Michelle Consolazio, MPH – 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 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 this meeting is being transcribed and recorded. I’ll now take roll.

Deven McGraw?

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

Here.

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


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

Here.

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

Hi David. Dixie Baker?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I’m here.

Michelle Consolazio, MPH – Federal Advisory Committee 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

I’m here.

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

Hi John. Kitt Winter?

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

Here.
Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi Kitt. Larry Garber?

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

Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi Larry. Leslie Francis?

Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics
Here.

Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi Leslie. Linda Sanches? Stephania Griffin? Wes Rishel? 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, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi Kathryn or is Joy Pritts on the line? And do we have anyone from OCR on the line? And is anyone from SAMHSA on the line? Okay, I’ll turn it back to you Deven.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Thank you very much.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Michelle, Deven, hi it’s Mickey just wanted to let you know I just joined.

Michelle Consolazio, MPH – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hey Micky.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay, great. Okay, terrific so what we’re going to spend time doing today is to continue our discussion on the recommendations that initially came from the Certification and Adoption Workgroup regarding certification of electronic health records to enable the exchange of behavioral health data and what you’ll see when we get to the slides is we have a bit of a framework for thinking through the progression from sort of where the technology is today and where the technology would be with the type of functionality that’s provided by the data segmentation for privacy pilots that we heard a review of versus what would be sort of the ideal state and many thanks to David McCallie for suggesting that framework.

And what our goal is today is to think through what recommendations we would have to be able to progress us from sort of where we are today versus where we ideally would like to be with respect to the technology, what are some recommendations that we would feel comfortable making at this stage given the technology is still not where we would ideally like it to be in order to make that progression, what do we feel comfortable with recommending.
We have a Health IT Policy Committee meeting in June, this is our last call in the month of May and it’s frankly our last call that gives us a sufficient amount of time to circulate materials for the Health IT Policy Committee in time for whatever recommendations we would make to be considered by the Health IT Policy Committee.

So, even though we do have a call on our schedule in the month of June, on that Monday, whatever we would be able to do in that meeting we would not have sufficient amount of time to have it be included in the Health IT Policy Committee materials which are required to go out further in advance than the day before.

So, for better or for worse we really do need to have our complete and final discussion on this today. There is of course the possibility that at the June Health Policy Committee meeting that they have some additional questions for us to consider, but I think it should be our goal to try to do the best we can to come up with some recommendations to put before them for the June meeting. Does anybody have any questions about what we’re doing today or the timing?

Okay, so with that what you have on the screen now and for those of you who are just on the phone and are following us on paper we’re on slide three. This is the sort of – this is a framework really of the progression of the technology from sort of where we are today and where we would hope to be in the future and how do we lay the foundation for that I think is a relevant question for us to answer.

And so with those – and I almost feel like I should let David McCallie explain what this is since he created it but I didn’t tell him I would put him on the spot. So, David do you want to go through it or do you want me to?

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

Well, I can certainly do a high-level.

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

Sure.

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

Run through just to sort of what I was thinking.

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

Yeah.

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

You so, you know, as we discussed in our previous calls it grew increasingly apparent to me that on the behavioral side when we have enabled the ability to share restricted information we now have to, on the receiving EHR side, decide what the impact of receiving that information is on the EHR and since this data has rules around it that are different from most of the other data that the EHR processes even most of the other so called “sensitive” data it may require that the EHRs have new capabilities added that aren’t common in off-the-shelf systems today.

So, I started just noodling during the call what a sequence of those additional features or services would look like if you could kind of stage it in terms of kind of the first and easiest things that could be done that cover the most cases with the least amount of work and then getting progressively more sophisticated to where you end up with an EHR that basically has the same capabilities as the customized behavioral systems, which, you know, might be a desirable long-term goal that all the systems are capable of all of these complicated behaviors.
So, I sketched this out circulated it to a number of the members of the group who then, you know, reiterated it and refined it quite a bit, so I can only take credit for starting the conversation but Micky and Wes, and several others weighed in on it. So, I haven’t read your distilling of it on the slide I’m looking at it as we talk but that’s the backdrop.

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

Right, right so thank you David. So, essentially you get from, you know, Level 0, which, you know, is arguably where we are today where – and frankly arguably also where we could be with just an enabling of, you know, the functionality on the behavioral health side where, you know, a document number one would never get sent – a document from a behavioral health provider or Part 2 provider might not even get sent to a – you know, someone with a certified EHR that’s not a Part 2 provider or it gets sent but it can’t be read.

And so it’s essentially, you know, you’ll see your status refuse the business, the recipient chooses not to receive data from Part 2 providers and so it doesn’t – either doesn’t have or doesn’t enable features to be able to at least read the document to Level 1 which is equivalent to what we saw presented with respect to the data segmentation for privacy pilots which is the recipient EHR can receive the document but it’s sequestered from other EHR data and is read only so it’s not parsable to be extracted into structured data.

That is essentially where we are or where we could be today. Certainly where behavioral health providers could be and where we could get the recipient level systems if they had that technical capability to at least receive it and then, you know, progressing to Levels 2 or 3 where Level 2 being the capability to parse it locally but not necessarily be able to share it external to the system.

And then the third level, which, you know, the penultimate level, which would enable the data at the recipient side to be treated just like any other data but have the restrictions continue to be honored so it can be parsed locally and it can also be shared with the appropriate redisclosure prompt included within it.

So, you know, so essentially we’ve got, you know, the opportunity to potentially move from all Level 0 to potentially Level 1 with the technology that we’ve seen to date and I think then the question for us is whether we are prepared – whether that’s something that we believe is important to support number one and number two, do we have a technology recommendation that would in fact support or build the foundation for sort of moving up the chain to get from 0 to ultimately to 3 acknowledging that where we are today is arguably at 0 and where we are potentially going to be able to go with the technology that might be available today is only to 1.

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

Deven, this is Larry.

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

Hi Larry.

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

So, I would argue that we’re not at 0.

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

Okay.

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

So, I mean, so that anyone who is connected to a health information exchange is open to all senders, well typically is open to all senders unless they’ve gone out of their way to specifically filter, you know, who they can receive from.
So, if I connect to the – I’ve connected to the Massachusetts HIway so that whoever sends to me who belongs to the HIway I’m going to be receiving and loading into my EHR and so if it turned out that the Part 2 provider in town here actually had gotten their act together to get connected they could have started sending stuff to me and I would be receiving it and I don’t have the ability to block it.

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

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
A provider who was covered by Part 2 who didn’t have the capability to alert you that they were sending you a document that had the redisclosure prohibitions it wouldn’t have been a choice for them not to participate in the HIE, they couldn’t participate in the HIE because they couldn’t honor their legal obligations and still do so.

John Houston, JD – Vice President – University of Pittsburgh Medical Center
But Deven –

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
They could have put the statement on.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Right, they could send it to you via Direct it doesn’t have to be an HIE.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well, this is David, my supposition here was a little bit of splitting the line that what we heard from some of the behavioral providers is that they don’t send to people without a specific arrangement in place.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So, if the recipient said basically “I can’t deal with this” then you wouldn’t send to them in the first place, that doesn’t stop somebody from ignoring and sending anyway in which case you – Larry’s point’s totally valid, you probably need some kind of an automatic way to sniff the incoming data and reject it which would not be a common capability today.

John Houston, JD – Vice President – University of Pittsburgh Medical Center
This is John Houston, I think to Larry’s point though there is sort of a 0(a) and 0(b) in my opinion.

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

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

John Houston, JD – Vice President – University of Pittsburgh Medical Center
Because I think the 0(b) is the recipient that may decide not to receive information but I think to Larry’s point is that somebody wouldn’t know necessarily that there was sensitive data coming in so they don’t – when they receive information they don’t necessarily know that they have an obligation anyway.
So, there are sort of two parts in my mind, there is the provider that just chooses not to send information because, you know, they’ve just made that value judgment that, you know, Part 2 data should not be sent because of concerns over whether a recipient can handle it but then there is the other part of it which is the recipient getting Part 2 data knowing it’s Part 2 data and not being able to handle it because they just don’t have a good technology solution to handle it. Does that make sense?

So, one’s on the recipient side one is on the sender side as to sort of the two parties in the equation one deciding either not to send it and the one deciding they really can’t receive it.

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

Right, right although now that I – something that I should have said from the beginning is there is an assumption in this particular framing that the focus is on the recipient of information from a Part 2 provider, so –

**John Houston, JD – Vice President – University of Pittsburgh Medical Center**

I think one of the –

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

We could also include a framing that has the Part 2 side as well.

**John Houston, JD – Vice President – University of Pittsburgh Medical Center**

But I think there are a lot of Part 2 providers that have made the decision until there is a technology solution they’re not going to send it and I think it’s important to probably put that in here for completeness then.

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

Right.

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

Right, right, but this does assume – just to build on that, this is Micky, that this assumes that we’re dealing with the recipient’s side and that the provider side, that there is behavioral health certification and that they have the technology available to them, right?

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

Right.

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

So, this is looking at it from the receiving system side now and the various types of options and capabilities that would be available to them as recipients.

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

And my – this is David again, my notion with Level 0 and the naming of it as 0 was to sort of this captures the current state of the art which is most of the time this data isn’t sent.

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

Right.

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

Right.

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

Because these systems are known to be unable to deal with it, but, so I wasn’t necessarily implying that we would ever want to stay in state 0 but it kind of reflects the – just keeps that data out of the system as the approach that most sharing networks take today is they just don’t let it get in the system in the first place.
Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
See I’m concerned, this is Larry, again, I’m concerned that so as a Part 2 provider, you know, connects here and in Central Massachusetts to the Mass HIway and they work out an arrangement with my organization that they will send to me and I’ll be able to handle it properly that, you know, they’ll be connected and in the provider directory, you know, in their EHR they’ll be now also see all the other organizations in Massachusetts and will inadvertently – someone will be inadvertently sending these to other people that they haven’t set up agreements with.

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

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
And then the other thing is so – and let’s say you did have the capability on the receiving side to reject it so I realize I’m receiving a Part 2 document then I’m going to reject it.

There are no standards for sending back a notice saying “I’m rejecting this. I know you wanted to communicate with me but you’re going to have find a different way other than electronic because I’m rejecting it.” That’s not happening here and the communication is breaking down.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
Well that’s – this is Dixie, Larry that kind of touches on what I was going to ask you is, you know, the status is called refuse the business, are there cases in which a physician or a clinic would say, well I can’t accept this Part 2 data electronically but can you fax it to me and it would just be kept outside the EHR system but it wouldn’t necessarily be refuse the business per se?

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
Right that would be falling back to the current process which is a paper process but I can – I am aware for instance of an organization in Massachusetts who is sort of setting up a directory on the receiving side saying these are the people who we recognize and will receive stuff from and anybody else who doesn’t – we can’t receive from we’re going to send back a Direct message saying we’ve refused it.

The reality is I’m not sure that any other organization who receives that is going to be able to process it; it’s probably going to be thrown away. So, there is this chaos about to be created, you know, both with the presumption of 0 and also others with the way Direct is being set up that we’re going to run into some chaos pretty soon.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
But this is David, I mean, I was hoping to resist over complicating the situation. I mean, you could theoretically automate with sniffers and read into the packet and decide that it’s got a sensitive header and automate the rejections and if an individual EHR vendor wants to do that this would be fine, I just – notion here would be Level 0 is the status quo you deal with it by contract and arrangement you don’t try to automate it. If you don’t want that data find a way to keep it out of your system.

John Houston, JD – Vice President – University of Pittsburgh Medical Center
Well, maybe that’s the way to state it rather than –

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
Yeah, I would say so too.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, yeah these were not worded with policy in mind they were just to capture –

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
They were, right – so is it just –
David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Incremental investment.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Like decline to accept electronically or decline to participate is that a better way to frame it or something?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, arrange to not participate or something.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
I mean, where there is a notion of an arrangement – now a footnote that I’m confused about because I read something outside of our calls that surprised me and that is that the disclosures are to specific individuals and not to organizations is that correct?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
No it’s the other way around.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
No.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
So, essentially what has to happen, so what David is referring to is the answer that SAMHSA provided to the question of whether the authorization that is provided by a patient to a Part 2 provider to share whether it needs to – that the patient is going to see or can it be to an organization or even to an OHCA and essentially the way that they answer it is that the authorization has to cover where – should cover where the information is sent.

So, if it’s sent to Larry’s organization it does not have to be directed to Dr. Larry Garber it can be sent essentially to his EHR but that should be what’s covered in the authorization so that essentially what’s authorized just says the patient authorizes the sending to the organization, but that can be done.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Good, thank you, I had read it otherwise somewhere and I was very puzzled.

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Evidently, I was wrong.

John Houston, JD – Vice President – University of Pittsburgh Medical Center
This is John Houston; can I ask a separate question about this chart just to get clarity?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Sure.
Between – I’m having trouble distinguishing between 2 and 3 and I’ll tell you why for a second. I get the sense like both 2 and 3 assume that the data element has some metadata in it that allows us to distinguish the fact that it is Part 2 data and if that’s the case then what is the difference between 2 and 3 other than the organization chooses not to use it other than for local use?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So, John, this is David, what I was trying to capture was that number 2 deals with the fact that you hate to have medically relevant information in such a tight lockbox that you’re clinical alerting systems can’t use it.

John Houston, JD – Vice President – University of Pittsburgh Medical Center
Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
But that you’re not prepared to go so far as to turn every physician into a redisclosure, re-authorizing, you know, Part 2 compliant provider and that the software to achieve the later would be much more complicated because you have to, at least in the current law, capture an actual paper release for each data element that you would want to let go out your system.

John Houston, JD – Vice President – University of Pittsburgh Medical Center
Okay, but –

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So I was envisioning – yeah, does that make sense?

John Houston, JD – Vice President – University of Pittsburgh Medical Center
Yeah, but the underlying metadata to support 3 exists within 2 but not the processes around which you would accomplish release, is that right?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yes, yes, the metadata is tagged on the inbound data if they follow the DS4P CDA conventions –

John Houston, JD – Vice President – University of Pittsburgh Medical Center
Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Which of course in and of itself is a complexity but let’s assume that that’s handled. Then I was envisioning a modest enhancement to EHR technologies to flag data that says basically this data cannot be automatically re-disclosed.

John Houston, JD – Vice President – University of Pittsburgh Medical Center
Okay.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
David, I think you should, this is Dixie again, I think and I was going to suggest this, I think the difference really between 2 and 3 is that sharing and I think it would be useful in terms of Deven presenting this to the Policy Committee if you re-titled that third one because 2 really is general use but 3 is general use and sharing.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah or automated sharing or redisclosure or re-redisclosure, I had a bunch of more colorful titles.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Re-redisclosure.
David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
Yeah, re-disclosure.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
Yes.

John Houston, JD – Vice President – University of Pittsburgh Medical Center
I think –

Wes Rishel – Independent Consultant
This is Wes.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Hang on Wes, was that John, was that you in the background?

John Houston, JD – Vice President – University of Pittsburgh Medical Center
I was just going to say, yeah, I think the key is simply what you – yeah that the metadata exists I think that’s an important concept to make sure it’s clear it is just that the processes surrounding redisclosure don’t exist or need to be refined in order to get from 2 to 3 and that actually makes it a very clear progression in my mind.

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

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
Yes.

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

Wes Rishel – Independent Consultant
This is Wes Rishel.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, go ahead, hi.

Wes Rishel – Independent Consultant
I joined the call late and so I may be out of order here, but then you tell me if I am, but first off any title that got me able to write a memo re: re-redisclosure would be good.

Second, did we agree to change refuse the business to something different? There is nothing about refusing the patient or the healthcare business here, I think that’s confusing.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yes, yes, no, we definitely did, it’s going say something like arrange to not participate or decline to participate, yeah, that’s –

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
Electronic –

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

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
Electronically, Deven.
Wes Rishel – Independent Consultant
Well, it’s really only decline to accept data. I mean, there’s no reason they’re going to – my point is that this does not – there is nothing in here about whether they’re going to take care of the patient or not.

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

Wes Rishel – Independent Consultant
Okay.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
And it’s not that we need to capture that electronically there too, Deven.

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

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
Because they could still accept it in a fax but we just –

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

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
By the EHR.

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

Wes Rishel – Independent Consultant
Right.

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

Wes Rishel – Independent Consultant
Okay and then on Level 1 I would like to suggest that the term read only will confuse those of us with propellers on our beanies and suggest view only instead.

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

Wes Rishel – Independent Consultant
The point is that it is not that it could or couldn’t be altered the point is that it couldn’t be parsed and put into the structured data.

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

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And can I offer an amendment to that comment by Wes?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay.
David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
That we had a different conversational thread where we – where I sort of moderated on that a little bit and said that maybe it’s not so much that it can’t be done but if it’s only done via a series of scary alerts to let the provider know the consequences of so doing, because we do know that there are channels for rediscovery of the knowledge about the patient that remove the redisclosure restrictions and should it be the case that the provider comes through one of those channels where in his judgment it’s no longer restricted based on the somewhat arcane rules that we got explained to us.

You might wish to actually go ahead and pull the data out of that structured CDA so as to avoid the overhead of retyping the diagnoses and the drugs and all that stuff but you’d be doing so knowing that you were abandoning the redisclosure preventions.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Right, right, so it’s almost like we –

Wes Rishel – Independent Consultant
I’d like to –

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Add a proviso that it can’t be done while – you know, continuing to – in a way that continues to honor the redisclosure provision.

Wes Rishel – Independent Consultant
I’d like to suggest that this be handled by a footnote rather than in the description.

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

Wes Rishel – Independent Consultant
I think that trying to express that to the Policy Committee in a table would be –

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, the print is already pretty small.

Wes Rishel – Independent Consultant
Right.

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

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

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
I was – thanks to Wes for pointing out the difference between read only and view only I was going to mention that and I think that last point about rediscovery outside of the existing Part 2 protected information is really helpful to me because that highlights another difference between the metadata that needs to be there for Level 2 versus the metadata there for Level 3.

For example, you might need in Level 3 additional metadata to point out that I, the physician, have discovered this information through separate means and therefore it can be re-disclosed without the Part 2 protection, right, if I understand it correctly?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Right.
Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Right, yes, that’s correct.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
It wouldn’t be that you would remove the flags that had been there before, so I assume that solution
would not be sufficient. You would need additional metadata to mark this field as being discovered in
two different ways and that would be very complicated and so I appreciate the difference between Level
2 and Level 3 and I would add my vote to renaming Level 3 to something else.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
To something that reflects the sharing?

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
Yeah, well, I mean, the Level 2 is –

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
May not send again.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
Local use only and right and Level 3 is about redisclosure beyond the local, right?

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

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
So, it’s not about general.

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

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

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Yes, that’s a good point.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, it’s really about advanced metadata from redisclosure.

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

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Advanced metadata to manage redisclosure.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
This is Larry, one more point on number 1, I just wanted to make sure that it’s clear, well at least we
understand, that whether it says read only or view only, that it’s still something that can be cut and
pasted within the EHR, you know, these are displayed using a style sheet typically and the text can
certainly be copied and pasted in most EHRs regardless of what, you know, the EHR is going to try to do
unless it turns it into a bitmapped image.
David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
This is David and I mean, I think there are all sorts of things where you could game the system, but we got that sense from our SAMHSA advisors that a lot of judgment is called for about when you have data that should or shouldn’t be re-disclosed and that in some cases it has never been legally tested. So, I wouldn’t want to put into a certification requirement things like cannot copy and paste it just seems too restrictive.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Agreed, you were just pointing it out Larry right?

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

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
Right, I just – I want to make sure no one thought there was magic here that’s all.

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

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
So, in a way there is no – I mean, Level 1 means, this is Micky, Level 1 means that there is no data level tagging whatsoever, right? Level 2 is data level tagging but that allow – well, it’s parsable for local use but there is no redisclosure type or no tagging that would help with redisclosure and then that’s what Level 3 adds.

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

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
That’s well said, that’s good.

Wes Rischel – Independent Consultant
Can we build that into the labels?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, Micky, can you help me with that?

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
That was good and even I got that with my – and I left my beanie with the propeller on it at home.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
My propeller has been spinning so.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I’m not sure I ever really earned one to be honest.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
Well, we’ll make sure to get you one.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
You get an honorary one.
Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I get an honorary one.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
I would extend that last suggestion a tiny bit to say that Level 2 provides metadata that actually helps prevent the redisclosure.

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

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
You said that it was not there to help with the disclosure.

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

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
When in fact it’s there to help with non-redisclosure.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Right, right and the paragraph kind of says that, I agree with that.

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

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay, great, this is all enormously helpful. So, then if you sort of get – that’s going to be very helpful for the framing with the Policy Committee. So, then moving us along to slide 4, are we prepared to say, as a Tiger Team, that we do agree with the Certification and Adoption Workgroup that the Level 1 that enables the passing on of documents from a Part 2 provider that does have the metadata that indicates it’s restricted should at least be part of the voluntary certification program that the Policy Committee has already endorsed?

And then if we are there then do we think that laying the foundation for progression up this framework also suggests that we should have a voluntary effort to provide the functionality at least at the view only level, which we’ve defined as Level 1, for the general EHR program?

And there I think we’d need to say a lot about sort of what the limits for this are, but the reason for proposing it to you all as a voluntary criterion is because of the concerns for some of the providers about not being able to engage this information at the Level 2 or even the Level 3 in terms of being able to parse it and determining that they would prefer to receive this information through another vehicle then the restricted C-CDA.

And there I think we have, you know, some folks on some earlier calls have indicated that they would like to put a recommendation that would lay the foundation for further progression for what we’ll call general EHRs, just as a term of art to refer to the certified EHRs that are part of the Meaningful Use Program for non-behavioral health providers, do we suggest it as a voluntary certification criterion?

Of course it is really up to the Standards Committee to decide whether the particular standards that have been piloted are mature enough, but we’re trying to lay a policy foundation here for progressing to where we need to go.
And then I think we also, you know, the ensuing slides sort of provide some rationale for the fact that we’re not at all close – we’re not at all at Level 2 and 3 so certainly with respect to the third stage of certification for Meaningful Use we won’t be able to get there but does having it as a voluntary criterion for behavioral health providers and also for general EHRs in fact lay the foundation for providing incentive for the work to continue to get us there.

But there are also some further slide notes about we really do need some clarity on the regulations that, you know, it is of concern that there isn’t a lot of clarity on how the Part 2 rules will play out in a scenario where we’re exchanging data electronically using metadata tags and data that comes from another source and to what extent can you talk with the patient and enable the data to be parsed within the EHR and then subsequently shared, how does that happen?

And in fact, SAMHSA is having a listening session on their regulations in the very near future; I actually think it’s in the next week or two. And I believe if we didn’t send out information for those of you who are interested in participating we’ll make sure we do that. But that actually does take place I know for sure after the Policy Committee hearing unfortunately and nevertheless even after the listening session SAMHSA probably needs some time to think through how they might want to proceed.

John Houston, JD – Vice President – University of Pittsburgh Medical Center

Deven?

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

So, I’m going to pause and invite comment from folks.

John Houston, JD – Vice President – University of Pittsburgh Medical Center

Deven, John Houston.

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

Hi John.

John Houston, JD – Vice President – University of Pittsburgh Medical Center

I guess the question I have is how does this get expressed? I mean, certification is one thing but I think that maybe probably as important as certification is for a sending organization to be able to understand what the level of certification that a receiving organization is at in order to decide whether it can in fact provide data to it.

So, I guess the question is, is this not just a certification but something that is going to be expressed electronically that will allow a sender to do a query and determine if it can send data or it won’t send data?

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

Right, well it almost is like from – John, I think that’s a good point, from some of our prior discussions that it’s sort of a needing to understand technology readiness and maybe even understanding interests in wanting to receive these documents and maybe those go hand and glove but it wasn’t entirely clear to me whether that was the case.

John Houston, JD – Vice President – University of Pittsburgh Medical Center

Because it’s almost like there is a contract – if I’m a Level – if I’m a Part 2 provider if I see somebody is only capable at a Level 1 I may not want to send them data or I might want to take additional steps before I send them data or the format of the data which I’m willing to send them whereas if I see they’re a Level 2/3 provider I know that they have the capability because of their ability to manage the metadata to be able to handle that data in a way that maybe I’m more comfortable with.
Wes Rishel – Independent Consultant
This is Wes.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Go ahead, Wes?

Wes Rishel – Independent Consultant
I agree with John that this concern exists. I think that any attempt to create the standard technology that would support that would require a great deal of work at the policy level and then work at the technology level.

Some of the issues have already been discussed today such as the difference between sending data point to point and sending data to or through an HIE.

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

Wes Rishel – Independent Consultant
And I think it would be good for us to advise or remind the Policy Committee that they might want to be looking forward but we’re far short of being able to say anything more specific.

Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics
This is Leslie, could I just – this is on a slightly different point, but I wonder whether there isn’t some reason for holding back on saying much beyond the including Level 1 until SAMHSA gets a chance to digest the listening session.

I know that’s a really big deal that session and – because I got notice of it through NCVHS not from the Tiger Team and, you know, I don’t know what they’re going to learn or say but it seems to me it would be a mistake to go too far down the road without knowing what they’re thinking.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
So, what – so Leslie what would you – what’s too far down the road?

Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics
Well, I mean, I guess the question for me is whether they’re going to – since we don’t know what they’re going to learn in the listening session whether it makes sense to temporize and to say to the Policy Committee, you know, why don’t you wait until after the June meeting or does this just got to happen now?

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

Wes Rishel – Independent Consultant
Leslie are you suggesting we temporize on Level 1 or on the higher levels?

Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics
No on any of the higher levels.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Oh, okay. Well, absolutely, I mean, I think our – the first point I’ll make is that we actually have the recommendations, you know, sort of solely sort of centered around achievement of Level 1 in a more universal way.
Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics
Right.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
You know having said that with an acknowledgment actually that Levels 2 and 3 there is still a significant amount of work to be done on that and I think we need to acknowledge the need for additional clarity on the rules probably even with respect to just Level 1.

Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics
Right.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
And certainly with respect to Levels 2 and 3.

Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics
Right, right and part of the reason I brought this up was I wouldn’t want us to try to decide what beyond Level 1 ought to look like because it might turn out for example that from the listening session we would learn that there is some really important kinds of research or pilots that are necessary. So, we might be able to say more.

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

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
Deven, I–

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
This is Larry.

Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics
That’s my only point.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
This is Larry.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah and I heard Dixie too. So, I think I heard Dixie first and then Larry.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
I think Dixie was first, yes.

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

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
I don’t see that Level 1 buys much. Certainly, I don’t think achieving Level 1 is sufficient to add as a certification even voluntary because it really is not much more than sending something using the Direct protocol and you can’t use it in – you can’t use the data in decision support.

To me, I think the minimum that should be included as a certification should be Level 2 and I think if we don’t feel comfortable putting 2 I think we’d be better off saying nothing.
**Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group**

And I, this is Larry, I absolutely agree with that and the statement that you have on the slide here, additional research and pilots are needed –

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

Right.

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

To demonstrate recipient behavior, I think that’s really the most – that’s the one thing I absolutely agree with, you know, because, you know, I find it very valuable to receive this information and I want to do it safely and properly across the healthcare system.

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

Right.

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

But we don’t – the pilots that were done did not study recipient behavior, you know, they were just figuring out if they could send this stuff and, you know, we’ve already discussed at our last meeting that there are a whole bunch of different problems that could, you know, arise, you know, even with Level 1 capabilities and especially if you’re trying to send it to someone who doesn’t have Level 1 capabilities that we don’t necessarily understand.

And, you know, and it’s just like, okay, asphalt is great for making driveways and it’s great for making roads and onramps to highways and highways, so, you know, if I’m on Ohio and I want to start building a road eastward, you know, asphalt is wonderful, yeah, but if it turn out where I really want to go is Europe asphalt is not going to get me there.

And I’m concerned that we can start, you know, making plans for what the senders ought to be doing but if we haven’t completely, you know, worked through, you know, the end game on this we may find ourselves half way and running into trouble and now we’ve got all of these EHRs that have new policies and functionality that are going to be useless.

I think, you know, SAMHSA is having a meeting, the world may be changing shortly, I think it’s prudent that we push for pilots right now and not push for new standards.

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

So, let me ask a threshold question for folks. Are people at least comfortable with the inclusion of Level 1 in the voluntary certification program for the Part 2 providers?

**Leslie P. Francis, JD, PhD – University of Utah School of Medicine – National Committee on Vital & Health Statistics**

Well, this is Leslie, the reason I raised the question about delaying actually is Dixie said the technical in a way I couldn’t, but I was worried that we would get locked into saying too little and so what I’d want to know from people is whether there’s a risk of that if we did go along with giving the okay to Level 1 without knowing more either from SAMHSA or from pilots.

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

Right, so here’s the timing issue as I understand it Leslie, is that in order for there to be any certification criteria for Meaningful Use Stage 3 we are up against a time constraint and it’s not just a – you know, if we were talking about an additional month I think we might be able to buy time.

SAMHSA is hosting the listening session around the policy issues, which by the way are – people need to keep in mind that the restrictions that operate around Part 2 data are not all in regulation, a good chunk of them are in the statutes.
So, I think the listening session is really about, you know, what are the ways that SAMHSA can think about achieving their statutory obligations given new challenges in a technology enabled world, but they can’t get rid of them altogether and they can’t change the fundamental re-disclosure aspect of it because that’s all embedded in statutory language.

Now having said that, it probably will – you know, they will need some time after the listening session to think through what it is that they might want to do from either a regulation or guidance perspective and it could be many months before we receive any additional information about that.

And we already have an approved recommendation on the table that there will be a voluntary certification program aimed at behavioral health Part 2 providers and so the idea about whether this particular piece, the functionality to enable them to at least send documents that have the restriction tag on it is the piece that my understanding from a time perspective is sort of part and parcel of that entire package of recommendations that would go to ONC.

So, the recipient issue is, you know, given the sort of trend that the conversation appears to be taking, we may not think are really ready to resolve and then some of those timing issues around Meaningful Use Stage 3 are not as pertinent.

Wes Rishel – Independent Consultant
This is Wes.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, go ahead Wes?

Wes Rishel – Independent Consultant
I am now confused which seldom keeps me from making definite statements. Are we discussing whether there should be certification for senders or for general EHR recipients?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
We were trying to have a recommendation – we were – so the way that this came to us both questions were asked.

Wes Rishel – Independent Consultant
Okay and are they still both on the table? I mean, I –

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Well, that’s what I was trying to tease out.

Wes Rishel – Independent Consultant
Right.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
And maybe I was just being confusing in my articulation.

Wes Rishel – Independent Consultant
Yeah.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
No, I think Deven is right, I mean, we’ve gotten lots of pressure from Joy Pritts and her team that they want these documents to flow and that they’ve –

Wes Rishel – Independent Consultant
Yeah.
David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Achieved what they consider to be a meaningful milestone in the DS4P CDA standard and therefore, you know, I was thinking of it, okay, now these documents are flowing where the heck are they going to land and what do we do with them when they do land.

Wes Rishel – Independent Consultant
Well, they can’t flow until they have a place to land, right? I mean –

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

Wes Rishel – Independent Consultant
I mean, we can have pilots but as far as there being any, pardon the expression, meaningful adoption there needs to be recipients that can receive the information with the formats and the headers and all that and deal with it. That doesn’t necessarily have to be a Meaningful Use requirement.

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

Wes Rishel – Independent Consultant
But it would, if there were a voluntary certification it arguably helps with various efforts to push there actually being some flow.

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

John Houston, JD – Vice President – University of Pittsburgh Medical Center
This is – I’m sorry, this is John Houston, you know, I think this becomes sort of a chicken and the egg sort of thing or, you know, I think we have to be very forward thinking about where we need this to go and I think it’s so – in my opinion it’s incredibly important that you build a roadmap that both satisfies, you know, where we can take our next step to but where we’re going to be in 5 years or 3 years as well as, you know, what we’re trying to do to support current regulatory requirements which frankly I don’t think are really going to change. So, I think it’s so important to express all of this in one shot.

Wes Rishel – Independent Consultant
This is Wes, I wanted to continue, I agree with John, but I have the impression that the table that we’ve been discussing constitutes a roadmap at the level of precision that we know it.

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

Wes Rishel – Independent Consultant
And that we are talking about an issue which is, is it better to put Level 1 into voluntary certification and therefore get some progress or is it better to say that is so little progress that we would be better off not to push it in order to create more pressure to get to Level 2.

I think that I would defer to all the physicians on the question of whether it’s better to have that information from a Part 2 provider in this constrained set, but everything I’ve heard so far seemed to be in favor of it’s better to have it then not to have it. Therefore, I am not, at this point, not persuaded that we would want to change our direction from recommending voluntary certification from Level 1.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
This is Dixie, could I say something there? I think that there is value in Level 1. I want to make two points.
I think there is value in Level 1 but I think it’s already in the 2014 edition because all certification at that level would need to support the Direct transport protocol which would allow them to do Level 1. So, I think that 2014 already covers Level 1.

**Wes Rishel – Independent Consultant**
I don’t think so.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**
No, Dixie, I don’t think –

**Wes Rishel – Independent Consultant**
Yeah, no.

**Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates**
– they choose to –

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**
No, Dixie.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**
You can’t read it.

**Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates**
Let me finish my thought please.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**
Okay, okay Dixie go ahead, sorry about that.

**Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates**
If they choose to accept information from Part 2 providers then the technology solution is already in 2014.

The second point I wanted to make is that Meaningful Use Level 3 one of its principle objectives is to start really integrating data with clinical decision support.

So, I think if we’re talking Meaningful Use Level 3, you know, Meaningful Use then Level 2 of this chart – if we’re talking Meaningful Use, you know, Stage 3 I should say, we’re getting levels and stages mixed up here, Meaningful Use Stage 3 2017 edition I think that at that point I would not – I don’t think that we should prescribe less than Level 2 because that’s the first level that integrates the data in any meaningful way.

And I do agree with everybody who says to hold off on the Level 3 but I think that Level 2 should be minimum for Meaningful Use Stage 3.

**Wes Rishel – Independent Consultant**
You’d better make a list of people who want to reply.

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

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**
I’m in the crease.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**
Wes, who else? Who else other than Wes?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**
David.
Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
David McCallie. Okay, go ahead, Wes.

Wes Rishel – Independent Consultant
Okay, so I think that the state of the art is that for Stage 3 we have no option for Level 2.

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

Wes Rishel – Independent Consultant
So, that being said, we’re faced with one of the many difficult decisions we make about whether it’s better to get some progress that might lead to future incremental progress or whether it’s better to have no progress to create pressure, additional pressure.

And I disagree with Dixie that having the Direct protocol in certification standards is equivalent to saying that we have the ability to deal with Part 2 data in the certification standards.

The proposed certification that we would undertake, if we go for Level 1, is that an EHR could receive this information and behave in a way that showed that the data was sequestered, that’s not a part of the Direct specifications and is the issue at hand I think.

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

Wes Rishel – Independent Consultant
Thank you.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Thank you, David McCallie you’re next.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yes, it’s David here, I agree with Wes as opposed to what Dixie said and Dixie, just, you know, in technical details once a document, once an attachment is received via a Direct message in many EHRs and certainly in ours it’s added to the patient’s list of active documents.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
Yes.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
At that point it can’t be protected from automatic re-release due to interface feeds and the like because it at that point looks just like an ordinary document. So, at least in our case, we’d have to enhance the EHR to respect that this document was sequestered or in a lockbox.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
Yeah, I agree with you both, yeah you’re right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So, that’s the reason that number one does require work on average from the vendors. Some vendors may do it automatically but I suspect most of them probably don’t.

So, I think Wes’s point is the real point is, do we want to make some incremental progress here, you know, in an attempt to get the data flowing albeit in a way that kind of mimics the fax world where you put the thing in a special file, i.e., a sequestered document or do we want to wait do some pilots and do a full blown metadata ready, you know, Level 3 at some point in the distant future.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Right.
David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And I think the incrementalism makes sense, but that’s just a, you know, that’s just my opinion. I think getting this data to move will be important for people to understand, gee, we really need more – we need more control over the data let’s figure out what that control is, get that feedback coming to the vendors who then can start to build out tools to manage the more sophisticated metadata.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Right, so with that, this is Micky, I just wanted to take the opportunity go back to Dixie now, Dixie with that clarification do you think that Level 1 makes sense then as a recommendation, as a, you know, an incremental step?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
Well, I think it does, but I don’t – I think it needs – we need to clarify the description so that it says that the document would be – the EHR would automatically recognize it as a Part 2 – as Part 2 data and sequester it accordingly.

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

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
I think the way it’s written it’s no different from Direct.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
It’s not clear, yeah, that is implied in there, but I agree it’s not clear so we can do that. I think that’s a great point.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yes, yes I agree.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
This is Larry.

Wes Rishel – Independent Consultant
This is Wes once again.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay. Larry? Thank you, Leslie.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
So, when we say that we’re sequestering the document does that also have implications on role-based security as to who can see it?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
This is David; that was part of my question around whether these releases are targeted to individuals or to organizations. The answer seems to be –

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
They do not have to be, they can be released to the organization.
Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

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

In which case I think your organization's security would apply to whatever that means.

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

Yeah.

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

Okay, but if we're going to be specifying a policy which to some degree I think implies some functionality –

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

Yes.

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

I would want to, you know, this is not just that it can't be re-released, you know, without another consent but also that based on role-based security you can determine, you know, who can view it and who can't view it.

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

Yeah.

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

Well, but that would be that you don't need to treat this – if in fact the consent it at an organization level you do not need to treat this any differently than you treat any other document that comes in from a role-based purpose.

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

Right, but we typically wouldn't have a secretary looking at these whereas we would let doctors and nurses see them. So, that – I don't know that all EHRs would necessarily have that capability specifically for documents but I think they would want that.

Wes Rishel – Independent Consultant

I guess –

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

We can certainly make note that this might be desirable on the part of some organizations but again that was part of the reason for getting the clarification from SAMHSA about whether these documents needed to provide an authorization for a particular individual and they don't.

Wes Rishel – Independent Consultant

Okay, Wes.

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

This is David, can I –

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

Yes, David Kotz?
David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
Yeah, can I – I want to jump back to something I think John said which was he was asking the question should we recommend this Level 1 voluntary certification as you – rewritten as it’s been discussed or should we be doing some pilots and strive for a Level 2 and Level 3, can’t we do both? Can’t we recommend that the certification criteria be about Level 1 and simultaneously be doing pilots to explore Level 2?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
I believe we can.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College
It seems that would make sense to me. I would be very much in favor of that. We want to keep pushing towards ultimately Level 3 but we don’t yet know fully all the nuances of getting there.

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

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

Wes Rishel – Independent Consultant
This is Wes.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
David McCallie, I agree with that. I think there is some standards body work on metadata but I don’t believe it’s at this level of sophistication so that could be a part of a parallel process with pilots is an effort to flush out the standard behaviors and then go pilot those behaviors.

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

Wes Rishel – Independent Consultant
Wes.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Wes go ahead?

Wes Rishel – Independent Consultant
So, I want to be clear what we’re talking about here is certification as opposed to anything else in particular if some developer were to come up with an approach for dealing with this data other than sequestering it and establish a working interface with a Part 2 provider to a general provider based on that approach I don’t want us to be prohibiting that from happening. I mean, that would be the finest kind of pilot in the world right there.

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

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

Wes Rishel – Independent Consultant
So, it is clear we’re talking only about certification is that right?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Well, you know, so, again we sort of leave to the Standards Committee the sort of decisions about whether it’s certification to a particular –
Wes Rishel – Independent Consultant
No, I’m concerned about it becoming a Meaningful Use requirement or something as opposed to that.

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

Wes Rishel – Independent Consultant
Yeah.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Well, you know, certainly I think we have a slide on that we would not – that it’s not a Meaningful Use –

Wes Rishel – Independent Consultant
All right.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Requirement at all to use it.

Wes Rishel – Independent Consultant
That’s – I’m covered, thanks.

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

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
This is Larry one more thought?

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

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
So, since we’re talking about these almost in pairs that we’re, you know, for the 2015 or 2017 certification of EHRs, you know, that they’ll be able to, you know, voluntarily receive Level 1 and that the behavioral health providers will be able to certify their EHRs to be able to send Level 1 I think there should be something required by the behavioral health providers such that they specifically have to turn on Direct addresses that will be able to be receiving these.

In others words, I still do have the concern that, you know, with the chicken and egg, that we’ll be, you know, sending these and receivers may not be ready to receive them and won’t be handled properly.

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

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
And so that they need to be able to specifically turn on this Direct address and that Direct address even though they may be connected to a directory that they can send other types of documents, you know, to any place in the state, but for these Part 2’s they have to specifically, you know, opt in the addresses.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Yeah, I mean, that’s a point that’s been raised multiple times that we don’t want to have an environment where data is being sent to someone who is not prepared to receive it.

Wes Rishel – Independent Consultant
I’m going to – fully supporting the concern there I’d like to argue against it –

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay.
Wes Rishel – Independent Consultant
From several grounds. I agree that it’s a significant concern, but ONC over the last few years has worked really hard to separate transport from content in terms of how standards are structured and asking the community of standards developers to go back and re-introduce that issue into Direct and specifying a specific mechanism by Direct address as opposed to some other means I think is at absolute best premature.

I think we should make a statement that the Part 2 provider should have a means of knowing that the recipient is honoring the Part 2 requirement, understands that they’re receiving Part 2 data, but we should leave it to further work to determine whether that happens contractually in some cases and technically in others and if so what is the best technical approach for doing that is it labels on the content, is it dedicated Direct addresses or is it still a third option that we haven’t considered.

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

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
This is Larry and I accept that friendly amendment, absolutely.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Okay, thank you, thanks to both of you. So, any other thoughts that folks have? Again, some of what’s on the other parts of the slides here involve, you know, expressly stating that, you know, while Levels 2 and 3 are beyond the capability we have today, we believe that at least getting to Level 1 could help us get there, but acknowledging again the point that David Kotz and others made about needing more pilots on the recipient end.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And possibly more work in standards bodies to address some of the behaviors.

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

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates
When we acknowledge that could we say it in terms of a, you know, encourage ONC to support additional pilots and standards development?

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
One of the, this is David, one of the – I think the term metadata is a good term, it helps me anyway to think about it with a slightly more precise focus and talk about obligations that come with the data and in particular the obligations around things like re-disclosure are what is not well understood today.

So, we all have metadata. Metadata is who sent it, when did you get it, what are the units of measure, blah, blah, blah, but this is a new kind of metadata that’s on the obligations and that the DS4P introduces new obligations that we now have to figure out how to handle on discrete data in the EHRs. So, that’s what Levels 2 and 3 would be refining –

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

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Is what are those obligations and what are the rules around respecting those obligations.
Thank you.

And you thought this was going to be hard.

Yeah, I did, I still think it’s hard, but I really appreciate all of the hard work that all of you are doing to get this to the Policy Committee in a way that they can understand and that lays a foundation for being able to move forward we hope, you know, so obviously there is work that the Standards Committee will need to do and Micky and I tried to articulate that in this set of recommendations that’s on slide 6, you know, whether it’s DS4P the standard or is it – you know, is there something else.

And then I do think we really need to make both the education of providers and patients, and the policy points around, you know, ideally additional clarity from SAMHSA within the scope of their authority to consider how the statutory requirements can be meaningfully operationalized to borrow another use of meaningful in a digital exchange environment.

So, any other thoughts or points? We will work up a revision of these slides including some changes to the chart articulating the very good points that all of you have made in preparing the deck for the Policy Committee.

We’ll work with the MITRE team that supports us, but Micky do you think we can get this at least out to folks on e-mail for some additional thoughts to make sure we haven’t missed anything at least between you and I in reviewing things, and preparing things before the end of the week so we have a deck ready by Friday for the Policy Committee?

Yes, I can do that.

Okay, so that’s what we’ll do so keep an eye on your e-mail we’ll get a revised deck that has the more appropriately I think and accurately captures the discussion that we had today and we’ll circulate it around to you all by e-mail for further comment.

Okay.

Anybody else have any other thoughts if not we’ll actually close up a bit early today? Okay, Michelle, I think we can open up to public comment.

Okay, operator can you please open the lines?

If you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the phone and would like to make a public comment please press *1 at this time. We do not have any comment at this time.
Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
All right, great, many thanks to my Co-Chair, many thanks to the Tiger Team members this is a hard issue, really appreciate all of your thinking and thoughtful comments and input. Keep an eye on your e-mails and look forward to speaking with all of you again soon.

Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group
Thanks a lot.

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

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

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

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