



**HIT Policy Committee
Privacy & Security Workgroup
Final Transcript
May 18, 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 the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Deven McGraw?

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

Here.

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

Hi, Deven. Stan Crosley? Adrienne Ficchi? Bakul Patel? Cora Tung Han?

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

Here.

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

Hi, Cora. David Kotz? David McCallie?

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

Here.

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

Hi, David.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Hi, Linda.

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

Hi.

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

Manuj Lal? Micky Tripathi? Sarah Carr? Stephania Griffin?

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

Here.

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

Hi, Stephania. And Taha Kass-Hout?

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

Here.

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

Thank you and from ONC do we have Lucia Savage?

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

Present.

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

Hi, Lucia. Kathryn Marchesini?

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

Here.

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

Hi, Kathryn. Anyone...oh, and Debbie?

Debbie Bucci – Office of Standards & Interoperability – Office of the National Coordinator for Health Information Technology

Yes, I'm here.

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

Hi, Debbie, anyone else from ONC on the line?

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

Helen Canton-Peters is here.

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

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

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

All right, great, thank you very much, let's go to the next slide. Okay, so we had hoped to be able to pick back up our discussion around health big data and beginning to drill down on what our recommendations might be to maximize the opportunities from health big data and to minimize the risks, but we were asked to further refine the recommendations that we put forward for Meaningful Use Stage 3 particularly on the issue of privacy and security issues related to increasing patient access to data either through view, download and transmit or application program interfaces, otherwise known as APIs, and I'll provide a little bit more detail on some of the feedback that we got and we'll go through some slides again where Stan and I have suggested some refinement of our recommendations so that we can pass them through the Policy Committee again and see if we were not a bit closer to what they were hoping we would deliver.

And then hopefully we'll have some time to begin to pick back up on the discussion of health big data. Mostly to refresh everyone's memory about where we were and where we left off because it's been several months since we had that topic on our agenda. So, with that let's go ahead...we can stay on this slide actually now that I think about it.

So, let me give you a little bit more detail. The bottom line is that the committee or at least some members of the committee were a bit concerned that the recommendations relied too much on guidance, that they were...they didn't disagree with us necessarily that guidance would be helpful, but I think it felt a little empty since guidance was the recommendation, the set of recommendations that received the most amount of discussion and focus for us, we had that recommendation on certification but I think that it got a little lost in the discussion around guidance.

There was...for those of you were either present or listening on line there was sort of a bit of frustrating moment for me and Stan and probably also for ONC where there was clearly a lack of satisfaction with what we had delivered in terms of recommendations but not a lot of clear guidance about what they wanted us to look into further.

But I was subsequently approached by members of the Policy Committee during the lunch break, we presented before lunch, who said they would like to see more on the idea of having a voluntary certification process for patient-facing Apps.

And so we have delivered...what you'll see in a minute we've developed some straw language that tries to flesh that out in a little bit more detail but essentially also calls for more work to be done to flesh it out. Because the deadline that we're operating under for Meaningful Use is the comment deadline for the NPRM and this is not an issue for which, you know, whether there is or isn't a Meaningful Use objective is necessarily in the balance.

I don't believe there was...there might have been...there was some discussion at the Policy Committee about some of the details around the patient engagement objectives for Stage 3 but there was...no one was suggesting that we not move forward with patient engagement objectives that involve view, download and transmit and/or the application...the API approach it was more along the lines of how do you manage the privacy and security aspects of that for which frankly the ability to do something about that does not expire with the NPRM because it's something...it's an issue that got surfaced by the Stage 3 NPRM but it doesn't necessarily need to be resolved in order for there to be a final Stage 3 rule although it certainly would be nice to have a process in place for having something occur.

So we have some language that both fleshes out guidance and the certification idea a little bit further which I want to discuss with the Workgroup today and then we can move to...if we've got time, we can move to big data.

So, I think that in a nutshell was what happened, nobody else suggested anything more concrete for us to consider, I invited other members of the Policy Committee to send Stan or me an e-mail or ONC an e-mail and essentially the certification idea was one that they wanted to see a little bit more from us on. At any rate it was a bit of a frustrating morning, but I think we're going to get through this.

We have a Policy Committee call scheduled for Friday to essentially bat clean up on some of these NPRM issues that were not fully resolved at the Policy Committee meeting last week and this is one of them. Did I leave anything out Lucia or other ONC staff members or anybody else who was either present at the committee meeting or listening on line who picked something up in the discussion that I missed?

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

Deven, this is Lucia, I don't think you left anything out.

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

Including the frustrating part?

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

You know I was thinking that the Mandarin Character...it was always explained to me that the Mandarin character for change means opportunity and I'm sure there is a correlation between frustration and creativity too.

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

Yes that's a good point, that's a good point. So, another bite at the apple that's not necessarily a bad thing.

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

Hey, Deven, it's David.

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

Yes, David?

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

Can you clarify what was the frustration about? Was the...I'm just curious; obviously we need to react to whatever was frustrating people.

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

Well, I think that folks felt that the guidance felt a bit empty to them. They wanted something more. But what was frustrating David was that nobody was specifically saying what they were looking for.

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

Yeah.

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

And that's what was frustrating is, you know, initially what I was told was "well, go back to the Workgroup and talk about this some more" without any direction. It was like...and what was frustrating was, well, we talked about it and we think this is a good...

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

Yeah.

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

Set of recommendations.

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

Well, and David, this is Lucia, I think guidance means a lot of different things to a lot of different people, it's somewhat based on context and somewhat based on the authoritativeness or the force of a law with which the guider acts and I think that was a source of frustration because people had different ideas in their mind and nobody could just say "let's do this."

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

So and that remains the state of things, guidance is that way, different people have different authorities to issue guidance that has different forces.

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

But one could obviously say that voluntary things have the same constraint like they either happen or they don't.

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

I mean, what's...that's where I'm puzzled by what's the difference.

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

Well, I guess what I took from the...

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

...

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

I'm sorry, what I took from that was certainly at the minimum a desire of the Policy Committee to understand better the pros and cons of a voluntary approach and whether it was feasible. And there is a lot to be said about that.

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

Yeah and didn't...my memory is that we discussed that and we talked and we enumerated some exemplar organizations that have arisen in the private sector that voluntarily certify the accuracy of health related websites and I think we said that we assumed that would in fact happen with respect to Apps.

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

Well, maybe that kind of detail is what was needed, you know, I didn't for example specifically raise the trustee example because I didn't think we needed to get into excruciating detail about what that program would need to look like in order for them to endorse setting off in that direction...

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

Yeah.

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

But we can and when we get to that language maybe in fact there are ways that you all will see that we can beef it up even more.

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

Was there some sense in which they thought the voluntary program should be coordinated through government channels or public/private kind of voluntary or was that...

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

Well, you know, David, if in fact we had a more pointed discussion about the certification program at the committee all of that might have come out.

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

Okay.

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

But in fact none of that was surfaced during the committee meeting.

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

Okay.

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

That is was just publically go back and see if you can't give us some more on this.

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

Okay.

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

Without a whole lot of guidance or a whole lot of additional time. So, you'll see what we're proposing is to start a process for investigating that certification...what a certification initiative would look like and to recommend that this get started but not tie it to the constraints of having to have it all fleshed out before the NPRM deadline.

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

Okay.

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

All right, well, let's go ahead and jump into this. So, the next slide is just a repeat of a slide that we put before the Policy Committee and that all of you have seen before that sort of identifies that the risks around privacy and security are both those that are experienced by the healthcare providers who are offering patients the opportunities to connect, download and transmit or APIs and then on the patient's side. And so these risks are experienced in similar and different ways by a multitude of stakeholders. Next slide.

So, you know, again, in the previous material we put before the Policy Committee we were clear that we supported the proposal for increasing opportunities for patient access through both VDT and open APIs but that we had concerns about the potential privacy and security risks and have added sort of a summary slide here that what we were recommending here is a mixture of timely and meaningful guidance for consumers and healthcare providers, and vendors, as well as a certification effort and I put certification in quotes only because, you know, frankly there could be other sort of accreditation or other types of programs that would meet the same goals as the certification process would, we talked about it as certification initially but potentially it could be a bit more open ended than that, but in an effort that facilitates a way to differentiate mobile tools that meet stakeholder needs with respect to privacy and security, and usability.

Usability is not our province but it is the province of the Consumer Empowerment Workgroup and they have had some concerns about some usability issues and are interested also in creating a process for vetting Apps that is not just about privacy and security but also includes other aspects of importance to consumers and providers in rolling out these interconnecting technologies. Next slide.

So, what we've done is to try to streamline some of the wording on the guidance because I don't think that we were told that...I mean, we feel strongly I think as a Workgroup that guidance, that good guidance put out in a timely way would still be really helpful in this space but some of those messages may have gotten a little bit lost because we did have a lot of text on the slides so we tried to streamline it acknowledging that ONC is already working with the Federal Trade Commission and OCR to develop mobile health best practice guidance for developers, which will eventually promote protection of user data.

Linda actually, Linda Sanches, you can tell us if OCR is involved in this effort because this language is from a previous bullet where it was combining both the guidance around HIPAA and the guidance around sort of more FTC oriented domains into one so it maybe that we need to clean this up a little bit, but acknowledging that there is some mobile health best practice guidance already in the works and, you know, that what we've urged here is that the agencies work quickly, ideally, sorry about this guys, to widely, you know, to get this guidance out so that it's useful for Stages 2 and 3 of Meaningful Use because that's when patients are going to, you know, begin to be offered opportunities more...more opportunities to be able to access data through EHRs and create connections through APIs especially in Stage 3 than is the case today.

And so guidance would include the guidance for App developers on best practices for protecting the privacy and security of information collected by the App as well as connecting with EHRs that are covered by HIPAA, this is something that John Wilbanks, one of our Workgroup members, had brought up on a prior call.

But we also do need guidance for patients, consumers and providers and the guidance would include a check list on what consumers should be looking for when they look at a privacy or a data use policy, or even mechanisms for consumers to be able to compare privacy policies across Apps which was a feature that was in a model PHR notice that ONC developed and disseminated several years ago but that is not a tool that's very widely used today and it could have been that it was released really before the need for it was as large as it is...that it arguably is today. So, next slide.

Then the third prong of guidance is the guidance that ONC and OCR would ideally work on together that addresses the intersection between the Meaningful Use patient engagement objectives and the certification requirements and HIPAA patient access rights, because I think...I know from talking even with folks in the field that this is a big issue, this was something that was on our previous recommendations but maybe not...we tried to sort of streamline it a little bit, again, ideally needed to help providers in Stages 2 and 3 of Meaningful Use and the issues include how the security risk assessment requirement needs to be done in order to evaluate connections with patient Apps or devices such as through the API and the extent to which a provider may reject a patient's request for electronic access due to a perceived security risk for the provider.

Paul Egerman talked about an App that he had seen available through the Apple Store that claimed to be able to connect to a number of healthcare providers including the Palo Alto Medical Foundation which is the home of Paul Tang, the Chair of the Policy Committee, and of course Paul Tang was not...the App was not identified by name, but Paul Egerman had looked at the App and was very concerned about the policies for use of the App, I don't know whether he also sort of investigated it more thoroughly in terms of attempting to use it, he is a software entrepreneur and has some experience in developing software so he may have cracked it open and really peaked under the hood, but he had some very, very significant concerns that he shared with the Policy Committee and so, you know, we had talked about this as a Workgroup, the ability of a provider to not connect with an App where that App would introduce potential security risks for the healthcare provider and that being an issue that would be helpful to have additional guidance on for healthcare providers.

And what is the extent to which a provider may reject a patient's request for electronic access in the absence of a security risk. So there is nothing in the patient's device or the patient's App that would cause a security concern for the provider but the provider is nevertheless not terribly happy with that App, but is that...what are the HIPAA rights to say "no" if any and how, if at all, does that intersect with Meaningful Use.

And then the ability of providers, sorry about the typo there, to charge fees for Meaningful Use access which is definitely something that I have heard not something that we've discussed a lot in the Workgroup but there isn't actually a single thing on these three prior recommendations that wasn't already part of our recommendations, but just trying to streamline them a little bit more. And then on the...

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

Deven?

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

Yes?

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

Are the slides we looking at right now the ones that you presented to them or are these the ones that you have reworked?

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

I have reworked them.

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

Okay, okay and was there any discussion about the fact that with the view, download and transmit none of these issues were addressed either?

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

We did say that and in fact, so next slide, we point out that we had previously issued recommendations urging specific guidance to healthcare providers participating in Meaningful Use and vendors of certified EHR technology to help them manage the risks of view and download and that the guidance should be updated to also address the risks of transmit and issued in time to assist providers and vendors in responsibly making VDT and APIs available to patients as part of Meaningful Use and here's what the guidance should address. So that was also...this was also part of the prior recommendations.

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

So, David, this is Lucia, to clarify, this is a compilation of all the recommendations that have been made historically up to last week.

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

And this compilation was in the deck last week.

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

Yes.

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

Both of those are true.

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

Right, but it says...it sounds like Paul was raising questions about a needing for a security assessment of an App but we don't require that of the consumers computer at home where they download a copy of their record.

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

Well, I think what Paul...

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

So I think the inconsistency is, you know, what I'm interested in.

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

Right. Yeah, I think what Paul; if I could translate a little, I think he was saying "tell us why we shouldn't be worried about this."

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

Or "tell us if we should be worried about this." So, actually to resolve something that, you know, if you looked at it the wrong way you'd say "oh, they want security assessments of things consumers choose to use on their own" and they...what you just said versus "should we be worried about not permitting technology to connect through our...to our EHRs through the view, download, transmit portal that hasn't met some relevant criteria." And I'm not saying what those criteria would be or whether there should I'm just trying to tease up the question.

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

Yeah and is the context for these worries strictly limited to privacy and security issues and not at all connected to for example bad medical advice or...

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

I can't speak for any particular individual. I can say that with Linda Sanches's help Deven did an excellent presentation about how the HIPAA right of access works right now and a provider, Linda maybe you want to jump in here, but can decline access when the vehicle of access causes a security problem for the provider's system...

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

Right, right.

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

Like say a thumb drive with a virus on it.

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

But not when the provider thinks that the person to whom the patient wants to send the data is, you know, not a good doctor.

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

Yeah, yeah, okay, because that's where the real risks come from.

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

That's a fine description.

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

Linda, were you trying to say something?

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

Yes, I was saying that you did a fine description.

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

Okay, thank you.

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

Whew.

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

Well they're really good slides and we did point out to the Policy Committee on Tuesday that...I think I gave the wrong date Deven, but the slides were out on the Workgroup's...on hit.gov, healthit.gov for the Workgroup and people would go get them. They were very good slides and they are just a really concise explication of how that rule works and it was helpful I think for the committee members who were there from the Workgroup, but maybe we just need to drive that content farther out into the stakeholder's universe.

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

Yeah, I mean, I suspect and this is no...I mean not intending to be disrespectful to ONC, but I suspect that one of the reasons why there was some pushback on the idea of guidance is that at least with some guidance it takes a long time and we had this recommendation from back in 2011 and it wasn't clear that it had resulted in guidance for Stage 2 at least not in a tangible way that people could figure out where it was. So, I think that may have been partly the rationale for why, you know, while guidance is perfectly fine and important it may not be enough, it may not address all the issues, it may not be as timely as we might hope depending on the type of guidance and how quickly it can get out and that's just, you know, a fact of life, but, yeah.

At any rate, let's go ahead and move to the certification slide which is the next one. And here is where we did the most amount of work from a wordsmithing stand-point in trying to both flesh this out but also take an approach that calls for additional work to be done on this issue rather than trying to resolve all the questions at this juncture given the looming NPRM deadline and the fact that we don't have a lot of time to really work through what could be some potentially thorny issues, but acknowledging that timely guidance while maybe needed, but in our view is probably not enough, and calling for further exploration of a multi-stakeholder including industry and patients developed voluntary.

I'm still calling it a certification program here, but I welcome feedback on whether we should be more open ended about that or if we should even be more open ended about the voluntary aspect of it, but a program for patient-facing Apps that will just provide an extra measure of education beyond just guidance but allow for, again that differentiation or the ability to differentiate among...that we talked about in earlier slides, and that the effort would address both the privacy and security protections as well as usability.

We might add some other factors to this that it would leverage guidance that was developed by federal entities, as we called for, acknowledging that while the effort is voluntary that the Federal Trade Commission, under its existing federal trade, FTC Act authority, can enforce voluntary best practices for those who adopt, certainly welcome feedback from anyone on that one including the FTC, that the Consumer Empower Task Force with assistance from our Workgroup should continue the work to flesh out the details on this program considering issues such as whether it should including testing, because that maybe the hallmark of a certification effort versus, you know, a set of best practices or a set of...or an accreditation program, you know, the certification technology, at least as we know it, in the EHR space involves, you know, really robust testing, is that what we're talking about.

What should be the role of ONC and other federal entities in this program? What about costs and potential impact on innovation and it could be in fact that this effort really ought to be one that isn't just, I was thinking about this earlier today, isn't just one of consumer empowerment and our Workgroup but also certification and adoption if in fact, you know, the idea that this is voluntary...let me rephrase that, that maybe there ought to be some connection to the EHR certification effort and potentially the Meaningful Use Program and if that's the case then there is probably a role for the Certification Workgroup to play in this as well in the way that they have delivered a lot of very good recommendations on both the formal EHR Certification Program for meaningful users as well as the voluntary effort that they endorsed for behavioral health providers who are not eligible for Meaningful Use incentives.

So, I just feel like there are so many different...it's a really interesting and good idea that needs more fleshing out and what I've tried to do is say, we should flesh this out, we should take the time to flesh this out there are sort of multiple Workgroups that might be interested in this, privacy and security as has been pointed is really just one aspect of this. There are other aspects of it and this should...but if this idea is one that the committee, that our Workgroup and the committee really likes it's going to take more time to flesh out what it would ideally look like. And so now I'm just going to...I'm opening it up to comments.

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

So, Deven, this is Lucia, I think that...and I don't know if it belongs on this slide or not but I want to go back to what I said at the Policy Committee. There are a lot of actually moving parts about this that are government works in progress.

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

Yeah, which is great.

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

And when they become...once they become ready for people like you guys to know more about trust me we won't keep them secret that's not really our style. But, you know, when we're working on something and we can't talk about it we just are working on it and we can't talk about it.

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

Well, I know.

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

But this issue of the complexity of the Internet of things and mobile Apps, and who is responsible and what are safe practices despite legal responsibilities or absence thereof it's kind of...you just have to open the, you know, press for our life, for Health IT and you'll see it.

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

Deven, hi, this is Linda Sanches, I just have a quick question and I apologize if you talked about it earlier and I missed it, but what is the motivation or the incentive for an App developer to go for this voluntary certification?

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

I think an App that wants to essentially do a good job on protecting privacy and security and wants to be recognized for that so that it can differentiate itself on that point with its potential customers would be interested.

If guidance to healthcare providers included a list of Apps that had been or linked to a certification process where providers would have a place to point to if their patients want to get advice on Apps or to be able to compare them that this is potentially one motivation.

I'm not sure honestly I think it probably depends on what the...whether there are in fact incentives to pursue something because it allows either...it's a market differentiator or it might enable your App to be a more preferential vehicle for, you know, providers and Meaningful Use not that the providers use it but in terms of, again, counseling patients.

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

So Linda...

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

I think those are good question.

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

Linda, one of the things that is always pitched to ONC about this is it sort of becomes the idea would be that it would be, you know, the equivalent of the Good Housekeeping Seal of approval, and yes I am dating myself now, but in which, you know, people who want to look out for that can find it and there are always going to be people who don't want to look out for that.

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

Sure. I always...not to throw anything on this, I actually really like this concept, but when we started out with the privacy rule we thought that people would use the notice to differentiate themselves and that of course did not happen. So, I am very curious about how to make this something that an entity that is not regulated would want to take on.

Who are...I mean, since this is coming from the committee who are you thinking would actually create this certification program? Would it be a government program or would this be something that would be done by a private group? What's the idea there?

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

Well, so that's why...I think that's a really important question Linda and I am not sure that we have sufficient time to settle it enough to make a recommendation on it.

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

Okay.

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

So, that's why this is framed as a recommendation for exploring what such a program would look like and figuring it out who stands it up, how does it get paid for, what does it look like, what does it, you know, aim at in terms of sort of desirable qualities or desirable aspects to measure, or evaluate that this all needs to be further discussed because I think...I don't think it's something that you can or should, you know, put together based on three weeks of conversation.

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

Thank you.

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

Yeah, but it's a really good question. I mean, do we have a...do we populate this with more issues but still say, you know, this is going to require a lot more thinking, but at least...

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

Deven?

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

The committee could endorse the idea and set up a process for fleshing some of it...fleshing it out and diving into these deep issues in more detail.

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

Deven?

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

Yeah?

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

This is David, just in the space of open ended comments...

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

Yeah?

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

I mean, I think that there is a high likelihood that these Apps as a whole are going to become extremely important in the care process not every App but a subset of the Apps I think will become kind of standard tools for the management of patients with chronic disease in particular and maybe even some acute things as well but certainly the chronic diseases.

And I think just to conjecture and project I think the way that may flesh out is that the risk holders, ACOs or the payers, who have an incentive to maximize quality and minimize cost are going to go and select or build themselves a library of these Apps and then, you know, urge them onto their providers to use with their patients almost as a prescription for the patient, you know, download this App and together we'll help you manage your congestive heart failure or whatever.

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

Yeah.

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

And I can imagine that that's going to result in, you know, dozens of groups that compete to be good at that and it really scares me that we would recommend any sort of notion that there might be a uniform or standard approach to this, well that's the wrong word, maybe there is a uniform approach but that there would be a unitary process because I think there are going to be many of them.

And, you know, maybe guidance could define, you know, policies and practices that you should use in assessing these Apps but, you know, for one ACO to say "our Apps are better than the other ACOs Apps" could be based on all sorts of things that go way beyond any notion of, you know, simple certification around privacy and security.

So, if we kick off this process I think it needs to be really open ended and anticipate that there may be many different groups and approaches who will try to create good Apps and to call their Apps out as being the best Apps under a variety of constraints not just technical and security/privacy issues.

And then on the other extreme I can also imagine that there are going to be vendors who will blacklist certain Apps because of the, you know, either technical or known security risk and they may do that for their own, you know, reasons, that they analyzed the API usage pattern and say this App is clearly trying to hack other patient's data we're going to just blacklist it just flat out, blacklist it because it's a security risk.

So, I think we...it's going to go in both directions, it's just a much bigger complicated space than a notion of a voluntary certification I guess that's where I was headed.

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

Okay.

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

In both directions...

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

So what is...

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

If that makes any sense.

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

What does that mean for this recommendation?

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

Well, I think it needs to be...maybe the voluntary...I mean, first off we should acknowledge that there are many different aspects of whether a consumer should be encouraged to use an App to connect to their record. So, there is clinical validity, there is the privacy and security stuff that we talked about, there is secondary harm from the fact that you're using the App itself which may signal certain things to certain people, I mean, who knows. There are going to be many aspects to it. So, I would hope that we would call out at least that.

That there are many aspects to this and it seems unlikely that there would be a single entity that could perform validation across such a complex space. So, maybe the call is to develop some baseline, I think we might have called that guidance in the past...

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

Yes.

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

Recommendation, you know, as to the specific privacy and security aspects that should be attended to, because that's our narrow focus, while admitting that many other groups will have much, you know, additional areas of focus. I don't have a concrete suggestion, I apologize, I haven't thought about this enough, but it's just a much bigger problem and the notion of a voluntary certification process that's just...

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

Right.

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

Way too narrow.

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

Right.

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

Particularly one that has no, you know, legislative mandate behind it or any particular financial driver for it.

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

Right.

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

You know it's not like the Meaningful Use criteria calls for the creation of a certification entity for consumer Apps because it doesn't, right?

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

No.

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

We don't have...

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

This is Gil.

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

Hi, Gil.

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

A complicated issue I'm not sure I have any, you know, piercing insights, just, you know, a couple of observations. I mean, it's not, you know, the comments from the Policy Committee it wasn't clear to me whether they were trying to, you know, create a process that would assure, you know, kind of robust privacy and security or they were trying to create a process that would accelerate innovation. And, you know, maybe, you know, they're trying to do both but, you know, those are kind of, you know, in some ways maybe a little bit opposed to each other, you know, which what kind of perspective one would take.

The other thing, just, you know, listening to just the conversation, you know, I wonder...I was wondering if there were models that were out there that, you know, allowed, you know, a component to play nicely in an environment, you know, and I don't know if, you know, like in the old days, you know, if Microsoft used to approve, you know, certain vendors, you know, in the Windows space or whatever, you know, how those kind of review and approval processes went. I don't know if there is, you know, just existing models that maybe could be alluded to that might give some kind of indication.

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

So, Gil, this is Lucia, and I know that other people probably involved in the Workgroup and/or the Policy Committee may have been exposed to this information as well, but I had an interesting presentation about Apple Healthkit recently from Apple and they do exactly that you have to meet certain criteria that they control in order to build Apps that interoperate with Healthkit. So, you know, they're kind of the masters of that universe.

And I understand from people on my team who are more technical than I am there are in fact models for this, but I think to David's more specific point, which is (a) what is the right role of ONC in fostering such models and (b) what...as a policy matter whether ONC is the driver or not, I have no idea, what should be driving the development of those kinds of models and people using them or to Linda's point, you know, is a Good Housekeeping Seal of approval, I'm using my language Linda's idea, do people really want that.

Like we don't know how this is all going to develop yet and we have to make sure that if we're going to start examining things we start examining an appropriate first point instead of something that maybe not right for examination yet.

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

And...

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

But, you know, to Gil to your notion, I mean, I think all of the App Stores that exist today have, you know, constraints and criteria that you have to meet in order to get included in the App Store some of them are more picky than others and it's an open ended question as to whether that will be true in this EHR space, you know, Apple charges a 20% fee or some such percentage fee to be in their App Store would it be legitimate for a dominant vendor to charge a fee to be on the right list of Apps that a consumer could use to access the portal. There are certainly going to be vendors who will want to do that and they could justify it under a lot of reasons in terms of verifying the Apps for security and medical credibility and safety, and appropriate use of the APIs, and adequate documentation.

I think it will be interesting to see how that plays out. I don't know if we're being asked to weigh in with an opinion as to whether that's a good idea or not, I don't think we have much legislative authority to render that opinion that I've seen.

The Blue Button Plus Group had this debate pretty vigorously and I think they ended up basically saying there needed to be a process to establish registries so that if somebody had a legitimate reason to create a registry an App could register itself through some approval process so there was a technical capability but there was not a political solution that I recall.

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

Okay, that's helpful, thanks.

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

Well, so, I mean, acknowledging that there would be lots and lots of sort of issues that would need to be hammered out and further debated, I mean, is it still worth calling for a process to start to unpack those and see if there is any there? Like, you know, again, this is why we said "further exploration." We didn't say, go off and...

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

Yeah.

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

Create a certification program. I think we've got some issues that have been surfaced in this discussion that are not necessarily well identified on the slide that we have currently but we can add them.

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

Yeah, Deven, this is David again, I don't mean to say we shouldn't say something. I guess my attempt to try to broaden the scope of the issues that are at stake was not to be taken as a let's say "file it" but let's just make sure we make people realize how broad it is.

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

Yeah.

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

And that it really is a lot more than just privacy and security that's just one sliver of it.

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

Right, yes.

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

And, you know, I think it's a good debate for the community to have and it may well be voluntary because I don't know what other rubric you could have it under. So, to that degree, I'm all in favor, but it's not a P&S group alone.

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

No and that's why we...

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

It's much bigger.

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

That's why I sort of passed the buck to consumer empowerment, but said that...

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

Yeah.

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

There would likely need to be some participation from some members of this Workgroup or we might get asked to address some particular piece of it.

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

Yeah, well that's a time honored medical tradition.

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

Well, you know, I meant it with all...not really attempting to fluff off the work but in recognition truly that it's just much bigger than our particular piece of it. So, all right, so is everyone generally in agreement that we'll ask for exploration of a possible program, certification or otherwise to allow for App differentiation but acknowledging that further work needs to be done on it, we shouldn't take the lead on it because the issues are broader than privacy and security although those are included and that there are many pieces of this that would have to be worked out, you know, what are the criterion which you evaluate an App from privacy and security and usability to the clinical validity point David that you mentioned that we don't have here. There could be other aspects too.

What's the role of government? Should it be voluntary or in some way connected to the current programs? What are the incentives to entities to participate in such a...to have their Apps evaluated through such a process if in fact it's voluntary? Yeah.

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

Those are all good.

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

All of those.

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

Yes.

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

The ones that are up there already.

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

Deven, the only thing I would add to that if you're going to make that recommendation it certainly would be helpful if it's a recommendation that the Policy Committee might adopt is that people need to understand that because of the complexity even if people are working with this batch it takes a long time to get it right.

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

Yes.

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

This isn't something that can be flipped around for meetings in June it's too complicated.

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

Oh, yes, no absolutely. No it needs to extend well beyond the NPRM period and, you know, the guidance as hard as that process can be is at least already in the works and is much more likely to be useful for Stages 2 and 3, you know, something like this will take some time to talk about much less stand up.

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

And the world where all of these Apps will have widespread access to the EHRs is pretty distant future as well. So, you know, not only do the Apps not exist yet there is nothing to...these APIs haven't been deployed and won't be in any significant fraction of use cases until probably at least a year or more. So, I don't think there is a rush on this. It's a good time to have these conversations as this new space emerges and before people get into bad habits perhaps.

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

Well that's good. It's nice to be ahead of something for once.

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

Well, it won't stay that way.

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

It won't stay that way is right.

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

It will move fast once it starts. I mean, there is a pent up demand that's intense, it's just the APIs haven't been deployed yet in any widespread way other than some proprietary ones.

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

Right, right. Okay, great, any other thoughts that we missed? Somebody hoping to chime in who hasn't had an opportunity yet? Okay, you know what I just thought of something, so Michelle, what do you think about pausing for a moment for public comment now or do you want to wait until the end on this piece, just because we're going to leave it behind, but I'm also fine with reminding myself better than I did last time we were on a call together to end early?

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

We can try it now, we don't have any comments in the public comment box yet.

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

But we can...

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

Well why don't...if people do submit on line...then if nobody has submitted anything yet we'll hold off for a few minutes and try to get through some of the big data refresher slides and then remember to break in sufficient time to build a queue in case...

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

Sounds like a plan, thanks Deven.

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

Okay, thank you. All right, so let's...I decided not to call the audible on that one. All right let's go to the next slide. So, we'll rework the recommendation on the potential certification program and see if we can't get clearance from the Health IT Policy Committee.

So, we'll move on to begin the big data conversation with the aim toward trying to get recommendations to the committee by the July Health IT Policy Committee meeting. So, we really only have two...it could be that the initial set of recommendations is at least the initial airing of the recommendations to the Health IT Policy Committee it often takes two, as we've just seen, it often takes two Policy Committee meetings before we get something through that's big and so it could be that we bleed this into August, but we'll endeavor to at least get an initial set out for the July, at least preliminary discussion with them in July. Okay, so, next slide.

We are, you know, sort of working on a recommendations document that in fact will be a fairly good sized transmittal letter because we want to build in a lot of background to what we are producing. We've done a lot of work on this issue. We had two days' worth of...two afternoons worth of hearings plus an additional call dedicated to exploring some security issues in more detail, we had terrific testimony from a wide range of people last December.

We then took the month of the end of December and into the month of January to start fleshing out some of the issues that we uncovered as well as beginning to sketch out what some recommendations were. We even made an initial presentation to the Health IT Policy Committee, I think it was either in January or February, where we got some feedback from the committee that we would be better off with them presenting a shorter list of big ideas than a lengthy list of small ones.

So, we are along those lines trying to sketch out some big themes for recommendations and we've begun to do that as your Co-Chairs working with ONC and with MITRE who supports us. We won't have sufficient time to begin delving into those on this call in a lot of detail but we did want to sort of refresh your memories about the various issue areas that we had uncovered through our work and some of the broader areas of recommendations that we're landing on so we can both use this time as a memory refresher but also to begin to narrow what we're going to say about this topic in terms of the topical areas that we'll address but also begin fleshing them out.

So, as you'll see here, you know, given again the amount...how big this issue is, no pun intended, and just how much sort of work and discussion that we have already had to date we think, you know, there is likely to be an executive summary, a bit of background on all of the other activities that are going on that implicate health big data, a summary of the expert testimony that we've had, what we think some of the issues are, the solutions and recommendations and then a bibliography of some of the sources that we used including the testimony that we gathered.

So, this could be quite lengthy in terms of what will be on the public record for this not necessarily what we will present in slides because we'll never...we would never get that much time from the Health IT Policy Committee so we'll have to be very targeted in presenting the material. Next slide.

So, in terms of the problem areas I think we've got, 1, 2, 3, 4, we've got four big topics in terms of some of the key issues that arose with our health big data discussion and again our bigger report will also be very clear that we see much opportunity in health big data, much potential but what we're trying to do is to have recommendations that help manage the risks in order to leverage the opportunities.

So, one of the issues was, you know, the potential for discriminatory practices which is a problem that often is a driver of privacy concerns for many people, you know, how do you ensure responsible use of data and the challenge of managing the increasing risk of potential harms such as, you know, decisions that are made that have an impact on people and their ability to get housing or employment, or they manifest themselves in terms of harms to dignity and harms to trust in the systems that gather information about people and that are necessary to leverage health big data. Lack of algorithmic transparency...

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

Deven?

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

Is one of the issues that surfaced in the testimony and in our discussions and that sort of fits into this bucket and when those algorithms are used to make decisions about people and it's unclear when they're used, what the components of the algorithms are, there aren't ways to challenge them. The discriminatory impact of them is often not...while it may be felt it's sometimes not obvious for many months or years after the fact.

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

Hey, Deven?

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

Yes?

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

This is David, one thing when I was reviewing the slides that I noticed is you call out discrimination as one kind of harm but you actually enumerate some other ones.

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

Right.

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

Is the title too specific?

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

Right, it might have to be harms.

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

Yeah.

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

Okay, good point.

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

I agree that the discriminatory ones are probably the main ones that you can actually, you know, explain and drive but the loss of dignity, loss of privacy those are, you know, sort of important ones as well.

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

Yes, good point David, thank you.

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

Always paying attention.

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

David, this is Lucia, just to remind everyone and I don't think Deven said this, whatever the content is here it needs to be digestible by people who are not the data geeks we are and so we're aiming for a report of around 20 pages. So, we may end up having to make tradeoffs between wide breadth and enough details to cause understanding.

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

Well...

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

Okay.

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

Because we can't write a dissertation on this.

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

No, I...

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

As much as we'd like to.

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

Agreed but we never want to be not understandable.

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

Right.

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

So, I think we would probably aim for paring it back and being more focused. But, let's call this "harms" for now but keeping in mind that we are trying not to boil the ocean or trying not to try to boil the ocean.

Okay, so then problem statement number two are that the different domains of regulation you have HIPAA but you don't have HIPAA for much of this space that collects data on health or data relevant to health, yielding contradictions and unpredictability, you know, it says challenge of having two regulatory domains it's really more than two regulatory domains but at least in terms of privacy and security, you know, we don't have a consistently regulated environment.

We have the issue that was pointed out in the interoperability roadmap about lack of harmony of regulation even in cases where it does exist and tries to aim at some similar problems. We have the issue that was surfaced in testimony about the sort of rules around reuse of data to contribute to research that may not provide the kinds of incentives that we would want to see to encourage people to contribute to generalizable knowledge, on the other hand lack of knowledge of the law, you know, we had a lot of things that sort of surfaced in this sort of over regulation/under regulation bucket, patient issues with accessing their data or exercising their rights under HIPAA and maybe not having access to data at all in the non-HIPAA covered space is another issue that may fall into this bucket.

The next slide we had a lot of discussion about how much we rely on anonymization or de-identification of data and yet there are still risks associated with re-identification and we don't necessarily have the right tools in place to evaluate de-identification methodologies much less crack down on inappropriate re-identification and so a set of recommendations that could strengthen de-identification or anonymization as a privacy risk reducing tool while acknowledging that it is not the panacea and we shouldn't treat it as such.

Problem statement number four involves security threats and gaps. We had some dedicated testimony on this issue. We had the HIPAA Security Rule that governs that space but we don't have, you know, HIPAA's coverage is not unlimited therefore there are a lot of collectors of data on health out there who may not be subject to any particular security provisions either under federal or state law that we don't have that sort of consistent policy environment that we would ideally want to have.

So, that's again, really broadly stated and just refreshing your memory about some of the key areas that we identified.

And then in the next several slides we begin to sort of take a stab at some ideas for some recommendations but these will all be subject to discussion during subsequent calls whatever time we have on this call we can begin going through both refinement of the problems as well as refinement of the recommendations so this is not at all language at the end of this process it's really just kicking it all back off again. Next slide.

Solutions for discriminatory practices we have had a suggestion already that we might consider this to be harms of which discriminatory practices is one aspect of it but isn't the only harm that we're concerned about. This is one where, you know, we're still sort of really struggling to say what we definitively would recommend here because it's a very deep issue on its own. We probably could have spent several months on this issue alone which is probably true of a number of the issues that we've taken on.

So, I think our challenge here will be "what can we say" from a recommendation stand-point that will begin to lay a pathway or a process for trying to address issues of harms. Where are the gaps in law in terms of protecting people from harm? Are there specific areas of additional inquiry that we want to pinpoint? If we wanted to identify some particular harmful uses that we wanted to really prioritize we should do that, we have an opportunity to do that if we think there is time to do that.

How do we create incentives for the type of harmful uses of data? How do we punish malevolent behavior and incent benevolent uses? Again, I don't think we...in the time that we have could even hope to address all of these so I think our challenge will be what do we want to do to spur additional effort on this very deep and multifaceted issue.

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

Deven, this is Lucia, if I could just jump in there. I just want to remind everybody on the Workgroup, you know, the audio for all of these listening sessions and the transcripts as well are up on healthit.gov and I understand, because I've heard feedback from the public at large, that you can download that audio and listen to it on your next road trip when you have 10 hours to spare, but if you need a reminder you can get...of what was said that's a great place for it.

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

I love that because it shows that there are people who are bigger geeks than I am out there.

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

Hey, Deven, this is David again, you've listed off some of these really big and broad areas...

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

Yeah.

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

Could you remind me, is the charge limited to health related big data or...

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

Yes.

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

Are we...

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

Yes.

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

Do we have some way of defining what that means? When is it not health related data? I mean, is my grocery store shopping data a health issue?

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

That would be...so we have scoped, it is not a precise definition, but scoped a definition around health that is about when it's used for a health purpose.

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

I see.

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

So if somebody is using your grocery list in order to evaluate you for insurance or to evaluate how healthy your behaviors are for purposes of...

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

Yeah.

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

Designing a program for you or other reasons than that's a health use of your grocery list and we would consider that to be health data as opposed to...

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

Okay.

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

The use of the grocery list for a non-health purpose like finding how much you're spending.

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

Yeah, yeah, okay, it will probably be a pretty fuzzy boundary in some cases, but that's a good start.

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

Yeah, undoubtedly. Okay, next slide. On the...so we've called this rebalancing privacy laws, you know, again acknowledging that HIPAA provides these comprehensive protections but only is going to govern health or health related data in certain context and then we've had some testimony about how we, you know, some improvements to HIPAA in terms of sort of reuses of data for research and learning purposes and so solutions could include, you know, calling for congressional action, we don't advise congress, so this would be sort of more of a bully pulpit kind of recommendation if we wanted to make it.

We had a lot of testimony about the value of the Fair Information Practice Principles in shaping good data stewardship, is there, you know, space for congress to act, we, you know, certainly lots of groups, my former employer being one of them, have called for congress to do this. There were calls for congress to enact a consumer privacy bill of rights in the White House Report on consumer privacy, it's been stated in other spaces, is that something that we want to take the opportunity to say.

Do we want to say something about the research rules for HIPAA and the Common Rule, federally funded research that doesn't...that really more evaluates what the risks are to the data versus what particular use was made of them, of the results of any particular data analytics. Is that a space that we want to take on since we had some testimony about that.

Do we want to take an opportunity to talk about improving patient access to data both in the HIPAA governed space where at least there is a right that patients can point to or should it be part of any legislation covering the non-HIPAA space or maybe we...if we're not feeling like we want to take on the non-HIPAA space in terms of broader legislation do we at least want to say something about it for the patient access piece? Next slide.

Solutions for transparency, should we be aiming...have recommendations aiming for greater transparency regarding actual uses of data both identifiable and de-identified. You know we have the notice of privacy practices that tells consumers what can and can't be done with their health data but isn't necessarily required to be a description of what the data is actually used for particularly around research and secondary uses. Is there value to some transparency there even if it's in broad groups and not necessarily telling a particular patient where her data was used, which might be difficult to do particularly in a de-identified data space.

We have had recommendations before come through the Policy Committee where we encouraged some transparency around de-identified data uses by intermediaries through their customers. Those were not necessarily patient customers, not context.

And space for disseminating more education to consumers about how data is customarily used rather than highlighting and trying to provide notice around actual uses is it better to invest our efforts in broader education about likely data uses among a range of data stakeholders and maybe it's both. Next slide.

De-identification and managing re-identification risk, I think here is where we probably have gotten the furthest along in terms of picking up some very specific recommendations such as developing federally approved standards for expert determination methods for de-identification for developing a certification program to credential experts.

Changing laws to prohibit re-identification or partial re-identification without some sort of oversight or meeting a particular need, public need that's identified like for safety reasons for example. Having additional guidance beyond what OCR has already put out there on de-identification around the need to re-assess re-identification risk upon certain events such as the combination of data, expiration of a prior expert methodology determination or other change in circumstances.

Is it possible to safe harbor more techniques than the one that's currently utilized under HIPAA but that are proven at least for certain types of datasets to raise a very low risk at the same...to the same degree of certainty that current safe harbor provides.

And the issues of using contractual commitments to achieve greater accountability is something that I think Bob Gellman had talked to us about. So this one is...probably might be the furthest along but again this is all going to be subject to our discussion I'm just taking the opportunity to resurface a lot of the prior discussion so we can jump right into them more quickly on subsequent calls. But I heard a voice or maybe I didn't. Okay, next slide.

The last area that we're sort of aiming to develop some recommendations around is security threats and we had some recommendations that the Tiger Team had developed and that the Policy Committee had endorsed around robust security frameworks for health data and sort of continually trying to evaluate the security policy framework so that they try to sort of keep up with where the risks are emerging, it's a very hard thing to do, but also we don't necessarily have real clear comprehensive security requirements outside of the HIPAA space, is that something to add to sort of the "wish list" and do we want to use these recommendations to make those kinds of points.

We circulated for this call the recommendations that we had put together previously, when I say "we" it was the Tiger Team so an earlier iteration of our group, but that were endorsed by the Policy Committee at that time, so we can take a look at that as part of our evaluation of this particular area in terms of what we want to say and see if we have anything further that we want to say or things that we would augment about that.

And so even trimming or grouping recommendations into those, I think it was five, no it's six, six areas there is still a lot there. There may be too much there and so...or it could be that we want to hold onto all six areas but maybe try to be more pointed about what we say about each one. I think those are all things that we can determine as a group in terms of the best way to move forward, but we...we got a lot of really great testimony about a lot of those issues.

So, confessing to all of you that trimming that list and trying to be more specific about what it is that we want to recommend has not been an easy effort on the part of your organizers but we're endeavoring to do that and we would...and feedback from all of you about what we should prioritize, what we should try to focus on will of course be enormously helpful as we go through this process.

So, with that I'm going to pause and go ahead and ask Michelle and the folks from Altarum to just cue up the number for public comment so that we begin to build a queue of people who might be interested in making public comment and then we'll turn back and spend some time in what little time we have left in gathering some feedback from the Workgroup members.

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

Thanks Deven. Lonnie or Caitlin can you please open the lines?

Public Comment

Lonnie Moore – Meetings Coordinator – Altarum Institute

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

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

Okay. So while the queue is building does anybody have anything they'd like to say about that little memory refresher and beyond the point that David made about harms versus just focusing on discrimination? It is still even with the grouping that we tried to do it still feels like a very big topic.

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

Deven, it's David again.

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

Yeah?

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

The output would be a white paper targeted at whom? Just the general anybody who cares or...

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

No I think we always try to aim our recommendations to the Office of the National Coordinator because that's who we...

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

Okay.

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

Officially advise.

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

Okay.

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

But we have, on numerous occasions, invited...given them recommendations to share with federal partners and given that, you know, one of the slides that we did not resurface for this discussion was the sort of call of the White House Big Data Report for some specific recommendations around additional policies or refinements to policies that would enable the leveraging of health big data. So, I think we want to feed into that process, but through our...

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

So...

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

I think we should stick with our official channels for how that gets...

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

So, to that end...

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

Communicated.

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

To that end just thinking, you know, from my stakeholder's group of the vendor community do we envision ways where this would intersect either certification or potential Meaningful Use incentive that requires a certification enhancement? I mean, for example you could imagine certain things around transparency for feeding data to various research registries and repositories, you could imagine something around de-identification capabilities for data that is released through those channels. I haven't heard us mention anything like that so I'm just thinking out loud here.

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

Hey, David, this is Lucia, I think to give you a little reminder context, this derives from the White House's report on big data and some other reports that PCAST and others issued subsequent to that and we were asked to help support through our Workgroup a deeper dive into the implications of big data techniques in the health space specifically just for the purpose of really informing long-term policy development. So there is no...

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

Okay...

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

There has been no...I mean, I'm saying it wouldn't happen sometime in the future that its connected to some rule somewhere but that's not the immediate request that we're responding to.

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

Okay.

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

Yeah, I mean, David, I sense that you're trying to use that as a potential way to sort of limit where we're heading here which I can completely appreciate, but we were...I think sometimes...I think we're victims, victims is the wrong word, but we've been successful at coming up with some multi-stakeholder recommendations that have been...well not all of them have necessarily translated directly into action have been very well regarded and so we...I think because of that we got asked to provide a set of recommendations on this issue and it's taking us into spaces that are beyond what we normally ordinarily try to influence.

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

Yeah and I appreciate that but I'll just disagree slightly I'm actually looking for ways to make it more relevant and...

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

Ah, okay.

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

Have teeth other than, you know, just being good ideas. You know so for example, you know, the transparency question, which I think is really one of the most important things that we can focus on, because transparency just has a nice way of sanitizing bad behaviors, is there transparency connected to the role that...the increasing role that EHRs will play in feeding data into the research enterprise in particular we've got this, you know, million person...personalized...and genome project that's getting ramped up a lot of interest in that. The vendors are being called on to commit to feeding data into that database, that database will mix, obviously, very sensitive health data with extremely sensitive genomic data, that's a big data enterprise if there ever was one, do we have something to say about that, about what the vendor should or shouldn't do and how they do it. So, I'm trying to give it actual concrete teeth rather than limited.

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

Okay. Well, I think we should take that under consideration as we begin to further refine these David I think that's a very good suggestion. But, I'm looking at the clock and I think we should see if we have any public comment so that we're not delayed.

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

We don't have any Deven.

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

Ah, okay. Well, David we'll definitely take that one into consideration. I hadn't really thought about...we were being very pie in the sky I think on some of these suggestions...

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

Well...

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

And thinking about ways to ground them or finding a way to prioritize those that we can ground is an excellent suggestion.

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

And it happens to be on my mind, there is a conference at Vanderbilt in a couple of weeks on that very subject and I have to think through what our attitude is for Cerner's perspective headed into that conference and it just connected the dots here that we're actually talking about the same thing just from a different perspective.

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

Okay. Well, great, well, thank you. Any other thoughts before we...as we begin to close? All right, well we have two calls in June. We will mostly likely spend those calls really drilling down on these recommendations but beginning to circulate text for the rest of the report so that people can begin helping us to wordsmith it but we've got a lot of work to do on these recommendations and I suspect that's where we're going to spend most of our next two calls on. So, with that I think we're done. Thank you everybody.

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

Thank you.

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

Thanks.

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

Thanks, Deven. Have a great day everyone.

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

Thanks, bye.