Conditions and Maintenance of Certification Requirements Task Force

Transcript
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Virtual Meeting

Speakers

Name	Organization	Role
Denise Webb	Individual	Co-Chair
Raj Ratwani	MedStar Health	Co-Chair
Carolyn Petersen	Individual	Member
Ken Kawamoto	University of Utah Health	Member
Sasha TerMaat	Epic	Member
Leslie Lenert	Medical University of South Carolina	Member
John Travis	Cerner	SME
Lauren Richie	Office of the National Coordinator	Designated Federal Officer
Cassandra Hadley	Office of the National Coordinator	HITAC Back Up/Support
Avinash Shanbhag Shanbhag	Office of the National Coordinator	Deputy Director of the Office of Technology
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. Welcome to the Conditions and Maintenance of Certification Task Force. We have Raj Ratwani, one of the co-chairs, also Carolyn Peterson, and Ken Kawamoto. Do we have any other task force members on the phone at this time? Okay, hearing none, I will turn it over to Kate, first, just to give us a rundown of today's agenda, and then we will go from there.

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

Sure. Thanks, Lauren. So, I know we wanted to continue the discussion of the recommendations. On the last call, there were some questions that came out with regard to API, FHIR, and the bulk data movement. So, Avinash Shanbhag , the Deputy Director of the Office of Technology at ONC has agreed to join us today. So, he could help clarify the proposal or respond to any applicable questions that the task force members may have. So, I guess I will…Raj, if you want to start it off, I don't know what recommendations we should get started with with regard to the API, or just generally if we want to talk?

Raj Ratwani – MedStar Health - Co-Chair

Yeah, I'd say, why don't we start generally. Denise has been running most of these meetings, so please bear with me as I jump into where we are now. I think where we last left off was the recommendation 22. But I think there are some questions about FHIR, and the APIs, specifically, it looks like between recommendation 19 and 20. There may be something there. And, Ken, I'm not sure if this is an area where you have had some questions and might be able to drive some of this, but let's use Avinash Shanbhag 's time while we have it, and Avinash Shanbhag , thank you for joining us.

Avinash Shanbhag Shanbhag – Office of the National Coordinator for Health Information Technology -
Deputy Director of the Office of Technology

No problem. And I can stay a little longer. I know at 3:30 I have another meeting, but that's an internal ONC meeting, so I can certainly stay longer than 3:30, if needed.

Raj Ratwani – MedStar Health - Co-Chair

Okay.

Ken Kawamoto – University of Utah Health - Member

Well, this is Ken. I think the main question I had was what's the state of bulk data, **[inaudible] [00:02:24]** maturity? And I think the big picture is, is it ready to be included as a requirement, or is it something that requires a little bit more work? So, I think that was the big picture question, at least for me.

Avinash Shanbhag Shanbhag – Office of the National Coordinator for Health Information Technology -

Deputy Director of the Office of Technology

Sure, thank you. We'll get it right into it. And, Hi, this is Avinash Shanbhag Shanbhag from ONC. Just to set the stage, and just to make sure, Ken, to clarify about the bulk API standard. The actual seven FHIR-based bulk access API is the standard that you are referring to, right?

Ken Kawamoto – University of Utah Health - Member

I believe so, yes.

Avinash Shanbhag Shanbhag – Office of the National Coordinator for Health Information Technology -
Deputy Director of the Office of Technology

Okay, so, just for context, that standard was developed, I want to say about a year and a half ago. It's currently being validated in the FHIR release four. And the reason I mention that, is because if you look at our current NPRM, the proposal actually refences FHIR release two, and the **[inaudible] [000:03:33]** in the NPRM that because the standardized bulk access API is not **[inaudible]** in the FHIR release two, for population services, it's a functional requirement, and not a standard base requirement in the current proposal as proposed. But, Ken, to your question, there are two components of bulk API standard. The base, which is the FHIR related data actually is part of the FHIR release four that was released at the end of 2018, and it's part of the FHIR infrastructure.

There is a related component, which is the security component feed that goes with bulk data access. That's similar to how a single access in the smart app authorization guide. For the bulk API, there is a parallel implementation guide called, Backend Services Standard. That's really based on **[inaudible] [000:04:30]** and smart app launch framework, but had some distinctions, just because it's for more than one resource, and it has some of the properties that needed to be added in. That standard was tested and validated in multiple **[inaudible] [000:04:47]** over the last year. And currently, it is actually being validated in the upcoming May HL7 working group meeting. So, in terms of different two components, the bulk access API is already in the FHIR for infrastructure. So, it's part of a base release for standard. And the security components, which goes by the name Backend Access, Backend Services Implementation Guide, is currently targeted for the May ballot at agile seven. Does that help?

Ken Kawamoto – University of Utah Health - Member

Yes, I think it does. I'm a little bit confused because I thought, perhaps, the bulk data was, in fact, reference for population health management purposes, as a requirement, separate from the whole EHR extract kind of notion, but maybe I'm mistaken there.

Avinash Shanbhag – Office of the National Coordinator for Health Information Technology -
Deputy Director of the Office of Technology

Yeah. Just to clarify, what you have described in the G10 API proposal, we are referencing population services, but because of the FHIR standard **[inaudible] [000:06:05]**, our specific proposal is that being separated into surge, and secure connection, and data response. For data response, we said that the data needs to be released to compatible and compliant with the Argonaut profile, but for actual API and for search criteria, we have, actually, not

specified a standard. We made it a functional requirement. The only question is, as you know, have a request for comment has four options, one of the options, actually two of the options are, either pick five **[inaudible] [000:06:43]** two and four, or five **[inaudible] [000:06:45]** four.

And really, if any of the options that get select based on file four, then we will, definitely, we'll appreciate comments from your group about putting in the standardized population health API. But yes, right now, as proposed in the NPRM, we have not specified the bulk standard because it is not a part of the FHIR release two.

Ken Kawamoto – University of Utah Health - Member
Okay.

Raj Ratwani – MedStar Health - Co-Chair
Okay, thank you, Avinash. Are there questions from other folks on the call?

Ken Kawamoto – University of Utah Health - Member
It is within our purview to recommend if ONC goes with FHIR four, to use the FHIR four bulk query mechanism? If so, I think we would then need to get into the, is it appropriate or not, and is it mature enough, at this current state?

Avinash Shanbhag – Office of the National Coordinator for Health Information Technology - Deputy Director of the Office of Technology
So, this is Avinash Shanbhag, again. That's definitely something you could comment on. From a maturity perspective, again as I mentioned, it's been about a year of that development of the standard, and it has through multiple standards forms. So, I would say that from, at least, my own personal perspective, I think it's has reached a stage of maturity that's, actually, a part of the FHIR release four. But having said that, defer to do your own analysis, and any understanding of the maturity levels.

Sasha TerMaat – Epic - Member
Avinash, does that represent live implementations, or just **[inaudible] [00:08:51]** demonstration?

Avinash Shanbhag – Office of the National Coordinator for Health Information Technology - Deputy Director of the Office of Technology
Right now, it's still connect-the-pawn implementations. Just because it's right now it's part of the FHIR release four. So, our expectation is because it just got into the FHIR four in the end of December when FHIR four was released, our expectation is that in the coming months, when they start implementing FHIR four, that's when the bulk access API, as **[inaudible] [00:09:20]** in the standard will get implemented, at least, it will get put into vendor products.

Sasha TerMaat – Epic - Member
So, just so we understand, I guess, when we recommend use of FHIR for medication data, in release four, we, at least, have real-world experience about the implementations of DSU two,

SU three, FHIR medication services. But here, we don't have any prior limitations because it's newly available with release four. And so, if we recommend it, we're recommending something that has never been implemented in real life. To be required at every health system in a certain time period.

Avinash Shanbhag – Office of the National Coordinator for Health Information Technology – Deputy Director of the Office of Technology
Yes. To be specific, yeah. This is currently only gone through **[inaudible] [00:10:11]**.

Sasha TerMaat – Epic - Member
I think it would be good for us to differentiate the timeline at least for pieces where…let me go back a step. I know we talked about previously in the task force that we would see it as undesirable to implement both data queries for population purposes in nonstandard ways, which was what was proposed by ONC with the expectation they work proposing the DSU two, which doesn't have a standard way to do that. And the task force had discussed and felt that a lot of nonstandard implementation was undesirable. And I wholeheartedly agree with that. I think one of the advantages of R four is that it permits standard implementations. But I do think that it might be a recommendation for us to consider to differentiate timelines for things that are already deployed in production, and could be upgraded to R four on a different timeline, than implementing a completely untested standard.

Ken Kawamoto – University of Utah Health - Member
Yes, this is Ken, I completely agree with that. I mean, we want a standard, and hopefully bulk data would be the way to do it. Yeah, before we find folks, we probably should be looking for some production implementations and experience.

Avinash Shanbhag – Office of the National Coordinator for Health Information Technology - Deputy Director of the Office of Technology.
Go ahead.

Raj Ratwani – MedStar Health - Co-Chair
Sorry. Ken, before you jump in, to close out some of that, is there anyone on the call but as a different perspective on that? I also agree with both of you. I see that John joined, I'm not sure if he's on the call yet. Carolyn/others have a perspective on the bulk data issue coming up?

Carolyn Petersen – Individual - Member
This is Carolyn. Yeah, I am in favor of not going with something where we really don't have much world experience. I think that's probably not a great thing to recommend at this point.

Raj Ratwani – MedStar Health - Co-Chair
Okay, so unless you have a different perspective on this, I'd say we should probably go ahead and make that change. Okay, Ken, please go ahead.

Ken Kawamoto – University of Utah Health - Member

Yeah, I have related question. So, when I asked some folks that I work with about when they evaluated whether to use it, they thought that the data formats, et cetera, looked a bit – maybe the query mechanism, et cetera, was still fairly early. Can you, using the current specification, say things like, for patients who have Blue Cross Blue Shield insurance, and who have diabetes as specified by having a diabetes on the problem list with these codes, tell me what their most current hemoglobin A1c test was? And give it to me as bulk? Is that something supported, or is it more along the lines of, there's some off-line mechanism to specify medical records that I am interested, and just give me all their data? Is it possible to do those fairly typical population health management data queries using this mechanism?

Avinash Shanbhag – Office of the National Coordinator for Health Information Technology – Deputy Director of the Office of Technology
I think each one will have to be evaluated. The way the functionality is defined, it lets you create – it particularly lets you do asynchronous. So, it's particularly an access of multiple patients by group ID. So, what is expected is there is this API call that's based on a certain group ID, and the patient population that's part of the group ID is **[inaudible] [00:14:02]**. So, taking your example, Ken, if it's like a Blue Cross Blue Shield, whatever is the patient cohort that you want to query on, the mechanism by which you come up with a list of patient's IDs, that represent your population is separate, but as you create a virtual group ID for it, then you can certainly access the relevant data for that group ID, and you can get whatever is the cohort of patient population.

Now, when it comes to what you mentioned about getting patient's information that have diabetes, and whose A1c are elevated, or the like, those are chained searches, and that's really a base-FHIR functionality. So, it's nothing that is specific to the bulk API, here. What it is, is the FHIR-based standard allows you to query patients, as you are aware of, based on certain chained information that is chained by important and related resources. So, patients with medications, or patients that have connected resource data. So, you have to build those APIs and search query mechanisms to be able to stratify that data. But in terms of the groups of patients that belong to a certain cohort, or a certain section, or certain query scope, that would have to be, at least in the bulk API proposal, is separately curated by the system that's developed and supported. And really, there's a group ID virtual collection that's used to create to that cohort. Does that help? I mean, that's the kind of –

Ken Kawamoto – University of Utah Health - Member
It does.

Avinash Shanbhag – Office of the National Coordinator for Health Information Technology – Deputy Director of the Office of Technology
Sorry, and then, there are additional parameters, just to close the thought, just in terms of what it allows. There are additional parameters that tell you start dates and end dates, and any updates too. So, there are mechanism by which once you get access to that cohort, and you build that population, then you can get from a certain date, to a certain date, or anything about it. So, those additional mechanisms, which are specific bulk access just to kind of curtail the amount of data. But in terms of the type of data you would use, specifically the files query, underlined query parameters.

Ken Kawamoto – University of Utah Health - Member

That sounds good. I guess, related to whether we specifically recommend that this be pursued at a different timeline et cetera, is the work on the bulk data phrase…how active is it? Is it something that if we want to be able to reference and make required at some later date, is there active ONC supported projects, Argonaut initiatives? Because it does seem like additional work is needed to address things like, well what do you do when, the notion of who my talking about, what population am I talking about? I'm leaving it completely off-stuck and point-to-point. It seems not ideal. Is there active work to try to address those things, or is it something that if you wanted that kind of thing to be supported when it is reference and regulation at some point, that we need to actually recommend that more work be done there?

Avinash Shanbhag – Office of the National Coordinator for Health Information Technology - Deputy Director of the Office of Technology

So, you can certainly request for more work to be done. As far as I'm aware, the consensus of the agile seven community was that the bulk API infrastructure related activities, specifically the ability to call a cohort of patients by a group ID, being able to query and get data of a large cohort. They thought it was mature enough, so it's in the standard, and as far as I'm aware, last year, before the agile seven community adopted it into the FHIR four release, Argonaut pilot group actually tested it and validate that it worked. So, really, I mentioned, **[inaudible] [00:18:21]** and there was pilot work that was done by Argonaut for both bulk API, and the parallel security components, the backend services. Went into the final chain, the final standard that was a part of release four.

So, as far as, at least, what I'm aware of, the FHIR community feels that it is ready to be put into FHIR release four. And they feel that it's ready to be implemented. I don't know if there is additional work that's been going on in the underlined in standard, though, if there are additional use cases that come up that require implementation guides on top of bulk API, then certainly, I haven't heard about it, but it could come.

I think right now, the main area where work is happening, as I mentioned was, that the security component and backend services of API was tested and validated during the Argonaut pilot **[inaudible] [00:19:23]**. But because it did not get into the smart app launch framework, implementation guide, but it was a separate IG that was deemed in parallel, useful to be developed. Even though it was validated and piloted by Argonaut, right now it's being validated to agile seven, so that it becomes a standard. That has the public and a larger stakeholder community input. That is the one that's currently being, at least, worked on, as we are getting ready for the May ballot. But once the backend services get balloted in May, along with the FHIR release four bulk API, technically the work is done.

We do anticipate some **[inaudible] [00:20:12]**. I would say that we do anticipate supporting and piloting the use of those APIs and that skill. For example, I think you are aware of the Mead grants that we were awarded last year, does reference the user population APIs, and **[inaudible] [00:20:32]** APIs for machine learning. So, we do anticipate its use in the future, but in terms of standardization activity, I think we reached – I don't see us doing anything

actively, unless we hear used cases that require more implementation guide development. Does that help? That's how, at least, I see the current work activities on the bulk API and the backend.

Ken Kawamoto – University of Utah Health - Member
It does. Thank you.

Raj Ratwani – MedStar Health - Co-Chair
Okay, other questions for Avinash, while we have him? Okay. So, let's jump back into the recommendations. Sasha, I see that you were kind enough to modify 20. Any further comments on recommendation 20 that's being displayed now?

Sasha TerMaat – Epic - Member
Yeah, I tried to reflect our conversation, though, the wording can be better there. I'm open to any suggestions from others.

Raj Ratwani – MedStar Health - Co-Chair
That current wording looks really…others?

John Travis – Cerner - SME
No, that looks good.

Raj Ratwani – MedStar Health - Co-Chair
Ken, you okay with that?

Ken Kawamoto – University of Utah Health - Member
Yes. Sorry, just reading it now. There's something on top of it right now. Could we get that document up again?

Raj Ratwani – MedStar Health – Chair
There it is.

Ken Kawamoto – University of Utah Health - Member
For some reason there's a conversation on top of it. That's over…

Raj Ratwani – MedStar Health - Co-Chair
I'm able to see it here, so I can read out loud. The part that Sasha just added was, "If ONC identifies R four FHIR for implementation, the standard method could be used for bulk queries, but on a different timeline of implementation of more established R four implementation guides."

Ken Kawamoto – University of Utah Health - Member

I think the only question is, if we explicitly call out things like, there should be more real-world testing and refinement of the spec that's needed before becomes required for everyone. I'm assuming in real-world testing, people run into things like, well there are common patterns of subpopulations you want to query because it's probably fairly unusual you want to pull the entire record for every single person in the HR. And it seems like it would be more useful if there was a way that to define that, other than it will be done completely off-stuck.

Sasha TerMaat – Epic - Member

I don't know, I guess one of the challenges I see with real-world testing, is that when you're testing something that is totally new and doesn't have any actual users yet, I don't actually know how you'd test it, right? If I wanted to implement this, and then implement it, I'd need some sort of app that's built on top of it. And if no one's implemented the FHIR services yet, then there probably aren't any apps that use it yet. And I don't know that the real-world testing that you're likely to do with a harness or with whatever app available, is going to be widely representative of the type of thing you're looking for, Ken. I guess, in my mind that would be better accounted by actual live implementation not real-world testing.

Ken Kawamoto – University of Utah Health - Member

Oh okay, maybe I just called it what it shouldn't have been. But I guess the big picture notion of we recommend; we believe in this thing; it sounds promising, but we recommend that steps be taken to make it more mature and validated, before – and whatever the wording is. I was sort of thinking the two were the same, but through actual implementations, perhaps.

Sasha TerMaat – Epic - Member

So, I just added a sentence that said, "The task force would like to see successful implementation prior to requiring adoption across the industry." Does that seem to reflect it?

Ken Kawamoto – University of Utah Health - Member

That sounds good. Bottom line, if it's real implemented and it provides value just the way it is, then that's great, and if not, I'm sure people will figure out, oh, this is what needs to get tweaked.

Sasha TerMaat – Epic - Member

Yeah, that sounds good.

Raj Ratwani – MedStar Health - Co-Chair

Okay, great. If everyone's on board with that, let's keep moving. I think we made it through 21 last time, is that right? I think we can jump down to rec 22.

Sasha TerMaat – Epic - Member

Do we need to incorporate the 328 comment into 21 in some fashion?

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

Staff Lead

So, what I had put on the memo, I added a specific recommendation just to add for these criteria, as we discussed. I guess it was 328.

Sasha TerMaat – Epic – Member

Okay.

Raj Ratwani – MedStar Health - Co-Chair

Okay, so jumping down to 22…and here I'm just following guidance that Denise had given me, and things we had talked about, but I think there was this last note, down where it says 328 on the bottom of the portion that's projected now, that we should briefly discuss. So, this is based off of Denise's comment where she spoke to several CIOs, and there seem to be some concern around what happens if an app developer doesn't work out, but still has, in her words, "Keys to the kingdom," and has access, or would have had access. Are there some security precautions that need to be thought about? And John, you may have had some comments in the space, as well, when we discussed this a few phone calls ago.

John Travis – Cerner - SME

Yeah, I know that I – Sorry, Sasha, go ahead.

Sasha TerMaat – Epic - Member

Go ahead, John.

John Travis – Cerner - SME

No, I was just going to say, the question of persisting, or what happens after an application is severed, if you will, for their connection, I know in our experience that would – relative to any new data, basically, there's no connection. I know in our experience that would, relative to any new data, basically, there's no connection. The concern may be over controlling data that they've already obtained through that connection. But if it's consumer use case, it's really no different than a consumer having obtained an electronic copy of their information by other means. Or if it's been transformed into another for form a different API accessing application, it's going to be under their control. But if they're disconnected, and it's been done under normal process of removal, I may not be following the question exactly right, but we are not going to – they're not going to persist an ability to connect.

Sasha TerMaat – Epic – Member

Yeah, I was going to say something similar to John's point. My understanding of the way that **[inaudible] [00:28:30]** works to provide access, seems like it already addresses the concern that Denise and the CIOs she's talked with have in their minds. So, there's different levels of keys, I guess, in a sense. So, a particular application with a specific URL endpoint, might need to be registered. But then also, the user with authorization to a particular data set, so, in many examples, the patient who wants to get access to their own data, would have to be presenting their credentials. And so, even if a particular developer registered an application, and then got FHIRd from the company that registered the application, I mean, that doesn't

give them the other things that would be necessary, like a users' authentication, or anything to have persistent access to the EHR data.

I mean, I guess if the app has some sort of database, and they don't terminate access to the FHIRd person, that could certainly be a security risk, but that's a risk of any company, right? Any company that has access to sensitive data needs to have policies to remove access for terminated employees. And so, I think that a lot of the security protections that are already proposed mitigate the risk Denise identifies. But I do know that I also hear a lot of concern about app setting. That's some of the questions that we asked earlier, in terms of clarifying what is expected there. So, I respect the anxiety that I think Denise is expressing in this comment. I hear that from other stakeholders also. But I don't know that the app developer/staff person gets FHIRd scenario, specifically, unless I misunderstand it, is a huge risk. I think other security protections of AWAS account for that.

Raj Ratwani – MedStar Health - Co-Chair
Okay, that's great. And I think, Sasha, to your point, some of the vetting things are addressed in the bullet points up above. So, I feel like we have that pretty well covered. Ken, Carolyn, any other thoughts around the points that Denise was bringing up?

Ken Kawamoto – University of Utah Health - Member
I don't think so, for me.

Raj Ratwani – MedStar Health - Co-Chair
Okay.

Carolyn Petersen – Individual - Member
No.

Raj Ratwani – MedStar Health - Co-Chair
Okay, so I think – Sasha, thanks for documenting that. I can talk to Denise about it, and just fill her in on the context here. But I think what you and John have described makes a lot of sense.

Sasha TerMaat -- Epic - Member
And I wanted to say something about the scenario, maybe someone will chime in and public comment, or something. Hopefully.

John Travis – Cerner - SME
Yeah, good point.

Raj Ratwani – MedStar Health - Co-Chair
Okay 23 was talking about the scope of the HI export. And I think this was also making sure that we're in sync, or aligned with what's happening with the information blocking discussions. Any additional thoughts on this one?

John Travis – Cerner - SME

The only other thing I'd offer, and I don't remember if we really talked about this in this context, while the concept of EHI bares a definition, and we understand its intent, I think ONC can do work to make clearer that it doesn't suddenly implicate all the EHI that may be held, particularly in an integrated system. So, what I mean by that is, like we are, we have in a common production domain revenue cycles, supply chain, ancillary solutions, scheduling, things of that nature that are really not any part of any basis of certified EHR technology we've ever represented in the scope of a certified module. And there certainly are certain levels of data objects, like a patient or a person, or an encounter that you really can't divide very well if you are applying a definition of EHI and all data held by cert, but integration does not mean inclusion.

So, for example, a supply chain system that necessarily occupies a database or table space, as a part of an overall architecture of the large integrated waterfront system, it doesn't suddenly become EHI held by cert, just by virtue of that fact, and that would actually be a discriminatory basis of judgment, compared to nonintegrated portfolios from the same vendors.

So, my suggestion is, they need to either make clear that a vendor is going to need to develop the way that they would apply that EHI definition, to what their certified module holds, or, certainly, to make allowance for the fact that the integration does not mean default inclusion in that EHI definition held by cert. So, either way, the way they proposed it, that's a burden that I presume that HIT vendors are going to have to sort through to provide a fairly reasonable level of inclusion of what belongs in the definition, and what is not within that definition unless they are, frankly to me, overreaching by suggesting that simple integration colors the nature of what all is included by some kind of default trigger. Does that make sense?

Sasha TerMaat – Epic - Member

I think so. John, do you think that's already accounted for in what we recommend, or should we add a sentence?

John Travis – Cerner - SME

As I read this, not really because a legal medical record is broader than cert purposes. I would say that, as a matter fact, I'm not so sure about the legal medical record being the right statement. And what does it do to me if I am presenting an EHR module that's much smaller in scope? Is a legal medical record at all – now you get into, let's say I present an EHR module for public health reporting, or for quality measure reporting, and it's a fairly standalone solution, the legal medical record definition really doesn't have anything to do with me, but maybe I'm not having the certified of the EHR export, but it depends on the construction of my module.

So, because that is no reliable base of definition, I think it needs to be that there is a requirement that the HIT developer needs to provide a reasonable definition, plain language, if you will, as best as they can, of what is EHI held by the scope of their certified module, and

provide a good statement of how they would – if you want to say, defend that or establish that through written documentation. I don't think the definition is functional as it is, unless you just simply say it's everything that's held in a production domain where cert is resident, and that's way overreaching .

Raj Ratwani – MedStar Health – Chair
Right.

Sasha TerMaat – Epic - Member
Okay. I tried to capture what John was saying.

John Travis – Cerner - SME
Yeah, I think that's good. Yeah, that's a nice and simple statement. You got the point of it.

Raj Ratwani – MedStar Health - Co-Chair
Carolyn, Ken, others: okay with this?

Carolyn Petersen – Individual - Member
Yeah, I think so. I mean, I'm not a legal authority, or at least, have the familiarity that John and Sasha do, but I think that sounds reasonable.

Sasha TerMaat – Epic - Member
This might also – and I just added another sentence, but Arien Malec had raised in a larger high-tech discussion, a concern that the legal medical record was not defined concept under HIPAA. And they didn't want to introduce more terms without a definition, which, certainly, I respect. So, I just added as another point that this alternative that John proposed seems like it would also address Arien's concern because it avoids the concept of an undefined term in that way.

John Travis – Cerner - SME
Yeah. It operates with the term of EHI, but it's applying that term to what you hold in boundaries of the cert module.

Sasha TerMaat – Epic - Member
Right. And I guess the other factor of it, John, would be not just EHI held by the certified module, but it would have to accommodate, I guess, in this alternative proposal, the same type of concerns we discussed earlier, which would be incomplete information, a half-written note was one of the examples. Or research information would not want to be exported if that would invalidate the research study.

John Travis – Cerner - SME
Yeah, I think that's a very good statement. I know something we came across was that it was very unclear, for example, of what to do with history and audit trails that go toward prior states of the record. Are you exporting the current completed record entry? Do you really

need to export the prior versions? Do you deal with transitory data? Like all of our – I'm pretty sure Epic does pretty similar things. Concepts of sticky notes, and communications between staff that happen to leverage messaging capabilities. So, they need a more elaborate definition of EHI, probably too. But, as long as it's a reasonably workable definition, it's one that will exist in this final rule, and should be what informs the way a vendor develops a written statement of what EHI held in scope of the cert module means.

But I absolutely agree, they need to take on some of the, if you want to call them, secondary considerations of the structure of a medical record, and really call out what's important to export that results in the whole integral record being exported. And I don't think legal medical record actually, as such, exists in anything. There are definitions of required content in a lot of things, but I don't think there is an actual, beyond at least not the boarders of one state, legal medical record.

Sasha TerMaat – Epic - Member
Yeah, I agree. I think legal medical record is often locally interpreted by a particular health system, with some amount of commonality, right? I've never heard a health system that included half-finished notes in a legal medical record, but there is a degree of variability that comes from each group's compliance; their legal department taking a slightly different approach.

John Travis – Cerner - SME
And to the credit of what that language may have been trying to do was to head off exactly what you just mentioned, with interim forms of data/incomplete forms of data. So, maybe it's, preserve the concept, but don't use the term as a scoping definition.

Sasha TerMaat – Epic - Member
Okay. So, I tried to articulate that in what became a lengthy recommendation.

John Travis – Cerner - SME
Yeah, I like that.

Raj Ratwani – MedStar Health - Co-Chair
Okay, this also works for me. Certainly not my area, either. But, yeah. Looks good.

Sasha TerMaat – Epic - Member
All right.

Raj Ratwani – MedStar Health - Co-Chair
Okay, so moving on, if everyone's okay with that. So, I think the next one is 27, I believe.

John Travis – Cerner - SME
Yeah. Let me go right in, I think I was the one who…So, multiple things here. Probably the biggest thing is, this criteria, as it's proposed is just simply too broad and unwieldy for real

practical effect. So, what I mean by that is that you've got almost three major subsets of transactions represented in this list, you could probably argue more, but they appeal to different audiences, and to ask any one audience to have to adopt the capabilities of this because it is going to become a required part of the base EHR definition, and part of the required capabilities of cert for adoption, in any sense, you have a subset of prescriber oriented transactions, you have a set of long-term care oriented transactions, and you have a set of pharmacy only oriented transactions.

And just take the example of a prescriber working in a physician practice setting, you're asking them to adopt capabilities of cert that have nothing to do with anything they have any ability to ever make use of, if it is the pharmacy transactions for example. And that's the first issue. The second issue is, I don't think it works to just simply make criteria optional within one criteria. Granted, if we answer the question of optional to whom, if it's optional to certify to them, that may work for a lot of cases, but if you do certify to them, they are part of the scope of the same criteria. And the possession requirements for a ONC is you have to have full legal licensure to everything that's within scope of a certified EHR module.

I think the only way to really work around these kinds of issues, is to separate this proposed criteria into more than one, possibly three. So, one would be to retain as a required scope of a criteria, the prescriber oriented workflow, that's probably the way most of the market thinks about E prescribing, and what traditionally has fallen within the historic definition of E prescribing functionality for EHR. Dating back to the **[inaudible] [00:44:13]** kick-back safe harbors.

And then separate out the long-term care for pharmacy optional criteria, that are not part of the definition of cert, and not part of the definition of the Bay CHR. That way you are effectively supporting what has been the traditional principle policy audience of the use of certified EHR technology for hospitals, and clinicians, and physicians. And you could allow for certification of those other criteria for those who wish to pursue them, without saddling the whole burden on a provider or hospital audience, who has no interest in certain of the transactions. So, that's the gist of it. So, maybe stop there and let people respond to that. But that was the main thing I wanted to raise.

Sasha TerMaat – Epic - Member
John, I had read over and added a comment yesterday, and I think you're spot on. I hadn't thought about the implications of making certain ones optional, in the sense of, what if a product wants to certify as a pharmacy product? It doesn't really make sense, right? Because the optionality doesn't – the way I propose it, it doesn't really work the best.

John Travis – Cerner - SME
Doesn't do them any good, right?

Sasha TerMaat – Epic - Member
Right.

John Travis – Cerner – SME

Yep, exactly.

Sasha TerMaat – Epic - Member

So, I very much appreciated your insight and concern here, and I agree. The only, I guess, suggestion I might have, is within the prescriber applicable group. I'm worried about putting the REMS transaction on a 1/1/2020 certification timeline.

John Travis – Cerner - SME

I agree, yeah. Yeah, I agree. Here's something that we've been chewing on, and I don't know quite how to say it, but I'll try. So, ONC has clearly written a language in the rule with the recognition to me, at least, that CMS has historically had a softness about the firmness of part D compliance states. In every single case, since the original E prescribing rulemaking back in about 2005 that adopted, I think it was 5.1, every single time CMS has either moved the compliance data or declined to enforce it. And I can't say that will happen this time around, but that, certainly, on a lot of the industry's mind, to some people, I think, even believing that's a very predicable thing that will happen.

We can't necessarily say, with any preordination that will happen, but I think it is good to do something, like I think you were about to suggest, maybe making the REMS transactions optional, at least for 1/1/20, or at least do something to not make them instantly effective as a result of the 1/1/20 data, if the 10.6 criteria is to be retired. The current B3, if I have that reference right. Now, at the same time, it seems to be kind of a weirdness, but not everybody seems to want, at the federal level, wants to acknowledge the reality of the presence of Surescripts, and they've announced support for doing data transformation through December 1, of 2020. I don't think in any sense we would suggest trying to carry things beyond that date. And I'm not suggesting putting that kind of stuff into regulation, but that's a market reality.

And the E prescribing transaction are little unique, in that they are truly voluntary for part D. If you do electronic transacting, then you have to use the standard. But that doesn't carry weight to other programs, it doesn't require use of electronic, whereas if you retire the 10.6 criteria, and you make it a part of the definition of cert, you are playing a stronger tactic there to compel adoption. So, I think there is a lot of wisdom in either suggesting deferring the retirement of the 10.6 criteria to some later date, or making optional REMS transactions, and maybe you pick a later date for those to become required. Something of that order.

Sasha TerMaat – Epic - Member

Yeah, I mean, I guess. REMS is new, and I think If someone wants to use REMS, I think this is the standard they should use, and it would be reasonable they certify to it. But I think, there aren't even any other REM systems available to use it with yet, as far as I know, and so I don't think people are going to want to use it on 1/1/2020. Maybe we make it a separate set of certification, and so that it wouldn't impede the ability to get certified and used cert for the prescriber applicable criteria, and people could phase in use of REM more slowly.

Raj Ratwani – MedStar Health - Co-Chair

All right, so watching the clock here. Let's see if we can break this one down into two segments, just to get everybody's feedback on it. So, I think John and Sasha, the first proposal is to break it up into these three components by prescriber, LTC, and pharmacy. Any other perspectives on that first recommendation? Is everybody okay with doing that?

John Travis – Cerner - SME

I think one last suggestion, I can't see if it was on the screen, but the Get Message transaction. It keeps showing up like a bad boomerang. Sasha, you may know, I don't even think that it's been used in any real way. Not for intermediate exchange for sure scripts, which is 95% plus of the market for transaction volume. Is that even worthy of inclusion? It's been there since the beginning; to my knowledge we have never seen much use of it. It is an old model of retrieval of messages that's an electronic mailbox form, not intermediate exchange.

Sasha TerMaat – Epic - Member

I don't see a value for it. I don't know of anyone who uses the polling mechanism that would even make it message applicable. So, I guess, I, in the document, suggested a little bit of different formatting along those lines, which we can look after we take public comment.

John Travis – Cerner - SME

Okay, good. I don't have anything else. We didn't get to that one, and I wanted to make sure we did.

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

Okay. Why don't we –

Raj Ratwani – MedStar Health - Co-Chair

Okay, so I want to make sure we – go ahead.

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

I was just going to say, maybe just take a quick public comment, and then we can circle back for the last seven or eight minutes. Operator, can we open the lines?

Operator

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 the question queue. You may press star two if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star key.

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

Do we have any comments in the que?

Operator

There are no comments in the queue at this time.

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

Okay, Raj, I'll hand it back to you.

Raj Ratwani – MedStar Health - Co-Chair

Okay, great. So, I want to make sure we get through this in the last seven minutes. So, Carolyn, Ken: thoughts on the format here proposed by John and Sasha?

Carolyn Petersen – Individual - Member

I certainly can't claim to be an expert in this, but it makes sense to me conceptually. I can see the value of the discussion points raised. So, I'm okay with it.

Ken Kawamoto – University of Utah Health – Member

Same here.

Raj Ratwani – MedStar Health - Co-Chair

Okay. All right, and Sasha, John, does this look okay the way that you have it now? John does this – Sasha's doing some **[inaudible] [00:52:20]** work here, which is awesome.

John Travis -- Cerner – SME

Yeah, that's good. See how Sasha treated the Get Message transaction, but otherwise, yes. I'm sure she'll get the Get Message one well-disposed of, as it were.

Sasha TerMaat – Epic - Member

John, you didn't have RX change request in there.

John Travis – Cerner - SME

Oh, yeah. That's a current requirement, so…

Sasha TerMaat – Epic - Member

Yeah, I think that would go in here, right?

John Travis – Cerner - SME

Yeah, yeah, it would.

Sasha TerMaat – Epic - Member

And then, renewal request is new…

John Travis – Cerner - SME

I think that that probably belongs there, don't you think? The REMS were the more challenging transactions for the reasons you stated.

Sasha TerMaat – Epic - Member
It can go either way, I guess.

John Travis – Cerner - SME
I would say if ONC were to go along with this, that's a pretty good response . I don't know that it's necessarily bad to have that in there. Unless it were thought to be insurmountable by – let's say worst case happens, and 1/1/20 holds up as a retirement date of the B3 criteria, what would you want it replaced with? Would that be –

Sasha TerMaat – Epic - Member
I do, and in my mind, I'm still feeling like there's some fuzziness as to the use case for it in differentiation the value of that use case and some of the other cases. So, I don't know that I'd prioritize it as highly for 1/1/2020, since it is new as some of the other pieces, where you clearly need it to replicate existing functionality. But I agree with you, it's less significant than REM.

John Travis – Cerner - SME
The only thing I'd say move down to the next category would be, if you took a hard standard of – if something did fall and hold the 1/1/20, you'd probably want it to be matching to the scope of the current criteria.

Sasha TerMaat – Epic - Member
We'll just put a comment that it's new and could be implemented after 1/1/20, without loss of functionality.

John Travis – Cerner - SME
There you go.

Sasha TerMaat – Epic - Member
Because that's true, and then if they are looking into modulate what's necessary on a short timeframe, we've made that clarity.

John Travis – Cerner - SME
Yes.

Sasha TerMaat – Epic - Member
Okay.

Raj Ratwani – MedStar Health - Co-Chair
Okay. Sasha, John, thank you both for driving that one. So, jumping into the last one, I believe, is rec 28. I think that's right.

Sasha TerMaat – Epic - Member

Yeah. Denise had asked me to add a sentence about why we are doing this, I guess, just to give a little context in one minute. The inpatient implementation guide includes a bunch of information, like hospital identifiers, that are not going to make sense if you are actually putting ambulatory data into a QRDA1, for a workflow of then importing it into another ambulatory system when you're transitioning systems. Similarly, if a hospital system wants to generate a QRDA3 to look at their totals; their numbers, it's not going to make sense to have to include ambulatory identifiers like a provider tax ID in that document, and vice versa. So, because the implementation guide formats are so domain specific, it is not practical to use an inpatient implementation guide in the ambulatory domain, or vice versa. So, I tried to add a sentence to clarify that. I can elaborate further, if that would be helpful.

Raj Ratwani – MedStar Health - Co-Chair

I think what you added there is pretty good.

Sasha TerMaat – Epic - Member

Okay, that's fine. Otherwise I could give another sentence of clarity if that's useful. But if this is enough, then I'll keep it short.

Raj Ratwani – MedStar Health - Co-Chair

Other folks have thoughts on this?

John Travis – Cerner - SME

The only other thing I can say is, maybe instead of, "Developers will not know how to comply," I think developers will be confused. Maybe it's the same thing. I take your point, Sasha. I think developers would look at this as, this is absurd. Yeah, I think that's important to say. That's a compelling example of why that is in need of being addressed.

Raj Ratwani – MedStar Health - Co-Chair

Okay, Sasha, thank you for making all these changes so quickly. I believe that takes us through other recommendations where we had comments to address. Is there –

Sasha TerMaat – Epic - Member

Raj, I think one other thing that was on the table, still. The self-developers.

John Travis – Cerner - SME

Oh, yes.

Raj Ratwani – MedStar Health - Co-Chair

Oh, that's right.

Sasha TerMaat – Epic - Member

We can just resolve that in one minute, for sure.

Raj Ratwani – MedStar Health - Co-Chair

Okay. That was 31, right? Is that right?

Sasha TerMaat – Epic - Member

I don't know that we numbered it. 31 was the security related one, and I added a clarifying sentence at Denise's request. But that is not about self-development. Self-development, I think, we have all of our notes. But I don't know that we had a recommendation about self-development proposed yet…oh, we do. It's way down at the very bottom of the document. It's not numbered.

Raj Ratwani – MedStar Health - Co-Chair

Oh, great. Okay, I see it.

Sasha TerMaat – Epic - Member

I would support Denise's proposal here.

John Travis – Cerner - SME

Yeah, I would too. I think I've read this before. It was a good summary about our conversation.

Sasha TerMaat – Epic - Member

Do we want to just vote to make this an official recommendation, then?

Raj Ratwani – MedStar Health - Co-Chair

Yeah, I think we should. Thoughts from others on the phone?

Carolyn Petersen – Individual - Member

I'm okay with this.

Raj Ratwani – MedStar Health - Co-Chair

Ken, you good with this?

Ken Kawamoto – University of Utah Health - Member

I think this was the issue of – and this is for people who are seeking certification, right?

Sasha TerMaat – Epic - Member

Correct.

Raj Ratwani – MedStar Health - Co-Chair

Yes.

Ken Kawamoto – University of Utah Health - Member

I'm okay with that.

Raj Ratwani – MedStar Health - Co-Chair

Okay, good. All right, so let's add that one in. And then…Kate, what's the next step now? So, I think we've been through all this, do we need to do a vote on this right now, or how does that work?

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

I think if the task force is in agreement on all of the recommendations, we will move them forward, but I think the question was the timing for next week because, I think, we total 37 recommendations at this point. Timing, and –

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

Yes, I agree. As long as we have consensus at the task force level, we do not necessarily have to have a formal vote at the task force level. If we feel comfortable with presenting to the full committee, and we want the committee to vote on them, then we can possibly do that for the 10th, as long as everybody feels comfortable don't that, and the other thing we discussed was is there a way to, perhaps, break the recommendations up, so that we're not doing everything in our next virtual call later in the month. But again, don't necessarily have to rush it for next week, if we do not feel like we're ready.

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

It seems like we are ready at this point. Are there other outstanding things that we need to look at?

Raj Ratwani – MedStar Health - Co-Chair

I think we've covered everything, now. I think we've been through a round of having this document available to everybody, people commenting on it, and then the last two calls, reconciling those comments. So, I feel pretty good about where we are. I know Denise was expressing similar sentiment, thinking that there could be some kind of vote, or whatever that would look like today. But I would open up one last time for folks on the call, Carolyn, Sasha, everybody, essentially. Are there any other – do you want more time to review these? Or are people feeling pretty good about this?

Carolyn Petersen – Individual - Member

I think I'm feeling okay. There are some things that I can visualize better than others, but I'm not sure that waiting any longer would really help that, given the other high-task work that I have at my own job, of course.

Ken Kawamoto – University of Utah Health - Member

Yeah, same here.

Raj Ratwani – MedStar Health - Co-Chair
Okay. John, Sasha, good?

John Travis – Cerner - SME
Yeah, I think so. We've covered them pretty well.

Sasha TerMaat – Epic - Member
I agree, I think –

Raj Ratwani – MedStar Health - Co-Chair
Okay. Okay. Okay, good, so –

Sasha TerMaat – Epic - Member
I would update that memo to make it final and share it with folks one last time, if that is
something folks would want to see.

Carolyn Petersen – Individual – Member
Sure.

Raj Ratwani – MedStar Health - Co-Chair
Yeah, I guess that's worth doing, but I think we should basically call these final, and then we
can talk afterward about what we want to present next week, and what we can hold off. I
think we could break this up a little bit, given that we have so many recommendations.

Ken Kawamoto – University of Utah Health - Member
Sounds good. I have to drop, but thank you, this was great.

Raj Ratwani – MedStar Health - Co-Chair
Okay, thanks Ken. I think we're almost five minutes over time, so I think we can conclude
here if that works for everybody.

John Travis – Cerner - SME
Yeah, that's fine.

Ken Kawamoto – University of Utah Health - Member
Thank you. Have a good weekend.

Sasha TerMaat -- Epic - Member
Okay, bye-bye.

Raj Ratwani – MedStar Health – Chair
Yes, thanks everybody. Have a wonderful weekend.

Carolyn Petersen – Individual – Member

Bye-bye.

John Travis – Cerner – SME

Bye-bye.

Raj Ratwani – MedStar Health - Co-Chair

Bye.