



HIT Policy Committee Privacy & Security Workgroup Final Transcript April 20, 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. Good afternoon everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Privacy and 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. I'll now 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? Cora Tung Han?

Cora Tung Han, JD – Division of Privacy and Identity Protection, Bureau of Consumer Protection – Federal Trade Commission

Here.

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

Hi, Cora. David Kotz? David McCallie?

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

Here.

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

Hi, David. Donna Cryer? Gayle Harrell? Gil Kuperman?

Gilad J. Kuperman, MD, PhD, FACMI – Director 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. John Wilbanks? Kitt Winter? Kristen Anderson? Linda Kloss?

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Here.

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

Hi, Linda. Linda Sanches? Manuj Lal? Manuj, I'm sorry? 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.

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

Hi.

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

Sephania Griffin? Taha Kass-Hout?

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

Taha is here.

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

Thank you.

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

No problem.

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

Is Helen Canton-Peters on from ONC?

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

I'm here.

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

Hi, Helen, 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 and with that I'll turn it back to you Deven.

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

All right, great, Michelle, thank you very much. Thanks to everyone who is able to join us today. We have a couple of things on our agenda. Next slide. We're going to briefly recap the presentation that Stan and I made to the Health IT Policy Committee on our interoperability roadmap comments and then launch into the beginning of our discussions on the Notice of Proposed Rulemaking both on certification of EHR technology for 2016 as well as for Stage 3 of Meaningful Use. We're not taking it all on, we're just taking on some specific components of both of those proposed rules that are related to our charge, which is looking at privacy and security policy. Okay, so next slide.

So, just to let you all know what's coming up for our meeting schedule, we will begin our discussion again on the proposed rules today. We will continue it on the 27th. We have one more call now on our schedule to finalize any recommendations or comments that we want to make and then we will be making a presentation to the Health IT Policy Committee on our recommendations on May 12th and I see here on the schedule it suggests that our comments are just about the certification rule, but I thought that we actually needed to finish up the Meaningful Use rule too. Michelle am I right about that and Helen?

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

You're correct.

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

Okay. So, that's just a typo on the slide. We have to have all of our NPRM comments in for both proposed rules for consideration by the May 12th meeting and that is because there is a comment deadline associated with this two rules and we need to fit within that.

So, quite a bit of work to do between now and then and on a very truncated time schedule so I suspect we'll use our meetings wisely but also try to use e-mail to work on precise language in advance of our phone calls so we can be as efficient as possible while we're on the phone. Next slide.

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

Hey, Deven, this is Lucia.

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

Hi, Lucia.

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

I'm sorry I'm late but I'm here now.

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

Oh, great, thank you.

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

You're welcome.

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

Anybody else join post roll call who wants to make themselves known?

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

Hi, Manuj is on, sorry I'm late.

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

Okay, great, thanks Manuj. All right, terrific, so briefly we had a very successful, next slide, please, presentation to the Health IT Policy Committee on our interoperability roadmap. Now there was concern expressed by one of the Policy Committee members regarding a recommendation that we made that ONC look into the use case of the circumstance when an individual authorizes or wants to have their information shared with another provider for treatment purposes and provides written authorization to do this whether that...in those circumstances where that authorization is present even when the healthcare provider may not necessarily be all that comfortable with sharing that information, if that's something that the patient wants to have done what's...you know, looking into that use case to enable that.

And the concern that was expressed by Paul Egerman at the Health IT Policy Committee is, what if what the patient is asking for would be harmful to the healthcare provider. And one of the examples that he provided was a circumstance where the patient was asking for a connection to be made that could introduce a security risk into the system.

But he also discussed issues involving, you know, where the patient is having data sent somewhere where the provider would have some concerns about the subsequent use of that data either because they have concerns about the patient or because where the patient is sending it is to a facility or to an organization that doesn't necessarily have the organization's best interest at heart.

So, we didn't have a full discussion of this necessarily during the committee meeting but it's pretty clear that, you know, certainly our recommendation to ONC that they look into this use case didn't necessarily introduce the possibility of a circumstance where what the patient was asking for could potentially cause some harm to the provider.

And so what we agreed to do in order to get the Policy Committee to endorse our recommendations was to suggest that anyone who follows up on the recommendations, ONC or CMS in the Meaningful Use context, would need to, you know, consider the circumstances where what the patient was asking for would cause...had the potential to cause some harm to the provider particularly in cases where security risks were introduced.

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

Was it mentioned...

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

So there was not a whole lot of discussion about that issue and frankly I think we'll be able to take that up in some more depth when we get to our discussion on the proposed Meaningful Use rule about patient access to data through application programming interfaces or APIs.

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

Deven?

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

So, I think we'll get another bite at that apple but for now what we agreed to do was just to note that possibility as something that would need to be investigated if that use case were to be fleshed out as we had recommended.

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

Deven?

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

Is there is anybody else who was there or on line to add any sort of more color to that anything that I've forgotten?

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

Deven, this is David.

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

Yeah?

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

Just a question, was the harm with respect to the patient or to the provider? You said...

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

Well it was more to the provider in Paul's examples, but certainly if you sort of really think through that issue and all of its dimensions it could also incorporate circumstances where the provider thinks that the patient is putting herself in some danger with respect to subsequent uses of the data.

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

Okay, of course the patient has the right to do whatever they want with the downloaded data so it's kind of a moot point technically.

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

Yeah, you know, again we did not...we weren't trying to come to a resolution of whether patients should be allowed to do whatever they want to or even...we didn't even sort of fully scope out the sort of HIPAA right of access and what patients can have done, you know, with data in terms of having it directly transmitted to a third-party, but I do think these issues are going to come up again for us when we take on the Meaningful Use Stage 3 proposed requirements around patient access because we have been specifically asked by the Policy Committee, by Paul Tang, who is the Chair, to look into that issue.

So, but we'll get there...we'll get that again, so we didn't dive in to that deeply but just agreed to make note of the possibility of an organization not wanting to sort of honor a patient request to have data sent directly to another entity even in a treatment context in circumstances, certainly where it's risky to the provider to do that, particularly around connections that would cause security risks.

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

So...

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

So, Deven this is Lucia, I also have a similar sort of follow-up question as David and I seem to be channeling each other lately. It would be helpful as that conversation unfolds to be really clear about whether the harm is a security harm that might or might not be addressed with technical controls versus a harm that's not in the realm of information security.

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

Right.

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

And then...and I think as one of the instigators of the, could you guys please tell us what you would like OCR to issue clarifying guidance on, because they've asked us to go get that information for them...

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

Right.

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

I think that this is going to help them figure out if what they're doing as they develop whatever guidance they deem appropriate, again, this is OCR's responsibility, we're just carrying information here, are they interpreting the privacy rule or the access rule, or the security rule. Those are all three really different parts of the regulations.

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

Yeah. Well, again, we...you know, in an interest just to sort of, I don't want to say pass the buck because that wasn't what we were trying to do, but just to say from an interoperability roadmap perspective, say the use case of the patient...that the patient desires in terms of exchange being sort of fully thought through and enabled that this is one aspect of it that needs to get fleshed out and I think we'll be able to sort of dive into the, you know, the much more specific use cases that when the patient is making that request in the context of exercising their HIPAA right to, you know, to have access to their data or to download their data, or to have it directly transmitted to the third-party of their choosing.

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

Right.

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

So it was interesting, it was kind of an unexpected comment but sparked a very interesting discussion that we will have another chance to think through as part of our API discussion and so noted Lucia, I think we probably do need to sort of separate the different types of risks.

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

Yeah, because, I mean, just to be blunt the business practices related to people's understanding of privacy were included in the blocking report that we supplied to congress and we did that very intentionally because we felt like people could use some clarity.

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

Got it. Okay, so we managed to put that through. Now we have...I see here in on the slide, please submit final thoughts by April 22nd. Apologies but can someone remind me why that's on there? Because I just assumed we would incorporate the...

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

Deven, this is Helen, we just wanted to give a little bit of room if you wanted to allow the Privacy and Security Workgroup members to provide additional comments.

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

Okay, okay, well that makes sense and I'm of course fine with that as long as they are not substantively different than what we presented to the Policy Committee. Maybe we should quickly...

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

Yes.

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

Just recirculate that slide deck with the additional language in it just to...

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

Yeah, thank you, Deven.

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

So people know what they're commenting on.

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

I mean, we've already had approval by the Policy Committee so we have to be careful.

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

Yeah, yeah.

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

Yes.

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

Nothing substantively different. Okay. All right, well let's dive into the NPRM. Really we're dealing with the certification NPRM today specifically the data segmentation for privacy which we went through a bit on our last call and our general task here is to determine whether or not we agree with what's been proposed for certification which is that the technology for sending and receiving should be part of the 2015 certification criteria. Is that the right year is it 15 or 16?

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

It's the 2016 edition rule that's what's been proposed.

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

Okay that's what I thought, we have a typo there 2016.

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

I'm sorry, 2015 edition rule.

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

Yeah.

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

My phone was ringing while you were asking me that.

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

Okay.

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

Yes.

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

Okay, 2015, thank you. So, it is correct. I was wrong it's 2015. And then the certification questions related to pharmacogenomics data but only those that have a privacy and security angle to them, we had a bit of discussion on our last call about whether standards for pharmacogenomics were sufficiently mature enough to pass the Health IT Standards Committee's threshold for whether they should be adopted and our task is not to evaluate the substance of pharmacogenomics or family history vocabulary and other standards per se but to try to get some feedback to ONC on the privacy and security issues that are implicated by a certification functionality that could encourage the collection of this data in there. And as you'll see there are some specific questions about whether the DS4P technology that is proposed in the rule would be helpful for protecting pharmacogenomics data as well.

And then in another call, I don't think we'll get to the Meaningful Use Stage 3 criteria that are in our bailiwick, but we're certainly going to review the privacy and security objective on a subsequent call protecting patient health information as well as what the ramifications are around the proposal to increase patient access to data both through the view, download and transmit functionality that was part of Stage 2 but also through APIs. Okay, next slide.

So, again, this is a little bit of the division of labor, we're going to try to get through DS4P and pharmacogenomics today but we do have an additional call scheduled to do some wrap up on all of these topics to enable us to get there. Okay, next slide and the next slide.

Okay, so, on DS4P I'm going to go through this a little bit quickly because we started to talk about it on our last call. What is in the proposed certification rule is two new certification criteria that would focus on the capability to separately track or segment documents and it's segmentation at the document level that contains sensitive health information.

There are two HL7 standards that are proposed, one that deals with sending of sensitive documents and one that deals with receipt of sensitive documents. It is not part of what's called the base EHR. So, providers are not required to purchase this certified functionality in order to be Meaningful Users but if they want to include exchange of sensitive data as part of other objectives that they're trying to meet for Meaningful Use or to enable them to share data that may be more sensitive they would be able to purchase that functionality and use it for Meaningful Use purposes because it would have been certified. Next slide.

Again, data segmentation is a descriptive term that refers to the electronic labeling or tagging of health information that allows patients or providers to share some parts of a record but not the information in the document that's been tagged that may be subject to particular laws like additional requirements for patient consent unless the patient's consent has been achieved.

The data segmentation for privacy initiative and its pilots focused on the exchange of health information in the context of 42 CFR Part 2, which are the federal rules that govern the sharing of information that is from a substance abuse treatment program that is federally supported and that identifies or potentially identifies an individual as someone who is receiving substance abuse treatment and so the segmentation capabilities were developed with those particular laws in mind. They are quite stringent and that's the...the pilots focused on that aspect of it and certainly the standard that HL7 has developed and balloted in response to that builds on the work that was done in the pilots. Next slide. Thank you.

So, some of what came up on our last call is a lot of the conversation that we had when we first took up this issue as a Tiger Team not even all that long ago. There is still a lot of discomfort with sequestration or segmentation that occurs at a document level because you both get the protections for the sensitive information that are in that document but non-sensitive information in the document also sort of gets swept up into those protections even though it itself may not be covered by sensitive data laws because right now where the segmentation technology has been tested and how the standard was developed, it was developed to enable document level protection.

And certainly the mere viewing of the sequestered data does not then, you know, preclude a healthcare provider from manually entering necessarily the data that they might have seen in the segmented document.

This is really just a handful of some of what came up on our last call and some of the rich discussion that we had as a Tiger Team on a previous call, you know, how is this sequestered data going to be handled, how are query functionalities impacted, how does the provider know or how can they be sure that, you know, they may have one document segmented but there may be other places in the record where sensitive data may live either expressly or where it's implied from other data. Next slide.

So, here I wanted to take an opportunity for those of you who are new to the Workgroup and who were not part of the Tiger Team when we had our initial discussions about this to refresh every...and maybe even for those of you who were there but it's...you know there has been enough passage of time or lots of other things crammed into our brains to remind ourselves about what we had previously said.

So, what's on the top of the...in the dark blue portion of this slide, and I'm on slide 12 for people who are following along by hand, what's proposed is that the technology must enable a user to create a summary record formatted in accordance with those HL7 standards or with other standards for documentation that are required for certification in an EHR, that it has been tagged as restricted and subject to restrictions on re-disclosure, which is really a hallmark of the Part 2 legislation and regulations, according to the standard that, again, was balloted by HL7 and based on the pilot and technology for DS4P.

So, when we had looked at this as a Tiger Team, you know, we really thought in terms of, you know, the sharing of this data that comes from a substance abuse program provider with a physical treatment provider for example, you know, the current state is level zero, which is where it's not really being exchanged digitally or from EHR to EHR at all it's being...if it's being exchanged at all it's being exchanged on paper or by fax.

And, you know, the sort of next level of enabling this exchange is to create a glide path for digital exchange but that doesn't...but that relies on this technology and so it's less than perfect, it's this sort of initial step where the document containing the information that would be subject to more stringent law, and in this case Part 2, would be sequestered or segmented and could be sent because once the patient had authorized that it could be sent, but it's tagged as restricted and the recipient provider can view it but cannot interdigitate the information within the EHR, it can be stored as a restricted document but not the document itself subsequently acted on.

And what has been proposed...what we had said at the time was, well this is far from perfect, it's not...in some cases one could argue not much better than a fax, but it does put the wheels in motion to enable the sharing of data among those providers who want to share data both from a behavioral health program stand-point but also on the physical health provider side. If you have patients that you are seeing that have substance abuse treatment histories and where the data is coming from a Part 2 covered program that you would be able to at least receive and view that data, you would have the option to have that capability in your EHR.

So, we really thought behavioral health care providers should have that as part of their certified systems, behavioral health providers are not part of the Meaningful Use Program but as ONC moves to expand certification and make providers who aren't necessarily part of the Meaningful Use Program assure that they can take advantage of it in terms of buying technology that's interoperable with other certified systems that there was some value to that. Next slide.

Now again, on the recipient's side, you know, it's a read only functionality of the document that's been sent as restricted and we really thought that on the recipient side that providers should have the option to have technology that had this type of capability in it. They wouldn't necessarily...shouldn't necessarily be required to purchase it but if they see value in having the technology so that they can receive documents from Part 2 covered programs they should be able to get a system that has that functionality in it and I think at the time we considered that to be a voluntary certification criterion that's not...there isn't really a voluntary certification program anymore, but there is this distinction between the base EHR that includes the minimum components that a provider who is meaningfully...part of the Meaningful Use Program would have to purchase, but there are other functionalities that are certified that are not part of the base EHR that a provider could then purchase and use to meet their Meaningful Use requirements.

And so we called it voluntary in this case what's been proposed is a functionality that builds on the DS4P functionality that we looked at as a Tiger Team but is not required as part of the base EHR but is a functionality for which there would be certification requirements in the 2015 edition if the proposed rule were to be enacted. Next slide.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

This is Donna Cryer, I just had a question. Is the intention that this only be restricted to behavioral health or are there particular criteria or definitions for what is sort of segmentable or, you know, sensitive information?

And then my second question would be about the read only functionality versus a provider being able to, you know, add to the record, you know, for example if we just use behavioral health, if a patient has a psychotic episode or something in the course of primary care treatment what is the process for the primary care doctor being able to add that to a record?

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

Hey, Deven, do you mind...this is Lucia, do you mind if I answer that in terms of long-term view, because it actually relates pretty closely back to the roadmap and what we've proposed there?

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

No sure, go ahead.

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

All right, so one of the complexities of this particular standard is that we developed it in the Part 2 space which has the nice tidy little feature of being the same in every state but has the untidy feature of being, in some ways, very prescriptive and restrictive compared to other laws that also provide additional privacy protections on top of HIPAA.

So, just kind of a dichotomy in the way the law works and that's part of why we set up in the roadmap what we did, you know, HIPAA basics, basic choice and then granular choices to try and get to the point where the concepts that...the technical capabilities that are reflected in DS4P can be applied in additional contexts.

Part 2 rules specifically state that everything within a Part 2 program whether it's a blood pressure cuff or actual, I'm going to just pick on Antabuse for a minute, prescription of Antabuse are treated the same because of the nature of the program in which the treatment occurred. That's not true with other conditions that have these special protections.

So, that's where all this additional work comes in is it's not plug-and-play for all the other categories now but we have...and we have some policy work to enable it to be plug-and-play in a kind of a nationwide standard way the way it would be for Part 2 because Part 2 is the same everywhere. So, that's a...I think hopefully that answers the first part of your question.

And the second one is, so Part 2 also has these very specialized rules about, you know, each time a provider obtains this information if that disclosure to that recipient was authorized one step in the daisy chain as it were and that's the read only helps keep that...help the receiving provider comply with that requirement.

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

Well, but Lucia, isn't it also the case and Donna's question of, you know, if the patient has a psychotic break or maybe has a relapse on substance abuse treatment but that's something that is sort of witnessed by the primary care provider or the patient comes into the primary care provider in order to be treated and then that information is then fresh not coming from a Part 2 program...

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

Exactly, no, I totally get where you're going Deven and I think that that's sort of where I was trying to get to is this was designed for the particularities of a federally funded substance abuse program. So psychotic episode maybe is not even in scope for how it was originally designed Donna because that might not be triggered by anything that's substance abuse related.

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

Right.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

So, I...can I ask?

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

Yeah, go ahead Donna.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

So...

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

You're breaking up Donna. I'm not sure where you are.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

I'm sorry, so as I was saying...my behavioral health episodes to when I'm before a behavioral health provider?

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

Well, so here's...getting to your first question is that the technology itself that's being proposed for certification isn't limited just to being used in the context of a Part 2, an exchange of Part 2 data, but Lucia's right that it was designed to accommodate the particulars of the Part 2 rule which number one, do not allow for sharing of this data even for treatment purposes without very specific authorization that is specific to the provider that it's going to not general for treatment purposes.

And that then require that authorization to be obtained for any subsequent disclosures, which is not going to be the case for a lot of other special laws around mental health treatment data for example where often times, especially at the state law level where number one the state can only govern its own providers they can't govern providers in other states.

And number two, they may in fact have just, you know, the way that the law, the coverage of the law extends it covers healthcare providers but maybe not some healthcare providers but not others, so it may not have that re-disclosure piece to it.

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

I mean, at the end of the day Donna, and we're not near that goalpost at all, we should have a system in which we have a standard way to recognize the coding in the system and what coding is susceptible to additional protections and what coding is not.

So, you know, one of my favorite examples is a chlamydia screen, right, pretty common, HEDIS measure but it's also an STD. So, you know, do we...what do we do about disclosing evidence of a chlamydia screen?

And another example is exactly yours in the mental health space that's not derived from a Part 2 regulated program don't we in fact want to be able to recognize...for the physician to especially protect that which they're required to specially protect which is the data that's specific to the mental health condition for example, but have data that's regular medical data not be swept up in that so that we have an under disclosure that might be harmful to patient's health.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

And might be harmful to others then who are treating that patient even the original referring physician who doesn't realize that the patient has had, you know, degradation of their symptoms in other provider offices and doesn't then have access to that because there wasn't any where to put it.

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

Yes, no, I'm with you I just think we have a lot of work to do on the complexities of this landscape because we have a very complicated rules environment and because our technology isn't...we could probably, if we had less complicated rules, whip up the right technology but we have sort of...if we're building a railroad track our rails aren't caught up to each other right now.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Okay, thank you, thank you.

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

Yeah, no, sure Donna and you're sort of picking up on some of the very incredibly rich discussion that we had when we took up this issue initially at the Tiger Team level. Let's go to the next slide.

Again, you know, we really thought that the proposed criteria were a good sort of initial step but there were still lots of challenges with respect to both the technology as well as the policies around patient choice and what is required when consent is required and how specific it often needs to be under the law and how there are differences in law as we talked about as part of the interoperability roadmap and as Lucia just mentioned.

You know, if a document is sequestered it doesn't necessarily get part of...the information there doesn't necessarily...is not permitted to become part of clinical decision support systems because that pulls it out of the sequestered document and could result in information being subsequently re-disclosed in violation of the law in circumstances where the law does prohibit re-disclosure in the way that Part 2 does. So, we have spoken about all of that. Next slide.

We also said, you know, we are going to continue to need pilots of this technology as well as to encourage, you know, sort of the next steps in the evolution of the technical capabilities so that we don't have to do segmentation of the whole document that ideally that there is a way to enable compliance with law at a much more nuanced and granular approach.

We have work to do on the policy side, lots of education of both providers and patients about what's capable and what's not and what the implications are of making decisions to not share data in circumstances for treatment purposes where there could be some downstream impact, Donna, as she just mentioned, you know, we really left it for the Health IT Standards Committee to address the issue of maturity or feasibility of that technology against their criteria for evaluating whether a standard is sufficiently mature enough for the certification program that's really the role that they play. And so next slide.

So, in terms of what we've got in the proposed criteria for Stage 3 does it really comport with the prior recommendations that we made on DS4P and EHR certification. I might posit an argument that they did exactly what we recommended that they do by making the criteria part of certification they're utilizing the HL7 balloted standard and it's not mandatory in terms of being required to be purchased as part of a base EHR and so that picks up the sort of voluntariness aspect of it that we thought was important.

We didn't think physical health providers want to take in documents that could not be used by their EHR such as through clinical decision support, if that made them uncomfortable they shouldn't necessarily have to purchase the technology and use it by...you know, I have...I presume that by leaving it out of the base EHR that it makes it more voluntary for providers but people can certainly disabuse me of that notion if I'm just off base there.

And so is there more that we want to say beyond what we have said and maybe it gets to Donna the question that you raised about whether this technology, which was tested on Part 2, is really a technology that ought to be extendable through, you know...through its use and certification to other types of data that may not be subject to the same restrictions just by way of example. I've just posed a couple of really open ended questions here to get the dialog going. We will, hopefully on this call...and we can go ahead and start engaging in the discussion of whether it's appropriate to think about this technology in the circumstance of pharmacogenomics data which involves the collection of genetic information that has implications for prescribing of drugs where there is evidence that genetic information is relevant in terms of dosing.

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

So, this is David, I mean on the surface that's obviously not a very applicable use case given that we've specifically said it can't participate in clinical decision support. You'd be communicating all this information that you can't use for the purpose for which you communicated it.

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

Right and is that because it would have to be part of a bigger document as opposed to being a discrete...I mean, even then you're right.

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

We've basically said sequestered means "does not get imported into local algorithmic...does not get parsed or imported." The scope of the document is not what is of relevance here it's the fact that the data is treated specially.

Now you could carve out a new kind of special use case but if you're just going to follow the current DS4P I don't think it would work very well.

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

Right.

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

It would work no better than this the current rule works which is to say "not very well." Because of that...

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

Hey...

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

Carve out, I mean, you...

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

Hey, David, this is Lucia, I just have a question about that because I wasn't here when you guys did all that stuff I was kind of outside in. Is that because it can't be accounted for in the analytic engines within the EHR even though the physicians got it in their brain?

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

Well, it's a couple of things, you know, the EHRs in general are not capable of keeping track at the discrete data level of which data elements have specific restrictions, which is not to say that no EHR can do that but I'm not aware of any of the major EHRs which do that. So, if you imported a sensitive drug, let's say an antidepressant into the patient's medication profile from a restricted DS4P restricted document you lose track of the fact that this antidepressant has re-disclosure restrictions on it in most EHRs today. In fact, I think all of them.

So, that's why we basically said, okay, this is a stepping stone, the doctor could be aware of it but he needs to know that it's not going to be imported into his EHR and used for clinical decision support simply because we couldn't stop it from being re-disclosed to the state HIE or to CommonWell...

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

Right.

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

Or to anybody else.

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

Right, well and the...and the flip slot also was true that...because we don't segment...we segment it for the entire document instead of...

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

Yeah.

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

Portions of the document, a patient who wants their prescription history to flow can't get it to do that.

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

Well, right so that's a secondary problem is that everything else gets swept up in that net.

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

Right so the over withholding problem.

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

Right you catch the tuna with the...or you catch the dolphins with the tuna whether you like it or not.

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

Right.

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

So, that's...but that's addressable by just refining the scope of the restriction in the DS4P that's technically solvable, you know, instead of restricting it at the document level you're restrict it at either the section level or at the actual discrete data element level.

But the problem is the vendors aren't prepared to deal with that specific knowledge and then if you, you know, if you propagate that data forward and it does have those restrictions on it how do you keep track of it downstream to understand where the restriction came from and what steps had been taken to remove the restriction it just gets really complicated.

So, with respect to the pharmacogenomics data if you communicated data that was on purpose to be not incorporated in the record because it was following this pattern then it's obviously not going to be useful for pharmacogenomics screening other than the doctor might just, in the back of his head, say "I think I read something about, you know, being a warfarin hypometabolizer, oh, yeah, here's the document. I wonder why my computer didn't tell me that."

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

This is Linda and one of the issues seems like we're setting up a policy dilemma for providers...

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

Yes.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

And perhaps you attorneys can think this through. If it's sequestered then what does the provider do about this document as part of the legal record? If it is the basis for which decisions are being made then it really should be part of the legal record, but, you know, I understand that it may be sequestered for purposes of Meaningful Use but it still, as a practical matter, is part of the legal medical record. So, I think we've got an issue that certainly will at least prompt a lot of comments on the NPRM.

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

Linda, this is Lucia, I don't think that we have an opinion about that. I think that the idea here was to ensure at the baseline that...where we had a system that could segment under DS4P...

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Right.

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

And send data to a PCP, that PCP...that receiving provider would be able to buy certified equipment that could adjudicate what was being received.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Right but I'm saying...

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

We don't sort of offer opinions about what constitutes a legal medical record because that's subject to each state's laws and the way they oversee their physicians.

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

Yes...

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

But as a practical matter if you are entering some legal hot water by not having that technology and having certain sequestered documents off the grid I just...I don't...there is no easy way to deal with this.

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

Right.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

But I think we ought to understand that this is going to create some new policy issues that are going to require guidance.

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

But what would happen today without this technology if a patient wanted it to flow from a Part 2 program to their primary care practice they would sign a piece of paper and the Part program would fax it to the primary care practice and the rule that applies to the data once faxed would still apply. The rule itself is media agnostic so the physician having received that fax would still be legally obliged to not re-disclose that fax. That all happens today.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Right, it's not...yeah, not re-disclose it but still use it and perhaps incorporate it into what they consider is the record.

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

But I think you're right, this is David again, I mean, I think it does create some liability.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Yeah.

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

Thorny liability questions for the physician who has come to trust his computer...

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Right.

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

To understand the patient's medications and to give advice and, you know, since many of the substance abuse medications are in fact extremely dangerous if combined with other medicines, this will create problems this is not a theoretical concern...

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Right.

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

It will happen.

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

Well and I remember when we discussed this previously that this was one reason why we said, you know, providers shouldn't have to buy this technology if they don't want to. They could continue to, you know, receive documents on paper and, you know, if they have patients who come to them from Part 2 covered programs, and again we really did evaluate this in terms of getting the Part 2 data moving not the sort of broader implications of what, you know, potentially having this technology would be for other types of sensitive data where the technology might provide some utility for complying with other sensitive data laws. So, and hence we were like "well you can get it if you want it but you don't have to buy it."

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

And it may be useful then to, you know, elaborate in the use case, in the NPRM, on that issue and, you know, remind providers that they have to make these decisions based on their own local and state...

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

Yeah.

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

But it's even...

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Sensitivities.

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

You know it's even worse and we had this...some SAMHSA officials on the phone to confirm this, you know, if the physician asks the patient what medicines they're on...

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Yeah.

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

And the patient says "I'm on a serotonin" you know "I'm on an MAOI inhibitor, MAO inhibitor" and then he turns and reads the SAMHSA document that's in his EHR and sequestered it's perfectly legal for him to go and enter the dangerous drug into the medication profile because the patient told him first.

If he reversed that sequence and was unfortunate enough to read the sequestered document before the patient walked in the room it's the exact opposite and that makes absolutely no sense to any provider that the channel through which you discovered the sensitive information trumps the patient's wishes around re-disclosure. It just doesn't compute.

And I wouldn't want to be in a position to try to explain that to people other than to say "don't read those sequestered documents until you have thoroughly interviewed your patient."

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

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
Which also isn't practical.

Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital
Deven?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yes, hi, Gil.

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

Hey, just a couple of comments here and maybe some of this is, you know, just reiterating what's been said, you know, I do think this issue of, you know, kind of what's considered in the record is somewhat relevant here, you know, here in New York, you know, stuff that's received through the HIE we don't consider as "part of the record" you know we may have it in our databases, but, you know, we don't automatically include it in decision making anyway, so I think that's a separate issue from the sequestration, but it may be related. So, that's just kind of a comment.

You know this issue of, you know, sweeping up the non-sensitive data with the sensitive data, you know, may be a big problem because, you know, here especially we have large provider organizations that have Part 2 programs, you know, as part of the overall healthcare facility and so when you're getting data, you know, there may be some in there and so, you know, some of our re-disclosure warnings say, you know, these contain data from Part 2 programs or may contain data and so, you know, you have to, you know, be concerned about re-disclosure even with a small risk that there may be data in there. So, it ends up affecting, you know, a lot of data that we receive through health information exchange here.

And just, you know, lastly, and this may be a question, you know...I'm not sure what...making it voluntary, you know, I mean, this is a certification criteria and, you know, if you're going to have this capability, you know, and it's part of the EHR, you know, it's not clear to me what making it voluntary...what value making it voluntary adds and maybe I'm just missing something.

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

Hey, Gil, this is Lucia, just to be clear the sort of over withholding because of Part 2 is something nobody can do anything about except SAMHSA or...we know they've done an RFI, we have to sort of wait for them to decide how they're going to do anything with their rules and then of course their powers are limited by whatever is provided in the relevant section of US code, which is not anyone in Health and Human Services purview to impact. So, we just have to live with that problem, but just, it is what it is and it can't be solved technologically and it' can't be solved with DS4P or anything else relative to health information from Part 2 regulated programs.

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

Right.

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

Long-term, you know, we need to go to...David and I were talking about this last week...somehow be able to figure out that slice and dice the data in the most refined way to improve patient safety and improve the health outcomes but we have lots of work to do between now and then.

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

Right, I appreciate that comment and I certainly understand. I guess I wonder, you know, is one of the questions on the table this proposed DS4P criteria, are they better, you know, are they better than nothing or are they not better than nothing?

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

Or maybe it's okay but it needs to...you know you guys can always give us recommendations about where it needs to go directionally. I don't think anyone here, certainly not in my office, thinks this is the end of the story, but always your guidance about where the story needs to develop is helpful.

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

So, this is David, just to recapitulate why we settled on the recommendation of this so called level 1 sequestered document approach, Gil, just for, you know, reconstructing the history I'll put my more compromising hat on instead of the one that thinks this whole thing is really problematic, the thought was we at least ought to have electronic systems that are no worse than what you can do with a fax.

So, if you get a restricted fax today and you're a provider you have to make some tough decisions about what parts of that data to act on in a way that might actually cause re-disclosure which could either be re-keying it into your EHR if you happen to have an EHR or just mentioning it to the person that you're transferring the care of the patient to after their serotonin storm in the emergency room explaining to them why in the heck they had the serotonin storm.

So, given that in the real world doctors make those kinds of thorny decisions all the time even perhaps without knowing that they might in fact be breaking SAMHSA rules we figured we could at least give them the electronic equivalent of that and then they can decide what to do about it. That's kind of how we got to where we got.

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

Yes.

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

All right, thank you.

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

Thanks, David, well-articulated.

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

Deven this is Gil...

Donna R. Cryer, JD – Principal – CryerHealth, LLC

That was very helpful.

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

Deven, this is Gil, can you just say something about why voluntary?

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

Oh, so the fact that having the capability that there might be providers who, on the physical health side, would just prefer to get this on paper because of the sequestered document not really being sort of fully incorporated into the EHR using clinical decision support. That given all of those...the imperfections of the technology which we recognized that, you know, even this baby step forward brought too much risk for them and they just didn't want it in their EHR because they didn't want anybody sending them something that had those kinds of downsides in terms of being, you know, fitting within their EMR system and what they had come to expect.

But that there might be providers who had a significant number of patients that they received referrals from for...subsequent to a behavioral health substance abuse treatment issue that they would prefer to have that data even with all of the downsides of the technology.

And that you can only receive and read an electronic document from a behavioral healthcare provider that has been sent using this DS4P technology if you have the recipient standard in your system, you can't even read it. So, you can't see it in advance of a visit and prepare.

And that there would be providers out there who might make the decision that, you know, the technology is not perfect but I'd prefer to have it rather than not and that was it.

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

This is David, the concerns that I have with the voluntary nature, and I understand sort of the thought process, is it now means that you have to have point-to-point negotiations on what kind of data can and can't be sent and received that just complicates life.

So, you know, if an EHR elects not to implement this then I don't...if you send it it's going to show up and be disclosed, right, they didn't implement the rule that respects those headers, so the sending system is going to send it to systems that aren't enforcing the header and either that or you require the EHRs that they must implement a rejection of the software that they've chosen not to implement which is really complicated.

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

So, what...so David, that's a really good point. So what happens if they receive it but they can't read it because they didn't buy the receive functionality?

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

I think they can read it, I mean, as I understand it the DS4P is just encoding additional information in the record it's not encrypting it or blocking it in some special way.

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

I thought...but that I thought was a pretty big...we should check on that because my recollection from our discussions of this the first time around was that this was the issue. If you didn't have the technology on the receiving end you couldn't...I mean, I know it's not encrypted but you couldn't read the document.

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

I would be surprised if that's true.

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

Okay.

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

But I agree I don't know the answer. I can find out.

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

So, if that is the case than what's the functionality of the recipient piece of this?

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

Well the...if a vendor was going to aggressively implement the receive capability what they would do would be to make sure that they see that header, that encoded information in the CDA document, and properly display headers in their EHR to remind the clinician that this is restricted information number one.

And number two, they might go the extra mile and implement a block on the ability to suck data out of that document using their data reconciliation tools that are the tools, you know, to pull it into the official record as Gil was describing the distinction.

So, that would be, you know, kind of two things and then they would probably, on three, they would implement blocks in their HIE interfaces so that no one from the outside could request a sequestered document. The sequestered document would be invisible to the outside world so they would have to upgrade their, you know, HIE interfaces to block view of that document.

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

But none of that would be required as part of certification.

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

Well, I'm saying if you chose to...well, the certification rules I don't think have been...well, I don't know...what does the certification propose to measure compliance with the DS4P specification itself?

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

So, David, this is Lucia, it proposes that a certified technology would have this capability and there are no Meaningful Use measures associated with it.

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

Right, but it has...

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

No but...

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

But it uses the HL7...

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

Right the HL7 balloted standard.

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

Yeah, so, okay, I'll admit my ignorance of what that standard says about the systems behavior towards the CDA itself. I don't know where that, if or where that is specified.

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

I'm happy to send you a copy, you should have come to my program at HIMSS.

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

Yeah.

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

Yeah, no, I think, we do, you know, given the questions that Gil has around, you know, why voluntary and some of the assumptions that we made about recommending this in the first place that we might need to get that nailed down.

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

Yeah, so then the question is, if it's well specified as to what it has to do if you are compliant with the receive certification test what does it say that you must not do if you are not compliant and that would be work for the vendors whether it's a certification test or not, right? Do you see what I'm saying? The negative is going to have to still be there.

If somebody sends you an HL7 message and it's got a CDA document in there and it's a sequestered document and you automatically show it because it looks like an ordinary CDA document to you are you breaking the rules there? I'd have to double check on that.

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

Okay.

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

I can find out certainly for what we do, but I won't...I don't know off the top of my head.

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

Okay. Well, it would be great to get that clarification just so that we can provide a complete set of recommendations on this.

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

Yeah, so, Deven, this is Lucia, just as a follow-up, in between now and the next Workgroup meeting we would be happy to put together responsive materials from our technology people if you guys...if we can get a sharp couple of questions. So, Helen, let's figure out the best way to get the right questions so we can get the right answers.

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

Okay.

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

Helen's laughing at me.

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

I'll take care of it, thanks.

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

This is Gil and, you know, just...and I wasn't part of the Tiger Team deliberations...

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

That's okay.

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

But, you know, it seems to me rather than the software being voluntary or not it seems that it has to accommodate a couple of settings and one of the settings is I am comfortable receiving these documents and another is I'm not.

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

Right.

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

And what does that...what's the behavior of the software in response to that choice by the physician.

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

But, Gil, isn't that handled by the physician who is comfortable or has a practice where this is relevant buying this optional capability within their system? And a physician who does not buy it would be sort of definitionally disinterested in it whether it's because they're uncomfortable or because it's not relevant to their medical practice.

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

Yeah...

Donna R. Cryer, JD – Principal – CryerHealth, LLC

What...

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

But if I understood correctly what David was saying before that the software would...the EHR would still need to behave a certain way, you know, if the physician declares themselves to be disinterested that there is some behavior that needs to happen in the software and it differs from...so, you know, it's not, you know, something or nothing it's something or something else is the way I was hearing it.

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

So, on the trail of a sharp question would a fair question be, where a physician doesn't purchase this capability how can they be confident they're not going to receive data they're not authorized to receive?

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

Well, not that they're not authorized to receive it but they don't want to receive it in that way...

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

Right.

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

Because they don't want it interdigitated into their EHR.

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

Yeah.

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

And they don't want to inadvertently get documents that they don't want to receive in that way.

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

Or to put it in sort of really blunt respects, does a system that has not purchased this optionality basically not understand this data when it arrives to compute it.

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

Or what happens?

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

Pardon me, Deven?

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

What happens to it?

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

Right.

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

I mean, this is Gil, if I'm a sending physician, you know, how do I know whether that physician I'm sending it to can receive or can't receive because ostensibly if they can't receive it I'd have to fax it.

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

Or not send it at all, right, they have to be prepared for the transaction.

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

Right, but, you know, if I'm sending, you know, I want to know, you know, I want to have expectations of whether it's going to be received or not.

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

Right.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

This is Donna, I just really have a question as a practical matter thinking about...all of the policy processes and the deliberation takes with an eye towards building the tracks just a little ahead of where the train is going and so one, yes, so Part 2 has been explained, you know, and currently exists with SAMHSA is simply around substance abuse.

I'm sure we could all contemplate that there will be very soon other types of sensitive information that would...from or that people would at least argue would benefit from some type of data segmentation given the number of sort of conditions. That said, I really can't imagine a medical practice that can simply opt out to say I only...I don't want to know about...I don't want to have a full picture of my patient. I don't want to have information. I don't want to be fully informed if my patient has substance abuse issues or other things that impact my care.

I don't understand how you can be a physician and report to be appropriately treating a patient or to predict in the future that I am going to set up a practice that will never have anyone with substance abuse issues or moving forward to the future any other type of sensitive condition coming into my offices. I just find that very...there may be some rare case but I really don't see how that can be practical.

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

Yeah, well, so Donna, it's Deven, that is not at all what we were talking about in terms of physicians not wanting to receive the segmented data, it gets back to the issue that David raised earlier which is that if the physician where to get this information directly from the patient it would not be covered by Part 2.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Right.

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

And therefore, you know, the idea that what we're...what a physician is signing up for here is the ability to get a document that's been segmented that will have some sensitive data and non-sensitive data in it that will not interact with the clinical decision support within its EHR and whether through that pathway is the way they want to get the information not whether they would not want the information at all. I don't think the latter is at all what we're talking about.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

I think it's just a burden on the patient and I'll just stop my comments there.

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

Well, and Donna, this is Lucia, there is already a substantial burden on physicians and patients collectively on this issue where pieces of paper have to be transacted and the physicians have to figure out based on a piece of paper that a patient signed which data gets to go out the door and which doesn't. So, the burden is there.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

I just...

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

Yeah, I think that...this is David, I think the burden is there, these automated systems just increase the visibility of some of the inconsistencies in the way we do things today.

But I think the real problem, you know, in the long run, is not more technology but is...and I know this is impossible for us to do anything other than just wish about, is to redefine the notion of what an inappropriate re-disclosure is.

I mean, if you give the patient the choice, the vast majority of the patients the choice "would you want me to restrict re-disclosure of data about your sensitive condition that could save your life when you go see another physician" I'm pretty sure that most of them would say "of course not."

But if you say "would you like me to prevent that re-disclosure outside the boundary of the people who care for you" they would say "yes, please restrict it."

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

That's right.

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

So, we've just got the wrong circle of where we're measuring re-disclosure, it should be a different circle.

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

I think...this is Lucia, I think David's right and we have to...that's why I think there is a really long game of baseball ahead of us, and I can say that now that it's April, but the instruments we have that create the burden today are far blunter of instruments than we might develop if we were developing instruments for a computer-driven age and we have to do some reconciliation to enable that bluntness to be more refined.

My favorite example is many of these laws have to do with preventing adverse underwriting. There is certainly an argument to be made that the Affordable Care Act has ameliorated that but there are other things that these laws are all designed to prevent we should be thinking about what are we preventing and what is getting swept up in that prevention that we wish we weren't preventing.

I'm happy to go back and listen to the transcript of this, this is fascinating, thank you all for bringing your "A" games today.

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

So, having a little bit more detail in the technology I think will help, you know, we have a few minutes left, let's make sure we've covered some of the pharmacogenomics stuff which we have on one level. Next slide, please. Next slide. Here's a description of pharmacogenomics data. Next slide.

I want to give you all a sense of all of the...can I have the next slide, please? All of the...generally what ONC was asking for input on in the pharmacogenomics space was factors to consider for Health IT to allow the use disclosure for genetic information in ways that comply with federal and state privacy laws, whether it's possible to leverage this DS4P certification criteria for segmenting genetic information particularly in the pharmacogenomics circumstance, we did talk about that on this call, how do we best balance the benefit to patients while avoiding the potential for discrimination that can occur with the sharing of genetic data.

And then there were...next slide, five really specific questions that were in the NPRM that were related to privacy and security and another five questions related to pharmacogenomics data that are in the background slides that don't have a privacy and security bend to it, you know, should ONC offer certification for Health IT functionality that would facilitate HIPAA compliant, HIPAA is not even really the issue here, HIPAA compliant sharing of discrete elements of a patient's genomic data from their record to the family history section of a relative's record, does the proposed DS4P criteria provide that needed functionality. Next slide.

Just giving you all a sense of all that was asked here. Do the proposed DS4P criteria adequately balance complex genetic privacy issues. Should Health IT be required to apply different rules for the use and exchange of genetic genome and pharmacogenomics data based on different groupings of these diseases or conditions based on sensitivity of the information and what other factors should be considered for Health IT that allows the user to use or disclose genetic information in a manner compliant with federal and state privacy laws.

So, that's a lot of fairly detailed questions that, you know, I had said to ONC, I don't think we could get to the level of detail required to answer each and every one of these but to provide ONC with some feedback on the particular pharmacogenomics use case in the privacy and security implications and whether the technology is sort of ready to provide some protection of that data in accordance with what are largely state laws other than GINA which is a non-discrimination law that applies largely to health plans and employers. Next slide. Can I get the next slide, please? Thank you.

And again, we're in an environment where you've got state laws that could extend additional protections to genetic data but they may not be structured in the same way that the Part 2 laws are, they may not have a re-disclosure provision or they may, they may have a treatment exception which Part 2 does not but some state laws do have those.

And in terms of sort of utilizing data that may be collected about one patient using it to treat a family member when it's genetic or family history data, it is the case that under HIPAA treatment includes the data for treatment of "a patient" it doesn't necessarily have to be "the patient."

So, with all of that richness and not a whole lot of time I know we've sort of talked about DS4P criteria and its limitations as applied to this particular pharmacogenomics use case, but are there any other issues that you all want to pick up and talk about that are raised by some of the questions that ONC has asked given the...I think the very real possibility that more and more family history and genomic data is going to be collected in EMRs assuming a capability to do so. What are the privacy and security issues and what does ONC need to be focusing on in terms of the technical capabilities here?

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

This is David, I certainly think it's premature to settle on it since we don't even know if pharmacogenomics is useful clinically yet.

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

Okay.

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

This is Gil and, you know, I had to drop off of the last call early but I did actually, through the miracle of information technology, I actually listened to the replay, so it was...

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

Now that's dedication Gil.

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

Yeah.

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

I'm glad I did because it was a great discussion, you know, and, you know, David made a lot of good points the last time about, you know, a lot of genomic decision support being, you know, as a service, you know, that you wouldn't store the genomic data in a...you would maybe send it elsewhere to come back with a decision, but, you know, the way I thought about it is, you know, okay, you know, what happens if you've got a result of a genomic analysis that says, you know, patient at high risk for developing Alzheimer's, you know, before age 60, you know, does that require any special handling.

You know and today, you know, in the family history if it says, you know, first degree relative, you know, had a heart attack or, you know, first degree relative, you know, had breast cancer you kind of know there is a high risk and we don't segment that today.

And so, you know, and if we got the results of a genomic analysis that said, you know, you're at high risk for, you know, MI, well, you know, that's no different than your family history. But if you start getting these other diagnoses do we feel that those are, you know, sensitive enough or maybe sensitive enough that they would require special protection, I mean, that's the way I kind of think of this problem.

I mean, the relationship to other family members, I mean, it's a big deal but, you know, maybe even leave that aside for just a moment, you know, would we want to, you know, segment this, you know, high risk of Alzheimer's and, you know, I don't know.

I mean, to me it seems like a real slippery slope, you know, there are so many data elements in the record that could infer, you know, diseases, you know, maybe we should sequester the fact that they're a smoker, because, you know, that may imply, you know, they have, you know, a risk of lung cancer.

You know, so, you know, it's just...it's hard to, you know, it's hard for me to think that we should segment genetic results at this point but that's just kind of very early thinking.

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

Yeah, this is...

Donna R. Cryer, JD – Principal – CryerHealth, LLC

This is Donna in some cases I think...in some ways this is an easier question than the previous one because the case for licensure discrimination or other foreseeable harms is so clear but yet the potential for importance in treatment whether you have, you know, a BRCA gene or are a, you know, have sort of a warfarin receptor or a predisposition to metabolize drugs quickly or slowly needs to be part of the record in a timely fashion when drugs are being administered or decisions are being made. So I think it poses in some sense the easier case because we see the need for protections in a harder case because it needs to deal in many cases that are growing more numerous by the day the necessity for having this as an integral part of the record sort of front and center for the physician is of such great importance.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

This is Linda and I would agree, I think this is a case where we're so early but to set up a mindset of sequestration of data that will probably over time be absolutely integral seems like a poor way to start using it. And maybe the issue is it's premature to be addressing this in the NPRM at this point.

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

Right.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Yeah.

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

Yeah, this is David, I would certainly agree with that. I would like to clarify my comments on the last call that Gil reminded me of because I think I hadn't thought it through, well I know I hadn't thought it through as completely as I should have.

If you do have a black box service that can take genomic information that's perhaps quite detailed and come back with a recommendation of how to change treatment it is possible that the genomic information never gets disclosed to the requesting service, requesting physician but it's also probably very high that the remote service would offer some explanation for why the recommendation was coming in that the physician who requested this would want to put that in the record to justify the decision that he made.

So, it's going to be disclosing at some level, it might not be disclosing of the actual snip variant that triggered the alert, but, you know, so if the patient is a...should have their Coumadin dose adjusted downward or upward the physician is going to record that information in the local record even if he doesn't have access to the actual gene sequence that caused the recommendation to come about.

So, I probably over simplified with this notion of non-disclosing black boxes they are going to disclose a rational of some kind and as Gil pointed out that rational could be risk factors that are potentially harmful to the patient as well as identifying information.

So, there are kind of two axis that we're worried about here is, does this expose the patient identity in some unique way because it's genomic, does it give us a stronger prediction on risk factors because we have this belief that the gene is deterministic even though the best evidence is it's only about 30% of the predictive power.

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

So, I'm going to interrupt the discussion to get them to open the queue for comments and then we have a bit of time to continue to talk about it while people are allowed into the queue. Go ahead.

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

Thanks, Deven. 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. Thank you.

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

Okay, so while folks are cueing up and mindful of the time what I'm going to do is work with ONC and the folks who support us at MITRE to come up with some straw responses, straw recommendations that we would surface to the Health IT Policy Committee on these two topics DS4P and pharmacogenomics based on the conversations that we've had.

We will probably try to take up the NPRM issues as we planned, the Meaningful Use NPRM issues as we planned, on our call next Monday and then use the May 1st call as our wrap up but we'll also circulate the text of these recommendations in the interim to try to get some early feedback from all of you to make sure that we've captured the discussion accurately.

Do we have any...I didn't leave as much time as I should have on this one, my apologies, we were having such a great discussion I lost track of time.

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

That's fine we don't have any public comment.

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

I feel a little bit better.

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

You can keep going four more minutes.

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

Four more minutes, well I interrupted David, I plucked right in the middle of the conversation that you and Gil and others were having, so I want to see if I interrupted you prematurely and allow you to finish your thought.

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

No I was rambling but I didn't have any more ramble.

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

I don't think you were rambling at all, but really good dialogue and thanks to everyone who was able to join us Donna, Gil, Linda, David, Manuj, our federal partners this is really helpful. These are not easy issues and we're sort of...often sort of stuck with the policies as written in terms of thinking about how we're going to implement all of this and so it's just enormously helpful to get the diverse perspectives that we've been able to get on the phone call and we'll do our best to try to capture them in some recommendations.

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

You're doing a great job.

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

Well, thanks, with that I think we're done Michelle. Thanks everyone and we'll see you all, hear you all next Monday.

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

Okay, thank you.

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

Thank you, have a good day everyone.

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

Thanks.

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

Thanks.

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

Bye.

Public Comment Received During the Meeting

1. With security/privacy guidelines being developed for education settings, the issue of PII re-identification is addressed explicitly. Because ACOs need / should perform complex analytics on their populations, S&P issues from Big Data variety, including "genetic" sources, should receive some attention. Would be easier to ignore, but policy is driving more robust analytics with such re-identification capabilities.