



**HIT Policy Committee
Privacy & Security Tiger Team
Transcript
May 12, 2014**

Presentation

Operator

All lines are now bridged with the public.

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

Thanks you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Privacy and Security Tiger Team. 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 the meeting is being transcribed and recorded. I'll now take roll. Deven McGraw? Micky Tripathi?

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

Here.

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

Deven's here.

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

Hi, Deven, perfect timing. Andrea Wilson? David Kotz? David McCallie?

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

Here.

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

Hi, David. Dixie Baker?

Dixie Baker, MS, PhD – Senior Partner – Martin, Blanck and Associates

I'm here.

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

Hi, Dixie. Gayle Harrell? John Houston?

John Houston, JD – Vice President – University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics

Here.

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

Hi, John. Kathryn – I'm sorry, Kitt Winter?

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

Here.

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

Larry Garber?

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Here.

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

Leslie Francis? Stephanie Griffin? Verne Rinker? Wes Rishel?

Wes Rishel – Independent Consultant

Here.

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

Hi, Wes. And from ONC do we have Kathryn Marchesini?

Kathryn Marchesini, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

Here.

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

Hi, Kathryn. And Joy Pritts?

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

I'm here.

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

Are there any other ONC staff members on the line? Anyone else that I may have missed?

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

Are any of the SAMHSA folks on the line today?

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

You have Maureen Boyle and Kate Tipping.

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

Thank you. And with that, we'll turn it back to Deven and Micky.

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

Great. Thank you, Michelle. So, we are going to spend our time on our call today continuing our discussion on recommendations from the – that came out of the Certification and Adoption Workgroup regarding certification to enable the exchange of behavioral health data. We'll have a very brief review of where we were before, to make sure you didn't forget. We'll give you an update on what we heard from the Health IT Policy Committee, where we sort of let them in on where we were beginning to head with this issue, and some of the issues that we had raised and got some good feedback from them. There are a number of follow up questions that we had on our Tiger Team at the end of our last call, and many of those questions were also articulated by Policy Committee at our meeting last week.

So, we have one of the vendor participants who have responded both in writing and have agreed to be with us on the call, which is fantastic, thank you. And Maureen and Kate from SAMHSA, helping us to sort of think through some of the policy issues here. And then I hope to be able to have time to begin talking about the straw recommendation discussion. We will at least have time for Micky and I to sort of show you some of the tweaks we made to the initial straw recommendations that we just began discussing on our last call. And then we have one more call in the month of May that we will use to wrap up our discussion on policy recommendations. Because our goal is to have something that is final to present to the Health IT Policy Committee at its June meeting. Does anybody have any questions about the agenda or Micky; is there anything I left out?

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

No, I think that covers it.

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

Okay, thanks.

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

This is Stephanie Griffin, I joined after you called roll call.

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

Okay. Great. Thank you, Stephanie. Is there anybody else who didn't make roll call who wants to chime in now? Okay. Great. So where we were previously, and this is obviously just a summary of the robust discussion that we had several weeks ago, there were a number of members who thought the functionality had been sufficiently piloted and ought to be in consideration for certified EHRs. Leaving to the Standards Committee the question of whether the specific standard is mature enough for certification. Others thought that the workflow issues, at least with respect to non-behavioral health

EHRs that recipients of this data from behavioral health providers had not been worked through sufficiently and that maybe more pilots were in order.

This is the – we essentially made the presentation to the Policy Committee that we began with on our Tiger Team call last week. And so their feedback we have used to tweak the policy recommendations and also to inform the questions that we provided for our technology vendors and for SAMHSA. So just to – for those of you who are not on the Health IT Policy Committee or who were not able to listen in on the call, the committee did unanimously agree that a voluntary behavioral health certification process is something that ONC should pursue.

And that this certification should include those privacy and security safeguards that are the ones that are currently required for certified EHR technology, the – just to – by way of example, the identity proofing and authentication – or authentication mechanisms really. Dixie knows these really well, because I think they originated from the Privacy and Security Workgroup of Standards, the ability to encrypt data at rest and in transit. So, those basic criteria that are part of certified EHR technology today were approved to be part of behavioral health certification. What remains uncertain, and is the question that's been posed to us, is whether the additional privacy safe – functionalities that would enable behavioral health care providers to share data outside of their systems, should be number one required for behavioral health care providers. And number two, what about the rest of CEHRT? And that is essentially, I think, where the crux of what we've been asked to opine on. And they had a lot of the same questions about how did the pilot technology work. And so we're going to spend some time in the beginning of our call today, sort of trying to hammer out some of those technical questions that arose both – that were posed both by Tiger Team members, but also by, in some cases, by members of the Policy Committee.

So in general, some of the areas of questions that arose were about how – organization of a restricted C-CDA that would be sent from a behavioral health provider, whether notes could be sequestered. What if a provider wants to block a sensitive document? What is the difficulty or expense of embedding this kind of functionality into EHR systems, and what's the demand for this kind of functionality? And then some of the policy questions that arose for SAMHSA on the issue of data sourced from a provider other than a behavioral health Part 2 covered provider, such as the patient. And this information also came up in the specific context of a health information exchange organization. And we have some sort of written responses that were provided in your backup slides, but we also have the benefit of once again having Maureen and Kate on the telephone to help us with that, and that is incredibly helpful. Thank you.

So I guess I'm going to go back to – so, for those of you following along on the phone without Internet access, we're going to take a hold on slide 5 and turn instead to see if Dan Levene from – who's the Director of Cerner behavioral health. To see if he's on the line to help sort of walk us through some of the questions that we had, he gave very complete answers in writing, but I have to admit, I am hoping and am glad for the opportunity to get some of this clarified on the phone here. Dan, are you on? Oh no, are you on mute? Okay, well we had hoped to have him on the phone.

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

Hmm.

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

Hello? No, I think that's you Micky.

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

Yeah, did he join – yeah, sorry? I was just wondering if he joined the – call at all?

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

We're looking for him to see if he's on the muted line –

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

Oh, okay.

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

Can you hear me?

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

The operator's in process of moving him over.

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

There he is I think I just heard him.

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

Dan?

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

Can you hear me now?

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

Yes.

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

Yeah.

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

Excellent.

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

Panic. Pressing all my buttons to see if I can make it work.

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

No, you may have accidentally – our wonderful operators accidentally put you in the wrong –

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

The wrong queue.

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

Right, so –

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

So this is David, I'll point out that he was segregated and we didn't know about his data.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

You can never give it a rest, can you David.

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

The operator's did, the operator's did. All right –

Wes Rishel – Independent Consultant

No, it was the system that did it, sequestered his data, right.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

I will point out that he is with us now and we are waiting to hear him, so – it worked.

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

Well, we couldn't predict the harm in advance.

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

No, but we're – good result.

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

And did slow us down.

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

But only for a minute.

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

We only get 7 minutes.

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

Okay, enough yolking. So Dan, thank you very much for providing the lengthier responses that you did. These are helpful because we have these for our record and can go back to them. But I'm wondering if I could bother you to just sort of give the summary, in terms of sort of the document organization issues, and the notes question.

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

Okay.

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

If you want to, I'll ask you more pointed questions. I don't want to put you on the spot to come up with your own sort of summary, since you took so much time to prepare this. But, there was a lot of really good detail in the document organization question, for example, and I'm wond – I think the basic question was, what happens when one of these documents comes in? Where does it go? How does the recipient provider find it? Is it flagged in some way, shape or form that the provider knows it's there and can go open it and look at it? And it seems to me that your answer suggested that there was some flexibility on the part of vendors, with respect to how they do that, but I'm wondering whether these issues came up in the pilots and how you dealt with them.

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

I think you're last point is important to start with, and I saw it referenced in your earlier slides as well. And I think it's an important distinction that as far as I could tell, our pilot and many of the other pilots, really haven't dealt in depth with the idea of what receivers of this information are going to need to do with it. The implication is there that they certainly have obligations to protect it and manage it. But as Dr. McCallie has pointed out before, that's going to get – that's going to be difficult and it's going to be – the key is going to be to try and find ways to do that that don't impact workflow and process in very negative ways.

So kind of having said that, we certainly have discussed it and have concepts and we're working towards solutions, but that's where some of the ideas came from that I put forth is, first of all, the approach that I think makes the most sense is to keep in mind that any kind sensitive information basically comes with handling obligations. Whether it's the individual patient who through HIPAA just said, I don't want to share my eye color with anybody, so you need to keep that out. That's a senseless, trivial piece of information, but it's certainly conceivable somebody could say that, so how do we handle that obligation if we – we either have to reject it and say sorry, that's unreasonable or we simply can't. Or we have to say yeah, we'll handle that obligation somehow. So, our idea is to attach obligations to the information, either at the document level or at individual data levels, like I just cited.

Then, within the document organization functionality, that can also be referenced. So I think the documents can appear to providers and then, really once a document has been accepted into an organization and they've accepted the responsibility to adhere by the obligations, then I don't think it's anyone's intention, especially on the behavioral health side, that that information be overly restricted. We want those organizations to participate, so therefore put that into the document workflow and then really at the point when it needs to be shared again, what would normally be called a redisclosure. That's when usually the triggers come into play, especially for 42 CFR to say, hold on, redisclosure means we need further consent from the patient or we're going to exclude this, it's really not our information.

So, I think, like in our case, the behavioral health solution at Cerner has document management functionality built into it with classifications and organizations and I think we'll just simply be able to build upon that to recognize the obligations for handling. And I'll pause now and you can ask me some – any more detail or what you're looking for.

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

Umm.

Wes Rishel – Independent Consultant

Wes Rishel?

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

Yeah, go ahead Wes.

Wes Rishel – Independent Consultant

So I think the workflow that we understand and seems feasible involves treating input from behavioral health providers as documents. And having various processes for limiting access to those documents and limiting retransmission of the document in its entirety. The questions that at least I'm the most boggled about relate to extracting information from an input that came from a behavioral health source, making that part of the structured data that is the patient record, and then controlling access to the information in the operations of the EHR and creating new patient summaries out of the patient

database. And I'm kind of curious, do you have a – you have obviously some way of dealing with that is it by not extracting the data into the structured data? Or do you have a way to recognize that some of the data in the database came from a restricted source and therefore not included in the summary that you might prepare and send on to another non-behavioral health provider?

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

Yeah this is – thanks for the question. This is where data segmentation for privacy work comes into play, because as you noted, usually the entire document is considered restricted as it comes from a behavioral health entity, but on the receiving side, you only – I may be only importing part of it. Like for instance, for Meaningful Use Stage 2, we have to reconcile medications and we want to be able to pull in medications from those CCDs if we can, certainly, so that they're part of structured data and then are considered, by automated systems or drug interaction determinations, for instance. So yes, we are moving towards metadata and metadata processes within the EHR that are able to recognize the restrictions on certain parts of the – certain pieces of data so that they aren't redisclosed or mishandled by any kind of obligation.

Wes Rishel – Independent Consultant

So, in your using the phrase “we are moving towards,” and this is not specifically meant to reflect on Cerner, but just on the general impact on EHR vendors in general, with my little propeller spinning on my head, I interpret “we are moving towards,” as saying there is sort of – there is work to be done down in the engine that controls the clinical data, in order to acquire and track this metadata at this detail level. And that it represents a significant new release of your product to be able to do it. Am I over-interpreting your couple of words there?

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

No, absolutely not. I wouldn't – I'm not at all reluctant to say that, that's not overstated. That's kind of, what I was getting at earlier when I may not have made it clear; the recipient side of things has a lot of work to do. We've kind of – the pilots and what I see going on has pushed on the, let's put things in place for the behavioral health vendors to release it, according to 42 CFR, but, not there's definitely a lot of work that would have to happen in order for structured data to deal with this information.

And our thoughts in that process were, yeah, let's get the information out there, because we feel our – we certainly believe that our approach complies with 42 as a discloser, and that recipients don't have to immediately bring it into structured data, they can treat it as view only, in which case they can sequester it relatively easily. But that next step is a big leap, very important, a lot of work. And I don't know of any vendor who had stated that so far that they're able to do that on any significant levels.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Larry Garber –

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

I could be wrong, but we aren't and I don't that anybody else is.

Wes Rishel – Independent Consultant

Thank you.

John Houston, JD – Vice President – University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics

This is John Houston.

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

I heard Larry first, then John.

John Houston, JD – Vice President – University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics

Okay.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Thank you. So, getting down to a greater degree of data segmentation and protection, you just said would require a great deal of work, yet despite that effort, that work wouldn't prevent a physician from abstracting the information and putting it directly into their record independently, correct?

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

That's correct.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

And that could also happen, even when the whole document is sort of sequestered, anyone could still abstract it. So I guess my point is that despite all of your best efforts, there's really nothing stopping a physician from redisclosing this accidentally or inappropriately.

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

Correct. Another way to state that, I think, that maybe turns it on its ear a little bit is, we haven't done anything that the existing paper paradigm didn't already allow. We have simply changed the transport mechanism, it's not a fax or a piece of paper in the mail anymore, it's now a document that can be received and viewed in a browser, but not necessarily imported. So, we haven't given them any more dangerous tools than they had before, since there's no automation at this point.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Except on the receiving side, it is maybe a little bit easier to accidentally release it because it could be coming in along with all the other CDA documents that are coming in from external sources, until the receivers are prepared to recognize this kind of stuff.

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

Correct. And just to clarify also, as part of what we've released – are releasing currently and really so far we are very clearly advising the behavioral health providers that use our software, you really need to have an agreement in place with recipients if there's going to be 42-covered data. That they understand they're getting this and that they review their processes and understand that, because it's a first step and likely they can't, in an automated fashion, deal with it.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Thank you.

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

John?

John Houston, JD – Vice President – University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics

Yeah, and maybe I'm a little thick and I think I'm going to ask sort of a redundant question or one that's obvious. So the bottom line is you're going to have enough metadata in order to ensure that we understand that in theory this data coming in will be recognizable as being sensitive. And as long as the recipient's system is able to understand that metadata, then it should be able to, in theory then, maintain that sensitivity, if, in fact it is redisclosed or as its integrated into the recipient medical record. Is that what I'm hearing?

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

Yes. As part of the DS4P work, there's a healthcare classification system that was developed and one part of that is some code sets called obligation policies and refrain code policies, which are basically codes for known things you may or may not be able to do with data. And what we've built upon is that if those codes are passed and we would store those codes as attachments to particular pieces of data, if you have those codes and there's a generally agreed upon understanding, which we're now glad that DS4P under HL7 has. Then you can always go back and interpret how to handle that piece of information.

John Houston, JD – Vice President – University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics

So then, is it down to the element basis or is it to like an encounter basis or is it – at what level of granularity can I choose this? And the reason why I ask that question in that way is that I think as you said, you want to be able to do clinical decision support, you might want to look at meds that aren't necessarily sensitive per se, but are part of a sensitive encounter. And be able to handle those in a way that is more open, because the sensitivity doesn't necessarily attach to the fact that a patient got a certain test or certain medication. So, what level are we talking here?

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

The technical implementation can handle it down to its most granular level. But it's – it becomes senseless to do it at a certain level, so it's going to be up to either some direction possibly from this group, or EHR vendor's decisions on their own to say, it's at the encounter level we're going to handle this or at the service level, that kind of thing. So I think what we're going to see first is that the granularity will sink through this ocean rather than do a deep dive immediately. So it will probably be the encounters or certain data category types, rather than being able to do it for everything right out of the box.

John Houston, JD – Vice President – University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics

Great.

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

So, this is David, I want to get in the queue when we get a chance.

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

Yeah, I think you're next, David, go ahead.

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

Okay. I think that Micky, the question that bothers me a little bit is that it's pretty easy to construct scenarios where data is abstracted out of the restricted document, into the operational tables of the EHR in order for decision support and things like that, to work in such a way or in such a sequence that it is impossible, at least under current rules, to determine whether that data is still restricted from redisclosure. Because it matters, as I understand it, and I could be wrong, but it matters the route through which that datum was discovered; if it comes through a restricted redisclosure route, it has certain obligations that that very same data coming straight from the patient without an expressed redisclosure restriction, don't have.

And so the EHR, when that data is migrated in to tabular structures, when it's teased apart and put in operational data stores so it can participate in decision support and the like, is going to have to not only track the provenance. But it's going to have to track the history of the provenance, in order to be accurate in what gets redisclosed at some point in the future when somebody request a CDA summary or something like that, of the record. And I think that that complexity is what worries us on the vendor side, on the EHR side of the house. Stan and his team have done great work on the provider who creates the restricted data in the first place, I'm not sure we have all the rules in place to efficiently handle it on the EHR side, because of the fact that source – the source pathway of the data affects it's redisclosure status.

John Houston, JD – Vice President – University of Pittsburgh Medical Center; National Committee on Vital & Health Statistics

Say that again, that very last sentence again.

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

So, let me just walk through as I understand a scenario. So let's say the patient is seen at a redisclosure protected environment, a SAMHSA center. A CDA is sent to the primary care physician let's say the person has a substance abuse of some kind and depression. The entire document is flagged as restricted, because that's, as Stan suggests, the common case, they're going to say, this is all restricted information. The primary care physician at that point could theoretically pull those things into the EHR and respect the restricted disclosure flag. But now the patient walks into the office and tells him about the depression, but doesn't mention the alcohol abuse or the substance abuse and the physician, for whatever reason, doesn't query him about it. Technically, now the depression med is unrestricted. Let's say then a week later he goes back to SAMHSA center and they send a new document out again, with the same restrictions on everything, does the EHR now have to toggle that data back to restricted, because the most recent update came from a restricted source? Or does the patient's one time expression directly to the physician trump the redisclosure. It's a logic problem that I don't think has been specified in enough detail for us to know how to actually build automated services. I'm not saying it can't be solved, I'm just saying it isn't in scope of any EHR that I'm aware of.

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

It – that's an excellent point and that it is something that we've discussed and the first path that I think about that on is, it's what I call the genie in the bottle problem. It's restricted information as long as the genie stays in the bottle, it's a secret, and we all know, once you tell a secret, you can't untell it. And the only special case is exactly the one that you brought up, when it comes from the patient, because they can change their mind. But just setting that aside for a second, I think one of the first steps could be the genie in the bottle approach that says, we keep track of whether its restricted.

If it ever becomes unrestricted, it generally stays unrestricted because you can't claw back information that's been shared. And even in the patient case, I would – I think it may be really something strongly worth considering, this body and elsewhere, on what even patient expectations are about that. Because even though the patient has the right to change the restrictions, it needs to be really clear that if they had it open for a while and now it's closed, they can't untell what got shared.

Wes Rishel – Independent Consultant

Wes Rishel, in line.

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

Okay.

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

David Kotz.

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

Okay. Go ahead Wes then David.

Wes Rishel – Independent Consultant

So the way I interpreted David McCallie's question and then the response, I'm looking for a little more information, which is essentially, do we know at a policy level, what the answers to the questions are about – disclosure? And if we do know those answers, and it is any datum that has been disclosed can now freely be shared, so outside of a Part 2 transmission, can now be freely shared, do we think that this is well enough specified that EHRs can implement it and those EHRs that are implementing it, are they taking this into account? In other words, it seems to be, David described it as a logic problem here, in terms of not only knowing where data came from, but when data from two sources is essentially the same information, and therefore can be shared. I mean just the question of when are two bits of data the same information is an interesting problem all its own, but – so I guess – I think I understood the question as being, what are the complexities that we're implying ourselves into here if we're going to have a solution that meets policy requirements?

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

Yes, and this is Dan again, and I want to make it clear that I – my last statement wasn't contradicting David, in fact, I agree with David. And I personally think there needs to be more guidance on this issue. And then everything else I said was the fact that actually – we actually have thought about it to some degree, but I think common understanding and guidance is warranted.

Wes Rishel – Independent Consultant

Thanks.

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

David Kotz?

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

Yeah, this is David Kotz. I may be rolling back slightly, I think that this conversation to me emphasizes why we need some technical support for this disclosure flagging, because it will be the case that people will manually extract information from the sensitive documents and enter it into the record. And there will be no tracking of that disclosure from the sensitive document into the record and so eventually, we need to find a solution, a technical solution that will extract the information and flag it. And then that

leads us to Wes' interesting questions about whether we have the current policy decisions clear, so that the technical people can implement those policies correctly. The more we dig into this, the more complex it seems and I guess a question for Deven or the group is whether we need to make policy recommendations at that detailed a level?

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

Well I think we sort of have the folks from SAMHSA teed up next to help tease out some of the policy questions that have come up, although I think they've acknowledged that there may be a distinction between what they've already issued written guidance on and where there might be some gaps. And this certainly is within our purview, if we want to make some recommendations in that regard. But we do have them teed up to try to help us grapple with at least what is existing policy and guidance and they're sort of next in the queue. I don't – I'll ask Dan if – are you available to hang on the line with us or do you have some time limitations?

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

I'm happy to hang on the line.

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

Okay, it would be great because then we can sort of have a discussion that involves the interplay of the technical and the policy to the extent we're able to, since we have the SAMHSA folks on the phone, I'm going to turn to them and let them jump in a bit on some of what they've heard. And I know Maureen and Kate that you're both aware of some of the questions that came up both in the team and on the Policy Committee. About sort of when data comes from the patient or you've heard it but – in terms of sort of manual entry into the EHR of the same data and the question that David McCallie put forth, I'm wondering if I can turn to you all now to get your reaction.

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

Deven –

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

Yes.

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

Deven, this is David. Can I inject one additional question into the debate that I think will fit in there in the reply?

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

Yes, David McCallie, go ahead.

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

And that is that if we – I just described in my logic puzzle scenario the notion that the provider discovers some – from previously restricted information, from the patient directly, and let's say the net of that discovery is that it's no longer restricted. My question is what documentation is legally required of that provider before the previously restricted data could now be released and redisclosed? And does that – is there, in fact, a – some paperwork that is required for this kind of rediscovery of previously restricted information? So, I'll add that question to the list.

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

And this is Maureen from SAMHSA; I'll try and take these in order. So we did reach out to our General Counsel kind of around some of these questions and specifically about the – having a patient verify data that they've received from a covered record. And basically, what that comes down to, and again, we're – like we don't give official legal advice on this, so, this is just kind of the general thoughts on this matter. Which are that if you are asking general questions, as you would in the course of a typical patient interview, and the patient reveals that they have a diagnosis – that they have a substance use disorder or that they're on medications that came in through that record. Then that information is now not covered because the patient has revealed it to you. If you are presenting it in the context of, we received this information from your Part 2 program and discussing it with them, then the information remains protected. So there are intricacies to this and a lot of it kind of comes down to how things are done.

And we did kind of just want to emphasize that we're not – we're hoping that people aren't looking for kind of ways to get around the regulations. That we believe that these protections are important and that they still serve a very important purpose for patients receiving substance abuse treatment. One of the things that came up as you guys were kind of discussing this idea of provenance and then what happens with when you receive restricted information and then the patient does reveal the information. I think there are multiple ways that an organization could handle that based on their own policies. And I think you could, as I can't remember who was speaking before, but as somebody was basically saying, once it's unrestricted, it remains unrestricted. So once you've kind of flipped that switch to the unrestricted, it stays that way.

But then alternatively you could say we're going to always err on the side of caution with this type of sensitive data. And if a patient has a record that has some information in it that is protected around these regulations, some Part 2 information in the record, that we're going to protect all of the substance abuse related information in the record, regardless of whether we get it from another source. So I think a lot of that just comes down to local policies around what you think is best for your patients.

And on the last question, so are there any legal requirements associated with that, not that I'm – I mean, no I think is the answer to that. There's no explicit legal requirements around how you document what's come out in – or how it – what different types of information get to you. But this is also an area that hasn't really been litigated.

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

So can I interrupt and just ask – this is David, just that was a very clear description, but I'm sort of dismayed at what I heard, at the potential complexity here. Did you say that if the physician is unaware of the restricted information and does a routine patient interview and discovers the restricted information, it's no longer restricted, even though it might have been in his record and he hadn't read that note yet. But if he read the note from the restricted source, and then asks the patient about it, it has to remain restricted. So in one case the patient tells him, because he's naïve and it's unrestricted, in the next case, because he's informed, it remains restricted.

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

No, I think it's more in the context of how you're asking the question. If you're bringing it to the patient in the context of, I've received this record, we are – and you're going over it with the patient to kind of discuss the issues and context to their treatment. Then – and I think what it comes down to for us is the,

is the patient aware that their kind of giving up their protection. And if you're asking them in the general context for a med reconciliation, what meds are you on and a patient reveals that to you, I think, and this is kind of – I don't necessarily think patients have a good understanding of how their information is protected in general.

But I think patients know that if you reveal that type of information, then you've personally revealed it. It's a different context if a provider is kind of going through and kind of talking about what they've read in your record with you. And then, I think a patient, if they know that that information is protected and they're just having a discussion about it with you, I don't think they would have any reason to believe that they've given up their protections.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Larry Garber.

Wes Rishel – Independent Consultant

Wes Rishel.

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

Okay, go ahead Larry, then Wes and then I'm going to put myself in the queue. Go ahead, Larry.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

So along this same line, if a patient comes to me, because I'm an internist, after they've been in a drug treatment program, they're going to know, whether or not I say, oh, I've got this document in my hand, they're going to know that I have it. Because they're the ones that consented to have it released to me in the first place. So how are those two situations different?

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

Good point.

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

Hold on for one second, sorry. So, and I think this kind of comes into that area of the law where it's going to come down to your local policies and kind of how your legal counsel are interpreting the regs. And I would say, what I would err on the side of caution on is, is the patient fully understanding how their – the implications of their sharing with you. So, I think in that context, like you're very close to the line there when the patient knows you have the record and you're kind of discussing things in that context, to me that information would still be protected, but like that's going to be a legal decision of your Counsel. It's kind of your local policies around how you're going to protect the information. And I say that mostly because like this really is not – this hasn't been vetted by – this hasn't been heavily litigated, there's not a lot of case law here. It kind of comes down to how you interpret the language within the regulations.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Thank you.

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

Wes?

Wes Rishel – Independent Consultant

Yeah, so I'd just add – before I get to my main point, I'd add to Larry's comment the observation that the patient, assuming that the physician knows it because they consented to sharing the information, may very well be making a false assumption in the other direction and a very dangerous direction at that. Interoperability just doesn't work that well. But, my main point here is that I wonder if the Tiger Team shouldn't just create a clear statement back to the Policy Committee that pending this litigation that's been alluded to, it's impractical to accept data from SAMHSA sources and use it in the way that we have expected to have the benefits of an EHR. I mean, this is just hopelessly mired in potential subtleties and how a physician asks a question, so pending changes in policy or litigation, this shouldn't be a goal – the goal should be clearly restricted to sequestered acceptance of SAMHSA data.

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

So, I think the one thing that I would say about that is, while there are some flexibilities in the law, in terms of how you're going to interpret it. And what makes it difficult to give explicit guidance is that how you're going to do this is dependent on how your systems are structured and what makes the most sense for you, both on the workflow side as well as the like systems implementation side. But I think you can absolutely say –

Wes Rishel – Independent Consultant

You're – .

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

...if you were to say like, erring on the side of caution, if you've gotten information from a Part 2 Program, then you just protect it..

Wes Rishel – Independent Consultant

Just –

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

– I'm not saying you can't share, that's saying you have to get consent to share.

Wes Rishel – Independent Consultant

I need to argue this point, I'm sorry. Erring on the side of caution may be putting a lot of investment into helping your clients become the subject of pilot litigation that solves this issue –

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

Well, I'm going to stop you right there Wes. I mean, I think we can all see the various sides of this –

Wes Rishel – Independent Consultant

But I'm calling for – the question in some sense, and I don't mind if we wait and talk longer,

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

(Indiscernible)

Wes Rishel – Independent Consultant

– but I believe the question is: Is it practical to do much here?

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

Well, so here, with all due respect to – we will have the discussion about the policy recommendations that we can and want to make here, first of all. But the second thing is that I’m sympathetic with the frustration of the SAMHSA folks, because their policies preceded all of this and yet we didn’t build the systems to acknowledge it and now we’re trying to backend it in.

Wes Rishel – Independent Consultant

Yeah Deven, I’m not meaning to criticize the SAMHSA folks as much as call attention to the point that we need policy clarification, through whatever level or interaction it take. I mean normally we recognize the difficulties in changing law-based policy and we try to find best practice solutions to get the most benefit in the presence of difficult issues. I’m just saying that this one we need to call it and say that it’s – and it’s not because of an ill will or lack of effort on the part of the SAMHSA folks, it’s just where we are is what I’ve stated. And I’m perfectly happy to defer the discussion until later, but I do believe it’s going to come down to that question.

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

Yeah, and we’re definitely winding up to it, Wes, there’s – about it.

Wes Rishel – Independent Consultant

Okay, thanks.

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

I just want to make sure that folks have ample opportunity to ask questions of either Kate or Maureen, or Dan on the technical side before we start going down that road. But absolutely, you’re – I don’t disagree with you that those are pertinent questions for us to address.

Wes Rishel – Independent Consultant

Thanks.

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

Deven, this is David –

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

I’d like to get in the queue, this is Dixie.

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

Okay, David McCallie, then Dixie Baker.

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

So Maureen, this is a question for you, a hypothetical. Let’s assume we had systems designed such that there’s a flag, a check mark beside data elements that could be sensitive and that check mark says, redisclosure allowed, redisclosure not allowed. And the data comes in from a restricted source, it’s imported into the record, that check mark is set that says redisclosure is not allowed, because it came from a restricted source and that was the policy of the restricted source. Now the physician is talking to the patient, whose come to see him a week later. If he just asks the patient, oh I see here there’s some

restricted information, do you want me to maintain that restriction on this data element for redisclosure, yes or no, would that be sufficient? If the patient says, please maintain it or please don't maintain it, and he either checks or unchecks that check box, would that be legally sufficient?

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

Unfortunately no, so to – for the patient to authorize that disclosure, they have to sign a Part 2 compliant consent form.

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

Ah ha, okay. That's what I was afraid of. Wow. Okay, next. Dixie.

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

Thanks David.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Yeah, this is Dixie Baker. I'm not sure I can understand or see the advantage of using this C-CDA metadata to identify restricted data over just us – continuing to use the source of the data and just making the data in a PDF where it's not as easily – as easy to extract data elements from. If we're not going to extract – if we're not going to allow the extraction of data elements from the C-CDA, it seems to be – me to be much cheaper, much more practical and frankly, much easier to protect if you just continue what people now do is just segregate the data based on its source. I don't understand why we're going to all this trouble.

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

So I think there are a couple of things to say about that, one is, I think people aren't even doing that initial part that you're talking about right now, electronically capturing Part 2 information in EHRs. I mean some are, but it's – and I think part of the issue for us, and one of the things that we'd really like to see, are kind of an expansion of the use of the HL7 standards for communicating what the kind of privacy obligations are that are associated with the record.

We absolutely think that a great first step is EHRs – general EHRs being capable of one, understanding those privacy policies as they come in, the privacy policy metadata. And also having some capacity to control the redisclosure of information, whether that's siloing the information as a PDF and just – and not sharing that whole record or there are systems that are more advanced and there are systems that are trying to build that capacity. And I don't think we want to say that there's any restrictions, right now, if they're legal, team can kind of comes together and has a mechanism for integrating that information and maintaining metadata tags on individual data elements. And protecting the flow of information, I mean, I don't think we want to do anything at all that would hinder that. But I think a great first step could be to say like you need the minimum capability of doing this view only and using kind of the standards to communicate policies.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Well you still can do that because you can use a C-CDA and its metadata to wrap an image, which is what a PDF is.

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

So this is David, I've got to interject that from the vendor point of view, if you're going to make it hard for the physician to pull incredibly important information into the record, for this reason, you're going to put far more patients at harm of medical malpractice because that sensitive data didn't participate in decision support.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

But they don't want it pulled in, David, that's point, they don't want it pulled out of the C-CDA. If you don't want it pulled out of the C-CDA, why are you going to all the trouble making it – individual data elements within the C-CDA? I don't understand those two don't mesh in my mind.

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

Well because patients don't understand that, the fact that it's in your PDF on the screen, but not in your data stores, means that you're not doing any drug-drug interaction checking, for example. No patient on the planet understands that.

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

Right.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Well but –

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

But that's exactly what would happen is that the drug interaction would go undetected and the patient would have their disclosure preserved and they'd die from an allergy to the drug.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

You can't pull that out anyway, you have to leave it in there. You have to do the drug-drug interaction separately from pulling the data elements out of the C-CDA.

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

No system works that way today. We could maintain completely separated data stores, a segregated store and an unsegregated store and run the CDS against them both, but nobody does it that way, so the impact on the vendors would be rather dramatic.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

So you're saying that despite everything that SAMHSA's telling us today, that Cerner's going to pull these data elements out anyway?

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

Well, what I'm saying is that the way systems are designed today, if you want clinical decision support rules to FHIR, you need to pull that data out.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Well then that's the question that should be discussed because everything I've heard says you don't pull the data elements out, you leave it in the C-CDA, it's sequestered from the rest of your system. That's everything I've heard.

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

Well Dixie –

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

So what we're proposing is that you'd pull it out, but you pull it out with a flag that says, you can use it for local CDS, but you can't redisclose it if it needs to be converted back into a CDA to be sent somewhere else, like a local HIE. So, that's the metadata thought.

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

So Dixie, I mean I think what you're – you may be kind of oversimplifying. I think what we're saying is kind of multiple things that it's where the EHR system is right now, that if all you can do is bring in a PDF as view only, that that's a great first step compared to only being able to like receive a fax, which many are – like that's the situation right now. If you can do what Cerner's doing and kind of maintain the tags on the data and have clinical decision support, then like that's that next step, which is a fantastic next step that we're encouraging. And we ultimately hope that EHRs will kind of get to the point where that type of thing is standard and you can maintain the protections on individual elements, but we recognize that that's not right around the corner.

Wes Rishel – Independent Consultant

Wes Rishel.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

So, if I understand what you're saying, what you're saying, that I didn't understand, is that the EHR can use the data elements, the C-CDA, but they can't extract it into the EHR record.

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

They can't redisclose it. It's been redisclosed to them by the patient, that's how it got there in the first place, they just cannot re-disclose –

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Integrate it with the rest of the data?

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

They can do that.

Wes Rishel – Independent Consultant

Wes Rishel.

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

Yeah, go ahead Wes.

Wes Rishel – Independent Consultant

So Dixie, I think you're trying to translate this discussion into internal implementation of the EHR more than anyone has intended it. I think the clear requirements, as we understand it, are that a) – first of all, as we've been saying here, it would be a step forward if we simply had the ability of an EHR to receive information from an identified source – source that's identified as a SAMHSA source, and based on

knowing the source, sequester it. Now what that means, we believe that in that circumstance, the practical implication is that sequestered data does not figure in to clinical decision support algorithms and would not be redisclosed by synthesizing a new patient summary from the structured data.

The SAMHSA folks would like to see 0.1 interoperability rather than 0.0 and see this as a step in that direction. And I think the clients of the EHR vendors will have issues about that in the sense that they become responsible for decisions when they have information, but their EHR is not allowed to use that information – or not practically able to use that information in clinical decision support. But that's a separate issue from the simple question of, would it be possible to certify accepting and sequestering data in an EHR.

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

Right. And the one thing that I would add to that is, organizations are receiving fax-based information on this right now, in the same legal liability issues would apply there that – because obviously – fax that's not getting integrated.

Wes Rishel – Independent Consultant

That's – that may be. I would argue that the expectations of anything received on paper and anything received in the EHR may be different, but I'm not in a position to even state a reasonable opinion on that point. But the next step forward, from 0.1 to 1.0 –

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Um hmm.

Wes Rishel – Independent Consultant

– would be to have the necessary additions at the engine level of the EHRs to be able to track the provenance of individual data items. And have the sophisticated workflow to understand when a – the releasability of information has changed, either because the patient signed a new release or because the same identical bit of data became available from an unrestricted source. And the implementations of the EHR are sufficiently nuanced to be able to know that the interview from the patient – with the patient did or did not release information based on how the physician had the discussion with the patient. We all agree that the step from 0.1 to 1.0 has many issues associated with it, some of them technical, some of the legal and some of them policy. But that it is a worthy goal, I don't think any of us think that it's worthy of being considered for certification in Meaningful Use Stage 3.

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

So let me piggyback on that question, Wes, since you've teed it up, and that is to say, is it possible to consider that that issue of sort of required functionalities or certification in bifurcated ways, in order to – or in two ways, in order to move from point 1 – to lay the groundwork for moving from 0.1 to 1.0. Which is to say, we have voluntary certification already having been approved for behavioral health Part 2 covered providers, should it contain the necessary functionalities to enable them to send a restricted C-CDA to be able to take that 0.1 step?

And then on the recipient side, are there steps that we can take on a voluntary basis, from a vendor's standpoint, that would even move us closer and continue to sort of seed the ground for the development on the technical recipient side, all that work that we know still needs to be done. But that would enable choices to be made on the part of providers and vendors about whether they make the recipient technology available. And then, of course, I think we probably also have some things to say on

the policy side, but I'm just – have my head in the technical space since you called the question and it sounds like we're already ready to go there.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Well that sounds like a policy question to me. Aren't you asking like, how you determine the releasability and the sensitivity of the result of the clinical decision support?

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

I'm not asking how, I'm asking whether the functionality that's been laid before us on the table, that came out of the DS4 pilots – DS4P, sorry, pilots, whether we would make a recommendation that it be part of certification, at least for behavioral health providers. And it's a voluntary certification that isn't required under Meaningful Use because behavioral health care providers are generally not eligible for Meaningful Use payments.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

But that's –

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

But again, the committee just approved, yes, ONC should pursue voluntary certification, what components should be part of that certification, should DS4P be part of it, to begin that – down the road from 0.1 to 1.0 to use Wes' metaphor, which I personally like.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

But that's a standards question, that's not a policy question.

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

No, but it's –

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Then once it comes over to the standards group, if we were to subject that question to the, is it ready for national standardization? Is it mature enough? And is it widely enough implemented? The – it's a standards question, number one, number two, I would – it's more than a guess, I believe that when that question were considered in the light of the metrics that we've put into place to judge the readiness of a standard to become a national standard, there's no question this is not ready to become a national standard.

Wes Rishel – Independent Consultant

Wes Rishel.

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

Umm –

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

And David.

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

Okay, I'm going to –

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

And then Larry.

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

All right, I'm going to turn to Wes, David and Larry, but first I'm going to say, Dixie, we have opined on many occasions as a Policy Committee recommending the capability – functional capabilities, but you are right, diving down into this particular standard is in your purview and not ours.

Wes Rishel – Independent Consultant

Umm, this – so, can I talk now?

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

Yes, I'm sorry Wes, go ahead.

Wes Rishel – Independent Consultant

No, that's good. Okay. So I think Deven did a great deal to help me orient my thinking by stating two questions, one is, I'm not sure it was a question or just the recognition that we should be able to certify behavioral health systems on a voluntary basis as sending SAMHSA restricted data. I guess the standards question is one of how they should identify this restricted data. And I think that that discussion deserves attention in the Standards Committee. However, it may be as simple as is there a standard that identifies a report as being restricted as opposed to the more difficult question of a standard that identifies individual data elements as being restricted.

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

Right.

Wes Rishel – Independent Consultant

Then the second question that Deven put was not should we proceed with the level – the jump from 0.1 to 1.0, but what can we do to enable progress in this direction? Well, enabling progress involves first not disabling progress, so what, if anything, do we have to be careful of that might make it impractical or discourage vendors at large for doing the kind of things that one vendor has described here? Which is, working ahead of the absolute Meaningful Use requirements to deal with structured data – with metadata attributes of data at the detail level in their structured database. The second sub-question would be, what, if anything, should ONC or any other body do to encourage that kind of development? And then just for completeness, you could put in a third question, which is, should that be a part of Meaningful Use Stage 3? And I think we would all agree the answer is no, but it sort of rounds out the picture.

So really, what I see is, and I'm just going to say I'm in favor of is recommendations to the Policy Committee that are proceeding with the ability to send data. I guess a sub-question would be would there also be a requirement on regular certified EHR technology to receive and sequester that data. It may not be necessary because the clients can't practically receive the information unless they can sequester it. Then that we work – that the Policy Committee work and we assist in finding ways to assist in the development of functionality that demonstrates the practicality of ultimately getting to a standard that involves sequestering individual points of data.

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

Thank you, Wes. That was – I wrote – I took copious notes on that articulation. David, I think it was McCallie, but if it was David Kotz, let me know.

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

Yeah, it was McCallie, or maybe –

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

And then Larry.

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

A couple of disconnected thoughts here, one, just back to Maureen’s comments about the paper system and the way it works in the paper world. We’re doing all this work and spending 20 plus billions of dollars to try to do better than paper, so it is, in fact, asking new questions and creating new complexities that didn’t exist in the paper world, but we hopefully are delivering new benefits as well, in terms of patient safety. So, the fact that the law works in the paper world doesn’t necessarily mean it’s going to work very well when we change the way these systems work, so I think we do have a legitimate struggle here to figure out, what does it mean to do this in an electronic form.

And the main reason for that, above and beyond just that it’s automated instead of paper is that the release of information in the paper-based world goes through a human who understands the local jurisprudence and legal subtleties of what’s releasable and not releasable. We’re trying to automate that and eliminate that human in the step that we’ve put tons of energy in our prior meetings into automated response to requests for information about the patient. We’ve taken the human out of the loop so we have to put that logic in the computer, which means we have to really understand that logic in order to write the code correctly and that’s where we’re stubbing our toe is, we don’t understand the logic well enough to write the code. So that’s my comment, doesn’t – just take it or leave it.

The question I have, in a more serious vein is, it strikes me that if the – my check box notion, you correctly said or you pointed out that the law would require recapture of permission to release the information. What that leads me to think is that if an EHR vendor accepts restricted information, restricted from redisclosure, and chooses to incorporate that into his active medical record, and then he effectively has become a SAMHSA provider. Because in order to release that information, he’s going to have to go through the same process that the SAMHSA site had to go through. He’s going to have to capture an expressed release. So we’re really basically promulgating the requirements to be a behavioral health system downstream to anyone who receives restricted data and chooses to operationalize it.

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

Well, we’re not, David. The law already did that.

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

Well, okay, but I’m just saying, so this notion of a voluntary certification of the behavioral systems is going to have to apply to any EHR as well.

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

Hmm.

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

Whatever you choose to certify as a test for the behavioral system is – the same rules are going to have to apply to the EHRs.

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

Although I would say that some vendors that we have spoken to have basically gone with a policy of, any information that they get, tagging it with a no-redisclosure. So basically saying that they're not going to manage consents for this type of thing, that if somebody wanted to share their Part 2 information, that they would have to go back to the Part 2 program. And their policy is to just never disclose the protected information that comes to them.

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

Yeah, and I can see that as a kind of quick way out of the responsibility. I'm not sure that it's terribly good for the patient's health, but that's certainly worth noting as one way out of the conundrum is just the Dead Sea, you get it but you never redisclose it, period, unless a patient accidentally tells you, in which case you can.

Maureen Boyle, PhD – Health IT Lead, Center for Substance Abuse Treatment – Substance Abuse and Mental Health Services Administration

Yeah, I mean I think our point is just that there are a lot of different policy options for dealing with the Part 2 data and so there's – we're not saying that there's only one way, there are a number of ways that things can be addressed.

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

Well, but remember, we're on the hook to produce something that can be tested and certified and then measured. So we don't have the luxury of saying, leave it up to local convention. I mean it's nice that that works in the paper world, but it just doesn't work in this world of certification and Meaningful Use incentives.

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

Larry, I think you were next in the queue.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Thank you. Yes, so I'm concerned about the notion of giving the okay using whatever standard for these Part 2 providers to electronically release information without having piloted and tested, understood the implications on the receiver side. It's kind of like saying, okay, we're always going to allow the treatment of urine infections with a sulfa drug, Bactrim, that's fine, we'll just have them start doing that and not considering what it's like for the patient who's receiving it. Are they allergic to it? Can the swallow a pill? Are they on Coumadin and they're going to bleed to death and die because we're giving them this medication, which, oh by the way, is the issue with Swiss cheese medical records.

But my point is that there are a lot of issues that we've been bringing up about what the receivers are going to be doing about – we may be putting them at risk for accidentally releasing this and their EHRs may not be prepared. And so I think it's got to be a – number one, we have to pilot more to understand what the policy and technology implications are for the receivers to receive such a document. And then after that, we could then go back and consider, is there some sort of package solution that both – involves both the senders and the receivers with matching certifications. And when that happens, then we would have to require that all of the receivers have the functionality in place, before the senders start sending them.

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

Well, so let me –

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

So I think we're –

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

That triggers a question that I think was part of the initial questions that we proposed for Dan, but I want to – hopefully he's still on and we can get some clarity. What would happen if you had the Part 2 vendor with the capability to send restricted information, but you had a provider recipient who didn't have the capability to view it? What essentially would happen? Would the document still go through but they just couldn't see anything? And do we have ways for providers to sort of say, no I'm not accepting that data. I mean I know Dan that you talked about warning the Part 2 providers that they should not – should only send to recipients that they know are prepared to receive it, but do we have a sort of technical way to indicate that or is that really still in the realm of sort of business agreements?

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

This is Dan. Today, it's in the realm of business agreements and my understanding of 42 CFR, and again, I'm not a lawyer, but I've had to delve into that statute pretty deeply to make sure that what we were trying to do here did what I thought made sense. And today, all of the obligation under that regulation lands on the part of the discloser. The recipient – however, there's a notice called for by 42 CFR that must accompany all disclosures, and this notice is clearly intended for human consumption. It's a warning label. And the warning label is obviously for the recipients, yet the statute doesn't call for any consequences if the recipient doesn't abide by it. So the consequences all fall on the part of the discloser. That's where the idea of the business agreement or some QSOA over the top of all participants comes into play.

We do feel, right now, today, that the 0.01 solution we've been talking about, where Part 2 provider discloses and a recipient holds it sequestered. If their way of abiding by non-redisclosure is to sequester it, that would appear to satisfy the legal requirement. And they are still able to make decisions based on that information, assuming that the prescriber or the practitioner has access to it, even if it's visual access to it. And then circling around, what David touched on as well, the Catch-22 comes in, but how do we handle drug to drug interactions when we now have an – because we can electronically test for that, we have the Swiss cheese problem if we have that. But – so, I think today there's no reason why disclosures cannot happen and I would certainly advocate on the part of behavioral health and substance abuse clinics who really want to be – who want to integrate their care with primary care and other parts of the world. We don't want to be sequestered, we really do want to be part of this, but it is acceptable to take that baby step first.

Wes Rishel – Independent Consultant

Wes Rishel.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Yeah I – this is Larry, I just wanted to finish up with that talk. Sorry. So, I mean I absolutely agree that this is important information, I want it in my medical record, and I want to be able to use it. But we need to do this properly, because my medical record right now does not distinguish whether I'm receiving a document from my hospital next door versus I'm receiving a discharge summary from a behavioral – a Part 2 provider. And so in the electronic world, even though there's going to be this written text on top says do not release or you're going to go in jail, it's going to be electronically released without a human intervention and that's the problem with our EHRs and that's why it's different than just the paper world. So just making sure there's that written statement on there saying do not redisclose does not

work anymore in the computer world. And that's why – we're not ready – I don't feel that we're ready to allow this to go forward.

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

Well –

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

Well, our – some EHRs, including the behavioral health one for Cerner, does not include electronic documents that you receive from anywhere else, we never include that in building our own CCD disclosures. So for us, it's automatically sequestered, we don't – we would advise our customer base that that's – they're not going to risk that at this point, because we don't include those kinds of documents, that we aren't putting in structured data. But you're correct, if an EHR does somehow include those as just wrapped up CCDs with the PDF inside it, then of course they have that issue as well.

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

Right, but what we're saying is that if the behavioral health EHR voluntary certification process included the technology that you all have piloted, it would go with that restriction. Is that what you're saying, Dan?

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

Yes. Yeah, I'm saying that there needs to be an understanding, as before, between individual senders and recipients that they're on the same page.

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

Right.

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

That is doesn't provide a blanket way for behavioral health people to send to any recipient without doing some due diligence on that recipient to make sure that they're – everybody's okay with it.

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

So you – so this is David –

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

It would be nice someday to get to that point where we don't have to worry about that, but –

Wes Rishel – Independent Consultant

Wes Rishel.

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

Okay, go ahead Wes.

Wes Rishel – Independent Consultant

So a minor point. I just want to make clear that I think the relative benefits are 0.1 and 1.0, not 0.01. Forgive me for being a nerd.

Dan Levene – Director, Cerner Behavioral Health – SATVA Pilot Technical Lead

My mistake.

Wes Rishel – Independent Consultant

Yeah. The more important point, I think, is that over the years, I've been spending 30 some years working in interoperability and mostly I've been witness to its failure. And almost always, one of the ingredients of a failure to interoperate is one party really wants to send the data and the other party doesn't really want to deal with the issues involved in receiving the data. Or occasionally the other way around, one party really wants to get the data, but the other party doesn't feel that their needs are being met in sending the data. And we have exactly that formulation appearing here.

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

Um hmm.

Wes Rishel – Independent Consultant

If we don't provide a framework for receiving, the data that successfully manages what is a difficult expectation, which is the belief that if an EHR receives the data, it will be used computationally. Then we have a situation where the behavioral health providers really want to send the data and as much as the general health care providers would like to have the data, they are going to be fairly reluctant to participate in these relationships.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

This is Joy; may I be so bold as to ask a question?

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

Well, I want you to, but I'm looking at the time and its 3:25 –

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

Okay.

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

So, is it a question that we can lead off our next call with?

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

Well, I guess so, but my curiosity from listening to Wes was, how much of that exists – the ability – I'm trying to differentiate what the issue is with general EHRs in this, because are general EHRs able to do this kind of functionality where all the information is incorporated by the recipient?

Wes Rishel – Independent Consultant

I don't understand the question, Joy?

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

I think the answer is yes, they reconcile the data in the CDA into the data structures of the EHR, that's the data reconciliation requirement.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

So certified EHRs are able to do this –

Wes Rishel – Independent Consultant

Yes.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

– across the board.

Wes Rishel – Independent Consultant

Yeah, in fact they have – in Stage 2, they have to be certified on doing that.

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

Right, right. But what they don't do today, Joy, is pay any attention to these new D4SP – DS4P flags.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

Well, I know that's why it's under consideration.

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

Right, they don't know how to handle that.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

Hmm, interesting.

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

Yeah, so that's where we're running up against the complexity of what does it mean to import a piece of data that came from a restricted source and now essentially that little piece of data has to track that restriction independently of the CDA that it came with. And it has to follow all these complicated rules about alternate methods of discovering the same data that are legitimate or not legitimate and re-release and the like. So I –

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

Okay, well I absolutely hate to cut this conversation off at such a – we're really just getting into this, but we have to make some time for public comment. We will try to pick up where this left off, right in the middle of it, on our next Tiger Team call that I hope will enable us to come to some recommendations that we can provide to the Policy Committee. And we'll always try to achieve consensus, but if we can't, we'll give a sense of where we are and ask the Policy Committee for its continued advice. So, thank you everyone. Michelle, we're ready for public comment.

Public Comment

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

Operator, can you please open the lines?

Rebecca Armendariz – Project Coordinator, Altarum Institute

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue. We have no comment at this time.

Wes Rishel – Independent Consultant

See, we could have argued for 5 more minutes.

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

You know, you could absolutely be right.

Rebecca Armendariz – Project Coordinator – Altarum Institute

We do have a comment.

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

There you go. Great.

Rebecca Armendariz – Project Coordinator – Altarum Institute

Marty, you're line is live.

D. Marty Esquibel, JD – Privacy Officer - Children's Hospital, Colorado

Oh, okay, thank you. This is Marty Esquibel from Children's Hospital, Colorado and I've been following this conversation. And one of the things that would help would be really distinguishing between the segmentation of the sensitive information and the redisclosure part of the other part of the conversation. And the challenges of the redisclosure and then the challenges related to protecting sensitive information, because they've been getting blurry for me as this conversation is going back and forth. So that was it. Thank you.

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

Okay, helpful comment. Thank you.

Rebecca Armendariz – Project Coordinator – Altarum Institute

And we have no further comment at this time.

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

All right. Terrific. Thank you all very much for providing your thoughts. You can also, if you want – if other things occur to you after this call and you want to email them to Micky and I as we prepare materials for our next Tiger Team call, which is not actually until – when is it?

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

May 27th.

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

Yeah, that's what I thought; it's after Memorial Day, so we have a bit of time between now and then, thank you, Larry. So if folks want to continue to reflect on this, provide more questions, sort of ways of thinking about this, to prepare us for the next set of conversations, we will be much appreciated – much appreciative. Thank you. Thanks everyone, have a good rest of your day.

Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology – Health & Human Services

Thank you all.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group

Thanks a lot. Bye, bye.

Public Comment Received

1. Even if an EHR vendor gets voluntary certification for Behavioral Health and can send sensitive PHI in a manner that provides the receiver the notation of what is sensitive (document vs. data), what happens if there is no responsibility on the part of the receiver to keep confidential the sensitive PHI sent?