



**HIT Policy Committee
Privacy & Security Workgroup
Final Transcript
March 30, 2015**

Presentation

Operator

All lines bridged with the public.

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

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

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

Here.

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

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

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

Here.

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

Hi, Cora. David Kotz? David Mc Callie.

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

Here.

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

Hi, David. 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

Gayle Harrell? Hi, Donna. 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. Gwynne Jenkins, I'm sorry, is no longer. Helen Canton-Peters?

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

Here.

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

John...from ONC. John Wilbanks?

John Wilbanks – Chief Commons Officer – Sage Bionetworks

Present.

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

Hi, John. Kitt Winter? 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

Hi, Linda. Manuj Lal?

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

Here.

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

Micky Tr...hi. Micky Tripathi? Stephania Griffin? Taha Kass-Hout?

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

And I'm sorry...

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

Here.

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

I called Helen...oh, thank you. I called Helen early from ONC, and Helen is here. Anyone else from ONC on the line? Okay, I'll turn it back to you Deven.

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

All right, great. Thank you all very much. We have...can I have the next slide, please; and the slide after that. So we have a couple of things scheduled for our call today. The first is to finalize the draft interoperability roadmap comments for the two sections where we were asked to address some very specific questions. And what I'm going to do when we get to these slides is to kind of click through them relatively quickly, because we had circulated the language in advance, to see if there were any potential changes.

And so essentially on this call rather than spending the time to go through those slides, which all of you have seen already; again, we've also been talking about these on prior calls, is to just see if there are any further comments that people have that they want to have incorporated into what we're going to present at the next meeting of the Health IT Policy Committee, which is next week, next Tuesday. Also if there's anything in the text that you had seen that you think does not represent the consensus of the group or that you want suggest be worded in a different way that now would be the time to pipe up.

But again, we won't go through them line by line, but there will be time for each set of responses for anyone to respond, because this is our last opportunity to finalize what we as a group, as a working group want to be able to say about this before we tee them up for consideration by the Health IT Policy Committee. And again, keeping in mind that this is...that these are comments that we are submitting to the Office of the National Coordinator for Health IT on their draft Interoperability Roadmap for which the public comment period is coming to an end very soon, so.

And then what we'll do is we'll do is we'll move into sort of an introductory discussion of what was in the notice of proposed rulemaking for the Health Information Technology Certification Rule, which was just released either early last week or the very end of the week before. There were two notices of proposed rulemaking; one is the Certification Rule, which we'll spend some time talking about today. And the other one was the Stage 3 proposal for...the proposal for Stage 3 of Meaningful Use.

We do not yet have our working group assignments from ONC and from the Chair of the Health IT Policy Committee on that Meaningful Use proposed rule yet, so we won't really spend time on this call delving into the details of that. Although certainly if we have time at the end of the call, if folks who have read it want to suggest some areas where focus from this particular working group would be helpful, we might have some time at the end of our call today for everyone to do that.

Instead what we'll do during the call today is take a look at the areas that we have been specifically tasked to address in the Certification Rule, and we have a lot of slides on the content of the sections that we've been tasked to address. So even if you haven't had time to read through the Certification Rule, you will not be handicapped by that because you're going to get a lot of information on this call about the relevant pieces of that. And so does anybody have any questions about our agenda today? All right, great; let's have the next slide.

So just keeping in mind our meeting schedule and where we are headed with this. Again, we have a Health IT Policy Committee meeting next week where the roadmap comments from all the workgroups will come in. Then our next two calls will really be dedicated to talking about the NPRM. And right now the schedule indicates the certification NPRM that we would go first with that, but we'll see if we, from a timing perspective once we get our tasks on the Meaningful Use Rule, whether we'll need to sort of intersperse some of that discussion in order to be timely in our response. But right now the plan is to start with the Certification Rule. Okay; next slide.

All right, so now our comments on the draft Interoperability Roadmap; next slide, please. So we have some overarching comments that were not...that are kind of general to the roadmap itself, particularly around the privacy and basic choice and granular choice sections and a request to sort of clarify the language regarding the relationship between what is basic choice and existing laws that permit sharing of health information for some purposes, such as among providers for treatment and care coordination, without the requirement to first...we're missing a word there, to first obtain patient permission.

And so what the bullets underneath are just sort of a little bit more explanation that the roadmap language around basic choice was not terribly clear and I think confused a lot of people about whether ONC was calling for a change in policy with respect to the sharing among healthcare providers for treatment and care coordination purposes or whether they were merely acknowledging that choice, even for those basic uses is often provided by health information exchanges, for example, and that we need a way to be...to have some consistency ideally in how that's represented. And so essentially what we're arguing here is that in many cases the law allows for such sharing without choice and that that needs to be made a bit more clear in the roadmap. Next slide.

The next thing we say is again, with respect to exchange among providers, the roadmap should focus first on removing the roadblocks to exchange that are pursuant to existing law in order to achieve more consistent interpretation of the law and then therefore achieve...assure greater interoperability. And one of the comments that came up in our discussion, our last discussion as a working group is, clarification around liability and you'll see that the third bullet point there says that it would be incredibly helpful to clarify whether when a provider makes a disclosure that's permitted by federal law, under what circumstances would the discloser then be liable for bad or careless acts of the receiver. Because often there's a perception out there that there ne...that a provider needs to be concerned about what the recipient on the other end of a transmission of data, even in a treatment exchange, is going to do with that data. And so we've asked for some clarity there. Next slide.

So those are the overarching comments, does anybody have any suggestions or concerns, and it's okay to sort of feel like they're good enough for now, but I also...this is the opportunity to put any bells and whistles or correct anything that's not quite right about them. Okay, so then we go to the section about consistent representation of authorization to access information, keeping in mind that the term authorization is used in this case not to refer to a patient's authorization to access data, but instead as a broader definition that refers to the legal authority to be able to access health information in an exchange of data. And that authority can come from the law or it could come from the patient's consent or authorization. But here it has that sort of broader sort of legal authority definition to it; it's not just limited to the patient's choice. Next slide.

And here there were a series of questions that we were asked; the first question is, who should ONC convene in order to develop policy recommendations and a framework to enable consistent decisions about authorized access to information. And here we had a suggestion of a pretty broad array of stakeholders in order to determine what are the common obstacles to demonstrating legal authority to access a record, particularly for treatment and care coordination purposes and starting, although not ending necessarily, with circumstances where consent is not required. Next slide, please.

Then there was another question about, is there agreement that the issue of “rules confusion” should be addressed at the state level and if we agree with that, what would be the three priority areas for clarification. And here our answer is that clarification from state as well as federal regulators and ideally with specific examples about what is acceptable for demonstrating legal authority to access information would be enormously helpful.

And we go on to say, and this was something that was emphasized on our last call, that the focus really should be on specific high impact use cases that achieve the interoperability goals of years 1-3 of the 10-year vision. And that ONC should work with stakeholders in order to define these examples and achievement of Meaningful Use objectives and sharing within accountable care organizations, such as pursuant to alternative payment models are just two suggestions, as well as priority areas around demonstrating the existence of a treatment relationship. And then, of course, the impact of consent or authorization to share information both in circumstances when it is required and even in circumstances where it may not be required, but it is present in the information that is sent along with data that’s being exchanged.

I’m going to pause there for a moment because we really sort of ticked through these questions...I’ve been ticking through these relatively quickly, but again, on the understanding that folks should be largely familiar with it...with the content here. Next slide, please.

We have a couple more points to make here referring to some previous recommendations of the Tiger Team that were approved by the Policy Committee about best practices for demonstrating legal authority to access a record in a HIPAA-governed environment and acknowledging that the confusion about laws, not just at the state level, but at the federal level as well. Any additional thoughts or comments on any of the foregoing?

Okay, the next slide deals with role-based access and how should role categoriza...sorry about that, how should role categorization proceed across the healthcare system? And here our response is that ONC should really be focusing, at least initially, on facilitating entity to entity exchange. And who is then permitted to access information within the entity? Which is how role-based access controls are commonly thought of, should really be left to internal policies. And ordinarily there is not a need to standardize, necessarily, with respect to this issue.

But again, clarifying that the sending organization is not legally responsible for how a receiving organization routes the communication, might be helpful to resolving what appear to be some residual concerns about liability there. And that the roadmap could also embrace best practices with respect to how these internal policies might be structured. Next slide.

But we also do note here that in terms of whether there is a basic set of defined roles that could be agreed upon, or even if one would need to have some standardization of role-based access, we're acknowledging that granular consent requirements in some cases, by the nature of the legal requirements and how they're worded, may in fact necessitate some role standardization. And as ONC explores the issue of harmonizing these more granular consent laws that might be the time to consider whether some level of role standardization, at least at a high level, might help resolve interoperability obstacles posed by granular consent requirements because again, some of these laws do allow for sharing among professionals who hold specific roles and so that might be something to think about in that particular circumstance. This comes out of some very good discussion that we had on our last call.

John Wilbanks – Chief Commons Officer – Sage Bionetworks

Deven, can I raise my hand real quick, it's Wilbanks.

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

Yes you can.

John Wilbanks – Chief Commons Officer – Sage Bionetworks

So just to point out the value here of...

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

And this is John, right?

John Wilbanks – Chief Commons Officer – Sage Bionetworks

This is John Wilbanks, yeah. Just to point out the value of coming to a balance between granularity and standardization. The...in other places where there's free software, free culture, what have you, you sort of start off with lots and lots of licenses in...space, which is sort of similar to the granularity of choice here. And so there's...and each of these use sort of a consolidation down to a core set of popular licenses that facilitate interoperability and so it might be ga...in open source software there are like 7 of them, in free culture there are 6 core creative common licenses now they've eliminated everything else, so to...one thing to maybe not as a nit here is, so it shouldn't be granular, you know, every choice for everyone at all times, but there's probably a sweet spot of 6-9 kinds of choices and ways to put those into standard ways so that you have some...as an algorithmic rules that know whether or not a given record is interoperable with a given request or not. So, just to sort of limit the universe of granularity to a smaller number whenever possible, so that facilitates interoperability a lot.

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

Okay, I think we can note that. And you know what, offline John, if you can send me some of those examples that you just cited, I think it might be helpful to include those.

John Wilbanks – Chief Commons Officer – Sage Bionetworks

Sure.

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

That would be great. Any other thoughts? Great; thank you. Next slide, please. Okay and then there were a couple of questions about standards supporting authorization and whether they exist and whether there's been sufficient uptake of them? And our response is that questions around standards for this are more appropriate for the Standards Committee. Next slide. And so then with section G, now we do get into the section where the questions are specific about permission from the patient to collect, share and use identifiable health information. Next slide, please.

And the first question we got is whether the states were ready to collaborate on issues of permission and why or why not? And while we don't actually know the answer to this question, we do think that collaboration is helpful and we hope that states are willing to do this, but the states of course are addressing a number of issues and there might be limited bandwidth to take this on, particularly because it's a very complex issue. And we also note very specifically that there is going to need to be a federal convener to really support and encourage this effort. That was a comment that was specifically made on our last call.

We have a little bit of extra text to support the recommendation about moving forward with this and sort of taking on even that federal convening role to try to help assure that it happens with some suggestions about looking at the framework developed by NCVHS and considering whether the Uniform Law Commissioners might even be helpful on this set of issues. Next slide.

We were also asked whether other methodologies, including technical solutions, should be considered to address this concern and we recommend that ONC evaluate the work that the Social Security Administration did in formulating a universal authorization to share data, which has been incredibly helpful for them in being able to access data for Social Security Disability Determinations, even in jurisdictions where there are more stringent consent laws for release of that information.

From our last call we also suggest investigating the...whether they Do Not Call Registry and that kind of a model would be workable and helpful in the context of permissions to share data for health. ONC could also look at existing exchange models to explore whether the approaches that they are using could be scaled. And using consent repositories was another approach. And these were some ideas that came out of our deliberations as a workgroup on our prior call; so we're including all of them as part of our comments. Next slide.

This is a question specifically about the ability to persist consent with patient information and they...and is it a valid assumption that consent is going to have to be able to persist with the information and what's the impact of non-persistence on the interoperability movement of data. And here our response acknowledges that a technical ability to persist consent or authorization is desirable but potentially only in circumstances where there is either a legal obligation for the consent to be persisted and honored across settings or in the circumstance of data shared directly by or at the request of the patient.

Because the...you know, if you've got a set of legal requirements, like the federal Part 2 rules that place constraints on redisclosure so that wherever that data is shared, the recipient is then bound by the Part 2 rules to seek additional authorization from the patient to disclose it. That there would need to be some ability to persist it but that in other circumstances where the law may govern the sending actor but not necessarily the recipient actor with respect to honoring the patient consent, the persistence of that consent does not necessarily mean that there's a legal requirement to honor it and certainly in such a circumstance, the individuals who have provided that consent would need to understand that there might be limits to the downstream honoring of that consent. So here we raise maybe more questions than we answer but if anything we note that the persistence of that consent in some circumstances may not nece...may not be necessary. Next slide, please.

And then there was another set of questions about whether approaching consent through basic choice, which is really the...a very coarse sort of all in or all out decision, especially as it relates to TPO, which is treatment, payment or operations, that focusing on that first makes sense, followed by granular choice supported by harmonized rules in terms of sort of priorities. And what alternatives should ONC be considering and what areas of health information would first be addressed for granular choice and what are some realistic timeframes? And we have the following answers, next slide, which is not frankly, an answer to all of the questions but is an answer to most of them.

And again we're urging ONC to focus on assuring that exchange can occur in circumstances governed by HIPAA where choice is not necessarily required in addition to focusing on choice circumstances. And just by way of example, they could look at the recommendations on "directed exchange" that the Health IT Policy Committee adopted back in August of 2010. ONC also should consider how to enable patients, such as through basic choice, to require that their data be shared for treatment purposes. In other words, they could clarify whether a provider can refuse to exchange data when a patient requests exchange, even in a HIPAA only environment. This should really be a fundamental use case for the interoperability roadmap and an example for which additional regulatory guidance could be promulgated. And both of these points were made on our last call. Next slide.

We also do think that wh...because basic choice has been implemented in one form or another by a number of health information exchanges and other exchange settings and since achieving exchange among HIEs is a desirable near-term goal, this bolsters the argument for an early focus on basic choice. But we acknowledge that granular choice is going to require more effort on the policy front and working with multiple states, but certainly the dialogue could begin, even if it's not going to be resolved on a short timeframe and is likely to take longer than basic choice.

Also wonder whether there are some intermediate options between basic and granular because granular typically gets defined as applying to the type of data. Maybe we could look at this as enabling choice at the level of provider or provider organization, which may provide patients with some greater level of granularity with respect to their choices than basic choice which tends to be all out or all in for everything. Versus concepts of granularity that are often present in the law which are based on the type of data. And these really came mostly from our prior phone calls. And in the next slide, we go on to another question, so I'm going to stop and see if folks have additional comments or any concerns that they want to raise.

Okay; and then finally here how should success be measured when addressing the complexity of the rules environment? And we urge that the success metrics be linking to interoperability goals and focus again on removal of obstacles to achieving high impact use cases. So this reinforces some points that we made earlier and some possible examples are convening a dialogue with the states with respect to harmonization within a year. Issuing more guid...now these are not necessarily in priority order, if we wanted to put them in priority order we could do that. Issuance of more guidance on acceptable mechanisms for assuring legal authorization to share information within 1-2 years; and this is again the broader concept of authorization, it doesn't necessarily require patient choice and we've called for that within 1-2 years, at least at the federal level.

Achieving some consensus on definitions for basic choice within the next 2-4 years and greater...and the ultimate metric, which is not really a process metric, but more of an outcome measure which is greater exchange of information for treatment and care coordination, particularly in circumstances where HIPAA governs or there are no state laws that restrict the sharing of information for those purposes. And that has...we just put a 1-5 year timeframe on that, but acknowledging that it's already occurring with respect to ePrescribing, which is a point that was made in one of our prior calls. So any thoughts on our success metrics and our timeframes here, they might still be a little ambitious, but we can always be hopeful.

All right, great; I think that might be it, let's see the next slide. It is. All right, well we're going to close the book on our roadmap comments unless anybody has any other thoughts or suggestions. We're a little ahead of schedule, so we certainly have time. So if there's something that you want to add to the dialogue, now would be the time to do it.

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

Deven, this is David Kotz, I'm sorry I joined late, after the roll call.

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

That's okay David.

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

I think it all looks great. As you said, we've discussed those things in prior calls and I don't have any suggestions or changes at this point. Great summary.

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

Okay, thanks David. Yeah, I think it's a very good set of recommendations. All right, thank you all very much, great work. I think...feel like this is really the first opportunity that we've had to deliver a pretty substantial set of recommendations as a new workgroup and I'm really thankful for all of your efforts. I think we've done some very good work here and hopefully the Policy Committee will agree. Stan and I will do our best to represent you.

All right, so now we're going to move into talking about the Certification Rule. Now, one of the things that we'll...that I'll note just right off the bat is that we always, in terms of the Certification Rule in particular, given that it's focused on...often on standards that need to be adopted in Certified Electronic Health Record Technology, the Standards Committee plays a very big role in commenting on this rule, but often there are policy choices reflected in the technical capabilities and standards that are proposed for electronic health record technology. And so it is relevant for the Policy Committee to weigh in on the policy choices that are made by decisions about what has to be in the technology.

And those types of comments can range from we don't think that the technical cap...that the policy issue requires the technical capability from yes there is a technical capability that's required here but we don't think that the options that are available on the table necessarily match where the policies are or there...is something missing from the certification program and a policy need that we think needs to be addressed. And so that...it is appropriate for us to comment on those aspects of what is otherwise a technical rulemaking.

We have done that in the past. What we leave to the Standards Committee are decisions about what's standard and what the func...what specifically with some degree of technical specificity the technical functionality to implement a particular policy choice would need to look like or should look like if it's going to be part of the certification program.

And also, for those of you who might be new to sort of the...what a proposed rule is and what it means, these are rules, both the Meaningful Use Rule as well as the Certification Rule that are intended to put into effect what Congress authorized in the HITECH legislation. The rules supply the details of what is needed in order for healthcare providers' eligible for the Electronic Record Incentive Program for them to be paid and there have always been two components of that.

One is, what are the objectives that they have to meet, that's the Meaningful Use Rule and the second is what are the...what type of system do they need to be using in order to be meaningful using certified electronic health record technology, which is what triggers payment under the HITECH program. Or in future stages of HITECH, what triggers not being penalized under the rule. So, the rulemaking process is one where rules are initially proposed, those are called notice of proposed rulemaking and they are put out for public comment.

And the Health IT Policy Committee and the Standards Committee have always participated in the process of filing comments, along with members of the public, to these rulemakings. They are regular rulemakings, not expedited in any way so there is a 60-day comment period, which in this case closes May 29. And then after the comments are received, the agencies then subsequently issue a final rule, which considers the comments that have been filed on the proposed rules and then responds to those comments and sometimes there are changes in what was proposed and sometimes not. But the final rule always is required by administrative law to include an explanation of...and response to, at least in general categories, what the public comments were.

So we're now in a public comment period and what we try to do as a workgroup is to come to some consensus comments that we would forward up to the Health IT Policy Committee that would then be forwarded on to ONC in the Case of the Certification Rule that we're going to talk about today and to CMS in the case of the Meaningful Use Rule, which we'll talk about in a subsequent meeting. But that does not foreclose any single one of you, or of course members of the public as well, from submitting your own comments to cover issues that we won't cover because of the limits of our charge as a workgroup or the limits of time and what we're able to take on during the time period that we have.

But you can...you're not foreclosed at all from submitting your own comments, from joining other groups and submitting comments. You know, this process is really about the advisory committee process and determining what the comments will be forwarded from the Health IT Policy Committee on these rules. Does anybody have any questions about the process and what we're doing here? All right, great; next slide, please.

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

Deven hi, this is Micky Tripathi, just to let you know I'm on.

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

Hey, Micky.

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

Hi.

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

Glad to have you on. Did you have a question about rulemaking or are you just telling me you're here.

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

It was a gripping description, I think I got it, but I just wanted to let you know I'm here.

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

Thank you very much, Micky. Okay, these are the two areas that we have been tasked to take on in the Certification Rule; data segmentation for privacy, which is an issue that the Tiger Team took on not that long ago in some sort of early suggestions to ONC on the Certification Rule. And then there are also some specific questions about pharmacogenomics data and whether in fact the data segmentation for privacy protections might also be helpful when pharmacogenomics data is collected and used in clinical decision support. And they've asked us to take that on as well.

The other section of the Certification Rule that dealt with privacy and security deals with the components of the Certification Rule that have really been in place since the very beginning of the program, since the 2011 rule, that require certified EHR technology to have certain functionalities for data security, including audit logs and role based access controls, encryption of data at rest, encryption of devices that connect into the certified technology and whether EHR modules would need to, each and every one of them, have to meet the certification requirements for all of those technologies.

This is an issue that the Health IT Standards Committee and its Privacy & Security Workgroup has always historically taken on. They were the group that initially came up with a proposed list for ONC to include in the very first Certification Rule and they have been chewing on this issue of how those requirements should or should not be part of certification for modules and the base EHR and particularly as the Certification Program moved from sort of this concept of a complete EHR to recognizing that a lot of EHR systems would be built through components.

And that's an issue that they have weighed in on previously, it's talked about in the rule and so we are not going to take that on as a Policy Committee because it deals...it really has been in the camp of the Standards Committee since its inception and there are no new policy issues necessarily that are implicated by the continuing discussion that has gone on with the Standards Committee since the beginning of the program. So we're not going to do that.

The other thing that's noted here on this slide is that we are going to have some pieces of the Meaningful Use Stage 3 notice of proposed rulemaking that we will take on, but we will not know until a later time, I'm sure by our next call, which issues we're going to be tasked to address in the Meaningful Use Rule and when our timing will be for that. We've been asked to prioritize the Certification Rule first, so that's what we're going to do.

Okay, so the next slides really are some...so here...oh sorry. So here's some sense of sort of what our meeting schedule looks like. We have, again, we dealt with the...we're going to deal with the Certification NPRM today, just introduce it. We will focus more on data segmentation for privacy in our meeting on April 20 and pharmacogenomics on April 27, although if for some reason we make faster timing on either one of those, we could begin, I think, talking about the Meaningful Use Rule in advance of the May Health IT Policy Committee meeting. And in fact, we may need to actually, as I think about it, because the comment deadline expires before the June meeting, so we're probably going to need to get that done. But, we do have two calls in April and we'll do...we'll be on the notices of proposed rulemaking during that time and fear not people who are lovers of our work on big data, we will be back to it as soon as we have completed our tasks with respect to these rulemakings.

Okay, next slide. Here's a bit of a schematic on our...on how we're going to go about doing this. We'll have intro today and we'll process both through meetings and through email what our comments will be and with the aim of briefing the Health IT Policy Committee on what we've been able to accomplish on both certification and I think also on Meaningful Use, but we will prob...we may not finish Meaningful Use by May, we'll see, given the comment deadline by the May 12 meeting. Next slide.

Okay, so there are a lot of quotes in these next slides. And I'm going to paraphrase some of them, but I'm not going to paraphrase all of them in recognition that a lot of you may not have had a chance to read through these rules, particularly with respect to these provisions and so we need to get everyone up to speed on content in the proposed rulemaking, and that's what we're really going to focus the final minutes of our call today on. And here, ONC is proposing to adopt two new certification criteria that would focus on the capability to separately track, i.e. segment, individually identifiable health information that is protected by rules that are more privacy restrictive or someone could say, privacy protecting depending on how you feel about all this, than the Privacy Rule. Next slide.

Overall the Data Segmentation for Privacy initiative, which the term DS4P reflects some pilots that ONC engaged in in order to test some technical mechanisms for segmenting data that is subject to stronger consent laws. And overall that initiative and its subsequent pilots focused on the exchange of health information in the context of 42 CFR Part 2; now that's the federal law governing substance abuse treatment data that does have the provision that I talked about earlier where the authorization from the patient to share from the substance abuse treatment provider was covered by the law to another provider, say a physical health provider, is required, but then that physical health care provider can't redisclose that information without subsequently getting the consent of the patient.

So it does have sort of that unique aspect to it where the protections need to flow with the data. And that initiative and the pilots were really seeking to develop some technical standards that would enable providers to be able to segment health information that was regulated by a law...by the Part 2 law and make compliance with the laws more efficient and also recognizing that the term data segmentation is often used to describe sort of a way of electronically labeling or tagging the information in a way that allows the sharing of parts, but not all of the patient record. Next slide.

These are all direct quotes from the rulemaking. ONC really views the proposed offering of certification to these criteria as an initial step on technical standards towards an ability of an interoperable health system to compute and then persist the applicable permitted access use or disclosure, whether it's regulated by state or federal laws regarding sensitive health information or by an individual's documented choices about downstream access to or use or disclosure to others of the identifiable health information and the application of the standard, at the document level, so we're getting to an important part of all this, is an initial step. Next slide.

So here's what they propose, and they are proposing it consistent with some recommendations that again came out of the Tiger Team and that were endorsed by the Health IT Policy Committee, that a health information technology module must be able to send documents using document level tagging in accordance with DS4P IG, and that's a reference to the HL7 standard that was developed for the tagging of documents that require additional consent. And it's at the document level. There's some language in the NPRM that talks about the capability to be able to apply these flags, the sort of segment flags, within a document at the discrete element...at the discrete data level but also an acknowledgment in the NPRM that that technology isn't widely available at this time and hasn't necessarily been balloted through the standards process, my recollection of what was in there from reading it yesterday, reading the NPRM.

And so what they're proposing is just to require the document level functionality so that if a substance abuse treatment provider who was governed by Part 2 wanted to be able to send a document to a treatment provider and had the consent of the patient, they could take a summary of care document and be able to put a data segmentation flag on it, again assuming they have the consent of the patient to at least share it. And then they're also proposing a certification criterion that would require a module to also be able to receive that segment...the document with the data segmentation flag on it with the HL7 standard incorporated. And that DS4P at the document level allows the recipient to then receive, recognize and view documents with privacy metadata tagging, indicating that it's restricted under Part 2.

And as we talked about in our...when we took this issue on as a Tiger Team and David and Micky will recall these discussions, but this may be new to many of the rest of you. What that means is that the document essentially can be read but it cannot be consumed into the electronic health records because the discrete elements can't be pulled out of it, it has to remain segmented as a document.

And David and Micky can correct me if I'm misstating, but it's, you know, it allows you to read...it allows the recipient provider to read it so that they get the information, but they...but it can't be subsequently used within the EHR in the way that other elements of a document can be, because the tagging is at the document level, it's not tagged at the discrete data element level and so the risk of redisclosing it without necessarily honoring the consent obligation would still exist if it was a document that came over that could be pulled apart or interdigitated is the word that I remember that we used. It just can be read only.

But, at a minimum, again, we did recommend that certification proceed forward because this was a good initial step, because right now this data is not really being exchanged at all digitally and that that would be a first step to get it moving, and would be an encouragement to vendors who were working with this technology to continue to work on the issue of being able to persist the tagging of the data at the discrete element level versus only at the document level. I think we have a few other...

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

Deven?

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

Yes David, did I get that totally wrong or...

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

Yeah, just to...

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

...am I close?

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

...no, I think unfortunately you're close. It's unfortunate because this is such an awkward notion for the physicians that use these systems or the providers that use these systems, although this is exactly what we proposed, so we're going to have to live with our recommendation, since this is what we said. But to clarify a little bit on the sequestration part, I don't recall exact details, but we discussed the notion that the...that you really need to do a little bit more fleshing out probably as to what's expected of the sequestered document.

So clearly it can be readable by the clinician. It's pretty clear that it would not be subject to any kind of automated incorporation, you know, being parsed and man...and automatically incorporated into the structured data of the EHR. It also is fairly clear that it would not be automatically swept into any data sharing with outside systems like an HIE, if there is any kind of an automated set up to do that. It would not be exposed to external systems that issued a query into the EHR, like from eHealth Exchange or CommonWell.

What's a little bit less clear is it might not preclude the provider from manually incorporating the data with, you know, some kind of clickable activity. So, if the provider has ascertained that the data needs to be incorporated and has captured, for example, redisclosure permissions through some other channel, he could incorporate the data with a click instead of having to just retype the darn thing, which of course you could always do. So there are some details there, I don't know how they propose to certify what sequestration means because I don't think there's an implementation guide for that that I've ever seen. So, that's not probably the purview of this group, but just to bring those details up.

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

Yeah, well they reference an implementation guide from HL7, so that'll be interest...I mean, if...

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

Yeah, there may be...I know there is one for the DS4P itself and how the documents are structured. I wasn't aware that it covered the sequestration proposal, but maybe it does and I'm just slow and haven't caught up on it. I mean...

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

Well we'll take a look at that...

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

...the other comment to make...

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

...I mean, one of the objectives of today should really be to find what additional information would be helpful for us to...

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

Yeah.

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

...get for this.

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

Yeah, no, that's a good idea. I...we certainly have folks who know the answer to that question, I just haven't...I wasn't aware that it went to the level of describing behavior in the EHR. The...I mean the thing that is uncomfortable about this is that, and I think most of the people on the call know it, although you didn't suffer through the meetings where we went into this in agonizing detail, is that because the sequestration is at the document level, there are all sorts of non-sensitive information about the patient, or information that most people wouldn't consider sensitive under most circumstances that gets swept up by the document level tag. And that will create technically all sorts of problems for the providers.

Now in practice, the provider can probably say that they discovered that information through non-sequesterable channels and therefore they're allowed to redisclose it, but any medications, including vitamins or whatever that come in with that document are going to be sequestered. And it leads to sort of ridiculous conundrums for any notion that you have decision support ensuring safety of the patient when all that data is kept outside of the decision support system because of being inadvertently swept up when it came in through a sequestered channel. So anyway, it...we went through all that, I don't know if we want to rehash it, but it really is unpleasant compromise.

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

Well, and you know, one of the things that we might do because we have so many folks who are new to this issue, is to circulate the comment...the set of Health IT Policy Committee endorsed recommendations on this issue so that people can see all of the richness of the debate that we engaged in.

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

Yeah, yeah, that's probably a good idea.

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

I think in the...this is Micky, in the rule there's a link to, I guess there's a link to the letter, right, to our recommendation letter?

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

Yeah, no, there are many things about it that were pulled out into the rule and there probably could be a link in there. I would not be hard to find and it's not that long.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I do think we should do that...

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
...so people can see where we...from whence this came.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Yeah, so just remembering...this is Micky again. I just, for added context, have been reflecting back on that discussion. As I recall, there was somewhat of the ask to us, and I forget where it came from, it was another workgroup, I think, it was a little bit of a leaning forward kind of perspective, which is to say, we feel a lot of need to certify something to move this forward and I sort of, as I recall my feelings at the time, it was a little bit with an eye towards saying, well if that was going to happen, what would it be? And then I think that led to what I thought was a very elegant framework.

That seems separate from the question of whether we were saying that this is ready for primetime given that there's maybe an implementation guide out there, there doesn't seem to be a big testing base in all of that. And then I guess another point to me, this is a question, a process question, is the Standards Committee going to be taking up this question as well?

And the reason I ask that is because they have the maturity framework that Dixie Baker and Jonathan Perlin and John Halamka developed and approved and I think they like to look at different standards through that maturity framework. And I'm just wondering if they are going to be looking at it, then they would be applying that. If it's really all on our side, do we want to think of it in that context?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, that's a good question Micky. We'll find out because again, typically we wouldn't opine on whether the...like the IG, the DS4P IG that's sort of technically...can we just go to the next slide...whether that is mature enough. But instead, the sort of policy choices that are inherent in the selection of the standard, but it...given that explanation, it feels like it might have some...pieces to it. So...

Helen Canton-Peters, MSN, RN – Office of Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Deven, this is Helen with ONC.

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

Hi Helen.

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

They do have that section...just so you know.

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

Okay. Great, thank you Helen, that's helpful. And so what remains here on the slide is again, what the two requirements are in the proposed Certification Rule which is that technology must enable a user to create a summary record, format it in accordance with the standards, and those are the document standards I think for the summary record, and that its tagged as restricted and subject to restrictions on redisclosure, according to the standard that's adopted at this provision.

And then on the receiving side, the technology has to enable a user to receive the summary record that's tagged and subject to restrictions, apply document level tagging and sequester the document from other documents that are received and then view the restricted document without incorporating it. So that's just the specific language that's there. We will circulate our recommendation from before, because the other thing that I remember about it, and Micky maybe this is part of the sort of elegant solution that you were referring to earlier is that we thought that this kind of capability ought to be mandated in any sort of EHR technology that might be made available to behavioral health providers.

But that on the recipient provider side, that there would need to be some judgment calls that a provider would make about whether their own technology would include this capability. And I believe that that's a dir...because there's no longer a voluntary certification, there are no longer voluntary certification criteria in the main EHR program, but this is not required to be part of the base EHR, it...

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

Right.

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

...and so, whether or not you buy this functionality I think may depend on whether or not you're actually interested in receiving documents that are coming from behavioral health providers.

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

And if...this is Micky again; when we did discuss this, though, there was voluntary certification.

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

Oh yeah, no, we got a...

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

Yeah, we were in that crossfire.

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

...there was and then suddenly there wasn't. I think by the time we actually talked about it, it was gone. But I do think that our recommendations spoke to this sort of notion of voluntariness on the part of recipient providers. So, but we'll get that all circulated and that'll be part of our discussion.

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

The other thing that occurs to me, now that I'm thinking about this...this is David again; is it's not on our purview here to talk about the API requirement or proposed requirement, but one of the API capabilities is to query for discrete data and there's no statement that I recall about how it would handle sequestered data.

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

Ahhh.

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

So, the API implementers will have to wrestle with this, even though the document level sequestration may be clear.

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

Right.

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

So...and it's, you know, the magic thinking is you have to know all of the impacts of the sensitive data, but you can't actually know what the sensitive data was, which is obviously an impossibility and so all these things are basically putting burden on the doctor to juggle the conflicting requirements on his or her relationship with the patient. So, that's, I think, why we were comfortable saying a document was an adequate starting point to learn from...

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

Right.

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

...but it certainly isn't going to be an easy thing and there will be a lot of people who really dislike it.

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

Yeah. All right, well, fodder for future discussion. So the next area to...for me to just give you an intro to is...begins on the next slide, which is on pharmacogenetics data. Pharmacogenetics data, these are all quotes from the NPRM, identified genetic variance in individuals that alter their metabolism or other interactions with medications and can lead to serious adverse events. Information is being included in an increasing number of FDA approved drug labels. And health IT systems can capture pharmacogenetics information that could be used to increase patient safety and enhance patient outcomes. Next slide.

For the use cases of CDS, which is clinical decision support, informed by pharmacogenetics information, considerable ambiguity exists with respect to the incorporation of CDS systems that facilitate providers taking advantage of pharmacogenomics information. There is some opportunity for further specification of standards and implementation of pharmacogenomics data for CDS within health IT systems. And also opportunities for capturing genomic patient data in lab results for drug-genome interactions and for genomic metabolizer status defin...which define risks to certain medications in a structured way within health IT. So this is all background information. Next slide.

Federal and state privacy laws and regulations that are more privacy restricting than the HIPAA Privacy Rule will impact any certification criteria or policy we might propose to adopt in future rulemaking. And so they're at this point asking for input on the factors to consider for health IT that allows the user of that technology to use or disclose genetic information in a manner compliant with federal and state privacy laws. And they put out there that the capabilities offered by the data segmentation for privacy criteria that we just talked about could be leveraged for the segmentation of individually identifiable genetic information.

So here they're talking about that the Meaningful Use rule does not require the collection of pharmacogenomic information, but they're acknowledging that this kind of information can be collected through certified health IT technology and if it is collected by this technology, do we have the capabilities in the systems to accommodate the fact that this data, in some circumstances, may be subject to additional laws regarding whether or not it can be accessed, used or disclosed without patient consent first...without first obtaining patient consent.

And to the best of my knowledge, those are mostly state laws, the GINA, the Genetic Information Nondiscrimination Act, is...really deals with what employers and health plans are permitted to do with genetic information when they have it or when they're able to collect it. It does not sort of put privacy regulations around data in the same way that the Part 2 rules do or that certain state laws do. But nevertheless, there are some...there are out there some privacy laws that do apply to genetic and genomic information and so some questions are being asked really by this NPRM related to data segmentation. And particularly for the use case of decision support, which is something that we grappled with when we talked about DS4P initially. So, next slide.

So here's just...can I have the next slide, please? I should be on 35; thank you. So here are some of the questions that ONC asks in the NPRM, whether the 2015 edition of certified EHR technology, whether that medication allergy list should include the capability to integrate genotype-based drug metabolizer rate information. Whether the drug-drug, drug-allergy interaction checks for CPOE or some sort of separate certification criterion should include pharmacogenomic CDS for drug-genome interactions and whether ONC should offer 2015 certification for clinical decision support that incorporates patient's pharmacogenomic genotype data into the computerized physician order entry prescribing process with the goal of avoiding adverse prescribing outcomes for known drug genotype interactions.

These are all questions that are in the NPRM but don't necessarily get to the privacy issues, but instead ask a substantive question about whether it's worth having certification for the inclusion of this information in the first place. Second...can I have the next slide, please.

And then there are some additional again questions on this issue. There are...are there certification approaches that could enhance the provider's adoption and continued use of health IT that...where CDS includes the pharmacogenomic data and whether there are standards to be able to capture it. Those are also two questions that are not typically in our wheelhouse, but just to give you sort of full background.

This final one, though, is definitely in our wheelhouse and that is, should ONC offer certification for health IT functionality that could facilitate HIPAA compliant sharing of discrete elements of a patient's genomic information from their record to the family history section of a relative's record. So not just the record of the patient whose data...whose genomic data is collected, but whether in fact that data could then be used to populate family history of a relatives record. Next slide.

And these next questions are ours as well, that the proposed data segmentation for privacy criteria would provide the kind of needed functionality with respect to the collection of this information that is subject to both HIPAA as well as potentially some additional state and federal laws, such as GINA. Again, I'm not sure that GINAs all that relevant here, but it is mentioned in the NPRM. And do the...does the data segmentation for privacy approach adequately balance the complex genetic privacy issues, such as those related to behavioral health with the clinical value of context appropriate availability of a patient's actionable genetic and genomic information. I think that's it; next slide.

Oh nope, there's more. Should HIT...health IT be required to apply different rules for the use and exchange of genetic, genome and pharmacogenomics data based on different groupings of diseases or conditions, based on the sensitivity of the information, such as those related to behavioral health. So not just the issue of the pharmacogenomic or other genetic data itself, but whether, in fact, the diseases to which that genetic or genomic data relates that we would make a further cut at in terms of sensitivity and the need for the technology to be able to recognize that and act on that in some way.

And our...and then the last...I think this, is the last question, whether there are other factors we should consider for health IT that allows the user to user disclose genetic information in a manner compliant with federal and state privacy laws. So here, nothing specific has been proposed in the Certification Rule, but a lot of questions about whether, certainly with respect to at least the privacy aspects of this, whether there are some additional functionalities that might be necessary in EHRs to accommodate pharmacogenomic and other genetic data that might be used in a treatment context, whether for the patient to whom it directly relates or to a family member.

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

Do you want some comments?

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

Oh sure, David; go ahead.

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

How long do you have?

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

Well, it's 3:10, I mean...

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

...speak up.

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

...I don't think it hurts to start sort of teeing up some issues for us to explore in a future call as well as what other additional information would be helpful for us to have to really fully flesh out the pieces of this that are ours to flesh out.

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

So I'll just make a very few high level comments, just for stimulating the conversation. One is that by the Dixie Baker maturity criteria, this is certainly not anywhere close to mature; it's not even mature to the evidence-based medicine world. It's been hard to demonstrate that all of this pharmacogenomic critiquing actually improves outcomes; although most people believe that it will it's actually been difficult to show that, even for obvious things like warfarin dosing. So, I think putting it in regulation at this point, by that criteria alone would be highly premature.

Number two; it's our experience that the decision making to actually generate a critique is complex enough that it's almost certainly going to be deployed as a service rather than as data that you shuffle around. The technical distinction a little bit like the enclave argument for accessing de-identified data; so the viable companies that are doing this today are doing it by you submit to them as...over their service interface the drugs that your patient is taking.

And they return with a critique that based on best knowledge of what's been learned in the labs with the patient's scans that they have on record, and those scans could be SNP scans, they could be whole genome or whole exome sequencing, a variety of things that effectively become a black box to the EHR vendor. It's just a critique that comes back that says this drug has the following contraindications based on best knowledge that we have. So in that case the data is never even in the EHR in the first place, is just where I'm headed with that long winded diatribe. If software as a service or CDS as a service looks to me like the most likely way this is actually deployed in the real world for cost reasons and all sorts of other reasons.

And then third, if you're worried about tipping other people off with the impact of the genomic information about the patient, it's been shown that a well captured family history without any genomic data whatsoever is more powerfully predictive about the outcome of the patient's life expectancy than is all the genomic data that we know how to gather, for the vast majority of patients. So to treat this genomic data as if it's somehow more powerful and more special it's not...there is not evidence to back that up yet; we'd have to treat everything that way. And as I think I've pointed out on some previous calls, you know blood type is a genetic test, so are we going to sequester blood types because that can tell you a lot about parentage and all sorts of other things. So anyway...

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

Hmm.

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

...I think this is all way premature is where the bottom line comes to me.

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

What's the...is it the service...the external service that you mention, what was the name of it?

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

Well there are some companies out there that are offering their own proprietary approaches. The Standards Committee API workgroup that Arien and I Co-Chair is proposing an approach to standardizing what you might call decision support as a service or remote decision support using FHIR and some of the emerging API standards to allow a vendor to query a remote service in a standardized way so that if there were competing companies out there offering genomic testing...genomic...pharmacogenomic screening, you could, each vendor or each provider could pick which service they like to use based on cost or performance or whatever.

So there's not a formal standard for it yet, there's an HL7 standard that nobody uses called DSS, but nobody uses that so I think it'll be a new what we call an orchestration of FHIR and OAuth and some things like that.

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

Okay.

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

But it's decision support as a service, it's decision support as a black box.

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

But if someone were to use an outside vendor to do some sort of decision support for which they wanted to get some credit for under Meaningful Use, it would have to be certified wouldn't it? I mean, is that just...

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

Well, I mean, I suppose; hopefully they would take a functional certification and say, you accomplished it with a service that meets some functional criteria. My point is the notion of sequestering the data in the EHR that would drive that decision may not ever be likely to happen.

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

Got it.

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

In other words, the EHR is not going to carry around the four million variants that a typical patient has in their genome and have to protect that. If they had it, they would have to protect it, but they're not going to do it that way...

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

Right.

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

...it's...in other words; it's not like...I don't see how the DS4P stuff applies at all is the other thought. To me that's a complete head scratcher, I'm not sure what they were thinking.

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

Okay. Yeah, I had the much more simple conclusion, potential conclusion that one of the thing...one of the concerns that we had about DS4P at a document level was that it would not...that CDS would not be enabled, so...

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

Yeah, yeah and I'm just not quite sure what they meant. I mean, they may have a clear idea of why they were proposing DS4P and I just need to be caught up on what they were thinking. But, I guess where I'm headed is that I think that increasingly the genomic decision support stuff is going to be black box because the knowledge base is, and the data are so immense that it's not something the EHRs are going to carry around inside their record. They may carry around summaries, high level summaries, particularly as common patterns and syndromes are...come to be understood. So, you may be classed as a low metabolizer for a certain family of drugs, I can see stuff like that being carried around, but that's not going to be terribly revealing since a third of the population is going to have it. It's not identifying information; it's not sensitive in that sense.

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

Right.

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

I'm not sure...I'm not quite sure where they were headed, I'll be you there's a...there's something behind this that we just need to learn what they were thinking, how they would propose to use it.

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

I'm not sure either. Other thoughts, other information that people think would be helpful to have to take on some of these questions? Those are helpful, David, thank you. All right, well those are our two areas for the Certification Rule that we'll be diving into more deeply. If you...certainly if you think of any additional things off while you're really thinking deeply about these questions off of the context of this call, shoot an email if something occurs to you that would be helpful in considering these questions.

Is there anybody that has rea...had a chance to read the Stage 3 Meaningful Use Rule that would like to suggest areas that they want me to fight for in our call that the Co-Chairs have tomorrow where we get our assignments for the Meaningful Use Rule, so that we would be officially tasked to at least the...to take something on maybe in conjunction with another group or solely. I suspect that we will be getting the privacy and security objective that is in Meaningful Use Stage 3, because we have contributed to it previously. But for the other issues, whether they land in our laps or someone else's lap is a little less obvious so if anyone has had a chance to read it and wants to weight in now on an issue that they thought having our input on it would be valuable or that it would be worthwhile to take on, now's the chance to say.

Okay, well stay tuned for learning more about what we're going to take on of that rule and we will find out very soon. I want to turn, before we close because we need to give some time for people to queue up to public comment, ask the Altarum folks to open up the lines so we can see if anybody's on for public comment?

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

Lonnie, can you please open the lines.

Public Comment

Lonnie Moore – Meetings Coordinator – Altarum Institute

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

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

Okay, so while we wait for folks to get in the queue if they want to make a comment, I will say that we...you're also going to be very soon getting some calendar invites for meetings for the second half of the year, because we only had meetings scheduled for the first half and we need to get to that and then we'll be getting those finalized I think this week as well.

Also to let you all know that we have had some members who were initially appointed who have really been unable to keep up with our schedule, which is completely understandable, it's not alwa...it's...we recognize that it's not easy to find the time to do these calls, so it's quite possible that we'll be joined by some new folks either during this NPRM discussion if we can on...get them on-boarded that quickly or at least by the time of our big data discussions. So I just wanted to give you all a heads up about that.

We'll be using the list of folks who have previously indicated that they are interested in joining our workgroup and trying to fulfill our need to have a diverse range of experience and perspective on the group, to add to the great representation that we already have. And so with that, I think we should...we probably...I'll turn to see if we have anyone who wants to make a public comment.

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

We do.

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

Okay, great.

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

Wayne Grigsby, I believe?

Wayne Grigsby – Clinical Director – Friendship House of American Indians Friendship House Association of American Indians

Not Gretsky.

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

Oh darn.

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

You'll have 3 minutes for public comment. Go ahead, Wayne. If you could state your organization that you're with, that would be appreciated.

Wayne Grigsby – Clinical Director – Friendship House of American Indians Friendship House Association of American Indians

The Friendship House Association of American Indians; Jen Sabala normally is in participation but I'm sitting in for one day so, I'm trying to catch up to speed on the electronic health records. I would just like to ask that the information and the meeting that we're having today or that was today, if it could be emailed to Jen's email, Jen Sabala.

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

Okay, can you spell her last name please?

Wayne Grigsby – Clinical Director – Friendship House of American Indians Friendship House Association of American Indians

S-A-B-A-L-A. She's on the list, she normally sits in, she's our point person...

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

Ah, is your representative, okay.

Wayne Grigsby – Clinical Director – Friendship House of American Indians Friendship House Association of American Indians

...but she's...if you could send everything from today's meeting, because I'm interested, I got it a little late as the Clinical Director I had about 20 things going on Monday morning, so I came in and started listening so. If you could just...any kind of information about the electronic health records we really need to be up to speed on it.

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

Okay. If she's already on the list and we have her email address, we'll make sure that she gets it.

Wayne Grigsby – Clinical Director – Friendship House of American Indians Friendship House Association of American Indians

Okay, she is on the list. Okay.

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

Okay, terrific. Thank you. Anybody else?

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

That's it.

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

All of our comments should be that easy.

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

That's it; so thank you very much Deven.

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

Thank you, Michelle and thanks to everyone, we'll be talking in a couple of weeks.

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

Great. Thank you.

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

Thank you Deven.

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

Bye, bye.

Public Comment Received During the Meeting

1. Have there been any efforts to revise 42 CFR Part 2 disclosure requirements? If so, who is heading up the efforts to revise the law?
2. Some of the existing text re: audit for patients, practitioners and analytics data consumers would be strengthened by more concrete examples.
3. I am interested in joining this workgroup and have submitted credentials separately. I work on the NIST Big Data Security and Privacy subgroup - mark.underwood@kryptonbrothers.com