

# Health IT Joint Committee Collaboration

A Joint Policy and Standards Public Advisory Body on Health Information Technology  
to the National Coordinator for Health IT



## Joint Health IT Policy and Standards Committee Application Program Interface Task Force Final Transcript April 12, 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 Standards and Policy Committee. 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. Meg Marshall?

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

I'm here, hi, Michelle.

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

Hi, Meg. 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. Aaron Miri?

#### Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center

Good morning, hello.

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

Hi, Aaron. Aaron Seib?

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

Present.

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

David Yak? Oh, hi, Aaron, sorry.

**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**

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?

**Drew Schiller – Chief Technology Officer & Co-Founder – Validic**

Here.

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

Hi, Drew. Ivor Horn could not join today. Leslie Kelly Hall, I believe she is traveling. 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**

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 do we have Rose-Marie?

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

I'm here, thanks, Michelle.

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

Hi, Rose-Marie. Anyone else from ONC on the line? Okay, with that I'll turn it over to you Meg and Josh.

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

Fantastic, thanks, so this is Meg I'm going to go ahead and get us kicked off, we've got a couple of things that we're going to talk about within that overarching draft recommendations, the first one is two recently written, newly written sections for the recommendations outlined that we haven't shared before and the Task Force members, Michelle I think, should have received a link to that but we're going to walk through it in today's call.

So, just a high-level review of those two new sections and then we're going to walk through the slides that were sent that Josh and I are going to leverage for our draft report or I guess our report out next week to the Joint Committees around our draft recommendations and then we'll talk about...we'll wrap it up a little bit talking about what our next steps are and as we're winding down to a close to know what the expectations will be over the next few weeks. So, Josh, did you have anything to add?

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

No that's just perfect I'm ready to dig in.

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

Okay, so, Michelle, do you by chance have those links available to display or should we flip them?

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

Yes, Altarum is ready.

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

Okay, perfect. So, this first section that Michelle has up is the consent/authorization framework and this wasn't a complete re-write but it has enough information that we wanted to make sure that we walked through it in a little bit of detail today.

So, a couple of things to note, we followed the same process that we had with the rest of the recommendations starting with the background then moving to findings and then outlining the recommendations.

So, from the background perspective it is just kind of...we'll just go through that fairly quickly. One of the things that I did want to pause and chat about for a few minutes is the notion that this process, which is broadly speaking, you know, can be referred to as consent, authorization, approval, request for access it's basically the notion that a patient is saying "yes it's okay for the App to receive my data." And recognizing that, you know, there are certain applications for HIPAA there is consent for certain processes it is authorization for others and we realize that not all Apps will be aware of those HIPAA processes as they won't be covered under that.

So, I wanted to just stop for a quick second and see if everyone was comfortable with how this is articulated that says, we get that there's a whole lot of different terms that could refer to this process, we'll try to use the correct one in its correct context, otherwise for lack of a better term just from a general perspective to refer to that as the patient's authorization but then making note that even that term is distinguished from how it is used when describing the technical authorization as we heard about in OAuth.

Our ONC friends provided them several really nice recommendations around other terms that we could use and I thought, well, instead of introducing a whole new term that may be construed completely differently maybe we just use one that everyone is used to and then, you know, just kind of make sure that we're using it correctly where possible but otherwise we note how we're using it. I wanted everyone to kind of have an opportunity to flush that out and to talk through it.

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

Meg, this is Aaron, you know, I've worked in the authorization space for years and always cringed when, you know, the wrong words were used so I really appreciate the approach that you're using and it reminds me that we do have a responsibility in our recommendations to talk about something regarding consumer education here as well about their role and what authorization means and why it is important.

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

Yeah, that's a really good point Aaron and I know that we cover some of the education components in the privacy practice, privacy notice section.

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

Yes.

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

But I think it's worth a real clear or a real good look through of the document itself to raise that as often as we can.

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

Even a little footnote, you know, would be good.

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

Okay.

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

But I've always been an advocate for using the word "authorization" when a covered entity's disclosing based on the patient's preference. So, yeah, that's the way it should be used. It's also used, like you say, as a...you know in the technical sense with OAuth and other authorization frameworks so there is some repetition there but I think, you know, picking a new word or trying to coin a new phrase would cause more congestion for many folks that are closest to this than it would help other people. I think we should educate on the right word.

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

Hi, this is David Yak, the only other word that we have been using regularly has been "consent" and I wonder if...I mean it's a word that doesn't seem to get confused with other things and it's a more

affirmative action on the part of the patient. Is consent a possible word here for the patient's positive acknowledgement that they are providing authorization for their records to be accessed?

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

I think, you know, Dave this is Aaron, just my opinion on the use of the word "consent" probably in almost any other domain it would make a lot of sense to use consent rather than authorization. But consent kind of gets down to human research protections a lot of times especially in, you know, large institutions and it is kind of conflated at least in my experience, you know...medical center and other places the meaning of authorization is a little more specific to me. Consent is actually in some ways broader in my mind.

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

Okay.

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

But I hear you.

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

I was thinking of what we were typically using and I think consent was the only other word we used, but I'm fine with authorization. I just thought I would ask the question.

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

No it makes total sense.

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

We could certainly think about it, you know, off line and come up with another proposal. I think we're recognizing here in this statement that we're not using it correctly all of the time so whatever term that we come up with, you know, albeit incorrect in some situations, you know, just somewhat of a general, you know, what folks...what a layman would recognize as that patient's okay process without immediately, you know, trying to nuance it with any legal barriers within there.

So, maybe that's one of the things we can do is if you do have an additional recommendation to send it to us we need to have our slides done and available to the committee by Friday so if you could, you know, maybe within the next couple of days or so shoot those to us, otherwise we'll keep authorization unless we can figure out another one.

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

We also need a comment about consent because there is an NCPD field for acknowledging that a doctor has received a patient's consent before they pull their medication history since the doctor may well be seeing medications that were prescribed by other doctors other than themselves so there is this flag called "consent" and that indicates that the patient has consented to the fact that his history can be pulled by this doctor. So, I'll send something to the e-mail list and I don't want to make this a big issue, but.

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

That makes sense.

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

Yeah, I'll send that over, thanks.

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

Yeah, thanks, David that would be very helpful and again, you know, whatever term we come up with as long as we all land on it and are just clear about how we're using it I think is fine.

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

Yeah, this is Josh, I'll just say that, you know, there are different places in this document where we do mean different aspects of the concept and in some cases we're literally talking about authorization in the HIPAA sense and maybe we just use the phrase HIPAA authorization when that's what we mean.

And when we're talking about an OAuth authorization we could even use the phrase OAuth authorization. It should be clear in those places where we actually do mean something specific and I have no doubt...

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

Yes.

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

That there will be plenty of gray area where we say "well, we kind of mean all that stuff" and there having a standard phrase that we use would be good.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Yeah and this is Aaron Miri and I'd just go back to that's why the definition is so important so that we're all talking to the same page. So, whatever we call it, whatever we say we just need to define it so that people know in writing what we're talking about.

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

Okay, I'm trying to highlight some of these without reading it directly. The next paragraph really...the intent of that is just to say, you know, we've got some ambiguity that we're trying to work with that basically what we're saying is we assume that providers are going to be fairly conservative in their compliance practices until they receive some official guidance or, you know, are able to incorporate that a little bit better. So, we're just making some assumptions around what those look like, conservative approach and obviously mitigating the risk there. So, again, that's just all in the background.

From the finding's perspective a lot of this was pulled from, you know, obviously our testimony but we received some great documents from our contractors as well as just some background materials and those were shared but looking at...I want to make sure that I'm actually on the right document. I may have moved ahead, hang on just a second. I think that's what I get for having too many of these Google documents out there. Okay so now I'm on the right one.

So, with our findings we looked at the patient's right to access his or her own data from a covered entity and talked a little bit about HIPAA and then on the individual's requesting their access to PHI. So, we did try to put some of the nuances of what HIPAA potentially meant to this consent authorization and then all of that feeds into the recommendations. So, this is really the main part.

And just to kind of backup and reframe this a little bit, so Josh and I are pulling out, for our slide presentations to the committees around these recommendations, we're pulling out the actual recommendations themselves, but the overarching...the large document that we have we're going to cleanup and make that an accompanying document that really has, obviously much more of the reference materials and all of the text that we've pulled forward around background and findings.

So, for today, because our main focus is on what we report as our draft recommendations this is really mainly the area that we'd appreciate some feedback on.

So, there are quite a few of them here, we start with recommending ONC coordinates with the agencies to publish guidance as quickly as possible and that included best guidance for API developers, App developers, providers and patients specific to authorization.

And maybe, since I know that there are several of them and we're pretty short on time, maybe we can just run through all of these and then pause and go back through and answer any questions or look at any issues or suggestions that come up.

The second one is around machine computable consent and I pulled this directly from the interoperability roadmap and just as part of the authorization in some of our conversations around the two "what" so you're authorized, a patient is authorizing access to what types of information and just wanted to encourage ONC to continue working to support that process, the standardized machine computable consent but recognizing that should not be considered a barrier, right, obviously we're able to effectively exchange data without those standards it is just...we want to make sure that part of the ONC roadmap continues to march forward.

The third recommendation, until clear guidance is available providers should proceed in defining practices for their EHR portals and again, this is around focusing on what that process is so it's approaching, the providers approaching their compliance processes in the most conservative way possible and really focusing on what ensures that the patient has all of the essential information and I already noticed here the word "assent" I'll change that back to our authorization, so let me...I'll just highlight that and come back through later.

And then here are some of the elements that would comprise that authorization. So, obviously the name of the patient whose records will be shared, the relationship of the authorizer to the patient. I did want to make a note because I believe, David this might have been you who raised or maybe Aaron, in one of our calls some of the issues, the nuances of authorizing on behalf of minors, so recognizing it here but we are providing any additional guidance on that, the name of the App requesting information, a description of the information specific to...well that identifies the information specifically and meaningfully such as the data categories.

And then a little note here because we did have some discussion around granular positions or permissions and just to say, you know, again we're focusing on the 2015 CEHRT edition that there is no expectation for granular positions, permissions beyond what the data categories support.

A statement as to whether the App can or cannot change information currently in the EHR. So, again our scope is read only access but this is an important part of the authorization, you know, what are the access rights that you're providing to the App.

The duration, so when the, you know, the patient designates an expiration date. Whether the App is authorized access to EHR asynchronously such as when the consumer is not there manually manipulating the App.

Some representation of the individual's signature so it's just capturing that e-signature part of the process of the authorization process and while we're not commenting on what those best practices for e-signature are we do recognize that this shouldn't be adding any additional burden to the process, no off line, you know, such as faxing a signature or special software it should be just as easy as clicking a couple of buttons or typing something within the App.

We heard quite a bit about the need for a "Save As" or an "e-mail a copy to" option, which is the patient providing...the patient being provided some sort of a mechanism to save this authorization in all of these data elements off line for future viewing either as a download or as an e-mail.

Access to the policies regarding API developer and the provider obligations to disable the App and we do talk quite a bit about disabling an App in a specific section so refer back to that, but as far as within the authorization itself some indication that, hey, there might be the need to disable this App above and beyond what your authorization looks like. So, just a high-level note there.

Recommending that the provider...so that is all part of the essential information for the authorization, so a separate paragraph recommending that the provider include statements, which are akin to HIPAA authorizations, to notify the individual of their right to revoke the App authorization, providing a description of the process to do so. Again, you know, this is a HIPAA statement. The covered entity may not condition treatment, payment, enrollment for eligibility for benefits on the authorization.

The potential for information may be subject to re-disclosure by the recipient and no longer protected by HIPAA. And we put this in here as an additional nuance that where feasible the provider, if possible, should be required to disclose its relationship to the App. So, some sort of an indication as to whether the App could or would be covered by HIPAA and I think some of that, you know, Leslie had raised around the commercial relationship and other types of nuances. So, it may not...we may not have the right...the exact answer to this solution but the notion is that we do think that it's important that if an App is somehow covered under HIPAA that there is an indication somewhat/somewhat to the consumer. So, we can certainly walk through that when we're done.

And then finally, an inclusion of the statement that refers back to the App's terms of service and notice of privacy practices for further details and then of course referring back to that whole section that we have on the privacy notices.

So, that's it in a nutshell, let's get your feedback and hear, you know, where you think we're perhaps misrepresented something that we had talked about, if you have suggestions or additions or certainly corrections to what is down here.

And I will note, I know Leslie is out of the country today and not able to make the call, but we did chat with her last week and walk her through these so from a high-level can represent that she was comfortable that these recommendations reflected the questions that she had.

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

Meg, this is Aaron. I apologize I had missed the meeting where you guys probably discussed this with regard to the recommended HIPAA authorization information. I'm just curious if you might recommend that we encourage OCR to provide standard language to be used there or something...what I would hate to see is a consumer, like me, who has access to, you know, 20 portals ending up with inconsistent content especially around some of the legalese and this kind of assumes some of the things we have here it assumes that a person even knows they have HIPAA rights which may not be true.

So, I think about when we recommend, you know, this one bullet here where it starts, we recommend that the provider include the following statement. We might encourage the ONC or OCR, or someone at HHS to provide some standard reusable, referenceable language in this particular context.

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

Yeah, so that's a good point Aaron and I think that we hit that pretty well in the privacy notices section.

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

Yeah.

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

So, making sure that we pull that forward as well here for the authorization. So, we do talk about, you know, is there a mechanism that a consumer can compare privacy policies between two Apps and I think, to that point, that lens that we are asking for transparency around the privacy notices should be applied here to the authorization. So, I'll take note of that and see where we can pull forward similar recommendations.

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

Great.

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

Any other thoughts? I appreciate your patience I know that you all are just getting this and probably going through and reading it as well. We could certainly move on and talk about the other section and then as you reflect on this feel free to e-mail any comments or suggestions or web line these as you want. After the call today I'll put it in the bigger document so that we have one source of truth for it.

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

Can I ask a question just generally Meg about representation of the individual signature?

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

Sure.

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

What is the, you know, the first principle there? Why is that important and how does that...what does that mean?

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

Well, I think the notion of an "okay button" or a "sign here button" or just some sort of a "you're finished" with this authorization once you click this and this completes the process, I think really is kind

of in general, you know, what the representation of the e-signature is. You can back out until you sign this and now you have this. Maybe that isn't the right term that we should use.

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

...

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

Yes?

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

What you said made a lot more sense than what I was...you know having just read the words what I was picturing, like I don't think that our recommendations should get as prescriptive as I was imagining it, right? But when you say an "okay button" that says "hey, you don't get to go back and un-okay this" without going through a different process that makes more sense to me.

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

Yes, exactly and I could...if you have any suggestions for that wording...I tried to nuance what I think you were headed towards the ink there around, we're not commenting on what that e-signature process should look like.

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

Yeah.

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

But if that's a loaded...if "signature" is too much of a loaded term we can, you know, certainly entertain something else.

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

Yeah, I just can see, you know, people getting either overly creative or, you know, not understanding what we're trying to say there. But I like the notion of, you know, this is you making the commitment, you understand that. I mean, there are successful ways of doing that, a number of ways to do that so I'll think about it.

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

Okay. I'll put a little note here too that...

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

Yeah.

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

That we can go back through and nuance that.

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

Yeah, I was just picturing somebody, you know, all of a sudden trying to capture visual representations and things like that.

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

Yeah, that's it, yeah, that makes sense. It is a pretty loaded term; there is a lot of history behind it certainly.

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

Yeah.

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

Okay, any other thoughts? We have another document to go through. So, if we're okay to switch gears a little bit and talk about the auditing and accounting for disclosures?

So, thanks, Michelle, this one isn't as much of a...new information we already had a section on this, this was just somewhat re-written and just wanted to walk through and make sure that everyone recognized what we did.

So, from a background issue identification perspective, you know, noting the roles that each of the parties in the "API ecosystem" plays, so we have the patient, the provider, the EHR API developer and the App developer and this is around the notion of auditing or understanding accesses to the PHI. So, this could be...and we do talk a little bit about this from a system logging perspective and from a disclosure, authorization of disclosure perspective. So, make sure to kind of view it with that lens and if it not clear what we're talking about which process to certainly let us know, but I think it's here under the rule for the API developer responsible for enabling both the auditing of the disclosure and auditing the authorization of the disclosure. So, again, just noting that as you go through be sure to flag it if that concept gets a little blurry here.

But, so essentially what we're saying is that we looked at whether the Apps that under the scope of our Task Force, so the consumer-driven, read only APIs, whether these APIs introduce risk that we wouldn't expect to be addressed in existing audit and accounting for disclosures practices under the CEHRT Program and under HIPAA.

So, we walked through, and this information isn't new this was out there before but what are the 2015 CEHRT rule requirements specific to auditing and here they are. And then just a little bit of a note that we're okay with those auditing requirements addressing the needs of the "read access" in this particular use case.

But we do note here that there are potential challenges inherent in the auditing App accesses to the API and I think one of the concerns that we had heard about was high frequency of occurrences. So if you're reviewing the audit log is the auditing of the API access reflected well enough that you're just not bombarded with a bunch of noise. So, just note that we recognize that we don't necessarily provide any comment or recommendations to it, but overarching, you know, we anticipate that practices and services will evolve to address these challenges. So, that didn't necessarily make it to a specific part of the recommendations and we'd love some feedback from the group as to whether it should be.

And then walking through the second process which is the patient's right to receive an accounting of their PHI under HIPAA and a lot of this information was background material from that document from GW and again thanks to those folks for that.

And then finally, if you scroll all the way down to the bottom by the full recommendations, recognizing that an App developer may or may not be subject to HIPAA audit requirements but we're trying to, you know, really articulate that it is important to still maintain audit access to that and trying to make the recommendations that Apps should have some level of auditing capability within that.

So, how this boils down to recommendations we've got...we recommend that ONC expand CEHRT criteria to require the technology, the certified technology, to make API access audit logs available to patients during accounting of disclosures via the portal and this would require showing patients a list of all the App authorizations that are currently out there, so active App authorizations.

The ability for the patient to revoke any of those App authorizations. Showing the patient a list of which Apps have accessed their data via the API including details around the access and we've got a couple of examples in here but basically, you know, source IP location, scope of data access so showing the patient somewhat around what that additional information around what that access meant.

And then working with OCR to provide guidance on what information should be logged to describe the information disclosed to the API, by the API to the App and already I can tell we're going to have to work a little bit on this reporting so I'll highlight this.

Recommending ONC should coordinate with the relevant HHS agencies to publish some patient-facing guidance that explains to patients what their rights are when the App developer is not covered under HIPAA as a Business Associate and therefore not required to provide such an accounting.

And then we link back to the section that we just reviewed on App authorization recommending that ONC review those recommendations as well to make sure that they're sufficiently addressed in auditing requirements around whatever this "artifact" is that represents the patient's authorization. So, when you're, you know, an auditing reviewer, system admin or whatever your role is and you're trying to recreate what this authorization document looks like just making sure that the two line up, that they align well enough to do so.

And then finally a recommendation that, you know, we get that these Apps aren't covered under the ONC CEHRT Program but we do think that there should be some guidance around voluntary best practices of audit capture and accounting for disclosures.

And we've got...not to make you too dizzy, but there are a couple of citations earlier that talk about...it's on the first page so it is footnotes to the last paragraph before findings where we do recognize that there are some guidance documents out there, in particular something from the CDC and then of course FTC as well. So, we do cite to something that's out there but it would be really interesting for ONC to make a statement that says, okay, if you're an App that's interacting with our certified technology then here's what we...you know here are either best practices that we think you should abide by or we're going to refer to others that do.

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

Hey, Meg?

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

So, opening up any of these for discussion. What do you guys think?

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

So, I have a question Meg, this is Aaron Miri...

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

Meg?

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

A quick question for you. We had talked about earlier on having a vehicle of some sort for patients and/or providers and/or anybody to seek out for additional assistance to maybe report or flag potentially, you know, APIs that maybe misused or violating terms of use or whatever. I don't see that listed here. Is that in a different section perhaps?

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

So, this is the patient's ability to report an App that they think potentially violates the privacy practices?

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Correct.

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

Yes, that's a really good point. I don't think we've got that incorporated here or elsewhere Josh do you remember?

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

Yeah, I don't think so.

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

Okay. Yeah, let's...I think that's a really good point and we can certainly add that.

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

Hey, Meg?

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Yeah, because I can tell you as a provider I get, you know, a bombardment of questions from time to time by patients visiting the portal, asking questions maybe to flag something inaccurate and so having that construct up front I think will help establish trust and show credibility.

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

Okay, so let's put that, Aaron if you're comfortable, on that second bullet that says, patient-facing guidance that explains to the patients what their rights are, let's see if...would you be okay if I noodled on that wording a little bit to make it clear around what that complaint process should look like and making sure that it is transparent to the patient?

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Absolutely, thank you.

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

Okay, yeah. Yeah, good point, thank you.

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

Hi, Meg?

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

Yes?

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

Yes, this is David Yak. In the case where an App is not covered under a Business Associate Agreement with a covered entity is the patient entitled to any protection under any sort of federal law or any privacy laws in terms of how their information is used?

In other words, if there is a click wrap approval that a patient gives to an App that they want to use and in that it says “we’re free to use your data however we want and we can sell it or whatever we want to do.” And if the patient has agreed to that and is using that App is that patient afforded any sort of protection under any sort of federal law in terms of how, you know, they can either inquire about the use of their information or get access to how their information is being used. Are there any protections whatsoever?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Hey, Meg, this is Lucia; do you want me to answer that?

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

Sure.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Yeah, so, David, in general there is actually sort of a parallel and a little bit overlapping protection from the Federal Trade Commission’s Consumer Protection Authority and they in general regulate the privacy and security practices of many different aspects of the Internet including an App that you might purchase retail that would be collecting your health data. What they are enforcing is whether that App is being unfair or misleading, or deceptive towards consumers.

So, there is a whole body of case law that the FTC has brought in this regard and they have pursued both unfair, deceptive and misleading security practices and unfair, deceptive and misleading privacy practices.

I’ll try to give you a hypothetical example but there are actually a lot of really great information about what the FTC thinks is right on their website that we just did this tool with them, but an example might be on the one hand the App says “I’m actually going to take your data, leave it identifiable and sell it to the mafia in some undisclosed third world country.”

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

Right.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

And you decide that that's okay with you that's not unfair and it's not...then the FTC looks at whether in fact you understood the value of that deal.

Conversely, an App has, you know, opaque, illegible, not health literate privacy policy that takes 16 clicks to get through and you can't figure it out at all and so you just kind of click "accept" and that might be unfair or deceptive, or misleading in many different ways. So, there actually is federal consumer protection available in this space.

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

That's really, really helpful. Thank you. So does that imply that we should recommend that it be clear that there is sort of a big distinction between applications that are covered through a Business Associate Agreement and therefore provide HIPAA protections to the patient as opposed to those which are not in which case there is...it sounds like an entirely different, although protections exist, an entirely different mechanism and expectation that a patient should have?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

I mean...

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

I mean, is that...

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

I defer to you guys on that. I think that is consistent with some of the testimony you had on the 28<sup>th</sup> of January from your consumers where they said, you know, on one hand don't patronize us, on the other hand, please tell us when we're leaving one type of security and going...one type of set of rules and maybe migrating to another type of set of rules that's that sort of popup that's been thrown around.

But it is really what you guys think is right given the third charge. What can ONC help facilitate or actually make happen to have consumers feel confident that at least they know what they're doing, right, on the don't patronize me front.

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

Yeah and to that point, in our larger outline of the document we do have a section on HIPAA and we had called it, when does an App developer need a BAA but it's growing into exactly this conversation. So, what are the enforcements, what are the oversight mechanisms of this whole process and all of the parties are involved in this. And so that's where those recommendations around additional guidance are shaking out.

So, I'm trying to think of the best way...maybe what we can do is take that section and forward it back, kind of do a similar process, pull it out and put it into its own document and then make sure that we're representing all of those concerns and then pull it back in.

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

Okay, sure or just highlight it in the next draft or somewhere in the document that this is where that occurs and I don't know how prescriptive we want to be on this issue but it does seem to me to be kind of a fundamental potential, you know, misconception on the part of a consumer where if they're using two different applications they're both accessing covered entity information of theirs from let's say their doctor, one is very different sort framework in terms of what they could expect or what is governing in terms of regulation and law compared to the other one.

I don't know how the heck you communicate that or what we do about it but I just wanted to ask. So, at least we're acknowledging that in the document in terms of BA versus non-BA or non-HIPAA Apps then it's a question of do we want to say anything further about what could be done about that distinction.

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

I think the distinction, you know, the fundamental distinction is, you know, the intent of the regulation and when I think about what is being regulated when a covered entity is representing that they are protecting that data versus a non-covered entity those are two different regulatory environments for a reason and I think that's easier to convey than talking about HIPAA versus FTC's consumer protections.

I worry a great deal, a great deal about creating a perception that now applications offered by covered entities are more secure or less secure than those that are not offered by covered entities. I think actually if we look at where breaches are occurring today we'll see many of them being related to where data is stored by covered entities, you know, in a very juicy honeypot compared to, you know, consumer controlled applications.

So, I think it's a slippery slope that we don't over emphasize or create a misperception that somehow applications covered by HIPAA have better security or are less risky than those covered by or operated by non-covered entities. That's my opinion; I may be the only one that feels that way.

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

So, this is Meg, I think that reflects a lot of what we heard from Leslie as well, some of her concerns around, you know, making sure that we have an even playing field and not, you know, leveraging a certain term that could indicate any more or less amount of security. I mean, the fact is that if you are a HIPAA covered entity or if you are covered by a BAA then you are held to a certain standard it's just whether or not there is misunderstanding...

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

Yes.

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

That standard couldn't be met by other ones, but I do like the idea of, you know, mentioning the different oversight mechanisms and we did just get that tool, FTC just recently published a tool to help App developers navigate that environment through ONC and FDA, and FTC. I think that this would be really interesting if there were something similar to a patient so you're not necessarily tripped up on is this FTC or is this FDA but you're saying, hey, if you've got a problem with this, you know, let's make sure that you know who to contact or what your rights are, you know, relative to that.

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

Yes, that's very...

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

Let's build out this section a little bit if that's okay the...

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

Yeah.

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

HIPAA/BA section and then come back.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Yeah...

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

I think that we can do that off line.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

May I ask a quick question Meg, I'm sorry, this is Aaron Miri?

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

Yes?

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

I like the discussion. Is there potentially something that we want to add as part of that first document on disclosures and what not where maybe for some sort of notification or some sort of, you know, I understand that, you know, a non-covered entity maybe using an API to access data from a covered entity given the right authorization but perhaps we have some sort of accounting for if there is a breach or some sort of issue that even a non-covered entity, be it a cloud broker or whatnot, has to at least make some sort of notification out there.

There is a lot of noise being generated right now by cloud providers being that there could be breaches going on and they're not telling anybody but their customers because they're not required to. So, I'm just curious if there is some sort of vehicle we can insert to help address these kinds of things.

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

So, I think that's really a good point that we should have a recommendation in there around breach disclosures and I'll...oops, I keep clicking the wrong button, but I'll add that to that authorization.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Yeah, because more and more hospitals are moving to the cloud myself included I'm telling you these gigantic brokers are...they're great, they're very helpful but they do not play by the same, you know, set of rules and I may get a notification that says "oh, 45 days ago we had an issue" but they don't tell the world, they don't tell anybody and it's like "okay" if I'm a customer now, you know, and I see that kind of going on I'm going to lose faith.

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

Okay, yeah, I think that's a really good point and we can, you know, certainly include that and then nuance what that wording looks like over the next couple of days.

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

Did we lose Lucia because I think the FTC's authority includes breach notification requirements for applications, I don't know that it would include or extend to cloud services where those applications are operated.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So, this is Lucia...

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

I can tell you that...if a structure is a service provider they do not...they do not follow the same rules. They just don't.

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

Yeah, they...whether they have to or not.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

This is Lucia just a couple of comments about that. So, breaches, a breach notification is as complicated as state privacy law. So, states have breach laws. The FTC has some standards related to breach but is not across the entire Internet of things, obviously there is the OCR Breach Notification Rule and then you have to imagine the universe in which the companies providing cloud services, I think that was Aaron Miri, right, some of those companies are going to have subcomponents that are Business Associates and other components that are not because they don't want to be in the business of handling PHI. Amazon would be a great example of that, Google as well, all those companies that rent space on their servers.

But, it maybe that we can't pull across the line for you a comprehensive understanding of that at this point in time but I kind of was interested in Meg's idea which is, you know, the multiple agencies involved here, federally at least, have put together a tool that helps the developers navigate, you know, is there a need for something like that for consumers about breaches or for the customers who are buying services to know which breach rule applies where.

Now, again, it's very hard for the federal government to give comprehensive analysis about state breach rules because that's a separate legal, you know, they have their own powers, separate sovereign states, but definitely would be a valuable...if you think that would be a valuable recommendation then the recommendations might be something like, you know, help the stakeholders understand which breach rules apply to which parts of this universe that we've diagrammed for APIs.

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

That would be...

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Absolutely, Lucia, and this Aaron Miri, I totally agree and I think that's very helpful especially as I, as a CIO, navigate, you know, infrastructure or service maybe cloud service offerings of an application and whatnot to understand truly what those rules of the road are because it becomes very murky and, you know, you listed some very credible and well known vendors in the states that try their best, I want to

give them credit, but there are others up and comers that just don't even answer this question and/or help their customers.

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

Lucia, this is Aaron Seib, would it help for us to also recommend that states be able to contribute their guidance as well.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Well, I mean, you know, in state law breach notification is a public document. So, you know, (a) a law is public and (b) you know the government just has...the federal government just has limited resources and states are independent after. So, you know, what I would say is make a recommendation that you think ONC can actually execute on in its capacity as a coordinator...

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

Okay.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Knowing that what we can do is exhort states but we can't make states do anything because states are independent, sovereign organizations.

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

Right and the tribes as well, is that true, the Native-American Tribes?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Just as complicated, yes, I mean, they are very independent.

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

Yeah.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

But Indian Health Services within HHS is complicated.

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

Got it, so I love that recommendation and Meg you probably stayed up all night thinking about that.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

No that was completely by the seat of my pants Aaron.

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

It was awesome, good job and that's what the...

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Thank you, Linda, this is Aaron Miri, I appreciate that. That was excellent, I appreciate that.

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

Okay, so we've got a few things that we need to kind of look through over the next couple of days to articulate and that's a great suggestion, this has been very valuable but there might be more, again, realizing that you've only had...you've had less than an hour to take a look at these. So, I'll keep you posted with the changes that come out of these discussions, but be sure, you know, to think about it, review what you've seen and if you have any further ones to let us know and again we're navigating toward that Friday deadline to at least get the recommendations onto a set of slides for the committee members next week.

And because we are only focusing on the recommendations we could certainly, you know, grow out some of background and findings as well without having to redo those slides. So, with that, Michelle if you wouldn't mind pulling up our slides and we'll go through what we already have around the existing recommendations and the document that you all have already seen and then just do a quick roster to make sure that everything is still aligned with what you're expectations are around how we're reporting out our recommendations. And then Josh I'm not sure if you wouldn't mind kind of taking a stab and walking us through the first few?

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

Yeah, absolutely and I'll just follow along with where we are right now on the list of draft recommendations on the slide. So, let's see if we can start, you know, going through sort of one through four at least, if we can move onto the next slide which will be types of Apps and the organizations who provide them. Perfect.

So, again, this is our attempt to distill a large amount of context into a small amount of space to hit the highlights and as such we recognize there is going to be nuances that are missed, but we want to take this as a starting point at least.

So, the summary of our findings here is that, you know, we heard from panelists in many parts of the industry who said that using healthcare Apps, you know, is going to be part of the way the ecosystem evolves and that the regulations from Meaningful Use and from the Certification Program, and ONC don't differentiate in terms of who writes the App or what the App is supposed to do or how credible it is, the regulations are simply about the ability to run Apps when a patient wants to.

So, what we're recommending in terms of our Task Force recommendation here is that we could make this explicit, ONC and CMS instead of just sort of not saying that could actually explicitly say that they don't make any distinctions based on the type of App or the organization who developed it rather than just sort of leaving that implicit.

And in terms of the relevant concerns, you know, technical compatibility is clearly one that is highlighted in the regulatory language and patient choice is the other one. So, we just...we liked what the regulations seem to intend here and we thought it would just be good to make explicit anything that might be implicit here. So, let me just sort of pause on this slide and see if there is feedback about the way that we've structured this?

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

Josh there doesn't seem to be...

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

This is Aaron Seib...

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

Any projecting on the connect.

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

Ah, you and I are having different experiences because I'm seeing the slide that's labeled in the bottom right-hand corner as number six. Is anybody else missing it?

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

I have slide six.

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

I see it, this is Meg.

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

Try to...

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

Okay, I don't see it at all.

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

Or if you have your e-mail on, the slide deck was e-mailed from the FACA e-mail address.

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

And if all else fails I'm pretty much just reading off of the slides. So, you can respond to what I've said even if you can't see it. I know sometimes getting everything in place is...

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

Josh?

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

Difficult at the last minute.

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

Josh, Aaron Seib, I like the format that you guys have provided I think it is clear and concise. This particular content I do have a question about the phrase "technical compatibility" and just curious, it's easy for the casual observer to confound that with a CEHRT requirement and, you know, I just want to make sure that that's something...what are we trying to convey there?

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

Right.

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

That they're interoperable through APIs or...

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

Well, so the intention here is to convey that Apps do need to have technical compatibility with a particular provider's EHR system before they can be expected to work. So, it's okay for a provider to say "no, that App won't run because it's not compatible with our system it doesn't meet the technical standards that we've put in place." So, that would be, you know, a legitimate concern that a provider organization might have and prevent an App from running.

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

I've got you the word that I'm struggling with I guess and maybe it's just a wordsmith thing and I apologize, but compliance kind of put me down the path of...

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

Yeah, sure, I think we could avoid that word.

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

Yeah.

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

You know we could say...

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

Yeah.

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

Meets...what if we just said meets the API technical specifications?

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

Yeah or supports the API's technical specifications or something like that, yes.

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

Works with would be too small words...

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

Works with would be better.

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

That are pretty clear.

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

Yes, eight grade level kinds of words would help I think.

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

Cool, all right, thanks that's an easy tweak. Other comments on this? Okay, cool, let's move onto slide number seven, which I'm going to focus on...

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

Actually, Josh, could we skip this one, I think we're going to have some changes in it and it would probably just be better to save our time.

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

We'll move onto slide eight.

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

Yeah, thanks.

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

This is dealing with the registration process and this is one of the bulkier topics that we addressed, we've broken this up into a couple of slides. But this one, first of all is to say, you know, there are recommendations to ensure that the App registration process, if there is a registration process it shouldn't impose an unreasonable barrier to patient choice and it shouldn't impose delays, and it's not intended to be a place where Apps go through rigorous testing or get approved by clearinghouses or, you know, where people descend upon the App developers data sites to inspect the hardware, there shouldn't be high bars of control here.

And that in particular, there is a process that we call self-service registration and dynamic registration, and those are two complimentary ways that you could use to ensure this kind of frictionless registration. So, the technical requirements of registration can be met without imposing a barrier to usability.

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

Josh, again, just as a casual observer kind of recommendation, you know, the registration, just the word registration you might want to expound on when you present this content, you know, are you talking specifically about an App registering or a deployed API controlled by one resource on here, right?

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

Well, so let's say by one clinical provider organization.

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

Yeah.

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

Is who would host the API, but, yes, so I think that's fair.

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

Yes.

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

So, I certainly agree that we need to make that context known when we talk about this. The question is how much goes into the slide versus how much goes into the sort of description.

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

Yeah, yeah, I just...I was just presenting it...

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

Yeah.

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

For your benefit I think.

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

Yeah, so maybe we could...you know since this is a recommendation slide it's probably not the place to provide the sort of background description in what registration means but we could add one before this which would be, you know, background on this point of registration.

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

Yeah...

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

Hey, Josh, there is a note just to reference; I'm following through on the outline as well, so there is a current outstanding note to clarify that term so we should make sure that we do that. That will be part of...that cleanup will be part of that whole process that we go through.

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

Yes, definitely. Even the background that we have I think there today there is a definition of this term...

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

Yeah.

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

And an explanation of what it is. So, in addition to the recommendation slides here, you know, it would probably be useful to pull in a little bit of that content from the background so that there is context for these recommendations.

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

It is just...

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

Hey, Josh...

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

Yes?

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

Did we...I remember we talked a little bit about this whether it's a one-time registration for an App and then that's good for every patient who wants to use that App or whether there should be an App registration process every time a new person wants to join. Did we settle on where we feel about that?

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

I think we need to articulate this better, but, I mean, the thing I think probably makes sense is to say, a registration takes place between a deployment of an application and a provider organization, and then there is an asterisk on that which is in many real world cases to make this easier vendors might just handle the registration process once for all their providers so that technically you don't actually have to go and register your App a thousand times you just do it in one place and I know many vendors who are planning to do it that way so that makes things easier.

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

Okay, yeah, that's sort of thing goes well onto an intro slide as to what registration we're talking about and what it is, yeah.

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

Yeah. Good. So, let's make a note to add that in as well so that way we can provide...when we provide background about what registration is we sort of set the cardinalities or the arities of these relationships in a way that people understand, you know, it's an App registering not a provider.

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

Right.

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

And we've got one more slide of recommendations on this topic which is slide 9 if we could advance there. And the recommendations here are there is language in ONC's regulatory guidance that seems to say, you don't need registration and I think we want to recommend that ONC should clarify the language here.

The language said certification criteria are sufficient to allow access without requiring further pre-registration of Apps and I don't know that this is true. I don't know that it's false but it seems like you have a pretty high burden to make that claim and many real world protocols like OAuth do assume that there is a registration process that takes place and we should probably just clarify that, you know, ONC thinks that this is...ONC should not have a position that registration is not a requirement that comes down to the technical specs.

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

So do we...

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

So, Josh, this is Aaron Miri, quick question for you. Is it possible again that we maybe use a nickname or something for what registration is? Because, I think from ONC and OCR's perspective they don't want anything burdensome for the patient, which does make sense...

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

Yes.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Because you can make it so cumbersome that nobody wants to adopt it, right, and suddenly...

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

Yes.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Disincentive to adopt.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

If...

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Maybe we say technical registration or something to that effect?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Or...

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

I missed the extra word you added there could you say it again?

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

I simply said technical registration.

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

Right.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

I think, Josh, this is Lucia, what I remember from that conversation and speaking for the rest of ONC, I think where we are going is that actually it is appropriate for Apps to make themselves known through this process. You guys called it dynamic registration but what you don't want that to be is something that becomes a barrier to patients or providers using this technology and so maybe what you're looking for is for us to sort of clarify what is appropriate registration whether that's technical or on a piece of paper legally, I'm just giving the two bookends, or something else and what it should be and what it should accomplish and what it should not be and should not accomplish and that would be helpful for us to know how we've confused stakeholders at large, we want to unconfused people so that we can take advantage of this technology.

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

Sure and the previous slide I think lays out what we think registration should and should not be. So, I think we provide sort of our recommendations on that point where we say, you know, just functionally here's what registration needs to do and it shouldn't be a barrier and it shouldn't get in the way.

But I wanted to make sure that we had a clear field for in fact saying, you know, in the real world we may indeed have these technical registrations and processes and the language that is currently in the regulation seems to suggest they wouldn't...they just aren't necessary because somehow there's enough guarantees in the registration process, sorry in the regulations that you wouldn't need them.

So, I hope that we're there between the sort of positive recommendations about what registration should be and then eliminating this confusing language, those two actions together I hope will clarify the situation.

Two more bullet points on this slide. So one is that API providers must not charge a fee for the registration process itself, so for this technical process, and we want to clarify that reasonable charges for patient access...this probably doesn't belong on this slide as I'm reading it here in the context of registration because reasonable charges are a concept that has to do with patient access to the data not registration, but in any case we do want to recommend that ONC and OCR should clarify that reasonable charges for patient access through an API would have to be incredibly low to the point where it probably

wouldn't even make sense to collect it because it would just represent the incremental cost of sending a few more bytes over the wire. So, other thoughts and comments on these recommendations for the registration process?

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Josh, this is Aaron Miri, something else that has come to mind, this is an excellent job by the way on the slides, is there any provision or potential to speak towards the ability for...during the registration process if that process is burdensome or onerous for the patient to be able to notify or flag, or let somebody know. Again, I can see this being a potential tool for those that don't want to play in the sandbox with each other and I think that if you bring a spotlight on the potential practice of that by giving people an outlet to reach out and say, you know what they are trying to make me fill out this 100 page form to just be able to access my data, you know, what's up with that. That may help curb some of that behavior.

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

Yeah, I think that's right...

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

And...

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

And we should...I think it would be a good recommendation for us to say that there should be a clear reporting path for any issues that patients or App developers encounter in this process. I don't know whether we want a specific reporting path that's all about App registration or whether this would tie in nicely to some existing feedback mechanism...

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

This is Aaron...

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

That's already available but either way we should say that the recommendation...

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Yeah, exactly and...

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

And then what the channels are.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

That's feedback. Yeah and I think that also helps, you know, with all the truth that is in existence about interoperability challenges, you know, I can see this being one of those weapons, especially as a hospital CIO that it's becoming burdensome and it's just ridiculous, so thank you.

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

Sure, yeah.

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

Josh, this is Aaron, I believe...I was at a PCORI conference last week where we got a presentation from the OCR they have an existing channel where they encourage folks who are having...from the consumer's perspective with the information blocking experiences to report that to them. We might want to include that in this concept that Meg came up with about figuring out who, you know, you would pursue if you were running into problems as a result of understanding what to do with regard to breaches and so forth as well. But I think there is...I know there is an existing path, at least Joyce described it as one or the OCR for a consumer to report to the OCR that they are experiencing information blocking.

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

Yes, definitely and so maybe the answer is just a tie in to that pathway.

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

Yeah.

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

Good. Other comments on this slide?

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

I think you should probably take that third bullet out and make it its own slide.

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

Yeah, so I think this belongs somewhere but it is not here.

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

Yeah.

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

It may actually belong in the sort of high-level summary where we talk about types of Apps and how they connect and that sort of patient's right. So, thank you, we will move that one as well.

All right onto the next slide then which deals with the topic of endorsement and certification of Apps and so again, we don't have the background here we've just focused on the recommendations and we'll see how this flows without that context right now.

So, the recommendations are basically that ONC shouldn't have a centralized process for certifying or testing Apps but instead should pursue regulations that enable a secondary market to emerge in this kind of endorsement of applications and then we described some properties of that solution. So, in that kind of market your various different kinds of organizations, which could be EHR vendors or security experts, or consumer advocates, or the clinician professional societies, or healthcare provider organizations various kinds of groups can endorse, get an App through a publically visible process in a distributed way and that doesn't need central oversight.

And if we have something like that, you know, we avoid the pitfalls of centralization but it still allows consumers to begin discovering, you know, who trusts which Apps, it allows things like aggregations of these endorsements downstream. And if we could move to the next slide because it's pretty closely linked here to this topic.

So, we've said that ONC should clarify that in this ecosystem provider organizations can't use the presence or lack of endorsements as a reason to block an App's registration or to prevent a patient from using or sharing data with an App, but in this kind of ecosystem provider organizations could choose to display some endorsements prominently at the time of approval and, you know, could choose a list of sort of trusted sources that it might use to dial up or down the severity of the warning language that they present to patients, so the presence or absence of those endorsements could certainly effect provider behavior but not to the point of preventing a patient from using a particular App.

And then there is a sort of asterisks here saying this really doesn't necessarily apply in a case where a provider and App are actually Business Associates this is more about the wider ecosystem where patients are bringing their own Apps to the table. Let me pause on this topic of endorsement and see if this does a fair job of reflecting our recommendations?

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

Josh, this is Aaron Seib, I have one thought that might be useful given...I don't know how much time you have, but to actually show in the flow where you thought these, you know, batches might appear. It's kind of without a context, you know, from the consumer's perspective. I think I understand kind of what you said.

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

Ah, yes, right.

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

Maybe just have some screens that show, you know, here's what we think it might look like might be helpful.

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

Yes.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Yeah, that might be helpful. This is Aaron Miri, and the other things I would add potentially Josh and maybe a quick win is maybe a wall of fame, so HHS could have a wall of fame, ONC could have a wall of fame for those APIs or those with the highest endorsement rankings which will encourage people to do right, to want to do right so they can be showcased per se that these are the ones who play ball really well, who really do what is easy and that's just...

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

Yeah, I mean, my only worry there would be that maybe the government doesn't want to get in the business of deciding which organizations to support in that way, but we can certainly call that out as an option.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Yeah, well, I mean...

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

We can recommend that they do it, we could recommend they could do it would be...

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

They could do it.

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

Yeah.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

I mean, they do a wall of shame so why can't we do a wall of fame?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Right, but just remember the wall of shame is required by a congressional enactment.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Correct.

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

Right, right, right. So, but I do think that...this is just Aaron Seib, you know, with a thought for Aaron Miri, is that what is very good for you and I might not be appropriate or useful to a person who is very senior or somebody with disabilities, or somebody with some other kind of criteria. So, it is really difficult to...the consumer has to be involved in making the choice of the Apps to really get to the point where you're presenting them with three or four that might be good fits for them, might be.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

So, Aaron Seib, very good point, I totally agree with that. I was just meaning as...you know since these are consumers that are kind of ranking and giving feedback endorsement, you know, if you have an API that has 500, you know, likes or stars versus one that has, you know, 500 one stars obviously the one that has the more stars, the higher stars would just bubble to the top and so it wouldn't be anything that the government would have to do it's just simply sorting by who is the highest volume, highest use based on consumer feedback.

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

You wouldn't...

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

So, I wouldn't...for anybody getting involved with making anything.

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

It seems if we went back a slide and if I understand Josh's conversation here those kind of things would emerge, you know, as the market wanted them and it would be natural for that kind of extension to the concept to occur in my opinion, right, so I actually think about the AARP as a great kind of, you know, 10 million people who share their opinions and, you know, work together. I could see AARP users recommending this application more than others and AARP using that data to share with their members as an example of kind of this model that makes a lot of sense to me. That echoes what you're describing the senior customer.

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

Hi, this is David Yak, if I could just come back to this slide for a second, I don't think I quite understand what we're trying to get at. The high-level bullet is very clear that you can't block but below that it says, okay, you can't block but if you have another application that you want to endorse that maybe an option for this patient that you're allowed...that we say it's okay for you to present that as an option during their...while you're confirming their decision to share data with this App it's okay for you to show them some other Apps that you endorse.

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

Okay, I think this is just unclear language on this slide that was not the intention. The intention was while you're displaying the approval screen for this particular diabetes App that the patient selected it would be reasonable to show the patient who has endorsed this particular diabetes App and in fact if no one that you trust has endorsed it, it might be reasonable to tell the patient, you know, by the way no one that we've ever heard of has endorsed this App, you're still free to use it but you might want to know that fact. That's what I intended to convey it was not meant to be a statement about promoting other applications at the time...

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

Oh, okay, well, I clearly read it the wrong way. But...

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

Of course, you know, there is nothing to prevent a provider from doing the thing that you just said, but I certainly wouldn't call that out as a good practice.

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

No I wouldn't call that out as a good practice and I wondered if we were almost encouraging that by what this said. Maybe it just meant...maybe we just need to change the wording here to make it clear that some endorsements of that App or of the requesting App something along those lines or other patient's experience something like that.

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

Yeah, we'll...I think we can wordsmith the middle dashed bullet on this slide to make that clearer.

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

So, just, you know, to confirm my understanding about a recent article in...about some folks who did some research on diabetes Apps and they found that were 271 of those Apps and you can imagine that there was the American Diabetes Association come up with an endorsement about, you know, Apps that they would help...that would be helpful to a consumer to pick 10 that were endorsed by the ADA versus, you know, those that may not have been. And I don't know that it would be our intention to prevent an endocrinologist from making a recommendation for anything or a consumer from choosing anything that they wanted to choose.

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

I don't think it is. Did we say something that makes you concerned about that?

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

No, no, I think examples help, guys like me anyhow, you know, something...

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

Yeah, yeah, yeah, so I think having a picture of what we mean in terms of displaying these things and picking an example like the AARP to talk about as one concrete thing I think those are both great ideas and we'll do them.

**Drew Schiller – Chief Technology Officer & Co-Founder – Validic**

Hey, guys, this is Drew Schiller, I'm wondering if this needs to explicitly be part of the recommendation. I just...I mean, I'm just sort of thinking practically about how this gets implemented and I guess my concern is that if it's part of the regulation it would lead to a spider web of recommending things that we do a bunch of unintended consequences, a bunch of market confusion whereas if it's something where it develops organically maybe there is, you know, a few different certification bodies that really own it. I don't know it's just sort of where my head is going. I just don't want to create something that ends up being a huge chaos for the consumer to try to wade through.

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

So, is there a structural thing that you think we could recommend that would be cleaner and likely to work?

**Drew Schiller – Chief Technology Officer & Co-Founder – Validic**

Yeah, I mean, I guess if there is...so I don't know is the short answer but I suppose...I mean, I guess I would ask are there existing sort of clearinghouses or certifications of frameworks today that we could leverage or recommend looking at. I just...we've already just been talking in this one really brief example, you know, the 10 Apps from the ADA and the AARP is recommending this and then we've got the American Heart Association recommending that, and then all of a sudden it is like, so everybody recommends everything, there's a lot of...I don't know I just sort of see this in my head going, okay, where...it might take a while for the market to actually wrap their mind around what this actually...what the intention of this actually means in practice.

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

Well, doesn't it also raise the concern that there is potential commercial interest or financial value in these recommendations and I guess I'm starting to wonder whether we need to even say anything in these sub-bullets at all.

I mean, the point about blocking I think is a good one. I think another point maybe that if there is a commercial gain to recommending a different App other than the one the patient is trying to register that maybe that ought to be disclosed, but other than that do we gain something by saying that it's okay to have recommendations on your registration process?

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

Well, so, let me see if I can articulate why I think this was important and part of the reason I thought this was worth calling out is it speaks to what are these endorsements actually doing? Where does the consumer see them? If it's just the App displaying the endorsement itself, you know, you don't really know if you can't trust it, right, maybe it's displaying many endorsements from organizations that never really endorsed it.

But on the approval screen, while you're in the process of actually telling your provider, yes, I want to use this diabetes App your providers actually has to opportunity to verify these endorsements, you know, to make sure they are indeed published at the locations where the App says they are and then

share with you the feedback so that you are not responsible for doing all that due diligence yourself. So, I thought that sort of calling that out might be helpful but if it's causing more confusion than it is clarifying the situation, you know, I think recommendations would be nearly as strong without those bullet points, without those dashes.

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

This is Aaron Seib and I wasn't sure who made that last comment, but one of the things that Drew said that I thought was kind of indicative of why this might be useful is that there are not many people doing this today, right? So, if there were other folks that we could point to and indicate that this would be helpful, you know, I think that this might be...I think the sub-bullets maybe over prescriptive but I think that there is a need to talk about and expand on how it would be used, I think that's valuable. I don't know I might be an outsider.

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

Yeah, maybe this would all fall out naturally if we didn't make these points in words on this slide, but we just showed an example of sort of an approval screen...

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

Yes.

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

Where the provider had good reason to give you assurances that this App was valid or had good reasons to be worried, we could just sort of show those two things as examples of what the approval screen might look like.

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

Yes that might be easier.

**Drew Schiller – Chief Technology Officer & Co-Founder – Validic**

Well, I suppose, I mean, so this is Drew again, just sort of thinking through this the App...in order for the patient to be requesting their data to be accessed by a third-party that third-party will have already had to apply for API credentials with the provider and already have provided some level of assurance to the provider that they're intending to do this with good...or that they're building this connection with good intentions am I correct in that assumption?

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

Well, they would have gone through a technical registration process and this ties back into this question of endorsement. One thing that a provider could do in that technical registration process is to tell an App, by the way if you have any endorsements please inform me of them in a well-structured, you know, cryptographically verifiable way and so then it wouldn't block the registration either way, but a provider could collect that kind of information optionally from the Apps.

And so then Apps that had provided that kind of reassuring information might get somewhat better treatment on the approval screen than Apps that weren't able to provide it. Those are the kinds of things that I think we could build with an ecosystem like this.

So, we would have the guarantee that patients would still have a choice but people could try to iterate and explore, you know, how to provide more usable systems on top without ever worrying that patient access would be compromised.

**Drew Schiller – Chief Technology Officer & Co-Founder – Validic**

Sure, yeah, no I get that, I think that's fair. So, putting my entrepreneur hat on another possible unintended consequence of this would be that if you have a new App that does something that nothing else can do and it's, you know, by virtue new technology you're not going to be able to have those endorsements out of the gate.

So, it's possible that this could be an unintended consequence to, you know, that would unnecessarily divert a patient away from a particular startup because it was new not because it was necessarily bad or otherwise unverified. I know that's not the intention I just feel for my startup brethren that I should call that out.

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

Yeah, I mean, I guess you're right that if we were looking for endorsements from establishment players who weren't familiar with new things then new things would have trouble. But I think this is a concern any time you're trying to share something new with consumers, they have to either just try it themselves because they're early adopters or they have to look for someone they trust who has evaluated the thing for them. I don't...

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

So, this is Yak, are we going a little too far by just focusing on endorsements? Could we say that the provider is free to provide whatever information or feedback or knowledge or information to the patient about this application but they cannot block it.

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

Yes, I think that's fine. I was trying to spell out, you know, how an ecosystem might evolve which, you know, maybe that's just too far for us to go in this space.

**Drew Schiller – Chief Technology Officer & Co-Founder – Validic**

Yeah, I think that's fine too. Josh, I certainly appreciate the efforts I'm just trying to think through it from the perspective as an entrepreneur and, you know, raising the questions there.

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

Sure, I mean, I think you still have the same issue in the proposed amendment where providers are free to display whatever information they feel like and words of caution and all that. I think any time you're trying to share new things with the community you do have challenges there.

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

Yes.

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

But...

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

I think about this in an interesting way, there are people who would want to discover those Apps and Drew you could be an endorser that says, here's this new App that does something that isn't supported by any other App that we know of...

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

Well, so long as it doesn't disadvantage someone I don't think there is a problem at all.

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

Yeah.

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

But I guess we're wondering if this could lead to unintended consequence, but I think, you know...

**Drew Schiller – Chief Technology Officer & Co-Founder – Validic**

That's exactly it.

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

If you broaden this out to the amendment it could be even more detrimental to new Apps or to those for instance if they didn't have a commercial gain potential from this particular App so there is a bit of Pandora's box problem here that we may be getting into if we go too far into this. I wonder if we're just making it worse as opposed to letting the market work this out.

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

All right let me put the pause button on this. I think there are two separate questions, one is how much we want to adjust our underlying recommendations and two is how we want to address the summary of those recommendations in these slides because there are a lot of things that we say in the underlying recommendations that are just sort of descriptive, rather in the background of our report that's just descriptive and so maybe the descriptive...

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

I mean...

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

Background is still helpful but our recommendations themselves could be much crisper and they wouldn't have to cover quite so much territory here that said...

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

I just want to add one thing...Josh, I just want to add one thing, this is Aaron Miri, so I will tell you that as a provider I'm going to provide very little information unless it is very black and white because you can get into a legal realm really quickly if you inadvertently state something about an App or an API, or whatever else and, I mean, this just gets into murky water.

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

Yeah.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

So, my compliance department would be very...

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

Understood and that seems perfectly fine and nothing we're recommending on these slides or in our report would prevent you from taking that approach. So, by all means that seems totally reasonable. We're at the three minute mark where we need to open up for public comment so let me turn it over to Meg briefly to see, Meg if you've got any closing remarks?

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

I'm sorry, I was on mute, other than just take a look at the document, we've got some off line work to do. Again, our deadline for the slide set is Friday so just a plea for your help if you've got any time over the next couple of days to help us make sure that those are representative of what you are particularly concerned about and the Task Force in general please set aside a few minutes, we'd definitely appreciate it.

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

Great and let me turn over then back to you, Michelle, to open for public comments.

**Public Comment**

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

Thanks, Josh, Lonnie, can you please open the lines?

**Lonnie Moore – Meetings Coordinator – Altarum Institute**

Yes, 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 already on the telephone and would like to make a public comment, please press \*1 at this time. Thanks.

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

We did have a comment in the comment box submitted so we will share that through e-mail with the Task Force. And we do have a public comment and just a reminder public comment is limited to three minutes. Kel if you could state your organization that you are with and please go ahead.

**Kel Callahan – Vice President & Chief Operating Officer – HIPAAT, Inc.**

Thank you, this is Kel Callahan from HIPAAT we're a company that's been involved with consent management and providing software solutions for that for over a decade. So, with that I just wanted to...I came on the call a few minutes late as you were reviewing the first document that had to do with consent and authorizations and there seemed to be a perception, at least on my part that there was a big move to going towards language that had to do with authorizations so I just wanted to speak to that semantic for a minute if I may.

That is that ONC has invested, and probably many people here know, quite a bit of resources and quite a bit of materials and activity relative to the notion of patient preferences embodied in consent and consent directives. So, first concern is that perhaps if the language of your work product does not necessarily align to historical references that it might be evaluated against number one might be a concern.

Number two is just to highlight the notion that there is a subtle difference between a security construct as it relates to authorization and a privacy construct that has to do with appropriateness of use for access or disclosure and I don't know if you've...because I didn't get a chance to review the material, if you've addressed the notion on purpose of use as it relates to your work product. So, I just want to leave you with those thoughts.

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

Thank you and we have no further comment at this time. Thank you, everyone. Have a great rest of your day.

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

Thanks, you too, take care all.

**Aaron Miri, MBA, PMP, CHCIO – Chief Information Officer – Walnut Hill Medical Center**

Thank you.

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

Bye-bye.

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

Thank you, take care, bye-bye.

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

Bye.

**Public Comment Received During the Meeting**

1. Kel Callahan: MITRE has used Consent Management
2. Kel Callahan: HHS Papers, studies and content has always referred to this process and Consent Management
3. Connie Patterson: Connie Patterson, Updox - Where in the process should the testing/approval occur? Does "registration process" refer to the 3rd party registration with a Health IT vendor (which should include testing and some type of vetting to ensure the app developer is who they say they are) or does this refer to registration by the patient to access their info via the app?