HIT Policy Committee
Privacy & Security Workgroup
Final Transcript
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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. Stan Crosley?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Stan. 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. Deb…Donna Cryer? Gayle Harrell? Gil Kuperman?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Gil. Gwynne Jenkins? John Wilbanks? Kitt Winter?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Kitt. Kristen Anderson?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Kristen. Linda Kloss?

Linda 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?

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

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

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Micky Tripathi? Sephania Griffin? Taha Kass-Hout? And from ONC do we have Helen Canton-Peters?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Helen. Kathryn Marchesini?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Kathryn. Jeremy Maxwell?

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology
Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Jeremy. Is Lucia on?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I got an e-mail…

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Okay, with that I'll…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
From Nikki that she is going to try to join while she's in transit from a meeting at the White House, so I didn't hear her come in but I expect that she will when she can.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Yes and we're well supported by her team.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yes we are.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Yes, so with that I'll turn it back to you Deven.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
Michelle, hi, this is Dave Kotz, I'm here too.

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

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

Gwynne L. Jenkins, PhD, MPH – Senior Policy Advisor to the Director, OCRBP – National Institutes of Health
Hi and this is Gwynne Jenkins, I'm on the line as well.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
All right, thank you Gwynne, well we have a good compliment of folks on the call today that's great. So, what we're going to talk about today is to try to get some consensus on some comments that we want to file to the interoperability roadmap. Next slide, please.

Our discussion on this draft roadmap is really aimed at some questions that ONC has tee'd up for us on two specific sections of the draft roadmap that are related to privacy and security. We have not been tasked to look at other aspects of the roadmap that pertain to interoperability, you know, a number of you who had time to give us some comments on some of the straw recommendations had what looked to me like some very great ideas around issues of interoperability but that were not necessarily just about privacy and security and I would strongly urge you to weigh in with them during the public comment period since it won't really be within our purview to try to take them up generally as a Workgroup. But they were good suggestions that are worth surfacing and I would encourage you to do so during the public comment period.

For us, next slide, please, we've got a bit of limited time to try to make some progress at least on the questions that were specifically tee'd up for us. As you'll see we have our call today and then the expectation is for us to present some material to the Health IT Policy Committee at the April meeting, we don't have any other call scheduled between this call and that one so we're limited to trying to make progress on what we're able to do both on this call and maybe some wordsmithing clean up that we might be able to do by e-mail in the interim.

Now keep in mind that these are comments on a draft interoperability roadmap that's part of an open public comment period and that anything that we say as a Workgroup still requires endorsement from the Health IT Policy Committee.

So, you know, I think we use our best efforts to try to get some group consensus around some comments that we want to make and that we hope the Health IT Policy Committee will move on to ONC, but we should not…we probably should try to focus a little bit on some bigger picture issues as opposed to drilling down in the minutia that might help us get through the material. I tried to do that on some of the slides but there still is a lot of text, explanatory text, nevertheless we can…we'll do the best we can essentially on this call and get as far as we can.

We will turn back to the big data issue with our April meetings, which are already on the schedule because we…whatever we have to say at the Health IT Policy Committee level even on the interoperability roadmap that comment deadline is coming up and we will not be turning back to that again, at least not at this particular juncture. So, does anybody have any questions about what we're trying to…what we're hoping to do today?

Okay, great, next slide. So, these are the two sections that we were asked to provide some feedback on and we've reversed the order of them and I'll explain why in just a minute.

Section H involves consistent representation of authorization to access health information and when this is coupled with identity verification that you know who the entity is on the other side of the transaction or you're reasonably sure, it allows for consistent decisions to be made by systems about access to information.

So, here this section is about authorization as a legal construct, as a legal concept, when is someone legally authorized to access health information in a record and sometimes that legal authorization comes from the patient consent but sometimes it comes as a matter of law, for example under HIPAA, and that's the meaning of authorization in this particular…in Section H which is not authorization as a description of a type of patient consent but authorization broader which encompasses consent but also encompasses the legal authority to access a record even in circumstances where there has been no specific patient choice that's been articulated.

And then Section G really is more about consistently representing permission when you have it from the patient to collect, share and use identifiable health information and a recognition that this is often dictated both by law but in some cases by organizational policy and how do we prevent hiccups in interoperability that might take place because the consent is needed and we don't have clear or consistent ways to transmit it or we have uncertainties about when consent is or isn't required and what the elements of that are. So, next slide.

So, one of the things that we talked about on our last call was whether it was worth making some overarching comments about the roadmap because there were…you know, our very first discussion of the draft roadmap we had a lot of questions about what ONC intended to convey in the draft particularly given the conversation around the distinction of basic choice, which is at a much more sort of in or out basis versus granular choice, which is much more granular, and what is the sort of…where does the loss fit in circumstances where you have basic choice and what's the role of a law such as HIPAA that permits sharing for treatment, payment and operations for example without necessarily needing to get consent.

So, there are two sort of overarching comments that Stan and I, and the staff have crafted based on some of our earlier discussions and then some additional explanatory text that was added and the one is to specifically request that language be clarified in the final interoperability report regarding the relationship between basic choice and existing laws that permit the sharing of information for some purposes without the requirement to obtain consent.

And then on the next slide is another overarching recommendation and that is that with respect to certainly exchange among providers that the interoperability roadmap should really focus on clarifying existing law and policies to enable exchange and not necessarily to consider it as a vehicle for considering or reconsidering rather what should be the policy around consent and recognition that, you know, these are conversations that we have had for many decades and are likely to continue to have and that, you know, really in an interoperability roadmap that's designed to sort of facilitate exchange given the environment we have and one that may evolve in the future how do we take account of that and make sure that exchange happens.

So, you know, just some overarching comments on, you know, asking for clarity around what was intended in the roadmap and frankly urging ONC to not use the roadmap as a vehicle for articulating policy change but instead to, you know, sort of consider policy as a factor for exchange of information and figuring out how to enable exchange given that environment.

So, any thoughts about these sorts of overarching comments. Manuj I know you had passed onto me some comments on an earlier draft, I'm wondering if there are any sort of pieces of overarching comments that you or frankly anyone else would want to make before we dive into some of the more specific questions around authorization access records and then consents and how you capture those and persist them.

Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer – PatientPoint Enterprise
Yeah, thanks, Deven, I think the only one that I would kind of apply as overarching would be the one related to liability.

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

Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer – PatientPoint Enterprise
As it relates to kind of the onward transfer, the passage of information amongst the participants in the learning health system. I know just from my company and previous experience, you know, we get hung up on a lot of what I'll call negotiation points between providers, business associates and other kind of registries that they might be using as to the kind of passing of the buck of people or entities that have been either abusing or not appropriately following the authorization requirements.

So, I think it would be really beneficial for the roadmap to lay out similar to the way they did in HITECH some direct liability for those entities that are involved in the interoperability process regardless of whether they're the provider or not.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
So, as a matter of sort of governance having some clarity around where the buck of liability passes?

Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer – PatientPoint Enterprise
Yes something like that, yeah, exactly.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay. Any other thoughts?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Deven, it's David, I have not a thought about the liability but about your earlier question.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
On the…and I'll respond to both of them, on the first point about clarifying the relationship between basic choice and existing law I think that's a great point. The very specific question that I have that maybe we can enumerate or maybe it's too detailed, but if someone is given the option for basic choice and they opt out of sharing does that somehow trump the HIPAA allocation that allows the sharing to occur in the, you know, scope of direct treatment?

So, in other words it's one thing to not need it but if you have it does it trump or should it trump, is that an organizational choice, that's the first thing that jumped out at me when I read it is so what happens if you give someone basic choice and they choose to turn off the provider's HIPAA rights, if you would. So, clarity on that in terms of their intent would be useful.

The second point is I'm not sure I understand why you're advocating that the roadmap not explore new policy options given that the roadmap is exploring newness everywhere else in the scope of…in the space of interoperability. So, we are asked to weigh in on new standards that are needed, new governance models that are needed, new APIs that are needed, why not new policies?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
You that's a really good question, David, and I'll tell you that the reason why we surfaced this up, and this is for your consideration as a Workgroup, I'm perfectly fine with peeling it back, but that these debates about when do you need consent to share information and when do you not are ones that come up persistently and are very, very difficult to resolve and in fact even if you sort of think about where HIPAA landed in terms of allowing the sharing of information among covered entities for treatment purposes, payment and operations, in some circumstances without the need to get consent of the patient that even that was a highly controversial decision when it was made and is one that people continue to question years later.

Similarly, with respect to state laws and efforts to sort of say, you know, we should have one national law and maybe it should be HIPAA I know that conversation has come up repeatedly that it is again a very controversial topic.

So, I'm not suggesting that any of the other issues that are taken on more substantially in the roadmap are uncontroversial, but this one in particular seems like if we're going to have interoperability in the next three, you know…if we're going to make progress on it in two years and continue to sort of escalate up there in the future.

It doesn't mean that we certainly can and should continue to have these discussions but starting with the draft roadmap that makes it unclear about all of the issues in fact that you just raised about when should basic choice apply and should we default to law only in circumstances when we don't have basic choice and does basic choice override HIPAA. But if we wait to resolve all of that in order to have interoperability then I think we wouldn't move forward at all, at least in the short-term.

So, I think to give you a briefer answer, it was an attempt to say, we need to move on this now with what we have and maybe this needs to be articulated not as…that we should never have conversations about where consent fits as a policy matter but we certainly shouldn't be trying to re-debate those questions in order to facilitate interoperability in the next two to four years. Does that make sense?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yes, it does that helps a lot. I think maybe then rewording it to say something like what you just said…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay, maybe a little more succinctly.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, but there are many important and useful ways that interoperability can proceed within the constructs of current law and those should be pursued before addressing needs for changes in the law maybe something like that.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
I mean, the way I also would…this is me shifting perspectives slightly, but when you talk about these rights and laws, and high-level abstractions it's very difficult to translate that into specific use cases in the real world.

So, maybe the approach is to think of it from what is it that we would like to be able to do to facilitate interoperability and then identify policy roadblocks or confusion and either address them by clarifying current policy and regulations or by proposing the need to change it, but do it more from a bottom up use case driven where we can get agreement on the value of the use case and then say, okay, here's a barrier.

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

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
Hi, this is Linda Kloss and I would agree with that. I think there are two issues that we'd probably want to weave in here, one is that sometimes we need to reframe the current policy so that users can see that they apply outside the walls or as we're enabling interoperability. So, that's an educational challenge.

But there is one other point that might be an overarching recommendation and that is kind of redoubling the push to see more uniform adherence to these current existing laws and practices. Because one of the issues is the uneven compliance conformity, adoption.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay, yeah, no these are all really good points that we can weave in. And so that's essentially, as I'm listening to the conversation, what we will try to do is weave in all of these points into what we're presenting to the Policy Committee and that will include sort of clarifying language so that it more closely articulates where we seem to be headed here.

So, that means it's incumbent upon you as Workgroup members if you hear anything that you think is just a really bad idea please raise it on this call because we'll just assume that as the conversation proceeds forward if there seems to be agreement among the group to pursuing a particular point in these comments then we'll pursue it.

Okay, let's go to some of the specific questions in Section H. So, next slide. So, again, this is the section that's on the broader topic of legal authority to access health information, having said that, next slide, there are some questions in here that do sort of get to the issue of consent or maybe one question that borders on the consent issue as well as legal authority to address it, but these were the questions that we were specifically asked in this section.

Who should ONC convene to develop policy recommendations and frameworks to enable consistent decisions about authorized access to health information, Linda this goes back to the point you just articulated so well, is there agreement that the issue of rules, confusion should be addressed from a policy perspective at the state level to advance the goals of a learning health system, if "no" why not, and if "yes" what are three priority areas for additional clarification.

Question number three deals with role-based access, how should role categorization proceed across the health system and question four, is there a basic set of defined roles that can be agreed on and built on.

And then the last two questions are about standards, are existing standards to support authorization and healthcare sufficient, and what are the reasons for the relatively low uptake of existing standards?

So, on the next several slides we tried to build some straw responses to these based on previous discussions but also potentially some areas that we weren't really able to hit as a group previously. Stan and I came up with some draft responses for you all to consider. So, next slide, please.

So, here who should ONC convene aside from saying everyone relevant ONC should gather information from a broad array of stakeholders who are trying to exchange or facilitate the exchange of health information both from the private sector as well as governmental partners to determine what the common obstacles are to demonstrating legal authority to access a record, particularly for treatment and care coordination, and even in circumstances where consent is not required.

So, next…I'm just going to keep moving on given time, we can always go back if people think of something. So, then the question about rules confusion, is there agreement that the issue of rules confusion really should be addressed and if so what would be the three priority areas, and here we had some…have a straw response of that clarification from regulators ideally with specific examples about what's acceptable for demonstrating legal authority to access information would be enormously helpful.

And just by way of example we had some previous recommendations that the Health IT Policy Committee endorsed regarding best practices for demonstrating legal authority to access a record in an environment governed by HIPAA.
Also noting confusion with respect to other federal laws as well as state laws where there is a lot of confusion about how to comply and we did suggest some areas for clarification but would love to have more in addition to any general responses you might have here, how do you demonstrate the existence of a direct or indirect treatment relationship, how do you demonstrate that you've got the consent or authorization of the patient to share information in circumstances where it is required are sort of two areas where some clarification might help but certainly hearing of others on the phone or other points you might want to make on either of these two questions would be most welcome.

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?

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

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

Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital
Hi, just, you know, just looking at the question, you know, I guess I'm not sure exactly how to read it, you know, is there agreement that the issue of rules confusion should be addressed from a policy perspective at the state level?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
You're right we went beyond the question, that's a very good point. Maybe we need to say it's more than just at the state level.

Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital
So, I guess the first thing would be, you know, if I understand you correctly you're saying kind of no dealing with things at the state level is insufficient or inadequate and there are things that need to happen at the federal level?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, I guess that would be a more precise way to answer the question, because ultimately I think that we would advocate, we certainly have in the past, that clarification around rules is needed at all sorts of levels in this space.

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
Yeah?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
I've been listening really intently, thank you, Gil. I think, you know, if I sort of channel my international coordinator hat the thing that really helps us drive that issue forward is if we have really clear examples of things that people don't understand.

For example, back on the liability discussion there was some great evidence given to the Standards Committee a year ago about the quantity of physicians who think they…what they think their liability is for actions done by somebody they disclose to.

So, we really need some concrete things potentially in a priority area, because you know we have a magic wand and we can do everything at once, in terms of what are the things that need the most, is it liability is that really the number one policy issue on which clarification could occur, is it, you know, whatever it is.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
This is Linda Kloss and I'm wondering if we shouldn't lead off this response by answering that state level question with a firm yes there are areas and really it goes beyond rules confusion. There are conflicting rules.

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

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
And I think perhaps we should be forthright on that and then go onto say that there are other areas as well where greater attention to rules confusion could be helpful.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And this is David, I will come back to the rubric that I'll use over and over again which is if the goal here is to further interoperability then we should enumerate specific kinds of interoperability, specific use cases or specific problems being solved or addressed by improving interoperability and then in the context of those very specific use cases enumerate the questions or the rule confusion or the rule conflicts that need clarification to convene yet another august body of relevant stakeholders to debate topics of opt in/opt out, basic consent, granular consent, SAMHSA mediated consent is just a waste a lot of our time again.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
This has to be very focused at this point.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I'm taking very copious notes.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
And this is Lucia, one thing I would add to that is as we go through the refinement process for all the Workgroup members on the phone certainly we will work with you guys to make sure that the things you're prioritizing are actually things that can be impacted, for example, statutory change, pretty big lift over…down the street a little bit, northwest of me, so some parts of SAMHSA are embedded in federal statute not regulation and we have to just be cognizant of the environment we live in and our own limitations.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Right and it's probably not very useful to debate whether those laws should or shouldn't exit what's more useful is to say, okay given those laws if you're running some kind of an interoperability capability or service what are you allowed to do under the scope of a reasonable interpretation of those laws and then, you know, if that leads to the logical consequence of there are things we ought to be allowed to do that we can't do and it's bad for the patient then at least you've got an explicit example of why the law should change as opposed to these abstract debates that we have that just go in circles even, you know, they're very interesting, but we've had them all already.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Right, right. Well and we've had a number, you know, of specific sort of bumps in the road that we've either dealt with previously on the committee or that have been articulated on this and prior calls, the issue of liability that Manuj stated earlier, the one that Lucia pointed to in terms of sort of how responsible are people for the behaviors of the on stream entity with whom they've shared data and determining when a treatment direct or indirect treatment relationship exists, you know, are all issues that we've surfaced in the past which get, you know, sort of right to the issue of, you know, sharing data even just for treatment purposes.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah and I think those have been helpful. I think the SAMHSA discussions that we had on the Tiger Team, what a year ago…

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Where we carved out some compromised positions, you know, it's not perfect but at least it's something you can go act on.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Right, right, okay, very helpful, great discussion. We will be reorganizing this from a wordsmithing issue and getting it out to you by e-mail in the interim to make sure we're capturing this right. Okay, let's move onto the role-based access questions. So, there are two, for role-based access how should role categorization proceed across the healthcare system and is there a basic set of defined rules that can be agreed upon and built on. Next slide.

So, with this answer…with this straw answer for your consideration, Stan and I, and the staff presumed that when we…what was meant by role-based access is the way that term is used in, you know, frequently in internal privacy and security policies, I mean, the HIPAA Security Rule frankly deals with the issue of role-based access but it's…does a particular individual…are they in a role that would allow them to be able to access data.

And so what we had circulated for your consideration is the question of whether in fact focusing on role-based access at all should be the goal of the roadmap because presumably if what you're focusing on is making sure that at least at an entity-to-entity level there is exchange of information then how that information then gets triaged so that it gets to the right person in the right role and isn't seen inadvertently by people who don't have the role to see it felt to us like more of an internal decision and that's a decision that people make differently within organizations and not one that we should try to standardize across organizations in order to facilitate interoperability.

And so we, you know, have noted that focusing on entity to entity exchange is really, you know, what should be the goal here and that role-based access and categorization of different roles is an internal matter and isn't one that necessarily needs to be fixed. There are purposes of facilitating interoperability, but we didn't really have…we talked about this only tangentially.

The other straw response here is around issue of, you know, how inappropriate access could be determined and the patient's right to understand who has accessed the record and my recollection was we had a question on that, but it certainly seems to have disappeared from the list and hence why we have a straw response on it because it is something that we've dealt with previously.

So, we can either take that answer out if in fact we were wrong that there was a question tee'd up on it or leave it in.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Deven, this is Lucia, let me ask the question a little bit differently than maybe it's tee'd up there so…and you guys can figure out if this is something or not but something that we want to make sure is not a problem is that one organization's determination of its role-based access doesn't result in another organization failing to exchange because of the lack of confidence of some type. We've seen that with regards to security standards and this is a kind of a security standard and so that's how that ended up in the roadmap just in my brain, the way I was thinking about it. If it's not a problem happy to hear that.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Oh, okay, but wait, let me understand, so it's…the one entity doesn't trust the role-based access decisions that are being made by the receiving entity so it's refusing to share?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
The question is, does that happen, is it a problem really.

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
I can see that, you know, if that were happening then maybe it's really a standards situation, you know, as we toggle back and forth in our domains, but, you know, from…and if it's not happening halleluiah.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Well it may be.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Workgroup what say you on that question?

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
I would say it's not happening because I just don't think one organization digs in enough to know what the role-based authorization of another is or they are, you know, handling it through some kind of agreement.

I think the opportunity here, and I do agree with the way you're framing this that it should be left to internal policy, but I think it tee's up an opportunity for us once again to find a way to reinforce the importance of those internal policies being in place.

And, you know, best practices, you know, through education, through some kind of leverage that every healthcare organization should have a sound process for role-based access and that should just kind of be part of the internal governance and so we need some mechanism to determine or to…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well, it's HIPAA.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
Step up the game.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
So, this is David Kotz, I strongly agree with this characterization, this straw response because it's been my impression from numerous studies of role-based access control in real organizations that the so called role engineering problem of determining what roles you have and what roles you need, and what roles individuals should have, and what roles should be allowed access to what data is an extremely complicated problem, one that's an ongoing problem that an organization constantly has to be re-evaluating and fine tuning it's roles and that would be very difficult to do across organizations or to standardize given the variety of organizations.

And so I really think this has to be left as an internal matter and for that…in that regard I think that we shouldn't necessarily be mandating role-based access control what we should be mandating is appropriate access control so that records or information are viewed only by those who should be reviewing them or modifying them.

And in the case of interchange between organizations then really shouldn't be left to the judgement of the sending organization to determine whether the receiver is capable of managing the information correctly, they should be able to simply trust the other organization, at least from a legal point-of-view, that the other organization is suitably certified and so forth is capable of doing that, otherwise it's a burden that they cannot bear to be able to make that judgement meaningfully.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So, this is David, so I've got either a very strong objection or I will agree with you all and declare that granular consent is an impossibility because the point of this question, as I read it, was if we want to give the patient the right to or the ability to declare access patterns for their data in the future they have to be able to declare that in some way in terms of who can access the data and the proxy for that is what roles can access the data since they don't know all the people in advance.

And so if you don't have some kind of a broad agreement on what those roles are you essentially make it impossible for a consumer to ever specify granular access control and I'm happy to take that as reductio ad absurdum and drop the notion of granular access control but that's what's at stake here.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Well, so David, I think that raises a…this is Lucia, I think that raises a really interesting point which maybe that we'll get to in your later deliberations which is, you know, granular consent itself has several meanings one is the clinical areas or the sort of factual areas which by law are required to have special protections and the other is, you know, I'm going to say subjective I know that's not the right word, but choices a person might make that are not required by law for compliance about whether they want to disclose one thing to one person and not to another that's just a personal choice that's not required for legal compliance.

And you're right, I think in all those circumstances you have to be able to have some parameter to recognize the data whether it's the role of the discloser or the role of the recipient, or the kind of data it is at a factual level, etcetera.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
This is Stan and I still don't think that this response is inconsistent with what you just said David the issue is I think…I mean I have not come across a granular consent concept that would reach inside an entity and say which individuals within an entity have the right that would be dictated by the use and it's still up to the entity to show compliance with those provisions.

So, I mean, I don't think it's…maybe this is your…I don't think it's conceivable that an individual can reach into an organization and dictate access control within that organization with any great type of granularity because I think you would end up with all kinds of problems.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well, this is David, I certainly agree you will end up with all kinds of problems which is why, you know, all attempts in the past to create computer mediated consent or computer mediated privacy have never scaled outside of a pilot project because getting this kind of agreement across that many institutions is so incredibly difficult, now I well suspect impossible, but having said that if I was told to architect such a system what I would say is that if there are high-level overarching role categories or role classes that were enforceable, let's just say hypothetically they did emerge in the future, then each institution would have to map their internal role policies to those broader categories.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So you wouldn't be reaching into the institution but you would require…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
But, you know what I think there is a way to have the answer that we've got here but also to acknowledge that, you know, depending on what is meant by granular choice and what's required at that level that, you know, some…

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Discussion around role standardization may be inevitable if policy goes in that direction.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah and that's my point is…I would certainly not disagree with what's on the slide now it is an internal policy issue, we have well-developed or reasonably well-developed ways of addressing it notwithstanding that it's very difficult all that's good and wouldn't change.

But if the goal is for, in a granular consent future, computable privacy I believe Lucia was your phrase, you know, then you're going to need to be able to specify some category to make it interesting otherwise it's sort of pointless.

So, you might have a category that says only physicians who are involved in my care can access my data but not marketers and not researchers. I mean, that's role-based, right? That's category-based but it devolves down to the role of the individual.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Or someone else may say researchers and my providers can access my data but not marketing, and somebody else may say I don't really care if I get a benefit from it let anybody have access to it. Those are all role declarations that would cross above in individual institutions definitions of whether the respiratory therapist level 2 is considered a direct care provider or not.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yes, okay, I think we can add something to this to acknowledge that. In the interest of time I'm going to move us onto the next slide which we may be able to dispense with quickly, are existing standards to support authorization in healthcare sufficient and what are the reasons for the relatively low uptake of existing standards and here, next slide, the straw response is, these questions are more appropriate for the Standards Committee to resolve.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
We have enough gnarly questions to…there's my word again, to have to answer at the policy level we don't have to take their questions on too.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, I agree, the answer is no and because they're bad.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay, so the next set of questions deals with the issue of, next slide please, consistent, next slide, okay, consistent representation of permission to collect, share and use identifiable health information. And here there were eight questions tee'd up. Next slide.

Are states ready to collaborate on the issue of permission and why or why not? What other methodologies including technical solutions should also be considered to address this concern? Three, the draft interoperability roadmap assumes that consent should persist with patient information, is this a valid assumption and what's the impact of non-persistence on the interoperable movement of data? Next slide.

Is there agreement on approaching consent through basis choice as it relates to TPO, which stands for treatment, payment and operations, followed by granular choice supported by a set of nationwide harmonized rules, what are the alternatives that ONC should be considering? What areas of health information should be addressed first for granular choice? What are realistic timeframes and how should success be measured when addressing complexities of the rules environment?

So, there are a lot of questions here and we came up with some straw responses to try to address some of them, I'm not sure we quite hit the mark on all of them and we'll just see what we are able to find time to discuss on this call and what we could move forward. So, next slide, please.

On the question of whether states are ready to collaborate on the issue of permission, I mean, we really don't know, but I think we could talk about how, you know, collaboration would certainly be helpful and, you know, hoping that there is a willingness on the part of states to come to the table and so harmonization of state law and consent, which doesn't mean everybody has the exact same language necessarily but does say, you know, are we asking for consistent things in a consent requirement so that there can be some degree of standardization across the states.

Certainly, if that were to happen it seems to me that it would be or it seems to us that it would be much more helpful toward assuring compliance and reducing the friction from an interoperability stand-point out there and, you know, as the imperative to exchange grows stronger, you know, you might get more and more pressure for people to want to participate and certainly there has been some work done on this. The National Committee on Vital and Health Statistics helped move forward some sort of standard categories for sensitive data which is one way to start.

There is also this entity called Uniform Law Commission which has on occasion enacted, you know, a set of uniform standards that when states adopt them creates consistency nationwide, the eCommerce, the uniform law around electronic signatures is one example of where that's worked fairly well. I didn't know what else to say here frankly.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Do you interpret, Deven, the word representation to be an encoding of the policies as in, you know, a way to capture the rules or is this representation the actual rule itself?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Oh, I don't know does that make a difference for you?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well, I mean, you know I think it does in a sense that you could say like you point out the NCVHS categories, you know, if that's consistently used by every state and each states picks which categories they want to enforce then you've achieve consistent representation of their policies even though the policies are wildly inconsistent.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So that would be a step forward because at least you'd have, you know, agreement on what the darn policy was in standard terms but I'm not sure that's what they're asking. Are they asking that the states actually agree on the permission, on the rules?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I actually thought it was the latter but I think we could raise that.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, I wasn't clear. I think it's vague, I mean, it's not well worded.

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

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?

Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital
Gil Kuperman here, you know, just thinking about it from my local perspective here in New York State, you know, are we ready to collaborate on the issue of permission, you know, part of the challenge is just bandwidth, you know, as a state, you know, we just kind of have our hands full trying to make things work here and, you know, dealing with our internal issues around the policies that we've tried to create, I'm not sure we really have the bandwidth to talk to Connecticut, you know, New Jersey, Massachusetts, Vermont.

So, you know, I think, I mean, you know, the complexity here and the idiosyncrasies across the states just make it very hard, you know, whether we're ready or not, you know, I don't know but I'm not sure there is enough hours in the day to really make good progress on that. I'm not sure if that's what this might be getting at.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
Deven, this is Linda Kloss and I think Gil really makes a great point.

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

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
Just getting the collaboration within the state is fulltime and continuing with funding and all of the other issues. You know perhaps this is an area that it would…there would be some benefit from a thoughtful federal panel to consider this, you know, whatever the mechanism is even through the Institute of Medicine, but, you know, I think back to the AHIC days and some of these issues were being discussed at that time by the working groups and, you know, I think cross state consistency and collaboration does need some kind of mechanism…

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

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
That could be convened federally.

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
So, this is Lucia, can I just ask Gil a follow-up question?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Of course, go ahead.

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

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

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

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

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
I work a lot with the states but the roadmap is a 10 year roadmap and so one of the things we've been charged with doing is thinking around the corner as best we can and one of the things we see coming around the corner is telemedicine which is by design across states lines.

Does the advent of telemedicine and it's potential for growth and more widespread use, does that impact what you think the appetite of people is over the long-term to grapple with this versus in 2015 or 2016 and the roadmap sort of lays this out as a long-term problem.

Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital
Yeah, I mean, it's hard, you know, so for example, here in New York we've got a 5 year Medicaid waiver to improve the coordination of care and, you know, we've got state policies here around health information exchange that make it very difficult to exchange data, you know, effectively and efficiently. So, you know, it just seems like, you know, we're going to be grappling with that particular item for, you know, 2-3 years.

I mean, telemedicine, you know, I guess is going to be part of our environment, you know, it just seems like there are big mountains to cross before we get there in a substantive way. I don't mean to kick the ball down the road but it's like I was saying before, you know, there just…there are so many other near-term pressing issues that just are kind of taking up the mental bandwidth that it's hard to think about how we give a lot of time to some of these other things.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Thank you that's helpful.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yes, all right, we will rework this answer so that it more appropriately reflects the reality.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
But, 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
I do think, I mean, I will, despite the fact that I'm not quite sure what the question is, if I assume that one aspect of consistent representation is, you know, some kind of a categorization scheme that would allow someone to understand a state's policies in such a fashion that it would permit decisions to be make about whether a particular interoperability use case can or can't occur like say telemedicine there would be value in that.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
I mean, it's like the uniform code for, you know, buildings, you know, the degree to which you express your codes in similar terms you can understand that one state may require different strength of rebar than another but at least you express them in millimeters or in inches, or in tensile pounds per square foot or whatever the measure is so that you can at least make a decision.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
I think that's really valuable to shoot for that over the course of 10 years, we may never get the states to agree but at least we should know what they say without requiring hiring a consultant one per state to interpret what they think the state's policy is.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Right, okay, all very helpful. All right, so let's next question, please. This one is, what other methodologies including technical solutions should also be considered to address this concern and here there was a suggestion raised by one of the federal partners, Kitt Winter from the Social Security Administration, you know, it's worth…it may be worth looking at the work that the Social Security Administration did to come up with what was a universal authorization form to enable them to receive data for social security disability determinations that would work in every state.

And while that was for a specific use case still they had to make sure that it was compliant with every state's law in order for that to happen so that they wouldn't have to have these one off conversations. So, it's really a suggestion that comes from Kitt. Beyond that, neither Stan nor I had any bright ideas for this.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well, this is David, I like that idea a lot and I think that you could, you know, create a parallel of hypothetical for example if a patient has expressed that they wish a state's physician to release their personal information to another location where it is needed for care would you allow that and what proof would you need that the patient has authorized that release, you know, come up with something very concrete like that and find out who would refuse it, I mean, if anybody would so dare. I mean, the social security release form benefits the patient unequivocally they're seeking disability.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So, it makes totally clear sense why the patient is giving that release waiver, they hope it will lead to a disability judgement in their favor, but we could have an equally compelling, my doctor needs this data for my care why aren't you releasing it, use case that, you know, could be sort of a floor, you know, at a minimum you should be able to get your data out of state regardless of what that states crazy policies are.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Well, and David, this is Lucia, to that point, maybe that's a point of guidance/clarification what is the patient's right to require that data be released.

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

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
I couldn't agree more. I mean, that just seems like the most fundamental use case, right? I mean, it doesn't get any more clear cut than that, it's not for marketing, it's not for research it's for care.

Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer – PatientPoint Enterprise
This is Manuj, one suggestion I was thinking about, this might be somewhat inappropriate, but there is universal kind of, at least to me, adoption of the do not call type of mechanisms used for, you know, restricting telemarketing and things like that. I think those programs have been quite successful in their simplicity and they're kind of central management.

I was wondering if a concept like that might be helpful here to establish the floor that David was just speaking to and allow people that kind of understanding of basic choice and then, if there is the idea of going into more granular choice allowing them to make those types of selections and making that information available by an API or some other mechanism to the individual providers.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I like raising that as a possibility for exploration.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay, great work guys. Next slide, please. So, this is the issue of…this question is about persisting consents and the straw response that we've tee'd up with some explanatory text as well is that achieving the technical ability to persist, consent or authorization is desirable but only in the circumstances where there is either a legal obligation for the consent to be persistent and honored across settings or in the circumstance of data shared directly by the patient, although given the conversation that we just had wanting patients to be able to articulate across a range of settings that they want their information shared sounds like you would need for that to be persistent across settings. You know what I was mostly worried about when formulating a response to this was this notion that, you know, in circumstances where the law may require consent for some things but doesn't require it for all the idea that, you know, you have a sort of consent that persists with data and the data flows into an organization where the provider doesn't even think to look for it before utilizing it for treatment purposes or doesn't have a sort of technical mechanism to know to honor it what's the point of that persistence in regimes where the consent rules are not ubiquitous or the same.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
Right and I mean, I think it also would require a statutory change because of the scope of the permission or the persistence though too, right?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
What statute are you talking about Stan?

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
I mean, it would have to be the original HIPAA statute to give authorization to persist it across an environment where it's not already specified, right? So, do they have the jurisdiction to dictate that authority that's what I thought you were getting at too.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Oh, okay, I wasn't exactly but that's an interesting point.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
How does it get enforced, yeah.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So, this is David, I'm confused again by the scope of the question, when computer people talk about persistence they're talking about, you know, permanent storage and memorization of…memoization I think is the technical term of the data, so I'm interpreting this to be analogous to the question for example of provenance of data so that as data moves around it carries provenance tags with it that allow one to assert that it has been, you know, free from tampering and you understand the originating source and so forth, that's what I interpreted this to mean, is should a patient…for example re-disclosure authorization be tagged to the data so that it follows the data around so that somebody downstream who says "oh, this is a sensitive, drug, oh, good, I see it's been authorized for re-disclosure" is that what's at question here or something else? What does persistence mean here?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
David, yeah, this is Lucia, that's kind of exactly what we were getting at is we were hearing a lot of noise, again we hear noise and we have a hard time and look to you guys to help us sort what's real sound, that people were not confident of their ability to use data received from someone else because they couldn't determine…I mean you called it provenance but it wasn't a fact that it was authorized to be released wasn't reflected and they didn't know whether they could re-release it, so back to, I think what Stan was saying, you know, if you think about permitted uses no authorization is required so you can have a whole chain of permitted uses in fact logically, right, but you have to know that it's within the realm of permitted uses not in the realm of something for which a patient had to provide a writing or some kind of documentation electronic or otherwise.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So, this is a digital rights management question if you want to translate it to non-healthcare settings, so do I have a right to play this song on this player, is the license that I structured when I purchased or licensed a song pertain to this downstream copy of a copy, of a copy on this particular player and, you know, while DRM kind of died a painful death in the music industry because it was unenforceable even though were billions of dollars at stake, I suspect the answer here is it sure would be nice but it's impossible.

I mean, it's just really, really hard. To persist the disclosure status you'd have to both track it with the data and then prove that it hasn't been tampered with, and prove that it was from an authorized source which is the most difficult and challenging digital signature capabilities and it's just really hard to do at this scale…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Well, but, David, so this is Deven, we just earlier articulated this sort of kind of do not call type of regime or a please do call type of regime where patients do have the ability to sort of articulate that they want their data shared…

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
And to ideally have that consistently honored across settings…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
No, I'm…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
So, whether that's done through, you know, some sort of tool where that permission sticks to the data or whether that's done through a registry, a consent registry…

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Or some other mechanism I think if we wanted to have something like that and have it apply across settings, you know, we'd have to investigate how we could…how such a sort of consent across multiple settings would get honored.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I think the point that we were trying to answer in this articulated response, the straw response, was to say, in the absence of a regime where a more universal consent is either needed or expected to be honored just having a technical ability to stick it to the data doesn't necessarily…may in fact in some cases be problematic because you might have conflicting sort of permissions to use data versus, you know, do you have the consent, do you not have the consent, did you actually need it, you know, in other words the policies dictate when persistence or some way of honoring the consent across settings is going to be needed.

It's not the technical capability to allow a consent to be honored itself should not drive the policy. The policy should in tandem with what we can technically honor is how we should be considering this issue. I don't know if that makes any sense.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
But it's sort of…what I was bothered by most about this was this assumption that we needed persistence…

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Without necessarily having a clear policy environment that would always call for it.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, so you're worrying about it…this is David again, you're worrying about it at a different level than I was thinking about it. I took the preposition "with" should consent persist with patient information, you know, literally and meaning…so I'm answering the question that says, whereas even though it's technically possible to tag actual data instances with re-disclosure status as well as provenance it would be extremely challenging to do so.

If you give up on that you could broaden out one layer and say, well could a patient persist policies or statements of their sharing preferences without tagging it to individual data elements but with broader statements of categories like "I'm comfortable with all of my data being shared with my providers but not with researchers or marketers" and it's not now declared at the data element level but at a broad statement then I think that would be a compromise that does make sense and we've talked about those for years as consent repositories or consent registries and the like where a patient could indicate, you know, my current data sharing preferences are in this registry and I could reserve the right to change them.

So, that's, you know, zoomed out but that's not persisting with the data so that's why I answered the question so picky…

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
In such a persistent way, because, I mean, I think that's the way it was written. But again, I think this where I think compromise is called for that, you know, it would be nice to be able to declare that my preferences that any provider that has my, you know, health data release it to any of my other providers when I authorize that provider to request it, if I could store that information somewhere and all of the remote systems would note that it could be trusted, that it was from me, and that it should be honored because it was up-to-date then that to me seems like a very positive compromise.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
It doesn't require tagging at the discrete level.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
So, David, this is Lucia, just following up on that with a question, so take the, you know, Part 2 situation and we've done our little test on data segmentation for privacy, right, and the Part 2 rules are very clear that each essentially patient action to choose a disclosure to a downstream provider is only…it doesn't repeat itself it's to that person and then you have to, you know, permit…you have to get permission to re-disclose after that, but that's not true in every environment.

And so we have to figure out…you know at the end of the day and I know this is the Policy Committee but this is what we grapple with is what's the policy that drives the standard that makes this something that isn't too complicated for the system to manage.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well, I think it's complicated, you know, as always on these difficult things the technology and policy issues are intertwined and it's difficult to talk about one without bringing in the other because, you know, if the technology can't support the policy then it's not good policy, if the policy is unimplementable, you know, it's a bad policy, even if it sounds good, you know, I'd like free ice cream every day but it's bad policy because I wouldn't sustain it.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
I think they'd sell that in college…they have that in college dorms ice cream every day.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, I missed that I must have gone to the wrong school. So, I don't know, I mean, again, I think this is where we get into, you know, actually designing systems around specific use cases, specific, you know, environments so, you know, in the CommonWell world that I work in a lot with the group of vendors trying to figure out how to facilitate data sharing across our products I would love to see…worked out a model whereby the patient could declare to the requesting physician "I give you permission to go get my data including my SAMHSA protected data because I want you to take good care of me and I know you need to know that I'm on a serotonin uptake inhibitor because if you don't you might kill me." So, how could I declare that in a way that those downstream systems would honor that, what's the policy statement that says, if there's a technical means to capture this in a provably correct fashion let's honor it. So, I think you could work it out in a use case like that. I don't know that you can work it out as a general purpose statement that always says we can figure out what to do. You have to make it very concrete.

And again, I keep coming back to this notion of if it's in the patient's best interest then shouldn't that trump these…and it's for their care, and it's their willful statement of what they want to happen, shouldn't that trump these other constraints?

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And if we can get that one solved at an operational level we've moved the ball forward a long way I think.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
This is Linda Kloss and I'm wondering if this response to Section G maybe needs an overarching response because the questions drill down to such a detail level and yet we're kind of looking a little more broadly and, you know, when I look back at the draft roadmap time table given where we are today it seems like critical actions for 2015 to 2017 technology developers begin implementing harmonized standards that document and communicate an individual's basic choice, you know, some of these seem…the timing of these seem not very realistic.

And I just wonder if we should just step back and take this G as a strawman and then reinforce kind of some of the framing ideas in answers to specific questions.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
So, that we have some…in the same way that we had some overarching recommendations…

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
They're combined.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Above that we would have overarching recommendations to Section G?

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
That was my thought.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay, we can certainly try to do that.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
There are just so many assumptions underlying…

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

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
These specific questions which are complex.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Right. Well, given, you know, the threads of conversation that have been occurring that we could do that and then to the extent that we have a specific response on some of the more detailed questions we'll offer it and otherwise we won't.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
And we might want to also comment on the roadmap timeline.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yes, so there actually is a timeline question and I'm just going to go ahead and go to that because we're, you know, sort of reaching the end of our call, so next slide.

You see that the next set of questions is all sort of about, you know, what should the priorities be, you know, between basic choice and granular choice and if there are other options and what are realistic timeframes, and while, next slide, we did have some straw recommendations it's certainly basic choice that makes sense to sort of start with that because it seems like it ought to be more…a bit easier given the significant policy morass that exists with respect to granular choice, next slide, please, in terms of timeframes I laid some out here and I did have a sense that you guys are going to think that I'm completely unrealistic.

Success metrics and timeframes for that, you know, issuance of more guidance on acceptable mechanisms for assuring legal authorization to share information, you know, I've got a 1-2 year timeframe on that one, maybe that's completely unrealistic.

Greater exchange and this is again a sort of success metric and timeline for getting there, greater exchange of information for treatment and care coordination particularly in circumstances where HIPAA governs that we might be able to achieve that particularly if we focus on some of the clarity about what can be done without necessarily having consent or we make some progress on allowing people to make sort of very clear choices about having their information shared and having those choices be honored across the board.

Achievement of consensus on definitions around basic choice 1 or 2 years, I don't know what I was thinking there. And dialogue among states with respect to harmonization at least has commenced, I think I'd had some optimistic coffee when we pulled these together but…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well, Deven, I think these are pessimistic numbers.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, I mean…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Really you think we can do better than this?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well, I think it already happens. I mean, you know, if you consider prescription information to be protected health information then we have nationwide exchange of protected health information that crosses state boundaries that's authorized by the patient at the point of care with their provider and that works extremely well. It works today. And there are some rough edges here and there and some issues that, you know, Surescripts might under pressure admit to, but for the most part it works really well.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
But your skipping the authorization part, it's not actually authorized by the patient.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
And Dave you have to remember Surescripts had a 10 year state legislative plan to change all the state laws so they could do that, 10 years.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well, so why wouldn't that pertain to others if the patient says I want you to release my information what states are going to stand in the way of that?

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
Well, there is…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
There are a few.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
There are some priorities here then, you know, certainly number four needs to…it needs to meet this timeline of 1-3 years and we need to be aggressive with that.

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

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
Especially on number three, the enabling step.

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

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
Yeah, three is ambitious I think but it's a good one.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So, all right, well, I think you're going to see a lot more of this happening in your timeline within the scope of this timeline it will be happening maybe not with every state.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
Well, this is Dave Kotz, the number four it seems like a relatively easy success metric all you need is two states to talk about it.

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
Then it would be between, we need between.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Right, but, right, I mean that's what the roadmap calls for is a dialogue, right, because states, you know, all are independent actors.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
Yeah I know and so we need that dialogue and commencing it is all we have to do in 1-3 years it would be nice to be able a little more ambitious, I'm not sure what the right phrasing would be but…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay, I can do that.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
The timing might be really…

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I'm mindful of…

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
Really good on that too…
David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
Yeah.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.
Because there's opportunity to save money and it might be a good time.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, I'm going to pause you guys for just a minute because we always try to queue people up for public comment ahead of when we actually go there. So, we're taking a momentary pause so that Altarum can do the announcement about what people need to dial in for public comment so that when we're ready to turn to it some people are tee'd up.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
So, operator can you please open the lines? Thanks, Deven.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay, so while we're waiting for some folks to queue up we don't have these metrics on the slide anymore but I think you…I mean, what we may need to do in terms of crafting consensus comment is to sort of…I think it's fine to acknowledge that, you know, we do have some exchange occurring today for treatment purposes and we can talk about the progress Surescripts has made, but certainly I don't think we'd be having these interoperability conversations if there weren't some roadblocks that people have pointed to on the privacy and security side and some articulated strategies for trying to get over them and so, you know, really love to get more feedback on what an appropriate sort of…if we want to tell ONC specifically to aim at some metrics of success that are much more ambitious and yet still doable, I mean, this is really our opportunity to do that.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So, again, Deven, I think that it comes down to pick some specific examples where we'd like for successful interoperability to occur and enumerate the barriers by those examples and there are some like ePrescribing where the barriers are minimal, it works reasonably well, there are others one step above that like eHealth Exchange and CommonWell and a number of state HIEs that cross state boundaries today where it works pretty well and they may have some questions that they'd love to get clarity on.

When you zoom all the way out to manage every data element with, you know, very granular consent including for research purposes de-identified or not then it gets much, much, much more complicated. So, I think, you know, the roadmap has a long vision, there are some near-term actions where it's not all that complicated, where interchange can happen I think much better than it does today within the existing scope of laws and call them out.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
David, this is Lucia, I actually really appreciate what you're saying and I think that's part of the reason why we drafted a 10 year plan. There are definitely things that cannot be accomplished in under four or five years or maybe seven or eight years. There are too many things that are unknown that are sort of conditions, precedent to whatever it is you're trying to achieve, some kind of, you know, think about all the moving parts in the space of research and consent, you know, there is Common Rule, rulemaking of some type going on, precision medicine all that kind of stuff.

So I think that's exactly what we need to hear from you guys is what are the things that can be done in that first three year period successfully are we going the right speed, too fast, too slow, wrong focus, what about the second 3 year period and then of course it all becomes a little bit unpredictable because now we're 6 years out.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah and Congressman Burgess may have eliminated your office by then. So, who knows what happens.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Who knows, well that's right, there are always lots of moving parts to these conversations.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
So, we'll turn to public comment in a minute. I think what we will endeavor to do, Stan and I, and the staff, to try to rework the language here in the ways that we've discussed on this call and get it out to you all to at least review by e-mail keeping in mind that all of it needs to pass through the Policy Committee so it's okay to make suggestions as long as they're generally consistent with the tenor of the conversation that we've had on the call today.

We'll also be noting to the Policy Committee what we were able to discuss and what we had less time to talk about so that they sort of understand the vetting process that took place ahead of time given the interest of time.

And also, I'll say again, you know, putting in your own comments to the draft interoperability roadmap is certainly most welcome and you're not confined to just privacy and security issues of course when you do that, you all are on this Workgroup because of your experience and the background that you have and it all will be very good feedback for ONC to have and I would urge you to submit additional comments for anything that we are not able to articulate through this process. And with that, Michelle, I think we should move to public comment.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
We don't have any public comment.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Oh, okay. All right, so does anybody else have anything to add to the discussion?

Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital
Deven, Gil Kuperman here, just, you know, just to echo maybe a little bit what David McCallie is saying maybe say it in a slightly different way with respect to the timelines, you know, if we try to think of, you know, what are the business goals that interoperability is trying to promote and whether it's accountable care or clinical care in general, or research, you know, how much further would we be down the road at a certain point in time, you know, it's kind of hard to put a metric on that, you know, but Secretary Burwell has said, you know, 30% of patients in alternative payment models by 2016 and 50% by 2018, you know, how well are those patients being served by interoperability, you know, if there is a way to get a handle on that…I mean, to me that's kind of, you know, the success metrics that I have in my head, you know, I'm not sure how that, you know, translates into question number eight, but I just wanted to mention that.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay, good point, driving this more along articulated goals.

Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital
Yeah, because I think as David was saying, you know, interoperability itself it's an abstract concept, you know, it's like electricity and so, you know, what are we trying to achieve really.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, I totally agree with Gil that's, you know, a couple of core, well understood use cases, I keep coming back to that word, I don't like it, but I don't have a better one.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
That cover, you know, clear value added interoperability scenarios some of which are relatively easy given existing laws and some of which are clearly visionary and would require changes to wholesale parts of our regulatory and statutory apparatus, lay those out and pick a few that are near and focus on them.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay that sounds…

Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital
This is Gil, I mean, I think people…I think the gut sense is, you know, I can exchange a summary, you know, a patient's summary, you know, whether it's via Directed exchange or a health information exchange organization, you know, that I have the ability to just have a general sense of what's going on with the patient, you know, if that's what's meant then, you know, you can put some things around it, but it's important to articulate that.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah and Deven as you well know from the Tiger Team work we tried doing that, you know, and we isolated push to come first because it was conceptually and regulatory easier to do and then query comes next…

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And now we need to refine, you know, what kinds of query across what kinds of boundary for what kinds of data authorized for what kinds of duration, there are a bunch of parameters but you could say, you know, non-sensitive, non-SAMHSA data authorized across boundaries for this particular encounter of care there is no barrier to that.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
I think that kind of thing would be really helpful David, this is Lucia, I think people kind of lost sight of the guidance you gave, I think it was in 2013, I wasn't here then so I'm having a hard time focusing on the date, but, you know, where you said it all depends on the relationship between the provider and the patient and the patients really trusting the provider to make a good choice on their behalf and when that happens in a query environment we sort of…we seemed to have lost sight of that a little bit about how that's really grounded in the permitted uses.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I'm happy to resurface that.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Yeah, but, you know, I mean, to David's point, resurface it but we need to figure out a way to resurface it and make the examples practical and connect it to the existing guidance in a way that…or work with OCR to develop more guidance so that it all connects together in a package that people can really wrap their hands around.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Right, right and given the timeframe for getting comments in I think probably what we're going to have to do is recommend that as sort of a next step in the process, because we won't be gathered enough as a group together to be able to drill down on it at this phase with any more level of detail, but, you know, we're your existing FACA, so where you go next with the Policy Committee and in terms of getting advice about how to take the next steps on this we would be happy to do that. So, but, we'll need to get the comments in to start that…to articulate that that's the way to go rather than thinking of these issues in this sort of big forest for the trees way.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Right, right and I think there is definitely, you know, to the extent you guys can help us figure out where guidance is needed and how that relates to practical things that can be accomplished in the next three years then we can really build, then we can build a three year plan on that.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay. All right, well we've now reached the end of our 90 minutes together so keep an eye on your e-mail if you want to have input on how we articulate this and pull it all together. We don't have another call scheduled again, it's unfortunate but we'll do the best we can and this will all get surfaced in a very public way at the April Policy Committee meeting. Thank you all very much for your input, really great, appreciate it and look forward to talking again soon.

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

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

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

M
Thanks, Deven.

W
Thanks.

W
Bye.

M
Thank you, bye.

Public Comment Received During the Meeting

1. The language proposed will be strengthened by citing existing models for security and consent sharing. SSA is an example; there are others in the federated cloud model via Cloud Security Alliance. In Big Data, architects dislike registry models b/c they cannot control latency, even if provenance quality is thought to be superior