



**HIT Policy Committee
Privacy & Security Workgroup
Final Transcript
July 27, 2015**

Presentation

Operator

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 & 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. Stan 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

Hey, Stan.

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

Hello, Michelle.

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

Hey, David. Gayle Harrell? Gil Kuperman?

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

Here.

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

Hi, Gil.

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

Hello.

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

John Wilbanks? I believe Kitt Winter's on, but she had to step away. 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 Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.

Here.

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

Hi, Linda. Linda 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? Micky Tripathi? I believe that we have Mary Kelleher in for Sarah Carr?

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

Umm, Sarah is here, too.

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

Hi, Sarah, thank you.

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

Hi. Thank you.

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? I believe Helen is on and then Lucia Savage is also on, but she is muted; anyone else from ONC on the line? Okay; with that I'll turn it to you, Stan.

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

Okay, great. Thanks, Michelle. And I did want to point out at the beginning of the meeting here that we'll likely only be about 45 minutes is what we estimate, so if we do have public commenters, they may want to be ready to queue up earlier than normal because the meeting likely will not go its full length, unless we get a lot of debate over a couple of the points that we have. But not anticipating a long meeting today; so thanks again to everyone for kind of interrupting your summer schedules today. It's been a little while since we chatted last.

I first wanted to give you just a quick update on the conversation that we had with HIT Policy Committee on June 30 and the comments we got back from there. And then we'll switch right to Section 6.1 of the transmittal letter on the Health Big Data Report and we'll work off the transmittal letter itself in our conversations today, rather than have PowerPoint slides. And that is how we will present, as well, to I think to the Policy Committee so we may have few slides, but will primarily talk off of the transmittal letter itself.

So to come back to the Policy Committee meeting; we did a, if you'll remember, we presented basically a penultimate draft, what we thought was a near-final recommendation to get feedback from the committee and see if they wanted us to consider other things or to add additional information. And the comments we got back were summarized basically in the first instance, you know, they wanted us to try and move from language we had, we would "call on" FTC to take action, or call on HHS or OCR or "they should consider" type of language. They really requested that we focus in on and use directive language whenever we could and use the phrase, in fact, "should" to be a little bit more directive in what we were recommending. They have had quite a few committee reports or workgroup reports asking them or asking them to consider or to perhaps take action and they really were hoping that we could focus in on the things that we felt strong enough to say that they should take action on.

So, we've modified the working paper to reflect that change as well. The other topic, they didn't really have any topics that we didn't cover; the overall sentiment was that Paul Tang thought the summary of the issues was comprehensive and that the recommendations were accurate and seemed to be spot on, in their opinion. They did ask us to think about, you know, when we moved away from a specific recommendation asking for legislation on re-identification penalty and on specific legislation for security, they asked us to consider if there were other things or other strategies we could come up with that would move things forward a little bit.

They specifically wanted us to think about if there was a blended approach potentially to work on the idea that we may not have direct call for legislation, but were there other things that we could consider that we would be comfortable recommending; and we'll talk a little bit about that in the paper itself. And then they also wanted us to make sure that we referenced private initiatives like Healthway and others that were moving forward to set up trust authorities or community risk assessments or that were setting up de-identification frameworks that we should reference if they had that to consider as they deliberated our recommendations.

And so all in all, the conversation went well. I think the feedback was under...we understood the feedback well. I think some of the feedback we got asking, you know, could we consider broadening, consider proportional liability, consider ideas of directing Congress to take action. My response to that was, we've kind of gone through that, we've deliberated, we looked at all the information that we have and based on the evidence we had in front of us, we just didn't feel comfortable making a direct recommendation for legislation. And instead we were focusing pretty strongly on self-governance and the interaction of the FTC as well as the Office of Civil Rights and HHS to interact with those groups developing self-governance codes so that they could become fairly structured and have accountability and use limitations involved with them.

So, that was the position that we took with the committee and they seemed to appreciate that. We said we would consider making the changes that they had recommended. Lucia, I know you're on mute, I'm not sure if you can comment or not but didn't know if you had anything to add to that or if anybody else who is listening had any other comments on that conversation.

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

I, I...this I...thanks Stan, this is Lucia; I can comment briefly. I'm just trying to, like David; sort of minimize the background noise. That's exactly the process that we've been through literally there were Boolean searches for "coulds" and then we analyzed whether that wording should become a "should." And I've already slipped ahead to Section 6 and I'm ready to go.

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

Okay. All right, so let's look at Section 6, in 6.1 and I, by the way, cannot see the screen, I'm actually on vacation on Lake Michigan, so I don't have connectivity here, but I'm assuming that you have the document in front of you, which is the transmittal letter or you're able to view what is on the screen.

But looking at 6.1, really the...most of the changes that we made in the document that were material in any way are in Section 6 and are addressing the solutions and recommendations. In 6.1 where we had, if you look at the first paragraph, we have a statement in there now talking about the voluntary efforts at creating trust frameworks across institutions such as Healthway and the Sequoia Project and PCORnet; and so we wanted to reference those more specifically. And there are footnotes now added for those reference points, to bring them into the conversation more specifically really in response to the committee's request.

You'll also see that we had a, in the next paragraph, we had a change from, we would like them to consider or would you consider adopting measures and we made that more forceful and said, we really do believe they should adopt measures that could increase transparency about actual health information uses. The idea is that if we could have multi-stakeholder workgroups to establish some consensus on privacy harms, this is our point around, harms are not well defined yet and we really would like to see policymakers convene these sessions to try and drive greater understanding around privacy harms, which then leads into the types of self-governance codes and other activities that can be taken to prevent those harms. I'll read through these...I'll cover the 6.1 and then we can come back and see if there's any comment from the workgroup.

The next change is at the very beginning, I mean, at the very end of 6.1, where we asked them to consi...that they're actions they may take, we switched it from, you know, any such regulation or best practice governing algorithms to say any such policymaker action regarding algorithms. Because we...if we're not recommending regulation, we wanted to come back and make sure that the actions they would take, we wanted to make sure that they would maximize transparency.

So if they're going to convene multi-stakeholder workgroups and they're going to come through with some potential codes that they would like to see adopted, we wanted to make sure that those actions increase transparency around algorithms. So and 6.1 really reference points and a more directed call to convene multi-stakeholder workgroups. Any questions from the...or concerns from the workgroup on 6.1?

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

Umm, Stan, it's David; can you hear me?

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

Yes.

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

I, like you, am without luxury of the screen, but you mentioned inclusion or reference to groups like Healthway, which is now Sequoia and others.

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

Um hmm.

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

And I'm somewhat mystified about that because the trust frameworks that they're working on are pure HIPAA constrained and are not big data and I'm curious, what was the connection? Why were they mentioned?

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

Yeah, great question. It wasn't that we knew that there was a direct correlation between a big data effort and framework, this is simply about a reference point of frameworks that we are aware of in the health space that we could look at and say, you know, is this a model that could be expanded to include big data activity? It's a good question and...

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

Stan...

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

Yeah, I would...go ahead

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

This is Lucia, just want to add for David, because I'm...I actually the text and I want to...so Healthway is one of three examples, David; so there's Healthway, there's PCORnet and then there's Community Research Boards that are sort of being sponsored by the Community Campus Partnership for Health. So we really tried to kind of give examples that fall in the footnote that would be of a diverse group of trust communities that are trying to build themselves.

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

Ah, okay, well PCORnet certainly makes...is a closer fit; I don't know that third one...

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

Um hmm.

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

...but I guess the point that you're just trying to cite examples. I mean, I'm not sure that, well, if the goal is voluntary efforts at self-governance, then maybe those are good examples. I think an equally important question is whether there's much chance that that works in the real world, when you don't have more of a relationship amongst the participants to actually enforce governance to quantify it and enforce it. But...

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

...that's off the subject. That helps a little bit that you're just painting a broad example.

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

Yeah...

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

There are lots of governing entities out there that you didn't mention, self-governing and...

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

Right, so there are just lots and David, this is Lucia; we could not have been comprehensive because that would have taken a whole page of citations. But what we did is tried to give the three citations that identify actually in the same sentence, but there are a lot of people who think that voluntary efforts will never be rigorous enough or widespread enough to do...to afford definitive protection to individuals.

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

Yeah, no, and I agree that that's an independent point. My only concern was this somehow falsely implies that Healthway and other HIE-like activities are addressing the big data problem that this report was targeting; I think those are really very different worlds...

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

Yeah, okay.

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

...don't want to confuse the two.

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

Yup, we can clarify a little bit to say that while these are not...certainly not big data type frameworks, they are voluntary efforts in creating trust frameworks and perhaps could be leveraged or learning from them...

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

Yeah, that...

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

...or something. Okay.

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

That makes sense, trust frameworks that address health data, patient-identifiable health data. Yeah, that makes sense, but it won't solve the big data problem because that's outside HIPAA.

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

Yup. Okay...

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

And then, Stan, this is Lucia; just one other comment for the whole workgroup because I know you guys read this stuff when it comes out, but in the same section, we sort of reference the NCVHS toolkit which we saw in draft as part of our testimony, but they actually published it I want to say about a week and a half ago, so it's out in final. And we'll update the footnote...the staff will update the footnote to reflect the final copy and the final link, but for those of you who are interested, they did just publish their new toolkit recently.

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

And just to...this is Linda Kloss; just to reiterate, that was really directed at community efforts to use health data. So again, not directly applicable, but a good model of a framework based on fair information practices, hopefully.

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

Okay. Great; anything else in 6.1? I think some of our next conversation in 6.2 we'll talk a little bit about...we'll continue this conversation on this topic, actually. But any other conversation, any other thoughts on 6.1? Okay. So 6.2, if you remember...

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

Stan?

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

...our...yes, I'm sorry. Go ahead.

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

Sorry, Stan, this is Manuj. I just wanted to make a quick comment here and I apologize if this is redundant but in the very last paragraph we reference the algorithms that are used to evaluate and make decisions that have an impact on health of individuals and communities. Do we want to clarify that on the use of health data as opposed to kind of the other way around, the way it's written? Because we're talking about big, large repositories of health data here, right?

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

Right.

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

And whatever effect they may have, regardless of whether it has an impact on health.

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

And so are you looking at the...when you say the la...you're looking at the paragraph that starts, any such um policymaker action regarding algorithms, is that the paragraph you're looking at?

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

Yeah, that's right.

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

Okay. And what was your recommendation again, I just want to make sure I'm following.

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

Yeah, I would try to kind of flip it around a little bit, the very last sentence where algorithms are used...are using large data sets or big data; we should have a broader understanding of what the impact those uses might have on individuals and communities generally.

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

Hey Manuj, this is Lucia; would you be willing to sort of do a cut and paste and send us what you think you want it to say?

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

Yeah, no problem.

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

I hear what you're saying, but I can't quite get it myself sitting here looking at the paper. I think you're saying we're sort of...we'd actually want to connect it more to the root activity instead of the resultant harm.

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

That's correct.

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

Right.

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

Yeah, I'll write it up real quick.

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

That'd be great.

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

Yup.

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

Okay. So on 6.2, this is where we're trying to address the uneven policy environment, the difference between, you know, the HIPAA environment and the non-HIPAA world and the changes we made again in here is that we kept the sentence that says Congress could address this through legislation, but the workgroup believed that such protection could better be achieved through voluntarily adopted codes. And then we go on, and this is where we made the request that those efforts should be encouraged and HHS, FTC and other federal agencies should offer to review and provide suggestions.

So, from a could offer, we really were...we are asking for action here to say that we believe HHS and the FTC and other agencies really should offer to review and provide suggestion. And really the premise here is that if they get involved wi...they could ensure enforceability, at least of the standards under Section 5 of the FTC Act and what other legislative criteria currently exist. And in addition we added at the end, we firmed up a bit. We originally had such codes of conduct should emphasize transparency, etcetera and made the change that in order to credibly meet the requirements of both protecting sensitive personal information and enabling its appropriate use. Codes at a minimum must include transparency, individual access, accountability and use limitations.

And those are the same criteria we had before, we're just trying to set the bar to say that it's likely that if a code does not meet...does not include these ideas of transparency and access and accountability that they simply aren't going to be taken seriously. And so this goes back to the, I think the prior section conversation about do we really think voluntary codes are going to work? You know, we're trying to make it as...trying to set the bar at least at a level where they can be taken seriously.

And then the final thing we included in this section was the inclusion of accountability, a risk review mechanism such as through community or risk review boards should be considered. And we drop a footnote there and that footnote is to, and Lucia, I'm trying to remember, I think you are...I think were the one who had the specific footnote on...do we have that...on, yeah, that was the Precision Medicine Workshop on Patient Engagement where they had a direct conversation about the idea of a community risk assessment review board. And so this also was brought up to some extent with the FTC's Internet of Things report where they were suggesting there should be something more than just a code, there should be some type of an enforceability mechanism.

So, those were our big changes to 6.2 to try and force a minimum standard on codes that industry could...should consider and then the consideration of a risk review...and independent risk review or accountability board to be considered. So, comments on 6.2 on those changes? Either incredibly non-controversial or there's a lot of mutes going on, but, it was in direct response, at least some, to the committee's request.

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

This is David; that sounds good to me, I think that we should be as strong as we can and then others can decide whether to back off or not.

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 think the sense of our discussions was that we thought these were good ideas and we were just being cautious in stating them, so I don't mind the changes; I like them.

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 I'm unfortunately going to have to disappear probably before the next round of comments. So, I apologize, it's a flight I can't control; I'll get left.

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

No, understand your problem. Thanks.

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

Yeah. All right.

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

Thanks for joining us.

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

Yeah, thanks. Sorry.

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

Any other comments on 6.2 and if not, we can move to 6.3. Okay and we can always come back at the end if there's specific questions. So on 6.3, this was the de-identification methodologies and registering risk of re-identification and really primarily what we've done here is change the kind of the general request of OCR to consider to be more proactive and we said now we've changed the considers and the could's to should be more proactive steward of de-identification standards. They should grant safe harbor status to methodologies that are proven to be effective and they should establish risk-based de-identification requirements.

In addition we dropped a footnote to include the HITRUST Alliance de-identification standards that are recently released, think they released them in March. And we dropped a footnote to those referencing, you know, methodologies that this should be considered. And so...but that was the primary change there and again, we didn't...we told the committee we just didn't think we; one, we had the capability really to go wide enough to understand the potential unintended impact of a direct legislative request. And so we resisted there they're urge for us to consider whether we should ask for something more directly. Instead we asked for a more proactive OCR approach and we've included a standard that has recently been announced. Comments on 6.3?

W

I think the changes are helpful.

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

I'm sorry?

W

Changes are helpful.

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

Yeah, okay. Good.

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

Stan, Gil Kuperman here; I guess the obvious question is has Deven McGraw seen these changes?

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

You know, I've not talked to Deven.

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

Gil...

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

Hi, this is Linda Sanches from OCR. Can you hear me?

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

Yes, please. Yes, please go ahead.

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

Okay. And I actually can't say if Deven has looked at this yet, although I will be talking with her about it soon. I just wanted to ask a little bit more about the granting of safe harbor status. Generally, you know we've put out guidance and it needs to be effective for a long period of time. Is there some way for us to somehow identify the methodologies that would continue to be effective, given changes and the ability to use big data? Might those safe harbors actually no longer provide protections at a certain point or were you thinking of a different type of concept; is this something you're thinking we would put out a new list every certain number of years? What would that...

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

We...

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

Linda, this is Lucia. I think this is from some of the early testimony so we can work off-line to get you the transcripts but the idea was that the safe harbor that exists right now is really excellent for data techniques that are kind of becoming not used. And maybe what we're really thinking is, are there new...can we figure out what new safe harbors would look like? I don't think this testimony which ran about 3-1/2 hours actually would be sufficient for you to have definitively decided what new safe harbors might look like and answer that very question you're asking which is, what is the duration of that concept?

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

Yeah and I think where...and also in response, we actually asked you to do both things, both to be the steward to kind of conduct ongoing review, and then to grant the status...the safe harbor status to those that you saw as being effective.

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

Okay. Thank you.

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

Um hmm, thank you; other questions or comments on that section? There was a paragraph...there was a paragraph that we had that we had and it was really an anecdotal comment in our testimony that talked about urging, you know, limiting the use of safe harbor to circumstances with random sample. And after talking further with the workgroup and with staff as well, we believe that that was kind of a misrepresentation of the overall opinion on safe harbor and we had some questions so we deleted that piece. And also we think it was redundant a little bit and that when we asked them...we asked OCR to be a steward of the standards and conduct ongoing review of methodologies, it considers that as a...that comment would be fully contained within that request from us and so we...it was an example we didn't feel fit well with the rest of the recommendation.

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

Stan I think...this is Lucia; the other reminder for the workgroup as a whole is we made a decision as a workgroup a long time ago to sort of take all the actual transcription citations and make them available through the footnotes and of course they're all online and so we tried really hard not to call out singular or unique opinions among our testifiers, but rather to reflect...

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

Right.

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

...what you guys as a workgroup had concluded based on what you heard.

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

That's a great comment, yup. Thank you. Okay, let's go to 6.4 and I don't believe actually we've had any changes to 6.4 and so I think that actually is the balance of the changes to the document. So are there any questions, overarching questions from the group with respect to the changes we made or for the tenor of the recommendations now that we've asked to be a little more pointed in some of the things we've modified? Okay, I'm not hearing a lot more conversation so, Lucia did you have any final comments on the changes we made?

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

No but I...Stan, let me know if you need...if people need to be reminded about what happens next with this particular report.

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

Yeah, in fact I was just going to ask you if you want to take that or if someone else could reference the next steps here...

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

Yup.

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

...and then also what's going to happen this summer.

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

Yeah, so I'll do the next steps for this report and then I'm going to hand it over to Michelle to talk about sort the future after that. So in the normal course, we would have had Privacy & Security Workgroup scheduled for August 10 and the only agenda item we would have had would be this report and so we worked really hard to get this report to you today and get your input today because there was logistically no time to take input on August 10 and have it ready for the Policy Committee which meets the very next day on August 11. So you will be getting a cancellation for the August 10 Privacy & Security Workgroup, if you do not have it already and hopefully that will align with everyone's vacation time.

The Policy Committee will convene in the virtual meeting on August 11 and this will be one of I think three items on the agenda and we fully hope that the Policy Committee will endorse your recommendations in the form of a final transmittal letter to the Coordinator. And then that will bring this particular project of the workgroup to a close. Are there any questions about that? And of course you're all free to dial in on the public line on August 11 if you want to listen to the action; I don't imagine it'll be a hot and heavy debate. Great; Michelle, I'm going to hand it off to you to talk about what happens after August 11.

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

Thanks, Lucia. So as you all know, you have been working very hard from early this year you've been responding to a number of different things like the interoperability roadmap and MU3 rule and the certification rule. Now...and you've also been working on big data since the end of last year so you actually are one of the few workgroups that has continued to meet over the summer, but we want to give you a few weeks off.

And while we give you a few weeks off, some of the chairs of the current workgroups have been busy; so Stan unfortunately doesn't get a vacation and a few other members we've asked to join an Interoperability Task Force that is working on some things that were requested by Congress. So there'll be a congressional report put together based upon the recommendations from that group. So while the chairs of the group...the Policy Committee groups meets, many of the Policy Committee workgroups will be kind of on hold and enjoying their summer rest and then once we finish that work, we will come back to the workgroups.

But the workgroups will function, I think Paul started to message this, or I know Paul started to message this at the last Policy Committee meeting that the workgroups will definitely start to function in more of a task force model, similar to what we've done on standards side. So workgroups will only be meeting with a specific charge, if there's a specific question asked of them so some groups may not come back until later on, maybe December and I think there will be some questions for this group, we just don't know what those are yet. But we will...we hope that you all will still stay engaged and be ready once we are ready to ask priority questions of you.

So stay tuned, we think probably around October/November timeframe we'll resurrect this group and so you get a little bit of time between now and then. And thank you so much for all of the work that you've contributed thus far; we know we've kept you very busy, so it's definitely a well-deserved rest.

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

Thanks very much, Michelle and yes, thanks for all the hard work folks and we will make the few tweaks that we had heard today and go...I think we should probably queue up public comment as we kind of...

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

...Linda Kloss...

Public Comment

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

Yeah, let's queue up public comment just in case and then we can come back. Lonnie or Caitlin, can you please open the lines?

Lonnie Moore – Virtual Meetings 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 telephone 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

And so while we wait, was that Linda Kloss who had a comment?

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

Yes. I just had a question with regard to this draft report, the health big data. Should we wait until after August 11 to share it with others? For example, I had in mind to share it with NCVHS and wonder if we should wait.

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

Well Linda, this is Lucia; I mean, this particular draft was published as a draft on the HealthIT.gov website for this FACA meeting.

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

Okay. All right.

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

But there could be changes and we don't know exactly what the HIT PC will do and when they make a final decision, that will be published as a final report. So it's really kind of up to you, but this is considered a public document in draft right now.

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

Thanks, I will go ahead and share it then. Thank you.

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

And it looks like we have no public comment.

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

Okay. Well, thanks again for everybody to dial in during the middle of summer here. Thanks for the great work; please dial in on August 11 if you have a chance to hear kind of our final committee recommendations live and then we will certainly get this document back out to you shortly, once we've made any final tweaks and certainly well in advance of August 11. So any other final comments from the group?

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

So Stan, this is Lucia; I just want to say thank you, too. I know exactly how hard everyone's been working this spring and the work is really great and sitting where I sit and seeing a lot of different things that we're trying to do to the healthcare system, I think this report is coming at the perfect time.

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

That's great; thank you, Lucia. And from my perspective, too; I also believe it's coming at the perfect time. There are so many conversations around self-governance and so many conversations around how we're going to deal with the Internet of Things and I think that we've made some good progress here and made some good recommendations. So I'm proud of the report we're going to submit and I really want to thank all of you for all of your hard work. So, have a great rest of summer and you'll see the report come back through final and then we'll be back in touch. Thanks all.

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

Thank you Stan and thank you everyone.