



**HIT Policy Committee
Privacy & Security Workgroup
Final Transcript
May 1, 2015**

Presentation

Operator

All lines bridged with the public.

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

Thank you. That's my favorite music. This is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Privacy & Security Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. Also as a reminder, if you are using the comment section of the webinar, we may share those comments during the public comment period at the end of today's meeting as well. With that, I will take roll. Deven McGraw?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Here.

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

Hi, Deven. Stanley Crosley? Adrienne Ficchi? Bakul Patel?

Adrienne Ficchi, MBA – Director Health Care Requirements – Department of Veterans Affairs

This is Adrienne Ficchi, I'm on.

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

Hi, Adrienne. Cora Tung Han? David Kotz? David McCallie? Donna Cryer? Gayle Harrell? Gil Kuperman?

Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital

Present.

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

Hi, Gil.

Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital

Hey.

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

John Wilbanks? Kitt Winter?

Kitt Winter, MBA – Director, Health IT Program Office – Social Security Administration

Here.

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

Hi, Kitt. Kristen Anderson?

Kristen Anderson, JD, MPP – Staff Attorney, Division of Privacy & Identity Protection – Federal Trade Commission

Here.

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

Hi, Kristen. Linda Kloss? Linda Sanches?

Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Office for Civil Rights

Here.

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

Hi, Linda. Manuj Lal? Micky Tripathi? Sarah Carr?

Sarah Carr – Acting Director – Office of Clinical Research & Bioethics Policy – National Institute of Health

Here.

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

Hi, Sarah. Stephania Griffin? And Taha Kass-Hout?

Taha A. Kass-Hout, MD, MS – Director, FDA Office of Informatics and Technology Innovation – Food and Drug Administration

Here.

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

Good morning. And from ONC do we have Helen Canton-Peters?

Helen Canton-Peters, MSN, RN – Office of Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Here.

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

Julie Chua?

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

I'm here.

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

Hi, Julie.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Hi.

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

And Johnathan Coleman is on as well?

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Yes, good morning.

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

Hi, Johnathan. Anyone else from ONC on the line?

Kathryn Marchesini, JD – Acting Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Kathryn Marchesini.

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

Hi, Kathryn. Okay, with that I will turn it over to you, Deven.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Hey Michelle, Stan's here now.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Oh, great.

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

Hi, Stan. Thank you.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Hi, Stan.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Hi, guys.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Terrific. Thank you. All right, welcome everyone. I want to say at the outset that I very much appreciate your attendance on this call today for the workgroup members. We also appreciate the members of the public who join in. This was a call that was added to our schedule in order to enable us to complete work on both of the proposed rules; the one for certification as well as the one for Meaningful Use.

And we didn't have enough time scheduled with our regular calls to be able to complete that, so we have this additional call on the schedule; two in one week. Unusual for us and we very much appreciate your willingness to make time for this, because it's an important set of topics that we're covering and we very much need your input; so, double thanks. And also because we don't normally meet at 10 o'clock in the morning Eastern, which is 7 a.m. for the West Coast folks, and so it's a bit earlier for a lot of people so even more appreciative on a Friday that you're here with us today; so thank you. Next slide, please.

We really designated this call to bat cleanup essentially on the recommendations that we had begun discussing in two previous calls on the certification NPRM and the Meaningful Use NPRM. Next slide, please. So we want to at least substantively finalize our comments, as you'll see, between today and May 12, which is the Policy Committee meeting. We do have a little bit of time that we could use to do any wordsmithing edits, but we don't use non-public time to make substantive policy recommendation decisions and so we really need to make sure that we have gotten as far as we can get with the issues that we've taken on from a substantive standpoint on our call today. And then we will present materials to the Policy Committee on May 12. Next slide.

So one of the areas that we discussed previously was the Data Segmentation for Privacy criteria that were...that are proposed for certification in the next round of certification. Pardon me...sorry about that. And when we had our discussion about the proposed criteria which are DS4P send to enable people to send documents that are covered by sensitive data laws, and then DS4P receive, which enables people to receive a document and understand that it's covered by particular privacy rules; some questions had come up that we wanted to make sure that we got clarified.

So here were some of the questions that were raised. We had previously recommended that the DS4P receive technology be able to receive and view the data from someone who has the send technology and understanding a little bit more about how this is technologically implemented. Similarly, how does someone with the send technology know that there is a recipient on the other end who has the technology so that they can recognize that level of sensitivity? And then, when a document is sent, if someone doesn't have DS4P receive, does that mean they can't view the technology or what are the consequences of having DS4P receive versus not having it in terms of the recipient provider? And then what happens to the data after the receiving provider views the data?

And so we've got...thankfully Johnathan Coleman and Julie Chua from ONC to help provide some clarification on some of these questions. So, we're not having them present on the DS4P technology, you know, many of us have seen this before; we certainly got a lot of presentations of it prior to the first round of recommendations that we made on it.

But these additional questions came up, I know that perhaps I had forgotten some of the particulars of this from the time that we saw it before to now so I'm wondering if Julie and Johnathan could opine on the set of questions, a lot of which stem, you know, revolve around the recipient provider and what is DS4P receive do with respect to that recipient provider in terms of whether they can view the document and what does it communicate? And what would not having it mean for a provider if they decided not to purchase the technology that has it?

And so I'm wondering if you can address that question and then we'll get into a discussion with the workgroup members to see if there are other questions that are either sparked by the answers or that we didn't raise specifically on the slide, but that people still have questions about.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Hey Deven, it's David McCallie; I'm joining late, sorry.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Oh, but David, I'm really glad you're on since you were one of the people that asked these questions.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yup, I recognize these questions.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, okay. Thank you.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

David Kotz just joined as well, sorry, the two Dave's are here.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Oh, great. That's perfect.

Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer – PatientPoint Enterprise

Hey, you've got Manuj as well, sorry I was late.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Oh that's all right Manuj; so terrific, anybody else other than the two David's and Manuj who have joined since roll call?

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

Yeah Deven, Lucia's been on all along, but on the wrong line so I'm here and I'm going back on mute.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay; anybody else? All right. Terrific. So Johnathan and/or Julie, whichever one of you wants...is dying to answer these questions, now is your time.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

All right...

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Well...

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

...thanks Deven. So Johnathan, maybe I can start it off and you can go into a little more detail with what I don't cover?

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Sure, that would be great.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

So basically Deven, for the Tiger Team's recommendation for level 1, right, it was at a minimum saying that for level 1 in the NPRM, the Privacy & Security Tiger Team recommended that it's read only and that information should not be automatically consumed interdigitated into the EHR. So that is still what we are understanding from the comments that were shared to us by Helen.

So for the question regarding if a receiver does not have the DS4P technology, they would still be able to read only, per the recommendation for level 1. But the difference is that they would not be able to see the privacy or security tags that are there if a sender system does have the DS4P that they are using. So let me stop there and see if that's the framing or the context that you were...you and the group were contemplating on.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes. So we did have questions about whether it could be read or not, because I was...I had originally been under the impression that it couldn't be read; but you're...what you're saying is that in fact it can be read...

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Right.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

...but the recipient may not know that the material is covered by a sensitive data law and having DS4P receive puts them on notice. And this would be...

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

That is right.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

...particularly important in circumstances where the law places redisclosure obligations on the recipient; and so we get that.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Um hmm.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Although I will say...so the Tiger Team was not trying to constrain the technology to read only, like we would love it if the technology were at a phase and had been tested to allow for the kind of interdigitation or consumability of the data where the privacy flag would continue to persist.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Um hmm.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

But it was our understanding was that that functionality had not yet been piloted and wasn't necessarily present in DS4P send and receive. So if we're wrong about that, it would be helpful to know because I think we were not necessarily trying to confine or limit, or maybe we were, but it was our understanding that the technology that had been tested was document-centered and read only, not that we had said...that we as a recommending body had necessarily been the source of that limitation.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Okay, there's an answer...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

But...

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

...to the first question real quick Johnathan and then you can talk about how it was piloted. So basically the standard does allow for more granular or more than just a document level exchange.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

But...

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

But...pilot, then Johnathan can speak a little more about that.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

But...before we...I think the misconception here...this is David, is the way the current certification rule is written, it is optional for a system to implement the send side and it's optional for a system to implement the ability to handle or receive correctly, which means that you could have very readily a situation where the sending system sends a properly DS4P formatted CDA and has absolutely no way of knowing whether the receiver can handle it properly. And the receiver may get it and they may even read the notice if their style sheet is good enough to pick it up, but their system won't block the interdigitation.

So you have sort of a situation where it makes no s...there's no way to know whether the sen...the receiving system can handle it properly and there's no enforcement that the receiver would, in fact, handle it properly. And so it...to separate and make both of those independent decisions and to make them both optional sort of defeats the whole purpose. That's the concern that I was raising, right? I mean there's no way for the two systems to know who can handle it and who can't, you'd have to negotiate that out of band with every single trading partner...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Right, but...

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

That's right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

...and then somehow...

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

This is Johnathan...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

...the sending systems would have to keep track of that and say to the physician, oh I'm sorry, I can't let you send it there because they can't handle it, which just creates, you know, unimaginable complexity.

Julie Anne Chua, PMP, CAP, CISSP - Information Security Specialist, Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Department of Health and Human Services

Um hmm.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I mean, unless I'm completely missing something.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Well, I don't think you're missing something David, that was definitely part of the question, but we did just as a reminder from the Tiger Team perspective, we did recommend that the criteria be voluntary. Because frankly...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I underst...yeah. Yeah, I understand, we recommended stuff because we had to recommend something. The cost and implications, I still think you have to be sane about it and just because the laws are written in a bizarre way, does that mean that we have to force all of this overhead onto the vendors and to the poorer providers who won't understand why data is disappearing and can send to here but can't send to there. It's...we're going to follow the letter of the law and create a lot of trouble downstream. Or we force it on everybody.

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

Well, I mean, David...this is Lucia. It is an optional criterion in the NPRM so at this point there's no proposal to force it on anybody, but to ensure that vendors building certified EHR technology build it...have this available for people who want to use it.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

No, I understand but the problem with...is if one party says I want to use it, let's say it's a behavioral health system and none of the other trading partners have chosen to use it, there's no way the behavioral health system can detect that, other than out of band contracts, and there's no way that they can enforce a behavior. They think they're sending a properly formatted DS4P document, following the rules but the receiver will do with it whatever they want because they're not going to know how to process the document correctly.

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

David?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

So you create a false sense that things can be handled. Yeah, Johnathan, I'm...

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

David this is...yes, sorry. I just want to right off the bat say I do not disagree with you; I just want to maybe add a slightly different perspective. So I think that currently as it stands, the onus is on the sending system to determine whether or not the intended recipient is authorized to receive that information and I think that's true whether or not there is DS4P technology.

So, if somebody wants to have information sent to them from a behavioral health system, there's an expectation that that receiver is already authorized to receive that information. So when the behavioral health system sends that information, whether it be tagged or not, the current state is that the receiving system would handle that properly. With DS4P tags added on to that on the sending side, there is the potential for the receiving system to be able to process those tags, if they have that capability, to help them automatically identify which of that information they received should not be re-disclosed without consent and which should be.

So I think it doesn't change the current state of affairs in terms of the onus on the sending system to make sure that the receiver is authorized to receive it before they send it. And we still have the situation where the receiver needs to know how to handle that information; so that's true whether the DS4P tags are there or not. With the tags, they have the potential to be able to do that in a more automated fashion...helps or not.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, no, that's good and that's a helpful clarification. I just wanted to bring attention to the notion that if you send a DS4P tagged document to an authorized recipient and you...and I agree, that's entirely the providers...they have that responsibility, the computer's not going to help them with that; that you can't just blindly assume that the receiving system will be able to handle it properly. You won't have any way of knowing whether the receiving system can enforce the redisclosure restrictions.

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

That's correct; yup.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

You may create the impression by saying, my system is DS4P compliant that in fact that means that the loop will be closed on the other end and that it'll get handled properly and the current standards don't make that possible. So by making it voluntary, which I'm not going to argue that we shouldn't make it voluntary, just want be...we should be really clear what the implication of that is, is that it means redisclosure restrictions might not, in fact, be reinforced by the receiver, even though you sent a properly coded DS4P to them. So, just as long as we're clear that that's what the state of the affairs will be, we're okay.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

So, one of the things that we had said in our recommendation, at least in the draft recommendations and I want to skip forward to slide 6, and this is more of a summary version of what we had distributed to you a couple of days ago in text format, because ultimately the form of the recommendations will be more detailed text to be in a template, but for presentation, the Policy Committee purposes we can't just read that information to them, it will be...there won't be time for that. We have to sort of present these at a summary level.

So the way that Stan and I and the staff had sort of framed this for consideration is the assumption that yes, we would continue to recommend that DS4P be part of certification, but not part of the base EHR, but to particularly note that there are aspects of this technology and parts of our recommendations from the previous round on this, that were not at all reflected in certification and that that particularly around the sort of the sender and recipient responsibilities and the out of band communication that's going to necessarily be required before these documents can be sent. That none of that...I mean, understandably so because certification rule on some level reflects sort of what's needed to be in EHR technology, but there's a lot of sort of additional consideration that goes along with that that wasn't really reflected and needs to sort of continually be part of the overall scheme for rolling this out for meaningful users.

And we tried to reflect that, to say look that this technology is an important initial step, but it doesn't self-execute in a way that would be...that makes it as seamless as some of the other certification criteria. There are other aspects to this that necessitate education of providers and probably also patients, in terms of sort of what this technology does and doesn't do, what might be required in order to make sure that people sort of understand what they're getting into when they send documents using it, which frankly would be the case if they were sending them through other means as well. But here, where it's going to...a received document is going to be absorbed into a system that...where legal obligations may attach to it, there might be some...there are some additional considerations at stake.

So we tried to really capture that. I'm not...again the slide is purposefully more summary in nature, you know, for those of you who may have had time to read through the text or if you didn't if you would take the time to read through the text of the recommendation so we can get it worded right. I think the bottom line is, yes, certification not in base EHR, but there's just a lot to this set of issues due to the policies involved and people need to be educated about the...how to use it and the consequences of using it. Does that make sense?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Uh, this is David, yeah, I agree. I just wanted to call attention to the notion that you have to know both parties and their status before you can feel comfortable that you've met the requirement.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yup.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And that's going to be difficult in a widely networked future where parties don't all have peer-to-peer data sharing arrangements; they have network-based data sharing arrangements.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Right. So, that's right. You know, one thing that does...so one thing though that I want to make sure that we don't misstate in the material we're presenting to the Policy Committee is this issue of sort of whether the segmentation is document level or is more granular. Because Julie both you and Johnathan suggested that it's a healthcare entity that bought this technology, wanted to deploy it in a more granular way, they could in fact do that; did I hear you right?

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Yes, the current...this is Johnathan. The current DS4P standard at HL7 does support section level and entry level tagging but it doesn't require it; so document level in the standard is also supported at just the document level.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay.

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

Deven, this is Lucia; just to sort of flesh that out a little bit. So one of the things we, you know, we've tested...it has been tested in an environment where the rules of sensitivity apply to every type of medical information generated by the program that would be a Part 2 program. It has not really been tested in an environment where there might be different rules that apply to different types of health information. For example, it hasn't been tested in a primary care practice that is diagnosing the potentiality for depression in its patients and ensuring they get referrals to behavioral providers. That has not been tested, as far as we know.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Got it.

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

So...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And I...

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

...if we think about the coded nature of the system, it has the capability but it has to be able to recognize the distinctions within that overall record; and we don't have a standard way for that...a standard rules engine for that to happen. There are rules engines that people use out there or value sets, but they are not standardized across the nation.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And my guess, this is David again; my guess is that by making element level and section level optional, you will have senders who restrict that section or element level and receiving systems that cannot process that and who knows what the heck will happen.

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

So David, this is Johnathan; that's a really good point and I think during the development of the standard that was factored in and there is a criterion in the standard that requires the document to be also tagged at the same degree of sensitivity as the most restrictive section or entry. So this highest watermark concept applies; if you were to only tag one section as sensitive, the document would also be tagged as having contained sensitive information.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

But then a receiving sys...I mean, how do you know...

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

So a receiving that could only handle...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

That does not work...

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

...so a receiving system that could only handle document level tags would default to the handling of the entire document as being sensitive...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Ahh.

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

...because it wouldn't be able to drill down to the section.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

So a system that can handle section level tags and it now also sees this document level flag, how does it know that some sections are, in fact, not restricted?

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Yeah, so...

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

Yeah so David, that's the point, in a Part 2 program the whole document's going to be restricted because all of the information from a Part 2 Program is restricted, whether it's a blood pressure cuff read or actual, you know substance abuse medication.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah but that's not...I don't think that's the question that David's asking.

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, my question is, number 1, why are we doing the work of section and element level if, in fact, no program needs that, you know, number 1 that's just a let's don't do more work than we need to do. But number 2, assuming that there are some programs that could benefit from section level and you've escalated it up to document level to take care of the fact that the receiving system might not know how to respect section level; if the receiving system does know how to respect section level and it's been escalated to document level, have you just essentially negated the benefit of section level? And I don't know the standard...

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

So...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

...well enough to know the answer, I'm hoping there's an answer.

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Yeah, there is and I think this was particularly demonstrated in the VA pilots where they were using Title 38 as their overriding privacy policy. And I don't want to speak authoritatively for what they did, but my understanding was that if, for example, in Title 38 they...wanted to restrict HIV data but not the rest of their information, that would be an example where it could be tagged at the section level and the watermark would apply to the document level and if the receiving system was unable to handle section level, it would treat the whole document as sensitive. If it was able to handle section level, then it would drill down past the document code into the section to see those entries.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

But how does the document level...is the document flagged in some way that says, I'm not really document level unless you are stupid, in which case I am document level? I mean, is it able to tell that subtlety?

Johnathan Coleman, CISSP, CISM, CBRM, CRIS – Initiative Coordinator, Data Segmentation for Privacy Principal – Security Risk Solutions, Inc.

Right. That was what I had the impression of, yes. But we...I can try and double check that with the people that wrote the code and did the technology implementation to see if that's actually the case.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Okay.

Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital

Deven?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes, hi Gil, go right ahead.

Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital

Hi, I think I made these comments when we discussed this initially and I don't know if my, you know, these ideas were kind of integrated, so maybe they were considered and set aside. But I just feel kind of...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

...Gil, please, let's make sure.

Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital

...obligated to say one more time, you know, kind of I think maybe rifting a little bit off of what David McCallie was saying a moment ago; if it's not obligatory that both sender and receiver have the componentry, then it's just going to be very confusing. And it's not clear to me exactly why this is being made optional; I think if we have a goal of advancing interoperability at scale that making these kinds of capabilities optional kind of runs counter to that. So I'm not...I don't really understand that.

We talked the last time about interdigitating data into medical records and we said that there are issues other than simply redisclosure considerations and so it's not...simply having redisclosure flags doesn't determine whether you can or can't interdigitate stuff into your records. However, redisclosure considerations are more than just automation and so even if I'm not going to interdigitate the data into my medical record, I still need to know that this data has redisclosure considerations so I want my EHR to be able to tell me that this document I received has sensitive data, even if I'm not going to interdigitate it, so, I just think that these capabilities are very important.

And just the last think I'll say, just the issue of document level versus more granular, I think there are a lot of issues there but frankly I think those issues are less important and I think these other things are kind more important. So, I'll stop there.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

So I'll...so I know when we took this up in the Tiger Team in our recommendations, the reason why we landed on it being voluntary was because the limitations of the technology suggested to us that for physical health providers, where they are more often going to be in the recipient role and particularly in a Part 2 situation, need to sort of understand that receiving this data then obligates them to protect it against redisclosure. That given that for some providers they would prefer not to receive these documents at all, or to have the technology that enab...that that was the reason why we came at this or...and said, this really ought to be voluntary.

Now that we...we're a different group, we have maybe a little bit better understanding of the technology that's being proposed here, if we feel differently about this and want to instead urge this to be more, you know, part of the base EHR, then we should discuss that as a workgroup. But just...background. And in terms of the interdigitation, again, we were looking at a technology that had been tested for document level segmentation only where the information would have been blocked from being parsed and there would be a risk if, in fact, the information did get sort of consumed and used in different aspects of the EHR, that it could have been inadvertently disclosed without the flag, which could have subjected providers to some legal liability.

Now if they've adopted the HL7 standard at the more granular level, then perhaps that's a non-issue. But, you know, again, this is not the Tiger Team, this is a workgroup that is largely new and if people feel differently about this and want to put forward a different recommendation to the Policy Committee, now would be the time to be more clear about that.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

So Deven...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes. Hi, Micky.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Hi, this is Micky. So I'm sorry I just joined about a minute and a half ago so I just heard the tail end of this, but if we're reconsidering this question, I'd like to actually put in a vote the other way which is that I think that DS4P is too immature for certification, even for voluntary, I think, at this point. So I'd...my suggestion would be that we actually go the other way because I think that there's already so much complexity in certification, I don't even...I don't think this is nearly ready for base EHR let alone for voluntary.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay. And there have been circumstances in the past where we have just decided to provide a set of comments versus coming to consensus or we say that most people feel X, but there were strong feelings in another, you know, for people who didn't want to do this. And so we can and should reflect that, given that these are comments as part of an NPRM.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Right. In terms of our purview as well, I mean, last time as I recall from the Privacy and Security Tiger Team work, we were asked specifically this question whereas, I mean in general, we don't as a Policy Committee workgroup, necessarily weigh in on the question of whether something should be certified or not, do we?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Well we have talked about...we have not weighed in usually on the issue of standards maturity.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Right.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

That's usually not our purview. What instead we do is make recommendations for functionalities that might be helpful for policy compliance. And so this fell into our lap because we had previously taken on the issue of granular consent laws and noted that there wasn't really a capability that was in widespread use to be able to honor these, and we specifically urged ONC to pilot technologies to enable this.

So we were, in fact, a source of recommendations to, in addition to HITECH making this a priority for ONC to address, we were a source of recommendation that said, hey, in terms of standards and certification functionality priorities, this is a policy need that should be addressed. So our recommendations really need to be about whether this...I mean, it's a good point. Our recommendations have historically been about whether this is a need in certification to match a policy...a desired policy or a policy requirement.

And so I think in the first round we were really sort of thinking about whether the technologies that we asked to be piloted were heading in the direction of assisting providers in meeting policy requirements. And we came to the initial conclusion that they were a good first step, but should not...but not yet really quite as functional as we would have wanted but that we thought it was important to start encouraging the use of, you know, some utilization so that we...there was momentum for fixing the pieces of it that were not quite on point. Again, at the...we had seen pilots with document level segmentation only, not the sort of more granular, and that was a significant shortcoming.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Right.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

So I don't think that we have necessarily strayed beyond where we've been in the past, certainly, with our discussions about voluntary, non-voluntary. But we're definitely, I mean, I think admittedly on the edge of where it's really Standards Committee purview and what is within our capacity to take on.

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

And Deven, this is Lucia; if I could just add something. This is a very confounding issue; we hear this over and over again and it's going to take a lot of work to get to a place where it doesn't at least confuse people let alone actually impede interoperable movement of data in a way that patients desire or is beneficial to them. So you shouldn't feel...I hear your...I hear everyone's frustration and that frustration is expected and you're not alone. It's just a very complicated issue, what should the technology do? Does the technology match to the rules environment? Which things are we understanding clearly? All of that.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

This is Micky, maybe there's sort of a nuance, but firm sort of tact that we could take which is reaffirming, and I don't mean to jump to the solution here, but reaffirming the framework that the Tiger Team came up with, which seemed to be well received and was pretty robust, it seemed. And then perhaps re, sort of emphasizing the need for or the desire to have ONC try to cultivate more pilot activity and signal to the market, perhaps in preamble language or what have you, that this is something, this is a pressing need and we need to accelerate market maturity and standards maturity in this area, perhaps with a signal that this could become a part of certification in the future, much as they did with FHIR and in the way they've treated FHIR in the certification language.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Right, but I will say we called for voluntary criteria for certification previously.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

I know I just personally have changed my mind.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

And you're permitted to do that, Micky. But we did...some of the comments, the draft comments that we did circulate did try to...were aimed at trying to reinforce some of the other points that we made and that have come out on this call. So, what do people think? Do we say no certification? Do we reinforce voluntary? Or do we head in the direction that Gil is urging us to go in, I think, and Gil you can tell me if I'm misstating you which is, if we believe this technology has potential, it shouldn't be voluntary it should be mandatory but...or it should be part of certification but it should come with a lot of education about sort of what the ramifications are and any potential shortcomings of the technology and what people can expect in using it.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Well the...this is David. There may be...maybe we've drawn the wrong functional constraint around what would be voluntarily certified and maybe, you know, it's either we make that simpler so that the cost of that experiment is less of a burden on the industry and on our users or we just back off. And what I mean by that is you could say that the minimal thing is to be no worse than what was true on paper, which is to say that the document has markers on it that says that redisclosure restrictions may apply, please treat this accordingly, but not otherwise require the systems to enforce any of those rules. In other words, leave that decision on the provider so rather than specifying that the system can't parse the document and intercalate it into the problem list or the medication profile, just drop that notion and say that's up to the doctor and the system isn't going to try to babysit him.

And if the hospital has a policy that every document is...is exposed to the local HIE, then they have to decide whether they want to delete those documents and get rid of them or ask the vendor to put in a flag to test and say don't expose these; but leave it up to local institutions to make that decision. And just at a minimum communicate that the document has special...needs special handling. In other words, don't try to over-specify what is clearly an immature technology.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

But still, if you want to leave it up to the providers, does that...are you saying volun...that it's not part of base EHR, but it's available?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Umm...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

I'm trying to get out comments to match to what's been proposed.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Right, right. Yeah, I don't know, I mean, it may be such that if you put it in the CDA as a header the way it's put in there that systems will handle it properly already, meaning they'll display the header just with the standard style sheets, which means you don't have to say anything and you'd have my baseline. But, I don't know; I think it's a hard question, you know, half-way technologies are always more expensive than full technologies and we're in half-way technology space and it'll cost us a ton of work and a ton of anger on behalf of providers, because we're not fully specified yet. And by the time this is widely deployed, a lot of people will be moving to FHIR-based exchange of discrete data and we'll have to revisit the whole problem all over again because there's no way to do that that reflect DS4P rubrics, at the moment.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Anybody else want to weigh in on this?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

It's a tough one.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, I know, I'm formulating a compromise in my head, but I want to make sure that I'm giving everyone...

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Okay, this is Stan, Deven. I was just going to ask if you had a compromise in mind because I don't think we're, at least just kind of sitting back and observing the conversation, I don't think we have a clear consensus on what we would recommend. And I think it's even hard to kind of get to a point where we can suggest that we have a consensus, given that we have a pretty broad range of perspectives here.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

So I do think it's going to be more comments on what the key issues to consider maybe would be.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, so that's sort of, in my mind what I was going to suggest is that our comment specifically defer to the Standards Committee about whether this DS4P itself is sufficiently mature for certification but that we spend our opportunity on this space raising both the strong desirability of having technical capability to enable people to honor these rules. Our both hope and concern about DS4P that it is good to have technologies begin...you know some starter technologies begin to be able to address this.

There is a standard that's been adopted by HL7 that does show some promise and that providers should be able to use, if they want to do that, and there is...there are more capabilities to this than what had been...that we had seen in the pilots, in terms of the segmentation or the sensitive data flags being able to be applied at the more granular level, should a provider decide to deploy it. But that there's still a lot of additional sort of out of band communication that is...needs to take place between sender and receiver to make sure that both are understanding that there are some legal compliance obligations that might not be...that are not going to be fully realized necessarily by the technology and that additional pilots and use and further refinement is still going to be necessary.

But that ultimately exchange of this data is critically important, because that was something that we said in our prior recommendations and we can reinforce all of that, as Micky suggested, but leave to the Standards Committee, as is their purview, the issue of standard...of maturity for certification, and that's really the penultimate question for a certification NPRM. So that's what I was thinking.

Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

I'm on board with all those comments because I think it touches all the range of comments we've made.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay. Any other thoughts? All right, well we will work...re-wordsmith that and get that around to folks just to eyeball and provide us with suggestions; but we'll go with that. So let me have the next slide.

So consequently on the pharmacogenomics issue, which was the other one that has DS4P implications, but not...isn't solely about DS4P. Here we're sending along to the Standards Committee, which will ultimately decide the maturity issue, the no...the idea that we don't think this is ready for primetime, but that it should be continually monitored by ONC in order to...and review issues around access, sharing and using pharmacogenomics data as the science evolves. Because this is one where it's not just about this particular standard, which...but also about whether there's sort of a sufficient substantive basis for moving this forward as part of certification and noting that DS4P, in particular where it's applied in a way that doesn't allow decision support, you know, even for those very clear pharmacogenomics cases where the science indicates that its valuable to apply it as decision support for prescribing, that it...if it had a segmentation flag on it that did not enable it to be utilized in decision support, that that would be...that would be...essentially be undermining the one use case where it could be very valuable.

So, that essentially what this says is that we'll make sure that comments that we make about DS4P in the prior example are accurately reflected in this one as well. Did we get it reasonably right? Are we off base on this one? Any other thoughts? This will also be sent to you for wordsmithing early next week, so we make sure we get it right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

This is David, I like this. I think we're just not ready to take this on yet, we don't even really know how to move this data around in a standard way yet, much the less move it around with attached restrictions.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

This is Micky; I agree.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

This is Dave; do we need to say anything about aligning, better aligning the state laws and federal laws that affect these? Because I think some of the challenges, as I recall, came from differences in laws or regulation.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Oh yeah, yeah.

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

Yeah and Steven, this is Lucia, you are invited to opine on that relative to the roadmap, which has a pretty, relatively speaking, long section on that. So, happy to hear what you think about connecting those two ideas.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Well we did say that in the roadmap.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

Yeah.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

We did endorse it. And we could do it again, if Lucia, particularly if you think that would be helpful, we can reiterate that.

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

Umm, I just think that anything that helps ensure that people are aware of the complexity that we face here, that we can't just flip switches electronically and make it all happen, is helpful.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay.

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

Don't you have your mag...where's your magic wand today, Deven?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, if only.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

I guess I raised it not so much to say that we want to recommend that those laws be straightened out, but just to say that one of the reasons why we're not quite ready to do this is because the laws are so different.

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

No, I think that's actually exactly the right message, Steven, so thank you.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

David, that's David.

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

David; sorry David.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

No problem.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

One of our Davids. Okay. All right, great; no, we will incorporate that, that's a very good point. All right. So next slide, moving on a bit quickly. We endorsed...now we're into Meaningful Use, we quickly came to consensus around endorsing the approach in the NPRM for objective 1, which is protecting patient health information through attestation to a security risk assessment that addresses administrative and physical safeguards, as well as technical safeguards. Anybody have any further comment on that one? Okay, next slide.

So in the area of the ramifications on privacy and security issues with...related to patient access to data, specifically through view, download and transmit and application program interfaces or APIs, we, you know, our...the way that we framed these comments is to support increasing these opportunities for patient access to information consistent with where the Tiger Team has been previously, but to acknowledge the potential privacy and security risk that are inherent in increasing patient access through different...some mechanisms obviously introducing more risks, more potential risks than others, as we discussed on our prior call. Next slide.

And in terms of our recommendations, we want to make the Policy Committee aware again of what it had already endorsed around best practices for view and download, and it's not as well reflected on this slide because it's more of a summary slide. But acknowledging that the points that we made related to view and download are also applicable in the transmit category. Asking ONC to continue the work that its already begun with the Federal Trade Commission and also with OCR to develop guidance for stakeholders on the use of mobile technology and Apps and APIs, which includes the third point here, educational materials from...on the safe use of Apps and APIs and also referencing our prior recommendations on the issues about identity proofing and authentication, as well as allowing for family members, friends and personal representative access.

In other words, we've been down these roads before and said some very good things from a policy standpoint and I think that they, in all of the excitement about...and debate about increased access requirements or decreased access requirements, depending on what state you're talking about, and this sort of new ve...potential technology vehicle for giving patient's access of the API that people may have lost sight of the ground that we've already covered. And we want to take an opportunity to essentially reinforce that here. And next slide.

We have some additional recommendations asking for guidance that addresses the intersection between meaningful use patient engagement objectives and certification and what HIPAA requires of providers covered by HIPAA with respect to patient access rights. And that includes the extent to which a provider may reject a patient's request for electronic access due to a perceived security risk, as well as whether that rejection can take place in the absence of a security risk. And the ability of providers, we'll fix the typo there, to charge fees for patients seeking meaningful use access through either VDT or APIs, which is an issue that's come up.

And then the last recommendation that we framed here is that there could be some value to a voluntary effort to certify patient-facing health Apps, you know, acknowledging that we haven't been...it's not necessary...it's stepping a little bit out of our purview, but that a robust program that was available out there could be...could end up being valuable given that there is not a lot of guidance out there for either patients or for providers in navigating this space. And certainly federal agencies could play a role in advising such an initiative, although we expect that it would come out of the private sector, at least that's the way we framed it; but the government could play an advisory role around privacy and security policies and helping to facilitate potentially some greater standardization of privacy and security approaches.

So did we capture this? Is there...again, the slides are much more lifted up than the text that we circulated to you all that you probably haven't had a chance to review yet, but that we'll give you another chance to review prior to putting it before the Policy Committee and we'll incorporate whatever discussion we have here today in those materials.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

Deven, this is Dave.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes David.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

I think you did capture it well; in fact, I've been multitasking reading through these documents while trying to listen to your summary.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

I can't do that, but I appreciate that you did, thank you.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

I'm not sure I'm doing it well. Anyway, I did add one little edit in this section about best practices recommendations to vendors or manufacturers of these Apps and APIs. I would...the text as its written focuses really on technical best practices, which is important, but I added a phrase that encourages them also to communicate their privacy policies and security practices well enough to the patients and providers so that they know what's going on in that App or API.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

Because that's, in my mind, been a real failing of much of the technology industries, that their privacy policies, when they exist, are vague and really don't give you much understanding of what's going to happen to your data.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yup. No, really good point, David and in fact, I do recall that we touched on this a little bit on the last call and we just...I think we just didn't incorporate it as well as we should have. Thank you.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

Okay. I'll the edited version back to you.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Thank you. Other thoughts?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

This, for one of the Davids, I think this is good.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay. Terrific. Well, we'll be using our time on the Health IT Policy Committee to both present these but also, where needed, go into a bit more detail on what some of our prior recommendations were on some of these points, since they're so...they're an important part of what we're passing along. So, any other thoughts? Okay, well this...it's been a great discussion. I'm going to go ahead and we're wrapping it up a bit early, so we need to have some public comment. So I'm going to pause for a moment and let Michelle direct the opening of the lines for public comment and then we'll return to some discussion and then move to our public comment period.

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

Lonnie, can you please open the lines?

Public Comment

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

So thank you all again, as we're moving to the close of this call a bit early, I was slightly worried that the DS4P conversation was going a bit long, but we had a lot of important issues to discuss there and we had a really full discussion of that. That was important and it turns out we were very close to the mark on the other issues that we had on our plates, so that was enormously helpful.

We will circulate text where we capture the compromise language that we talked about on this call for DS4P, as well as for the other recommendations that we discussed. So you'll have another opportunity, really again, this is for wordsmithing, not raising additional substantive issues, but just making sure that we get the communication of what we've agreed to accurate when we present it to the Policy Committee. Does anybody else have anything to add substantively to any of the issues that we've discussed?

All right, well you've just been really amazing. Thanks also to the folks from ONC; to Julie and Johnathan who joined us to be very helpful in answering our questions and always to the MITRE and other ONC staff that support us, it's been really helpful. Do we have any public comments?

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

No public comment.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Well Gil didn't have to miss a single minute of this call; we were able to get it finished so quickly. Thank you all very much; we'll meet again later in the month. We'll be able to report back on how our recommendations were received. So keep your eyes on your email next week for circulation of some final language on this and very much appreciate your time and attention and I hope everyone has a terrific weekend.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Thanks, Deven.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

You too, thanks.

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

Thanks, Deven. Have a nice weekend.

Cynthia Baur, PhD – Senior Advisor, Health Literacy, Office of Communications – Centers for Disease Control and Prevention

Thanks, Deven.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Bye, bye.