



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

Presentation

Operator

All lines are bridged with the public.

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

Thank you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Privacy & Security Workgroup. This is 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? Stan Crosley?

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

I'm here.

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

Hi, Stan. 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.

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

Hi.

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

David Kotz?

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

Here.

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

Hi, David. David McCallie? Deb Bass? Donna Cryer?

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Here.

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

Hi, Donna.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Hi.

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

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

Hey, Gil. Gwynne Jenkins?

Gwynne L. Jenkins, PhD, MPH – Senior Policy Advisor to the Director, OCRBP – National Institutes of Health

Here.

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

Hi, Gwynne. Helen Canton-Peters from ONC?

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. John Wilbanks? Kathryn Marchesini from ONC?

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

Here.

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

Hi, Kathryn. 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.

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

Hi.

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

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 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

Manuj Lal? Hi, Linda. Mark Sugrue? Micky Tripathi? Stephania Griffen?

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

I'm here.

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

Hi Stephania. And Taha Kass-Hout?

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

She's here.

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

Hello. From ONC, do we also have Lucia Savage?

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

Hi, Michelle, I'm here.

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

Hi. And anyone else from ONC on the line? Okay with that, I'll turn it back to you Stan.

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

All right, great.

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

David McCallie's late joining.

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

Hi, David. Thank you.

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

Thanks, David. Okay great. Well, we have a lot that we've covered as a workgroup with all the hearings and so we're going to dive back into a pretty deep discussion; you can go to the next slide. We're going to try and cover two topics in depth; we're going to kind of cover the work plan, what's coming on the horizon as well as the scope of what we have to cover, including some of the key themes we still have to discuss more. And then what we're going to talk about today, spend the bulk of our time on today was de-identification, consent and then in this slide deck is a summary of the hearing testimony that I think you all will be able to review and get a good feel for what was actually discussed in the hearings. So that's a nice utility to have for us. So, that's the plan, that's the agenda. Let's go to the next slide and let's dive into it.

As we look at where we are now, we have the...we're in our meeting here on big data privacy in healthcare, we have one more on February 9 and then we have some initial draft, basically high level findings and recommendations. The discussion point that we're at now is when we're going to be able to deliver final recommendations or final reports and we'll find our way through to that. But right now the March 10 date shouldn't scare anyone too much; we are going to work our way through two big topics today that are probably the biggest topics that we have to discuss. I doubt very seriously we'll get to a final position place, but hopefully we'll get to a place where Deven and I and the rest of the HHS folks, the ONC folks can get to a good draft to get back for you to consider on those two points. So, that's the work plan right now. Other's at ONC, do you have comments or thoughts on the work plan?

W

No, sounds good.

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

Okay, let's move on then. We are going to, again, in scope we're going to...for the project is privacy and security concerns and then harmful uses related to privacy. As we've gone through the conversation, we've tried to refine what is out of scope, sometimes even more important than what's in scope and data quality, data standards is not our purview and the non-representativeness of data.

This is a hard one, but from the standpoint of is this accurate, is this type of data representative of what we're trying to, of...within a data set, we're not going to address whether or not or how we improve the representativeness of it. And it will come about in harmful uses to the extent that it's related to privacy and when it comes to civil rights and other types of activities that are related there. But beyond that, we're just not going to get into that representative activity. Everybody kind of in alignment on that...anyone not in alignment on that or have a comment on that? Okay. Let's move to the next slide.

So really our key themes now, as we've set these up and these aren't...these are fairly consistent with where we started the conversation, de-identification, patient consent versus norms of use and by that we mean, can norms of use play some role in alleviating patient consent and how those two play off one another. It's not that they're opposed to one another, but that there is a sliding scale between the two.

Transparency; collection, use and purpose limitations and then security. And then beyond that, going to the next part is preventing, limiting and redressing harm; so, the activity around harm. And then we still have our legal landscape as a theme, particularly as we start to think about, where is a gap? What isn't regulated that should be? And what's over-regulated or importantly, mis-regulated? So that's kind of our thematic platform, if you will that we're going to develop the rest of our conversations and our recommendations around.

Next slide. So, we're into topic one. The way that we've kind of set this up is we're going to try and do about a 20 minute run-through and then kind of a workgroup discussion around this. Of course, as we go through each of these topics, I think it may be that we have some discussion as we go and certainly I don't think I have to tell this group to jump in if you disagree with a position or a thought that's been put on these slides. But, we will both discuss as we go and then at the end come back to a broader discussion where we'll have some time to develop this out.

But, the two topics we wanted to cover today, again, de-identification and then consent. These are, I think, by all accounts the two big issues, the most complicated and certainly the ones that have a lot of emotive content wrapped around them. As we look at de-identification, this slide; the critical tool for protecting privacy, no question. But concerns persist about re-identification risk and in particular, there is this concept that even though it may be de-identified in accordance with HIPAA...as a safe harbor or expert determination, the mosaic effect is always in play where different data sets are combined to actually present the picture for which the data was de-identified. So the upshot of that is, safe harbor is intended to be easy and low cost and to encourage the use of de-identification, but is the safe harbor method at risk at this point?

There is no prohibition penalty against re-identification, you know, is that...that's a concern that's been unearthed. When expert determination is used, there is no transparency around the types of methods or any scrutiny or monitoring for accountability around that. Also, de-identified data while it's useful for a lot of analytic needs, in the long run it may not be at all what researchers need when they get into longitudinal analysis or when they get into more tailored medicines or therapies. And so de-identified data, if we go through all these hoops, is that really worth the effort? And then when individuals are not re-identified, sensitive information about them may be revealed or inferred. And so again, there are some of these initial concerns. Let's go through the next slide as well.

The help...definitions are also a little bit elusive, obviously HIPAA has a lot to say about it, § 164.514. For those of you who are involved in HIPAA routinely, this is a very common and highly used provision within HIPAA. Standard de-identification protected health information, a health information that does not identify an individual with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information. And in that...but that second phrase in there is where it's really...it really comes to pass with respect to which there's no reasonable basis to believe the information can be used.

So, NIH has a data enclave, the controlled secure environment which eligible researchers can perform analyses using restricted data sources, but not take the data with them. So again, the data enclave concept limits the mosaic effect by limiting other data from being able to be associated with it. So those are the key definitions, I think, that we're working within. Let me pause there. With either the previous slide when we talked about the concerns that we have with de-identification and in the definitions, is there anything we're missing in the concerns that we didn't document with de-identified data?

Donna R. Cryer, JD – Principal – CryerHealth, LLC

This is Donna Cryer; I wonder in our file report in maybe an overview or some other manner, there's a way of sort of setting expectations for this space that there is never going to be perfect privacy and never going to be perfect security and we're acting within that construct. To just sort of, as I said, set expectations.

And the other thing is, is there a place perhaps as we talk about de-identification, of having a sentence or case examples as were given in the hearings, particularly as we were talking about population health, of why there are cases when having identified data do have value. And particularly as individuals are looking to use this information not just researchers under a traditional definition, that we will see more and more cases of identified data and data that we purposely want to be able to understand a lot of circumstances around a particular individual to be able to guide their care. And so, language about why identification sometimes can be a positive.

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

Okay, so cases where using identifiable data can be a positive, is that...

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Yes.

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

Okay. Yeah, I mean we talked in the...I think, in the public hearing, we talked a lot about cases where de-identified data could not be...wouldn't be useful, but we didn't really take that all the way out and say, where is it that identifiable data actually is useful and beneficial? Okay, so that's what I'm hearing you say, right Donna?

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Yes.

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

So this is David, just a question on that. Are you suggesting identified data useful for purposes other than the routine things that we associate your healthcare data ought to be used for? In other words, outside of some valid care process? In other words, is there some space in between...

Donna R. Cryer, JD – Principal – CryerHealth, LLC

I think we're redefining what a valid care process looks like and I would hate to have our recommendations be referring to last year's world instead of anticipating next year's world.

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

Could you give us an example of what you have in mind? I mean, I think it's a really good point, but I'm just not quite sure how far you're pushing compared to kind of things that happen under normal circumstances today that are covered by HIPAA and nobody's particularly raising those as issues.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

I think about...I'm sort of thinking along the lines of use of patient-generated health data or combining various sort of Apps and work streams of data. I don't know the details of what will happen once HealthKit, for example, is used extensively. But I would like that information to start shaping my routine care...but I also think as I'm listening back and looking through my notes about what some of the testimony around using not only clinical data but environmental, neighborhood, other data that very quickly point to a community, family...

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

Right.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

...neighborhood, house, individual and what the health risk of people are; I think that anticipating, and I think I see the value of our work in terms of as an educational piece as well giving...helping people sort of think through different use cases and different possibilities where they might have just a sort of an initial gut reaction to something but if we were able to sort of connect the dots a little bit or extend that and create a framework for that to be able to be done appropriately, I think we would have made a contribution.

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

So this is Lucia; I think part of what Donna's saying is, I think we actually have some good examples that are manifest now so one example might be, nobody really thinks twice about a provider doing outreach to remediate a HEDIS gap in care but people wonder when states want to do that and that's...the state is doing big health data analytics to identify those gaps in care, but it's not necessarily in the same position that the provider is as to remediation. So that's like a manifestation right now and I think we actually did have some testimony about certain kinds of research that would be...where identification was really inherent and I think the President's remarks last week regarding precision medicine sort of tell us what those examples might be that we want to include in the report.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Exactly.

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

Yeah. I agree on both of those and also just to remind, we are looking beyond the HIPAA world for data...for...on this data world so again we had some testimony from patient advocates talking about wanting to have their full data accessible to them and whether generated by consumers or generated within the HIPAA covered world. So, I do think that there are some case studies...I do want to get back to the de-identification concerns though and what you highlight a little bit, Donna, is that as we think about the definitions, we only have a definition of de-identified within the HIPAA spectrum, we don't have a concept of what's acceptable de-identified outside of that world. And I think that is certainly a concern of de-identification that right now, we'll get to it with gaps in regulation...

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Um hmm.

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

...but I think it also goes to the concept of de-identification and we do want to, as we make recommendations, we want to keep in mind, as always, the beneficial and the concerns for a topic. So, as we walk on that de-identification path, I think it's good to capture what you and Lucia and others said.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Thank you.

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

Okay, any other, as we think about again the idea of concerns with the use of de-identified data or a risk that we haven't captured?

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

I mean I think...even though you're sliding the HIPAA definition of de-identification, we might not necessarily be limited to that definition, right?

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

No, that's correct. Yeah.

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

So it could be that we broaden it or narrow it, whichever way we go.

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

Well, and...so, right, when we get to recommendations around de-identification, you know, one of the things we are definitely going to have to think through are...we only have a small world right now that this definition applies to, is this definition...do we want to make recommendations to the definition itself as it's currently applicable and/or do we want to suggest that others...other definitions should be created.

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

Yeah, that was what I was getting at, is that we're not stuck with a given that it has to be the HIPAA definition.

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

Right, no, that's very true, we are not.

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

And this is David Kotz; actually I think this may not be a sufficient definition for some uses because there are lots of demonstrated examples where a researcher...a clever researcher with access to an outside data set, and has been able to mix that outside data set with the health data set and re-identify people.

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

Right.

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

And this definition doesn't seem to anticipate that, it seems to be inward focused on the given data set and I think especially when we start thinking about non-HIPAA covered entities.

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

Right, I mean there is a...it's not captured here, but there is, within the HIPAA definition, there is the overarching concept that whether a...whether data disclosed via the safe harbor or disclosed via statistical analysis, if on disclosing you have reasonable belief that the individual who received the data will be able to re-identify it, then it's not a valid disclosure. So, there is that but other than that, I think you're right.

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

I mean, yeah, the individual receiving it, using any means necessary and other data sources, that's the challenge, I mean, this is why, as someone said earlier, there's no perfect security, there's no perfect de-identi...well, short of just zeroing the file...

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

Random, a good random number generator is pretty...

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

Okay, so let's go quickly...we're moving in to some recommendations and I probably should have gone through these slides first on de-identification, but let's look at the solutions real quick and then let's come back on our solutions and recommendations, let's come back. So possible solutions, and we're on slide 8 for those of you following along offline, possible solutions. And, as indicated here, it would be nice to have actors, like who is going to undertake these things.

So, feder...so one recommendation, consistent with what we just talked about a little bit, federal regulators should work together to set consistent de-identification standards for all personal data and provide incentives for use of de-identified data. Re-identification risk reduction measures applied should depend on context, so more applied for public use data sets versus circumstances where access is controlled, such as through data enclaves. The other one, regulators led by OCR should continue to define standards and best practices for expert determination. Regulators and industry should collaborate to establish mechanisms to objectively vet statistician procedures and should they be published?

And then propose certification or accreditation for de-identification experts, following along the previous bullet. And then package statistical expertise via automation and see if there's something alternative to the safe harbor example; who should do this? How that should be set up is still a question. Let's go through all the solutions first or recommendations. Let's go to the next slide.

I think we have one more slide and then...Congress should enact prohibitions on re-identification, establish penalties for unauthorized re-identification. Regulations may need to establish public policy exceptions for health and safety, etcetera. It would give us de-identification techniques that are actually designed to and heighten security, so the white hat testing. Regulators should require reassessment of re-identification risks when datasets are combined. Again, there is an issue here with source of the data and understanding when the dataset that you've received has actually been de-identified and when it's combined with others and to know that there's a re-identification risk. But I think these are all possible.

For re-identification or the mosaic effect should be approved by IRBs. OCR should re-evaluate or limit use of safe harbor; for example, limit use to those data sets that meet the presumption upon which the safe harbor was created or has been tested. No public release datasets, perhaps. And then regulators should impose security requirements to protect de-identified data so that even though it's de-identified, security still needs to be applied around it in some manner. And how to deal with privacy...with risk of privacy disclosures or inferences that are not due to re-identification; so you can have enough de-identified data sets and you can do grouping of health inferences.

And I think...is that our last...is there one more slide? I think there's one more recommendation slide. Yeah. Regulators should examine potential for reduced requirements for de-identification in certain circumstances for validated research. In other words, this is the opposite side of the standard where now we're saying, you know, for certain circumstances, we may not need to remove quite as many identifiers and if its controlled access for certain uses. And then access to data in controlled environments, this is the NIH data enclave, internal use only versus exposure to others, execution of data use agreements, patient-controlled research initiatives and where research has been approved by an IRB or Privacy Board.

So, we've gone through a lot of de-identification issues. We have consent to talk about, too. And it...and then so we have about 60 min...about 50 minutes to public comment and we want to cover both of these topics. I think let's try and have some conversation around the recommendations first on de-identification then I'll move into topic two. I know that's not exactly how we identified the slides first but after having gone through all of these; I think it's probably better if we handle this topic first and then save some time still for consent. So, recommendations, high level, we already had some additional suggestions here that we've written down. Other possible solutions; I mean, some of these are fairly straightforward, others are more complex. Are we missing any? Are there any that we think shouldn't be on here?

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

So the idea is to submit...this is David Kotz; a list of possible solutions rather than a specific recommendation of one or two solutions?

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

Well, and so this is a...kind of think of this as a whiteboard session right now. I mean, I think these are all the things that are on the board that have been discussed, that came out with public testimony and they've been discussed with staff and this is kind of what made the whiteboard. So now I think our job here is to say, you know what, we don't think this is a valid solution or why or discuss it out and see if we either narrow this or refine it or craft it in some way.

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

Um hmm.

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

So this is David. I really like the third slide and the notion of enclaves where requirements for the de-identification might be reduced in exchange for more rigor around who can use the data and what they can do with it. And I wonder if one of our contributions could be to suggest clarifying some of those constraints; for example, internal use versus disclosure to others; what does that mean? What is internal and disclose to others?

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

And David, let me just ask this, if we do this, if there are...because we need to think about compensating controls or what pressure this might relieve in a system. If you set up a solution like this...in certain circumstances, you could actually lessen the de-identification criteria to help validated research. If we did that and we come up with what you suggest and come up with those criteria, do you think that would then lessen the impact and strengthening de-identification in other areas?

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

Well, I think we have two conflicting high level things we want to achieve.

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

Yes, yes.

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

One is, protect privacy and two is, advance science I'll just say, broadly, right? Learn from all this big data and do a better job. I mean, there are other things, marketing and stuff, I'm going to keep those off the table for the moment. So the thought here is, the de-identification rules that we have today are burdensome in many settings and limit the work that can be done because of either they're hard to do, hard to de-identify it adequately, in some cases impossible to de-identify it adequately so the researchers either will take gamble or they'll just give up and try something else, go to some other research.

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

Right.

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

If we could shift the balance and say if you are a legitimate researcher working in a controlled setting where we can define you as an extended notion of this enclave, and give you reduced friction in accessing that data, we could do that conceivably without higher...without raising the risk to loss of privacy.

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 so it would seem like it's a rebalancing, if you would, by saying not everything that's de-identified is, in fact, intended for public exposure and there can be intermediate levels, which is I think what the enclave idea is about and I'm just thinking...I think it's the best idea that we heard and is there something we could do to enhance that notion of an enclave so that within a well-controlled environment, whatever that means, is that you could use these data with less worry about the fact that you haven't eliminated 100% of the re-identification choice. I think it needs to be coupled with the prohibitions against re-identification as well...

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

Right.

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

...so that if, in fact, some untoward event does happen, you have grounds for pursuing it, legal grounds; you can say, you couldn't have done that unless you re-identified, you broke the law.

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

Yup. And I agree...yeah, I think it's a very good idea, a very interesting idea that we can put down to pursue and try and see if we can craft what that enclave might look like. I think the NIH folks can help us and there's a...in Canada, Ontario has a very similar approach to controlled access for research that we could potentially explore. I do...

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

Actually...

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

...go ahead, I'm sorry.

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

Sorry, I was waiting for you and I...but if you're not done, go ahead.

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

No, go ahead.

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

This is David Kotz, again. I like the data enclave idea as well, I guess I would want the recommendations to end up being a spectrum of options because de-identification and release of a data set not through a data enclave I think should still be an option, when that's feasible and necessary perhaps for some kinds of research. But, I totally agree that de-identification to that standard is often very difficult either because you can't do it safely or by the time you've achieved it, so little utility left in the data that it can't be used for research.

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

Right.

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

Or it's too expensive to achieve or people are too risk-averse fearing that they haven't achieved the level they need. So I like the idea of enclaves and I think it could include a lot of these other proposals. So, for example, data use agreements would be...or IRB approval presumably would be part of a data enclave solution, you know, you would only be allowed to use the data inside the enclave for IRB approved research and for...under some terms of use that have been hammered out...

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

Um hmm.

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

...between the data provider and the data users. And those presumably would include a contractual agreement not to re-identify or not to expose identities anyway, outside of the enclave.

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

Right.

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

And that would also save...I mean, you wouldn't necessarily need new laws and regulations against re-identification in order to achieve that goal, it would just be a contractual arrangement. I've done that...

Multiple speakers

(Indiscernible)

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

I think the one thing on re-identification is that if you're also trying to target those who...instead of a prosecution for those who aren't necessarily part of the contract or aren't...

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

No, I un...yeah, I get that. I guess my point is that it could take a long time to get regulation or laws like that and although they may be useful if very carefully crafted, you could solve the immediate problem through contract law.

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

Okay. Great.

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

And with respect to laws, I just...sorry, to add one more point; I would want to just be very careful, we've had promise of this before where Congress makes laws about no reverse engineering or attacks against secure systems, etcetera, that preclude research uses...make research into those things illegal as well and that's a real harm to the security research community and therefore indirectly to the broader world. Because sometimes the best way to improve security of systems is to study how to break them and so if we do push for laws that make re-identification illegal, we need to make sure there's a good research exemption of some kind.

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

Right. Yup. I think that was anticipated in one of the comments, so, I think that's a great point.

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

And, I think combining the notion of the enclave, an expanded notion of the enclave with de-identification...re-identification occurring if the data crosses out of the control of that enclave might be one way to think about it. So within, you may in fact be doing re-identification risk assessment all the while, but as long as the data is not being exposed outside the controlled environment, it's not considered having violated the law or the proposed law.

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

That would be one way to do it, uh huh.

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

...so we need to also think...about that because I think this is a...getting some traction as a possible solution to at least explore further. And then beyond research, we need to think about that as well and even within reach are there other options or are there other issues here. Again the risk of re-identification I think is pretty significant throughout this, at least that's a harm that kept coming up. Any other recommendations?

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

So what was...your question was other settings besides research where it might...

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 think we're...we've talked a lot about the research issues and the enclave makes complete sense as well as maintaining an option outside of the enclave for...to continue to use de-identification. But part of the solutions we're looking at here are, how do we make this usable by folks who aren't doing research? Can de-identified data still be used for other things? So for instance, you've got a very large medical device community where they do a lot supporting technical aspects and use; they rely a lot on de-identified data to do machine and device improvement, they're not strictly research, not IRB research, so are there standards that are going to be maintained that enable that...but also the, just in general, the risks that we've talked about here.

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

So David again here; I mean, that's sort of what I was thinking of in this notion of an expanded notion of what an enclave was that would be...that would include things that aren't traditionally considered research as in associated with IRB and academic institutions. And your example is a good one, I'll use our example here at Cerner where we have access, at least technical access, to lots of patient data and would love to be able with less friction, to go through that data and improve our software products by doing a better job of tailoring alerts and you name it, whatever you could do with machine learning.

And that's very difficult to do under the current rules; sometimes you can call it, and it is legitimately quality improvement and it falls probably under HIPAA exemptions. But there are some cases where it's not really clear that that's what it is, but the data is heavily protected, it's the full EHR so it's in an incredibly secure environment and it would seem that we could ease the restrictions on use of that data, because it's being controlled in the same way that we control access to the EHR data, but it's cross-patient and it's not for HIPAA. So I think yes, there are plenty of examples.

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

Well...and it's Deven; apologies for joining late, I just landed in Nashville. The other issue is commercial uses of information so David, your example to improve the software product is one example where there's a public benefit piece to that, but it's...of interest to the company as well. Similarly, if you're talking about a consumer-facing product, whether it's a social networking site, for example, or an App where the business model involves advertising, I mean, we've seen with some of the latest controversy over healthcare.gov a bit triggering this, you know, what constitutes sort of use of data where some identifiers are masked but some are not in order to support certain uses of a product? I mean, do we stray in that direction? Do we try to have in our consideration as a group to just those that are aimed at improving the healthcare system, whether through internal quality improvement or otherwise?

Didn't mean to drop a bomb; I just...the big data uses have lots and lots of tentacles and I think we can either try to tackle them or we can decide that we're just going to focus on the one that preserve the kinds of opportunities in big data that are most important to improving the healthcare system.

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

So these things seem to have in common, and I'm just being very vague here, but the notion that the work with the data is done by people in a controlled environment who will not identify anything outside that environment; they will not leverage anything they have gleaned about patient...personal identity outside that environment. So it's broader than just the HIPAA exemptions and it's broader than what you get with an IRB, because many of this...much of this occurs in settings where there is no IRB. Maybe there needs to be a Privacy Board, something analogous to an IRB, but there isn't probably today. And yet the risk to individual re-identification is still manageably low and if we got the right laws associated with it, it could in fact be prosecuted.

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

Deven, this is Gil Kuperman. I mean, to answer your question, my impression of the charge to this group was that economic benefit was in scope and not just healthcare benefit, so if we can find appropriate privacy models whereby commercial entities can benefit, I think that's one of the things that we're trying to do was what I was thinking...

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

Yeah.

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

...and, I mean, if I'm wrong then I'm wrong, but I thought that trying to find models that supported multiple sectors of the environment was what we were trying to do.

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

No, Gil, I think you're, I think...this is Deven; I think you're right, I just wanted to sort of do a gut check because all of our examples that we've been sort of talking about, at least on the portion of the call that I've been on for the last 15 minutes, have been very sort of white hat, how to sort of arguable public benefit, not the commercial...gain it's not necessarily devoid of public benefit but I just wanted to make sure we were expanding our discussion of some of the examples. So...

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

Deven...

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

In part I think, Deven, is because we kind of started in the enclave world...

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

Ah.

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

...and so...but now, I think it was a good time to broaden out so your comment was well-timed.

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

Can I jump in? This is David Kotz. I think Deven's question is a good one and in the end, it's somewhat of a philosophical question, to what degree to we wish to support, societally, the broader range of uses of the data? And some might agree that commercial use for sort of profit is a good use and others might disagree. I think it may complicate the consent question which is coming up, though, right?

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

Yeah.

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

Because some people might be more than happy to see their data used, even without their notice...even without notice for research purposes or quality improvement, but not for some company to make a bundle of money off analyzing the data.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

I think that's...this is Donna; I think that's a very important point and I think it goes also to the transparency section. I was informed recently of a platform that is built...is collecting information in the infertility space without disclosing that their ultimate goal is to be able to use that data to create an insurance project...product for profit. And so, to me the big point in that was the lack of transparency because as you point out, there would be some patients who would...or some people who would be willing to participate in that project and some who wouldn't, but depriving them of that information up front to me is the true damage.

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

So, this is David, I think it's a great point to continually come back to transparency, but it's pretty naïve to think that all research is not eventually for somebody's profit. I mean, the vast majority of funded research has a target to develop a new sellable technology, be it a drug or a procedure or some kind of intervention; just be transparent, it's getting paid for by somebody.

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

This is Gil Kuperman; just a couple of general comments, I mean, in general I think the recommendations are good. And...I mean, I do think that this issue of a data enclave is intriguing and especially to what extent can it be used beyond a traditional research environment. I think the problems that we have with the current approach to de-identification, as was said before, is that it's burdensome, it's vague and it inhibits effective use of the data.

It seems that most of the recommendations here are either to address the vagueness, and so I think those are good, when we wring out the vagueness, but some of them actually increase the burden. So, I think we have to recognize that. The enclave aspect, to me, seems to be like the one angle here that might actually allow us to get more value out of the data. So if that's one of our goals, of all the recommendations that are listed here, that seems to be the one that kind of creates opportunity. So, thinking about how to promote that aspect is something I think would be worthwhile.

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

And my...this is David; my concern is that if you start to add restrictions to reduce the risk of re-identification with...particularly if you have access to other data sets that can be mosaicked with it, you'll end up with completely untenable data, because you will have removed all the value of it. Fuzzing the data elements isn't good enough anymore so if we really want to de-identify it, we're going to have put much more stringent requirements on the HIPAA 18 identifiers. And then I think that's got too many downsides. So we need to have a way for people to use that data in a way that is low risk managed inside a controlled environment, but doesn't necessarily contain 100% foolproof de-identified data. There's no such thing, except for random.

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

Okay. Others as we look at these, we've not really discussed the recommendations by bullet, but there are recommendations that are...I think these comments all kind of go to the issue of are we recommending a different standard or are we recommending a modification or a more restrictive standard? If we're looking at what uses or what purposes we're trying to emphasize, maybe that's a way to get into the de-identification criteria but I still think there are, as Deven said, there are broad uses that where in some cases we are going to say, like in research we'll be fine with an enclave. But would we do that for other commercial or more readily identified as commercial uses to the point. So, anything else on identified recommendations. If not, we can move to consent and then certainly circle back. Because we've obviously not killed this topic yet.

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

Stan, this is David Kotz, unfortunately I have to run to another meeting, but thanks and I'll catch you later.

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

Okay, thank you, David. Deven, any other observations on this before we go to consent and then I think inevitably we're going to circle back on this.

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

Yeah, no, I think...all of these things are interconnected, Stan, so I think it's good to try to just to work on consent and circle back.

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

Yeah, because I think we're going to move into also appropriate use also has been thrown out a couple of times, as well as transparency. So, let's soldier on to consent. Let me go through the couple of slides here and then we'll discuss this and then kind of try and think a little more holistically. So consent; clearly a valued tool for protecting privacy and individual autonomy and I do want pause there before I get to the but because I don't think there's...it's not really in debate that consent has a place and that consent has value. And that's not just in the US under the HIPAA paradigm, that's outside of HIPAA within a consumer context and directed consumer data collection. It is the current norm for the attempt to protect privacy. I don't think there's any dispute about its current role and that there is value in it.

But, it's difficult to obtain informed consent upfront, especially when you're talking about big data. Secondary uses may not even be...may not...may be unexpected or unanticipated at the time would have big value in data analytics models where the data creates the hypotheses. It may be impossible for large scale studies, even allowing opt-out may skew results; we heard that from Richard Platt. Lays burden for privacy on the individual; that's the ethical argument of if you are a decent attorney or even a middling attorney you can get people to sign consents all day long. They give you extremely broad authority to use their data and so all the burden is on the individual to scrutinize the consent that everyone routinely understands they don't scrutinize.

May work best when not over-utilized; for example, not requiring for expected uses. People tend to equate consent with, well, I wouldn't...I trust these people, this is the expected use and if it's not that, maybe there will be more attention to it. Policy tension with the technical landscape; technologies to enable are evolving, but policies may not reflect the technical capabilities. And again we've got the Security Standards Workgroup document that goes into that in more detail.

When is transparency a better strategy for engaging individuals and seeking their individual consent or even allowing opt-outs? And we may want to, at some point, talk a little bit more about the difference between notice and transparency. Transparency is the concept that can be undertaken in many different ways whereas notice is more of a legal construct that has certain definitions around it. Is there...I think we have one more slide on consent or two more? Yeah, go to the next slide, please.

Regulators should evaluate...so now we're getting into recommendations. So, those were our concerns on consent and it's a pretty decent list of concerns, honestly. Let me go through the recommendations and then we can discuss consent.

So, recommendations, regulators should evaluate policies governing the research uses of health data to determine when and under what circumstances the research uses can be pursued. Presume that research is defined as currently done in HIPAA and the Common Rule. Considers whether secondary use of information introduces additional risk; this comes back to some conversations to Deven's point that we're already crossing over, is it being done in a controlled environment as part of the enclave we were just talking about? Are there limitations on who's permitted to see it? Is there...is research intended for public benefit? Are there reasonable security protections for the data?

So, again a consent paradigm to say when it can be pursued without opt-in and when it would have to be for opt-in; and some of the testimony we heard some of the researchers talking about there was clearly activity that should be impermissible and clearly activity that should be permissible and then we have a lot in the middle that we have to consider on whether we get consent for or not. It could be accomplished through changes in regulation or guidance under existing regulations. And then the last slide on consent. Regulators and industry should explore technology options that enable it; so the metadata based concept it would have more granularity. The PCAST report suggested that metadata could be used more broadly, have the technology option.

And then transparency to individuals about actual data uses is key where choice isn't given. And then when choice is given, it would mean something. So here, even if we don't get consent, transparency has to be paramount. So, those are the recommendations, the concerns and recommendations on consent. We've got about 20 minutes to discuss this and circle back on de-identification. So let's start first about the concerns; did we capture the list of concerns that you heard in testimony? Are there other concerns that we should be listing or some here that we think probably aren't as primary?

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

This is Gil Kuperman; let's see, I may be off base here but just one of the topics I think came up repeatedly was that the data that are currently covered by HIPAA are a subset of kind of what's really relevant. So, I wonder if one of the concerns might be that the current HIPAA framework is kind of incomplete, even if you could do consent right, for HIPAA, there would still be a big problem with other data that's not covered by HIPAA. So, I don't know if that's...if I'm kind of making that up in my own mind or if that's something that kind of came up on the calls or if it's something that we kind of would just want to leave out of scope, which is, I guess, another option.

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

Yeah, I mean at this point I think we consider things. I don't see it necessarily as being out of scope, it's a matter of fitting it into our framework here on concerns and what we might not have.

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

I mean, most of the consent models currently in use are related to healthcare provider organizations and...

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

...as we've talked about, or as came up at least a couple of times on the calls was that there is other relevant data here that the public gets nervous about.

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

Um hmm, yeah.

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

I'll leave it at that.

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

Right, so you're saying the outside...take the HIPAA framework and see where would a consent model apply outside of make sure we document that?

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

Yeah, yeah, I mean, I think a robust privacy framework that allows effective use of big data would go beyond healthcare...

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

Right, that's...

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

...data currently managed by HIPAA, I guess.

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

Yeah, this is your...there's a lot of data that can be used to infer health data or health status that isn't necessarily health data.

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

Correct. Thank you.

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

Yup, that's right. And you know, that actually, quite frankly, highlights one of the issues we have is as you think about the scope of the recommendation and we're going to extend and say anything that can possibly be used to infer health data, you have to have the consent of the individual in order to use it, it becomes a little bit difficult because, for two reasons; one, there's an ever growing list of things that can be used to infer health data. And two, you're not sure where you have to go to get that consent to use. So, I think it's a...I think you're right, we have to think about that framework as being a very broad framework and this is where we get back to do you de-identify the data, do you keep it until you consent? Is it transparency or is it use? But I think it's the right framework.

Other thoughts on concerns we haven't captured here? And Deven, are you on the phone still?

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

Yeah, no, I mean these are very good points, since I drafted the slides, I definitely had exhausted my brain on that.

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

Yup. Okay, well what about recommendations? And it looks like we have a lot of concerns with consent and with the essential limitations of it while recognizing its value. So what are the recommendations we come out of this? If we...the list of concerns is, we're not sure it's scalable, then recommendations should add some relevance to that issue.

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

Yeah, and you know the one thing I do...this is Deven, notice about the recommendations is that at least the very first set of them is pretty heavily focused on the research issues that were uncovered in our hearings, so...

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

Yeah, I agree Deven. Yeah. We probably need to build out the other issues.

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

Yup and you know, some points were raised on this call that will help us do that, but...

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

But the effort here, especially with the first set of recommendations, was to really try to look at the issues that were raised about requirements to obtain consent for research purposes when identifiable data are used and the consent is not...requirement is not waived by an IRB. Or whether or not such a requirement or the need to get a waiver should even be in place for certain types of low risk research.

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

Right. And I think what was raised just a little bit ago was then as you start to work your way through that, even in the public hearing testimony we did hear about uses of data that weren't strictly IRB related uses but were either therapeutic improvements within covered entities within healthcare providers where they were sharing best practices, where they could actually improve, this is your...is this observational research or is this healthcare operations kind of activity.

So recommendations that start expanding and saying there are uses of data beyond research that should be permissible and transparency may play a huge role in that. But there may be a role at some point with where you say, okay if it's used to improve a product and it can use a certain level of data, it's permissible but beyond that it has to have consent. And I think that's going to be imp...we've heard that a couple of times now.

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

This is David; is it...does it make sense to think that you're...that there are different consequences or kinds of things that you're consenting to or that you need to give your consent for that would be worth teasing apart, and maybe we already do this and I'm just slow on the uptake here. But for example, your data will never be used to directly affect you; however, we might make a lot of money from it is one kind of consent, where there's no risk of privacy, there's just leverage versus another kind of consent that says, we're going to use this data to improve our services for people like you, but we won't actually ever target you in particular, which is kind of in between. And then the third is, we're going to actually deliver services to you based on the use of this data, like for example, targeted mailings from Target that we talked about in one of our previous sessions. Is there...the privacy angle, there's a financial reward angle, there's a benefit to society angle; does consent...should consent treat those separately?

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

Well...David, I think that's an interesting point but it presumes that you would ask for consent...

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

Um hmm.

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

...in all of those circumstances and then vary the...make it variable in terms of what you're asking of people based on the circumstances as opposed to defining a set of circumstances where you wouldn't necessarily require consent to be asked, you might require some transparency, per Donna's earlier point, but you wouldn't ask people, per se, give them either an opt-in choice or an opt-out choice necessarily. Versus when you do ask for consent, what are some of the variations within that, along the lines that you suggested because I think what I'm struggling with in your point is that it seems to presume, well, we'll just vary the wording of what we're asking of people so that it's clear that some things are off the table, but some things are on the table, which is certainly doable, but it presumes that we're going to ask people.

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

Well, I'll combine your thought with mine and say that maybe within those categories of the way the data can be used; you might set different thresholds as to when consent is required, depending upon how it's going to be used. So for example, we might say that if your data is used in a completely...in a way that never exposes your identity and somebody profits from it downstream, that doesn't require consent. But if your data is used in a way that will eventually target back to you in some very personal intervention of some kind or another, be it an ad being sent to you or a phone call from a public health worker, then you do need to consent to that.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

You know...this is Donna. I take this a little differently, from a very sort of 30,000 foot level, it has always concerned me that it's...to date it's been an all-in or all out process that either I seem to be able or required to provide my data for all potential uses, some I may refuse, some I don't or not be able to receive the treatment or benefit. Or I have to opt out completely. And I think that we do want to get to a state where it is a bit more granular, I certainly look to things like Sharon Terry's project with PCORnet as one example of very, very granularized sharing settings for data. But even something perhaps a little step back at this point, I really would like to be able to somehow get to a framework where it's not like, give up all your rights at this point forward or not participate at all.

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

Yeah, so you're...I mean, and Deven we've talked about this a little bit, I mean, people are kind of describing appropriate use framework that is...that includes transparency and consent where appropriate. It's creating that expected use and an opt out and anything beyond that directly expected use as an opt-in and explain those worlds.

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

That's a heavy lift.

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

It is a heavy lift. It's a very appealing one, it does hinge on a presumption that there are, you know, sort of there's a baseline of expectations that attaches to some of these different purposes and data flows that may not be...that may not necessarily be accurate as of yet. I mean, we used to say in the privacy advocacy community that people had no idea how their data were used when they logged onto the Internet or loaded data into an App. And there's been a lot more awareness through reportin...through media reports and people's experiences on Facebook that people are a bit more generally aware, but I don't...how far down that's penetrated and...

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

...it's also true in the healthcare system, too, right? How much do people sort of really understand about how much gets done with their data when it gets collected in their doctor's office or by their health plan? And how much do we need to craft...do we need to catch people up and how much do we craft policy based on those expectations that may not be...but I do want to go in that direction, just...

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

And the only thing I would say, the only thing I would say to that is that we have the exact same issue with consent, right? I mean, people are consenting...

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

...to the very same uses that we're saying, well, we have to try and figure out how to define the expected use. We've already...

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

...and so presumably it's a...no matter which answer you come with or which solution you embrace, at some point there has to be a level of expectation that exists on use that you document such that for a given function, you say yeah, this is what the consent should mean and this is what the use should mean. So...

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 agree, I mean I don't know...it's a big lift and maybe it's that we keep it...the scope as narrow as we can to address what we think is effective. But I'm not sure how we address many of these issues if we don't at least take it on in some way. Even when we're talking about the data enclave, for research, I mean again, we're going to have to define expected research, what would research be covered or wouldn't be expected? So at some level I think we're going to have to go in this direction, I am worried about scope.

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

Yup, agree. Yeah, one thing that we could do, Stan is try to massage these bit in the interim, based on some of the comments that we've gotten today. I know we still have a little bit of time left on the call, but...

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

...we could get a little more robust in our thinking around these recommendations.

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

And we might also, as I'm thinking through these now and looking at the concerns, kind of mapping through the recommendations, we actually may want to do a more direct, more linear mapping of the concerns to the recommendations. And it may be that we...maybe we can't necessarily separate out into...topics but we identify the concerns and recommendations kind of together.

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

We can certainly...

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

I like that idea.

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

We can certainly do that with the group and come back with another document for further discussion and refining and I think that's how it's ultimately going to have to go.

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

And these two are, I mean, just so people don't get completely discouraged on progress, I think these topics really do kind of encompass everything else, too and so when you kind of wrestle through these, the others will fall in place; that's the hope.

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

Yeah, that's our hope.

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

Yeah. Did we want to mention...we are going to come back on a separate...and try and get more information or a separate hearing on security?

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

Yeah. So not a full hearing, but to spend some time during one of our dedicated calls hearing from some outside folks on the security issue. That came up in our last call as an area that was not well covered during our half-day long hearings back in December, so we're going to tee some folks up for that. And we got some good suggestions from David Kotz so if anybody else has any others, now would be the time to get those in.

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

So we're on next steps and so I think that was a next step item, right?

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

Yeah. Yup.

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

We want folks to continue communicating with us, call or email or any other recommendations or gaps that we may have in the evidence that we're building or the case file we're building on this. I think Deven you recommended that we refine these topics, these two topics and recommendations based on what we've heard here and try and come back with perhaps a little bit of a different framework that advances the ball a little bit for our next conversation.

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

Yeah, I think we need to do that; I think we also though, in keeping with the interconnectedness of all of these concerns as we talked about it do need to, even as we continue to refine what we're saying about the topics that we've already begun to discuss, to start diving into new ones, too, so that we're sort of continually making progress on a whole comprehensive set of recommendations that address the concerns that were raised and allow us to maximize the opportunities that we learned about through multiple interconnected angles.

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

So does that mean we try and pull in transparency and use into the next...

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

Yeah. I think so, don't you?

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

Okay. I think we're going to have to, yes. I think it has to be kind of looked at in that light.

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

So that means I think for all of us as workgroup members, we might have to be sort of pursuing kind of multiple pieces of this conversation collectively over this period of time where we're working on that. But I think everybody's up to it.

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

I'm with you.

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

Good. I can say that this is the absolute best airport to ever have a conference call in is Nashville, when the whole Eastern seaboard of the country is basically shut down.

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

Okay. Well, we've got about five more minute...when was public testimony supposed to...was I supposed to ask for that now, I guess.

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

We usually lea...I mean, sometimes we run right into it, we occasionally dedicate 10 minutes and sometimes it depends on whether there are any...but it's been rare that we've had more than five minutes worth of commentary when there are people. So, we have some time.

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

I'm just looking through these slides to see if there's anything that we might want to try to get some additional feedback on.

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

Under regulation was something that also we talked about a little bit on the call here, where we're recognizing that the definition of de-identification isn't really going to help us in large ways outside of HIPAA. And so understanding how to apply that...elements that we're trying to figure out.

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

Yeah, I heard that. I have to say that I have had a little bit of trouble wrapping my head around that because the definition that is...that was on the previous slide, is not necessarily methodology driven, right?

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

No, it's not.

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

It's no reasonable basis to believe that the information can be used to identify an individual and so I'm sort of struggling with, what's wrong with that definition applied to different circumstances? And if it is...and if it doesn't fit, then why doesn't it fit and what definition would be better?

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

I mean, it's one thing to say...sorry, go ahead Stan.

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

No, I was going to say, the on...one answer was, you contain the environment so the enclave...you contain what the environment and the purpose...

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

Oh.

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

...and the other is, you look at potential harm. But I think that you're right, if we look at the environment and the intended use that may help us on the de-identifica...in a vacuum, the definition of de-identification is not helpful.

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

Right, it's not, although...so I'm not sure that you can use a de-identification standard necessarily to...or definition to protect from harm, although I certainly would entertain some suggestions about how you could. It seems like a separate but worthy issue to deal with, but you could foresee a change in this definition that is not just about the data, but about an environment that does not allow individuals to be re-identified or where there's no reasonable basis to believe that they could be re-identified in the data set.

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

Now did you say that de-identification is not used as a method to prevent harm?

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

Right, it's just about how identifiable the data are. So when I think about...

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

Well, so all the data...

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

(Indiscernible)

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

All the data breach laws have that concept.

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

They do, but that's because they're...okay, so let me rephrase then. De-identification is a strategy to prevent the harm of re-identification...

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

...and data use farms that deal with knowing who individuals are and...

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

I agree with that.

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

...them are using the information. I think I saw the harm piece as being a little bit broader than that where you could sort of use information in the aggregate and by not even re-identifying anyone at all, use it for the data redlining issue that...I mean, that might be more of an identifiability issue, but Paul Tang has brought up an example in previous Policy Committee meetings where, and this was pre-health reform where decisions get made about sub-populations based on aggregate data.

So there's no idea...it isn't about re-identifying you in the data set and doing harm to you individually, but basing a decision on something that's revealed in the data that ends up harming you because you are a member of that sub-population.

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

And it's also...and it also somewhat in the language of the slides, I was wondering whether there was room for the concept of differential privacy, right, where you're not re-identified per se in the data set. But it's known that you are in that data set somewhere and we know something about the data set and so therefore we know something about you, even though we haven't identified you specifically in the data set. So, like everyone in this data set has HIV, oh, I know you're in that data set; I didn't re-identify you in there, but I know something about you now. And that's a really broad example, but...

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

...then from coming from someone who...

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

Harm...

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

...yeah, who doesn't really understand differential privacy all that well.

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

So harm that can apply because you're making decisions based on aggregated data and that decision ultimately affects you as a member of that group.

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

Well, that's right and that's the one that I think is divorced from the concept of de-identification, from a harm standpoint.

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

And my only issue there is that that is also a big lift to try and figure out how to address that in this context.

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

Yes. Right. Right.

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

Okay.

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

I don't disagree. We may, and it's not...it's something that we heard something about in our hearings, but we didn't sort of dive into what people may be doing to resolve it. And I think we might just have to see sort of where we're able to get with the large amount of concerns that were laid on the table through our own efforts and it may not be everything.

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

Okay. Final comments from members and then we'll open up for public comment, but, any other comments from workgroup members? Do you generally agree with the next steps or let me say, do you disagree with next steps? All right, hearing none, we'll proceed apace and should we open it up for public comments Deven?

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

I think so, go ahead Michelle.

Public Comment

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

Operator, can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

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

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

While we wait to see if there is any public comment, just a reminder the next meeting is on Monday, February 9, 2015 at 2 p.m. We're trying to wait a little bit longer just to make sure that we give sufficient time for people to call in; so thanks for waiting and we do have a public comment. Carol Washburn? As a reminder Carol, please state your name and the organization that you're from and you are limited to 3 minutes for public comment. Please go ahead, Carol.

Carol Washburn – Johanson Washburn Consulting

Hi, Carol Washburn from Johanson Washburn Consulting and I'm working with mobile medical device data and as the mobile medical devices are getting more and more available through FDA approval, I'm a little bit concerned just because I was reading some of the legislation and it doesn't seem to be very specific about what the device companies could do different than like Fitbit or anybody else. So I think they can actually use the data any way they want and just embed in the disclosure that it could be used any way if it's not specifically being sent to a hospital. And so I think this is going to get a bit more gray and I just wanted to put it out there that this needs to be addressed.

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

Thanks, Carol. And we don't have any other comment at this time; so thank you, everyone and we'll talk to you on February 9.

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

Great.

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

Thank you.

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

Thanks Michelle.

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

Okay, bye.

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

Thanks everybody.