



**HIT Policy Committee
Privacy & Security Workgroup
Final Transcript
October 14, 2014**

Presentation

Operator

All lines are bridged with the public.

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

Thank you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Privacy & Security Workgroup. This is actually the first meeting of this workgroup under our new restructure. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Deven McGraw?

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

Here.

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

Hi, Deven.

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

Hi, Michelle.

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

Stanley Crosley?

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

Here.

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

Is it Crosley or how do you say it, Stanley?

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

Crosley.

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

Crosley, okay, thank you.

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

Yup, you're welcome.

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

Adrienne Ficchi? David Kotz? David McCallie?

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

Here.

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

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

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

Here.

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

Hi, Gil.

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

Hello.

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

John Wilbanks? Kitt Winter?

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

Here.

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

Linda Kloss?

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

Here.

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

Hi, Linda.

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

Hi.

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

Linda Sanches?

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

Here.

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

Hi, Linda. Manuj Lal? Mark Sugrue? Micky Tripathi? Stephania Griffen? Taha Kass-Hout? And from ONC, do we have Julia Cassidy?

Julia E. Cassidy, JD – Office of the 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, Julia. Is Kathryn Marchesini on the line?

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

Here.

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

Hi, Kathryn. And with that I'll turn it back to you Deven.

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

Great, thank you very much Michelle. Let me welcome all of you to yes, this is the inaugural meeting of the newly constituted Privacy & Security Working Group, which is a workgroup of the Health IT Policy Committee. It's...with the new ONC head on board, a decision was made that we needed to do a bit of a rethink on some of the workgroups, in terms of both the topics that we're taking on as well as bringing some new members into some of the groups. And so the group that was the Privacy & Security Tiger Team, which was the working group that handled privacy and security policy issues for the Health IT Policy Committee, was sunset and now we have a new workgroup, which is composed largely of new members, but with some overlap with the prior membership of the Tiger Team.

I wanted to start by giving everyone a little bit of time to introduce themselves and then we'll go over just a few introductory slides. We don't have a long call today, we're not planning to dive into any substance but instead, to take about an hour, maybe less, to get to know one another a little bit, to go over what our committee's charge is, talk a bit about what are likely going to be some near-term issues that we're going to take on. And to give you all a little bit of a grounding on some of the work that was done previously on privacy and security, so that you have a sense of work that has been done previously, but you also get to see that we've been frankly a very effective working group in the past. I'm biased; of course, since I was on the previous group, but we have a good track record of teeing up recommendations to the Health IT Policy Committee which then get adopted and sent on to ONC and those recommendations have found their way into ONC policy. I thought it would be worthwhile for you to at least hear a little bit about that so that you know you're joining a group that is, in fact, an active one and one that has made a difference.

And so with that, I'll start with the introductions. For those of you who don't know me, I'm Deven McGraw. Up until several months ago I was the Director of the Health Privacy Project at a non-profit organization called the Center for Democracy & Technology and just recently became a partner in the healthcare group of Manatt, Phelps & Phillips and I work here in Washington, DC. I chaired the Tiger Team over the past few years and will continue to chair this working group as well. Stan, my new Co-Chair, would you like to go next?

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

Sure, thanks Deven, appreciate it. I am Stan Crosley and up until a few years ago anyway, I was the Chief Privacy Officer of Eli Lilly and Company for about 11 years. Prior to that, was in private practice for privacy and technology at a couple of different law firms and then after I left Lilly, since then, since 2009, I've been the Director of Indiana University's Center for Law, Ethics and Applied Research in Health Information, more easily remembered as CLEAR. And then I'm also of counsel to Drinker Biddle and Reath, a law firm in DC.

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

Great. Thanks Stan. Did Deb Bass join after we started? Okay, I know Donna Cryer wasn't joining. Linda Kloss.

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

Yes, good afternoon. I'm Linda Kloss and by background I'm a health information management professional and formerly the Chief Executive of the AHIMA Association, whom a number of members serve as Chief Privacy Officers for Healthcare provider organizations. Since retiring from that, I've been writing and consulting and speaking on my own, particularly focused on the topic of information governance and contemporary health information management practice. I am also serving as a member of the National Committee of Vital Health Statistics and Co-Chair its Privacy, Confidentiality and Security sub-committee. So my Co-Chair, Leslie Francis, was a member and a liaison from the NCVHS Privacy, Confidentiality sub-committee to the Tiger Team and I'm happy to also try to wear that hat as we go forward with the newly constructed workgroup. And I can share a little bit later on about what the NCVHS is currently working on, when that's appropriate.

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

Oh, terrific Linda, that actually...

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

Thank you.

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

...that's great, we will work that in because it's helpful to have that liaison role and to understand what each of the groups is handling since both are really charged by Congress to provide recommendations to ONC.

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

Yes.

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

And I know your mandate is even broader than that, so, that's terrific. I know David Kotz is out, Gil Kuperman, how are you? It's good to have you on the group.

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

Pleasure to be here, thanks very much; hi all, Gil Kuperman, I'm Director for Interoperability Informatics at New York Presbyterian Hospital here in New York City. What I'm involved with mostly these days in my hospital role is helping to put in the information infrastructure to support care coordination and activities like that, whether it's accountable care or Medicaid redesign projects, a lot of which involve exchange of information among providers and all of the activities that go along with that, including the governance activities and privacy and security related activities. So, that's what I'm involved in a lot these days.

From about 2005 to 2011, I ran a health information exchange organization in New York City, a RHIO known as the New York Clinical Information Exchange. And, as I say, when I was doing that we spent more time talking about privacy than we spent talking about technology. And that organization has kind of morphed and merged and is in another form these days, I'm still on the Privacy Committee of that RHIO and on the Clinical Committee of that RHIO, but I don't have an operational role there. And that's about it, I'm also very active in the American Medical Informatics Association, I was board Chair in 2012 and 2013, I'm the past Chair now so, also active there and very happy to be here. Thanks.

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

Great, thank you very much. We're really glad to have you. Manuj Lal, I know he...

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

Hi, folks.

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

Hi. Apologies if I've totally butchered your name.

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

That's okay, it was pretty close, Manuj Lal.

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

Great, go ahead and tell us about yourself.

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

Sure, I'm the General Counsel, Chief Privacy and Information Security Officer for PatientPoint at the Enterprise level. We're a patient engagement company that does health education, population health management, care coordination and a few other things in our new landscape here. I previously served in a similar role with Press Ganey Associates, which is a patient engagement vendor mainly focusing on patient satisfaction. And then previously I served in the Privacy Center of Excellence for Deloitte and Touche's National Privacy Practice and then also worked earlier in my career for a couple of law firms as well as for Allstate's privacy practice as well.

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

Terrific, thank you. Good to have you onboard.

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

Thank you.

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

David McCallie?

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

Yeah, hi, can you hear me okay?

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

We can.

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

Good. David McCallie, I'm one of the holdovers from the previous Tiger Team and it seems like we've got a major upgrade underway here based on the number of very qualified people who are joining the team now. So, maybe I'll just shut up instead of doing all the talking like I used to do. I am Senior Vice President for Medical Informatics at Cerner where I've been for 20+ years. My official duty at Cerner is to run an R&D group that focuses on evolving informatics trends and capabilities that work their way into our product line, but the last couple of years I've seen much of my time focused on outward facing work around interoperability, mostly through the HIT Standards Committee and the associated workgroups and events that are associated with the Standards Committee and the Policy Committee.

So, I noticed the other day that my calendar seems to be almost entirely filled with ONC activities, so I hope I'm not overextending, but it's been a fruitful way to spend a lot of time and the Tiger Team in the past was one of the most fruitful and enjoyable parts of that work. So, I'm looking forward to season two or whatever we're up to of the Tiger Team.

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

Great, thank you David. We'll try to keep it enjoyable for everyone. Mark Sugrue from Lahey? I don't know if he's been able to join us as we once again try mightily to pronounce his name.

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

At least your pronouncing all the same ones I had trouble with. I don't think he's joined, yet.

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

Okay, all right, terrific. I know Micky Tripathi is out. Did John Wilbanks join?

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

I don't see him either.

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

How about Gayle Harrell?

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

Nope.

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

Okay. Then we have some folks from the federal partners, Linda Sanches?

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

Hello. I'm with the Office for Civil Rights. My expertise really is in HIPAA privacy. I was actually on the writing and development team for that Rule way back when and I've focused mainly on enforcement activities over the last 10 years. I recently took on the role of Health Information Technology policy lead for OCR, which means I get to work with you good people on this committee, and I have the opportunity to collaborate with ONC on many projects, such as the Model Notice of Privacy Practices. So, I'm excited to be working with you all.

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

Yes, thank you. We're glad to have you, Linda. Kitt Winter?

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

Hello, I'm Kitt Winter. I'm the Director of the Health IT Program Office at the Social Security Administration. I've been doing this for about five years now to really look to expand the number of partners that are exchanging medical records over the eHealth Exchange. We were the first federal partner to exchange on the eHealth Exchange with MedVirginia, so that was in 2009. And mostly my...I also am the Chair of both the eHealth Exchange Coordinating Committee as well as the managing board for the Federal Health Architecture Board. So, I really bring to the table looking at how to really expand the exchange of medical information as well as addressing many of the concerns dealing with the patient identification and provider directory type of issues.

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

Yeah. Kitt, it's great to still have you onboard. Thank you for joining us, even for the brief time you're able to today, appreciate it. And then we have the staff from the Chief Privacy...office of the Chief Privacy Officer at the Office of the National Coordinator who are with us on these calls. Julia?

Julia E. Cassidy, JD – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Hi everyone, my name is Julia Cassidy and as Deven said, I'm with the Office of the Chief Privacy Officer. I am an attorney by training and I work on privacy policy issues here at OCPO. And I did want to just briefly note something that I'm sure many of you have already seen, the announcement that we will be getting a new Chief Privacy Officer. Her name is Lucia Savage and she is coming to us from UnitedHealthcare where she was the Senior Associate General Counsel. And she will be starting with us this coming Monday, October 20, so we look forward to working with her and getting to know her, and I'm sure she will be joining us at some point in the very near future.

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

That's great news, Julia. I know you guys are also excited about having a new leader, that's terrific. Helen? Is Helen on, I didn't know if she was coming.

Julia E. Cassidy, JD – Office of the Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

I don't think she joined today.

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

Okay and Kathryn Marchesini.

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

Good afternoon everyone, this is Kathryn Marchesini. I'm an attorney and I've been with the Office of the Chief Privacy Officer here at ONC for about four years. I've previously helped with the former, I guess Privacy & Security Tiger Team. I'm currently Acting Chief Privacy Officer for the past three months now, with the transition from Joy Pritts to, as Julia mentioned, Lucia Savage. We are excited for her arrival next week. And I just wanted to echo what both Deven and David McCallie mentioned earlier, we really appreciate the work that this group does and thank you for volunteering your time. I know sometimes it can be intensive, but we at ONC take it very seriously, the recommendations that we receive from this group. And I think Kris from MITRE, later on the call, will talk through some of the areas and the impact that the group has had here at ONC from a privacy and security

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

Sorry about the echo...sorry about that Kathryn, go ahead.

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

So just I guess in closing, we really appreciate everyone's time and dedication to this group and ONC takes the work and the recommendations that the group makes to ONC very seriously. And Kris from MITRE later on the call will talk through some of the areas that the group has made impact...long-term impact from a privacy and security policy perspective.

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

Thanks Kathryn, my sincere apologies for that interruption, I didn't have my mute on and I just was able to log into the site and ended up with that feedback. You have just done a tremendous job at filling in after Joy's departure in the Office of the Chief Privacy Officer and so we're both excited for the new leadership and very thankful that we had your stewardship for these last several months. And we're really glad that we get to continue to work with you as well.

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

Thank you, Deven.

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

Okay, so then I thought we'd just go over what the charge is to the working group. And for those of you who are online, the slide is up, but if you're following along on paper, we're on slide 4. And this charge is developed really by the Chairs of the Health IT Policy Committee, which are Karen DeSalvo, the National Coordinator for Health IT as well as Paul Tang. So we don't have a lot of flexibility with respect to defining the charge, but it's fairly broadly worded. Certainly when we were the Tiger Team we were able to...we found that it covered a great many of the issues that we thought were important to address, and I suspect you will feel the same about this broad charge.

To provide input and make recommendations on policy issues and opportunities to ensure that information captured and exchanged electronically is protected and shared consistent with consumer needs and expectations. Oftentimes the topics that we are asked to discuss come to us either from ONC or from another agency or come to us from the Policy Committee or are sort of part of an overall Policy Committee schedule for handling a number of issues. But we also do have the ability to identify topics that we think are important to address.

And so while later in the call I'll show you sort of what looks like a short term schedule of what we're expected to take on fairly early in our tenure. That doesn't mean that there are not openings and opportunities for each member of this Privacy and Security working group to suggest topics and for us to have a discussion about whether we would formally add them to our agenda. And so as you'll see, some of the issues that we're going to take on in the more immediate timeframe include any issues around privacy and security that crop up with respect to the Health IT Policy Committee and ONC's effort to address the challenges of interoperability in health information exchange. But we are also being asked to take on the issue of big data and privacy in healthcare.

So before we jump into the schedule, just a couple more sort of introductory remarks on the next slide, which is slide 5. The original group, which was the Tiger Team, was formed in 2010, so about a year into the work of the Health IT Policy Committee. And the objective was to enable very quick progress on a number of privacy and security issues that were of immediate importance to ONC. In fact, we were called the Tiger Team because our initial charge in 2010 was to come up with recommendations related to consent for electronic health information exchange and to do that within a 3-month time period. And that was in the summer of 2010.

We have thankfully not been under such a tight timeframe for any complicated issue since that time and we've been able to largely remain with a schedule of phone calls that are about two times a month, with an occasional add-on in order to clean up some issues in advance of a Policy Committee meeting. But we really do try to stick with a schedule. We have some meetings on the calendar already for the remainder of 2014 that we'll be using for this group, but we'll have a new schedule that will be set probably relatively soon, for 2015.

And so this is sort of the infrastructure here. You've got your co-chairs, Stan and I. We are staffed by the Office of the National Coordinator, but also with MITRE, who provides us with technical assistance in preparing for the calls and enormously helpful. We've had their assistance for several years now, I don't know how we would get all the work done that we get done without them and without ONC and then, of course, all of the members. We make recommendations to the Health IT Policy Committee; we do not have a direct conduit to ONC or to any agency. Anything that we come up with as a recommendation, we essentially have to convince the Health IT Policy Committee to adopt it and forward it on to the relevant agency, most of the time ONC, occasionally CMS and OCR, then OCR's oversight over HIPAA and CMS's oversight over the Meaningful Use Program. We also did once submit public comment to the Office of Human Research Protections as part of an open RFP. That's an example of somewhat of an internally generated issue that we decided to weigh in on.

So on the next slide, these are some of the...which is slide 6. So these are some of the core values that we...that have been really sort of have formed a foundation for a number of the recommendations that we have made over the past 3-4 years. These have helped us reach consensus around a number of very difficult issues. Usually they have led to much more detailed recommendations that are appropriate to the particular use case or context that we're talking about, so they're meant to be sort of broad and overarching.

But I also think with a brand new group, if there is any one particular core value that's implicated in any discussion we have about any recommendation, we may decide to put our own spin on it or to add a different core value or to make a modification. But I thought it would be helpful for you to see at least those core values that were pretty central to the work that was done at least over the first several years on the topic of privacy and security for the Health IT Policy Committee.

They are as follows: the relationship between the patient and the healthcare provider is usually the foundation for trust in health information exchange, particularly with respect to protecting the confidentiality of personal health information. And that as key agents of trust for patients, providers then are responsible for maintaining the privacy and security of their patients' records. This is not always an easy job for providers to take on, but it is who patients typically look to with respect to exchange of their information. We must consider patient needs and expectations.

Patients should not be surprised about or harmed by collections, uses or disclosures of their information. This patient should not be surprised principle is one that has come up a lot in some of the work that we've done. And that ultimately for health information exchange to be successful and improve patient care and healthcare generally, we really need to earn the trust of both consumers, or patients, and physicians as well. There is a very heavy physician/provider emphasis in these core values. To date, most of the issues that have come onto our radar screen have been ones that have some tangent to the...or some connection to the Meaningful Use Program and so our recommendations have tended to be more relevant to how healthcare providers collect and handle and disclose information and how they share it with patients pursuant to both Meaningful Use and Patient Rights of Access under HIPAA.

Okay, so before I talk about sort of what some of the topics are going to be for our initial tenure, our initial year, I wanted to see if anybody has any questions about anything that we've gone over so far?

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

Deven, this is Linda Kloss.

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

Hi, Linda.

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

I have a question with regard to the charge. It wasn't clear to me whether this charge was changed in any way in the restructure, in the migration from Tiger Team to Workgroup, or is this the charge as it's been consistently presented?

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

I think it's changed, Michelle?

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

Yup, all of the charges for all of the workgroups have changed and been updated to align with ONC's strategic priorities.

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

Because it's so focused on interoperability and perhaps it was...that seems to be very central and I wondered if it had always been.

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

Probably a greater emphasis than in the past.

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

Yeah. Yes.

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

And then secondly, as you review the core values, I presume it's possible for the workgroups to consider adding core values or struggling with that as it relates to this upcoming charge on big data.

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

Yes, absolutely Linda, and that's a really good point. These core values did not...we didn't spend an initial discussion of core values and set them up in advance of having any particular discussion on any set of issues. They sort of arose out of the deliberations that we were having on a particular set of challenges, like the consent discussion that I referred to earlier is one where frankly all of these core values were initially established. And then we then relied on them to deal with different sets of issues, but that's where they arose. And so I think it's quite possible that we would want to add some and/or refine these as we take on particular issues like big data. I think that's a very good point.

Any other questions? Okay, well we'll go to slide 7 then. So with respect to our work plan, so this is our kick-off meeting, we're not planning on diving into any issue of substance today, we'll begin that on our next call. And we have been asked by ONC to take a look at and develop recommendations for a legal and technical framework to address the challenges related to the privacy and security of big data in healthcare. And that is a big topic, but it's a very important one. One that the White House has spent some time thinking about, one that PCAST has spent some time thinking about and one that is arguably very critical to achieving a number of healthcare reform goals.

It's a big topic, it has a lot of dimensions. We're fortunate to have, I think, some very good expertise on the workgroup that will help us think through these issues, but it very well may be the case that we will want to do some outreach to others to give us testimony or feedback or to help us think through the range of issues. And the way that workgroups typically do that is through...sometimes through face-to-face hearings, although we haven't done as many of those lately, they're a little more expensive to pull together. So more recently we've been relying on online hearings or listening sessions where we ask people to come and talk to us and that helps to both educate us and augment our expertise in areas where we think that there are gaps. And so I don't want to go too much into this topic on today's call, we'll have a substantive slide deck to really kick off the discussions on this topic on our next call, which is later this month. But I did want to give you a preview that this really is the first topic that we'll be expected to take on.

Other topics that are in our near term agenda include comments on the Federal Health IT Strategic Plan, which is being developed and will be issued by ONC, the Notice of Proposed Rulemaking for Meaningful Use Stage 3. The published version of the Interoperability Roadmap that ONC is developing, so this is the version that will go out for public comment and we'll have an opportunity to talk about that. And then the last topic, which is one that the Tiger Team had intended to get started on just before we made the decision to reconstitute the groups and bring some new people on board, is the issue of minors, adolescents, young adults and the special protections on their health information.

It's a big topic. One of the things that we will probably need to do when we get to this is to define the parameters under which we will consider that issue. But we didn't want it to sort of disappear off of our agenda, since we had planned to take it up and actually had a very introductory call on the issue, one call, as part of the previous Tiger Team. So, we're going to turn to that renewed, with our new group, in time although probably, as you'll see in a minute, not for several months because these other issues have more of a sense of timing associated with them.

So if you go to the next slide, which is slide 8, you'll see a schematic of sort of projected working periods for each of these issues. And you'll notice that there is some overlap, we may while we're taking on big data, for example, have to do a little back and forth with some issues that have more hard deadlines associated with them, for example the commenting on the Federal Health IT Strategic Plan, which we will probably need to return comments on by the end of the first quarter of 2015. So we may need to do some multitasking with our Big Data Initiative; similarly with Meaningful Use Stage 3 NPRM and commenting on the published version of the Interoperability Roadmap.

So you'll see there that the minors and adolescent issue is really reserved for spring to late spring of 2015, assuming that we are actually able to get the big data work that we want to do done by the projected due date of March 2015, and that's really a projected due date. We could take more time on that issue if we need to and none of these are sort of in order of sort of importance necessarily. I don't want anybody to think that because minors is last on the list that we don't think it's important, it's just there is only so much multitasking that any of us can do and we don't want to give any issue short shrift. So we will need to turn to that when some of the other issues that we have, we've cleared our decks.

I think the next slide might be on a bit of a schedule, too. So the next slide actually sort of starts to map some of what this might look like in terms of our calls. So we have our initial call today. Tomorrow there's a joint meeting of the Standards and Health IT Policy Committees to discuss the Interoperability Roadmap. We'll start our next call on October 27 with a bit of a summary of the Interoperability Roadmap briefing that's going to occur at that meeting tomorrow. But we really will take the bulk of the call to get started on the big data and privacy issue and we'll keep with that issue through November.

Now the December Health IT Policy Committee meeting is when other working groups that are specifically tasked to comment on the initial draft Interoperability Roadmap will be making their recommendations to the Policy Committee, we will largely still have our heads buried in big data and health privacy. But we, as you'll see in December, we have to make a bit of a transition to comment on the Federal Health IT Strategic Plan and we may need to be on that through the end of December.

Does anybody have any questions about the schedule or the topics that we have teed up?

Gayle Harrell, MA – Florida State Representative – Florida State Legislator

Deven, this is Gayle if I could jump in. I just got on the phone about 5 or 10 minutes ago, so I haven't heard all your discussion.

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

Hi, Gayle, thank you. Great, we did a little bit of introductions in the beginning of the call which I'm sorry you missed, but since you're on now, can you introduce yourself to the other members of the workgroup?

Gayle Harrell, MA – Florida State Representative – Florida State Legislator

Sure. I'm Gayle Harrell, I'm a state legislator from Florida. I have a background in health IT in that I ran a large medical group for many years and we were very early innovators in the process, way back when it was cutting edge stuff, but have been very involved in healthcare policy, both at the state level and the federal level. But my question really has to do with, I notice on the work plan and all the topics you've just gone through is, you have not really looked at the recommendations that are going to be coming out of the JASON Task Force and I know that, being on that, I know there are going to be some things. They did not really discuss privacy and security issues and there is a real gap there in what they did not discuss and I notice it's not on this work plan, to really look at they're coming forth with some recommendations on APIs.

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

Yeah.

Gayle Harrell, MA – Florida State Representative – Florida State Legislator

So I didn't know if you are going to address that in any way.

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

Okay...

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

Deven, do you want me to speak to that or do you want to, sorry?

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

I was going to ask you, Michelle. Go ahead.

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

Okay, so Gayle what we have decided to do is we have asked a few members from the JASON Task Force to continue on with the Interoperability and HIE Workgroup, who will be charged with informing the Interoperability Roadmap using the JASON Task Force recommendations and the governance recommendations that will be reviewed at tomorrow's joint meeting. So Deven has actually been asked to stay on the group and provide a privacy and security perspective and also provide continuity to this group, just in case there is something that needs to be brought back to this group. Hopefully we don't need to divert you from your big data discussions, but there could possibly be something, so if there is, we'll bring it back here.

Gayle Harrell, MA – Florida State Representative – Florida State Legislator

Okay.

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

And the same goes for David McCallie, who is also on the phone, will be the liaison for the Architecture Services and API group, as well as Arien, who's actually on the Interoperability and HIE Workgroup.

Gayle Harrell, MA – Florida State Representative – Florida State Legislator

Okay, thank you, I was very concerned about that.

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

Yeah. Good question, Gayle. And does anybody else have any questions about the schedule or topics?

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

Deven, its David, just one elaboration on Gayle's concerns; you and I had some brief conversations about one of the JASON suggestions that really isn't so much about the APIs, but is about elaborating on a patient's right to decide how their data gets used, particularly with respect to the research community.

Gayle Harrell, MA – Florida State Representative – Florida State Legislator

Oh yes.

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

And you and I had some informal conversations that we might...some of that might flow into Tiger Team work at some point, so, maybe Michelle's thought is that it would go through the IHE Workgroup first, but there were some that were really very much fundamental, they're not even HIPAA issues, they're Common Rule and the like. So, just remind you that that's out there somewhere to be corralled at some point, that thought.

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

Yeah, no, absolutely and it could be that our conversations about big data in healthcare will bring us opportunities to take on that issue. Because the big data uses do, for many folks, big data in health is just another way of describing research uses of data. Again, when we start really digging into the substance of this, we'll talk about sort of how is big data defined and what does it mean and how do we want to scope it out. But research certainly reuses of that data for learning purposes, which is customarily what we've considered to be research or one facet of research, is part of that. So I think we'll have opportunities in that discussion to touch on some of those issues as well.

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

Good, that makes sense. Thanks.

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

Anything else? Okay, I'm going to turn this over to I think it was MITRE that was going to walk us through just some summary slides of sort of the impacts that we as a working group have historically had on ONC. Yeah, so Kris Miller of MITRE is going to take us through this, mindful of time, since we decided to truncate this call for just an hour and we still need to leave a little bit of time at the end for public comment. Did I leave you enough time Kris to at least give an overview?

Kris Miller, LLM, JD, MPA, CIPP/G, CIPP/E – Principal Privacy Strategist, Enterprise Strategy & Transformation Division – MITRE Corporation

I think so. Thank you very much, Deven, can you hear me?

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

Yup.

Kris Miller, LLM, JD, MPA, CIPP/G, CIPP/E – Principal Privacy Strategist, Enterprise Strategy & Transformation Division – MITRE Corporation

Great. Thank you. So as Deven mentioned, my name is Kris Miller, I'm with the MITRE Corporation. I'm also assisted by Iona Miller, formerly Iona Russell, who also assisted my predecessor at MITRE, Linda Koontz, who worked very closely with this workgroup since its inception. And essentially MITRE's role, as Deven mentioned, is technical support and helping put together some of these meetings and doing the research. And what I'm basically going to do, I'll run through the next few slides very quickly, but I wanted to kind of put them in some context for everybody who may be new.

This workgroup is a very special workgroup, it's a good workgroup and if I could stick to a theme, it's that this group has addressed a lot of complex issues first and second that the workgroup has been very productive and had a lot of really good impact. As Deven mentioned, the workgroups purpose here, the charge is to convince the Health IT Policy Committee with some of these recommendations and submit them to the Policy Committee and 95% of the workgroup's recommendations have been adopted by the Policy Committee. And of those, 154 recommendations have been ultimately approved by the Policy Committee and transmitted on to ONC. Six actually were withdrawn, but that's because ONC had already taken action to address them.

So the impact is very significant for this workgroup and the range of the issues, as Deven mentioned, have been quite broad; 55% of the recommendations, that's about 85 recommendations, were dealing with that initial issue, the consent and the meaningful choice. But also there have been 12 recommendations on topics like authentication, identity proofing, another 12 recommendations dealing with digital certifications and verification and another 12 recommendations on query and response. So it's a lot of diversity there. In addition, the recommendations as they relate to the ONC Privacy and Security Principles, about a third of them have dealt with safeguards and this particularly is important because it goes to that concept that Deven also mentioned earlier, that patient-centric focus on trust and that's where a lot of these recommendations have been shaped by the values and by the topics that have been addressed.

This slide is essentially just an example of some...one issue and some of the impact. And if you look here, starting at the bottom, March 2010 was the Policy Committee recommendation to include in Meaningful Use Stage 1 the requirement that eligible professionals and hospitals conduct a security risk assessment under HIPAA and that ONC should provide appropriate guidance. A little bit later, by July, HHS released Meaningful Use Stage 1 Rule requiring professionals and hospitals to attest to having conducted the security risk assessment in order to receive payment. And by February, just a few months later, ONC released the Security Risk Assessment Tool to Regional Extension Centers. So this is an example here where the recommendation has kind of flowed up, it's become actual policy and then the workgroup has helped to shape some of the guidance that ultimately gets transmitted. Next slide, please.

So this is slide 11, and again, this is just another example of some of the impact. These are the Program Information Notices that the workgroup has helped ONC come up with, again, when ONC needs to provide some program guidance. Next slide, please.

And here, this might be helpful for some of you, too; these are individual links. And so these are sort of impacts that the workgroup's recommendations have had on ONC projects. And so we see up here Data Segmentation for Privacy, the eConsent Trial Project, which again it kind of ties back to consent and meaningful consent and the project particularly coming up with short videos in the pilots that were run. Video's to educate the patient at the point when their consent was being collected, that they were making a conscious decision and they were well informed. And the other ones on here that you see have an asterisk next to them, these are the ONC projects that were directly influenced by Privacy & Security Workgroup or formerly Tiger Team recommendations. And so you can actually go, after this, and click on those and go get a little bit more detail. Those are all hyperlinked.

Next please. And as well as these, if you click on these, these are hyperlinks. So this is sort of the annual report, and the first one that was produced was this past year. You'll see there's an executive summary, a slide deck with some of that data that I mentioned earlier, kind of the breakdown. One of the things that we've been doing for ONC is collecting all the recommendations in a spread sheet and tracking them. And you can see some of the data and how it's worked out there and the different issues that we've covered and the different privacy principles that have been addressed. And that infographic is there as well, for your consumption.

So finally, these recommendations, the main thrust of what the workgroup does, in the end they really help to reinforce that trust relationship between patients and providers. So, you're on this workgroup. This has been sort of a model workgroup, I think, for a lot of the...both the Policy Committee and the Standards Committee workgroups. This has been very impactful work so you should enjoy this time and realize that this is very beneficial to ONC, it's beneficial to the country and all the work is taken very seriously. And that's all I have, Deven, unless you had anything to add.

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

No, I didn't although I have to admit I'm feeling a bit sheepish about how much we've patted ourselves on the back on this phone call.

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

Hey Deven, this is Stan Crosley and I was just going to say, at least you set the bar low. That is a pretty impressive body of work that you've accomplished over the last year.

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

Well, you know, we thank you on behalf of some of the members who remain on the group who are also to thank clearly for all of this. But we do this mostly so you understand that it's not just one of those in name only groups.

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

Right, no, I think it's really good for those like me who are new to the workgroup. I think it's great to know that there's impact, right. You join a lot of workgroups where you call in, you wait for the next call and this is clearly a workgroup that has a serious agenda and a good work ethic and really produces some valuable material, so that's great to be a part of.

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

Thanks Stan. Do you have anything else you want to say, Stan? Or does anybody...because we're sort of reaching the end of the call, and I talked a lot...

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

For me, I'm just glad to be a part and I appreciate the opportunity and looking forward to working with everybody.

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

Great. Thank you. You will be talking more in subsequent calls. Anybody else have any thoughts or questions before we turn to public comment? Okay, great. Michelle, we're ready for the public.

Public Comment

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

Operator, can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

If you are listening via your computer speakers, you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the 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

We have no public comment at this time. So, I also want to thank everyone for agreeing to participate in this group and I look forward to many more successful calls going forward. So thank you also to Deven and Stan for agreeing to Chair this group and I'm excited to see you all, or some of you all tomorrow at the meeting.

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

Okay. Thanks a lot Michelle. Take care everybody.

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

Thank you everyone.