



## HIT Policy Committee Privacy & Security Workgroup Final Transcript June 22, 2015

### Presentation

#### Operator

All lines bridged with the public.

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

Thank you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Privacy & 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. The airport got louder. 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

Hi, Stan.

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

Hello.

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

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. Gayle Harrell? Gil Kuperman?

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

Present.

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

Hi, Gil.

**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**

Hi, Kitt. Kristen Anderson?

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

Here.

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

Hi, Kristen. Linda Kloss?

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

Here.

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

Hi, Linda. And 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?

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

Present.

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

Hi, Manuj. Micky Tripathi?

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

Here.

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

Hi, Micky. Sarah Carr?

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

Here.

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

Hi, Sarah.

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

Hello.

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

Stephania Griffin? And Taha Kass-Hout? And from ONC do we have Helen Canton-Peters?

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

Here.

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

Hi, Helen. And Lucia Savage?

**Lucia C. Savage, JD – Chief Privacy Officer – 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, Lucia. Anyone else from ONC on the line? Okay, with that I will turn it to, Lucia, should I turn it to you first?

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

Sure, if Stan doesn't mind.

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

No, absolutely.

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

And the senior staff prerogative and Deven, if you're on mute, I know you can hear me and I think that a few other people will want to weigh in, too. But, I think that most people on this workgroup have now heard that next Monday Deven will start in her new role as the Deputy Director for Health Information at Health and Human Services Office for Civil Rights. And we are thrilled. Well, we're not in that building anymore, we're thrilled at Health and Human Services to welcome her officially to our leadership team.

But what I wanted to do today was actually just give a few words of thanks; Karen could not be here today. Most of you know that Deven has been a Chair of this workgroup in its current or earlier form since the beginning. She's been an intrepid leader; she has taken the workgroup through thick and thin. She has made a priceless contribution to the advancement of health information technology in the United States and of course she's here today to help us with Big Health Data, so she's going out with a bang. So, I just wanted to express the entire of ONCs thanks to Deven for her incredible and irreplaceable and priceless service over the last 6-1/2 years; so thank you very much Deven.

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

Thank you, Lucia. I will miss the...doing this work, it's been incredibly rewarding. There are a number of you on the call who have either been with me from the very beginning on this working group or I've been working with you in other ways for many years and I really appreciate it. I appreciate the kind words; I'm looking forward to this next step in my professional life and working with a great team over at the Office for Civil Rights.

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

And then before we get to the substance of the day, I know that there are a number of people on the workgroup who have worked with her over the years and I want to make sure they have a chance to say nice things about you, too, if they want.

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

Yeah, this is David; I'll jump in. I think I was at the very beginning Deven, or certainly shortly thereafter and...

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

I think you were, David.

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

..I have to say, it's the one workgroup call I look forward to every time and it's in large measure because of your leadership and the way you kept us focused, balanced, fair, organized, productive. It's been a pleasure to work with you and you've made amazing contributions and I'm honored to have been part of it. Thank you.

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

Thank you, David.

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

And any...this is Lucia; anyone else feel compelled? Of course you know where you can reach Deven through the HHS Directory starting next Monday in case there's something you forgot to say.

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

Yeah, well and I've also gotten lots of nice notes from people, so...

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

Yeah, this is Micky. I would echo certainly what David said and I would double or triple it. And also I had the privilege of being Co-Chair with Deven both in this workgroup as well as the Interoperability Workgroup and she always made it fun and Deven I learned a ton from you and I'm going to miss you; so good luck. Thank you.

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

Thanks. Thank you all so much. And we have a lot of work to do today, so...

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

All right Stan, this is Lucia; I'm going to turn it back over to you to lead us through the slides and what we need to get done. Let me just say one other thing, so we're going to get through all this big health data stuff with or without Deven; she's laid a great foundation, but I don't want anyone on the workgroup to think that we won't...we're...Stan and I will be pushing this through, along with the ONC staff, so whatever the dates and deadlines are that we come up with at the end of today's workgroup, we're going to stick to them. It's all yours, Stan.

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

All right. Okay, great. Well thanks very much and obviously with that type of a farewell announcement to Deven, it's...I am in no way trying to step into Deven's shoes. But we'll labor, as Lucia said, to try and work this through as efficiently as possible. And in Deven's typical style, she's asking us to just get on with it now; so, let's do that.

So we have the readout for you all to consider, based on our last conversations. We've made some changes to the slides as well as to the foundation document and so we're going to focus on the slides here today and if you can go into the meat here and go to the next slide, please. The goal of the...there we go, the goal of today is to set us up to give a presentation on the big health data recommendations to HIT PC meeting. We have an initial discussion, I believe and Lucia, you can clarify if this isn't correct, on June 30, next week and potentially a final presentation later. We're trying to set so they get to...this call.

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

Yes. I mean if we...for example, I can imagine a universe in which the workgroup today feels satisfied that the draft needs mere stylistic edits and that we could deliver it to the Policy Committee next Monday. But we think that that's...we have to plan for that not happening and so we've asked Michelle and team to make sure we have time reserved on our meeting on July 14.

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

Very good. Well, our goal today is to see how comfortable we feel with the recommendations. There are some substantive changes we made to the slides from last time and these slides then are really a summary of what we changed in the overall report and so to the extent that we have a conversation here that alters something, we'll translate that back into the report and then redistribute. But, along with the slides you should have gotten a copy of the draft report we have.

So, next slide. We can dive into things here and we're going to start back with the draft solutions and recommendations; §6.1, if you recall, was a slide on addressing harm, discriminatory practices being one of the more significant harms, as we've all discussed. We took that language that called specifically on action and moved instead to a slide that talked about promoting a fuller understanding of the harm that's occurring to individuals and communities.

And this is really a primary issue for us, we've come across this on many circumstances where we simply don't have well defined harms yet and so this is stated to encourage stakeholders to promote this activity, to come up with a better scope of the harm that we're trying to deal with. And then more...in a more focused way monitor the use of health big data and try to identify gaps where we could see harm and where further inquiry is necessary.

And then on the final bullet, what we had discussed was increasing transparency of algorithms. And we had a fairly lengthy conversation last time about the difficulties of that call and the idea that there are...there is not only issues with the size of the algorithms and the size of the data sets they're using to analyze and how could transparency work to the proprietary aspects of an algorithm. And so we...we fell back on the idea that the FCRA has been doing this for, you know, for more than 40 years and fairly effectively and so a transparency similar to what they offer but to respect the access to the data and understanding what the impact is of algorithms was where we landed. So any conversation; any thoughts on those three bullets in particular and as we talk about the discriminatory practices?

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

This is David; in our discussion we touched on the changes to health insurance around things like rescission and pre-existing conditions and such, as an evidence of the kind of harm that could be ameliorated by changes in law, is there any thought that mentioning something like that as part of...as just as an example would be useful in a presentation of this topic? I'm not...I assume people know what we mean here, but a concrete example that everyone can identify with would...might make it just more vivid. Not...doesn't change the recommendation, but it just makes it more vivid.

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

Yeah and I'm all for illustrations, it makes things more vivid. We can...we're in a solution, so do you think we should add on a solution slide or...as part of an illustration to what we're...to the harm we're trying to solve with the solution?

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

I was just thinking of just as an example that everyone can sort of resonate with and you know it's not out of the woods that that could change, the health...is still not settled policy.

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

Right.

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

And the degree to which one feels predisposed to want to share your health information, I think ought to be governed in large measure by whether that sharing does more harm for you than it does good. And if the laws are changed, it could actually flip back to where the sharing of data is a bad idea.

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

Um hmm.

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

Yeah, so I just...so this is Deven. We, you know we do actually have language about insur...health insurance discrimination as part of the text of the larger report. And I think we probably pull it out in our description of harm as the problem, which is part of section 5 of the report, but we certainly could make sure that it is highlighted in the slide that's just one example of where there was an identified harm and there was...there were policies, at least cu...or on the table to try to address that.

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

Yeah, no, that's good; I'm glad to know it's in the written testimony. I would...I just think that it's a vivid illustration, that's all I would...my only point. So thanks.

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

Thanks and we'll look back through the report again, David, the most recent draft and make sure we have language in that as well and then pull it forward. Okay, other comments on these first three bullets? Any other gaps? We actually backed off of the recommendation from (1)(4)(a) for a kind of a more draconian call for action to one that is encouraging stakeholders to undertake further inquiry based on a lot of the comments that we received back, so. All right, let's move on to the next slide.

So the second recommendation on solution was the policy environment, and this is where we have uneven policy across the big data ecosystem where we have some activity covered by HIPAA, some activity not covered by HIPAA and the idea that one, we want to reco...we want to leverage what we've already recommended in the past with respect to the privacy and security laws and uses of the data both inside and outside of HIPAA. And then promote the FIPPS-based protection for data outside of HIPAA in particular; FIPPS-based protections being those protections that are the Fair Information Practice Principles that include things like consent, although not speci...not explicitly and not solely. But depend on a more balanced approach for things like transparency, access, accountability and use limitations.

And so we're trying to call on HHS, FTC and other agencies very specifically to help guide and establish these voluntary codes that are really the only things that can be enforced right now outside of HIPAA for the big data world. And so we're leaning heavily on FIPPS-based self-governance code and a call to try and address the uneven policy environment by that activity. Thoughts on whether the language is sufficient; other things you'd like to see?

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

Stan, Gil Kuperman here.

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

Hi, Gil.

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

You know I'm looking at here, you know, I think the language is pretty good. In...when we were having the discussion I, you know the way, you know the kinds of take-away I had was that kind of a FIPPS-based approach versus an FTC-based approach were kind of alternatives. I mean, that was just kind of the way I was digesting the conversation, you know, in my own mind when we had it. Here they're kind of blended together like FTC enforcing a FIPPS-based...

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

Right.

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

...approach, but I think it's okay. I don't know if there's really any value to kind of contrasting...

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

Um hmm.

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

...those two things anymore, so...

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

It, umm, you know and the conversation really was pretty broad and wide ranging on this topic Gil and you're right. The idea is that the FTC right now, in order to enforce their Section V authority under deception, they have to have an affirmative statement by an entity that says they're going to protect data in a certain way.

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

Um hmm.

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

If they don't have that statement, they really don't have much regulatory authority except potentially unfairness, which requires the proof of harm to the individual.

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

Okay.

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

And so FIPPS...the idea of FI...of a self-governance code is to establish something to make an affirmative public statement that could then be enforced under deception by the FTC. So they were meant to work together, it's different...it's apart from, I guess, FTC authority in that...the FIPPS really is the first step really is a self-governance activity and you can...that has to be a primary mechanism before FTC could act. So we can try and explain that a little bit more or separate that out a little bit more, perhaps.

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

Yeah, I actually...so this is Deven. I think it's a little more clear in the text of the report; it could be that this got...

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

Yeah.

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

...a little lost in the slide translation because we definitely didn't juxtapose those as being like well; it's either FIPPS-based protections or its voluntary codes of conduct. The reason why this particular bullet says "for now" voluntarily adopted codes of conduct can be enforced is because...

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

Right.

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

...there's a bunch of discussion in the text about how Congress could certainly establish FIPPS-based protections as a matter of legal requirement, but we as a working group did not feel like urging Congress to act was necessarily the step that we wanted to take. And that's why it says "for now." So, I guess it's a little unclear.

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

Umm, and for those of you who are following along on the actual document, that's the middle paragraph on page 24 if you want to pull down the whole document. And Deven's right...this is Lucia; there's a very clear sense is that although there could be legislation here's how it work in the current environment which is as Stan stated, an affirmative statement by a priv...a private...essentially private organization which is then enforced when they fail to live up to it by the FTC.

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

This is Gil; thanks very much for the clarification, that helps.

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

All right. Other thoughts on this topic? Okay. All right, go to the next slide and see what we get. Next slide, please. Okay, so as we continue on, this is where we're...we start to talk about a recommendation that's consistent with the recommendations that we've made, policymakers should re-evaluate existing rules governing data use as they contribute to a learning health system; to be sure they provide incentives for responsible reuse of data for learning purposes such as provide incentives for use of privacy protecting architectures such as data enclaves.

So this is where we're kind of turning back and saying, in addition to protection, we need to incent the appropriate activity including privacy protecting architectures. And then also, and we talked a lot about this the last time we were together, about strengthening rules on patient access to data, particularly outside of the HIPAA space, make sure there's a voluntary code...but also within to make sure that they can be more easily extracted. And then the overall concept of making sure that consumers and healthcare providers and others were on the same page with respect to what really is limited, from a legal perspective, what, you know, what data exchange could occur without legal barrier and then reinforce, again, the previous comments that the working group has made.

So we're trying to turn back here and make these recommendations all as part of the uneven policy environment in addition to the first slide. Did we capture what we discussed last week, people who are commenting on this? We had quite a bit of conversation around these three bullets, actually.

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

Is...this is David; is bullet number 1 intended to...is the subtext that there's not enough sharing or that there's not enough attention to privacy or both?

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

It's a great comment; David as I was looking at that bullet again for about the third time I realized that it is a little confusing, I think; the first half appears to be talking about improving the sharing, the second half gives an example of privacy protecting architectures.

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

Right.

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

So we can certainly do some clarification around that. I think, in actuality, it was...it is supposed to be both.

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

Yeah.

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

But I think the example we may want to use consistent with the first half of that bullet is the...is to encourage reuse.

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

Yeah, this umm...this is Deven; again this is another place, I mean we'll definitely have to take a look at these slides to make sure they capture a little bit more of what's in the text of the document, but this is the section of the report that deals with the sort of operations versus research distinction and whether we need to sort of think about whether there...we have the proper incentives in place, even amongst regulated entities for reuse of data for learning purposes. But I think you're right that that second example doesn't necessarily flow as well from the first but the reason for the little asterisk after that first sentence is that providing a reference to the previous work that the Tiger Team did that the Health IT Policy Committee endorsed that calls for re-evaluation of the sort of different treatment of research versus operations when reuse of data for learning purposes takes place in a controlled environment, so.

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

Yeah, I think we probably need to separate those...maybe separate bullets.

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

Yup.

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

And then a...

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

And then in...David here; in the same spirit, bullet number 2, strengthen existing rules on patient access to data...

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

Oh, right.

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

...is that, is that meant to be on patient's right of access to data?

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

Yeah, good point. We don't have existing rules on patient access outside of HIPAA.

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

Yeah.

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

This is Linda Kloss and I'm wondering if we need to address here, in the spirit of stewardship and governance, greater transparency, because even in...particularly in light of the uneven policy environment, to err on the side of increased transparency might begin to support education.

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

Hey Linda, this is Lucia. I think that's right, but my thought would be that would be covered by FIPPS-based standards in the non-regulated space, right? Transparency is one of the FIPPS.

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

It is.

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

We can certainly tease that out in the previous slide, that third sub-bullet, we can certainly talk a little bit more about transparency.

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

We could use it as an example, yeah. Thank you.

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

Good point.

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

And...this is David, again; I don't remember in our conversations whether we talked very much about the learning healthcare system process being vectored through the patient for...as a bridge for those places where we have unclear policy governance between HIPAA and the Common Rule. So you have networks like the Peer network that Sharon Terry's group has put together where the consumer is the channel for the flow of that data. And the Precision Medicine Initiative is putting some emphasis on that as well. Do we need to call that out here or is that really just kind of straying into a particular space that's too preci...too focused, too specific?

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

David, this is Lucia; we have a really nice sentence about that in the text where we say, this is on the top of page 25 about existing rules giving people access to rights over time and how we need to expand that so that patients can easily access their information for their own use or facil...or to facilitate research into diseases that impact them or in any area of learning they seek to support.

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

Well I'm glad that's...I'm glad it's in the letter.

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

We can't, yeah, we're unfortunately unable to put 20 pages of text into slides or you guys would be reading all day.

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

Yeah.

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

Well I know, but it's interesting, this has been an interesting exercise; it's Deven. You know we...these are things that the workgroup said we'd really like to see and while we can't put 20 pages in, we can certainly grab the stuff that we know is already in the report and highlight it in the slides for things that people are noticing look like they're missing, so...

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

Um hmm, I agree. Okay, other comments on §6.2? This has been some good input and we need a little bit of work here on these slides, I think on the §6.2 for sure. Let's move on to §6.3 and our favorite topic, at least mine on de-identification. Okay, so we've been around a number of places on these recommendations and so now here we're settling in on calling on OCR to be a better steward of HIPAA de-identification standards and conduct; conduct ongoing review of the methodologies and policies and seek assistance from third party experts such as NIST. PGWG desires accountability for re-identification or negligent de-identification but recommends against specifically asking Congress to address at this time.

So on both of those bullets we had quite a bit of conversation and Deven and I actually had some conversation around this as well. And these are where this slide landed; so thoughts on whether this captures what you want to capture?

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

So, this is David; I...we...I remember we discussed a little bit about the, I mean there's improve the ability to do the de-identification, that's captured here. Umm, I assume the improving the trust and reducing a risk are two sides of the same coin, but did we...do we want to say anything about alternate approaches that put emphasis on penalizing abuse of the data, as in attempts to re-identify it inappropriately or to exploit the re-identified data in some untoward way? I know that's covered in FIPPS, in the broad sense, but every time I get into a de-identifications discussion in the real world, it really comes down to, what are you allowed to do with the data and that's what you're going to focus on.

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

Right.

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

Yeah, and we've...and Deven, correct me if I'm wrong, but at one point the rec...we had a fairly strong recommendation asking for Congress to act on re-identification...I don't know if we've ever gone down the path of giving examples.

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

So, this is Deven; so first of all, we sort of...we still have a few more slides on de-identification so one thing that we might do is just to go through the whole...all the recommendations on this topic and make sure that they hang together as a whole before sort of seeing where the holes might be and what we might need to switch around. On David's point about sort of what people do with the data, that has always felt to me to be part of the harm discussion with re-identification being a separate issue and that I think we do...this may be the only point we make on re-identification; sorry, airport. So at this point on slide 6, but we, in terms of sort of what Congress would do to address it, that we did have a lot of discussion about and there was reluctance on the part of the working group to ask Congress to specifically address this, even though...

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

Yeah.

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

...there was a strong desire for some accountability here. But I think on the harm issue, you know, when people are using data not just re-identifying it or even not re-identifying at all but using de-identified data in inappropriate way, guess that's a harm iss...it's tucked into the harm bucket, at least as we envisioned it.

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

And this is a point that Deven and I kind of discussed virtually by e-mail and I agree with Deven here, but on the next slide...I forgot that we separated these into two slides. On the next slide, let's flip there real quick and we can come back; if you look at the bottom, we're urging OCR to carefully consider the following recommendations. And the last bullet, they have it as re-evaluate whether context of data sharing should be part of evaluation of re-identification risk. And this is where I think we get into the example of saying, if there's a...the context of the data use of the data sharing of the recipient and the and where the re-identification risk is high or not, originally this was drafted and it was presented as a harm. And so I think we can discuss some of that in the harm section, but for re-identification risk here, I think this is where if we were going to do any type of examples, we would want to consider those two points.

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

Well although Stan, it's Deven; I don't think we ever looked at that last bullet point as being, I mean, at least I didn't, as being one to address the normative context of good bad use of this data. Instead, this is about whether use of data enclaves, for example, reduces risk in a way that you don't have to treat the data quite as robustly or if you take another step to reduce re-identification risk, is there any way to count that in the evaluation of, in fact, whether the risk is very low and that that has an impact on what you then need to do with the data.

This is something that OCR has addressed previously in guidance and I think what we're doing here is saying, you might want to reconsider whether there's a role for...that context can play, but not context in terms of what you're doing with the data is a bad idea; but context in terms of how that shapes re-identification risk.

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

Right.

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

So this...yeah, so some of this I think does come back to the first slide now where we're recommending a relook at harm and in the scope of harm because the testimony did include comments about there were clear, obvious good uses, clear, obvious bad uses. And we discussed that both when we were having our de-identification conversation as well as when we were having the harms conversation. But you're right in that this bullet likely is talking about the context of the data sharing meaning is the recipient of the data sharing in a...have a context where it would be highly...more unlikely to have a risk of re-identification...it's hard for me to separate a re-identification risk without a resultant harm. But you're right, it...they are technically separate.

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

Umm...

**M**

The data gets...Stan.

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

Maybe it's a slight change of focus, but maybe it will help with that last question is the first sub-bullet point there, I'm not sure what it means; limit use of safe harbor only when data represents a random sample; it needs a preposition somewhere or a comma or something. Is it limit use of safe harbor too, only when data represents a random sample? Or limit use...

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

Oh.

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

...of safe harbor when data represents a random...I don't understand what it means.

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

Oh yeah, it is...

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

What's the point?

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

This is a point made by one of our testifiers, right? It's "too only when."

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

So...

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

So in...

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

...we don't allow safe harbor if it's not a random sample?

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

Uh...

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

I think...yeah, the recommendation David is the safe harbor should be allowed only when there's a random sample. So we're not saying...

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

(Indiscernible)

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

...that's an idea, right Deven?

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

Yes, no, it was from Khaled El Emam because the...certainly the basis for, I mean at least in the view of the de-identification expert, I mean this would have to be corseted with OCR and sort of more deeply thought about and that's why it says, OCR should consider this. But it...and it's not...and it's a recommendation from Khaled, but I understand it's not necessarily one that all de-identification experts agree to. But the idea is that safe harbor has been tested against large, random sample populations and it's proven to be fairly robust, but it's not likely to work as well in smaller populations or ones that are less based on random sampling and therefore may not provide the same degree of protection in other contexts.

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

But there's no safe harbor that I've ever heard of that's a true random sample of the population; they're all constrained to some source of data that is then subsequently blurred.

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

Right, right.

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

So nothing would meet this criteria in a literal sense.

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

Right.

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

Um hmm.

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

You know, we've just never had a...it came across as a recommendation. I was recently at a conference where another de-identification expert said to me, I don't know that that's a good idea and so perhaps we didn't vet this one enough to include it. It's been on some prior slides, but we may have just inadvertently overlooked it or had...we always have very little time on these calls, so we may have been overly focused on some other things, so...

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

I'll vote that it's not precise enough to merit a bullet on the slide at this moment. I mean I think...

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

I could get that.

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

...I get the spirit of what's behind it, but I think it needs a more rigorous definition.

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

Okay. All right, Stan?

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

I don't know I'm not an expert on it.

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

I mean I would support that as well or to try and give a little more context because what David says is true, actually. I had a conversation recently with a covered entity in a research context and they made this exact same point that the problem with limiting safe harbor further is nothing is ever going to be a big enough data set to completely randomize. So, umm, I'm...I support taking it off and exploring it further in the paper.

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

Yeah, yeah. I would agree with that; Deven.

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

Okay. Other of the bullets here then that we had in that list, the re-evaluate de-identification sets or data set when the context changes, i.e. when the...if there is a...if it's been declared specifically de-identified or even safe harbor and the context of the other data sets or larger data sets could impact the de-identification status. Then develop...

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

If...

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

...programs to...go ahead.

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

I was saying...hey, Stan, this is Lucia. When I read this slide, and I've looked at it a couple of times, if we could be clearer about which context we mean, whether we mean the collection context or the use context.

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

Yeah, I...

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

That would be really helpful because the context is ambiguous.

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

Yeah and unfortunately I think it's ambiguous in our paper.

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

Yeah.

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

We can go back over that and check it, but I wanted to actually put that out there for the workgroup to comment on whether they had the same...I would profess to being too far in the weeds on this. If that feedback came back to me, I would probably exceed...accede that point.

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

I think it's also the case, and this is Deven; I seem to keep talking at the same time as the airport announcements. That second...that bullet that we're talking about about re-evaluating de-identification status when context changes is one that's...that it turns out is actually covered in OCRs de-identification guidance and Linda Sanches pointed that out to us by e-mail. So we may, in fact, want to go back and re-take a look at that and either clarify what we mean by that or again relegate that one to text.

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

That was with the statistical de-identification, correct Deven?

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

I believe so, yes.

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

Yeah, because that's the only time they would have that authority, I think.

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

Yup.

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

Because the other thing is if you meet safe harbor data, the patient is disclosed, the receiving entity is no longer covered under the regulation so there couldn't be a consideration of the data set after that point.

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

Right.

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

Okay. All right.

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

That's very interesting.

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

I think clarity there would be good.

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

Yeah.

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

So it would have to be the analysis on the front-end of the de-identification status prior to declaring it when you...when the context of combined data sets changes; so ongoing disclosure and reliance on a status. Okay. Other points, so then it was...the next point was develop programs to objectively evaluate statistical methodologies; consider granting safe harbor status to methodologies proven to be effective in a particular context. Again, these slides are very difficult because obviously that's a very high level comment.

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

Is the though there that you would expand the definition of safe harbor to include some new approaches should they be proven worthy? Is that the gist of what we're saying?

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

Yeah.

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

I think wha...yeah, I think it was as well fairly contextually specific, I mean, it would...

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

Yeah.

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

...have to be fairly contextually specific.

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

Yeah. No, I like the spirit of that thought, I think that's a...I don't know that...

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

Right.

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

...how you would define when you've achieved success, I guess that's the statistical argument.

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

And the last bullet, re-evaluate whether context of data sharing should be part of evaluation of re-identification risk.

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

We...you kind of imply that in number...in bullet point 2, sub-point 2, right?

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

Umm.

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

Yeah.

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

I mean, I'm not saying take it away, but I think it...you've already admitted the importance of context affecting the de-identification status and therefore the risk.

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

Is this just supposed to be the opposite way, I mean...?

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

Uh huh.

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

...in essence, saying that the context of the enclave could actually reduce the re-identification risk analysis. You know Deven, this is a...I may have to come back and think through this one a little bit more because this is one that Deven and I didn't have a chance to catch up on and I went back and forth and I'm still not sure we quite have it right.

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

It doesn't seem...this is Linda. It doesn't seem to me that this should begin with re-evaluate.

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

Yes, you're right.

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

Ah, yup.

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

Yeah, I think that's right, that's just a great point.

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

Yeah, I'm with Linda...this is Lucia. I sort of read it as in the course of handling data we should be constantly re-evaluating whether there's a re-identification risk because we're doing something new or different to the data than we started out with.

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

Yeah...

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

That's how I read it. But that...

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

But...and the bullet was meant to be the opposite. The bullet was meant to be consider whether the context of the data sharing or the enclave should be part of an evaluation of a re-identification risk and...

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

Right.

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

...to some extent, that's implicit in the definition of statistical de-identification. My point on this initially was more of a harm point on whether the likelihood of harm should be considered as part of an evaluation of de-identification.

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

Oh whoa, really? Really?

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

And that's what...I mean, that's what we were...yeah, I mean, this was a comment about the idea that if the recipient has a data enclave, and it's sealed and it's secure, is there a place for consideration of re-identification risk in that circumstance?

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

Yeah, but that's re-identification risk not...

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

Well is...okay, is there consideration that...of a harm than a re-identification risk, maybe that's a better way to put it.

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

No, well, all right...so this is Deven. I see re-identification risk and harm as two different things. Could you harm somebody just by knowing that they're in a data set and revealing them in a data set? Yes, technically yes. But here, this to...in my view, the way we've been having discussions around this whole section §6.3 is about reducing re-identification risk regardless of whether the re-identification actually hurts somebody or not, which is about the normative issues around...

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

And so...

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

...which I don't think should...that I don't think should play in to an evaluation of whether you can find someone in a data set or not.

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

And so then, and again, I'm fine with that then we can go back up into harm perhaps and look at the...look at how we discuss that from a harm perspective because the issue is, if we have a research recipient or recipient of de-identified data and we've now extended some of these other requirements or recommendations to...around security and we have secure data such as secure data enclave, is that a different analysis? Does the harm come into play? I mean part of the conversation that I've had with entities is that there's no incentive, there's no ability to go back...for the recipient to go back and re-identify. If it's...if it's just as a risk that the data would be disclosed from a security perspective.

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

I mean, that is essentially what we meant by number 4 is if, and Linda Kloss is right, it's...we shouldn't have used the word re-evaluate in this last one...

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

Right. Right.

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

...because it's about the initial evaluation of whether you've got a data set that's likely to have a higher than acceptable re-identification risk associated with it. And so the idea here, it sounds like it's one that people are endorsing, is that we should consider whether things like this is going to researchers who have no motivation to re-identify. This is going with contractual protections against re-identification. This is in an enclave or some combination of all of those, whatever would be acceptable. We're not trying to get this analysis perfect, but just suggesting that there's room for consideration about whether these contextual factors play into the evaluation, not re-evaluation, the initial evaluation of re-identification risk.

And then obviously if context starts to change, that's when number 2 bullet comes into place in terms of, well the original determination of de...you know, that the data set was sufficiently de-identified, that the re-identification risk was sufficiently low, now we've got a contextual change.

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

Yeah so I like that...this is David. I'd say then change number 4 to be evaluate and move it up into number 2's position and slide number 2 down to 3.

**W**

I agree.

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

Does that make sense, Stan?

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

Yup, that's fine. Yup; that works. Okay, good. Other thoughts on this slide? We're dangerously close to actually having one more slide and then wrapping up a slide conversation, so, if you have thoughts on the de-identification methodology, it would be great to hear. Okay. All right, well let's see where we can go on to §6.4; next slide, please.

So, and this was...and Deven, correct me if I'm wrong, we didn't actually have a lot of robust conversation around this and this is the one where I think we were...we had some fairly consistent comments from week to week. We've landed on urge the development of voluntary code of conduct to address robust security safeguards that can be enforced by FTC. Call on public and private sectors to educate stakeholders about cybersecurity risks. Call on policymakers to write incentives for entities to use privacy enhancing technology and architectures, like secure data enclave.

Re-endorse prior Tiger Team recommendations which were including security policy (collecting, storing and sharing). Electronic health information needs to be responsive to innovation. Security policy needs to be flexible and scalable. And providers need education and guidance on how to comply with security policy requirements.

We did talk a little bit about how HHS should have a consistent dynamic process for updating security policy and rapid dissemination of new rules and guidance. And call on NIST to update the NIST 800-66 Revision to include description of technology.

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

Yeah, that was the one add-on...

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

Yup.

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

...from prior slides because it was a suggestion from Manuj that people seemed to really like.

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

So any thoughts? Did we capture that well? Anything we'd like to see different?

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

Yeah, this is Lucia; the only thing I guess I would friendly amendment, suggested to that last bullet, the Manuj, I think we should be clear, at least certainly in our text that whether we're asking for an update from NIST to all potential types of access or access...this has to be scalable, right? So do we need to distinguish between the access that an individual has to data about them that results from big data techniques versus what a further user, researcher/analyst type person might have access to because of the volume of the data? I would hate to have a situation where we get an updated...something updated to reflect cybersecurity which then undermines individual's access to their own data.

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

Yeah my...this is Manuj; my thought was more for the analyst.

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

Okay, so your point...at a level of volume, right Manuj? That's what I thought you were talking about.

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

Yes. Right.

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

Yeah, so maybe we can just make sure that I'll flag it and when we go back over the edits, we'll make sure that we're not depriving individuals of rights by doing this.

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

Yup, absolutely; that's not the intent.

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

Okay. All right. Well, we have time if there are any other thoughts on earlier sections or any other questions. Our goal here again is to try and get to a circumstance where we can easily exchange this via e-mail and kind of come to a conclusion or make recommendations on June 30, at least as a...either a penultimate or potentially an ultimate circumstance. So, how comfortable are people that we've gotten closer? I guess I'll ask that for all on the call, staff and Deven as well.

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

So think...so, Stan, I think we had the most amount of discussion around some of those de-identification recommendations so we might want to just take a...recirculate some of the text around that as we...based on the discussion that we've had on this call. And just do a quick e-mail round with the workgroup to make sure everybody's comfortable with where we landed. But otherwise it sounded like we're on the right track for these.

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

Yeah. We had, yeah and we had §6.2 we had a little bit of comment on make them a little clearer on the recommendations and consistencies in bullets 1 and 2, so we can do that. But yeah, I think; I agree. Anybody have a different perspective; feel like we're close enough? Are there other areas?

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

Just for clarification; this is Linda. I presume that the executive summary, the report goes with this, correct?

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

It does, it does, Linda.

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

And I just wondered whether, as I read the report, I mean I think it's very well done, are there sort of some outstanding questions that need to be teased out? And pulled out, you know, we aren't saying that we've addressed all issues of this rapidly changing environment. So I guess I have...I guess just I have a question of process. Once this is adopted, how does this then go forward as part of a learning environment and continual to be updated because it's such a rapidly changing environment?

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

So Linda, this is Lucia. I think I can give a little bit of insight into that, but honestly this report was requested from the White House and we don't know what they'll do with this. My assumption is that working with a lot of people over there every day is that they will take the report and they will use it to inform their thinking as they work on issues related to whether it's responding to current legislative proposals in Congress or what might need to be put in place to make precision medicine really come to life. They're asking me about this and they want to look at it as a process of informing them.

There's...as far as I know, there's no present either commitment by ONC or request by the White House to update this work on a regular basis, which doesn't mean that request couldn't be made. But it was intended to be sort of best shot thinking in a one-time basis, if that helps.

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

I just wonder if it would be responsible of the workgroup to note some recommendations with regard to continuing to study this environment and update...

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

So Linda we do have...this is Deven; we do have those with respect to the harm issue.

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

Yeah.

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

We don't specifically note that in any of the other areas maybe because for the uneven policy environment we have some more specific recommendations that we're suggesting for the near term and similarly with de-identification and security whereas for that harm discussion, we were...we just really thought that there, you know beyond sort of saying look to the Fair Credit Reporting Act and see whether there are protections there that can be leveraged in this setting.

We were...we sort of felt it was...there's still so much more to, you know, the environment is so rapidly evolving and there's so much we don't know about what harms there could be. Nor do we necessarily have clear consensus on what those harms are beyond areas that maybe have already been addressed, like under the Affordable Care Act or in other areas where people are already urging legislative or regulatory change. So, it's in some way...go ahead.

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

No, I was just thinking as a general suggestion, well it may...there may be an additional general suggestion that, you know that assigns accountability to continue to look at this and update a rapidly changing environment. Something that demonstrates our understanding that, you know, we've done the best job we can in the current context, but we know years from now this is going to be a different world.

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

I don't think it's out of bounds to say that this is on the whole going to be an environment that's just continually going to be evolving and it's important for relevant policymakers to always sort of be keeping their eye on it and to understand where things are headed. And maybe that's not even just limited to policymakers now as I mention it. It's, you know, we only get a snapshot look at these things sometimes, but it doesn't hurt...

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

Right.

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

...to sort of say that this is...this should never be the last time anybody looks at this stuff.

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

Particularly in this...particularly this topic.

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

Um hmm. Yup.

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

So what do you think Stan, we can add that?

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

So Linda, Linda, this is Lucia; just a quick question about that? So in terms of how you would want that reflected, is that something that, from your perspective, is sort of thematic so would theoretically go in the executive summary or the introduction versus for each particular analytic point; other than the way we've called it out already on the slides?

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

Yeah, I really did see it in the executive summary.

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

Okay.

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

Okay, any other thoughts? We're getting dangerously close to agreement here. Okay.

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

So Stan, this is Lucia; can we spend a little bit of time before we get to the public comment on how we want to have people give any further comments in advance of Monday's meeting? We had sort of thought here that if people had particular edits we should get those by Friday; Helen, I don't know if you're still on and whether you're rethinking that, so that we can turn them around and get them back out to the Policy Committee for Monday.

Or, that's sort of Option A; Option B would be we revise the slides, give the Policy Committee an update, but hold back on the actual summary while we make sure all that we've talked about today shows up in the narrative. Those are the options as I see it, but I don't know if you or Deven had other options, but we sort of need to know what to do next because we have a week.

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

Yeah, I mean I said something, iterate fast is basically what I'm hearing from you and I think that's fine based on the changes that we have. I don't think there's anything that's going to be terribly difficult to get...comment on. Deven, you've had a lot more experience, if you're able to comment on that.

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

Yeah, no, I mean generally if we could get people some revised slide text within the next day or two and give folks a couple of days to comment, we should be able to resolve any issues. And if it turns out that we're still sort of stuck in a certain area, based on the e-mail response, what we can do is just raise with the Policy Committee that we had discussion around a number of points and it's quite possible that they may provide extra guidance on it for the workgroup to either consider or they may resolve the issue themselves. So...

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

Deven, this is Helen. I am about to resend to the group a word version of the draft big data report so folks can, if they wish, make comments and track changes on that particular document so that if they want to return that to us in addition to the slide revision, we can take that comment...we can take those comments up until Friday morning, if that works for you.

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

Okay. Deven, were you going to try and comment or, I couldn't...

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

Yeah, no, no, no; no, I mean, certainly if that works for everyone else, it certainly works for me.

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

I couldn't tell whether you were commenting or that was the background.

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

Well, it's a little bit of both.

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

All right. Okay, well I mean, that sounds like a reasonable plan and again, I think that the de-identification piece is the one that really had the most robust conversation this time, so, focus in on that one you get the changes and we will...before we can iterate that and come back. So, do we think that on June 30 then we're ready for a full recommendation on the slides and the report...or, barring some disagreement, continuing or some additional conversation is needed?

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

I think we should aim for that, Stan; this is Lucia; but...

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

Okay.

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

...it's you guys who are doing most of the work, so it's really up to what you want.

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

Okay. Well let's see, I mean if we just don't get a lot of comments back or if we don't have a lot more to talk about, then I think we're in a good place to try and wrap it on June 30. And that's a virtual conversation with the Policy Committee, isn't it Lucia?

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

Correct, that's dial-in only.

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

I'm sorry, I couldn't...did someone comment...

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

It's a virtual meeting, Stan.

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

I'm sorry...Monday is dial-in only virtual, virtual all.

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

Okay. All right, I think we're ready then for public comment.

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

Caitlin or Lonnie, can you please open the lines?

**Public Comment**

**Caitlin Chastain – Virtual Meeting Specialist – 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 do have a public comment, Madeline Jay; please state your name and the organization that you're coming from. And as a reminder, you have 3 minutes for public comment. Go ahead Madeline

**Madeline Jay, CIPP/US – Senior Software Engineer – Johns Hopkins Hospital**

Hello, my name is Madeline Jay; I'm from the Johns Hopkins Hospital and I just want to congratulate Deven McGraw on her promotion and appointment to the OCR; I think that's what it is and just say that I have really enjoyed listening to and learning from her over the past few months that I have been a listener on...as listening to the public call. Thanks.

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

That was really nice, thank you.

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

Thanks Madeline. And we have no more public comment. I too want to thank you Deven; I've learned a great deal from you and it's been amazing hearing you on all of these calls so thank you so much.

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

Well, I want to...thank you Michelle, thanks to ONC for the opportunity and a special thanks to my workgroup members for letting me do this last call while interrupted by all this airport stuff; I'm so sorry guys, I really appreciate it. I've enjoyed working with you so much and I hope our paths continue to cross. Thank you.

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

So do we; we'll miss you.

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

Yes, we will. Thank you, Deven.

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

Yes, we all will. Thanks, Deven. Thanks all.

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

Bye.

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

Bye.

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

Thank you.