

Privacy & Security Tiger Team
Draft Transcript
August 16, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning, everybody, and welcome to the Privacy and Security Tiger Team Call. This is a FACA Committee, so there will be opportunity at the end of the call for the public to make a comment. Just a reminder for the workgroup members to please identify yourselves when speaking, and let me do a quick roll call. Deven McGraw?

Deven McGraw – Center for Democracy & Technology – Director

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Paul Egerman?

Paul Egerman – eScription – CEO

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Latanya Sweeney? Gayle Harrell?

Gayle Harrell – Florida – Former State Legislator

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Carol Diamond? Judy Faulkner? Carl Dvorak? I know they're on, so—

Judy Faulkner – Epic Systems – Founder

Yes, I know. You got really faint all of a sudden, Judy.

Carl Dvorak – Epic Systems – EVP

We're on.

Judy Sparrow – Office of the National Coordinator – Executive Director

Did I?

Judy Faulkner – Epic Systems – Founder

Yes, you got really faint.

Judy Sparrow – Office of the National Coordinator – Executive Director

Hello?

Judy Faulkner – Epic Systems – Founder

That's better. Yes.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay. I know Judy and Carl are on. Dave McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
David Lansky? Dixie Baker?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Micky Tripathi? Ellen Flink for Rachel Block?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Micky's here.

Ellen Flink – NYS DOH OHITT – Director Research, Patient Safety & Quality
I'm here. It's Ellen.

Judy Sparrow – Office of the National Coordinator – Executive Director
Eva Powell is on for Christine Bechtel. John Houston?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Wes Rishel?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Adam Green? Joy Pritts?

Joy Pritts – ONC – Chief Privacy Officer
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Did I leave anybody off?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Judy, this is Micky. I'm not sure if you got me.

Judy Sparrow – Office of the National Coordinator – Executive Director
I did. Thank you. Deven and Paul, I'll turn it to you.

Paul Egerman – eScription – CEO

Good morning. I want to again thank all the members of the Tiger Team for participating in this morning's phone call. I very much appreciate your dedication to participate through all these calls through the summer months. This is our last scheduled call during the summer.

I also want to thank any members of the public who may be listening in to our call. We appreciate your public comments, and so if you are there, Les, we are hoping that you will make a comment that says you had in this past. There is an opportunity at the end of the call for members of the public to make whatever comments they want to make relative to what we are talking about.

As Judy Sparrow said, this is an advisory Tiger Team. We are part of the HIT Policy Committee. We were formed to answer a number of questions over the summer months that were presented to us by ONC, and this is, as I said, the last call for over the summer. What has happened is we've deliberated over a number of questions. They have been presented in the form of a letter that is now 19 pages long, and what is the purpose of today's call is really to review that, to make sure that we're okay with that letter, and to finalize it.

In that regard, a number of Tiger Team members have sent Deven and me a recommended wordsmithing changes and we really appreciate that. Basically what we're going to do is— I can't tell you we're going to incorporate all of your changes, but we're going to do our best to incorporate most of them to make sure that the wording is correct and clear, and so that was very much appreciated. In particular, Christine and Dixie sent some very thoughtful and helpful comments, and so we will be including those as much as we can.

What we want to accomplish today is talk less about the format and the words in the letter, and more about the actual substance and in sort of the little short e-mail lizard that we got before the day's call, Deven and I sort of got the sense that there were three major issues that we should probably address. The first one is really a discussion to make sure we're all clear on what is written about the impact if you don't give consent under the consent conditions. The second one relates to—it's a complicated thing to explain, but it relates to what I sometimes call the New York approach, and the New York approach is basically an approach where data is sent into the HIO, and the consent has to deal with when it becomes accessible out of the HIO, so we wanted to talk about that. The third area is the whole sensitive data area and how that's handled. What we tried to do there is write up what had been discussed before, but it's just that wording, that presentation is not something this group has seen.

So what we want to do is to go through those three issues since those are the three substantive issues that have arisen so far. Then after that there will be an opportunity for you to raise any issues you want, but also an opportunity to view the entire letter as a whole to see what we think of the whole letter.

So, unless you have anything to add, Deven—

Deven McGraw – Center for Democracy & Technology – Director

I just wanted to make a note for members of the public who are on the call. The letter that we're speaking of—the draft that the Tiger Team received—is available in the download section of the Website if you're on the Webinar with us today. There's a little download section on the left hand part of your screen and you can access the letter there.

Paul Egerman – eScription – CEO

Excellent comment because you should access that letter. That will be helpful. Also to make sure that we're all understanding what the schedule is, the purpose of this call is to sort of finalize that letter because then we will be presenting it to the HIT Policy Committee on the 19th, which I think is Thursday,

and asking the HIT Policy Committee to approve it. In other words, our letter is just—we really exist to give advice or a recommendation to the Policy Committee and the Policy Committee is the group that will then review the letter and approve it.

So the letter is on the Website. If you're signed on, you can see it on the left side where it says Downloads, and I think the thing to do is to dive right in and deal with the very first issue, which is the impact of what happens when consent is not given.

So, that's a brief view of Deven's two nephews—

Deven McGraw – Center for Democracy & Technology – Director

That's actually intended. I'm just trying to get the document up on my screen so people can see it as we're— There we go.

Paul Eggerman – eScription – CEO

Okay. And also, just to set the stage for this to make sure people understand this, so remember this is what happens when you have— The previous part of the letter describes the concept of a trigger condition, which is a trigger when the basically ability to gain access or control access to the patient's data becomes under the control of a third party service organization. So the issue is this: The patient does not give consent. The question is what happens?

So this is something that we wrote that is sort of like a proposal. It really hasn't been discussed by this group yet. It was influenced a fair amount by a comment that Wes made at the end of the last meeting where he talked about an example of a laboratory result passing through an HIO and that that's a common circumstance.

So, what you should see on your screen is this section in yellow that says, "We note that if a patient does not consent to having his or her information be exchanged through one of the above models—" Then it's really the centralized and federated models specifically that I mentioned. "The provider has the option of controlling the exchange through a directed exchange model, in which case the HIO may function as a service organization to facilitate the exchange, so long as the provider maintains control over the decision to exchange."

So what do people think about this? First, is it understandable and does this sound right?

Gayle Harrell – Florida – Former State Legislator

I'd like further explanation of that. I think the public is going to be extremely confused to what exactly that means. Are you saying that as long as the provider has control over who sees that, that it can go through an HIO, even though the HIO has access to it? And does the HIO have the ability to hold that, to attain it, to—? Be more specific is what I'm asking so the public will understand exactly what the process is and what it means.

Paul Eggerman – eScription – CEO

Yes, so here's the way I picture this, which is— And again I was thinking about the example that Wes gave at the last call, where you might have an HIO where—and this is the way apparently a lot of them get started—where what happens is you order laboratory results through the HIO, but the lab sends the results back to the physician through the HIO. In the process the HIO captures the lab results and starts to create a database that they make available to other people.

So if we're saying, "Well, gee, you have to provide consent before anything ... that happens," or one issue is what happens if the patient says, "No, I don't want that to happen." It puts the physician in a tough place because if that's the only way they can order the labs is through that HIO. So we're saying well then the HIO really has to operate like in a dual tract, so that if the patient doesn't give consent, the HIO can send and receive data as long as it doesn't make the data available. That you could still use it, but it's only being used for directed exchange.

Deven McGraw – Center for Democracy & Technology – Director

Right, and keep in mind that we have a whole set of recommendations already in this letter about HIOs and other third party organizations being limited with respect to their access use and disclosure of data and retention only for the purposes that are needed in order for them to perform the service, etc. So all of those recommendations would apply here and we can certainly reference them if we need to.

Paul Egerman – eScription – CEO

So if you're on the call, Wes, first of all I don't know if I described your example correctly.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Yes, yes you did. I think that understanding what it's about, the wording clearly applies to it. But I think that someone who's coming in without that understanding might have a little bit of difficulty with the term, "The provider has the option of controlling the exchange through a directed exchange model."

It strikes me that another formulation we might ... note is that an HIO may provide two kinds of services, those in support of community access to healthcare information and those in support of directed exchange. Directed exchange, as defined, doesn't require consent other than the consent that is given for care under HIPAA. If an HIO is performing both roles, which should be precluded from using information transferred under directed exchange unless the patient has had a meaningful chance to opt for the use of their data for community purposes?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Paul, this is Dixie Baker—

Paul Egerman – eScription – CEO

Hold on a second, Dixie. So, that was great Wes. I'm doing my best to write that down.

Deven McGraw – Center for Democracy & Technology – Director

I did too.

Paul Egerman – eScription – CEO

Did you get that, Deven?

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

Basically, if I hear both Wes and Gayle correctly, we knew what this meant because we knew what it meant, right? But, what we were intending to say. But the way it's written doesn't come across at all, so I think the way Wes just described it, we need to capture that.

So, I'm sorry, go ahead, Dixie. I didn't mean to—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes. I think, yes, he captured a lot of it. I think that one piece he did not capture, and that is the point that, Paul, you emphasized to me in a private telephone call, and that is if a directed exchange involves a third party or an intermediary, that the information has to be secured by the person in control, by the provider in control, through that intermediary. In other words, as you put it, end to end encryption. So I don't think this captures that point.

Paul Egerman – eScription – CEO

Although, I think we do capture that—you know, descriptions about directed exchange, we're talking about how you have to be secure in the process.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Right, but we don't here.

Paul Egerman – eScription – CEO

I think we have got to be careful we don't keep repeating the same stuff over and over again.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Says here, "So long as the provider maintains control over the decision to exchange," which I agree with, but I suggest we add, "and responsibility for securing the exchange." I think this is important, Paul, because in my opinion, I could envision an acceptable scenario of a provider sending information encrypted to a third party and that information become unencrypted when you get consent, which might enable workflows that are more convenient, and yet at the same time, the sender would have control over both the decision to make the exchange and the securing of that information.

Deven McGraw – Center for Democracy & Technology – Director

Except that, Dixie, we had a discussion many calls ago about the fact that for some providers, they need to hire somebody to do the encryption for them. You can hire a third party service organization to do that for you, but that would of course mean if that's the function that they're providing, that their access to the data that is encrypted is limited. But if we suggest that the provider has the sole responsibility to encrypt it and there isn't room for an HIO to provide an encryption service, I think we're going to be in some trouble when we deliberately did not require the provider to do the encryption. They can hire someone to do that for them.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

They certainly can. They can hire a business associate to do that—

Deven McGraw – Center for Democracy & Technology – Director

But wait, but in some cases that could be the HIO, and I was concerned that your particular wording here would suggest that that would not be possible.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Another way to achieve this, my problem here is that you don't use the word business associate. You use HIO. We have defined an HIO as an organization that has these relationships with more than one party and brings information from multiple points. If you have a word, in a case, a third party may function there, it would be fine. But no, getting down to the nitty gritty, I don't think that a provider should be sending information to an HIO wherein it is not encrypted; it is clearly not the patient's consent.

Paul Egerman – eScription – CEO

I think those are good points, but I think that those concepts should be described in the description about either directed exchange or about the FIPS, the fair information practices. Because we did already say in the FIPS that the provider is responsible for the security of transmission and they're responsible to make sure things go from point A to point B. So that's the right place to put that material.

Deven McGraw – Center for Democracy & Technology – Director

Yes. I'm not averse to making a mention of a business associate.

Paul Eggerman – eScription – CEO

Yes, I think we could add a mention of a business associate.

Deven McGraw – Center for Democracy & Technology – Director

Yes, if that would resolve that issue. I think we're all substantively on the same page.

Paul Eggerman – eScription – CEO

Yes, I think that might be an easier way to address Dixie's issues.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes.

Paul Eggerman – eScription – CEO

Okay.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

I'm sorry. I'm missing something. Say that one more time, what Dixie's proposal is.

Deven McGraw – Center for Democracy & Technology – Director

Essentially, what I committed to make more clear here is that when a provider is exchanging in directed exchange, if they're using a third party service organization like an HIO to help them perform that service, there's a business associate agreement in place that is clear about how the HIO can access data, and that the exchange is done in a secure manner. I'm wordsmithing on the fly here, which is not my strength. But the issue is that anytime a provider uses another organization to help facilitate the exchange of data, we already have a set of recommendations about how they must follow FIPS in doing so, including doing it securely, and that they can hire someone with a business associate agreement to assist them.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

How does this differentiate from a healthcare clearinghouse?

Deven McGraw – Center for Democracy & Technology – Director

It may or it may not. They perform particular functions under HIPAA, and in fact are covered entities but the HITECH legislation made it clear that health information exchanges are business associates. So how OCR distinguishes a clearinghouse from an HIO or HIE is—

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Right, because my fear is that you could almost have two halves? You could have this entity acting as an HIE in one context and as a healthcare clearinghouse in another. There's a gray area there that I'm having trouble understanding. I understand some of the nuances, but it just seems like there could be some misunderstanding when people read these recommendations.

Paul Egerman – eScription – CEO

Yes, when you talk about healthcare clearinghouses, I assume you're talking about claims clearinghouses. Is that correct?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Well, it's interesting. When you look at HIPAA, I don't think the healthcare clearinghouse necessarily has to be a claim, though, does it? It just talks about going from a nonstandard to a standard transaction format, but—

Deven McGraw – Center for Democracy & Technology – Director

I think also keep in mind that our job is not to resolve every—I mean, the question, quite frankly, we've got to set of policy recommendations ... if ONC adopts it and there are questions in the implementation, they can either throw them back at us to provide recommendation on or they can resolve them.

Paul Egerman – eScription – CEO

John, also this doesn't really impact clearinghouses or interface engines because again the trigger for consent is the issue of controlling access to the medical record in effect and so clearinghouse doesn't do that. Clearinghouse really just helps you get from point A to point B by making sure that the formats are correct and handling some communication.

Joy Pritts – ONC – Chief Privacy Officer

The clearinghouse issue is a little bit fuzzy and always has been, in times when clearinghouse is acting as a covered entity versus they could be acting as a business associate. Just like other covered entities can act as business associates depending on what functions they perform. But a standard transaction has a very distinct meaning under HIPAA, and the standard transactions are all administrative simplification oriented. They are not necessarily clinical information oriented.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

You're right. I got off track. Sorry about that, Joy.

Paul Egerman – eScription – CEO

So, getting back to— I'm sorry, go ahead, John.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

No, this is Micky. Sorry. Just, maybe there's just something to clear in my own mind. So it seems that the point here is just that if a provider is doing this through directive exchange, as we have defined in other places, it doesn't figure consent, right? So all we're saying here is that however a provider decides to organize that—either themselves or through an HIO or a third party or whatever we call it—however they do that, it still has to meet the requirements or the definition of directed exchange.

Paul Egerman – eScription – CEO

That's correct, and the fact that the HIO might offer other functions doesn't mean anything. You can still use it for this directed exchange function.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

Right, as long as they meet the requirements of directed exchange.

Paul Egerman – eScription – CEO

That's correct.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I agree with Micky. I think that's about all you need to add to this sentence is as long as they meet the requirements of directed exchange as defined earlier in this document.

Deven McGraw – Center for Democracy & Technology – Director

Got it.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes, I agree. I agree. Okay.

Paul Egerman – eScription – CEO

So, before I move on to the next topic, is everybody comfortable with this? Does this answer your question, Gayle? Are we all set?

Gayle Harrell – Florida – Former State Legislator

Yes, that makes it much clearer. I think, especially when someone who's not been involved in these discussions reads these things.

Paul Egerman – eScription – CEO

Absolutely and so, I appreciate those comments. That was the first issue, and I think it was a good discussion because I think we were able to clarify both the wording and the intent here of what we wanted to do.

Now, the second issue is an issue that is somewhat related and it relates to what I call the New York Model, which is— And Deven tried to capture this. If you get to the section on the screen that had that wording on it, because actually I have to say, she explained this to me last night. I didn't understand what she had written here at first.

But what I call the New York Model—say if I get this wrong Ellen—in New York, what happens is providers basically send all their data to the New York regional HIOs. I think there's eight of nine of them in the state. They basically keep all of that data and when a patient gives consent to allow it to be accessible, then they sort of make it accessible. Until then, there's not consent involved in transferring it to the HIO, the consent is only at the point in which it's accessible.

Deven McGraw – Center for Democracy & Technology – Director

Right, and so what I had intended with the language that's in yellow is to tee up for a discussion whether our recommendation about consent being required for HIOs that are either centralized or federated was whether we were comfortable with providing two options for how this consent could occur. So the yellow language is intended to be the alternative to stating that consent is required before the information is transferred to the HIO.

What I was intending here was to tee up for discussion whether there was an acceptable option of having the consent apply before any of the information can be accessed, but it can flow into the HIO without necessarily having to ask the patient first. So this was not intended to mean two levels, two layers of consent—one before it goes in and one to get it out. I did not intend for it to be read like that. But clearly, based on some e-mail correspondence that we had with Ellen and Rachel in New York, it was interpreted that way.

It was intended instead to tee up the very discussion that we're having now which is, is the Tiger Team recommending to the Policy Committee two different options for having consent apply to an HIO? So,

perhaps we ought to let the folks from New York talk about— Ellen, are you comfortable with being on the spot now?

Ellen Flink – NYS DOH OHITT – Director Research, Patient Safety & Quality

Yes. can you hear me? I know I have background noise. I am in the car and there's nothing I can do about it, so I will try to talk fast and hopefully everyone can hear me.

Deven McGraw – Center for Democracy & Technology – Director

I can hear you just fine, Ellen.

Ellen Flink – NYS DOH OHITT – Director Research, Patient Safety & Quality

Okay, great. One of the reasons in New York we developed this model was because in the event of a medical emergency or for public health reporting or in the case of other situations, we felt that a consent was important and in New York, we have laws requiring consent for specific types of access to information. So what we felt was that if we provided consent to be able to allow providers to access the information but we allowed to information to flow to the ... initially, then that information would be available in the event of a medical emergency and also for public health reporting purposes.

Deven McGraw – Center for Democracy & Technology – Director

Great. Thanks, Ellen.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I support this language and the idea. I think that the goal here should be to define what you're allowed to do and what you're not allowed to do rather than the exact technology that you use to do it or not do it. And as I think, in one the e-mail exchanges that went around, I tried to come out with three or four or five variations on the spectrum from federated to centralized to copy before demand to copy on demand to copy after demand, and to speculate that we really should be talking about what you're allowed to do rather than the technology that's underneath what you're doing. There are security issues on the technology, but that's a different conversation. So, I think this language makes sense.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I want to offer another dimension on this that we really haven't discussed. I think a lot of our discussions around consent have been about requiring it in situations where the risk or the exposure might be something that the patient needs to know about. I personally think that our agreement on those issues is quite brittle, so I think we should be very careful about how we view this.

One thing I would say is that if the only way information can be exchanged in an exchange is by aggregating all of that information in one place. There has in fact been a decision made about policy. I would offer that while I appreciate the situation of break the glass and also public health, as David just pointed out, there are lots of other ways to try to address those issues without making the only possibility for information exchange to be hinged on bringing all that information together at the get-go.

The other thing I would say is that the risks that we talk about are not really just in access later. In other words, we collect the data but we won't let anybody access it unless they've given consent, right? We've talked about security risks. We've talked about inadvertent disclosure risks. There are a lot of other things go with this that I think we should just be very mindful of.

Gayle Harrell – Florida – Former State Legislator

I think you all know where I am on this kind of subject. I have very great concerns about this. As we just discussed, the security issues are significant when things get dumped into an HIO. People need to know that up front and they need to consent to that. I have a major problem with this.

Paul Egerman – eScription – CEO

On this issue, I tend to agree with what I just heard Carol and Gayle say. One concern I have is we have this core value that patient's should not be surprised by what happens to their data, and the whole idea that— I might view this the same way. Say to my provider, "You mean you sent all my medical record data to the government without telling me?" I know it's not really the government. It's sort of like a government—it's a public-private entity, but it's sort of run by the government, and that just seems like a surprise.

Gayle Harrell – Florida – Former State Legislator

Big surprise.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I understand the sentiment. I think, though, that there would be a lot of surprises if people knew what happened to their data, and it's about what the data is used for and whether it does or does not break policy or the law that matters.

Paul Egerman – eScription – CEO

You've got a good point there. There's actually sort of headline news in the Boston area over the weekend. I don't know if people have heard about this. A *Boston Globe* reporter found a lot of pathology reports at the local dump—paper documents. So it was actually a major security violation, the only silver lining for us it had nothing to do with computers. It's all paper documents that basically, apparently some pathology medical billing service organization, instead of shredding all the documents—it had diagnosis on it, it was probably claim information—instead of shredding it, they just dumped it at the local dump and the *Globe* reporter found it all and it involved four hospitals.

The interesting thing just—this relates to a comment ... you just said, David—was what it said in the newspapers. People would be surprised if they found all the different places where their data ended up. So some service bureau ended up with the data. So, that is correct, but that was also one of our core values is they shouldn't be surprised by that.

Deven McGraw – Center for Democracy & Technology – Director

That's the failure both of policy as well as compliance with contractual obligations, I mean, that company just went off the rails, clearly.

Paul Egerman – eScription – CEO

All they had to do was buy a shredder and they would have been okay.

Deven McGraw – Center for Democracy & Technology – Director

Yes, and thankfully we've got the business associate rules ratcheted up by HITECH. The government now has greater ability to go after companies like that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Clearly, all of us on this call know that there are things that happen to patient's data that they would be surprised to find out, and all of us on this call would consider some of them fine and some of them not fine. I think it's this Tiger Team's responsibility to more clearly denote which ones are not fine and say,

“You shouldn’t be doing that.” So, just because it’s happening today, I don’t feel an obligation that our policy come out and sanction what’s happening today.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I agree.

Deven McGraw – Center for Democracy & Technology – Director

I agree.

Paul Egerman – eScription – CEO

I think this example from Boston actually is very illustrative of the point that has been made here. The fact is that the constraint on the amount of the data that was put in the dump had to do with the physical waste of carrying the data. In a model like the New York model, the amount of data that could be exposed in a breach is substantially higher. I really am torn on this issue because on the one hand I fully agree with this point and on the other hand I have thought all along that the New York Model was really necessary to get HIOs going.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

I have a couple of questions about this because I think when we talk about the notion of data—I guess I can think of it on two different levels. I mean, there’s demographic data, and basic patient information that may not be necessarily medical or healthcare in nature. The reason why I bring that up is in the context of our last discussion point which is that if data is going to potentially flow through an HIE—such as from a lab provider or otherwise—it would be good if there was a method to at least have basic demographic data about patients such that when a patient’s information is flowing through an HIE—such as our first discussion—and that patient has already decided to opt in, that that data could be captured by the HIE rather than going to the provider and then having to come back to the HIE, which may or may not happen consistently. Because I know those patients that opt in will often say, “That is something that I find very important and I want to make sure there is complete information in that HIE for me.”

Deven McGraw – Center for Democracy & Technology – Director

Yes, but, John, in this case, we are asking a question about where the opt-in occurs, and in your example, the patients have opted in to their data.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

No, no, no. My point is even if they haven’t, I think there’s a need for some type of demographic data to be stored within the environment so that at least you could decide whether the patient has or has not opted in to decide whether you capture that data as it flows through it.

Deven McGraw – Center for Democracy & Technology – Director

Yes, but I don’t think we’re talking about just demographic data in this triggered circumstance. We’re talking about patient-identifiable health inform— I mean, the trigger has to apply for us to even be having this conversation.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

I was very involved in the New York process, and one of the things that I think is important for this group to consider is just that in the New York approach, there was a very explicit conversation, A, about what state law allowed. So in some ways we’re getting into this issue of are we going to be pre-empting what a particular state says that they believe that their law allows, and that’s fine. But just so that we understand, whereas in Massachusetts, we felt pretty strongly when we went through this consideration in Massachusetts, that the law as far as we could discern required what I think of as ex-ante consent,

meaning the data cannot even be aggregated without having consent. Where here the consent is ex post, meaning that it's applied at the point of accessing the data rather than aggregating it.

In the New York deliberations over this, there was a lot of thought given to this question of control, which we've talked about in other parts of our conversation here with the Tiger Team. That the issue isn't about aggregation per se, because you start to get into all these issues that David is raising about how do we think about the spectrum of aggregation if we have ASP/EHR models, other things. Aggregation happens where you're not asking for patient consent, but the real issue is control at the end of the day, so just wanted everyone to understand that it was really in that context that the New York conversation led to this kind of approach.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think Micky said it well. There are all sorts of aggregations of data that go on. Remote hosted EMRs aggregate a tremendous amount of data, but they do so in a way that preserves control and security. Even though a patient might be surprised to know that their doctor's medical record is on a computer that isn't even under the desk of the doctor, I think they would in fact be comfortable if they explained how that works.

Paul Egerman – eScription – CEO

Yes, but this is not a remote-hosted EMR.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

My point is that at large aggregations of data in a physical facility is commonplace, and we tolerate it as an acceptable risk—

Paul Egerman – eScription – CEO

But depends on ... definition of aggregation is, David. Those EMRs are not aggregating. They're not combining data from multiple sources into a single record.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, they are in the sense that that patient's data is in that building. I mean, what's the difference between a join across databases and a join within databases? If you're the DVA, there's no difference.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I think this is very revealing because we are to a certain extent holding HIOs to a higher standard than we're holding EHR vendors. In both cases, we have two issues to deal with. One is the surprise the patient might find from disclosures that happen according to the rules. The second is the breadth of impact of a breach or some other disclosure that is not according to the rules. Separate issues, separate considerations.

Now, with regards to when you think things are going according to the rules, it seems that—was it ex-ante and ex post or whatever it was—models are essentially the same. However, it is in viewing with the risk that something goes wrong, the impact on public confidence and trust of that happening that I think is of serious concern. We are, in fact, not making any statement about an EHR and we know that some of the very large vendors do this. We're not making any statement about them having all that data in the same center and presumably accessible to a breach as opposed to these are the rules. So we seem to have some difficulty enforcing our theory about the danger of disclosure versus the fact of it, the likelihood of it.

Paul Egerman – eScription – CEO

I don't see the HIO and the EHR thing being the same. I mean, if I run a hosting facility and I'm lucky enough to host 100 EHR customers, I don't make the data available on emergency basis. I don't need to make the data available other than on the direction of my customers.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

That has to do with the situation according to the rules.

Paul Egerman – eScription – CEO

That's according to the rules. You've got a situation in New York that's a little bit different, which is, if I understand it right, Ellen—Ellen's got to tell me if I've got this wrong—they accumulate the data. They will make the data available if there's an emergency condition, which I think they define what an emergency condition is, and they can make the data available for what they consider to be public health reporting, how they define that also. So they're exercising some element of control over when that data's going to be made available.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Then we should be debating over whether that is a wise control, whether those are wise decisions. Not whether the data is in a database or not.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

And we should be debating—

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

We're not debating if it's in a database, though. I think Paul's exactly right.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But, Carol, I thought you were making a strong proposal that we not condone the aggregation of data in an HIE prior to consent.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I made a strong case that says if the only way that a patient's information can be exchanged is to pre-collect it, that that violates our policies. But I agree with Paul. This is not a question of aggregating data or storing it in a database. It's a much more informed view of both the pre-collection, the role of consent, and the subsequent uses or exposures of it.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I don't think I understand the nuance then of— Can you describe how your position would impact the current situation in New York state?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I don't think this is a New York state issue. I think this is more a question of if all of my data is sent somewhere and I have not yet been in to the physician to consent or to understand how it's been shared and that information is inadvertently exposed or breached or inadvertently disclosed or the consent got charted inadvertently from the wrong way or whatever. My ability as a consumer to sort of understand what's happening and to have a say in what's happening is greatly diminished if the consent is kind of after the fact.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I agree with all that, but I don't see how you can do anything but take it to the next step, and that's why I'm asking you to help me understand. The next step being that that should not happen and therefore be

approached in New York and then as far I can see the approach of the centralized EHR, are all out of bounds for you.

Paul Egerman – eScription – CEO

Well, I don't agree with that statement, the last part. You can still do a centralized EHR because I actually have come to the conclusion that there's a lot of reasons why a centralized EHR, a lot of circumstances under which it's a good thing. The issue, though, is when do you send the data to centralized HIO? Do you send it once you've got the patient's consent or do you send it and then ask for patient's consent?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Although I absolutely disagree with ... different, I will back off from ... mentioning the EHR again. The fundamental issue as I understand it is ... accessible or not or under what conditions is it accessible to send the data to an HIO that will retain that data and has the potential for a breach or to make it accessible without the prior consent of the patient.

Paul Egerman – eScription – CEO

To me it's not so much an issue of the breach, although the breach is important. It's also what are they using the data for?

M

That's a separate question.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

But no, we've already agreed that that's off the table. We've already agreed the New York rules—I see. So you're saying that the fact that New York uses it for public health and break the glass is the issue that distinguished New York State, not the fact that it's aggregating it.

Paul Egerman – eScription – CEO

Yes, the way I look at it is if New York was simply acting as a storage facility, in other words if they said, "We'll do off-site storage of your data for you," then I would shrug my shoulders. I would say there's some risk, but all they're doing is storing it. But they're doing something more with the data. That's where it's a trigger.

Deven McGraw – Center for Democracy & Technology – Director

Let's keep in mind that our triggers for consent are all about control of the information, not about the external physical storage issue. It's does the provider still have control of the information. We have said that when the provider doesn't have control, and we've given examples of federated and central HIOs, that those are examples of a loss of control model.

So, going back to Micky's point earlier, the control issue is the key here. What we are talking about in this particular circumstance is assuming the loss of control, consent is triggered. When does that consent get applied and does our recommendation say—we say to the Policy Committee, "We urge you to say that consent apply before the information is released from the control of the provider," versus going from optionality. It doesn't have anything to do with physical storage at all because that's not the direction that we went in and we deliberately tried to save ourselves from getting wrapped into the kind of conundrum that we appear to be getting right back into.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

So I believe that an act by a legislature is a kind of community form of consent. If the legislature says releasing this data for public health purposes is acceptable or required, it is acceptable or required. I

believe that the discussion that we need to have is in the absence of law for the jurisdiction in question, what should be the approach that's taken up? Does that make sense?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

But, Wes, the only thing I would say is the releasing it for public health purposes doesn't necessarily have to happen through an HIO or through a pre-aggregation by an HIO.

Joy Pritts – ONC – Chief Privacy Officer

I'm a little concerned about the voice approach given the existing framework with HIPAA and HITECH, which is that a federal law preempts less stringent state law except in certain areas. And so what you just voiced may be the opposite.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

What do you mean?

Joy Pritts – ONC – Chief Privacy Officer

Well, what Wes—I think it was Wes—just proposed was that if state law allows something that your policy would not allow, then the state law would stand. But that's kind of back—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Let me amend that. All laws applicable to jurisdiction, wherever they were passed, are laws that we cannot pass policy that overrides them. Now how those laws are interpreted when they're conflicted is a matter for how the laws are constructed in the courts, not for us.

The question I think we need to ask is in the absence of law, what should be done? Or, if we want to make recommendations to the Policy Committee that there be longer term changes to the law, I guess that's within our power too. But fundamentally what I'm trying to say is in New York State, Micky said there was a close examination of the law, in both Massachusetts and New York State that led to different conclusions. And then I have to say, Carol has said you could interpret the requirements to release information as not requiring an HIO, not requiring that the data be aggregated with the HIO. I guess that depends what you mean by public health. If you mean the specific disclosures that are typically mandated for infectious diseases and certain other diseases, I think that's true. If you mean the Minnesota Law, then I think it's different.

Paul Eggerman – eScription – CEO

Yes, I think you have some good comments though, Wes. The way I look at this if New York or any state passed a law that said it was mandatory that providers send this information to the HIO, then I would say in my amateurish view, is if there's a law passed by a legislature, there's a public debate on it, well that's like patients gave consent. That's—

Gayle Harrell – Florida – Former State Legislator

I'd like to get into this argument a little bit too. I think certainly as you know I'm a big proponent of the 10th Amendment, and I think states do have the ability to write specific laws that say how things in their state will happen, as long as it is not in conflict with a federal law. We do have preemption in some areas where federal—their constitution, of course, takes precedence.

However, I think, at the national level and the policy levers that ONC has and the way money is directed needs to be considered here. When we're talking about something as important as privacy and security, I think ONC and we as the policy committee have the distinct responsibility to make recommendations that

take into consideration those fundamental, foundational privacy elements that are guaranteed by the constitution, which does preempt, especially on privacy issues, state law.

Joy Pritts – ONC – Chief Privacy Officer

There are a number of issues that were raised in this last discussion that I think it might be helpful to have a little bit more clarification as to how this interacts with current federal law. One is under the current paradigm of HIPAA, whenever a state law mandates some sort of exchange of information—if it's required by law—that is one of the exceptions to the privacy rule, right? So, a provider may make a disclosure without the individual's permission when doing so is required by another law. Okay? There's one concept there.

The other concept, which would require much longer discussion, is that HIPAA has a general carve-out for public health purposes at the statutory level and a very detailed one at the regulatory level. So when you start getting into the area of either voluntary reporting or disclosure of information for public health purposes, it's a little different than the discussion that surrounds disclosing information for treatment purposes.

Deven McGraw – Center for Democracy & Technology – Director

Well that's right, but keep in mind that our particular frame for this set of recommendations is stage one of meaningful use, which, in the public health arena are the mandated reports.

Paul Egerman – eScription – CEO

Right, I think to sort of refocus this discussion, as you said, Deven, earlier, the trigger is all about the circumstances under which a provider gives up control of the record or control of access to that record. That's what the trigger is for the consent. So to me, the issue is if you don't give consent, what that ought to mean is that the provider retains control over that record or over that future access to that record. That's what it ought to mean, and so what it should mean is that if you don't give consent, the provider has to retain that control; that somebody else can't have that control. In the New York model, unfortunately, even though it's an emergency situation, there are circumstances under which the providers no longer have control.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I agree. I would also remind us that in all security is a matter of risk management and if you think about the risk here that as Wes brought up, the breadth of the impact here, should there be a disclosure there, is huge, and should they make the wrong decision or whatever, is very large. I would also point out that if you think about what is required to enable a healthcare provider to not disclose it until they get consent, it's not a tough technical problem to include a rule in your rule base that say the consent has to be there before this information flows. I agree with Paul. I think it should not flow until they have the patient—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I'm getting a little frustrated here because I hear one issue alternately being said is on the table and isn't on the table, and that issue has anything to do with the risk of breach. I think I hear pretty clearly from Deven and Paul that we understand there is a risk of breach. We are not concerned to use that as a basis to setting policy for what data is retained in an HIO or not.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

That's why I added the second point.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

For what data is accessible from an HIO without prior consent. So, I understand—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

We are concerned about what control that HIO can exercise, which is the second—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I understand that we are discussing the policy issue of whether HIOs should be able to release data without patient's consent serious. We're not concerned about whether collecting the data creates technological risks associated with aggregation because I'm kind of arguing both sides of this because I'm getting mixed signals on what we're ... here.

Paul Egerman – eScription – CEO

Well, Wes, the reason I'm framing the discussion this way is I'm trying to frame it as it relates to the trigger situation. The argument that I'm trying to make is if this is just an organization that offers offsite storage as a value added function, that should require consent from a patient, and we could argue whether or not that that's a smart thing for a physician or provider to do, but that's not necessarily relevant. It's really what happens to the data because that's what our trigger was all about.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

So do we really need to more specifically define control than we have up until now? That's what it seems like the issue is revolving around because I agree with Wes. I think we're jumping issues and what we don't want to be straying into is this question of technological risk because this is really just about the control question, not about that.

Paul Egerman – eScription – CEO

Yes, and also technological risk is hard to evaluate because I'm sure the people in New York are doing an excellent job and they probably, in many cases, do a better job than the providers are doing.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

So if, for example, the New York policy—and I forget what the details are on what a patient is allowed to give consent about with respect to accessing for break the glass, for example—but if it was that there was no other use permitted without consent except for required public health reporting, which a provider is required to do anyway regardless of whether the HIO or RHIO is doing it for them, or they themselves were doing it directly to the department of public health, presumably you would feel comfortable with that, right?

Paul Egerman – eScription – CEO

That's right.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But you'd carve out several other things too like state—fraud and abuse, monitoring and other things that are allowed, but I agree with that principal. I want to come back to the provider control question and suggest that I think that is really the issue. It's pretty subtle because what the provider really has is responsibility to implement the patient's wishes with respect to the exposure of the data, so it's the patient who has the control decision, and the provider has responsibility to implement that. Now, maybe we don't want to get into that subtlety, but—

Deven McGraw – Center for Democracy & Technology – Director

Yes, and I actually disagree with the premise, David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Okay.

Deven McGraw – Center for Democracy & Technology – Director

That the patient controls the data.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Controls the decision of access to the data outside of the care process.

Deven McGraw – Center for Democracy & Technology – Director

Yes, but we're in the care process. We're in the realm of only stage one exchange for which the major clinical purpose for exchange is treatment.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So, just a thought experiment. If, in a situation like New York, the data has been pre-aggregated, or, I don't like that term, but it has been gathered, and the patient, the consumer contacts the HIO and says, "I give you consent to share my data," does it happen or not? No provider action occurred there. Are we saying that's not allowed? Are we saying that a health bank or a—?

Deven McGraw – Center for Democracy & Technology – Director

No, no, no. We're not saying that's not allowed at all, but it's not the question on the table.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But what that does is it frames it such that the question of when the data flowed, did that somehow transfer responsibility for control? So, I'm just begging the question that it isn't really—it's the consumers intent or wishes for the sharing of the data that really matters outside of the EHR where the provider has the legal mandate to maintain that EHR. It seems like if we say— Well, I'm going to get tongue-twisted, so let me stop talking. It occurred to me that if the consumer releases the data, that could happen without an express permission of the provider under a variety of circumstances, which I think we would all be quite comfortable with.

Deven McGraw – Center for Democracy & Technology – Director

Well, that's absolutely right, but all of this comes up in the context of when, where otherwise provider would be in control of the decision making. When the provider releases that control, we are actually inserting the patient into the equation, and I'm just wondering whether we ought to maybe make this paragraph clear and true to the control model, which is the trigger for consent, by stating that the patient must have an opportunity to give consent before the control is released.

Paul Egerman – eScription – CEO

That's correct. I think if we did it that way, that clarifies things a little bit.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I like that. I think that's the intent of the language, but that's a better way to express it.

Paul Egerman – eScription – CEO

Yes, and I'm just curious—I don't want to put you on the spot if you're still on the call, Ellen—do you have any observations about this situation? What we're talking about?

Ellen Flink – NYS DOH OHITT – Director Research, Patient Safety & Quality

I do and I've been on mute because I don't want to have background noise. But again, I understand and I think that I outlined to you, Paul, some scenarios in which case if under some circumstances, if a provider

has to obtain consent from a patient in order to allow information to flow into the HIO, then that process can take a number of years because it means that a patient, all of the various providers that they see, would have to give consent in order for that information to be aggregated. The reason, again, that we have the model in New York is because we felt that we wanted the information to be accessible for mandated public health reporting in the event of the medical emergency, where that information could be made available in aggregate form and we don't take this lightly. As Micky outlined, we have the full ... of privacy and security policies in place that surround the health information exchange, so we don't really feel that— We're taking appropriate precautions to prevent breach and exposure for other purposes and so forth.

I mean, this process that we've implemented in New York is really focused around treatment purposes and quality improvement care management purposes. So, again, it's a different way of looking at it and we've debated it in New York for a few years and there was much, much discussion and we didn't take it lightly. But the reason why we went with this model was because we felt that it was important to be able to create a system for facilitating health information exchange while still considering a patient's privacy and security and the ability to consent to having their information be accessed in this aggregate form through an HIO.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

Just for clarification question because I just can't remember, and I think it might help the Tiger Team in our deliberations here about how we think about this issue of control and how to define it. What accesses of information are allowed in the New York model without patient consent?

Ellen Flink – NYS DOH OHITT – Director Research, Patient Safety & Quality

In the event of a medical emergency, a provider who is treating a patient can so-called break the glass and they would have access to that information. There's an audit trail that follows it and so forth, so it's not like just anybody can do that.

And then for the purpose of mandated public health reporting, say you wanted to do— Take the H1N1 reporting, okay? Instead of each hospital having to build an interface to have that information flow to the Department of Health on the number of cases of H1N1 or any other disease outbreak or whatever, the idea would be that this information, you could build one interface through the HIO, and that way that information would flow from various hospitals through the HIO to the Department of Public Health.

It's just a different route of a way the information flows but if you tried to obtain consent from a patient first before that information was able to be so-called ready to be accessed through an HIO, then you would not have a complete data set. You wouldn't have all of the information from all of the patients, and therefore, it's not a reliable way to make sure that you're having complete public health reporting.

Paul Egerman – eScripton – CEO

In reading the material, Ellen, I got the sense there's a few other accesses to the record. For example, when you do a name look-up, all names, addresses, last four digits of social security numbers are exposed during any name look-up. Is that correct?

Ellen Flink – NYS DOH OHITT – Director Research, Patient Safety & Quality

That's correct.

Paul Egerman – eScripton – CEO

So there are other accesses. It also said that you keep statistics on internal operations of the HIOs. I don't know if that's just counts, but there were a few others that were written down.

Ellen Flink – NYS DOH OHITT – Director Research, Patient Safety & Quality

I mean, it ... comes under healthcare operations and the ability of the HIO to assure that their systems that are in place for accessing information and purposes and uses are validation of that process. That's essentially what that is.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Ellen, you said that in this way you can assure that you have a representative sampling across the whole state. Does New York require that physicians be part of this exchange?

Ellen Flink – NYS DOH OHITT – Director Research, Patient Safety & Quality

Not at this point, Dixie. We're still trying build the pipe for this system and we have some operational RHIOs. We have a number of participating providers in those RHIOs, but it's not completely across the state at this point in time.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I also question the physicians don't even have the information other than demographic information and the appointment information before they've seen the patient, which seems to me like you would at least have had the opportunity to get that patient's consent before the information was sent. Is that incorrect somehow?

Ellen Flink – NYS DOH OHITT – Director Research, Patient Safety & Quality

Well, that provider can't access that information until they have the patient's consent and they have an established relationship with that patient.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Well, what kind of information do they send, is what I'm saying. What kind of information do they have before they've seen the patient and have the opportunity to ask for their consent?

Ellen Flink – NYS DOH OHITT – Director Research, Patient Safety & Quality

They don't have any information about that patient, other than what they might have in their own office.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

Right, I think that's a great point, Dixie. That this ex-ante/ex post distinction as a practical matter is much less salient when you think about the fact that a lot of physicians aren't going to have electronic documentation. So I think it applies mostly to hospitals where there is a store of information going back over time that could be made available immediately as soon as the health information organization stands up with operations.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

I will tell you that one of the things I hear consistently within my own organization regarding physician access to data is that there's a great desire and need to have access to patient data before they ever see the patient if in fact they know there's going to be either an office visit or a consultation's being asked of them.

Deven McGraw – Center for Democracy & Technology – Director

Well, that's right, and that's the reason why the original HIPAA rule that required consent for treatment, it's one of the reasons why the Office of Civil Rights changed it in 2002 was to enable providers to gather information in advance of the visit. But, we are talking about in a directed exchange model that is not

precluded. You could do so, it's just that the providers maintain control over decisions to release information from their records.

So, I'm going to back to my earlier suggestion, which at least some folks agreed with, which is to keep this document internally consistent, the consent should apply, in our recommendations, before the control is released and worry less about the sort of storage functionality issues that seem a bit more reflected in the current language. Ultimately I think that this is likely also going to be a discussion at the Policy Committee level. I think one of the circumstances we're running into is that we're addressing a set of policy considerations after many states have gotten out ahead and put some infrastructure in place. Ultimately I think there are some choices that ONC is going to have to make with respect to its policy levers but my own opinion is that our Tiger Team recommendations ought to be internally consistent.

Paul Egerman – eScripton – CEO

Yes, I think that last point, Deven, is really an excellent point. I think a lot of discussion is because there are some models that have already started. In particular, we think the people in New York have done really great work and we don't want to mess up what they've done, but if we had had this discussion before the New York HIO was put into operation, then I think it would've been a shorter discussion.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

I agree with the phrasing that you're talking about. I wonder whether we need to—maybe it's already done and I just don't remember where it is in the rest of the document—define control more precisely than we have up until now.

Paul Egerman – eScripton – CEO

Yes, we should just define it the same way we did it for the triggers.

Deven McGraw – Center for Democracy & Technology – Director

Well, I mean, what do mean by a definition of control? I mean, it's—

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

Yes, let me give you a specific example. It seems that the areas where we feel some discomfort around with the New York model are the break the glass, right? That that seems to be a giving up of control in that model that I'm sensing that a number of members of the Tiger Team here feel uncomfortable with. I'm just wondering in the current world, let's just say there is a medical emergency and an emergency department calls the primary care physician, and says, "There's a medical emergency. The patient's unconscious. We need to know what medications they're on." In that model, what does the physician do?

Deven McGraw – Center for Democracy & Technology – Director

The physician makes a judgment call about whether or not to disclose. The physician has the control of disclosures from the record to do that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

And it's a directed exchange.

Deven McGraw – Center for Democracy & Technology – Director

Yes. So control really, to the extent that we've defined it at all, it's who decides? Is it the physician that you have the trust relationship with or is it another entity that you may or may not know?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I like the wording, Deven. The only additional comment I would make is in the paragraph that you have displayed, I would make the first sentence and the last sentence consistent because they aren't right now. One's an opportunity to give and the other said obtain but I like the changes of the wording to control.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Just back on, Paul, on your former comment, I think New York State has put this issue in front of us in a very clear way, but I do think there are other up and running HIEs that pre-copy the data, so it's not just New York State—

Deven McGraw – Center for Democracy & Technology – Director

No, I think that's right. I think that's right. We've had the advantage of having folks from New York on our calls to be able to give us a lot of detail about what's going on in that model, and also having Micky knowing both New York and Massachusetts really well. But that doesn't mean that there aren't a host of models out there, some of which are talked about in that consent paper that Dixie mentioned the other day, that ONC commissioned and that is publicly available, and that we've had some discussion about in the past.

So, we recognize these recommendations are coming at a time when in some parts of the country, the environment is already robustly moving forward. Again, I reiterate that I think at least with respect to our recommendations, which are based on control, they ought to be internally consistent.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Agreed.

Deven McGraw – Center for Democracy & Technology – Director

It doesn't mean that there aren't questions that are going to need to be resolved. That to me is an implementation issue.

Paul Egerman – eScription – CEO

That's right. There could be a glide path to existing systems too.

Deven McGraw – Center for Democracy & Technology – Director

Should we move on?

Paul Egerman – eScription – CEO

I think so. Is everyone ready to move on?

Deven McGraw – Center for Democracy & Technology – Director

Okay.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

Paul Egerman – eScription – CEO

So our next issue is the sensitive data issue and basically I don't think there's necessarily anything new here except for the fact that it's all new. In other words, this is the first time we wrote it all down. And what happened here, Deven tried to summarize the information that we heard in the hearing, that basically what we said is, we said that the technology that exists right now for granular patient consent is promising but it's in an early stage of development. Then we basically said that there is a scenario that should be a priority for ONC to explore further, and basically it also says to find evidence for models that

have been implemented successfully. Christine sent an important message that says prior to this process, perhaps ONC should be doing some piloting, but the emphasis is to make sure that we don't just do theoretical things; that we look to see how these things operate in actual practice.

Deven McGraw – Center for Democracy & Technology – Director

Yes, and that's something that actually did come up on our call that I just had forgotten to weave in, so we definitely want to include the pilots in the recommendation.

Paul Egerman – eScription – CEO

So the question here for the team is to make sure that this—because in one sense, Deven didn't put it in yellow because it'd be like three pages in yellow, so it might look a little annoying. But this is new. We want to make sure people thought that this was right and they were comfortable with it.

Deven McGraw – Center for Democracy & Technology – Director

Yes, I can't quite fit all of the recommendations on our screen. The fourth prong deals with the issue of patient education and patients sort of understanding the extent to which their requests can be honored and the setting of realistic expectations, which is something that we did have a fair amount of comment on. This is another section, I mean, again, what I'm displaying on the screen right now is the actual recommendation language, which is bolded. It's Tiger Team recommendation number four. There's a lot of explanatory material up in the front—more so than is the case for our other recommendations—but that's in part reflective of the fact that we did have a fair amount of discussion about what we had seen and heard in the consent technology hearing. We thought that it was important to include more of that and to really do justice to this topic, since it's one that is quite complex, I think.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I'll kind of kick off the conversation here. The only recommendation I made with respect to this section is that it seemed to read to me like we were hardly endorsing granular consent. I felt that we should capture some of our considerations and concerns that we have discussed in the past, such as the implications for quality care and the need to educate patients on how to do it and the technology implications, implications on safety, those kind of things. I gave you some suggested words, but I suggest we capture this in both the second bullet, and I think the fourth bullet. In particular that ONC should really study the full gamut of issues around granular consent.

Deven McGraw – Center for Democracy & Technology – Director

Right, the full implications for quality of care and patient safety, operation implications— Yes, that was helpful, Dixie.

Gayle Harrell – Florida – Former State Legislator

I think it's very important that ONC play a role in making sure patients understand the extent to which their request for granularity can indeed be accomplished. The legislation required it and if we read the law as it was passed, it's indicated that patients would have that ability and there would be granularity. But from a technology point of view, that's problematic, and patients need to know that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Well, Gayle, the law didn't say how segmentation was to do nor how it would be done, nor how granular the control needs to be. I think that those are the issues that I think ONC really needs to look at.

Gayle Harrell – Florida – Former State Legislator

Absolutely, I agree with you 100%. Patients read it one way, the public reads it one way, and the technology is not there. How they interpret it versus how we understand things can happen is very different.

Deven McGraw – Center for Democracy & Technology – Director

Yes indeed. Good point.

Paul Egerman – eScription – CEO

I don't know if you're still on the call, John. I had a question for you. Is this consistent with what MCVHS is recommending also in terms of like further study?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Well, again, MCVHS has tried to be fairly mechanical in its recommendations it's coming up with, which is let's just very clearly try to describe what are categories of sensitive information. What makes them sensitive, and what parts of it are sensitive? So in theory, they should plug into, I think, what you're proposing, from my perspective.

Paul Egerman – eScription – CEO

So to ask my question differently or say it differently, is anything that we're doing here inconsistent with what MCVHS is saying?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Not that I have read.

Deven McGraw – Center for Democracy & Technology – Director

Yes, I didn't think so either. I mean, not being from MCVHS, but certainly in terms of writing this letter or even in our discussions, I thought we were sort of going along two related but slightly different pathways.

Paul Egerman – eScription – CEO

Yes, I think that's right, although my impression is MCVHS is going to come up with some new letter in another month or so.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Right, but the point that I'm trying to make though is our new letter that we're coming up with I wanted to steer clear of this discussion of technologies, the support, sensitive information. But rather again, if we tell people what the sensitive information categories are, and what parts of them are sensitive, then somebody could take model, what you're proposing in terms of granular consents, overlay a technology on top of both of them, and end up with something that works together.

Paul Egerman – eScription – CEO

Yes. Based on some study and research and piloting, stuff like that.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

I think the biggest issue is going to be— I mean, there's a couple of areas of issue that I think we're going to find. One is how do you deal with information that is non-structured? And then how are going to deal with different parts of an encounter that might be sensitive, yet aren't in themselves sensitive? So, if a drug is prescribed that has multiple uses and if that patient is treated for something entirely different, what's our proposal with regards to the sensitivity of that particular drug? That's where I think the technology and the consent's going to have to wrap around some of this.

Paul Egerman – eScription – CEO

Does that make sense along with the issue that Christine and other people raised, which is basically going to be what's the user interface? How usable is this going to be for patients to be able to do this and to make this all work right?

Deven McGraw – Center for Democracy & Technology – Director

Or usable for both patients and providers.

Paul Egerman – eScription – CEO

And providers, right, to make sure ... for a lot of reasons.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

I think this also comes back to the discussion about fair information practices because I think patients are very conservative as to when they get into these sensitive encounters, what information they want to have released. Yet, at the same time, you hear from providers very clearly that a lot of that information that's part of the sensitive encounter's absolutely vital to other encounters that are non-sensitive in nature. So, I think fair information practice is also going to have to be a part of this as well.

Paul Egerman – eScription – CEO

Makes sense.

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

So, are there other comments though about what's written here? Are people okay with the way this was approached?

Deven McGraw – Center for Democracy & Technology – Director

Yes, I mean we have some modifications that we'll make that we talked about on the call.

Paul Egerman – eScription – CEO

Yes.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Can you scroll down to the bottom bullet again?

Deven McGraw – Center for Democracy & Technology – Director

Yes. Sorry.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

And that last bullet again, back to the fair information practices, I think you might want to explicitly state that since you do talk about fair information practices by name.

Paul Egerman – eScription – CEO

Where? In the last bullet?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Yes, you talk about patient education. You might want to say education. I don't know how you want to incorporate that, but it might be good to do that.

Deven McGraw – Center for Democracy & Technology – Director

Okay. Which ... are you thinking about in particular? I'm not sure I understand the context.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

In the interim, it says situations where ... of capabilities are being developed and not uniformly ... patient education is paramount. ... weave in the fact that regardless, fair information practice is important.

Deven McGraw – Center for Democracy & Technology – Director

Oh, well yes. I mean, it's overarching through the whole letter.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Right, but I think again, incorporate it back into that because you talk about patient education. It might just be good to reinforce that. That's my only point.

Deven McGraw – Center for Democracy & Technology – Director

Okay. I never disagree with reiterating FIPS.

Paul Egerman – eScription – CEO

Are there any other comments though about the sensitive information? The way we've presented it? What is written on the screen? What was in the letter? I'm hearing silence to indicate either people are starting to get tired or they're okay with it.

Deven McGraw – Center for Democracy & Technology – Director

I think we're good.

Paul Egerman – eScription – CEO

I think we captured it. So that's great. So we went through the three different issues that we wanted to raise, specifically in this call, but this is also a call for if you have any other issues you want to discuss from the letter or if you've had a chance to look at this letter as a whole, if you have any reactions to it.

Deven McGraw – Center for Democracy & Technology – Director

Dixie, you had one comment about moving the meaningful consent piece above the trigger. My gut reaction to that was I think you have to talk about when consent would be required before you can talk about what it's components would be to be meaningful. I just—

Paul Egerman – eScription – CEO

Yes, I agree.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I'll leave it up to you. I noticed you added a whole paragraph that seemed to be attempting to establish the context, right, of this is meaningful consent, right? And I thought, "Well, we could just move that up so that you wouldn't need that introductory paragraph."

Deven McGraw – Center for Democracy & Technology – Director

Right, which I understood that, but I feared that without laying out the context in which we were saying consent ought to be required, it made less sense and people might think we were saying that we were making some recommendations about consent that were going beyond the trigger factors.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Oh, okay, whatever you decide is fine.

Deven McGraw – Center for Democracy & Technology – Director

Okay. I didn't want you to think I hadn't seen it, and since it was an overarching recommendation, I wanted to bring it up.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

That was the only other comment. I thought you guys did a great job of putting this together.

Paul Egerman – eScription – CEO

So, let me first ask, does anybody have any topics? We raised these three issues. Are there any other topics that people want to discuss from this letter?

Judy Faulkner – Epic Systems – Founder

I'm not at my office, I'm in the far north, and I'm listening to this via the computer which means I'm a couple of seconds off. So if I'm a little delayed now and then, that's the reason.

A couple of things I had. One was on page nine, this is just a question for you, Deven and Paul. It says, "What has been customary practice." ... was just a little bit behind, but it was just a little hard for me to get the phone. You have that explanation below that says, "Customary practices apply to paper or fax." I'm assuming that explanation goes with the recommendation so that people can see that. Is that correct?

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Judy Faulkner – Epic Systems – Founder

Okay. So, don't need to elaborate on that. Then the one on page 11, the second bullet on patient's consent meaningful, is not compelled or used for discriminatory purposes. E.g. isn't a condition of receiving medical services or benefits. I think that's something I don't understand because we have talked about situations where that's the way the healthcare organization works, and if the patient isn't able to feel comfortable with that, then that patient might not be able to get services that way. I guess I don't understand how those two go together.

Deven McGraw – Center for Democracy & Technology – Director

So this is only in circumstances where there's a trigger, where we deliberately— The examples are when the provider loses control of the record and it doesn't include circumstances like an organized healthcare arrangement. So, this is when the consent applies, which is with respect to federated or centralized HIOs where the provider loses control over decision making or the control is out of the decision making capacity of either the provider or the provider's organized healthcare arrangement. So we were deliberately making a distinction between HIO-type models and models where there's an organized healthcare arrangement where the care is delivered. And the consent is triggered in the federated and centralized HIOs, not in the case of the former. So this meaningful consent piece is about when your information is out of the control of your provider and in the control of another entity like an HIO.

Judy Faulkner – Epic Systems – Founder

So I guess my question with that is—because I don't know, maybe Wes does or someone—are there circumstances under which the healthcare organization, even though it's no longer under their control, still needs certain things to be done in order to take care of the patient properly and this will get in their way? That's the question I didn't know the answer to.

Deven McGraw – Center for Democracy & Technology – Director

I think we're assuming no, in part because we also started this call with a discussion about how if a patient says no to a triggered consent situation—no, I don't want my information to be in the control of the HIO—then the provider still can exchange it in a directed controlled manner.

Judy Faulkner – Epic Systems – Founder

Which could be paper.

Deven McGraw – Center for Democracy & Technology – Director

Well, paper, no. It's still electronic. It's just they have to do so in a way that they control the decision to disclose. It's not an issue of electronic or paper.

Judy Faulkner – Epic Systems – Founder

So, if in fact what they're doing—and maybe this is New York, maybe this is somewhere else—is not going through directed exchange but are using other organizations and facilities to do that. Is there no situation where they don't have the patient's consent but that is how they need to do it in order to do their work? That's kind of my question.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I flagged that bullet point as well with just a question mark. I think I probably had the same question as Judy. I believe there are organizations that would flunk this test, or at least would not be in the spirit of what you're trying to capture here.

Deven McGraw – Center for Democracy & Technology – Director

Right, but on the other hand, this may be another one of those implementation issues because it's very hard to say that consent is meaningful if patients really actually don't have a choice. And ideally when there's a role for the patient to be able to have some choice over whether their records are or are not part of a particular infrastructure, if it can't be made in a meaningful way, then there's no point in having it.

Judy Faulkner – Epic Systems – Founder

Sometimes, and I remember it in an earlier time, we had said it just may simply be that the healthcare organization can't take care of the patient then.

Deven McGraw – Center for Democracy & Technology – Director

Well, that's right, but that's exactly why we had a lot of discussion about making sure that we were not saying that in organized healthcare delivery arrangements that that's the consent trigger.

Judy Faulkner – Epic Systems – Founder

Yes, but this isn't—

Deven McGraw – Center for Democracy & Technology – Director

...be the provider or the provider's organized healthcare arrangement, in control of that record.

Judy Faulkner – Epic Systems – Founder

So you're saying that, and maybe I'm exaggerating this, Deven, but is the only case in which the healthcare organization can turn down a patient is the ORCA, and for other ways that they do things, they can't turn down patients even if they don't have the technology to do it in a different way and get their work done. That's my concern underneath it.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

It does raise if an organization can simply ignore these principles by saying this is the way we do business, then why are we making the principles?

Judy Faulkner – Epic Systems – Founder

That's kind of what I'm saying.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So, but that would preclude the whole output of the Tiger Team, I think.

Deven McGraw – Center for Democracy & Technology – Director

I think so too.

Paul Egerman – eScription – CEO

I'm listening to this and I'm also wondering if the example's not quite as strong as the first statement? Says it's not compelled or used for discriminatory purposes. That's a very strong statement. Then when you say it's not a condition of receiving services or benefits, first of all, I guess I haven't really thought about this. I'm not sure what benefits has to do with this if you're talking about payment or from insurance companies.

Deven McGraw – Center for Democracy & Technology – Director

Alright. Well, that's fair.

Paul Egerman – eScription – CEO

And then, receiving medical services ... the observation is there's a range as to whether or not it's necessarily compelled, or if—I don't know—I'm going in for like an annual physical. I'm an otherwise healthy person. I have a lot more options available to me than if I'm showing up in the emergency room with chest pain. I don't know if that's causing your problem, Judy because at first part, I think, is fine.

Judy Faulkner – Epic Systems – Founder

The first part is fine.

Paul Egerman – eScription – CEO

We're not trying to force somebody to sign something. I think the second part is what's creating your problem. To me there's a little bit of a

Judy Faulkner – Epic Systems – Founder

Yes, it goes beyond ORCA.

Paul Egerman – eScription – CEO

It does, and maybe the real issue is we need to fix the example a little bit. In other words, consent is not—I don't know.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Isn't refusal to treat in exchange for consent the classic example of coerced consent?

Deven McGraw – Center for Democracy & Technology – Director

Yes.

Paul Egerman – eScription – CEO

Well, no. If you have a surgical procedure, you have to sign something called informed consent. I mean, I just—

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

But ALA prevents you from not being able to at least stabilize a patient, even before consent is provided. So, having compelled consent is not really germane, I don't think, in this regard.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, let's say it's not an emergency situation. I mean there are edge cases that we cover with our caveats about emergencies. It's routine care. Are we saying that it's completely okay and that it's considered meaningful consent if the provider says, "I must share this data or I can't treat you?"

Judy Faulkner – Epic Systems – Founder

I'm not sure ... ORACA but with others too.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, I'm saying not in ORCA, you know a broader community-based sharing.

Deven McGraw – Center for Democracy & Technology – Director

But if ... the provider is, "I share the data," meaning, I'm in control of the data-sharing.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Well, but he said, "I will not treat you unless you let me share the data."

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

But in a non-emergent circumstance, what's wrong with a provider that says that?

Judy Faulkner – Epic Systems – Founder

Because it says the patient's consent must be meaningful and it is not a condition of receiving medical services.

Deven McGraw – Center for Democracy & Technology – Director

All of your examples are of directed exchange, where we're not requiring—

Judy Faulkner – Epic Systems – Founder

No, that's not the case at all.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

We're thinking of an indirect exchange, a centralized, aggregating copy, that's not an ORCA. It's an existing—

Deven McGraw – Center for Democracy & Technology – Director

What's an ORCA? There's no r. It's an OCA.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

OCA. Sorry.

Judy Faulkner – Epic Systems – Founder

An orca's a fish.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

An OCA. Okra.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

It makes it cuter.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

It does.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

It's actually a mammal, not a fish.

Judy Faulkner – Epic Systems – Founder

I knew that was coming.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

It's something that swims in the ocean or in a big tub where they have people watching.

Judy Faulkner – Epic Systems – Founder

Yes, we happen to have a big blown up one right here where I am.

Deven McGraw – Center for Democracy & Technology – Director

So, doctor has electronic—this gets back to— I guess I'm confused then about why everyone was so on board with this idea that, okay, in an centralized or federated HIO model, we've said that consent is triggered, right? So, one could presume that in some circumstances, there's going to be a patient who says no, and we've said in those circumstances that the provider, who by the way has an electronic medical record, and send it in ways that are under his control.

Now whether that's in paper or electronic is of no consequence. But presumably, they have other options. Otherwise, I think it would be ridiculous to make that point. So what we're saying here is that in the case of a patient's not consenting to an HIO when in fact there still is a way to share information, we're not comfortable with the idea that doctors shouldn't be able to turn to patients and say, "Well, then I'm not going to treat you."

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

Maybe I'm missing it, but, Deven, there's other models for which data could end up being shared ... even a misnomer. There's the idea of community records where the physician contributes to the community record and that's all there is. Maybe I'm misunderstanding your example, but—

Deven McGraw – Center for Democracy & Technology -- Director

The community record example was one that we deliberately tried to carve out of the consent trigger, I thought.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That's by abusing of the OCA.

Judy Faulkner – Epic Systems – Founder

I think you did carve that out.

Deven McGraw – Center for Democracy & Technology -- Director

OCA or the ORCA, so—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes.

Judy Faulkner – Epic Systems – Founder

That's why I'm asking the question, which is I have a situation where it is not directed exchange. I need stuff to go all over the place for lab, for billing, for other purposes, and in some cases it may go to some place where my patient's brother-in-law works, and I as the provider organization am saying, "This is what you have to live with. It goes there." Maybe my examples aren't right. Sometimes I'm afraid that we'll run into things later on that are really going to harm us and this one is one that worries me.

Paul Egerman – eScription – CEO

Would you feel better, Judy, if we got rid of the example? If it just said—

Judy Faulkner – Epic Systems – Founder

I think getting rid of the example is really good because I absolutely agree with it can't be used for discriminatory purposes.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

I don't like the idea that the word compelled, now that I look at this—

Judy Faulkner – Epic Systems – Founder

Well, that was going to be my second thing because I don't know how the "or" is used. It's not compelled can be separated from or used for discriminatory purposes. It may be compelled, but it's compelled for discriminatory purposes, our English isn't making it clear how that sentence words.

Paul Egerman – eScription – CEO

Is Carol on the phone? Carol Diamond?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. I'm here.

Paul Egerman – eScription – CEO

Yes, I mean, since a lot of this came from our call, I'm curious. Do you have a reaction to what Judy is saying?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I'm really lost in this discussion and I'm going to go back to the question that somebody asked five minutes ago, which is are we saying that in the situation where consent is triggered, that it is meaningful to have consent where you say to the patient, "If you don't consent, I won't treat you."

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I agree. That's the question. I was the one who asked it.

Deven McGraw – Center for Democracy & Technology -- Director

And that is not meaningful consent.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

No.

Judy Faulkner – Epic Systems – Founder

No, but we have specifically said earlier that some organizations are going to say, “This is the way we work,” and that is allowed to be said.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

The bottom line is, is for a very large organization like where I work for, we can’t afford to be changing consents because then we ... honor them.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, but one more time, we’re not talking about large organizations or OCAs or integrated delivery models or any of those things, right?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

Sure you are.

Deven McGraw – Center for Democracy & Technology -- Director

No, we are not. They’re not triggers.

Judy Faulkner – Epic Systems – Founder

I agree with you ... not, but that’s where I’m asking folks, are there situations where this is the way an organization works? It’s not an OCA, it’s not a community shared record, but there are ways that they do their work that are going to require this consent and the patient doesn’t give it and they can’t work otherwise. That’s a risk we have.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

Large and small, us large organizations are going to be parts of HIEs and other things and frankly, I don’t know how we do vary consent and then— I’m just concerned about that.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

So what does meaningful consent mean if it’s not really a choice?

Deven McGraw – Center for Democracy & Technology -- Director

Right.

Judy Faulkner – Epic Systems – Founder

Well, I think meaningful consent means that you understand what you’re consenting to. It doesn’t mean that they have to treat you if you consent. It means that you understand what your consent is.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

If you choose not to, you choose not to. You go somewhere else.

Deven McGraw – Center for Democracy & Technology -- Director

Correct and that’s what we’re defining is what meaningful consent is. It is not what we have said. So these are the definitions of what it is not.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, I also want to remind everybody that the consent in this situation is not similar to, maybe, other situations in your life where you have choices about going somewhere else or you’re not sick and scared. I just think that we have to get used to the fact that the patient has to have the ability to say, in these

trigger situations where we are not talking about OCAs or integrated delivery models, where the patient has to have the ability to say, "I don't want that. I have certain things about my life that make me sensitive to this and I don't want that to be done."

Judy Faulkner – Epic Systems – Founder

Then my question to that is for some organizations, is that simply going to be the way they work and they can't live with that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Well, I think that the point that Deven was made is really critical here, is they would always have the option of a directed exchange. So even if you're in that kind of an organization, you could always do directed exchange.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think there are organizations where that's just not allowed for the provider. Their system doesn't give them that degree of control.

Paul Egerman – eScription – CEO

I'm not sure that's right, David. ... define provider at an entity level. So, it's not like you can go to UPNC and say, "I want this thing to work differently with one doctor versus another doctor." UPNC gives consent for all of UPNC, one way or the other.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

It becomes impossible to vary—

Paul Egerman – eScription – CEO

Yes. I view UPNC, for example, as one entity. So if I were a patient at UPNC, I give consent to UPNC or I don't give consent to UPNC, but I'm done as far as the UPNC thing is—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes, but if they wanted to send you to Kaiser or something—

Paul Egerman – eScription – CEO

Well that's directed exchange.

Judy Faulkner – Epic Systems – Founder

That's directed exchange.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

That's right. That's the point. They still would have that option.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

But there are, and, Judy, maybe this is what you're getting at, there are organizations that, like a hospital that purchase a particular type of EHR system for their employee group, let's say, who are ambulatory, and then they offer that to independent physicians, whether it's under star safe harbor, investment, whatever it is.

Judy Faulkner – Epic Systems – Founder

That's the OCA.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

Well, but there are some who—and I don't fully understand the details of what's an OCA—but I know of some entities who are offering it to other practices purely to support them as a cheaper way to get on EHR, and they're just saying that the way our EHR works is your data is a part of the single database.

Paul Egerman – eScription – CEO

But, Micky, that example is probably not to trigger. That's probably not a trigger.

Deven McGraw – Center for Democracy & Technology -- Director

I don't think we intended to trigger in those circumstances in shared records, integrated delivery systems, where there's some agreement to provide care together, to share records and, of course, that is in some ways transparent to the patient. But if we take the meaningfulness out of this consent, it might as well be a big fat transparency recommendation. Not consent.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

Right. Right. But I would just go back to there are many cases that I know of where I think the patient would be genuinely surprised to find that their data is being commingled with 20 other practices plus a large hospital employed group because they're a part of a same contracting network, but they're not a part of an IDM.

Paul Egerman – eScription – CEO

Well that's a different issue though. That's a transparency issue that we have to deal with. That does not trigger consent the way we've defined it.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

But the things Micky's describing are, in fact, used for data sharing, so I think it is what we're talking about.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

I don't understand why it's not a consent trigger.

Paul Egerman – eScription – CEO

The consent trigger doesn't include an OCA.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

They're not OCAs—

Judy Faulkner – Epic Systems – Founder

They are an OCA by definition of what an OCA is.

Paul Egerman – eScription – CEO

I think they are OCAs.

Deven McGraw – Center for Democracy & Technology -- Director

Yes, I think they're OCAs too.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

They're OCA just because they bring their data together?

Paul Egerman – eScription – CEO

That's pretty broad.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Then that's a gigantic loophole to the entire set of recommendations.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

Right. Then anyone can aggregate anything and say, "I'm an OCA."

Paul Egerman – eScription – CEO

I don't think so. OCA's defined in HIPAA, and so it's got a pretty broad definition.

Deven McGraw – Center for Democracy & Technology -- Director

Yes. For those of you who missed our previous call, where there was a circulated definition of an OCA, we will re-circulate it.

Paul Egerman – eScription – CEO

Yes. Maybe one of the solutions, Deven, as I'm listening to this is we should just also put that as a footnote into the letter.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think you're going to have to, Paul.

Paul Egerman – eScription – CEO

Because maybe other people knew what an OCA was before Adam explained it at the last call, but I didn't. So I assume other Policy Committee members won't necessarily know.

Judy Faulkner – Epic Systems – Founder

So, I'm still going to go back on my two issues here, though. I don't disagree with what you're saying as long as the organization—and this is where I don't know and I'm a little worried that maybe the people on the phone don't know—that there aren't situations where organizations, large or small, have to have consent in order just to do the work that they do through mechanisms that we would say they need consent for ... the patient doesn't give consent and they have no choice. And that's my first concern. It has nothing to do with directed exchange.

I don't know the answer. I'm saying is everyone quite comfortable that there won't be any situations like that? If we are, then we can say it. If we're not, we having to figure it out.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I think the other way around is to say if there are situations like that, then they may not be giving meaningful consent and they should rethink that.

Paul Egerman – eScription – CEO

I want to hear Judy's second. You said you had two things?

Judy Faulkner – Epic Systems – Founder

So wait, and I don't understand what was just said a second ago. The second one is just the first sentence there, is there a stop, kind of, after a semicolon, after, "is not compelled." So, is the sentence, "is not compelled; and is not used for discriminatory purposes," or is it, "is not compelled for discriminatory purposes, is not used for discriminatory purposes." I don't know which way the grammar is on that sentence, and it's two different interpretations.

Paul Egerman – eScription – CEO

Let me try to answer your first question, Judy. As I read this letter and think about this conversation, what we're really saying as it relates to these triggers is we're saying providers have to offer consent, which means they have to offer the option to the patients as to whether or not they're going to participate in the HIO. So they just have to offer that as an option.

Judy Faulkner – Epic Systems – Founder

Yes, and the question I'm trying to ask, Paul, is are we going to have a significant number of providers across the country who say, "You've just killed my business because I have no means of operating other than this."

Paul Egerman – eScription – CEO

I don't think so. I can't think of why that would be the case.

Judy Faulkner – Epic Systems – Founder

That's what I'm asking.

Paul Egerman – eScription – CEO

I understand your question, but I can't think so. I mean, as I think about the comments that Ellen made and the comments that a number of the HIO people are making, they're more concerned about the opposite. They're concerned we're putting up too many obstacles to make it hard for people to participate. I don't know of any situation where providers ... say that's the only way they can do it.

Judy Faulkner – Epic Systems – Founder

That was my main question there. I'm still nervous about it, but maybe they're right.

Deven McGraw – Center for Democracy & Technology -- Director

I don't want it to sound like I don't appreciate where you're going with this, Judy, because I do. I just would hate to lose what I think is an important thought because we're uncertain about whether there's a universe of folks out there for whom it won't work. I'd much rather have that be part of what gets dealt with in the implementation context and keep our recommendations, again, as just ... accommodating of circumstances we know of, acknowledging that there may be some that we don't.

Judy Faulkner – Epic Systems – Founder

Okay, and we may have to amend this if we find out that we have a gap in our knowledge.

Paul Egerman – eScription – CEO

That's correct.

Deven McGraw – Center for Democracy & Technology -- Director

That's correct.

Paul Egerman – eScription – CEO

I understand, I think, where you're coming from, Judy. I don't think this is a problem.

Judy Faulkner – Epic Systems – Founder

Okay.

Deven McGraw – Center for Democracy & Technology -- Director

And then I actually would be happy to separate those two thoughts in ... two.

Judy Faulkner – Epic Systems – Founder

Okay. So is it, “is not compelled for discriminatory purposes,” or is it, “is not compelled?”

Deven McGraw – Center for Democracy & Technology -- Director

“Is not compelled.”

Judy Faulkner – Epic Systems – Founder

Okay.

Deven McGraw – Center for Democracy & Technology -- Director

“Or used for discriminatory purposes,” and the example is more about compulsion, then—

Judy Faulkner – Epic Systems – Founder

Okay.

Deven McGraw – Center for Democracy & Technology -- Director

Although one could argue it’s— They’re sort of in many respects closely related but not entirely the same.

Paul Egerman – eScription – CEO

Are you okay with that, Judy?

Judy Faulkner – Epic Systems – Founder

Yes, thank you.

Paul Egerman – eScription – CEO

Do you have any other issues in the letter?

Judy Faulkner – Epic Systems – Founder

Let me see. By the way, I thought it was very well done. No, that was about my main issue.

Paul Egerman – eScription – CEO

Does anybody else have any other issues or topics they want to raise about the letter?

Gayle Harrell – Florida – Former State Legislator

The only thing I would add ... is that we have not gotten into the whole discussion of the opt-in and opt-out and I assume that is ... purpose.

Deven McGraw – Center for Democracy & Technology -- Director

Yes.

Paul Egerman – eScription – CEO

Yes, because fundamentally, this was the best we thought we could do based on the discussions we had.

Gayle Harrell – Florida – Former State Legislator

Okay. I’m fine with that.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

No, let’s do it now.

Paul Egerman – eScription – CEO

We have plenty of time, but I think the result is predictable. In other words, I think we heard where people are on it, and it's a very interesting discussion and I think it was very healthy and helpful to have the discussion, but it's even the same discussion that Ellen was sort of raising when she was talking about the issues in New York. On the one hand, people are very eager to make sure that these HIOs that add values get implemented and there are good arguments there. There's other people who are very focused on rights of the individual and individual autonomy and there's very good arguments there. So those are the arguments and I guess it's probably like a lot of stuff in policy. It's not like there's a right or a wrong answer. Those are both valuable comments.

Deven McGraw – Center for Democracy & Technology -- Director

Yes.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

The only other thing I would note is I just want, just for the record, and I apologize; just coming back from vacation, I haven't had a chance to go through the letter in great detail, but I'll do that tonight. But I am still concerned that this definition of control issue is something that's very, very important to all of the arguments here and that we may not have specified it as well as we may need to and in effect, that it's sort of a ... machine ... right now, but I don't want to push that point too hard without having read the letter in its entirety.

Paul Egerman – eScription – CEO

Yes, and that's a good point, Micky. It's like it after you do this, so I don't know if it's possible, why don't you read the whole letter in its entirety and re-read that section, and if you have some suggested changes or wording to that, to let us know. But if you do that today because we're on a tight time frame because we've got Thursday thing and we've got to get our letter together and get PowerPoint slides together and there's a bunch of stuff. So if you were able to do that today because your perspective on that would be very helpful.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

Will do.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

The PowerPoint, as I understood it when I read this letter, our real recommendations and what we'll put in the PowerPoint is what's in bold?

Paul Egerman – eScription – CEO

That's correct and so that's exactly right. When we do the PowerPoint, we'll probably take some or all of the bold stuff and we'll repeat it in the PowerPoint. So everyone will get the letter, but we'll use the PowerPoint just to guide the discussion.

Deven McGraw – Center for Democracy & Technology -- Director

Yes. Everyone's getting the whole letter.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

So maybe Micky and any of those who haven't read the whole letter might want to focus for time limit's sake on the bold. Is that right?

Paul Egerman – eScription – CEO

Whatever. I don't know if it hangs together if you just read the bold.

Deven McGraw – Center for Democracy & Technology -- Director

The whole reason for doing the letter was to put the context in.

Paul Egerman – eScription – CEO

Yes.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

... our real recommendations are the bold.

Paul Egerman – eScription – CEO

That's correct. What we're supposed to do, when we do these letters, is we're supposed to be clear on what our recommendations are, but we're also supposed to explain it. So that's why there's some stuff in bold, and some stuff is not. I don't know what necessary italics means, but—

Deven McGraw – Center for Democracy & Technology -- Director

That's like extra emphasis on words.

Paul Egerman – eScription – CEO

So, the purpose of this part of the agenda is to look at the letter as a whole and see if anybody has any comments. Micky and Judy have made some comments. Does anybody else have any comments in terms of the letter, how we're doing this, are you comfortable with this letter based on the discussions we had today?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

When will we get a final version?

Deven McGraw – Center for Democracy & Technology -- Director

It has to go out to the policy committee tomorrow, so I've got to get it out tomorrow morning, so today is really the last time to get any other suggestions in for language.

Paul Egerman – eScription – CEO

Do you have any reactions, Carol?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Not that haven't been discussed already, but I wanted to know when we would get a final version that reflect any changes that were going to be made. That was my question.

Paul Egerman – eScription – CEO

It would be probably tomorrow, but I don't think you're going to have a chance to react to it before we present it to the Policy Committee.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Well, I'm assuming we've discussed it all on the phone. I just want to know when we're getting a final version.

Deven McGraw – Center for Democracy & Technology -- Director

Tomorrow.

Paul Egerman – eScription – CEO

Do you feel okay or good about how it's turned out?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes.

Paul Egerman – eScription – CEO

Gayle, how do you feel about it all?

Gayle Harrell – Florida – Former State Legislator

Well, I ... don't come up with a ... recommendation on opt-in/opt-out. I think it's the closest we could get, so I'll certainly make my comments on my preferred way of doing thing at the policy

You all did a remarkable job. I want to commend both of you for putting it together and really getting the gist of our conversations over the entire summer. This is a lot of work, and I think the whole committee really participated in ... well in coming to the end result that we have come to.

Deven McGraw – Center for Democracy & Technology -- Director

Yes, thank you, Gayle. I don't know if you noticed, but I put your poster example in the letter.

Gayle Harrell – Florida – Former State Legislator

Yes, I noticed.

Paul Egerman – eScription – CEO

What I hope everybody noticed is we tried hard to listen and make sure that everybody's viewpoints were reflected, so this should be the team's view. David, do you have any reactions?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, I do have a reaction. I have no objection. I like the letter. I think it synthesizes the breadth of our discussion pretty well. I will go out on a limb and predict that the buzz word of the day will be these accountable healthcare entities that are, I think, new to most all of us. I think the debate is going to shift into figuring out what those entities are and how they differ from things like HIEs. So I think we've opened the door to a new phase of meaningful discussion.

Paul Egerman – eScription – CEO

Okay. It could be.

Gayle Harrell – Florida – Former State Legislator

I'd like to address that also. I think that in itself is going to need further conversation and perhaps this is not the group to do it with, but I think perhaps there may be some legislation coming out of that because these are going to be very powerful organizations. My fear is that if you want to get around what meaningful consent really means without a defined opt-in or opt-out, then you become an OCA.

Paul Egerman – eScription – CEO

It's a possibility. Okay. I was asking for other comments on the letter. John, do you have any?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

I just ... with the comment. I think the letter's good. I think it's a lot of deliberate debate, and I don't mean this negative, but nobody's going to be completely satisfied. I think everybody's in agreement that it's the best that this group can really put together collectively. I think it's going to be very challenging for people

to understand the nuances because we, amongst ourselves, are getting confused as we start to speak about what's what. But I don't have any other comments other than what we talked about.

Paul Egerman – eScription – CEO

Great, and Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

No, I have no further comments.

Deven McGraw – Center for Democracy & Technology -- Director

Okay, great.

Paul Egerman – eScription – CEO

So, did I leave anybody out? Is Eva on the call? So, I am assuming as long as we get a letter that reflects the comments today, that's what we need to do.

Deven McGraw – Center for Democracy & Technology -- Director

Yes. How about if we go to public comment?

Paul Egerman – eScription – CEO

Yes, I think that's great. Before we do that, I want to make sure I thank everybody for hanging in there, not only for today's call but for the entire summer. This has not been an easy process. It's been very intensive. Your comments are really appreciated.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

I have one question generally. What happens to the Tiger Team now and what is the plan?

Paul Egerman – eScription – CEO

That's something that I don't know the answer to. Deven, do you want to say anything on that?

Deven McGraw – Center for Democracy & Technology -- Director

I don't either. ONC has created a governance workgroup, for example, that is going to taking on some issues that we had originally slated on our plate, but we have a lot of other things that we put in our parking lot, and how we're going to handle those going forward is a little unclear. I know we do not want to keep the same schedule.

Joy Pritts – ONC – Chief Privacy Officer

That's correct.

Paul Egerman – eScription – CEO

I think we all agree on that, but I think the Tiger Team's done a great job. At a minimum, I think we deserve our own flag and a secret handshake. But this has really been great work.

Joy Pritts – ONC – Chief Privacy Officer

Or at least "I survived the Summer of 2010" t-shirts, right?

Paul Egerman – eScription – CEO

That's right, a t-shirt or something.

Joy Pritts – ONC – Chief Privacy Officer

To put a little bit more meat on Deven's response, the work that this group has done clearly is going to have some governance implications in it and there was an NHIN workgroup that originally was scheduled to work on governance. I think some of you are members of that workgroup. And so there will be a governance workgroup.

But the work that this group has done is going to not be reiterated by that group, and it is going to feed into it. We're thinking that once we have these recommendations and the Policy Committee has weighed back on them, that there are items of ... have been discussed over the summer that really are very, very, very related to governance and so that we could have some discussions on the governance implications of some of these recommendations, among other things.

We are hopefully getting much, much closer to getting ... back on board, and giving the other demands in this office, particularly my little office of chief privacy officer at the moment, I really need them back on board before we can commit to doing much more. I appreciate Deven and Paul, and I can't tell you how much I appreciate all the work that they've picked up on this, but we really need to have staffing in place going forward because I don't want to put this group back in that position again. But we're close.

Paul Egerman – eScription – CEO

Okay. That's great. I think we're very, very close. So, unless anybody has any other comments, and thank you for that last comment, Joy. We really appreciate that. Why don't we go ahead and open the discussion up for public comment. So, Judy Sparrows?

Judy Sparrow – Office of the National Coordinator – Executive Director

Operator, can you please check if anybody wishes to make a comment from the public?

Operator

Our first comment is from Lester Keepper with LHK Quality Associates.

Lester Keepper – LHK Quality Associates

Three points. I'd like to add the word to what Judy said when she said this is real well done. I think it's extremely well done, number one. Number two, you've been discussing this in terms of the provider, which is probably the most important contribution you could make, and that's properly focused on. But we also have community care organizations, all the rest of it are going to be a big problem. So therefore, in my opinion, identity, granularity, and roles rights privileges written into the protocols are going to be the answer to the many questions that are answered here. I thank you.

Paul Egerman – eScription – CEO

Thank you, Lester, and thank you for listening to all of our calls. I really appreciate your comments.

Operator

We do not have any other public comment at this time.

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay, thank you. Thank you, everybody.

Paul Egerman – eScription – CEO

Yes. Thank you very much. Enjoy what's left of your summer.

Deven McGraw – Center for Democracy & Technology -- Director

Yes. Bye.

Public Comment Received During the Meeting

1. Useful discussion on Data Classification as a Policy enabler

<http://healthcaresecprivacy.blogspot.com/2010/08/data-classification-key-vector-through.html>

2. Why is a DIRECTED exchange the only solution for emergency? If regulations allow a region to have break-glass that overrides a patient opt-out in condition of life and limb.