



Joint Health IT Policy and Standards Committee

Application Programming Interface (API) Task Force

Final Transcript

April 26, 2016

Presentation

Operator

All lines are now bridged.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you, good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Joint Health IT Policy and Health IT Standards Committee's API Task Force. This is a public call and there will be time for public comment at the end of today's call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Josh Mandel?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

I'm here, hello.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Josh. Meg Marshall?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Hi.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Meg. Aaron Miri? Aaron Seib? David Yak?

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, David. Drew Schiller? Ivor Horn? Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Leslie. Linda Sanches?

Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Department of Health & Human Services

I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Linda. Rajiv Kumar? Richard Loomis?

Richard Loomis, MD, CPC – Senior Medical Director & Informatics Physician – Practice Fusion

Yes, I'm here, good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Richard. Robert Jarrin?

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Robert. And from ONC we have Rose-Marie is anyone else on the line? Okay, with that I'll turn it over to Josh and Meg.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Hi, good morning everyone thanks for joining, we'll go ahead and really what I hope will be discussed kind of a streamlined process of winding things down and making sure that we've captured all of the discussions and the things that we've heard over the past few months.

So, you should have received, and this was last evening and I apologize for the delay in that we just...this is a 30 page document as it stands so quite a bit of work was going into it, but the document called "A Single Source of Truth API Task Force Recommendations."

So, what Josh and I talked about, and we shared this with you last week, rather than trying to present from two different documents one of which is a presentation slide set and trying to maintain some of it back into a document that keeps the context or the text, if you will, we've just decided to have one large document and then that will become incorporated into the transmittal letter. So, everything that we're working toward and gearing for will be to make sure that this document is as up-to-date and it contains all of the information that's possible.

So, with that the organization that you see of the document today has some new sections, not really anything material just perhaps some new organization of existing material, so we went through and put in an introduction and then kind of explained really articulated the scope that we had focusing on the read only access through a single patient's record and then we expanded a little bit on the regulatory oversight and the enforcement of APIs section.

And then we organized the use case scenario with the topics that it introduced and now we're at eight topics from within the use case itself and we list all of those in order and for each of those sections we maintain that approach of background or issue identification, findings and then ultimately recommendations.

So, we do still have some work to do above and beyond the discussion today, but with that I just wanted to kind of open it up and see...I don't know Josh, we didn't really talk about the best way to go through this document, recognizing that folks probably didn't have the time to digest with a ton of detail, but maybe just kind of open it up for initial feedback on, is everyone okay with that approach, any recommendations? Did you at least get a chance to look at the organization somewhat and then maybe we can go through section by section.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, so thanks, Meg and I'll just comment briefly that for folks who haven't had time to get oriented to the document yet it's not too different from the structure we've been looking at for the last couple of months but it brings up to the front a bunch of the material that sort of provides context and frames the scope of the workgroup and frames our recommendations before we dive right into the details.

And I think maybe, you know, rather than going section by section from the beginning we could see if...it's a small call today, we could see if folks on the call have particular areas where they know they want to dig in and if there are we can make sure to hit those first and then if not we can just take things chronologically.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Hi, this is David Yak. Hello?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Hi, David.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Yeah, hey, I think the only thing I'd like to quickly review is there has been some discussion on the e-mail regarding identity proofing of the person and I see there is quite a bit of information in the document about identity proofing of the App and I think I would just appreciate if we could talk about that for a couple of minutes to make sure that we have clarity when we're making some recommendations to ONC, clarity about the distinction or the overlap in those two particular items.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Sure, great, we'll make sure that we are able to touch on that.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Thanks.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Other topics?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Les, Josh; did we get a final opinion on the sponsorship issue from OCR?

Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Department of Health & Human Services

Hi, this is OCR; could you say your question again?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It was the question of sponsorship as a way to say that if this App is sponsored by a covered entity then that App has to be covered as a BAA, it was one of the outstanding use cases that we had for comment. Did we get response on that?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

We did, Leslie, let me...do you have your e-mail in front of you if I forward it to you? And of course OCR certainly can respond, but we did receive that and I apologize if that didn't get onto you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, yes, that would be wonderful, thanks Linda. And I'm afraid...I'm sorry to say my document had an error in it so I didn't read it last night, so I'm sorry, I'm not prepared better, so I defer to the group in what we're talking about and commenting on.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

No that's fine I'll also just make the quick comment that one of our recommendations in this document itself is still to, actually, present a set of scenarios to OCR for feedback. So, we're not expecting to have all the answers, although we're very pleased that we've gone through a few cycles of iteration.

You know one of the things that we're proposing in the document itself is, you know, there are some areas that we think should be treated more broadly and so those scenarios Leslie that you worked on with us are referenced still from the current document.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you, Josh.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Sure. Other topics that we know we want to touch on today's call?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Do we have a formal response, this is Les again, or a discussion in the document that talks about why the idea of having an overarching BAA for everything didn't seem to be rational. So, we talked a lot about it, we heard a lot about it at the Joint Committee and I'm sorry, again, I just got an error so I haven't read it, did we address that as well?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So, yes, there is some language that I think Meg added to the introduction section of the document or rather the part at the beginning that describes, in terms of regulatory oversight and background, that notion that HIPAA oversight is really something that applies to Apps that are offering services on behalf of a covered entity and that some patient Apps really aren't working on behalf of covered entities. So, we do try to bake that in early on.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Yeah, Leslie, this is Meg; to your point I did not include a proactive statement that says we don't think that the overarching BAA or that comment that Apps should automatically be required. Take a look at the section and if you think it still requires some clarification we can certainly add that. It didn't seem to be a very popular statement so it did not seem like it was very compelling to get in front of, but if you disagree we can certainly put one in there.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So the only reason I'm concerned is when we have a Joint Committee meeting and we get comments back we should acknowledge the comments we've received.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Yeah, okay...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And...

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

That makes sense, yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right, so being proactive to say after, I think, months of discussion on that issue and good due diligence this is where we landed rather than just ignoring the statement and having it be inflammatory in the next meeting.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Gotcha that makes sense. Yeah, I'll certainly add something. Aaron Seib you had...did you have a chance to take a look? I know that you had some issues that you had kind of flagged as potentially outstanding. Do you feel like they were all incorporated or have you had a moment to kind of take a look at that?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

I don't think Aaron is on Meg.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Oh, okay, well that explains the silence. So, Josh, shall we take a quick walk through the identity proofing?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, so let's do that and maybe the thing that I would propose is that we actually start towards the end, which is to say, this is Section 8 or use case topic 8 in our document...

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Actually...

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Pages 28...

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Hey, Josh, this is Yak, I could...I'd like to cover one thing before we get to Page 28.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Sure.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Okay, so up on Page 9, which is use case topic 2 for App registration and in the background...

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yes.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Section 1, self-service registration portal, so this is where the developer can register a new App. At the end of that paragraph, the second to last sentence says, mere act of registering the App does not share the data with the App, data won't flow until a post registration step called App approval, where the API provider verifies the patient identity and records of the patient's decision to share, this last sentence I was sort of interested how we came to this conclusion?

So, registration itself is a low risk activity. So, what we're talking about here, App registration or rather App developer registration with the source of data, and we're saying that it's low risk because that registration doesn't really involve the release of data, that there is a subsequent step for patient identity verification which does release data and therefore we consider that to be a higher risk item, just want to confirm that is what is going on here, right?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah and maybe this is an area where we should use clearer terms, but the main point that I tried to spell out here was that at the time of registering an App no patient data are flowing.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Right.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So, there is not a risk of data breach at registration time.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Okay, so, good, I think we're okay here. I don't know if anybody else feels we want to tighten up the wording but I just wanted to confirm that, because then when you do jump ahead to Page 28 and the whole category, I get the feeling in here there are really three registration or identity verification pieces that are going on here, one is the actual identity of the App developer, the other is the identity of the App and then finally there is the identity of the patient.

And I feel sort of in topic 8 here that those ideas are getting a little bit munched together. I think they are clearly stated but I don't know that we're distinguishing the recommendations for the App versus the developer, versus the patient clearly and I wonder if there is, you know, either some more work to do on this or whether we really care about all three of those. Because, I think with the patient side what we're saying is that that's covered already given recommendations that have been made around portal identity management and identity proofing, etcetera.

So, maybe we can just take that patient piece out and only talk here about App and App developer identity or, I don't know what are other people's thoughts about this?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think this is where...

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Sure, I mean, I can say...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

A picture is worth a thousand words, you know, a diagram that shows this is worth a lot.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yes, but I think the issue with the diagram...so let me just sort of share sort of my sense here. If I could only describe one of these three things I would make sure we kept our discussion about patient identity proofing because that is the piece that needs to actually work in order for this ecosystem to come together.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Correct.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

And I think our recommendations here are very conservative, which is to say, we think this is a solved enough problem that we don't need special rules for identifying patients. Every organization needs to have rules and they need to work, but they're not a special concern for APIs. And I think that's probably the most important thing that we say in this section.

When it comes to how you identify Apps or App developers I think, you know, we have some sort of general principles that we try to describe here, but the details are going to depend on the particular technologies that you use. So, if you're doing OAuth implementation, for example, than you need this registration step where you record some information about the App ahead of time. But there are other models for hooking Apps up as well and, you know, we're not explicitly saying, you have to use this model or that model.

So, the most general recommendation we make here is really about how we identify patients. And then I think when it comes to developing...to identifying Apps and App developers what I've tried to write here and what I hope we could maybe clarify in the recommendation is, you know, we have examples of existing standards that can be used but we're not trying to recommend one over another.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Right. Well, I wonder if they really are distinct in terms of the App/developer identity versus the patient and I agree, I think the patient identity is the piece that is the highest risk of course and probably the most important and in the e-mail thread from last night Leslie Kelly Hall wrote, the existing use case via portals is generally considered to be at level of assurance 2 but I've heard arguments that it is at 3 when certain internal controls of the provider are used.

And so I wonder if there is a good NIST reference document on this recommendation or someplace where portal level of assurance is recommended for patient access to portal information? Whether we ought to reference that and then really keep a good distinction between what we're saying about patient identity and what we're saying about App/developer identity.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, I mean, so my hope would be that we're not going to say anything new about how patients sign into their portals, right, in terms of levels of assurance or...

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Well, of course not about their portals but we're also going to say that there is nothing new in APIs that we have to say, that we're going to assume or expect that levels of assurance or whatever identity proofing management standards or accepted practices occur is going to be sufficient and appropriate for APIs.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, so let's take a look at the recommendations on 29 or on Page 29, or if you think it's helpful to go to the background. I want to see if we can focus on sort of either specific changes or tweaks, or if you think we need a whole scale rewrite here it would be helpful to sort of understand how you would want to break it down.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

So, I think it was much more about the background and a little bit about the findings, but why don't we got through the recommendations since those are the most important. So, the first is, you know, guidance, ONC should provide guidance that they're not different and specifically the organization must have an appropriate level of assurance, it must authenticate and the same sign up and login process that's used can and should be used to bootstrap the API access. So, everybody's good with that?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, that's where we start. I hope that we're good with that, yeah.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Yeah. I think so, I hope so. Okay, standards like OAuth can be used to leverage. API providers must not impose patient identity proofing or barriers that go beyond what is required. They should collaborate with appropriate agencies to provide distinct API developer and usage privacy security standards to encourage adoption. So, this is patient, patient, patient, patient, which I think is great.

I think where it was getting...and I only looked at this last night quite frankly for the first time, so I think the background though gets pretty muddled in terms of the App developer and maybe that's the part that needs to get cleared up. And do we say specific recommendations about App and developer? No.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So, in the registration section we talk a little bit about the kinds of things that would be appropriate to verify and the kinds of things that would be inappropriate to verify. But the heuristic that it always comes back to is what can be automated and made frictionless.

So, verifying that you own a domain can be automated and frictionless, verifying that the developer controls an e-mail address can be automated and frictionless and so those are the kinds of things that would be appropriate to verify about developers.

But things that you can't automate and things that you can't make frictionless would be inappropriate to require verification.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

And where are you seeing that piece Josh? Is it like that fifth bullet?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So, that's in the topic on registration.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Oh, in the topic on registration.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

We address that topic.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Okay.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

But...

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

I see, okay. Do we have a good citation to the identity proofing recommendations for portal access or can we get one?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Say that again?

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Do we have a good citation for identity proofing requirements for portal access or can we get one?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

I don't have one; I don't know the extent to which there is on a sort of regulatory front. But I guess it's a good question for us to raise if anybody does know them.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Say that again?

Rose-Marie Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Yes, this is Rose-Marie...

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Oh, I'm sorry.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

So, the question is do we have a good citation that would be a reference for the identity proofing and security requirements around a portal access to patient information?

And Josh, I think it's important that we do because if we don't have a good citation, a place to point people we're saying that what's in place is good enough for APIs, but if we don't have a citation to that then we're not really pointing to anything you know.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Isn't it in the HIT CEHRT Rule for portals?

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

I would assume so.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think that's worth looking into and I think your point is well served because if there is nothing to cite then we need to state more explicitly our assumptions around current, at least current best practices of portals.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Yeah, I'm assuming there's something good to cite.

Rose-Marie Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Yeah, this is Rose-Marie...

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

I just don't see where that is.

Rose-Marie Nsahlai – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

This is Rose-Marie with ONC, we do have...I don't know what you mean by a very good citation, we have recommendations for patient's access to portals but we also are working internally on providing some good recommendations around that. It's not yet available but it will be, but we do have existing recommendations that came out of the Health IT Standards Committee or Policy Committee, I need to clarify that and I can provide you those citations.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

But I think...

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Okay, those...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's just access to medical records period whether it's electronic or not. The long-term history has been a patient presents and must present an ID and that ID has to be checked with someone within the organization sometimes its internal controls and possible access will require another step, but most often there is identity that's provided. So, there's a long history before any electronic access case.

With electronic access the same would apply for signing onto your portal, you present to the physician's office, you present your ID, they establish a relationship, they give you a portal user ID and you then generate your...or change your password. So, it follows the same sort of medical record access laws versus any...I think it's just something that's grown out of the current manual process, but...

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Okay, so to bring this to a bit of a close, I didn't mean to make it a total rabbit hole here, but I think one thing is if we can get a good citation we should reference it because we say that what's used for portals is acceptable so we should have a reference there. I don't think we should just let that flow.

And secondly, and I'd be willing to contribute if we should maybe reword this background a bit just so it's a little clearer as to where our focus is around patient identity proofing and we can...we have some comments in other places regarding App and developer identity and verification but I think the key one is around patient. So, I think unless there are other comments on that we could just go on those two points.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, that sounds good, just from my perspective, if we have a reference to something concrete that's great and if we leave it floating because we don't have a reference I actually think that's fine too because what we're referring to is whatever a provider is comfortable with to actually make the portal data available to their patients.

So, if we nail it down I think that's fine but if we can't I don't know that we have to go overboard and try to specify any more than portal access has been specified. Let's just find out...let's see what we can learn on that one.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Yeah, let's see what we can learn. I'd be concerned...first of all I think there are going to be some decent references and secondly, I would be concerned if there isn't something to point to.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

All right we'll see what we get and then in terms of reworking this section, yes, sure any edits that you want to share would be great, we'll take a look and see how we can incorporate them.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Okay, thanks.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Sure. So, the other areas that we identified that we wanted to talk through on today's call included what else? Leslie's topic on sponsorship I think we already just touched on. Is that a topic that we want to dig into in terms of what's written in the PDF today?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Josh, I got to it and it sounds like all the questions were answered in dialogue and discussion in a nutshell unless PHI is being passed there is no requirement for a BAA. And when PHI is being passed, which means that it's probably pre-populated by the provider to that App and therefore not only...it's no longer a patient specific initiated App that has no connection to PHI.

So, it sounds to me like my questions were answered that unless there is PHI it is not a requirement and there is no PHI unless it's been handled by the App developer themselves and the provider and not initiated by the patient. I'm good.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Okay, excellent.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Sorry, now that I'm starting to look at editing this piece I'm looking at there is one sentence that I'm going to have to raise here Josh, so back to use case 8, background, introductory sentence, when healthcare data flows from a HIPAA covered entity into a patient selected App there are several points.

So, what about the case where the data is flowing into a non-HIPAA covered entity, oh, I'm sorry, from a HIPAA covered entity into a patient selected App, it doesn't matter whether the App is HIPAA covered or not it's the...

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Exactly.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Okay.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

We know the source is HIPAA covered and we don't care what the destination is.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Okay, sorry, yeah, that's good, got it, thank you.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Sure. Yeah, I know there is a fair amount of dense language and nuance in here. So, are there other topics...and I know we haven't given everybody a lot of time to go through this document, are there other topics we know right now that we should skip over to? Otherwise it might make sense to have Meg take us on a quick tour of the header material which is to say that the introduction and then the description of the regulatory oversight section which has been brought up to the front of the document.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Yeah and I thought Josh it might be a good use of our time as well, as folks kind of digest the whole document, is if we...because now we have what I think nine sections for recommendations, one general and then eight specific to the use case, maybe it might make sense just to focus the rest of the discussion on those recommendation pieces.

Because ultimately I think that's what...while the background and the findings are very important we're not going to probably get all of these right, but certainly we want to make sure that the recommendations are nailed down pretty tightly.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, I think that's right.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Okay, so just a quick drive through, new navigation within the document. Essentially there are two sections we have an overview section and then we have the use case topics section. The overview section includes an introduction, so the material that we had originally, I believe from the beginning of our Task Force meeting, within those slides, what the API is, what the CEHRT criteria are, what the scope is...

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

...

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Yes? I heard someone pipe in? Okay, one comment I do want to make because I did mention definition Josh, and we forgot to bring this up earlier, we are finalizing the glossary with our resource help at ONC and I think that Rose-Marie, correct me if I'm wrong, but we were looking at toward the end of the week having that glossary finalized, but we had shared this with the group before several weeks ago and had asked for your feedback and now it is just finalizing the terms and being able to incorporate it as an appendix to this, but we'll have the generally agreed upon terms if you will.

So, we do highlight the limited scope and we did get several questions on that so I hope that this was clear in that section, motivation for limited scope, but we really tried to carve out what it is that we're trying to do.

And Josh we had a new comment, I'm trying to pull up my notes, but to further limit what that scope was. Could you remind me of what that is?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

I'm trying to remember this myself Meg.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

It seems like we've had a lot of conversations. So, we will likely change the wording on the scope just slightly to tighten that down as well because ultimately what we're saying is that topics that are not included in this scope...we feel like this is a good foundation and will provide learnings for future analysis but these feed into the recommendation that we have that ONC should address these other use cases and potentially convene another API Task Force to help flush some of these out and that includes APIs with an update access, APIs that access multiple patients or the aggregation of populations of patients so kind of anything above and beyond that.

We were trying to at least document that we were intentional about how we considered whether or not it should be in our out of scope and then, again, those that fall out of scope we would recommend that for future analysis.

And then for the background on the regulatory oversight and enforcement of APIs there is probably a lot more authoritative guidance out there. What I tried to pull together were just some of the high-levels around FTC oversight, FDA oversight, HIPAA oversight because we do want to highlight the complexities of this legal framework and, you know, regulatory framework that applies to the API ecosystem. So, in order to do that it was fair that we had a little bit of background that kind of piloted some of the work that had already been done as well including the FTC tool that was recently released, the guidance for APP developers, FDA has several pieces of guidance and then certainly OCR and a lot of the work that they have done.

So, trying to draw on some of what the agencies themselves are trying to do to make this easier for actors to navigate within this ecosystem, really that's just what it is, I'm not sure...so, you know, certainly take a look at it, but, you know, again it's not necessarily intended to be authoritative just more intended to be educational. And then it developed into some recommendations that we have around that regulatory oversight.

So, I think a couple of points, if we could pause and just spend a little bit of time here to make sure Michelle is caught up. So, the recommendations at the end of the regulatory oversight that begin with ONC should coordinate with the relevant agencies and congressional committees.

So, I think to Leslie's point this is where it would be a bit...this is the place for us to make that statement that says, around the overarching BAA for example that we don't believe that there is a bright lined rule that all Apps that connect to these EHR APIs should automatically need to have these BAAs and we can go into a little bit more detail around that.

But, you know, approaching this from a larger step all the way down, you know, macro/micro ONC should coordinate with the relevant agencies and congressional committees with jurisdiction where legislation is needed to give the agencies the ability to implement rules and regulations, and ensure privacy and security, and, you know, this is, I think, common sense and I'm sure that it is work that they are already doing through the role of coordinator, but basically it is us recognizing that there is...the next bullet that we have that says, analyzing the feasibility of a simple, single, comprehensive oversight framework that, you know, we don't have to...any technology that touches any type of health data, right, that's kind of the ideal situation recognizing that this is not something that ONC can certainly do by itself and even with its coordination powers across the agencies, a lot of what we're talking about would still require congressional action.

So, I think, again, we're really just emphasizing the work that they're already doing from a coordination perspective but highlighting, hey, this is complicated and we think that there could be a simple framework and we would like ONC to pursue that simple framework, but the remainder of our recommendations are really around navigating that complex framework. So, then that is when we get into additional guidance.

We do mention a single location for all API actors so this would include the developers of both the APIs and the Apps, providers and patients, to access in order to become educated, a single location to

log...for patients to log complaints or to launch investigations. Right now each of the agencies, as they provide their own guidance, it is on their own website and you can access each agencies own FAQ or log a complaint here, each one kind of does something a little bit differently, so based on our conversations that we had a couple of times, really to try to centralize this and say, hey, the patient is not going to understand whether to navigate from FTC to FDA versus CMS even or whatever the agency is that we think that there is one single location that could do some of that.

And the FTC tool, the interactive tool, I think we all really appreciated the thought that they put into that and kind of the logical questioning and the link that were contained within that tool to launch the user to additional materials.

So, this I think, again, it's a new section, new recommendations, but nothing that we haven't talked about before. So, of the entire document I think that this will probably be the one that is, you know, worth a little bit more of our time to make sure that this was wordsmithed in the best way that represented where our discussions went.

So, with that I'm just going to kind of pause. I know that it's up on the screen. And Leslie, I apologize, you didn't get the PDF, if you don't have it up on screen I can send you a Word doc or even a different link, but if we could kind of walk through these that would be great.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I was reminded by Lonnie, very kindly, that it is to the left of my screen, just click on a button. So, I slapped my forehead said “duh” and downloaded it.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Okay, great, perfect, awesome.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I just have one comment, we're asking a lot of things to be done and we have not very long before this comes into effect. So, should we mention timeliness? Should we mention that these things are recommended to be done but should not preclude or should not require a delay of the project or do we want to stay silent on that?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

I think that's a really good point. I do think that it is worth mentioning that these are...the recommendations for education and guidance, and coordination, and things like that are to help facilitate and ease the current process, it's not to necessarily remove any barriers. So, it is working it's just that we think that it could work a little bit easier and certainly worth pointing out that to prioritize the education and guidance but not to disrupt the current timeframe, I think that's a good point.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks, Meg.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Any other feedback or gut reactions on kind of the approach within this section?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Meg, this is Aaron.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Hey, Aaron.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I just wanted to make sure I was audible I didn't want to interrupt when others were talking. I'm good.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Okay, good.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Welcome.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Sorry, I'm late the Metro kind of ate my afternoon it seems.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I had one other comment, recording, this is Les, with relevant agencies...do we want to put in a parking lot item or other items where there may be federal agencies like the VA or others that might have a different level of security that needs to be addressed? Do we want to be silent on that? Do we want to assume that everybody has the same level of Apps with security with LoA?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Well, that's interesting. So, we do mention and call out the specific agencies, as far as their role as data holders and potentially influencers for the endorsements and criteria that would support the endorsements, we did not, to my knowledge, well, no we didn't, we didn't discuss anything like the DoD's additional level of assurances that would be required for example.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And I don't know enough about the Regs maybe staff can help us. If an organization is a Meaningful User then they have to adhere to the standards and that's the minimum bar, can they set additional bars if they are a federal agency?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

For...I'm sorry, Leslie, set additional bars for...like the LoA?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, security or LoA. So, if you're going to go into the DoD's environment.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I might be able to help a little bit, you know, at least with the VA, who, you know, they have a different set of applicable law which requires them to do certain things for certain conditions and so forth which, you know, had them take a look at how they were approaching the Vet's decision on which tools to disclose their PHI to, but they've actually taken the step, and I think it's the...you know we talked about two alternatives here as far as getting access via the portal to, you know, do that binding between the authentication and authorization to an API where they have the Vet login to My HealthVet, their federal portal, and then provide an end point, in this case a Direct address, for that Vet and regardless of the LoA between the application that the Vet is, you know, pointed to and the Vet themselves, because the user has authenticated into the portal that's sufficient for the purposes of disclosing. So, I think there's...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's wonderful.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yeah, they are doing it in multiple sites now, piloting in multiple sites today. We probably should have them come out and present to us, well, we're not going to be working on this much longer, but I think that they've moved in that direction, but what I was trying to lead up to is it took a couple of years for them to get to that point.

So, as we get other methods out there I think as long as we can demonstrate that they are secure and privacy preserving that the VA would also move in that direction as would I think maybe the DoD with some of its populations but not necessarily all of them. But they do have different applicable laws and that's why they take longer to move forward it seems...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

But that's...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

But they are actually ahead of everyone.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's great news and I think then that goes to maybe do we want to talk about the fact that this really addresses so many barriers that have existed in other areas by coming up with this approach and having patient mediated exchange we actually have the chance to unblock data like we never have before.

I just think this is profound and we haven't...perhaps in the opening section talk about this as a liberating and profound change to the ecosystem.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

So, Leslie, I'm trying to figure out how...you know, what the action item is. Do we provide some additional...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think perhaps in our comments when you guys present the final to the Joint Committee that maybe you can do it in oral, but I don't think it can be overstated.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I think a lot of people will follow their pattern and then with time, you know, as we see the OAuth pattern mature and typically in the healthcare space it's very mature, but there will be ways that we'll be able to even improve it further, we'll see adoption and acceleration unbelievably. Meg I can send you the deck from the VA.

I guess the original question that I was answering though for...that Leslie Kelly had asked was are there laws that apply to federal agencies that exceed HIPAA that make them, you know, have to do something in addition to what might be appropriate for a HIPAA covered entity and I believe that there are and that's why they have so much effort in that and making policy work right.

Another thing, I was at...this variance in state law is always a confusion that we have to make clear because of the way that the Omnibus Rule was written, a lot of things...there is some counterintuitive things there about the HIPAA being preempted by state law because the consumer's right of access is a right, it's kind of inversed in the sense that a state law that provides for less access is superseded or, you know, HIPAA is preferred because it gives the patient's right to access, whichever of the two laws give more right to access is the law that preempts the other, which is kind of the inverse of the typical HIPAA pattern.

Usually state law that is more stringent preempts HIPAA except for in the case, you know, of this patient's right to access. The only state law that can preempt a patient's right to access are state laws that make access more easy for the consumer to actually get their data. We probably should get something maybe from OCR on that.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Well, so, I mean, I'm trying to think, we've talked about harmonizing conflicting redundant and confusing laws in our recommendations. Is there something additional or specific that...I think that's a fairly broad coverage so if you have, you know, a specific example in mind we could certainly include it?

Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Department of Health & Human Services

Hi, this is Linda Sanches, I'm hoping this is helpful and not just more information, but the previous speaker is generally correct where HIPAA calls for greater access by an individual it would in fact apply even if a state law had lesser requirements and vice versa. I would point out most of the time that doesn't actually involve preempting because normally you can comply with both.

If HIPAA says you must provide access within 30 days and a state law says you must provide access in 10 days you can provide access in 10 days and be compliant with both laws.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Right.

Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Department of Health & Human Services

So, normally, they can work together even if the standards might be more or less rigorous. You just follow whatever...

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

So, thank you for the definition.

Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Department of Health & Human Services

Is most rigorous.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

That's much better than I put it, this is...and I would just share with Meg, you know, the reason that I'm bringing it up is I was at a Get My Health Data meeting this morning where they had a bunch of tracers out in the field and they're hearing from the HIMSS professionals, well our state law is going grant the right of access, where we have, you know, we have 90 days versus 30 days.

So, I think there is still some confusion in the market about how the right of access works in comparison to applicable state law and it would be helpful if we could make it very clear to people just what Linda said, exactly what Linda said.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So, in terms of sort of concrete language that we could consider sort of adding to either recommendations or to findings are there some specific areas that you would propose?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Sorry, Josh, was that directed to me? Could you restate it?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, so, concretely speaking what would you propose that we might change about our document at this point? Where would changes go and what form would they take?

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

We have a section where we talk about education, right? I think that there is education that we targeted to the consumer about their rights; we also might have some clarification or education that is needed to be targeted at the organizations that are covered entities as well, specifically with regard to that statement that Linda shared. Does that seem rational? Like a good...

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, I guess what would be helpful is if you...you know if you can target a particular spot in the document and share a couple of sentences of language for insertion that would make it easier for us to make sure that we were talking about exactly the same thing.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Fair enough. Can someone...when you get a chance there is a...I need a link to the Google Doc, I've lost track of that.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So, we're trying to do our editing now outside the document and I think the easiest thing to do is just e-mail proposed changes directly to Meg and me.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I thought I was out of sync...

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

No that's fine.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Yeah, I'll shoot you my marked up version; can I do it by Wednesday?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, I think that works.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Okay, thank you.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, Wednesday being tomorrow, yes.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

Wednesday, 2400 hours.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Good are there other topics that we want to cover on today's call? All right well let's...let me just check in with Meg and say from my perspective I think that we're probably in an okay shape to close early unless there are other parts of the document that it makes sense for us to focus on, we do have another half hour left if we need it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I would like to talk about...

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

So, Josh...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Not to the document but to the discussion formally of how great a job you two have done, really appreciate the work, the careful thought, the listening, the technical expertise and just the volume of work that you've had to do for this, so thank you.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Thank you, Leslie, appreciate that very much. This is a great group to work with.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, thanks very much, it's really nice to hear, it's been a real pleasure working with everyone here.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Before we do wrap let's if we could talk through next steps so we have a meeting on the books for May 5th and then May 17th is the Joint Committee where we present final recommendations. So, from a

process perspective because this PDF was included as meeting materials today it's available for the public to provide some feedback on.

I know that we've kind of wrapped up our discussion today but if we could...Josh, we haven't talked about this so give me your feedback, maybe just tentatively keep the May 5th meeting on the books to see if, as folks read the document and go through a little bit more detail if, you know, we can't work this out through e-mail or if we happen to get some other comments that we want to discuss in a face-to-face meeting, otherwise I would think that we could...if we don't get that feedback and if everyone is comfortable with the document perhaps the May 5th meeting we could just...we could cancel once we get...

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Hi, this is David Yak...

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

This is Josh, I think...

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

I would think that it would...I don't need to see every revision but I would like to see it one more time and maybe just before May 5th and then we have a May 5th touch base and see if there's any items that need discussion that would seem best for me. I'm a little worried if we just leave it to e-mail that we might not get enough input, contribution and sign off. I mean, you'll be looking for sign off I think at that point right?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Yeah, so assuming either we...the things that we talked about today...so we're going to add a couple of statements and David I think you were going to help us reword some of the background on identity proofing, you know, timeliness, we've got a couple of things to clean up, but I think it's pretty safe, if you review the document as is, we'll make very clear any editions that we make and if you're not comfortable...if you would rather that not happen through e-mail or that we can talk about that in addition to e-mail we could certainly do that but I just want to kind of, you know, emphasize we're ratcheting down, this is the mile stretch in the...

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

Oh, yeah.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Yeah, okay.

David Yakimischak, MBA – Senior Vice President & Chief Quality Officer – Surescripts

I think what...at least what I'd like to see then would be a candidate final document, you know, before it's published just so that I can see it in one place. Because I know in looking at this and the edits that I see and I'm starting to make, I think what's happened here is there is a bit of overlap between use case 2 and use case 8 so I'm not sure how many more things are going to change, but I have to believe that there's going to be enough that I'd probably like to see it one more time in its entirety before I said "yeah, I'm good with it." And if that can all be done by e-mail that's fine I just wanted to comment that I'd like to see it one more time before it's published.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, I think that makes sense.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Absolutely, yes.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Certainly we'll be sharing those updates as we get any last proposed changes. I know we'll look forward to hearing from you, David and from Aaron as well with a couple of proposed editions and we'll share out any changes that we're incorporating and we'll keep the meeting on the books but we'll just evaluate as we get closer to the date whether we want to actually use it or not.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Great, this is exciting we're closing in very cool. It's been a fun couple of months. I think we've really made some good recommendations and I know that the agencies have been listening to us this whole time but to have a final document to refer to I'm sure will be well appreciated by them as well. So, thanks, everyone.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Absolutely and with that shall we turn over to public comment?

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Let's do it, Lonnie, can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

Sure, if you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press *1 at this time.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

While we wait to see if there is public comment this is a reminder if the public would like to e-mail any feedback there is an e-mail address up on the screen that you can send your feedback to or this is Michelle Consolazio you can always send it to me as well.

It looks like David Tao has a public comment that he put in the chat. He says, please clarify what the public comment process on the Single Source of Truth document is, e-mail to who, and who may comment at May 5th meeting. So, I think I just answered that so I should have read it before I said it. So, hopefully that answers David's question and it looks like we have no other public comment. So, thank you, all.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Thank you, everyone, take care.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Have a great day, bye.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

You too, bye.