



**HIT Policy Committee  
Privacy & Security Workgroup  
Final Transcript  
October 26, 2015**

**Presentation**

**Operator**

Thank you, all lines are now bridged.

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

Thank you. Good 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 today's call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. As I just mentioned to our workgroup members Stanley Crosley is not available today so David McCallie has kindly agreed to facilitate today's meeting on behalf of our FACA members, so David McCallie?

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

I'm here.

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

Hi, David. Adrienne Ficchi? Bakul Patel? Cora Tung Han? I believe Cora is on. David Kotz?

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

I'm here.

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

Hi, David. Gayle Harrell?

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**

I'm here.

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

Hi, Gayle.

**Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature**

Hi.

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

Gil Kuperman?

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

Gil Kuperman is here.

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

Hi, Gil. John Wilbanks?

**John Wilbanks – Chief Commons Officer – Sage Bionetworks**

I'm here.

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

Kitt Winter? Hi, John. Kitt Winter?

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

I'm 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.**

I'm 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 – Department of Health & Human Services**

I'm here.

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

Hi, Linda. Manuj Lal? Micky Tripathi? Mary, I forget your last name, for Sarah Carr?

**Mary Kelleher-Crabtree, MS – Health Science Policy Analyst – National Institutes of Health**

Hi, I'm here.

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

What is your last name Mary I'm sorry?

**Mary Kelleher-Crabtree, MS – Health Science Policy Analyst – National Institutes of Health**

Mary Kelleher.

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

Thank you.

**Mary Kelleher-Crabtree, MS – Health Science Policy Analyst – National Institutes of Health**

No worries.

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

Stephania Griffin? And Taha Kass-Hout?

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

Taha is here.

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

And from ONC do we have Lucia Savage?

**Lucia C. Savage, JD – 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, Lucia. Peyton?

**Peyton Isaac – Senior Privacy Analyst – Office of the National Coordinator for Health Information Technology**

I'm here.

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

Hi, Peyton and I think Helen Canton-Peters is on as well?

**Helen Canton-Peters, MSN, RN – Senior Health Information Privacy Program Analyst – Office of the National Coordinator for Health Information Technology**

I'm here.

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

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

**Kathryn Marchesini, JD – Deputy Director for Privacy Policy – Office of the National Coordinator for Health Information Technology**

Kathryn Marchesini.

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

Hi, Kathryn. Okay with that I'll turn it to you David.

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

Okay, thank you. I was asked to run the meeting today in absence of Stan at the last minute so I'm hoping that our colleagues from ONC who have a planned presentation can walk us through their expectations but that's our activity at the start of the call is to get an update from Lucia and her colleagues on computable privacy state-focused activities and then to have some discussion triggered by their presentation. Lucia, you want to introduce any beyond that or do you guys just want to jump in?

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

I'm ready to jump in whenever the assembled team is ready for me to start David.

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

Do you want to set a broader context for this? I think I missed...

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

I...

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

The last meeting and I may...we may need to be reminded of the broader context.

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

Sure, this actually comes out of provisions in the draft interoperability roadmap but had a little bit of a different shape and content in the final roadmap as we separated the main from the supplemental, but if you will remember back last spring, way back in the way back time machine, we had proposed in the draft roadmap to tackle three basic things on privacy one was sort of HIPAA basics, what does it actually prohibit, what does it actually allow.

A second one was to sort of help stakeholders have a clearer and more fundamental understanding of the various recommendations that in fact the Privacy and Security Workgroup and the Policy Committee had made regarding people making a choice to have their data electronically exchanged and we had a big dialogue about that last spring what did we mean by basic choice.

And then the third thing was we had proposed, in the draft roadmap, to take up again the issue of state privacy laws. We had suspected that it was causing a lot of confusion, a lot of mismatched expectations and was in that respect interfering with the interoperable amount of data particularly for patient's health. So, is everyone reminded of that conversation we had last spring?

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

Yes, David is.

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

All right, great. I think everybody sort of remembers that. So, I was going to sort of give you a little bit of background about what happened between now and then and in fact what I wanted to do today, what Peyton and I wanted to do today, was tell you about what our plans are for this topic for the next few months and make ourselves available to answer questions on the work we might have because you of all the different Policy Committee Workgroups have sort of grappled with this issue at the margins the most and your insights are always very helpful to us.

So, since we published the draft roadmap of course we finalized the final roadmap, but in the intervening time we got a lot of feedback on various aspects of the roadmap. On this particular issue of confusion because of state privacy law we heard a lot of sort of sighs of relief that somebody was talking about this again. Now, I'm characterizing it in my own unique way, but the feedback we got about our willingness to take this issue up again was very positive and so we've pursued some particularized plans and that's what I wanted to talk to you about today.

So, looking at the agenda, slide two on the slides, do we have the slides up Michelle? I don't think they're up.

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

I see them.

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

David, I must be on the wrong part of the website, hang on, out of sequence. So, on slide one, the slide number one, I'm going to talk about what the rules environment is, I'm going to talk about the stakeholders and the feedback we've gotten from them in more detail. I'm going to talk about a recent report from the GAO and then I'm going to talk about what it is that the ONC's Chief Privacy Office is doing about that.

So, moving onto slide two, as I said, this is kind of an identified source of confusion and one of the things we know about this is that there is a wide variety of these laws, we catalogued that in detail in the roadmap and it's now available in the supplemental materials and so those of you who have been watching this space for more than 10 years you'll remember that ONC actually took a stab at this in the early years of its existence in the 2006 to 2008 timeframe before HITECH.

And we described that in the roadmap, moving onto slide three, we defined interoperability the ability of a system to exchange electronic health information, you guys are familiar with that definition, and we diagnosed the following problems with regard to state law that through different...legal requirements across the states differ and that at the end of the day to have interoperability we need a consistent way to represent permission and a consistent understanding of when permission is required so that permissions, when required, can be collected and when they're not required information can move as intended by public policy and law.

So, moving onto slide four, when we talked to you all about this in March these are the sort of exerts that you came up with for us that ended up in the transmittal letter to the National Coordinator. Obviously, you asked us to work on clarifying what we wanted to do to help people understand the choice to have their data electronically transmitted or not and we were working on a plan for that and we'll bring it back to you when we have it more fully fleshed out and then also you encouraged us to in fact work on this problem of harmonizing state law.

So, moving onto slide five, I just wanted to remind people of the environment that we have. So, we have this graphical illustration of the different layers that we have in this space regarding whether you need to have a patient sign a piece of paper in ink or electronically before you move their data to the next appropriate place in the healthcare system.

So, starting at the bottom, obviously we have consent models some of those are implicated by this complex environment of opting in and opting out, opting in with restrictions, etcetera. And within those consent models we have models that have been adopted by states as a matter of law and we also have models that have been adopted by organizations as a matter of organizational policy but are not in fact part of a statutory scheme.

Then we have the way the EHRs systems operate themselves, that's the second layer, whether they're correctly understanding and adjudicating various privacy information that may accompany the electronic data.

Then we have...the next layer up is whether the patient's consent is required at all and if so can that be done in an electronic format like it is when we manage our finances to on-line banking or is it required to be done via paper and on top of all that sort of covering the whole thing in a big ball of wax are all the laws and regulations so if you could flip to slide...stay on this slide...so you guys will remember the statutory scheme works something like this, HIPAA covers the entire country as the privacy basics and then states are allowed to and do enact laws that are more restrictive from a privacy perspective than HIPAA, about half the states have enacted them, common clinical categories of specialized restrictions are mental health data, substance use data other than that which is regulated by the federal government under Part 2, reproductive health, sometimes the age at which a person is not an adult becomes eligible to manage their own healthcare, HIV/AIDS status and sexually transmitted diseases other than HIV/AIDS those are common categories and within those categories the laws in fact vary.

So, if you could flip to slide six, this is just an example from DC and North Carolina, we've actually done a lot of sort of dabbling, I won't say dabbling, we've done a lot of research here and what keep finding that's a little bit interesting is that states that are adjacent or geographies that are adjacent, DC is not quite adjacent to North Carolina, but there is some travel, often have rules which are similarly intended but have different words on the page in this space and the difference in the words on the page actually make it hard for people to understand what's going on.

So, this is an example from the Washington, DC code compared to the North Carolina code. You can see in the yellow circle that in Washington, DC mental health means any written recorded or oral information acquired by a mental health professional acting in a professional capacity and then in North Carolina mental health information is confidential information and confidential information is recorded or not relating to an individual served in a facility so it is not so much connected to who collected it as to where it was collected and this is often the difference that we find when we dig down into the statute. And we found this in many pairings, we have a kind of CT/New York example, we have a couple of examples from the Northwest and from the Midwest as well.

So, we know that this confusion is out there and interestingly enough in the GAO's recent report on barriers to interoperability they identified the same thing. So, if you could flip to slide seven please?

So, this report is available on-line, we've given you the link, and this got a lot of coverage in the press because in this report the GAO interviewed many organizations, perhaps some of your organizations, and vendors about things that those organizations and people thought were barriers to interoperability when they were private actors. And a lot of different ideas were brought forth but one that was brought forth by almost every interviewee was that they were confused about state privacy law.

So, these are some of the key takeaways we took from that report. Obviously, those are the laws that are more stringent than HIPAA, the various privacy laws may or may not require consent across state lines and across states. There are variations between when states require a patient to opt into having their records available for exchange and what that often means whether there's a break the glass exclusion or not for opting out.

And finally, that, you know, it covers different categories of sensitive information some information which is really among the most important types of information to get to integrated comprehensive care and to achieve better health with smarter cost. Next slide, please.

We also think that this process of these state laws which are really well intentioned to protect health status discrimination have to account for patient attitudes about electronic health information. So, we've given you, on slide eight, a little summary of what our survey data and survey data from the National Partnership show about healthcare consumers and one of the key things we know is that most consumers express support for electronic exchange and in fact a majority of consumers actually think their doctors are already engaging in it in some form or other.

So, at the treatment level consumers have these expectations that may not match what the laws processes are requiring and I think for the people on the workgroup who have been here since the beginning or have been monitoring this from the beginning you'll remember in the very early Tiger Team letter from 2010 a key principle in that letter was that consumers actually trust their doctors to make good judgements about these types of things.

And then lastly, when we look at this landscape and we see this wide variety of laws the most common clinical area in which we find this law has to do with mental health information and that's an interesting synergy with the fact that in our healthcare system a very common and untreated condition because of the lack of integrated care is mental illness or a mental health condition that is comorbid with a physical condition, it could be depression with pain or you guys...the physicians on the phone will know all this and the data is quite widespread. So, we would really like to focus our attention as we try to harmonize these laws or help states harmonize them on mental health information. So, I just wanted to give you a few facts that we'll be sharing with the states as we go forward in this process.

Obviously, the comorbidities, patients with comorbidities have higher costs on average, \$450.00 more per month, so \$5000.00 more per year in costs. And there is pretty astounding evidence that if you can integrate care and make sure that the person with a comorbid mental health condition is getting comprehensive care that looks at the totality of what they're experiencing, the totality of their medication, the totality of the social determinants of health in their lives you can actually reap these cost savings and improve the patient's health as well. Next slide, please.

We also know that this...

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

Lucia...

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

Complexity...yes?

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

Which slide are we supposed to be on now?

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

Well it's 10.

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

I think we may be running one slide behind.

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

We should be on 10.

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

Okay, I think we're running one behind.

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

All right.

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

There we go.

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

All right are we caught up?

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

Yes.

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

So, we also know that this problem of lack of comprehensive treatment for mental health conditions has a pretty significant impact on our service people. I had the great privilege of having a Lieutenant Colonel detailed to my office this year from the Army War College and he has been really helpful in educating my team about this and I thought I would share that not only with the PSWG but will be sharing it with the wider audience.

So, according to the military statistics there are almost 18 million beneficiaries of military healthcare who live in every state in the union. In that group 50,000 are wounded service members from our recent wars in Iraq and Afghanistan and 10,000 are in the National Guard or Reserve which means that they are not currently in active duty but they could be called to active duty at any moment.

In addition 22% of the veterans receive mental healthcare outside of the VA system. When they do that they are receiving care in the commercial environment and state laws relative to those providers apply instead of what laws might apply to their receipt of care in the VA system.

From the military's perspective what they're looking for is that when disaster strikes and we need to call service people to active duty that those service people are ready to serve and in order to reach that goal they have to get the care they need in whatever setting they're in whether it's at the DoD, at the VA or out in the community at large. So, we're hoping that this project will have at least a small drop in the bucket towards the military readiness for those who are receiving care in the commercial healthcare system.

So, given all those facts, slide 11, what is our plan? Well, we have this overall plan, which I'm not going to go into detail today, but I can answer questions about it, Peyton can answer questions about, to really sort of reinvigorate the way we explain what HIPAA allows and what it doesn't allow, what can be disclosed, when are individual permissions required and to really help people focus on processes that make the documentation of permissions something that's computable so we don't have a situation where the data is digitized but the permissions that attach to it are stuck in manila folders.

And we have an active plan in place to collaborate with many other organizations that for whom this issue is really their primary responsibility to take it up so that would be the National Academy for State Health Plans, the National Council for State Legislatures and the NGA or the National Governors Association, sorry I didn't mean to be acronym heavy with you guys. Slide 12?

So, in our final roadmap we actually called this out as a commitment we were making and, truth be told, we started down this path based on the positive response to the draft roadmap so we have been putting all of these pieces in motion for some months since about April and they're beginning to come to fruition starting about now and running through the next 12 months or so.

So, one commitment we made was working with state, local and national associations to launch a project to better understand the complexity of the rules environment and I'm going to turn this over to Peyton Isaac in just a moment and she'll tell you what that entails.

And then we're going to be working on basic choice sort of opting in and opting out. What are the consequences for health for choosing a system where you require people to make a choice about electronic exchange but you actually are not requiring them to make a choice about facts for telephonic or oral exchange.

And then lastly, we're going to start looking at the coding in the system. We made a commitment, and I don't have a timeframe for this for those of you who are wondering, to kind of look at how have we mapped existing clinical codes on the data to these statutory rules and provisions? Do we know which codes are definitively connected to HIV/AIDS? Do we know which codes are definitely connected to mental health conditions or mental health prescriptions for mental health medication and if we know that can we use that to build more robust and, I hate to say it but I'm going to, granular systems so that, you know, at the end of the day when we're looking at things like data segmentation for privacy we're not tagging a C-CDA we're actually tagging data itself and by doing that we can make the holes in the data smaller, there will still be holes because these data are specially protected but we can at least start to reduce the size of those tools and give people the ability to make very specific choices that we don't have right now because we're stuck in a paper-based consent system.

So, let me turn it over to Peyton Isaac a Senior Privacy Analyst on my team, she joined us from the VA in the spring and she is our Project Lead for our project with the National Governor's Association. Peyton?

**Peyton Isaac – Senior Privacy Analyst – Office of the National Coordinator for Health Information Technology**

Okay, great, thanks Lucia and stepping back again the project I'm about to describe is one of the ways we hope to meet our commitment set forth in the roadmap. So we are very excited to get started and I'll start by explaining just the purpose of the project it's really a cooperative agreement and the goal is to convene, I would call, selected states to develop a roadmap, so this would be a state focused roadmap that the states can utilize to address policy barriers related to interoperability.

So, our end goal I would say is to really accomplish some useful analytics maybe around how the various state laws impact their ability to achieve, I'll call it, nationwide machine computing. After all how can we develop systems that support nationwide exchange if the underlying rule, right, for each state use different language?

So, at a high-level the project is a two year agreement awarded to the National Governors Association and as Lucia mentioned we're really just getting underway the project was awarded at the end of September.

The selection is centered around our ability to leverage state relationships in key areas such as NGA has deep experience we know working with state health policy makers, they've got knowledge of state policy processes and we thought that this was really the skillset needed in order to have a successful project.

So, we're again, newly underway with the goal of selecting between 5 to 8 states to participate. If you had the opportunity...

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

Peyton?

**Peyton Isaac – Senior Privacy Analyst – Office of the National Coordinator for Health Information Technology**

Yes?

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

This is Lucia, we just need to have Altarum move to slide 13.

**Peyton Isaac – Senior Privacy Analyst – Office of the National Coordinator for Health Information Technology**

Oh, I'm sorry.

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

That's okay.

**Peyton Isaac – Senior Privacy Analyst – Office of the National Coordinator for Health Information Technology**

Okay.

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

There you go.

**Peyton Isaac – Senior Privacy Analyst – Office of the National Coordinator for Health Information Technology**

Great, we're caught up, okay. So, we're now underway with selecting the 5 to 8 states that we hope will participate in this effort. If you're familiar with the opportunity announcement that we published there were criteria in there and some of the states we're hoping to pull to the table are probably going to be Medicaid expansion states, we're looking at whether states have any current activity related to health data exchange we believe if so the environment will be kind of ripe to participate.

We'd like to know whether or not, or we would like to attract states maybe that have reached out to ONC for guidance or whether or not the state is participating in CMS's state innovation work because again, it's really about selecting states where the policy environment is ripe for participation and open to looking and taking a deep dive at some of their health policies.

Also, we needed to decide how to have the most useful discussion. So, as mentioned by Lucia we believe the way to do this is to focus really on mental health. We know, as she said, that there's a lot of confusion but yet widespread agreement that mental health is really an area that's ripe for examination.

When we look at those mental health laws, and I'm not going to repeat a lot of what Lucia said, but as she pointed out I thought were the two statute examples, we know that there is a lack of harmony around the conditions and terms used to define mental health and how we speak of mental health and it's that lack of harmony we want to address.

I should have stressed at the beginning the focus of this project is really not to ask states to change their state law to the extent states have made policy choices we want to respect those policy choices. Really the focus is on opportunities for the states to understand how their selection, again, of terms and definitions, impact our ability to get to a consistent set of business rules that underlie computing.

So, I don't want to get too far ahead of our contractor, the National Governors Association, really with detailed project activities, but I do want to say that much of our early work right now is focused on identifying those state participants and really we're deep into working on development of working materials that will help us convene states and make sure that we facilitate a useful discussion and we expect really the convening of states to occur if not by the end of the calendar year first thing in the new year.

This leads to what we are looking at is we're calling model criteria and I think we're interested in your feedback about this. We'd like to understand or better understand what role model criteria should play and what do I mean by model criteria, we're looking at maybe documenting a standard definition of health information.

So, for example, we know we have the HIPAA definition of protected health information would it be fruitful, we believe so, for states to perhaps adopt that definition. We're interested in maybe developing a list of providers to which these laws should apply and so forth and so, again, we're excited about that aspect of the project, we continue to work closely with NGA to flesh that out. And Lucia I'll turn it back over to you.

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

Thank you and we do have time for questions and we've given some in the slides as we get further on but we wanted to go over one more thing with you so could I have slide 14, next slide, please?

So, the last commitment we made in the roadmap, and again, you will hear more about this later because we don't have complete plans to get your feedback on it at this time but Kathryn Marchesini is charged with coming up with a plan here and I know you guys have all worked with her for a long time.

We know that there has been a lot of dialogue within ONC, the PSWG and the Policy Committee about whether...to what extent should individuals have the right to indicate through a permission, preferably electronically but even on paper, that they want their data exchanged electronically or they don't want their data exchanged electronically, we call this basic choice in our roadmap.

And one of the ironies that we find here when we look at this through the lawyer lens is that this is a very important discussion and at the same time HIPAA itself does not require that type of choice that's a policy question not a legal question if you will. And people are very, very confused about this and they ask me about it pretty much every time I go out in public and I'm not talking about cybersecurity.

So, we asked Kathryn to put together a private plan by which we would take all the guidance and input, and recommendations that have been made in the last five years and try to distill it into some actionable information for state level policymakers and organizations so that they understand if you go down...if you chose this path on this important policy question here's some things that might flow from that good and bad. So, it's really sort of about the consequences of making relative choices here.

And we want to go down that path for a couple of reasons actually we have to get people unconfused in order to get them to feel comfortable with more data moving more freely for care, but at the end of the day we also have long-term national goals for more data available for learning and the choice of opting in to digitally available data or not have consequences for that as well.

So, we want to give people a chance to look at both the near-term personal impact on an individual or a provider and the long-term impact on a health data system for the country. Next slide, please.

So, that's kind of what we'll be focusing on from a privacy side for the next 12 months other than other things that we're asked to do by the coordinator or that we engage the Policy Committee and it's Task Forces in and I wanted to turn now back to the state privacy law challenge and solicit some input from you.

So, we've posed a couple of questions for you on this last slide and if you answer these that would be great and if there are other questions you want us to answer or things you want us to think about that's why we wanted to make this time to come and talk to you. So, we're always happy to receive examples from your own states of things that confuse you.

We know you are out in the field and you have practical experience and we have some great people here doing great research and great resources but there is no way that we can be comprehensive on this so that is one question for the assembled workgroup is are there specific examples of privacy laws that you want to call our attention to.

And the second would be sort of digging deeper today for your input on this issue of model language. A lot of people involved in this have asked ONC will we be putting together a model statute. I don't know that the work will go that far but I do know that we have ambitions to help state policymakers understand what they might put into a statute that would accomplish two goals, one goal would be preserve protections from health status discrimination that they have already agreed to adopt in those states as embodied in these laws, but the other thing that those laws might want to accomplish is to be as clear as possible and maybe as similar as other states to have made the same policy choice on health data protections so that a computer and a software engineer can open that statute book and without too much trouble understand exactly what is being protected.

Something that people always ask me about for example, just to seed the conversation, is, you know, what's the difference between psychiatric notes and prescription drug history and are they both protected equally? So, that's something that might be useful to sort out and if you have a law like the ones we've showed you before they don't give you the clarity to help sort that out. So, David, I'm going to turn it back to you if you have input on that or questions from you or the rest of the workgroup.

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

Okay, thank you Lucia and Peyton. I have so many questions I don't know where to start, but...

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

Oh, that's good, excellent.

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

Let me zoom way back out and just where is this going? What's the point of all this? And I mean by "all of this" not just this particular state project but in the context of the roadmap is it your belief, your collective, ONC's belief, that machine enforceable, computable privacy is possible and that we should in fact build systems to do that? Is that a given assumption that drives all this or is that up for debate?

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

I think we believe that it's possible to tag the data more specifically so that you know whether it can be re-disclosed.

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

Well re-disclosed is a separate thing..

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

And that is...

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

Right?

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

Well, what you were...let's say you're a doctor, you receive it, right, it's been disclosed by the patient to you that's kind of fundamental to the treatment relationship you have with your patients. Now the question is what can you, as a doctor, do with it next, where can you move it next?

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

Well, but that's...

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

The disclosure is what the patient does.

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

Right but you...codifying these state rules presumably is not about re-disclosure it's about disclosure, I mean, re-disclosure is going to be important also but isn't this fundamentally about disclosure to start with?

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

No, the rules tend to work the same way in all environments which is they impose on a provider or a collector of the data some obligation to disclose it or not disclose it without additional steps. So, they're not really regulating what I would call, and we need to be really clear about the language so thank you

for pointing this out, you know, what a patient tells their physician that happens every day, a patient chooses to tell you or chooses not to tell you and that's not really regulable.

And then the question is, what does the law tell the collector of that data, you, an HIE, a hospital, whoever they can do with it next. So, I consider that sort of re-disclosure that's the verb I would use for that because the disclosure comes from the patient in the beginning.

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

Okay, yeah, I was using it in a completely difference sense so I appreciate that clarification. I'm not sure how others would use it so it's something to watch for.

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

How does the law use it? Sorry to interrupt but this is David Kotz. Maybe that's where we get the definition from? How does the law use the word "disclosure" in which sense?

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

Okay, that's helpful. Are you asking a question David or are you making a statement about something we should consider so I can make sure I'm answering?

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

I'm asking the question, yeah, there is David and you had two different senses of when is disclosure happening and when is re-disclosure happening and it seems to me since we're talking about regulations and laws we should look at those, the language of those to see how they use these terms, because we want to be consistent with those. I don't know the answer.

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

Well and one of the things I think that's problematic is while a lot of these laws are trying to do the same thing in fact they're using different words to accomplish it...

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

Well...

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

And that's what makes it so confusing.

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

Yeah.

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

Sure, so we would need to recognize...we would need to sort of tabulate all the different laws and where they are consistent or inconsistent in that regard.

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

Yeah, this is David, the other David, the use...the term I was thinking of was in the context of some of the SAMHSA rules which put additional burden on data that has already been moved from one system, the system where it was initially captured to a secondary system, perhaps the primary care physician, and rules on that physician what they can do with it subsequently that differs under SAMHSA from data captured via other routes.

So, I could be wrong, but my understanding of the SAMHSA laws is that downstream...that the data carries with it downstream constraints that other protected health information typically doesn't carry with it. And maybe we should get rid of that notion entirely but that's a different question, but that's the sense in which I was using re-disclosure. But I don't want to get us too far off track.

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

And I actually think that's a really good example David McCallie because one of the interesting things in this space is that a fair amount of space not half, but a countable number, probably about a dozen, have their own laws on substance use. So, interesting point here is the SAMHSA law at least it's the same everywhere that it applies, right?

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

Yeah, it does have that advantage.

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

That makes it a little bit easier even though it applies differently than HIPAA, every federally funded substance use program is impacted by that law, but you could also have a situation where you're in a substance use clinic and some of it is federally funded and some of it is privately funded and they've got the SAMHSA rule for their federally funded patients and the state rule for their non-federally funded patients. Now how are they supposed to deal with that?

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

So, let me take the...my temporary chair's prerogative and shift us back to my initial question. I certainly acknowledge that we need to be very careful how we use words like "disclose" and "re-disclose" and that will be a useful thing to track.

But I've got the...you know, the final version of the roadmap open in front of me and there are three milestones identified in the...under the rubric of consist understanding and technical representation of permission to collect, share and use identifiable electronic health information whichever, those are the high-level goals that...and from 2015 to 2017 it's HIPAA enabled exchange, 2018 to 2020 its basic choice and then 2021 to 2024 its granular choice. And I'm just trying to fit what this project is into that framework?

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

Oh, sure. So, I think that we need to give ourselves a lot of time to get to the point where we have more consistent meaning, more consistent words or more consistent understanding of those words as they relate to these state laws. So part of that has to do with state legislative calendars, we have legislatures that meet every year and odd years, clearly they're not going to take any action in 2016. We also know that this is a very complicated process in our federal society.

So, ONC's hope is to bring some new information and expertise to this situation now that data is flowing and is sort of sitting at the door ready to flow. The last time we looked at this with states in 2006 it was not really ready to flow.

And then states will have to take action and that's why we didn't list granular consents until the last three years, David, because it will take a very long time to get to nationwide ubiquitous...a nationwide ubiquitous system in which patients can clearly and in a way that is understandable when it is needed to by computers choose whether they want their mental health information to flow just like their medical information flows or not. That's why that...this is the beginning of something that's going to take nine years.

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

Okay, yeah, so I think it's going to take...this is my opinion, this is David again, that this may take a lot longer than nine years because I'm not sure it's achievable at all, you know, the many attempts to do computable privacy, computable consent have never gotten past pilot stage because the complexity and the overhead is so high both on the patient and the provider not to mention the systems that have to implement them.

And it seems to me today we have data flowing across state boundaries within increasing, you know, liquidity not the least of which is a nationwide ePrescribing system that works pretty well, many of the vendors have, within the vendor's own community, many statewide flows of data.

I guess I'm just calling in a little bit of the question of what problem are we trying to solve? Do we believe that we need this level of granular computable? Do we believe that it's feasible? Would we...

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

Most of this...so I always like a doubting Thomas, a doubting David, as it were.

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

Yeah.

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

I will say that when we put this forth in the roadmap people said "yes we need that." That was a vast majority of the commentary we heard. It was independently the GAO heard the same thing. Independently people have written to Senator Alexander at the Health Committee identifying this as a problem that interferes with their ability to build sustainable business models across state lines to serve patients better across state lines, we have, you know, systems that sit on borders all that stuff.

So, we got a lot of positive feedback. I think if we'd had negative feedback we probably would have regrouped.

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

So, then, again, another just observation and maybe I'm dominating the conversation way too much, but it would be nice to know what we think the use cases for the information that you're going to extract from this process are so that you can tailor the way you extract it to fit the use cases.

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

Yes and I think that will be part of what we hope will result from the work with the NGA, they have some specific obligations under our grant instrument to them and one of them is, at the end of the day, the publication of sort of an interoperability roadmap for states so states can identify the things that, in their collective wisdom, they think are the top things interfering with interoperability within their borders where this is a challenge and sometimes across borders as well but I can't guarantee it. Obviously, the states have to decide what use cases are important for them.

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

Well, I was thinking more at the level of, you know, the notion of a system or multiple systems where data is moved to where the patient needs it, you know, most people agree with the notion that when you see your physician regardless of where you see him or her, your clinician I'll say, that with your permission your data should be able to find its way to that clinician. And I think we're fast moving in that direction, we'll be there I believe a lot sooner than this roadmap, but I don't think we'll be there with encoded detailed state-specific computable consent. I think patients will trump that and just authorize it, but we'll see, that's off the subject of the call.

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

I think that would be great if my work was rendered unnecessary that would awesome.

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

Yeah. So, why don't we open it up for others...

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

This is Linda Kloss...

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

Discussions, I've said way too many things so I'll kick it...you know, please the rest of the group weigh in.

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

This is Linda Kloss and thank you so much for bringing us up-to-date and briefing us on your thinking and the project. I agree this is a long-term initiative and, you know, I think there's a lot of water under this bridge from the AHIC days and even before and a lot of that learning is still very relevant.

And it does seem to me that the most important issue here is to identify the key policy issues and then back that up with education and demonstrations of how states have successfully navigated it and then, you know, perhaps not focus so much on the computable solutions part of this but the trickier issue in this regard is always the policy discrepancies and I would think that of the states that get selected to be part of this you'd want to focus on those that are really progressively solving some of these problems because I think there is such a wide variety of states some a passed a law that, you know, is on the books and they don't even really revisit it to understand the consequences to those that are right now stepping up to beef up the laws they have like California. So, I think I'd err on the side of states that are pretty deeply and actively in this.

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

Yeah, Linda it's interesting because what we really hope to do is to make this useful to the states is to sort of pair states who have actually made headway here with states who want to.

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

Okay.

**Peyton Isaac – Senior Privacy Analyst – Office of the National Coordinator for Health Information Technology**

This is Peyton I'll say that comment is especially helpful as again we are at the phase where we are taking a close look at what states we should bring to the table. So, thank you for that.

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

Yeah, this is such a broad range of sophistication and, you know, there's not too much to be learned from those that passed a law a couple of years ago and aren't paying much attention to it.

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

Right.

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

This is David, I'll...I think it's a great comment. I would add the constraint that it would be nice to include states where it's actively being done as opposed to just being legislated.

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

Yes, agree.

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

In other words is anybody actually doing this kind of granular control of consent? I'm not aware of anybody outside of very limited pilots, but if you can find one that would be the place to go learn from.

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

And David and Linda, one of the challenges we have is we know there is some granular consent systems that have been built that are about patient preference not about legal compliance and we have to sort of figure out how to help states...which do they want first, because you could have a lot of patient preferences that are not legally compliant where the physician still hasn't done what was required by some, you know, old law buried in a statute book.

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

This is Gil Kuperman, first, you know, I just want to, you know, applaud ONC for, you know, tackling, you know, getting ready to eat the elephant again, you know, we...I think this group takes on a lot of big topics, you know, big data and, you know, now we're revisiting this, so, you know, I think it's important to acknowledge that this is an important topic, it is a hurdle to interoperability and it's not small.

I guess, you know, one of the things I'm grappling with is, you know, and I'm looking at the very last slide, you know, the very last bullet, you know, should the model criteria be considered to support state computable privacy and, you know, I guess what I'm wondering is, is the plan to try to, you know, create formal structures around what exists today or is the plan to kind of, you know, get more details, see where there is inconsistency, see where there is conflicts, try to make recommendations to get more consistency first and then apply a computable model to that, you know, reconciled structure, you know, because to me those are kind of like two different approaches, you know, automate what's in place today versus remediate and then automate.

And I would be a strong proponent of kind of, you know, trying to, you know, remediate or get consistency first, you know, because I think then there will be a much deeper understanding of what really is and then, you know, apply a computable model to that.

So, you know, I'm not sure, you know, if the distinction I'm trying to make really exists, but if there is a distinction I would be a proponent of trying to resolving these first and then...

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

Yeah, I think you're asking an excellent questions Gil and I really appreciate the way you've structured it. I think my vision, when I Karen and I sketched this out, was the former. So, work on raising the level of consistency and then...that's why we gave ourselves 10 years, and then figure out a way to bring technology into adjudicating that consistency.

So, that's why we gave the example of North Carolina and DC, right, one is about people who collect and the other one is about places where it's collected. So, that's a fundamental inconsistency even though both of those statutes are trying to protect the mentally ill from disclosures that might cause harm due to their health status because of discrimination, right?

So, you know, and that's why when I'm talking about this in a small group they sort of harp on prescription drugs and yes we do have an ePrescribing system but we don't have the right level of comprehensive understanding by the person we're charging with care coordinating in our value-based purchasing world of, you know, all the pain killers for a person who really needs mental health services might be taking. I was thinking about Patrick Kennedy's Op-ed in the Post over the weekend.

So, I'm with you but at the end of the day we have a federal system and our job at ONC is to make our expertise available to the states and they will choose the path that works for them.

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

Thank you.

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

Any other questions or comments?

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

Well, this is David Kotz I had...I was a little surprised with something you said maybe toward the beginning actually about the notion of computable privacy, because you said there is a question when data is disclosed to you as to whether you can disclose it or re-disclose it to someone else, you being a clinician, and the goal, if I understood you, was to help clinicians make that decision, but my understanding of computable privacy is to make the rules codifiable sufficient so that an automated system can make that decision or support a manual decision and I just want to make sure we're on the same page there.

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

Yes. You're exactly right. What I want to do is enable physicians to take advantage of computing power as they try to make these decisions.

I was struck by, just to go back to the last time you all convened and we were taking testimony on OCR's behalf about the complexities of getting copies of records to patients and I was struck by some of the written testimony that described this process of, you know, figuring out what was in that designated record set that could be released and I was thinking to myself but the patient asked you to release it like isn't that good enough, my lawyer brain was thinking that, right, so why is it that we have a person sitting down and figuring all these little pieces out and can we speed that process up, make it cost less money and make it more effective by, eventually, it takes a while, bringing computers to bear on some or all parts of the process.

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

Fair enough, yes, thanks.

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

So...

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

But to your point, this is Linda, but to your point, which why this is an important initiative, part of the reason why that review needs to be done is because of the variation in state law as it relates to various forms of sensitive information.

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

No, I get that, yeah, I totally understand that.

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

So, no matter what the patient's say...yeah.

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

But, this is David, is there a sense, Lucia maybe you can help with this, I asked Deven a couple of weeks ago and didn't really understand her answer, but is there a sense in which the state laws could trump the patient's ascertain that they want the data released here and now?

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

I think that this is a little bit of an open question. I haven't read every one of the state laws that apply, they apply one way to providers and physicians, and hospitals, they might apply a different way to payers, and there is definitely situations in which, you know, HIPAA may give a patient a right to get a copy of their record but that's not a definitive statement about who owns the record for permanent record keeping purposes or many other responsibilities.

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

It seems to me that this is, because of the complexity of the way states work and red states versus blue states, and off year legislatures, that the chance of getting coherence to a rational set of policies is near zero. The incredible difficulty of codifying that in a scalable way has been overwhelming demonstrated to be extremely difficult, never been done.

So, would we not be better served by working on the inverse problem of finding ways for the patient to declare their intent at the moment the records are needed or when they engage in the care, engage a new provider in their care and give that provider the ability to go assert on the patient's behalf the records the patient wishes to have?

In other words, address the pull side rather than the push side? This just seems hopelessly backwards to me.

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

I think what you're saying has a lot of validity but I don't think that solves the problem that we want which is what we're really trying to take to the states. So, the basic purpose of this next 24 months is to remind the states that they have some responsibility to create an environment in which that tool can work David.

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

But it's...

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

If the laws regulate the providers and the hospitals, and the insurers, and the ACOs within the states and don't account for the patient's direction because there is some intervening control by statute which hasn't maybe been changed in 40 years, and some of these laws are quite old relative to HIT life, short for law, long for HIT, the states have to take responsibility for that.

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

But if you...

**Peyton Isaac – Senior Privacy Analyst – Office of the National Coordinator for Health Information Technology**

Well, and so this is Peyton, I really still...we need to be respectful of that underlying state policy. So, you know, again, to the extent these states have made their policy choices already I think our...we're really focused around how can we help the states operationalize those policies so that physicians won't be really confused about what those rules are. So, I hope that's helpful.

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

But, I...so this is David again, again, you know, since the...I'm going to just...whatever, I'm going to just talk. So, it could be that the goal of this is to computerize state existing laws and we will succeed in doing that with incredibly complex XACML constructs and SAML assertions and no one will ever use it because the implementation cost is just overwhelmingly high or we could come and approach this from the point-of-view of, if I need care and I need it now and I want my doctor to have my complete record and I'm willing to let him have all of it or all of it except my mental health provider shouldn't the computable assertions that we're worried about be driven from that side of the equation so that the state gets that, the health provider within that state gets a clear assertion that trumps the states sort of de facto rules which are basically protecting if the patient hasn't spoken up.

If the patient speaks up and says "give me this data because I need it, my provider needs it." It would seem to me that's a much more fruitful avenue to pursue and it doesn't cover...

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

I...

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

The research use case, I realize it doesn't address all the use cases but it goes after this pressing problem that we get beat up about every day that there is no interoperability. I don't think we can stand another 10 years of that constant drumbeat that there's no interoperability. We can do it right now if we just make it clear that the patients can release their records when needed for care trumping states...

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

But...

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

As far as I know all states.

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

But it has to be true that the state legal environment enables that assertion to work.

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

So, are there...do we believe there are states where that's not sufficient that the patient can't get their data released? I mean, let's take off the edge cases of criminals and you know...

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

Right, no criminals, no correctional facilities.

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

Right.

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

There are time constraints, there are requirements of paper so a computer assertion may not be considerably reliable.

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

But shouldn't that...

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

In different states.

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

I'm sorry, I interrupted you, finish up, I'm sorry.

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

No that's okay.

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

I get passionate about this.

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

I know, I'll put you on the list of potential experts David and then we can drill deeper in it, but I hear exactly what you're saying and I think we have to recognize that there have been a lot of attempts to make that work in the last six years that haven't moved the needle as far as we would like to have it moved.

So, the purpose here is to go back to the states who have some responsibility that interoperability is a shared responsibility for everybody it's not just ONCs and it's not just the vendors, and it's not just large systems and it's not just congress, it's everybody's responsibility and here we know, to Linda's point, because we did so much research on this in the 2006 to 2008 timeframe, we know that there are...underneath the federal layer there are other issues to be solved and we want to remind the states that they have some responsibilities if these are important issues to them because they do have their own powers in the federal system and we can help them solve them but the states have to want to solve it.

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

So, again, just to make my pitch, I would think we'd be better served by a project that was focused on computable assertions to release your data as opposed to computable assertions to prevent the release of your data. So, that the angle...

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

Okay.

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

We're taking today is the latter, we're trying to codify the existing preventions of release of data that's called privacy but I think we'd be better served, at least from the healthcare delivery system point-of-view, to codify assertions that allow for the release of the data for care driven by the patient or their proxy and solve that problem instead of codifying these arcane rules that are essentially unenforceable by electronic systems. We could codify how to get the data out rather than how to keep it in.

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

This is Gil, you know, if I'm understanding correctly or let me test if I'm understanding correctly here, so, you know, I'm in New York and in New York we've got this patchwork of state privacy laws, I mean, I think there are six agencies that have regulations, you know, on the books about what you can and can't do with various kinds of health data.

What we did in New York, you know, to facilitate health information exchange, you know, rather than trying to kind of understand all of those in depth and, you know, kind of create a slalom course, you know, to get around all those, you know, what the DOH did here basically was said, okay, you know, for, you know, supporting health information exchange there is going to be a consent, you know, and if the patient says, you know, I approve...if I give you, provider, permission to access my data through the health information exchange you can have permission to access my data through the health information exchange and it kind of, you know, cuts through, you know, the various state agencies that are here, it kind of...in some ways it kind of trumps those or, you know...

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

Yeah.

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

I don't want to say supersedes, but, you know, it enables the exchange without dealing with each and every one of those regulations and so David I don't know if that's maybe the kind of thing that you're saying where, you know, you don't really need to get into the details of all the existing stuff you just need something that says, I allow my data to be exchanged, you know, despite whatever kind of regulations are in place. Now that's New York, but, you know, so I...by anyway I just...I don't know if that's kind of maybe, you know, what David was saying.

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

Gil...

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

No and I know, this is Lucia, I know the New York example really well and it's a great example Gil and it came as part of a comprehensive health information statutory enactment that New York, you know, where they invested in their own health information exchange infrastructure most states haven't done that. Most states haven't had a chance to sit back and look at...

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

But...

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

What is their current environment and what is their best cure for it.

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

So, this is David, again, and Gil that's exactly what I'm talking about and I don't see any reason why that couldn't apply across state lines, it is exactly how Surescripts works today and it applies obviously across state lines, it's how the EPIC Care Everywhere network works today and it applies across state lines, and it's how CommonWell works today and it applies across state lines.

The weak spots are that there isn't a standard way to express that consent that's cryptographically trustworthy so that on the receiving side the most stringent and picky disclosure officer at a particular facility says, I trust this, it's good enough for me, I'm releasing the data and we do that with...

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

Well...

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

Contract enforcement today in Surescripts and CommonWell, and Care Everywhere but we could buttress that and that seems to be fruitful work because you may not want to release everything, you may say, I don't want my mental health office notes released but everything else I want released right now because I'm in the emergency room and I'm having a heart attack.

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

I was going to make that point that you could make the permissions granular enough to require a specific override of a state law that would otherwise put barriers in place...

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

Right.

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

For the patients by delineating those and you could, if you got really creative, you could go a step further and think about how to give some definition to the concept of minimal necessary for various applications. So, release to other providers for my care is unlimited but release to a third-party for another purpose I may put some different barriers on them.

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

The other thing I wanted to say, this is Lucia, I want to...I hear what you're saying David but we've also heard, as per some of the vendors, and they told the GAO that this is a problem for them. So, what we heard as to some of the larger EHR developers is the first thing they ask the physician on an installation is, what state are you in, so they can take, you know, whatever their largest system is and conform it to particular rules for non-disclosure or non-re-disclosure in that particular state. So, I think that when we...if we look under the hood we're going to find a lot more dirt than we wish was there.

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

Well, I agree that as long as we worry on the computable...the challenge of computable codification of restrictions on release of data you're going to find a lot of dirt and it will be a lot of work and when you're done I'm not sure you will have something that will facilitate any of the goals of nationwide interoperability.

On the other hand, if we work hard at figuring out ways to codify what the patient does want released when they want it released you invert the problem and you solve for an actually powerfully beneficial use case as opposed to trying to codify what we basically all admit has not worked well.

So, why would we want to codify what hasn't worked well when we have an opportunity to codify a new approach that nationwide connectivity with things like Surescripts, Care Everywhere, eHealth Exchange, CommonWell make available. I mean, CommonWell will be able to connect every EHR to every other EHR anywhere in the country in a fraction of a second, wouldn't it be better to focus on how the requesting system can assert in a computable and provable way that the patient sitting there with the doctor says, I want that data to be released.

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

But that still may require states to change their laws David that's the conundrum we have. We have to start with the architect of the environment we have which is state laws. So, I understand what you're saying but I'm not sure that we can solution it by pointing to a technological standard.

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

But if you...but I'm saying if you go into that state and let's say you stumble into a state that's actually willing to change the laws based on advice from a federal person, which, you know, at least in what 25 of the states is probably not going to happen, but let's say they're willing to, what would you want to tell them?

What you don't...what you want to tell them is here's the way we're going to send providers in your state an assertion describing the conditions of release of data right now for the purposes of care, we want you to put that in your laws so that no one has any question that this is an acceptable real-time need for release of data. That doesn't mean you have to change your old laws about, you know, passive ways data gets released, which the patient is not actively in the middle of, those laws can stay.

I'm saying going in with...go in with a solution that will actually improve the status quo and have the states react to that solution, find out what their concerns and objections might be, what proof would they need that the patient actually made the assertion to the provider that's requesting it, what kinds of identity minimums would they need before they trusted that it was really the patient or an appropriate proxy.

I'm, you know...my bias is towards building things that work and I'm just trying to think we've stubbed our toes on this so long. I did a little review of computable privacy for this call when I found out I was going to chair the call and, I mean, we have 15 years of hundreds of attempts to do this dozens of incredibly complex standards that have been proposed by HL7 and IHE, and other entities and none of them have gone anywhere. I apologize for being, you know...I'm just old and grouchy I guess, but I want to see us move this thing forward you know.

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

This is Gil, you know, I'm sympathetic to David's approach and I think what Lucia is saying is that, you know, the states would have to want it, that, you know, I think there is a desire for kind of a light touch from the federal government and so, you know, how to kind of, you know, meet the states where they are maybe, but, you know, I wonder if there's a, you know, I wonder if there's a way to, you know, maybe propose this in a way that, you know, if, you know, to those...to the folks who you're recruiting and say, you know, is there may be a preferred approach here, you know, doing kind of a deep dive and a deep analysis or just assessing the receptiveness to a different kind of approach and...

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

I appreciate sympathy Gil and the other thing we have to really think about is, so one of the fundamental things we find when we dig through the HIPAA structure is that most data moves without patients having to take action at all and human beings are famously susceptible to inertia so there will definitely be instances when a patient and a physician are engaged in an active conversation and the patient is making specific choices and specific directions, but what we know from the survey data is that patients kind of expect doctors kind of to move the data for that and so we have to figure out as well, to your point Gil, at a state level, you know, what does the state want, do they want to sort of do the...being in the system where no data moves unless directed by a patient that would be a very granular opt in system. Is that what people want?

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

But...

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

I'm not sure that's the right policy for the country.

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

But...

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

So, how do we have a policy that helps us account for inertia and the fact that the vast majority of people won't realize they should have taken action until they already present at the hospital and they're sick?

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

Lucia, this is David, let me respond to that because I don't think...I think you've set up a strawman and it's not the strawman that I'm proposing, I have a different strawman. I'm saying that the data should always move if the patient asks for it. We need to make that the case that if they take the trouble to authorize that release, authorize is a bad word, apologize, to, you know, whatever the right word is, lower case authorize that release, lower case "a" authorize that release then it should happen.

Now what happens in the default case, okay, that's still complex and what most people would do is just to say we'll, you know, and this is the world today, they say "we'll protect the stuff that is generally agreed upon as sensitive" and so forth. And we can go work on that problem but that's not the interesting problem. Codifying that will not push us forward.

If we said, on the other hand, let's go make sure that the active case, when the patient actively consents for this to happen, it happens seamlessly across the country. And if you give providers that choice and they're operating in a system where there are financial incentives to have access to that data, in other words, value-based futures, then they will go capture that consent from their patients and they'll just capture it that's what happens with ePrescribing today. They capture permission from the patient to go get their medical history and to go get access to their formulary data through the PBMs. They actively capture it. Now it's relegated to a check box but it works.

And we need to make that work at the larger scale and then allow for the computable aspects would be where you come in and you say, well, it's not an all or none decision Mr. Patient you could actually control this in some ways, you could specify what subset you want to actively release.

And I think...I can't imagine there are very many states when if you put it to the people in the state and said "do you want the ability to authorize the release of your doctor when your doctor says he needs it, yes/no" that the answer would overwhelmingly be "yes." "Do you want the state to tell you when you can release it?" "No." Right?

I mean, I don't think this is a difficult political thing we just are...we're asking the question backwards.

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

This is Gil, you know, we've got one organization here that, you know, participates in the statewide health information exchange, they are an EPIC client so they participate in the EPIC exchange, and they're participating in the, what I guess is being called the "Sequoia Project" now the nationwide health information exchange network. So, you know, they've got one form where they basically capture these three consents from the patient and so, you know, one of those is state oriented, but the other two are kind of interstate kinds of things.

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

Yeah and that's how CommonWell works the same way. There is...you opt in and by so doing you say you give the provider the right to go and get your record when he's doing direct care of you and you're mentally competent we put some constraints in there.

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

But David is that for all the...let's say you're in a state like, I'm going to pick on Washington State because I know they have a really complicated rules environment, is that for all the data in Washington State to your knowledge or is that for the data the doesn't require additional permissions from the patient?

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

Well, this is being, you know, figured out on the fly and this is where I think we can come in, we, you and your team can come in, and help clarify what the rules ought to be, what's consistent with HIPAA, what's consistent with current state policy that would say if the patient sitting in Florida has authorized electronically for his or her record to be fetched from Washington because he's in the emergency room what should Washington do about that and what are the constraints that you would expect technically to assure that this isn't a spoof.

So, there's, you know, going to be some sense of proof that it was a legitimate request that the patient really authorized the local physician that he is who he says he is, all of those technical things, and then in Washington when they get that request they should feel comfortable that they know exactly what they're allowed to do because it's the patient asking for their records.

If the patient got on a supersonic plane and flew to Washington and said "give them to me, print them out while I'm standing here." They would do it, you know, they might charge him a thousand dollars but they would do it and then he could get back on his plane and go to his hospital in Florida and say "here they are." And there is no reason why we can't make that electronic.

I mean, there's no...I can't think of any reason why we can't make that electronic. I think that's what we're trying to do with these nationwide networks is for the case of direct care when you need your records in the hands of your provider you should be able to authorize that on the spot and have essentially immediate return of those records.

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

But...

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

Not dealing with research and all those other complexities those are different, those are harder, but direct care...

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

So, at the end of the day David what you want is a state that has specialized rules to recognize what this patient has executed in their relationship to their physician and their EHR?

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

Yes.

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

Despite the state rules?

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

And then have that...

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

So, we...the states would still have to figure out if they want that to happen, right, and hopefully legislatures, you know, again, this...a state could have many more important problems than this one to solve in 2016 or 2017, or even 2020, but we have the capability of pointing out to them the consequences of failure to address it.

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

Yeah, I mean, you've given yourself 10 years to solve the passive problem of codifying what they can't do, so let's give ourselves 10 years and solve the problem of codifying what they can do because I think we'll get it done a lot faster than 10 years, because it's a lot simpler.

If the patient says "let it go" then it goes. I mean, you know, again, the alternative is the patient physically shows up and asks for a copy which they have an absolute ironclad federal level guarantee they can get not trumpable by the states is my understanding. So, we just want to make that electronic.

I mean, we want to make a standard way to make it electronic, it happens today electronically all the time with eHealth Exchange, Sequoia, CommonWell, Surescripts. It happens across state lines in Kansas and Missouri but it's all done ad hoc with different language, different forms and it is not electronic.

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

Right.

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

It's based on essentially contracts and trust. I think we can go beyond that. We could make it electronic.

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

Yeah, I don't think there's a reason why we can't certainly make forms not paper but that's a whole other problem.

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

Yeah, yeah, well, yeah and I realize that under the law the difference between electronic and paper is real maybe that's an artifact of time and history more than anything else, but you've got to deal with it that's what Deven told me when I pushed this notion with her is, you know, the HIPAA right to release is just talking about...HIPAA right to a copy of your record is unfortunately talking about 30 day turnarounds and pieces of paper.

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

Yes.

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

But I don't think that the spirit of that law is in question and I'm sure that 99% of people would say "of course I want it to be electronic instead of paper and have to wait 90 days or 30 days and pay \$1000.00."

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

Well, hopefully Deven will solve this \$1000.00 problem.

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

Yeah, yeah, yeah.

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

That's in her court right now.

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

Good point.

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

I know it's almost time for public comment.

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

Oh, yes.

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

So, are there any last questions from the workgroup members or comments?

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

Hearing none are we ready to open up?

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

Sounds good to me.

**Public Comment**

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

Okay, operator can you please open the lines?

**Marcus Hudson – Project 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 phone and would like to make a public comment, please press \*1 at this time.

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

While we wait for public comment David thank you so much for helping us lead today's discussion and for all your thoughtful questions we really appreciate it.

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

Yeah, I apologize if I've spoken too much, but this is a good opportunity to talk about I think an important, you know, consideration.

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

We wouldn't have brought the topic to you if we didn't want the input of everyone on the workgroup who wanted to weigh in frankly.

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

And you...

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

It is a very complicated process.

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

It is and you were brave to ask me to actually chair the call, you'll know better next time.

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

It looks like we have no public comment so thank you everyone and thank you again, David.

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

Thank you, all, thanks, Lucia.

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

Have a great rest of your day.

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

Thanks, everyone.

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

Thank you, bye, everybody.

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

Bye.