasha, is there is a definition of legal medical record. What is the definition?

Sasha TerMaat – Epic – Member
The challenging part is that the definition varies by healthcare organization. Each organization applies a degree of interpretation as to what they think constitutes legal medical record based on the designated record set from HIPAA.

Denise Webb – Individual – Co-Chair
How do you as a developer accommodate that?

Sasha TerMaat – Epic – Member
With a lot of **[inaudible]** option.

Denise Webb – Individual – Co-Chair
Then that's just a **[inaudible]**?

Sasha TerMaat – Epic – Member
I think that's one of the challenges of this, which is that this presupposes that those same configuration options would be available for this export. The feasibility of that is questionable. The feasibility of the export overall is also challenging. I don't want to imply that that is super practical from a development perspective. Certainly, having something that's not standardized is very challenging.

Denise Webb – Individual – Co-Chair
The research data, as far as exporting that to move to a different platform, wouldn't be an issue. It's if you're going to give it to the patient.

Sasha TerMaat – Epic – Member
The research piece for platform would not be a problem. The half-finished note for platform changes

would not be a problem. Those are challenges for the export to patient piece.

Denise Webb – Individual – Co-Chair
I think it's going to be as I consider – having been in development, it's going to be very complex to deal with the use case for the patient export.

Sasha TerMaat – Epic – Member
I agree.

Denise Webb – Individual – Co-Chair
It does say it does not have to be real time. The API piece does, which – that has a defined set of data elements, where this does not.

Sasha TerMaat – Epic – Member
[Inaudible] [00:28:39] aren't in real time either. If you request your download from Facebook or Twitter or LinkedIn, they start to queue it up behind the scenes and then tell you when it's ready to download. I think this will be similar for people who have large quantities of data in their electronic health record. It's going to potentially take hours or days to run a query, gather all the data together, format it into a way that can be downloaded or exported, and then make it available to the patient.

Denise Webb – Individual – Co-Chair
There may need to be some sort of data mining capabilities or something that the data provider would have to do to scan the data to make sure nothing appears in the data that is part of the research. I don't know. I just think this is going to be very difficult for the developers to guarantee that –

Sasha TerMaat – Epic – Member
We had a different recommendation about a manual review, right?

Denise Webb – Individual – Co-Chair
Yeah, we did.

Sasha TerMaat – Epic – Member
Where is it?

Denise Webb – Individual – Co-Chair
I think it's right after this. We haven't gotten to it yet. Do we want to be stronger about – instead of saying developers could, don't we want them to do that in terms of the documentation? And others, Carolyn, jump in. I think Ken, I think you're just on the phone, right?

Ken Kawamoto – University of Utah Health – Member
[Inaudible] or the Adobe.

Denise Webb – Individual – Co-Chair
Oh, I just didn't see your name. I didn't know if you were seeing this. Carolyn and Ken, you haven't had

a chance to say anything. Do you have any particular thoughts on this?

Carolyn Petersen – Individual – Chair
I'm squinting to read it in the light blue type on the white background. I can tell you I certainly don't have any additional light to shed on the legal medical record definition. I think "should provide" is in the first sentence I think should provide plain language definitions of things.

John Travis – Cerner – SME
I like that. I was going to make a suggestion that would maybe help us feel a little unstuck. In that prior sentence to the blue text, we say apply only to the EHI that is commonly understood to be part of the legal medical record.

There is a subjectivity to it in that it's jurisdictional and it will vary. The task to the EHR developer to try to provide the best plain statement that they can of what the EHI is that their product holds.

For certification purposes again, I kind of return to that. That's going to be a working statement. It's a good effort to try to provide a full definition that I have to believe most everybody is going to try to work towards. It isn't going to be the same vendor-to-vendor for a variety of reasons, but it's a responsibility to try and make a good-faith effort to make a full statement of that, that then is the basis of the conversation for any given instance of actual use.

If there is to be additional conversation or you are going to accept that as – it's what you would accept as a known starting point or an end state if you only relied on the vendor statement as the user, or it's going to be the starting point of a discussion to scope it to be more or less than that. Yeah, I think it possibly could be more. That is not something you lose your head over if you are a regulator.

We will do our best to try to define it. It certainly could expand the future because the form of HIT does more stuff and holds more data. That can happen.

The USCDI is going to expand and we might determine that we do something in response to a new data type that we hadn't thought about before. I think the less prescriptive you are on that, you still have to put it on the vendor to try to provide a good faith statement of what it is that informs other conversations.

Denise Webb – Individual – Co-Chair
I don't know if any of you have been following this discussion that the Carin Alliance – the technology workgroup – but they're going to be proposing that the CHI export everything via an API, which is the way I guess it could be done. There is going to be some interesting comments coming out of that group.

John Travis – Cerner – SME
I have been, actually. I think their main aim is to make this as standards-based as possible so it's not so dependent on proprietary means, which is going to be the reality, obviously.

Denise Webb – Individual – Co-Chair
One small change, Sasha, if we could put health I.T. developers. We use the terminology that they are using. Do we want to be stronger and say that the CMC task force further recommends that the health

I.T. developers be required to provide? Do you really want to leave it to should?

John Travis – Cerner – SME
I'm fine with required.

Sasha TerMaat – Epic – Member
Yeah, I'm fine.

Denise Webb – Individual – Co-Chair
The only last thing I want to note from our previous discussion about all the other data that doesn't exist in certified health I.T. is provided in module that is offered by the certified health I.T. developer. Do we just want to be silent on that? I worry about the full committee. I think they need to know that we recognized and discussed that.

John Travis – Cerner – SME
I think it's simple for acknowledgement.

Denise Webb – Individual – Co-Chair
Under the discussion.

John Travis – Cerner – SME
I think it's a simple acknowledgment that doesn't have to get elaborate, but we are very aware that there is a broader set of requirements that apply to the information blocking provisions for non-certified HIT, something like that. We're not reaching a conclusion about it. It wasn't within our scope. We know what's going on and we are aware of it.

Sasha TerMaat – Epic – Member
I don't know if that language is –

Denise Webb – Individual – Co-Chair
I can work on that. Then, when we send it out, you can guys can accept it.

John Travis – Cerner – SME
What's interesting, talking to Sasha and I, is that we're in for a penny and a pound on this. You know that.

Denise Webb – Individual – Co-Chair
Carolyn and Ken – and I know we don't have Raj yet, but they'll be able to look at this if they don't get on. Then Les is still on?

Sasha TerMaat – Epic – Member
No, we don't have him yet.

[Crosstalk]

Denise Webb – Individual – Co-Chair
Let's quickly go through the rest of the recommendations. I think those will be really quick. It's really 25 that we're going to have to come back to. Recommendation 27, I added the preamble section. Any concerns with any of the rest of that? This is the one you were talking about, Sasha, complying with state laws.

Sasha TerMaat – Epic – Member
I'm glad it's still in there.

Denise Webb – Individual – Co-Chair
Recommendation 28. I just added some terms in here to clarify what we were talking about.

Sasha TerMaat – Epic – Member
Sounds good.

[Crosstalk]

Ken Kawamoto – University of Utah Health – Member
Sorry I missed it. Why audit the data? It's very large.

Denise Webb – Individual – Co-Chair
Because, Ken, if there was an investigation –

Let's say a health system is going to transition from one platform to another platform. They would need to bring their audit log data with them because, at least for a period of time, because of investigations into particular matters concerning HIPAA or coding, reimbursements.

Ken Kawamoto – University of Utah Health – Member
I wonder if something like appropriate audit log data – I'm just thinking specifically with –

When I looked at our log data, it is almost indecipherable and it is massive. It's not as simple as this person looked at this person's record at this time. It's – the content of the audit log is huge. I'm just worried it could be – I don't know.

Denise Webb – Individual – Co-Chair
Well, the **[inaudible] [00:39:07]** can say "I don't want the whole thing."

John Travis – Cerner – SME
It might depend on its nature, too. The audit log is stored in a distinct database or something like that that might persist beyond the transitional systems and continue to be usable. That's one thing.

If it's available in no other form, it's probably more what the burden of the provider is to make sure they're meeting record-keeping requirements and are able to continue to be able to access audit trails for purposes of investigation downstream if they don't convert it.

But this is a capability we are speaking of here, not an implementation requirement.

Denise Webb – Individual – Co-Chair
As part of the implementation, the health system can say, "I don't want all of that." Do you think it's necessary to put that? "Appropriate?" Then what's appropriate? We have to define appropriate.

Ken Kawamoto – University of Utah Health – Member
Or legally requ – If the HR vendors are okay with it. I mean, when I looked at our stuff, it almost seems like you have to have a PhD in **[inaudible]** analysis to actually understand it. It gets down into the very detailed level.

John Travis – Cerner – SME
That's true of it as it is, though. Isn't it, Ken? If you needed to know how to export, you needed to be able to use it as it is. That's not really a problem occurring to the ability to export it. That a problem of it containing a lot of unneeded information.

Ken Kawamoto – University of Utah Health – Member
I'm okay. In particular, folks who are on the HR vendors site think it's fine. I'm okay with it.

[Crosstalk]

Sasha TerMaat – Epic – Member
I think it's very straightforward. It's already a clearly defined and organized data set. It is very large, so as Ken points out, there could be hardware storage considerations, but if a provider is transitioning systems, they would have to determine, "Do we want a preservative after we've exported it?" Or, if it's not worth it the hardware storage because they have other ways to meet their legal obligations, it would be up to them to delete it.

Denise Webb – Individual – Co-Chair
We have 14 minutes and we do have to go to public comment in a few minutes. Recommendation 29, I just added the preamble section.

Sasha TerMaat – Epic – Member
I added a comma for clarity.

Denise Webb – Individual – Co-Chair
Thank you. 30. Here, what we're asking for will impact the final regulatory text and I put the citing there. The preamble would have to be updated. Otherwise –

Sasha TerMaat – Epic – Member
I wonder – Is it clearer, Denise, to move this to here?

Denise Webb – Individual – Co-Chair
Thank you. Then, if you'll scroll down a little bit, please? That's it for that. No other change there. On quality, we also **[inaudible] [00:43:03]**. Recommendation 32. I actually took the verbatim text from the proposed rule on what ONC was asking us to comment on. Our comment here really didn't change. I

just added some clarification around it. Carolyn, are you okay with that? John, Ken?

Carolyn Petersen – Individual – Chair
I think so.

Denise Webb – Individual – Co-Chair
Then I just put transparency in the heading section to match what's in the **[inaudible]**. Recommendation 33. I added the preamble. 34. We're asking them to add a text box. They would need to modify the final rule, regulatory text, and the preamble because right now the regulatory text just says, "Yes/no adaptation."

I noted we had no recommendations for the modification charge just so they know nothing's missing there. Then deregulatory, again added the site. That brings us to the end.

Let's go to public comment and then let's back up to recommendation 25 and see if we all can work out what we're going to do with that.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Operator, can you open up the public line? Operator, are you able to open up the public line?

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

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

Operator
There are no comments at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
All right, Denise. We've got nine or ten minutes left.

Denise Webb – Individual – Co-Chair
Let's back up to 25. The proposed rule asked us to consider whether the conditions and maintenance of certification requirements apply to self-developers. Under the information blocking section, it does talk about self-developers principally being healthcare providers. I was going to sign the page where it defined that.

I think we're all in agreement – and we were to entertain the CMC that we are looking at the information blocking task force looked at information blocking assurances and communication and put

forth that the CMC does apply to self-developers or should apply to self-developers, except this one exception related to communications where a developer could prevent their employees from speaking about the product, but where it's a self-developer, which is presumed to be a healthcare provider or health system, they would not be able to prevent the users of their self-developed product within their company from speaking about the usability of the software.

I think we generally agreed as a task force that the conditions and maintenance of certification requirements for real-world testing, API, and attestation would also apply to self-developers – so for that matter all developers as defined in regulation. But then we go into these, one through four. That's where I start having a problem with what we have here because there is a lack of clarity. Like on number 2, if you take out "or provide," we are saying "maintain burden or provide for moderation of burden." I don't think we want to say that we want to maintain burden to self-developers seeking certification.

I am wondering if we put our recommendation forward and then have some discussion items because coming from an organization that did self-development and developed their own EHR practice management, revenue cycle management, LIS, RIS, to the extent that any of those products are certified, and have interoperability components, I don't see a difference and we didn't see it differently. We needed to meet the same requirements as commercial vendors when it came to these things.

The way we can handle this is we could just say we recommend these all apply to self-developers, – all developers and be silent on the rest of this because I don't – One of the changes, I sent this to you all in an email, number 4, Les wanted to propose that we have substantial disagreements among its members and no consensus and I don't necessarily agree that that's correct. I think we generally agreed that the conditions should apply if the self-developer is going to certified technology. I open up the floor for discussion.

John Travis – Cerner – SME
The only qualification – the general statement is probably fine. The only qualification would be what you mentioned about those that do not apply to you if you are not engaged in the commercial sale of the certified product. The GAG clause provision may be some for the things regarding fees for API.

Sasha TerMaat – Epic – Member
We went through those, didn't we? If they did not apply, they were not problematic, right? Because we did go talk through each one. I agree. Conceptually, some of them might not be applicable, but it didn't matter. If you're not involved in it commercially, then provisions about pricing wouldn't matter. If they decided to commercialize –

John Travis – Cerner – SME
They do need to say that. I think the general statement would be fine and if there is any qualification on that that is not self-evident in the way that Sasha pointed out, that would be the only thing I could think of. As you say, that may not be necessarily self-evident.

Denise Webb – Individual – Co-Chair

The other thing I know Les was concerned about, coming from an academic institution, is this stifling innovation if self-developers have to meet the CMC, but the CMC is for products that they have certified.

John Travis – Cerner – SME
I think he was beyond that.

And they're already subject to information blocking because most self-developers, as acknowledged by ONC in the proposed rule, are – and I'll read it to you.

"Last, we clarify that a self-developer certified health IT is determined to be used in this program and described in this rulemaking in a previous rulemaking would be treated as a healthcare provider for the purposes of information blocking."

I think all we're talking about here is conditions of certification and maintenance of that certification for those products which they get certified. They may not get anything certified. In the last organization I was in, we were certified to the 2014 edition, which now goes away. They did not further certify their products which creates a different set of issues for them. I don't think it's necessary to say all these things.

John Travis – Cerner – SME
I think he was concerned about – and this may not be the example he had in mind, but I go build my own application that heretofore is able to stand in isolation. It's a tumor registry that I maintain or it's some kind of internal application that is used by one of the **[inaudible] [00:53:33]** areas or departments of an academic facility.

I get it if you really face the issue that these requirements intruded into that, the information blocking provisions for you, the healthcare provider are what you have to deal with regardless of whether or not you develop anything. That's where your burden, so to speak, goes in terms of compliance requirements for you as a healthcare provider.

What Sasha and I were particularly wanting to maintain the focus on was if you're representing this to be a certified product, it's qualifying you for federal programs and for penalty avoidance and for incentives. You're making the same representations as a vendor of commercial software would. For you to be held to a different level of standard in terms of the things that truly matter to the certified capability, that should be not an unlevel playing field.

Denise Webb – Individual – Co-Chair
I absolutely agree. I came from an organization that exclusively had developed products that were certified. Is that Les?

Leslie Lenert – Medical University of South Carolina – Member
It is. I'm sorry I was delayed **[audio cuts out] [00:54:57]**.

Denise Webb – Individual – Co-Chair
Les, we're at the end of the call and what we're proposing is to remove – or at least I'm proposing to remove everything after, on recommendation 25 in particular, remove the four items and just state

that the task force agrees that the conditions for certification and maintenance do apply to all developers, including self-developers.

This would only apply to self-developers who chose to certify something they've developed. It would not prevent them from doing innovative things because at my last job, we did all kinds of innovative things and had a research institute and it does not preclude that they wouldn't be subject to information blocking regardless of whether we think CMC applies because on page 338, ONC **[inaudible]** self-developer that they would be treated as a healthcare provider for the purposes of information blocking. Could you live with that if we removed one through four? You and the rest of the members of the task force?

Leslie Lenert – Medical University of South Carolina – Member
You're gutting my whole point, which is I think that – the question really is, as far as conditions of maintenance of certification as it applies to a healthcare organization. If an organization develops a non-certified module that – and fields it in their healthcare setting, does the organization lose its maintenance of certification?

You're saying that if they do do that, that that is the consequence of fielding a non-certified module. My –

Denise Webb – Individual – Co-Chair
We fielded non-certified modules all the time. We did a thing called Image Locker. That wasn't certified. Didn't prevent us from doing that.

Sasha TerMaat – Epic – Member
Les, I don't think a non-certified module would have any impact on the condition certification.

Leslie Lenert – Medical University of South Carolina – Member
The point is that to self-developers, a non-certified module wouldn't have any impact on the maintenance of certification?

Denise Webb – Individual – Co-Chair
No, because this is the maintenance of certification of their certified products. It's the original certification requirements, conditions of getting the certification for your module, and then the maintenance of the certification for that certified module.

I don't know, Lauren, if it's okay to go over a few minutes, because this is the only recommendation preventing us from finishing the transmittal letter.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
No, that's fine. You can continue.

[Crosstalk]

Denise Webb – Individual – Co-Chair

Go ahead, Sasha. Sorry.

Sasha TerMaat – Epic – Member
I was just going to say it seems like we have that clarification that these conditions and maintenance of certification would apply to all developers of certified health IT including self-developers. I think the concern that Les has is about developers of uncertified health IT, which would be out of scope.

Denise Webb – Individual – Co-Chair
Right. I don't know, maybe we could stay here because I want to be respectful of your concerns, Les, and make sure this addresses what you're worried about. We could say that these requirements apply to these developers and their certified products.

Leslie Lenert – Medical University of South Carolina – Member
If you limit it to certified products, I think that that's – to maintain –

Denise Webb – Individual – Co-Chair
Then – yeah.

Leslie Lenert – Medical University of South Carolina – Member
Including self-developers of certified products.

Denise Webb – Individual – Co-Chair
I think it's –

[Crosstalk]

Denise Webb – Individual – Co-Chair
If we say "and their certi–" whether they're a self-developer or a regular developer and their certified products, because if it's not a certified product, API doesn't apply. Attestation doesn't apply. Real world testing doesn't apply, because if it's not a certified interoperability product, you're not subject to the real-world testing. Am I interpreting that correctly, Kate and Lauren? That the CMC applies to the certification program and products which you get certified?

Leslie Lenert – Medical University of South Carolina – Member
Does it apply to your organization?

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

Sasha TerMaat – Epic – Member
I mean, some of them do apply to the organization, like the condition of the – the communication provisions are about the organization and the limitations they place on communication, not about a specific product.

Denise Webb – Individual – Co-Chair
That's a good point. We're only talking about three of the conditions. What we could say here, "Including self-developers and their certified products for the CMC of real-world testing, API, and attestation," because that's the scope of the other information – of the information blocking task force.

Sasha TerMaat – Epic – Member
For real world testing, APIs, and what was the third one?

Denise Webb – Individual – Co-Chair
Attestation.

Sasha TerMaat – Epic – Member
Could you write the other worker pad – that other one?

Denise Webb – Individual – Co-Chair
Yeah.

Leslie Lenert – Medical University of South Carolina – Member
I could –

[Crosstalk]

Denise Webb – Individual – Co-Chair
Do you want us –

[Crosstalk]

Sasha TerMaat – Epic – Member
– proposal is to take this out.

Denise Webb – Individual – Co-Chair
Do we want to say "and their certified products," so it applies not just to the organization for these three CMC Health IT modules is the term I believe they use.

Leslie Lenert – Medical University of South Carolina – Member
I think that the issue is that – even if it's a self-developer, you've certified it for a purpose, right, which would be to distribute it? Potentially?

Sasha TerMaat – Epic – Member
No, the purpose of **[inaudible]** would be to participate in federal programs, probably.

Denise Webb – Individual – Co-Chair
Yeah, that's why we did it in my last job. Just so we could meet the –

[Crosstalk]

Denise Webb – Individual – Co-Chair
EHR incentive program requirements… or get a penalty as a healthcare provider.

Would everybody be willing to endorse this as written now?

Leslie Lenert – Medical University of South Carolina – Member
I still have my concerns that this will limit innovation. You're saying that –

Denise Webb – Individual – Co-Chair
Les, I'm giving you real world experience where it didn't limit, and in fact, in my last organization, they are going forth with modules that are not certified that integrate and work with certified technology and they're not subject to any of these requirements for that module. We worked with **[inaudible]** and I have personal experience with this.

John Travis – Cerner – SME
I think the matter is – it would be interesting to know what is stifling about it if you're not intending to seek certification. If you are, I think you're on a level playing field for the fact that you're seeking certification and that holds very significant meaning for your organization to qualify for federal programs and incentives on par with any other certified product, so you get dealt with the same as to what those requirements are, but putting all that aside, you're subject as a provider to information blocking provisions which remain anyway. I think…

Denise Webb – Individual – Co-Chair
Might be concerned that the information blocking provisions would more stifle innovation than the –

John Travis – Cerner – SME
Or maybe very legitimate statement there. The example I used earlier, if you built something that was very much for your own use, you didn't think about the need to provide information to someone who sought access to it because you built is as fundamentally an internal-use application to support research or to support program function. Maybe you built it to be a utilization management capability for looking at a particular line of service where you used it to support your own internal activities and you never gave a thought to somebody approaching you externally for access to that information necessarily, the information blocking provisions would hit you.

My point is to think that would create additional consideration that wouldn't have been there before and now you have to be concerned about it. But you're not –

Denise Webb – Individual – Co-Chair
John, let me jump in and suggest **[inaudible]** that based on what you just described, Les, I think the area that you might need to be concerned about, and as a member of the committee, you can raise this, is around the definition of EHI.

That is going to directly intersect with self-development that's done by a health system or a healthcare provider, an academic institution, a health institution because EHI has a pretty broad definition and if

information that's in the tumor registry is used to make decisions about the past, present, and future care of a patient, that's just under the EHI definition and would be subject to information blocking if you didn't provide the information if the patient requested it and had legal authority to have the information.

If there weren't any state or local laws or federal laws preventing you from – allowing you to meet one of the exceptions of information blocking, you would have to provide that information to the patient. I think that's what John's trying to say. Maybe the proper place to elevate the concern is around the definitions and not whether the CMC is the culprit for stifling innovation.

Are you still there, Les?

Leslie Lenert – Medical University of South Carolina – Member

I'm still there. I'm just thinking about what – again, that – how to capture the sp – My view still remains that… The issue is **[audio cuts out] [01:07:28]** down to a certified module that is self-developed or – when someone develops a module that is intended to interface with a federal program, it has to be certified and the path for that is the same as a commercial product, even if it's self-developed, which would pretty much undercut any kind of incentive to do the self-development. It would because of the cost of certification to a commercial standard.

I'm still feeling the conundrum here that if you require self-developers to work at the level of certifying something for a national distribution of a product to participate in a federal program, that's going to put undue barriers in front of self-developers.

Denise Webb – Individual – Co-Chair

Well, I think, having come from a health system and also having worked with – I'll give an example, the Chief Digital Officer at Providence Health, St. Joseph's. What a number of us have done is we look to our commercial EHR to solve problems. Then, if the commercial EHR can't solve the problem, then we look at – is there an extension or something that exists in the commercial market that we can put on top.

If not, then we go and self-develop. In the case of Providence Health, they do it totally in partnership with entrepreneurs and so forth. If they're going to commercialize something, they actually say, "Our core competency is to provide healthcare, not be a commercial IT vendor," and they have their partner go commercialize it.

This is the path. The health system I came from is the only health system, I think – large health system remaining that still has its own self-developed EHR that it's using. Where things are available on the commercial market, it doesn't prevent innovation. What it does is it says, "Well, we decided we had one policy person and we couldn't keep up with the federal regulations and all of these things are available on the commercial market." I think there's' a distinct line between what's innovative and what features and function that exists in the commercial market.

I'll get off my soapbox. Anyway, do you want us to put a statement in here that there was not a consensus on – by – and we don't have to name names – by one member of the task force due to concerns about it stifling innovation?

Leslie Lenert – Medical University of South Carolina – Member
I don't think that you've really – I think you've described one past innovation that was successful potentially sometimes in the organization that you worked. Having worked in a variety of organizations that, including public health and other things like that, I don't think that one path will **[inaudible] [01:11:14]**.

Denise Webb – Individual – Co-Chair
Les, would you like to draft up something to send to all of us to include in this recommendation this evening?

Leslie Lenert – Medical University of South Carolina – Member
Sure. You mean just to say – a statement that there wasn't consensus? Or do you want me to try to fix it?

Denise Webb – Individual – Co-Chair
Well, I was going to suggest a discussion. Have our recommendation standards, because this is not 100 percent consensus, but the majority of the task force members are in favor of this recommendation and it is going to have to go to a vote for the whole committee. Certainly, you can vote against it. It's not a requirement that there's 100 percent agreement on every recommendation that we set forth to Carolyn and Robert.

What I guess I'm asking is we can add a discussion section here and if you'd like to propose what you'd like to see in the discussion that covers your concern so that the full committee's aware. And if you would like to do that, we're going to need that this evening because we need to **[inaudible]** to the full committee tomorrow afternoon.

Leslie Lenert – Medical University of South Carolina – Member
Sure. Why don't I come up with one slide that would summarize my concerns?

Denise Webb – Individual – Co-Chair
You don't have to send the slide. If you'll just put it in an email to Raj and I.

Leslie Lenert – Medical University of South Carolina – Member
I think the best thing would probably be to put into a PowerPoint slide and then we can continue to hash that out. If you want to use my slide, fine. If not, that's fine too, but I think I'll just put it into a slide and that would be the best way to express the… It may only be half a slide, perhaps.

Denise Webb – Individual – Co-Chair
I apologize for us running over. I will go ahead and go through this document and accept the changes and send out a clean version to the entire committee. If everybody is in agreement, we'll submit it tomorrow afternoon to the full committee – actually, to Carolyn and Robert. If you do have any issues and concerns, we would need to know by noon tomorrow so that we can work through those.

All right, thank you, everybody, for your contributions. I really appreciate it.

Carolyn Petersen – Individual – Chair
Thank you, Denise.

Denise Webb – Individual – Co-Chair
And thank you for keeping track of our notes, Sasha. I appreciate it.

Sasha TerMaat – Epic – Member
You're welcome.

Denise Webb – Individual – Co-Chair
Lauren, I'll hop on a quick call with you and Kate.

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

Denise Webb – Individual – Co-Chair
Thanks.

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

John Travis – Cerner – SME
Thank you. Bye-bye.